Nursing Home Quality Care Collaborative (NHQCC)

Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES

HSAG HEALTH SERVICES ADVISORY GROUP

Improving Dementia Care

Reducing Antipsychotic Medication Use in Nursing Homes Toolkit

This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. Publication No. CA-10SOW-7.2-110113-01.

Improving Dementia Care

Reducing Antipsychotic Medication Use in Nursing Homes

Table of Contents

Tab 6. Policy & Procedure

Tab 7. Assessment

Tab 8. Advancing Excellence in America's Nursing Homes Resources

Tab 9. SBAR for Antipsychotics

Tab 10. Care Planning

Medicare Quality Improvement Organizations engage providers at all levels of performance in projects for collaborative learning and action that accelerate healthcare quality improvement.

Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES

HSAG HEALTH SERVICES ADVISORY GROUP

Health Services Advisory Group of California, Inc.
700 N. Brand Boulevard, Suite 370, Glendale, CA 91203

Nursing Home Quality Care Collaborative

Your Learning and Action Network

Join us in leading rapid, large-scale improvement in health quality.

Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES

HSAG HEALTH SERVICES ADVISORY GROUP

As the Medicare Quality Improvement Organization (QIO) for California, Health Services Advisory Group of California, Inc. (HSAG-California) invites your nursing home to participate in the Nursing Home Quality Care Collaborative. As a participant, you will strive to instill quality and performance improvement practices, eliminate healthcare-acquired conditions, and dramatically improve resident satisfaction.

The Collaborative offers a rewarding opportunity to learn from high-performing nursing homes regarding their processes as they pertain to resident safety and clinical outcomes. The Collaborative aligns national nursing home quality initiatives and partnerships such as the Advancing Excellence in America's Nursing Homes Campaign, The Partnership to Improve Dementia Care, and Quality Assurance Performance Improvement (QAPI).

Who is invited to participate?
All nursing homes are eligible for the Collaborative. The Centers for Medicare & Medicaid Services (CMS) encourages the participation of facilities that are able to commit to remain active in the project beginning January 2013 through July 2014.

The Nursing Home Quality Care Collaborative will:

- Provide the foundation to focus on quality, data-driven, resident-centered care;
- Support the development of strategies for overall quality;
- Identify opportunities for improvement; and
- Address systems gaps through planned interventions in order to improve overall quality of care.

Quality areas of focus:
CMS requires all participating nursing homes to work on the reduction of the use of unnecessary antipsychotics in residents with dementia. Other areas Collaborative members may choose to focus on include consistent/permanent staff assignment; healthcare-acquired conditions such as falls, high-risk pressure ulcers, and urinary tract infections; avoidable hospital readmissions; finance; team-building; quality of life; healthcare-associated infections such as *Clostridium difficile;* and vaccinations.

Nursing homes actively participating in the Nursing Home Quality Care Collaborative are expected to benefit from:

- Learning and Action Network sessions that bring together participating nursing homes for networking, learning, and sharing;
- Access to best practices and strategies of high-performing nursing homes;
- QAPI tools and resources; and
- Intervention development ideas and assistance.

The success of this initiative depends on the mutual commitment and collaborative efforts of the QIO and participating nursing homes. While there is no fee to participate in the Collaborative, partners and QIO will commit to the following:

Quality Improvement Organization	*Participating Nursing Home*
✓ Provide qualified staff with expertise in nursing home quality improvement.	✓ Form an interdisciplinary team to work with the Collaborative and apply strategies and principles of overall nursing home quality.
✓ Provide best practices, tools, and resources to support overall nursing home quality.	✓ Commit to remain active in the project through July 2014.
✓ Provide training to support QAPI.	✓ Implement strategies for QAPI.
✓ Develop and facilitate opportunities for participating nursing homes to come together in collaborative educational workshops for learning, sharing, and networking.	✓ Participate in educational Collaborative sessions, teleconference calls, and Webinars.
✓ Provide comparative data reports, practical assistance, and best practice resources to sustain and challenge participating nursing homes.	✓ Collect data to measure the impact of changes and submit the data to the QIO.
✓ Maintain a strong commitment to advance the project through partners and stakeholders, and to promote the accomplishments and best practices of participant nursing homes.	✓ Actively share best practices and lessons learned.

Thank you for your commitment to improving healthcare quality and the lives of residents in nursing homes. Please return the participant agreement form by fax or e-mail by December 31, 2012. For additional information, please contact Joseph M. Bestic, Director, Nursing Home, jbestic@hsag.com or 818.409.9229.

This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy.
Publication No. CA-10SOW-7.2-102312-01

Launch of the Initiative to Improve Behavioral Health and Reduce the Use of Antipsychotic Medications in Nursing Homes Residents

A Centers for Medicare & Medicaid Services (CMS)
Video Streaming Event

Premieres Thursday, March 29, 2012
1:00pm EST – 2:00pm EST

On March 29, CMS will launch a new initiative aimed at improving behavioral health and safeguarding nursing home residents from unnecessary antipsychotic drug use. As part of the initiative, CMS is developing a national action plan that will use a multidimensional approach including public reporting, raising public awareness, regulatory oversight, technical assistance/training and research. The action plan will be targeted at enhancing person-centered care for nursing home residents, particularly those with dementia-related behaviors.

Goals for the Video Streaming Event
CMS will provide an overview of the national initiative, resources for technical assistance, and plans for upcoming educational offerings on this topic.

Handouts
Handouts for this broadcast are attached and are also available at the following website:
http://surveyortraining.cms.hhs.gov.

Objectives
Join Patrick Conway, MD, MSc, Chief Medical Officer for the Centers for Medicare & Medicaid Services and Director of the Office of Clinical Standards and Quality, Shari Ling, MD, Centers for Medicare and Medicaid Services, Deputy Chief Medical Officer serving in the Office of Clinical Standards and Quality and Alice Bonner, PhD, RN, Director for the Division of Nursing Homes in the Office for Clinical Standards and Quality in the introduction of this national initiative, discussion of behavioral health opportunities and the announcement of upcoming training sessions.

Target Audience
State Survey Agencies, residents and family members, nursing home staff, clinicians, providers, advocates, CMS Regional Offices, and others (Non-Mandatory)

Registration and Viewing Instructions
Register today at http://surveyortraining.cms.hhs.gov.

Video Streaming Information
This program will be available for viewing up to one year following March 29, 2012, at http://surveyortraining.cms.hhs.gov.

This event is open to the public, so please share this invitation with anyone else who may wish to attend. Thank you for joining CMS in our efforts to improve the quality of care and quality of life for America's nursing home residents.

####

Press Releases

Details for: CMS ANNOUNCES PARTNERSHIP TO IMPROVE DEMENTIA CARE IN NURSING HOMES

Return to List

For Immediate Release: Wednesday, May 30, 2012

Contact: CMS Office of Public Affairs
202-690-6145

CMS ANNOUNCES PARTNERSHIP TO IMPROVE DEMENTIA CARE IN NURSING HOMES

GOVERNMENT PARTNERING WITH PROVIDERS, CAREGIVERS, PATIENTS TO ENSURE APPROPRIATE USE OF ANTIPSYCHOTIC MEDICATIONS

CMS ANNOUNCES PARTNERSHIP TO IMPROVE DEMENTIA CARE IN NURSING HOMES

Government partnering with providers, caregivers, patients to ensure appropriate use of antipsychotic medications

Today, Centers for Medicare & Medicaid Services (CMS) Acting Administrator Marilyn Tavenner announced the Partnership to Improve Dementia Care, an initiative to ensure appropriate care and use of antipsychotic medications for nursing home patients. This partnership – among federal and state partners, nursing homes and other providers, advocacy groups and caregivers – has set a national goal of reducing use of antipsychotic drugs in nursing home residents by 15 percent by the end of 2012.

Unnecessary antipsychotic drug use is a significant challenge in ensuring appropriate dementia care. CMS data show that in 2010 more than 17 percent of nursing home patients had daily doses exceeding recommended levels.

"We want our loved ones with dementia to receive the best care and the highest quality of life possible," said Acting Administrator Marilyn Tavenner. "We are partnering with nursing homes, advocates, and others to improve the quality of care these individuals receive in nursing homes. As part of this effort, our partnership has set an ambitious goal of reducing use of antipsychotics in nursing homes by 15 percent by the end of this year."

CMS and industry and advocacy partners are taking several steps to achieve this goal of improved care:

Enhanced training: CMS has developed Hand in Hand, a training series for nursing homes that emphasizes person-centered care, prevention of abuse, and high-quality care for residents. CMS is also providing training focused on behavioral health to state and federal surveyors;

Increased transparency: CMS is making data on each nursing home's antipsychotic drug use available on Nursing Home Compare starting in July of this year, and will update this data;

Alternatives to antipsychotic medication: CMS is emphasizing non-pharmacological alternatives for nursing home residents, including potential approaches such as consistent staff assignments, increased exercise or time outdoors, monitoring and managing acute and chronic pain, and planning individualized activities.

"A CMS nursing home resident report found that almost 40 percent of nursing home patients with signs of dementia were receiving antipsychotic drugs at some point in 2010, even though there was no diagnosis of psychosis," said CMS Chief Medical Officer and Director of Clinical Standards and Quality Patrick Conway, M.D. "Managing dementia without relying on medication can help improve the quality of life for these residents. The Partnership to Improve Dementia Care will equip residents, caregivers, and providers with the best tools to make the right decision."

These efforts will help achieve the 15 percent reduction goal by the end of this year. In addition, to address this challenge in the long-term CMS is conducting research to better understand the decision to use or not to use antipsychotic drugs in residents with dementia. A study is underway in 20 to 25 nursing homes, evaluating this decision-making process. Findings will be used to target and implement approaches to improve the overall management of residents with dementia, including reducing the use of antipsychotic drugs in this population.

Comparative Effectiveness Review
Number 43

Effective Health Care Program

Off-Label Use of Atypical Antipsychotics: An Update

Executive Summary

Background

Antipsychotics medications are approved by the U.S. Food and Drug Administration (FDA) for treatment of schizophrenia and bipolar disorder. These medications are commonly divided into two classes, reflecting two waves of historical development: the conventional antipsychotics and the atypical. The conventional antipsychotics served as the first successful pharmacologic treatment for primary psychotic disorders such as schizophrenia. Having been widely used for decades, the conventional antipsychotics also produced various side effects requiring additional medications, which spurred the development of the atypical antipsychotics.

Currently, nine atypical antipsychotic drugs have been approved by FDA: aripiprazole, asenapine, clozapine, iloperidone, olanzapine, paliperidone, quetiapine, risperidone, and ziprasidone. These drugs have been used off-label (i.e., for indications not approved by FDA) for the treatment of various psychiatric conditions. While it is legal for a physician to prescribe drugs in such a manner, it is illegal for the manufacturer to actively promote such use.

A 2006 study on Efficacy and Comparative Effectiveness of Off-label Use of Atypical Antipsychotics reviewed the scientific evidence on the safety, efficacy, and effectiveness for off-label uses. (Clozapine was excluded because of its association with a potentially fatal blood disorder of bone marrow suppression, and it requires frequent blood tests for safety monitoring.) The 2006 study examined 84 published studies on atypicals and found that the

Effective Health Care Program

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

The full report and this summary are available at **www.effectivehealthcare.ahrq.gov/reports/final.cfm.**

AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

Effective Health Care

most common off-label uses of the drugs were for treatment of depression, obsessive-compulsive disorder (OCD), post-traumatic stress disorder (PTSD), personality disorders, Tourette's syndrome, autism, and agitation in dementia. It concluded that with few exceptions, there was insufficient high-strength evidence to reach conclusions about the efficacy of any off-label uses of these medications. It also found strong evidence that atypicals are associated with increased risk of adverse events such as significant weight gain, sedation, and, among the elderly, increased mortality. Future research areas suggested by the report include safe treatment for agitation in dementia, association between the increased risk of death and antipsychotics drugs, and comparison of the development of adverse effects between patients taking atypical antipsychotics and those taking conventional antipsychotics.

Since publication of that report, important changes have occurred that make the report out of date. Studies have been published on new off-label uses, such as treatment of eating disorders, insomnia, attention-deficit hyperactivity disorder (ADHD), anxiety, and substance abuse. New or increased adverse effects of off-label indications have been observed and new atypicals (asenapine, iloperidone, and paliperidone) have been approved by FDA for the treatment of schizophrenia and bipolar disorder. In addition, the following previously off-label uses have been approved for on-label use by the FDA:

- Quetiapine and quetiapine ER (extended release) as monotherapy in bipolar depression
- Quetiapine ER as augmentation for major depressive disorder (MDD)
- Aripiprazole as augmentation for MDD
- Olanzapine/fluoxetine combination for MDD
- Olanzapine/fluoxetine combination for bipolar depression
- Risperidone and aripiprazole for autism spectrum disorders

An update is needed to better understand the trends in off-label use and the associated risks and benefits. Further, a number of issues remain unclear due to insufficient information in the previous report: subpopulations (i.e., race/ethnicity, gender) that would benefit most from atypical antipsychotics, appropriate dose, and time needed to see clinical improvement. This update will try to address these issues.

This report covers the following off-label uses of atypical antipsychotic medications: anxiety, ADHD, dementia and severe geriatric agitation, major depressive disorder (MDD), eating disorders, insomnia, OCD, PTSD, personality disorders, substance abuse, and Tourette's syndrome. Autism, included in the original systematic review, is now reviewed in a study on the comparative effectiveness of typical and atypical antipsychotics for on-label indications, conducted by another organization.

This report addresses the following Key Questions:

Key Question 1: What are the leading off-label uses of atypical antipsychotics in utilization studies? How have trends in utilization changed in recent years, including inpatient versus outpatient use? What new uses are being studied in trials?

Key Question 2: What does the evidence show regarding the efficacy and comparative effectiveness of atypical antipsychotics for off-label indications?

Sub-Key Question 2: How do atypical antipsychotic medications compare with other drugs, including first-generation antipsychotics, for treating off-label indications?

Key Question 3: What subset of the population would potentially benefit from off-label uses? Do effectiveness and harms differ by race/ethnicity, gender, and age group? By severity of condition and clinical subtype?

Key Question 4: What are the potential adverse effects and/or complications involved with off-label prescribing of atypical antipsychotics? How do they compare within the class and with other drugs used for the conditions?

Key Question 5: What is the effective dose and time limit for off-label indications?

Conclusions

Key Question 1: What are the leading off-label uses of atypical antipsychotics in utilization studies? How have trends in utilization changed in recent years, including inpatient versus outpatient use? What new uses are being studied in trials?

Atypicals have been studied as off-label treatment for the following conditions: ADHD, anxiety, dementia in elderly patients, depression, eating disorders, insomnia, OCD, personality disorder, PTSD, substance use disorders, and Tourette's syndrome.

Off-label use of atypical antipsychotics in various settings has increased rapidly since their introduction in the 1990s; risperidone, quetiapine, and olanzapine are the most common atypicals prescribed for off-label use.

One recent study indicated that the 2005 regulatory warning from the FDA and Health Canada was associated with decreases in the overall use of atypical antipsychotics, especially among elderly dementia patients.

Use of atypicals in the elderly is much higher in long-term care settings than in the community.

Atypicals are frequently prescribed to treat PTSD in the U.S. Department of Veterans Affairs health system.

At least 90 percent of antipsychotics prescribed to children are atypical, rather than conventional antipsychotics. The majority of use is off-label.

No off-label use of the newly approved atypicals (asenapine, iloperidone, and paliperidone) was reported in the utilization literature.

Key Question 2: What does the evidence show regarding the efficacy and comparative effectiveness of atypical antipsychotics, for off-label indications? Sub-Key Question 2: How do atypical antipsychotic medications compare with other drugs, including first-generation antipsychotics, for treating off-label indications?

The efficacy results are summarized in Table A below. It is important to note that no trials of the three most recently FDA-approved atypicals (asenapine, iloperidone, and paliperidone) were found for off-label use. Cells shaded in dark blue indicate areas with the strongest evidence of efficacy, followed by the areas in orange. Areas containing circles indicate areas where no clinical trials exist. Light orange and light blue areas indicate areas where evidence of inefficacy exists. Areas in medium blue indicate mixed results.

Table A. Summary of strength of evidence of efficacy, by drug and condition

	Aripiprazole	Olanzapine	Quetiapine	Risperidone	Ziprasidone
Anxiety					
- generalized anxiety disorder	O	-	++	-	-
Anxiety					
- social phobia	O	+	-	O	O
Attention Deficit/Hyperactivity Disorder					
-no co-occurring disorders	O	O	O	+	O
Attention Deficit/Hyperactivity Disorder					
-bipolar children	-	O	O	O	O
Attention Deficit/Hyperactivity Disorder					
-mentally retarded children	O	O	O	+	O
Dementia overall	++	+	+	++	O
Dementia psychosis	+	+-	+-	++	O
Dementia agitation	+	++	+-	++	O
Depression					
-MDD augmentation of SSRI/SNRI	++	+	++	++	+
Depression					
-MDD: Monotherapy	O	-	++	O	O
Eating Disorders	O	--	-	O	O
Insomnia	O	O	-	O	O
Obsessive Compulsive Disorder					
-augmentation of SSRI	O	+	--	++	-
Obsessive Compulsive Disorder					
-augmentation of citalopram	O	O	+	+	O
Personality Disorder					
-borderline	+	+-	+	O	-

Table A. Summary of strength of evidence of efficacy, by drug and condition (continued)

	Aripiprazole	Olanzapine	Quetiapine	Risperidone	Ziprasidone
Personality Disorder					
-schizotypal	O	O	O	+-	O
Post Traumatic Stress Disorder	O	+-	+	++	O
Substance Abuse alcohol	--	-	-	O	O
Substance Abuse cocaine	O	-	O	-	O
Substance Abuse methamphetamine	-	O	O	O	O
Substance Abuse methadone clients	O	O	O	-	O
Tourette's Syndrome	O	O	O	+	-

++: moderate or high evidence of efficacy
+ : low or very low evidence of efficacy
+- : mixed results
- : low or very low evidence of inefficacy
-- : moderate or high evidence of inefficacy
O : no trials
□: Approved by FDA for the indication

MDD = major depressive disorder; SSRI = selective serotonin reuptake inhibitor; SNRI = serotonin-norepinephrine reuptake inhibitors

Note: Symbols denote strength of evidence, not size of portential effect. For example, in dementia "++" indicates moderate-to-high strength of evidence that there is a beneficial effect; however, the size of the effect is small.

Table B below shows how our current efficacy findings compare with those of our original Comparative Effectiveness Review (CER) submitted to the Agency for Healthcare Research and Quality (AHRQ) in 2006. The evidence that atypicals have efficacy in treating symptoms of dementia has increased in the past few years; this evidence must be weighed against possible harms described in Key Question 4 below. Evidence of efficacy as augmentation for MDD and OCD patients who have not responded adequately to selective serotonin reuptake inhibitors/serotonin-norepinephrine reuptake inhibitors (SSRIs/SNRIs) has also increased. Table B is organized as follows: First, all conditions dealt with in our original CER, in alphabetical order; second, all the new off-label indications in alphabetical order.

Key Question 3: What subset of the population would potentially benefit from off-label uses? Do effectiveness and harms differ by race/ethnicity, gender, and age group? By severity of condition and clinical subtype?

There are insufficient data regarding efficacy, effectiveness, and harms to determine what subset of the population would potentially benefit from off-label uses of atypicals. Only one study conducted a subgroup analysis by gender; there were no studies that stratified by racial or ethnic group. Although many studies specified age in their inclusion criteria, few studies stratified results by age.

Examination of the literature for differing efficacy of atypicals by clinical subsets did not reveal studies reporting subgroup analyses. Our own meta-analysis found efficacy for combat-related PTSD in men but not for PTSD in civilian women, although these data come from separate literatures, and head-to-head comparison of gender effects within study have not been performed. Due to the varying measures utilized in determining severity of illness, it was not possible to analyze treatment effects by severity of illness across any other condition.

Key Question 4: What are the potential adverse effects and/or complications involved with off-label prescribing of atypical antipsychotics? How do they compare within the class and with other drugs used for the conditions?

Table C compares the most important findings regarding adverse events, by age group and study design.

Table B. Summary update: efficacy of atypical antipsychotics for off-label use				
Usage	**Strength of Evidence**	**2006 Findings**	**2011 Findings**	**2011 Conclusions**
Dementia	High	A published meta-analysis of 15 placebo-controlled trials (PCTs) found small but statistically significant effects favoring treatment with risperidone and aripiprazole. There were effects that favored treatment with olanzapine for the BPRS and the NPI, but these differences were not statistically significant. Three studies of quetiapine were considered too clinically dissimilar to pool and results for the individual studies showed, with one exception, trends favoring treatment with quetiapine that did not reach conventional levels of statistical significance.	Overall – In our meta-analysis of PCTs, aripiprazole, olanzapine, and risperidone were superior to placebo as treatment of behavioral symptoms as measured by total scores on BEHAVE-AD, BPRS, and NPI. Effect sizes were generally considered to be "small" in magnitude. Psychosis – In our meta-analysis risperidone was superior to placebo, as measured by the psychosis subscales of the BEHAVE-AD, BPRS, and NPI. Results for aripiprazole did not meet conventional levels of statistical significance. Agitation – In our meta-analysis, aripiprazole, olanzapine and risperidone were superior to placebo, as measured by the agitation subscales of the BEHAVE-AD, BPRS, NPI, and CMAI. Three head to head trials compared atypicals; none was found superior.	Aripiprazole, olanzapine, and risperidone **have efficacy** as treatment for behavioral symptoms of dementia.

Table B. Summary update: efficacy of atypical antipsychotics for off-label use (continued)				
Usage	**Strength of Evidence**	**2006 Findings**	**2011 Findings**	**2011 Conclusions**
Depression – MDD: augmentation of SSRI/SNRI	Moderate – risperidone, aripiprazole, quetiapine Low – olanzapine, ziprasidone	Three trials assessed the combination of olanzapine and fluoxetine, one trial each assessed augmentation of various SRIs with risperidone, ziprasidone, and quetiapine, and one study assessed adding risperidone versus olanzapine to SSRI. The combination of olanzapine and fluoxetine was no better than fluoxetine alone in improvement of depressive symptoms at 8 weeks, but three trials reported more rapid improvement in depressive symptoms (at 2–4 weeks) with combination therapy using olanzapine or quetiapine. The one trial that directly compared augmentation therapy between olanzapine and risperidone reported no differences in outcome.	We conducted a meta-analysis using "response" to treatment and remission as outcome. Pooling trials that reported the HAM-D as outcome, the relative risk of responding for participants taking quetiapine or risperidone was significantly higher than for placebo. Olanzapine had only two trials, so pooling was not performed; the trials reported olanzapine superior to placebo. Other trials reported MADRS scores; the relative risk of responding for participants taking aripiprazole was significantly higher than those taking placebo. Risperidone and ziprasidone were included in two trials and one trial, respectively. These reported the drug superior to placebo. One trial compared ziprasidone at differing levels augmenting sertraline to sertraline alone. This trial found a greater improvement in CGI-S and MADRS scores augmenting with ziprasidone at 160mg than either augmentation with ziprasidone at 80mg or sertraline alone. However, there was no significant difference in HAMD-17, CGI-I or HAM-A scores.	Aripiprazole, quetiapine, and risperidone **have efficacy** as augmentation to SSRIs/SNRIs for major depressive disorder. Olanzapine and ziprasidone **may also have efficacy**.
Depression – MDD: Monotherapy	Moderate	The three olanzapine studies (above) also assessed its efficacy as monotherapy. Olanzapine alone was no better than placebo in improving symptoms at 6 or 12 weeks. Outcomes were too heterogeneous to allow pooling.	In our meta-analysis of five placebo-controlled trials, quetiapine was superior according to relative risk of both responding and remitted as measured by MADRS.	Olanzapine **does not have efficacy** as monotherapy for major depressive disorder. Quetiapine **has efficacy** as monotherapy for major depressive disorder.

Table B. Summary update: efficacy of atypical antipsychotics for off-label use (continued)				
Usage	**Strength of Evidence**	**2006 Findings**	**2011 Findings**	**2011 Conclusions**
Obsessive-compulsive disorder – augmentation of SSRI	Moderate –risperidone Low – olanzapine	Twelve trials used risperidone, olanzapine, or quetiapine as augmentation therapy in patients who were resistant to treatment with SSRI. Nine trials were sufficiently similar clinically to pool. Atypical antipsychotics had a clinically important benefit (measured by the Yale-Brown Obsessive-Compulsive Scale) when used as augmentation therapy. Relative risk of "responding" significant for augmentation with quetiapine and risperidone. There were too few studies of olanzapine augmentation to permit separate pooling of this drug.	Our updated meta-analysis found risperidone superior to placebo, as measured by changed in the Yale Brown Obsessive Compulsive Scale (Y-BOCS). There were too few studies (two) to permit separate pooling for olanzapine; both trials reported olanzapine superior to placebo. One new head to head trial found no difference in effect between olanzapine and risperidone as SSRI augmentation. One new head to head trial found quetiapine more effective than ziprasidone as SSRI augmentation. One new trial compared quetiapine to clomipramine as SSRI augmentation. Quetiapine produced a significant reduction in Y-BOCS score, while clomipramine did not.	Risperidone **has efficacy** in improving OCD symptoms when used as an adjunct to SSRI in treatment refractory patients. Olanzapine may also **have efficacy**. Quetiapine is more **efficacious** than ziprasidone and clomipramine for this purpose.
Obsessive-compulsive disorder – augmentation of citalopram	Low–quetiapine Very low – risperidone	One trial of risperidone reported no differences between groups in achieving a response to therapy, but patients maintained on risperidone had a significantly longer period of time to relapse compared to placebo (102 days vs. 85 days)	Two new trials found quetiapine superior to placebo as augmentation for citalopram, according to Y-BOCS and CGI-I scores.	Quetiapine and risperidone may be **efficacious** as augmentation to citalopram in OCD patients.
Post-traumatic stress disorder	Moderate – risperidone Olanzapine – Low Quetiapine – very low	Four trials of risperidone and two trials of olanzapine, each of at least 6 week duration, treated patients with PTSD. Three trials enrolled men with combat-related PTSD; these showed a benefit in sleep quality, depression, anxiety, and overall symptoms when risperidone or olanzapine was used to augment therapy with antidepressants or other psychotropic medication. Three trials of olanzapine or risperidone as monotherapy for abused women with PTSD were inconclusive regarding efficacy.	Three new trials of risperidone were found, allowing us to conduct a meta-analysis using the Clinician Administered PTSD Scale (CAPS) as outcome. Risperidone was superior to placebo. There were too few olanzapine studies (two) to pool; one reported olanzapine superior to placebo, while one did not. A new trial found a 3-fold decline in CAPS scores in patients treated with quetiapine monotherapy compared to placebo. Exact scores were not reported. We also conducted a meta-analysis by condition; atypicals were efficacious for combat-related PTSD but not PTSD in abused women.	Risperidone is **efficacious** in reducing combat-related PTSD symptoms when used as an adjunct to primary medication.

Table B. Summary update: efficacy of atypical antipsychotics for off-label use (continued)				
Usage	**Strength of Evidence**	**2006 Findings**	**2011 Findings**	**2011 Conclusions**
Personality disorders – borderline	Low – aripiprazole Very low – quetiapine, olanzapine	Three trials provide evidence that olanzapine is superior to placebo and may be superior to fluoxetine. The benefit of adding olanzapine to dialectical therapy in one trial was small. Aripiprazole was superior to placebo in one small trial.	One new trial found aripiprazole superior to placebo in improving SCL-90, HAM-D, and HAM-A scores at 8 months and less self-injury at 18 months. One new trial of ziprasidone found no significant difference in CGI-BPD, depressive, anxiety, psychotic or impulsive symptoms compared to placebo at 12 weeks. Two new trials of olanzapine found no difference from placebo in any outcomes, while another new trial of olanzapine found greater change in ZAN-BPD scores at 12 weeks, compared with placebo. One new trial found quetiapine superior to placebo on BPRS, PANSS scales. Due to heterogeneity of outcomes, we could not perform a meta-analysis.	Olanzapine had **mixed results** in 7 trials, aripiprazole was found **efficacious** in two trials, quetiapine was found **efficacious** in one trial, and ziprasidone was found **not efficacious** in one trial.
Personality disorders – schizotypal	Low	Risperidone was superior to placebo in one small trial.	One new small trial of risperidone found no difference from placebo on a cognitive assessment battery.	Risperidone had **mixed results** when used to treat schizotypal personality disorder in two small trials.
Tourette's syndrome	Low	Risperidone was superior to placebo in one small trial, and it was at least as effective as pimozide or clonidine for 8 to 12 weeks of therapy in the three other trials. One trial of ziprasidone showed variable efficacy compared to placebo.	No additional trials.	Same as 2006: Risperidone **is at least as efficacious as pimozide or clonidine** for Tourette's syndrome.
Anxiety	Moderate	Not covered.	Three placebo-controlled trials of quetiapine as monotherapy for Generalized Anxiety Disorder (GAD) could be pooled; relative risk of responding on HAM-A favored the quetiapine group. One head to head trial showed no difference between risperidone and paroxetine on HAM-A score improvement. One trial each found quetiapine equally effective as paroxetine and escitalopram.	Quetiapine **has efficacy** as treatment for Generalized Anxiety Disorder

Table B. Summary update: efficacy of atypical antipsychotics for off-label use (continued)				
Usage	**Strength of Evidence**	**2006 Findings**	**2011 Findings**	**2011 Conclusions**
Attention deficit/ hyperactivity disorder – no co-occurring disorders	Low	Not covered.	One trial showed risperidone superior to placebo in reducing scores on the Children's Aggression Scale – Parent version (CAS-P).	Risperidone may be **efficacious** in treating children with ADHD with no serious co-occurring disorders.
Attention deficit/ hyperactivity disorder–mentall y retarded children	Low	Not covered.	One trial showed risperidone led to greater reduction in SNAP-IV (Swanson, Nolan, and Pelham teacher & parent rating scale) scores than methylphenidate.	Risperidone **may be superior to methylphenidate** in treating ADHD symptoms in mentally retarded children.
Attention deficit/ hyperactivity disorder – bipolar children	Low	Not covered.	Two trials of aripiprazole showed no effect on SNAP-IV (Swanson, Nolan, and Pelham teacher & parent rating scale) scores than placebo.	Aripiprazole is **inefficacious** in reducing ADHD symptoms in children with bipolar disorder.
Eating disorders	Moderate – olanzapine Low - quetiapine	Not covered.	Five trials of olanzapine were found; three reporting Body Mass Index (BMI) could be pooled. There was no difference in change in BMI at either one or three months compared to placebo. One trial of quetiapine reported no statistical difference from placebo in BMI increase at three months.	Olanzapine and quetiapine **have no efficacy** in increasing body mass in eating disorder patients.
Insomnia	Very low.	Not covered.	In one small trial (N=13) of quetiapine, sleep outcomes were not statistically different from placebo.	Quetiapine may be **inefficacious** in treating insomnia.
Substance abuse – alcohol	Moderate – aripiprazole Low – quetiapine	Not covered. Not covered.	Two trials of aripiprazole and one of quetiapine reported % of patients completely abstinent during follow-up. In our pooled analysis, the effect versus placebo was insignificant.	Aripiprazole is **inefficacious** in treating alcohol abuse /dependence. Quetiapine may also be **inefficacious**.

Table B. Summary update: efficacy of atypical antipsychotics for off-label use (continued)				
Usage	**Strength of Evidence**	**2006 Findings**	**2011 Findings**	**2011 Conclusions**
Substance abuse – cocaine	Low	Not covered.	Two trials of olanzapine and one of risperidone reported there was no difference in efficacy versus placebo as measured by the Addiction Severity Index (ASI).	Olanzapine is **inefficacious** in treating cocaine abuse/ dependence. Risperidone may also be **inefficacious**.
Substance abuse – meth-amphetamine	Low	Not covered.	One trial found aripiprazole inefficacious in reducing use of intravenous amphetamine, as measured by urinalysis. Another trial found aripiprazole inefficacious in reducing craving for methamphetamine.	Aripiprazole is **inefficacious** in treating methamphetamine abuse/dependence.
Substance abuse – methadone clients	Low	Not covered.	One trial of methadone clients found no difference between risperidone and placebo in reduction of cocaine or heroin use.	Risperidone is an inefficacious adjunct to methadone maintenance.

ADHD = attention-deficit hyperactivity disorder; BEHAVE-AD = Behavioral Pathology in Alzheimer's Disease Scale; BPRS = Brief Psychiatric Rating Scale; CGI-BPD = Clinical Global Impression Scale for Borderline Personality Disorder; CGI-I = Clinical Global Impression Improvement; CGI-S = Clinical Global Impression-Severity; CMAI = Cohen-Mansfield Agitation Inventory; HAM-A = Hamilton Anxiety Scale; HAM-D = Hamilton Depression Rating Scale; MADRS = Montgomery-Asberg Depression Rating Scale; MDD = major depressive disorder; NPI = Neuropsychiatric Inventory; OCD = obsessive-compulsive disorder; PANSS = Positive and Negative Syndrome Scale; PCT = placebo-controlled trial; PTSD = post-traumatic stress disorder; SSRI = selective serotonin reuptake inhibitor; SNRI = serotonin-norepinephrine reuptake inhibitors; ZAN-BPD = Zanarini Rating Scale for Borderline Personality Disorder

Table C. Summary update: safety of atypical antipsychotics for off-label use			
Adverse Event	**Head-to-Head Comparisons**	**Active Comparisons**	**Placebo Comparisons**
Weight gain– Elderly patients	In one large trial (CATIE-AD) patients who were treated with olanzapine, quetiapine, or risperidone averaged a monthly gain of 1.0, 0.7, and 0.4 lbs respectively, compared with a monthly weight loss of 0.9 lbs for placebo patients.	More common in patients taking olanzapine than risperidone or conventional antipsychotics, particularly if their BMI was less than 25 at baseline, according to a large cohort study.	More common in patients taking olanzapine and risperidone than placebo according to our meta-analysis.
Weight gain– Adults 18–64	More common in olanzapine patients than ziprasidone patients in one trial.	More common among patients taking olanzapine than patients taking conventional antipsychotics in three trials. More common in patients taking aripiprazole than patients taking conventional antipsychotics in one trial. More common among patients taking olanzapine than patients taking mood stabilizers in two trials.	More common in patients taking aripiprazole, olanzapine, quetiapine, and risperidone than placebo according to our meta-analysis.
Weight gain– Children & adolescents	No head-to-head studies.	No difference between clonidine and risperidone in one trial.	More common in patients taking risperidone in two PCTs. No difference in one small PCT of ziprasidone.
Mortality– Elderly patients	No difference between olanzapine and risperidone according to a meta-analysis of six trials of olanzapine published in 2006.	Six large cohort studies compared mortality in elderly patients taking atypical and conventional antipsychotics. Four of these studies found a significantly higher rate of death with conventional antipsychotics, while two found no statistical difference in mortality between the drug classes.	The difference in risk for death was small but statistically significant for atypicals, according to a 2006 meta-analysis which remains the best available estimate. Sensitivity analyses found no difference between drugs in the class. Patients taking atypicals had higher odds of mortality than those taking no antipsychotics in the two cohort studies that made that comparison. There are no trials or large observational studies of ziprasidone in this population; therefore, we cannot make conclusions regarding safety here.

Table C. Summary update: safety of atypical antipsychotics for off-label use (continued)			
Adverse Event	**Head-to-Head Comparisons**	**Active Comparisons**	**Placebo Comparisons**
Endocrine/ diabetes – Elderly patients	No evidence reported.	No evidence reported.	No difference in endocrine events in risperidone patients in one PCT. Regarding diabetes, risk was elevated but not statistically significant in one industry-sponsored cohort study of olanzapine patients.
Endocrine/ diabetes – Adults 18–64	Diabetes more common in patients taking olanzapine than patients taking risperidone in one trial.	No evidence reported.	Endocrine events more common in patients taking quetiapine, risperidone, and ziprasidone in one PCT each. More common in olanzapine in two pooled PCTs. Diabetes more common in patients taking quetiapine in six pooled PCTs; however, the pooled odds ratio was elevated at 1.47 but not statistically significant. More common in olanzapine patients in one PCT; the odds ratio of 5.14 was not statistically significant, with very wide confidence intervals (0.6 to 244). Lower odds of diabetes in risperidone patients in one large observational study

Table C. Summary update: safety of atypical antipsychotics for off-label use (continued)			
Adverse Event	**Head-to-Head Comparisons**	**Active Comparisons**	**Placebo Comparisons**
CVA – Elderly patients	No evidence reported.	Hospitalization for CVA was increased in the first week after initiation of conventional antipsychotics, but not for initiation of atypicals in a large cohort study.	More common in risperidone patients than placebo according to four PCTs pooled by the manufacturer. In our new meta-analysis of PCTs, risperidone was the only drug associated with an increase. More common in olanzapine than placebo according to five PCTs pooled by the manufacturer.
EPS –	More common in patients taking aripiprazole and risperidone patients than patients taking quetiapine in one large trial (CATIE-AD).	No evidence reported.	More common in patients taking risperidone, according to our meta-analysis. Quetiapine and aripiprazole were not associated with an increase. More common in olanzapine in one PCT.
EPS – Adults 18–64	No evidence reported.	Less likely in patients taking quetiapine than mood stabilizers in one small trial. Less likely in patients taking olanzapine or aripiprazole than patients taking conventional antipsychotics in one trial each.	More common in patients taking aripiprazole, quetiapine, and ziprasidone than placebo according to our meta-analysis.
Sedation – Elderly patients	More common in elderly patients taking olanzapine or quetiapine than risperidone according to our analysis, but not quite statistically significant.	No difference in one trial of olanzapine versus benzodiazepines. No difference in three trials of olanzapine and three of risperidone versus conventional antipsychotics.	More common in patients taking aripiprazole, olanzapine, quetiapine, and risperidone than placebo according to our meta-analysis.
Sedation – Children and adolescents	No head-to-head trials.	No difference in one small trial of clonidine versus risperidone. More patients on haloperidol than risperidone reported sleep problems in one trial.	Less common in aripiprazole patients than placebo patients in one PCT. No difference from placebo in one small PCT of ziprasidone.

Table C. Summary update: safety of atypical antipsychotics for off-label use (continued)			
Adverse Event	**Head-to-Head Comparisons**	**Active Comparisons**	**Placebo Comparisons**
Sedation – Adults 18–64	More common in patients taking quetiapine than risperidone in two trials.	Olanzapine patients had higher odds than mood stabilizer patients in two trials. No difference in one trial of risperidone versus olanzapine. More common in olanzapine and quetiapine patients than SSRIs patients in three and two trials respectively. Olanzapine patients had lower odds than patients taking conventional antipsychotics in our pooled analysis of three trials.	More common in patients taking aripiprazole, olanzapine, quetiapine, risperidone, and ziprasidone than placebo in our meta-analysis.

BMI = body mass index; CATIE-AD = Clinical Antipsychotic Trials of Intervention Effectiveness-Alzheimer's Disease; CVA = cerebrovascular accident; EPS = extrapyramidal symptoms; PCT = placebo-controlled trial; SSRI = serotonin selective reuptake inhibitor

Key Question 5: What is the effective dose and time limit for off-label indications?

There are too few studies comparing doses of atypical antipsychotic medications to draw a conclusion about a minimum dose needed. Most trials used flexible dosing, resulting in patients taking a wide range of doses. According to a meta-analysis we were able to conduct using the percentage of remitters and responders according to the MADRS as outcome, 150 mg quetiapine daily augmentation has equal efficacy as augmentation with 300 mg for patients with MDD who respond inadequately to SSRIs. More trials examining different doses of other atypicals for MDD would help guide clinicians in treating this population. In addition, more dosage trials for treating conditions such as OCD, PTSD, and anxiety disorder would allow for pooling and comparison of results.

Though there is some trial data regarding duration of treatment in PTSD, eating disorders, and borderline personality disorder, the outcome of treatment appears to be the same regardless of reported followup time.

Remaining Issues

The overarching finding of this review is that although atypical antipsychotic medications are used for a large number of off-label indications, there is moderate to strong evidence of efficacy for only a few of the drugs and for only a few of the off-label indications. Most of the evidence is for the drugs risperidone, olanzapine, and quetiapine, for the off-label indications of dementia, depression, and OCD. For the newly approved atypicals (asenapine, iloperidone, and paliperidone), we found no clinical trials assessing their use for any off-label condition, and for some off-label uses, we found no or only a small number of trials. Head-to-head comparisons of atypical antipsychotic drugs for off-label uses are few, and evidence from placebo-controlled trials for off-label use suggests that efficacy differs between drugs, meaning that the assumption of a "class effect" for atypical antipsychotics may be unwarranted. This means that each drug requires its own evaluation of efficacy for each off-label indication, which is a large task; drugs demonstrated to be efficacious will need to be compared in head-to-head in trials.

There is almost no evidence about how treatment efficacy may vary within populations, including variations due to gender, race, ethnicity, or medical comorbidities. In addition, existing evidence about the role of baseline severity of disease is too heterogeneous to allow us to draw conclusions. In future research, standardized measures of disease severity might allow for greater knowledge of the patient populations who would benefit from treatment with atypical agents.

Regarding adverse effects of the atypical antipsychotics, existing evidence varies by drug and by description of the adverse event. It would facilitate assessments of comparative effectiveness if future studies contained a standardized list of assessed side effects. As many trials report only those side effects observed, we are unable to compare between trials for many of the side effects.

Another area where clinical guidance is needed is in the dosages required to achieve effects in off-label indications. The dosages used in off-label indications varied from those used in on-label indications. There were few trials that compared effects by dose. Most studies used "flexible" dosing, where a patients dosage can be adjusted during the trial. Thus, a dosage comparison across trials was generally not possible. More research, examining differing dosages within the same population, is required in order to guide clinicians in the appropriate doses to prescribe. A similar issue is that of treatment length. More research reporting responses at various time points would be helpful in determining how long treatment is required. Given the risk of side effects when using these agents, clinicians need to know when a result is expected to prevent continuing an inefficacious agent, unnecessarily.

Newer agents, such as asenapine, iloperidone, and paliperidone, cannot be assumed to have efficacy and harms similar to the older atypical antipsychotics, since the evidence to date does not support that there is a general "class effect" in terms of either efficacy or harm for most off-label indications. Trials assessing the newer agents' efficacy and safety are necessary if they are to be used off-label for any of the above treatment areas.

Full Report

This executive summary is part of the following document: Maglione M, Ruelaz Maher A, Hu J, Wang Z, Shanman R, Shekelle PG, Roth B, Hilton L, Suttorp MJ, Ewing BA, Motala A, Perry T. Off-Label Use of Atypical Antipsychotics: An Update. Comparative Effectiveness Review No. 43. (Prepared by the Southern California/RAND Evidence-based Practice Center under Contract No. HHSA290-2007-10062-1.) AHRQ Publication No. 11-EHC087-EF. Rockville, MD: Agency for Healthcare Research and Quality. September 2011. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

For More Copies

For more copies of Off-Label Use of Atypical Antipsychotics: An Update: Executive Summary No. 43 (AHRQ Pub. No 11-EHC087-1), please call the AHRQ Clearinghouse at 1–800–358–9295 or email ahrqpubs@ahrq.gov.

AHRQ Pub. No. 11-EHC087-1
September 2011

CMS Initiative to Improve Behavioral Health and Reduce the Use of Antipsychotic Medications in Nursing Home Residents

RESOURCES

Updated 6/4/2012

CMS Launches Initiative to Improve Behavioral Health and Reduce the Use of Antipsychotic Medications in Nursing Homes Residents

On March 29, via a video streaming event, CMS launched a new initiative aimed at improving behavioral health and safeguarding nursing home residents from unnecessary antipsychotic drug use. As part of the initiative, CMS is developing a national action plan that will use a multidimensional approach including public reporting, raising public awareness, regulatory oversight, technical assistance/training and research. The action plan will be targeted at enhancing person-centered care for nursing home residents, particularly those with dementia-related behaviors. Watch the CMS video.

CMS' National Initiative to Improve Behavioral Health & Reduce the Use of Antipsychotic Medications for Nursing Home Residents:

Clive Ballard's Presentation on Management of Behavioral and Psychological Symptoms in People with Dementia Living in Care Homes: A UK Perspective

From Dr. Peter Rabins:
Assessment Form for Residents with Dementia

Additional Resources from Advancing Excellence Partners

Alzheimer's Association

http://www.alz.org/professionals_and_researchers_dementia_care_practice_recommendations.asp

Contact:
Cyndy Cordell
cyndy.cordell@alz.org

The American Geriatrics Society (AGS)

http://www.americangeriatrics.org

American Health Care Association (AHCA)

http://www.ahcancal.org/QUALITY_IMPROVEMENT/QUALITYINITIATIVE/Pages/default.aspx

Contact:
Sandy Fitzler
sfitzler@AHCA.org
202-898-6307

American Medical Directors Association (AMDA)

Psychopharmacologic Interdisciplinary Medication Review

Sample Psychotropic Medication Policy

Contact:
Karyn Leible
kleible@jewishseniorlife.org
585-784-6405

AMDA's Clinical Practice Guidelines
Dedicated to Long Term Care Medicine: Excerpt from AMDA Dementia Clinical Practice Guideline

http://www.amda.com/advocacy/brucbs.cfm

American Society of Consultant Pharmacists

http://www.ascp.com/antipsychotic

Contact:
Arnold Clayman
aclayman@ascp.com
703-739-1300

California Advocates for Nursing Home Reform (CANHR)

http://www.canhr.org/stop-drugging

Contact:
Michael Conners
Michael@canhr.org

Contact:
Anthony Chicotel
tony@canhr.org

The Consumer Voice

Long Term Care Ombudsmen Resource Center Issue Overview

http://www.theconsumervoice.org/advocate/antipsychotic-drugs

Fact Sheet including guidance to residents and advocates regarding individualized assessment where an individual has behavioral symptoms

http://www.theconsumervoice.org/sites/default/files/advocate/advocacy-groups/INDIVIDUALIZED_ASSESSMENT_with_Behavior_Symptoms.pdf

Contact:
Janet Wells
jwells@theconsumervoice.org

Person-centered Care Planning

http://www.theconsumervoice.org/sites/default/files/resident/nursing-home/assessment-and-care-planning.pdf

Department of Veterans Affairs

http://www.ncbi.nlm.nih.gov/books/NBK54971

The Eden Alternative

The Eden Alternative has created a webpage that summarizes new groundbreaking educational offerings designed to introduce providers to fundamental and advanced techniques in person-directed care proven to reduce the off-label use of antipsychotic drugs.

http://www.edenalt.org/how-we-serve/reduce-the-use-of-antipsychotic-medications-in-people-living-in-long-term-care-settings

Contact:
Meredith Burrus
Education Coordinator
The Eden Alternative
(615) 785-1600
(585) 461-3951
mailto:education@edenalt.org

LeadingAge

http://www.leadingage.org/Newsletter.aspx?id=4694&pv=t

Contact:
Cheryl Phillips, M.D.
cphillips@leadingage.org

National Gerontological Nursing Association (NGNA)

http://www.ngna.org

The National Long-Term Care Ombudsman Resource Center

Person-centered Care Planning

http://www.ltcombudsman.org/ombudsman-support/training#Training_Programs_and_In-services

Toxic Medicine

What You **Should Know** to Fight the Misuse of Psychoactive Drugs in California Nursing Homes

CANHR
Long Term Care Justice and Advocacy

"...you have probably got 15,000 elderly people in nursing homes dying each year from the off-label use of antipsychotic medications for an indication that the FDA knows the drug doesn't work...With every pill that gets dispensed in a nursing home, the drug company is laughing all the way to the bank... We have got so many clinical trials that show these drugs don't work, that it is like malpractice to be using it."

— Testimony of Dr. David Graham, a prominent FDA drug safety expert, at a February 13, 2007 hearing of the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: The Adequacy of FDA Efforts to Assure the Safety of the Nation's Drug Supply.

About CANHR's Stop Drugging Campaign

This guide is part of CANHR's Campaign to Stop Chemical Restraints in nursing homes and other long-term care facilities. Ending the misuse of psychoactive drugs is one of CANHR's top priorities because over-drugging is a leading cause of misery, neglect and death for residents who suffer from dementia. The Campaign features a one-of its-kind website where you can join the Campaign, examine drugging rates for each California nursing home, view CANHR's 3-part video series on chemical restraints, learn about better methods of care, read and participate in CANHR's Stop Drugging Our Elders Blog, and much more.

Please join the Campaign today and help us improve residents' lives and end this form of elder abuse.

www.canhr.org/stop-drugging

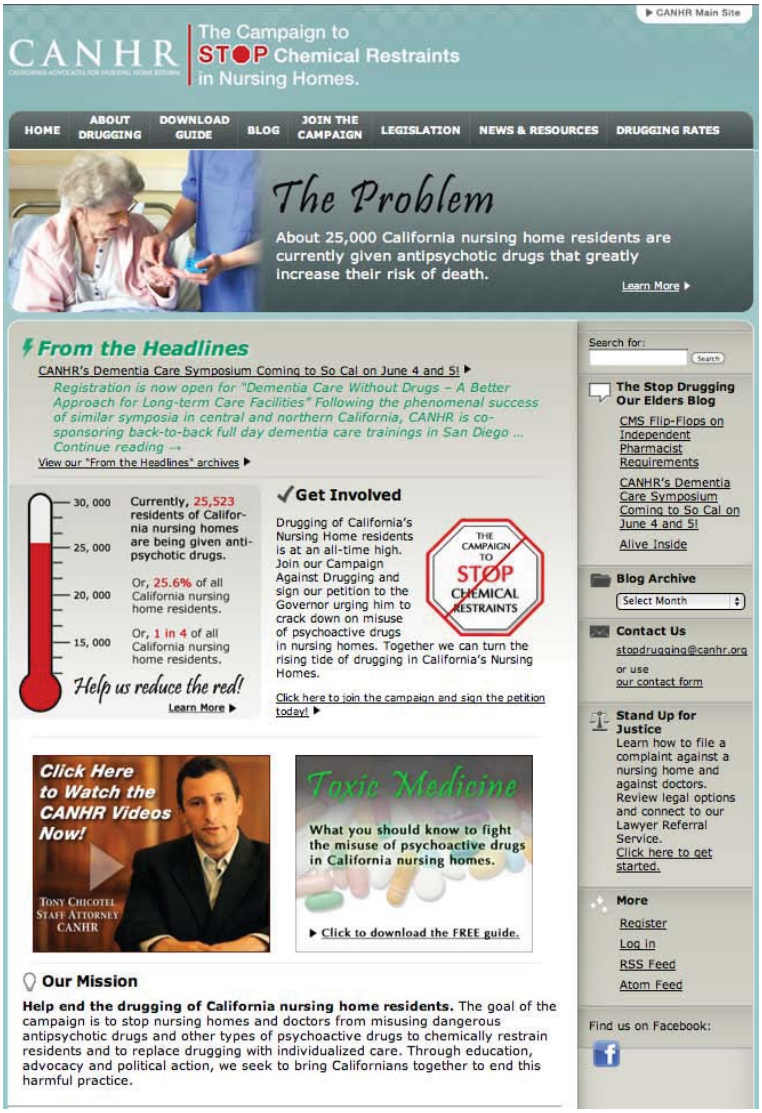


Table of Contents

Introduction

Nursing homes often conjure images of elderly people lying in bed or slumped in wheelchairs completely detached from the world around them. Many visitors and even staff members believe that unresponsive residents are the sad evidence of unavoidable mental declines brought about by dementia or simple old age. However, the poor quality of life for many nursing home residents is often caused not by the symptoms of their disease but by the side effects of their medications.

There is rampant misuse of psychoactive drugs in California nursing homes. Nearly 60% of all California nursing home residents are given psychoactive drugs, a 30% increase since 2000. Many psychoactive medications have dangerous side effects, especially antipsychotic drugs.

Tens of thousands of nursing home residents with dementia receive powerful antipsychotic drugs that are not intended or approved for their medical conditions. Rather, the drugs are often used to sedate and control them, a terrible substitute for the individualized care they need and deserve. The U.S. Food and Drug Administration (FDA) has issued its most dire warning – known as a black box warning – that antipsychotic drugs cause elders with dementia to die.

Antipsychotic drugs don't just hasten death, they often turn residents into people their own families barely recognize by dulling their memories, sapping their personalities and crushing their spirits. When families win battles to take residents off these drugs, they sometimes find that the person they've always known is still there. As one resident's daughter told us, "I got my dad back."

The increased use of psychoactive drugs in nursing homes has been accompanied by an epidemic disregard for the rights of residents to give or withhold their informed consent. Despite legal requirements, the informed consent of residents or their representatives is often ignored.

It is possible to stop a loved one from being drugged by a nursing home. This Guide gives you important facts about psychoactive drugs and advice on how to stop their inappropriate use.

What are Psychoactive Drugs?

Psychoactive drugs – sometimes called psychotropics or psychotherapeutics – contain powerful chemicals that act on the brain to change a person's mood, personality, behavior, and/or level of consciousness.

Types of Psychoactive Drugs

THERE ARE 4 MAJOR CLASSES OF PSYCHOACTIVE DRUGS:

- antipsychotics such as Zyprexa and Haldol;
- anti-anxiety drugs such as Ativan and Valium;
- anti-depressants such as Prozac and Zoloft; and
- sedative/hypnotics such as Halcion and Restoril.

Psychoactive drugs have positive uses. However, many nursing homes routinely use psychoactive drugs as a substitute for needed care and as a form of chemical restraint.

Antipsychotics are the drug of choice in California nursing homes. These extraordinarily dangerous drugs are designed to treat schizophrenia and psychosis, but nursing homes often use them instead to drug residents with dementia into submission. One of every four California nursing home residents is given these drugs on a daily basis. Risperdal, Seroquel, Zyprexa, and Haldol are the most commonly used antipsychotic drugs. Page 17 lists the brand and generic names of antipsychotic drugs.

Antianxiety drugs, such as Ativan and Valium, are also often used to sedate or restrain residents. Like antipsychotic drugs, they are often prescribed for unapproved uses and can cause serious side effects.

Antidepressant drugs are sometimes prescribed in nursing homes without attempting any non-drug interventions even though antidepressants have important downsides, such as increasing a resident's fall risk.

Psychoactive drugs are not the only type of drugs used to sedate or subdue residents with dementia. For example, antiseizure drugs (such as Depakote and Neurontin) are sometimes misused for this purpose.

Risks Galore, Including Death

Psychoactive drugs have numerous, potentially fatal side effects. Some of the most common include tremors, over-sedation, toxicity, anxiety, confusion, delirium and insomnia.

Perversely, psychoactive drugs often cause the agitation and anxiety they are prescribed to treat, leading to even more drugs or higher doses. Elderly nursing home residents are especially at risk of harmful drug interactions because most take many other medications and are in poor health. The use of psychoactive drugs puts them at greatly increased risk of falls and serious injuries that lead to immobility and often death.

The U.S. Food and Drug Administration (FDA) issued an advisory in June 2008 to healthcare professionals that states:

- Elderly patients with dementia-related psychosis treated with conventional or atypical antipsychotic drugs are at an increased risk of death.
- Antipsychotic drugs are not approved for the treatment of dementia-related psychosis. Furthermore, there is no approved drug for the treatment of dementia-related psychosis. Healthcare professionals should consider other management options.

The risk of death from antipsychotic drugs cannot be overstated. The California Attorney General characterized them as "deadly weapons" in

criminal charges against Kern County nursing home officials who are accused of causing the deaths of three residents through misuse of antipsychotic drugs.

The FDA has also issued its most dire warning – known as a black box warning – that antipsychotic drugs cause elders with dementia to die.

Sample FDA Black Box Warning for Risperdal. This warning applies to all antipsychotic drugs:

WARNING:
Increased Mortality in Elderly Patients with Dementia Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. RISPERDAL (risperidone) is not approved for the treatment of patients with dementia-related psychosis.

Antipsychotic Drug Use Varies Widely

Why are so many residents given antipsychotics if these drugs are so dangerous?

In many cases, nursing homes use them to sedate and control residents and as a substitute for needed care. Caregivers may be poorly trained and facilities understaffed. Drug companies heavily promote misuse of antipsychotic drugs through illegal marketing campaigns directed at doctors and nursing homes. Absentee doctors often rubber-stamp drug orders requested by nursing home staff. Resident or family consent is rarely sought and almost never truly informed. State licensing officials do little to enforce the laws against drugging.

Yet some nursing homes rarely use antipsychotic drugs, showing that it is possible to avoid their use. At the other extreme, there are California nursing homes that give antipsychotics to all, or nearly all of their residents. It is primarily the culture of the nursing home, not your medical needs, which determines whether you (or your relative) will be subjected to these drugs.

Advocacy Tip

See how your nursing home compares with others by reviewing its antipsychotic drugging rate on CANHR's stop-drugging website (www.canhr.org/stop-drugging). Obtained from the federal government, the ratings show the percentage of residents taking antipsychotics and other types of psychoactive drugs at each nursing home. This is useful information if you are trying to prevent use of these drugs or if you are trying to find a facility that doesn't have a drugging problem.

Psychoactive Drugs Cannot Be Used Without Informed Consent

Informed consent is a legal right that requires doctors to respect the decisions of their patients. As the term suggests, the concept has two components: information and consent.

The information part of informed consent requires doctors to explain any proposed treatment to their patients and, if applicable, to their patients' legal representatives.

The consent part of informed consent simply requires that patients or their representatives agree to any form of health care treatment before it is undertaken. Failure to obtain consent before administering treatment is battery against the patient.

California nursing home regulations require doctors to disclose the following information when seeking consent from residents or their representatives for the use of psychoactive drugs:

1. the reason for the particular psychoactive drug;
2. the medical condition for which the drug is needed;
3. how long and how often the drug will be used;
4. how the resident's medical condition will be affected;
5. the nature, degree, duration and probability of known side effects;
6. the reasonable alternative treatments; and
7. the resident's right to accept or refuse the psychoactive drug and, if he or she consents, the right to revoke consent for any reason at any time.

The key informed consent regulations are found at sections 72528 and 72527(a)(4) &(5) of Title 22 of the California Code of Regulations. See the Laws and Regulations section on page 18 for a complete listing of pertinent laws and regulations.

Nursing homes are required to verify that consent has been given for psychoactive drugs, even when the drug was prescribed before the resident's admission. Consent is not required in an emergency.

Informed consent requirements are often completely or partially ignored by doctors and nursing homes. However, there are steps you can take to protect your relative from being drugged.

Questions to Ask Doctors and Nursing Homes When Psychoactive Drugs are Proposed

- What specific, documented behaviors or symptoms prompted the need for a psychoactive drug? (e.g., are there delusions or is the resident simply agitated?)
- Have all possible medical or environmental causes been ruled out? (e.g., pain, dehydration, infection, sleep disruptions)
- Has the doctor recently physically examined the resident to determine the need for the drug?
- What alternative treatments have been tried? Are other options still available?
- What are the risks and side effects of the drug?
- Has the FDA issued black box warnings for this drug?
- Has the FDA approved the use of this drug for this purpose?
- How will side effects be monitored? Who will do it?
- Will the proposed drug interact with any of the resident's other medications?
- Is the proposed drug duplicating other current medications?
- Will the resident start on the lowest possible dose of medication?
- When and how often will the need for the drug be reassessed? (the law requires a reassessment at least every three months)

Advocacy Tips When Psychoactive Drugs are Proposed

- You do not have to accept a doctor's recommendation to use psychoactive drugs.
- Do not give consent if the doctor has not directly examined the resident to determine the need for the drug.
- Antipsychotic drugs can be deadly. Don't consent to their use unless you are certain that all other care and treatment options have been exhausted.
- Insist that the doctor or nursing home provide written information on adverse consequences of the proposed drugs, including black box warnings.
- Carefully review and consider the written information before making a decision.
- Consider seeking a second opinion from a trusted physician or advocate if you have doubts about giving consent.

Periodically request a complete list of current medications from the nursing home and/or review the resident's medication administration records kept by the facility, especially if unauthorized drugging is suspected. If you discover that psychoactive drugs are being used without consent, file a formal complaint with the Department of Public Health, notify the local ombudsman program, and consult with CANHR about other actions you can take. See page 14 for more information on remedies.

Ask for a care plan meeting to discuss the need for proposed psychoactive drugs. The nursing home should hold a care plan meeting because the need for psychoactive drugs signals a significant change in the resident's condition. You have a right to attend and participate in this meeting. Use the care plan meeting to determine if the drug is really needed and whether the home has carefully considered all alternatives. Before the meeting, review CANHR's fact sheet, *Making Care Plans Work*, to learn about care plan rights and effective meeting strategies.

Your Right to Review Medical Records:

Nursing home residents and their legal representatives have the right to review their records within 24 hours of a request. Copies of records must be provided within two business days of a request. Requests for copies should be done in writing. If the nursing home refuses to honor a request to review records or for copies, see page 14 for possible remedies.

Important Note: Before instructing a nursing home to stop administering an unwanted psychoactive drug, seek information on withdrawal symptoms. Sudden termination of many psychoactive drugs, especially antipsychotic drugs, can cause serious withdrawal symptoms. If such a drug is being stopped, the doctor should write an order to gradually discontinue it.

Who Can Exercise a Resident's Rights?

If the resident is capable of granting or withholding consent, only the resident may do so. If the resident lacks capacity to make a decision, then the resident's representative may grant or refuse consent. A resident and legal representative can withdraw consent to use a psychoactive drug at any time.

Under California law, persons who may act as your representative include a conservator, an agent designated under a valid advance health care directive or power of attorney for health care, your next of kin, or someone appointed by a court for this purpose.

Right to Refuse

Even if a nursing home resident has problems making health care decisions, she may refuse psychoactive drugs at any time. The right to refuse treatment is a basic constitutional right that may not be violated without a court order. A doctor's declaration that a resident does not have capacity is not enough to override the resident's right to refuse treatment. A nursing home may not retaliate or try to evict a resident who exercises her right to refuse psychoactive drugs.

Chemical Restraints and Unnecessary Drugs are Illegal

Even if a nursing home resident or representative has given informed consent to the use of a psychoactive drug, the drug's use may violate state and federal laws prohibiting chemical restraints and unnecessary drugs.

A chemical restraint is any drug imposed for purposes of discipline or convenience and not required to treat a resident's medical symptoms.

An unnecessary drug is any drug when used in excessive dose, for excessive duration, without adequate monitoring, without adequate indications for its use, or in the presence of adverse consequences that indicate the dose should be discontinued or reduced.

The federal government has even tougher standards on antipsychotic drugs. Nursing homes must not give these drugs to residents who have not used them unless they are necessary to treat a specific condition that has been diagnosed and documented in the resident's record. Federal guidelines state that antipsychotic drugs should not be used if the only symptoms are:

wandering	unsociability
poor self-care	inattention or indifference to surroundings
restlessness	fidgeting
impaired memory	nervousness
mild anxiety	uncooperativeness
insomnia	behavior that does not represent a danger to others

Measured by these standards, most antipsychotic and antianxiety drugs used by nursing homes to treat residents with dementia are both unnecessary and a form of chemical restraint.

Gradual Dose Reduction

Whenever a nursing home resident agrees to take an antipsychotic drug, the nursing home must nevertheless attempt to reduce or eliminate the drug use whenever possible. The use of antipsychotic drugs for each resident should be reviewed at least once every three months. Nursing home regulations require the drugs be reduced unless a doctor has determined that a dose reduction would be unsafe.

Nursing home residents or their representatives who have agreed to psychoactive drugs should closely monitor their administration and insist that they be discontinued whenever possible.

Behavior Problem or Unmet Need?

Behavior problem. Combative. Agitated. Difficult. These are just a few of the ways used to describe the distress so commonly shown by people with dementia. The key to preventing the distress, it turns out, is to use the behaviors and other information as a means to identify and resolve the root causes of the anguish.

Behavior is communication, not a disease. Dementia diminishes a person's ability to communicate verbally, so people with this condition often compensate by communicating behaviorally. Rather than drugging residents to suppress the behaviors, nursing home caregivers must try to figure out what the behaviors mean and respond appropriately.

Some nursing homes are showing that drugs are not needed to prevent or treat challenging behaviors. Their caregivers know the residents, their needs and preferences well enough that they can prevent or diminish distress before it becomes a big problem. These facilities show that behaviors aren't so challenging when residents are comfortable, live in a pleasant environment, get timely medical care and are supported by well-trained caregivers who care about them.

Least Medicating Approach

Psychoactive drugs should always be the last resort for treating symptoms of dementia, not the first option. Nursing homes should look first to treating underlying medical problems, relieving pain, improving the environment, personalizing care, engaging the resident in pleasurable activities, and doing everything possible to make residents feel comfortable and at peace. This "least medicating" approach is the key to better dementia care.

Advocacy Tip

The best step most nursing homes can take to stop unnecessary drugging is to improve staff training on how to respond to symptoms of dementia. The quality of staff training is not necessarily outside your control. Ask the facility if it has arranged for the local Alzheimer's Association chapter to conduct trainings for its staff. If not, urge it to do so.

Ask the doctor to assess possible medical causes of behavioral concerns. Agitation and confusion may be caused by untreated infections, dehydration, malnutrition, adverse medication reactions, pain, and other medical problems. If the doctor won't conduct a thorough medical examination, explore options for replacing the physician or consulting with a geriatrician.

Individualized care and more attention are the best substitutes for drugs. Insist that your loved one's care be customized by adapting personal care, sleep schedules, meals, bathing methods and other services to his or her preferences. Urge the facility to consistently assign caregivers who work well with your relative.

Adequate staffing is needed to respond quickly to physical needs such as help with toileting, getting in and out of bed, bathing, hunger and thirst. If staffing is not adequate, encourage the administrator to improve it.

Improving and simplifying the environment can relieve resident anxiety. Nursing homes must offer a homelike environment. Insist that it do so. For example, distracting noises (such as intercoms and buzzer systems) should

be eliminated. Temperatures should be comfortable. So should seating. No one wants to sit in a wheelchair all day. Hallways should be uncluttered. Lighting should be pleasant. Decorate and furnish your loved one's room to make it comfortable.

What is Comfort Care?

Life in a nursing home can be a difficult adjustment, especially for someone who is forgetful or easily confused due to dementia. Surrounded by new faces and new routines, institutional care can be disorienting and isolating.

To help prevent the distress that often triggers psychoactive drug use in nursing homes, enlightened care providers are increasingly turning to "comfort care" to enhance residents' quality of life. As its name suggests, comfort care strives to keep residents comfortable through a nurturing, individualized approach that focuses on their emotional, social, and spiritual needs, as well as their medical and personal care needs. The goal of comfort care is to keep each resident comfortable and avoid unnecessary drugs by:

- anticipating their needs;
- knowing them so well that basic needs never become major problems;
- embracing a philosophy of individualized care;
- adjusting the pace, approach and communications with them to suit the needs of people with dementia;
- recognizing and treating pain aggressively; and
- treating family and friends as partners in care.

To learn more, read Encouraging Comfort Care: A Guide for Families of People with Dementia Living in Care Facilities, available free from the Illinois Chapter of the Alzheimer's Association: http://www.alzheimers-illinois.org/pti/comfort_care_guide.asp

Help the facility staff plan to engage your relative in pleasurable activities throughout the day with whatever he or she likes, such as walks, music, exercise, reading, visits from pets, group activities, and singing.

Roommate problems may trigger conflict. If this is a problem, ask the facility to find a compatible roommate or, if available, offer a private room.

Encourage patience and understanding. Common symptoms of dementia such as restlessness, pacing, and repeated questions should be expected and accepted.

Meet with the staff to plan care approaches at regular or specially requested care plan meetings. Learn about care plan rights and how to make care plan meetings effective in CANHR's fact sheet, *Making Care Plans Work*.

To learn more about the least medicating approach, visit CANHR's stop-drugging website to see the "Alternatives to Drugs" in the News and Resources section at http://www.canhr.org/stop-drugging/archives/188.

Remedies to Illegal Drugging

If a California nursing home is using or threatening to use psychoactive drugs without consent, call CANHR at 1-800-474-1116 to discuss actions you can take to protect your rights.

There are a variety of actions you can take, including using the suggestions in this guide to seek change from the facility and the physician. Other options include:

Seeking help from local advocacy organizations: The local long term care ombudsman office (http://www.aging.ca.go/Programs/LTCOP/Contacts/) may be helpful. The ombudsman program helps residents resolve concerns about care and rights. However, the ombudsman does not have any powers or direct authority over the nursing home. Local legal service programs may also be able to offer advocacy assistance. Contact CANHR for information.

Filing formal complaints: The California Department of Public Health (CDPH) licenses and inspects nursing homes and enforces state and federal standards. Read CANHR's fact sheet, *How to File a Nursing Home Complaint*, for instructions on how to file a complaint with CDPH. The fact sheet also explains how to file a complaint with the Bureau of Medi-Cal Fraud and Elder Abuse within the California Attorney General's Office. You can file a complaint against the doctor who prescribed the drugs through the Medical Board of California (http://www.medbd.ca.gov/consumer/complaint_info.html).

Suing the facility and doctor: Legal actions can help enforce your rights and seek damages if you or a family member has been harmed. Call CANHR to discuss referral to a qualified elder abuse attorney.

Alerting state legislators: CANHR is working to strengthen California laws against the drugging of nursing home residents. You can help by informing your assembly member and state senator about the inappropriate use of psychoactive drugs. Find your legislators at http://www.leginfo.ca.gov/yourleg.html.

Alerting the media: Nothing gets a nursing home's attention faster than the local media. If other options fail, consider asking the media to help expose dangerous drugging practices.

Resources

CANHR's Stop-Drugging Website at www.canhr.org/stop-drugging

Related CANHR Fact Sheets available at www.canhr.org/factsheets:

- *Making Care Plans Work*
- *How to File a Complaint*
- *Nursing Home Care Standards*
- *Restraint Free Care*
- *Outline of Nursing Home Residents' Rights*

For more suggestions on caring for older adults with dementia without relying on psychoactive drugs:

- Encouraging Comfort Care: A Guide for Families of People with Dementia Living in Care Facilities, free from the Alzheimer's Association at www.alzheimers-illinois.org/pti/comfort_care_guide.asp
- Dementia Beyond Drugs: Changing the Culture of Care, by G. Allen Power, MD
- Visit www.bathingwithoutabattle.unc.edu

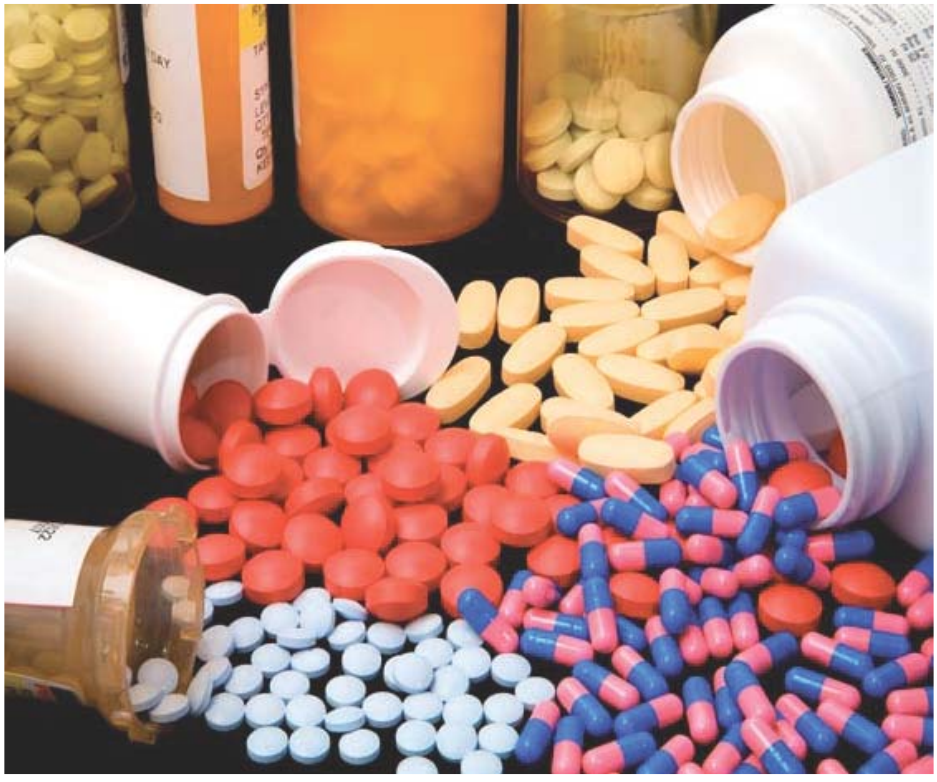
Antipsychotic Drugs

Conventional Antipsychotic Drugs

Compazine (prochlorperazine)
Haldol (haloperidol)
Loxitane (loxapine)
Mellaril (thioridazine)
Moban (molindone)
Navane (thiothixene)
Orap (pimozide)
Prolixin (fluphenazine)
Stelazine (trifluoperazine)
Thorazine (chlorpromazine)
Trilafon (perphenazine)

Atypical Antipsychotic Drugs

Abilify (aripiprazole)
Clozaril (clozapine)
FazaClo (clozapine)
Geodon (ziprasidone)
Invega (paliperidone)
Risperdal (risperidone)
Seroquel (quetiapine)
Zyprexa (olanzapine)
Symbyax (olanzapine and fluoxetine)



Laws and Regulations

Visit CANHR's stop-drugging website to read the content of the following laws and regulations.

Laws on informed consent:
California Code of Regulations (CCR), Title 22, §§ 72527(a)(3), (4) & (5), 72527(e) & 72528; California Health and Safety (H&S) Code §§ 1418.8 & 1418.9; United States Code (USC), Title 42, §§ 1395i-3(c)(1)(A)(i) & 1396r(c)(1)(A)(i); Code of Federal Regulations (CFR), Title 42, §§ 483.10(d)(2) & 483.10(b)(3)

Laws on the right to refuse care and treatment:
22 CCR §§72527(a)(4) & 72528(a)(6), H&S Code §1599.72; 42 CFR §483.10(b)(4)

Laws authorizing representatives to exercise rights:
22 CCR §72527(d), H&S Code §§1599.3 & 1418.8(c), 42 CFR §483.10(a)(3) & (4)

Laws on the right to review and obtain medical records:
42 USC §§1395i-3(c)(1)(A)(iv) and 1396r(c)(1)(A)(iv); 42 CFR §483.10(b)(2); H&S Code §§123100-123149.5

Laws prohibiting chemical restraint:
22 CCR §72527 (a)(23) & 72319; H&S Code 1180.4(k); 42 CFR §483.13(a); 42 USC §§ 1395i-3(c)(1)(A)(ii) & 1396r(c)(1)(A)(ii)

Laws on unnecessary drugs and gradual dose reduction
42 CFR §483.25(l); 42 USC §1396r(c)(1)(D)

Laws requiring care and services for mental or psychosocial adjustment difficulties:
42 CFR §483.25(f); 42 USC §§ 1395i-3(b)(2) & (4) and 1396r(b)(2) & (4) and 1396r(b)(2) & (4)

"The misuse of antipsychotic drugs as chemical restraints is one of the most common and longstanding, but preventable, practices causing serious harm to nursing home residents today."

— Testimony of Toby S. Edelman, Senior Policy Attorney for the Center for Medicare Advocacy at a November 30, 2011 hearing of the U.S. Senate Special Committee on Aging titled: *Overprescribed: The Human and Taxpayers' Costs of Antipsychotics in Nursing Homes*. Experts testified that antipsychotics are dangerous and expensive for "treating" dementia and are typically surpassed by simple nonpharmacologic options.

WARNING

Antipsychotic drugs nearly double the risk of death for older persons with dementia. These drugs are not approved for the treatment of dementia. In addition to death, antipsychotic drug side effects may include stroke, heart attack, increased risk of pneumonia, excessive sedation, lethargy, dizziness, falls, agitation, confusion, restlessness, delirium, hallucinations, tremors, involuntary body movements, muscle weakness, seizures, parkinsonism, cognitive decline, neuroleptic malignant syndrome, headache, dry mouth, constipation, weight gain, weight loss, urinary retention, and blurred vision.

California Advocates for Nursing Home Reform (CANHR)
650 Harrison Street, 2nd Floor, San Francisco 94107
(800) 474-1116 (Consumers only) • (415) 974-5171 • **www.canhr.org**

The Centers for Medicare & Medicaid Services

National Partnership to Improve Dementia Care in Nursing Homes

A mission to:

- Improve the quality of care provided to individuals with dementia living in nursing homes.
- Deliver health care that is person-centered, comprehensive and interdisciplinary.
- Protect residents from being prescribed antipsychotic medications unless there is a valid, clinical indication and a systematic process to evaluate each individual.

The Partnership promotes the three R's:

Rethink our approach to dementia care.

Reconnect with people using person-centered care approaches.

Restore good health and quality of life in nursing homes.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Did you know?

- According to a 2011 report by the Health & Human Services Office of Inspector General, **22 percent** of atypical antipsychotic medications were not administrated in compliance with CMS standards.
- A CMS study found that over **17 percent** of persons living in nursing homes had daily doses of antipsychotic medications exceeding recommended levels.

CMS is partnering with federal and state agencies, nursing homes, other providers, advocacy groups, and caregivers to improve comprehensive dementia care. The national goal is to reduce the percentage of long-stay nursing home residents who receive antipsychotic medications by **15 percent** by the end of 2012.

CMS promotes a multidimensional approach that includes:

- Public reporting
- Partnerships and state-based coalitions
- Research
- Training for providers and surveyors
- Revised surveyor guidance

To learn more about this partnership:
Email - dnh_behavioralhealth@cms.hhs.gov

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Dedicated To Long Term Care Medicine

American Medical Directors Association

11000 Broken Land Parkway
Suite 400
Columbia, MD 21044-3532

(410) 740-9743

Washington DC
(301) 596-5774

Toll Free
(800) 876-AMDA

Fax
(410) 740-4572

www.amda.com
www.ltcmedicine.com

June 18, 2012

Dear Medical Director,

Over the past few months, AMDA-Dedicated to Long Term Care Medicine has partnered with the Centers for Medicare & Medicaid Services (CMS), as well as several other organizations, in an effort to improve care provided to nursing home residents with dementia under a new, joint behavioral health initiative.

Dementia can significantly impair a resident's ability to effectively communicate his/her needs and concerns. Communication attempts may appear as behaviors that are disruptive or distressing. It is therefore essential to gain an understanding of what is driving these behaviors prior to initiating an intervention or treatment. Sometimes these behaviors may result from an undiagnosed medical condition, an adverse reaction to medication, unmet physical need, or mental illness.

In April 2011 the Department of Health and Human Services Office of Inspector General (OIG) released the report, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf). The report found that in some circumstances antipsychotic medications are being prescribed in an attempt to manage the behaviors of patients with dementia and psychological symptoms, but who did not have an approved indication for their use. While off label prescribing in this context does not always constitute inappropriate prescribing, use of antipsychotic drugs do have significant health risks in this population. This report, and other recent reports, has led to heightened regulatory, legislative, and consumer awareness of the potential dangers these medications may cause for individuals with dementia. Such efforts also complement the recently released, "*Draft Framework for the National Plan to Address Alzheimer's Disease*" by the U.S. Department of Health and Human Services.

We are asking you, as the medical director of your facility, to join with AMDA and CMS, in the nationwide effort to reduce the unnecessary use of antipsychotic agents by refocusing the interdisciplinary team on a better understanding of the root cause of dementia related behaviors.

In this regard, we encourage you to share and discuss the following information with your facility.

Medical Director's Role as Clinical Leader in Dementia Care

The medical director leads the team that provides the clinical care to the residents in the facility. In that role, medical directors should help to implement policies and procedures that promote a process of person-centered care, learning "the story" behind each resident, evaluating the behavior changes and excluding potential medical causes of behavioral symptoms. If policies are already in place, the medical director should help to educate the team in existing policies and procedures and ensure that those policies have been implemented. Nursing home policies should direct the staff to identify resident-specific needs, optimize choices, and promote consistent assignment so that staff knows residents well enough to meet their specific care needs. Education should foster the staff's understanding of dementia-related behavior as a form of communication.

Policies should also promote staff's ability to identify relevant risks to any medication, provide parameters for monitoring medications, and institute a process for staff and prescriber reassessment of the resident's response to treatment over time. While there is an established, evidence-based role for antipsychotic medications in managing psychoses, such as schizophrenia and bipolar mania, we are concerned about potential unnecessary use of these medications in persons with behavioral and psychological symptoms related to dementia (BPSD). Medical directors are encouraged to educate facility staff, residents and families about appropriate use of antipsychotic medications, and to begin an ongoing dialogue and collaboration that focuses on non-pharmacologic interventions and person-centered dementia care for BPSD. Educational efforts should also address proper monitoring and the tapering of antipsychotic drugs when used.

As part of the facility's Quality Assessment and Assurance Committee, the medical director along with the administrator, consultant pharmacist and director of nursing should assist the facility with a review of the processes of care for those residents with BPSD on antipsychotic medications. Questions medical directors often ask during the review include the following:

- How many residents in the facility with BPSD receive antipsychotic medications and how is the use monitored?
- What is the process in the facility to initiate the use of these medications?
- What is the process for gradual dose reduction and discontinuation of these medications?
- How is the resident/family/or legal representative informed of the risks and benefits of the use of these medications? How are these discussions documented?

Use of An Interdisciplinary Team

One effective practice for monitoring the use of antipsychotic medications in a facility used by several of our AMDA members is to have the medical director work closely with an interdisciplinary team composed of nursing, social services, therapeutic recreation specialist and a pharmacist. This team meets regularly to review psychotropic drug use. Individual residents are discussed by the team during their quarterly assessments, or with initiation of psychotropic medications, or when there has been a change in the condition of a resident taking a psychotropic medication. During the meeting, the care plans and medical records are reviewed and resident's functional status, medications, presence of medication side effects and presence or absence of achieved goals for medication use are discussed. This practice emphasizes person-centered care. Recommendations from the interdisciplinary team are then made to or with the resident's attending physician. The team tracks the recommendations for acceptance by the primary care providers and effectiveness in the quality of care for the

resident. This information is further reviewed by the facility Quality Assessment and Assurance Committee for effectiveness in addressing the needs of the residents in the facility.

AMDA has developed comprehensive resources to assist medical directors with these issues. These include talking points, a medication management manual, clinical practice guidelines, a series of webinars, and a handbook for nursing home staff. A complete listing of AMDA resources is attached to this letter.

AMDA looks forward to working with you to improve long term care by standardizing our practices, educating the interdisciplinary care team, further developing strong relationships with residents and their advocates, and supporting caregivers in long term care. Increased prescriber training will help reduce unnecessary antipsychotic drug prescribing. AMDA looks forward to an ongoing collaboration with its medical directors.

Sincerely,

Matthew S. Wayne, MD,CMD
President AMDA

AMDA Resources

- In 2011, AMDA released a series of talking points entitled "Appropriate Prescribing of Antipsychotics" to help minimize the *potential for inappropriate prescribing of psychoactive medications* (http://www.amda.com/advocacy/AMDA_Antipsychotics_Tlkg_Pts.pdf).

- AMDA has several tools for clinical use in the nursing home including:

    - Clinical Practice Guidelines: To establish best practices for medical staff, AMDA has developed clinical practice guidelines on dementia, delirium, and acute problematic behavior for use as evidence-based tools to guide care.

        - http://www.amda.com/tools/guidelines.cfm

    - *Mental Health Documentation in the Nursing Hom*e and *Practical Psychiatry in the Long Term Care Home: A Handbook for Staff*, which is aimed at educating nursing and other staff.

        - http://www.amda.com/tools/mentalhealth.cfm

    - *Multidisciplinary Medication Management Manual*, provides practitioners in long term care with information and tools to help them improve patient care, enhance medication management, and reduce medication errors. This manual includes a chapter on appropriate prescribing of psychoactive agents in the long term care setting, which is designed to help guide physicians regarding such issues as the clinical and regulatory documentation necessary when residents are prescribed psychoactive medications.

        - http://www.amda.com/resources/print.cfm#MED

- AMDA has hosted a series of educational Webinars on the issue including:
    - *Medication Management: the Doc, F329, and the OIG*. The learning objectives for this webinar included: delineating medication management as it is regulated in nursing homes; discussing the May 2011 report by the OIG concerning psychotropic drug use in nursing homes; and discussing roles of the medical director and physicians practicing in long term care concerning optimizing medication management for nursing home resident.
        - http://www.amda.com/cmedirect/webinars/web1106E.cfm
    - AMDA's eUniversity is hosting a webinar on June 28th, titled *Medication Management: Antipsychotic Drug Use Reduction 2012*. To learn more and register, visit, http://www.amda.com/cmedirect/webinars/web1206E.cfm.
    - *Use of Psychoactive Medications with Special Emphasis on Antipsychotics in the Long-Term Care Setting*. The learning objectives for this webinar included: recognizing how to analyze and evaluate problematic behavior vs. behavioral symptoms related to dementia; discussing approaches to changing or removing triggers for problematic behavior with non-pharmacological approaches; and describing the appropriate use of psychoactive agents in the long-term care setting.
        - http://www.prolibraries.com/amda/?select=session&sessionID=773
    - *The True Meaning of Non-Pharmacologic Management of Behavioral Symptoms in Older Adults with Cognitive Impairment* emphasized the use of non-pharmacologic interventions as the first-line approach to managing disruptive and/or potentially dangerous behavioral symptoms in persons with dementia. The webinar provided a comprehensive, multi-disciplinary approach to these challenging clinical situations and also provided participants with knowledge enabling them to effectively design and implement non-pharmacologic interventions in their facilities.
        - http://amda.networkats.com/members_online/members/viewitem.asp?item=WEB1112E&catalog=SELF&pn=1&af=AMDA
- More resources on this topic are also located here: http://www.amda.com/advocacy/brucbs.cfm

TO DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-35-NH

DATE: **May 24, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advanced Copy: Dementia Care in Nursing Homes: Clarification to Appendix P State Operations Manual (SOM) and Appendix PP in the SOM for F309 – Quality of Care and F329 – Unnecessary Drugs

Memorandum Summary

- **Guidance –** This memo conveys clarification to Appendices P and PP related to nursing home residents with dementia and unnecessary drug use.
- **Training** - Mandatory surveyor trainings are available online at http://surveyortraining.cms.hhs.gov.

National Partnership

On March 29, 2012, the Centers for Medicare & Medicaid Services (CMS) launched the National Partnership to Improve Dementia Care and Reduce Unnecessary Antipsychotic Drug Use in Nursing Homes (this is now referred to as the Partnership to Improve Dementia Care in Nursing Homes). The goal of this Partnership is to optimize the quality of life and function of residents in America's nursing homes by improving approaches to meeting the health, psychosocial and behavioral health needs of all residents, especially those with dementia.

The CMS has joined with various stakeholders to improve dementia care in nursing homes. We are doing several things to support this work, including producing surveyor training videos as well as updating Appendix P and Appendix PP of the State Operations Manual (SOM). Individualized, person-centered approaches may help reduce potentially distressing or harmful behaviors and promote improved functional abilities and quality of life for residents.

It has been a common practice to use various types of psychopharmacological medications in nursing homes to try to address behaviors without first determining whether there is a medical, physical, functional, psychological, emotional, psychiatric, social or environmental cause of the behaviors. Medications may be effective when they are used appropriately to address significant, specific underlying medical or psychiatric causes, or new or worsening behavioral symptoms. However, medications may be ineffective and are likely to cause harm -if given

without a clinical indication. All interventions, including medications, need to be monitored for efficacy, risks, benefits and harm.

The problematic use of medications, such as antipsychotics, is part of a larger, growing concern. This concern is that nursing homes and other settings (i.e. hospitals, ambulatory care) may use medications as a "quick fix" for behavioral symptoms or as a substitute for a holistic approach that involves a thorough assessment of underlying causes of behaviors and individualized, person-centered interventions.

Antipsychotic medications are frequently prescribed for residents with dementia who have behavioral or psychological symptoms of dementia (BPSD).[1,2] The term BPSD is used to describe behavior or other symptoms in individuals with dementia that cannot be attributed to a specific medical or psychiatric cause.

When antipsychotic medications are used without an adequate rationale, or for the purpose of limiting or controlling behavior of an unidentified cause, there is little chance that they will be effective. In addition, they commonly cause complications such as movement disorders, falls, hip fractures, cerebrovascular adverse events (cerebrovascular accidents and transient ischemic events) and increased risk of death. [3,4,5,6] The Food & Drug Administration (FDA) Black Box Warnings Regarding Atypical Antipsychotics in Dementia provides, "Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo." [7]

Dementia Care Principles

Fundamental principles of care for a resident with dementia include an interdisciplinary approach that focuses on the needs of the resident as well as the needs of the other residents in the nursing home. Sections 1819 and 1919 of the Social Security Act (the Act) and current regulations already require a number of essential elements to be in place in order for facilities to be in compliance with federal requirements on quality of care and quality of life. This revised CMS guidance and surveyor training highlight and re-emphasize a number of those key principles, including:

1. Person–Centered Care. CMS requires nursing homes to provide a supportive environment that promotes comfort and recognizes individual needs and preferences.

2. Quality and Quantity of Staff. The nursing home must provide staff, both in terms of quantity (direct care as well as supervisory staff) and quality to meet the needs of the residents as determined by resident assessments and individual plans of care.

3. Thorough Evaluation of New or Worsening Behaviors. Residents who exhibit new or worsening BPSD should have an evaluation by the interdisciplinary team, including the physician, in order to identify and address treatable medical, physical, emotional, psychiatric, psychological, functional, social, and environmental factors that may be contributing to behaviors.

4. Individualized Approaches to Care. Current guidelines from the United States, United Kingdom, Canada and other countries recommend use of individualized approaches as a first line intervention (except in documented emergency situations or if clinically contraindicated) for BPSD.[8-10] Utilizing a consistent process that focuses on a resident's individual needs and tries to understand behavior as a form of communication may help to reduce behavioral expressions of distress in some residents.

5. Critical Thinking Related to Antipsychotic Drug Use. In certain cases, residents may benefit from the use of medications. The resident should only be given medication if clinically indicated and as necessary to treat a specific condition and target symptoms as diagnosed and documented in the record. Residents who use antipsychotic drugs must receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort discontinue these drugs.

> **NOTE:** If during a survey, the team identifies a concern that an antipsychotic medication may potentially be administered for discipline, convenience and not being used to treat a medical symptom, the survey team should review F222 - 483.13(a) Right to be Free From Chemical Restraints.

6. Interviews with Prescribers. None of the guidance to surveyors should be construed as evaluating the practice of medicine. Surveyors are instructed to evaluate the process of care. Surveyors interview the attending physician or other primary care provider (NP, PA), behavioral health specialist, pharmacist and other team members to better understand the reasons for using a psychopharmacological agent or any other interventions for a specific resident.

7. Engagement of Resident and/or Representative in Decision-Making. In order to ensure judicious use of psychopharmacological medications, residents (to the extent possible) and/or family or resident representatives must be involved in the discussion of potential approaches to address behavioral symptoms. These discussions with the resident and/or family or representative should be documented in the medical record.

Guidance Updates and Surveyor Training

1. Surveyor training videos

Through work with our partners, CMS has developed a series of interactive training sessions around behavioral health and dementia care. Materials currently available to surveyors may be accessed on the surveyor training website at: http://surveyortraining.cms.hhs.gov/index.aspx.

We have made available three mandatory surveyor trainings (see S&C memo 13-34-ALL). The first training provides an overview of dementia care and potential approaches to addressing behavioral distress. The second training walks surveyors through portions of an annual survey and focuses on the evaluation of one resident with dementia. These two trainings are currently available on the surveyor training website. A third training video is under development that will provide a review of the revised interpretive guidance at F309 and changes to Table 1 for antipsychotic medications at F329. This final training will present case studies and discuss how

to identify potential F Tags and determine severity for non-compliance related to care of a resident with dementia.

2. Updates to Appendix P (Attachment A) include:

- Changes to the resident sampling process for the traditional survey (changes to QIS were included in the recent 10.1.3 release).

The change is intended to ensure that the survey sample includes an adequate number of residents with dementia who are receiving an antipsychotic medication. See Attachment A.

3. Updates to Appendix PP (Attachment B) include:

- A new section of interpretive guidance at F309 related to the review of care and services for a resident with dementia;
- Revisions to the antipsychotic medication section of Table 1 at F329;
- New severity example at the end of the interpretive guidance at F329 (Unnecessary drugs);

A surveyor checklist that may be used in either the traditional or QIS process (modeled after the CE pathways) is also provided (Attachment C). This checklist is not part of the SOM.

References:

1. Briesacher BA, Limcangco MR, Simoni-Wastila L et al. The quality of antipsychotic drug prescribing in nursing homes. Arch Intern Med 2005;165(June):1280-1285.

2. Levinson DR. Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents. Department of Health and Human Services Office of Inspector General Report (OEI-07-08-00150)05-04-2011 accessed at https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf

3. Schneider L, Tariot P, Dagerman K. Effectiveness of atypical antipsychotic drugs in residents with Alzheimer's disease. N Engl J Med 2006;355:1525-1538.

4. Ray WA, Chung CP, Murray KT, et al: Atypical antipsychotic drugs and the risk of sudden cardiac death. N Engl J Med 2009;360:225—235.

5. Schneider LS, Dagerman K, Insel PS: Efficacy and adverse effects of atypical antipsychotics for dementia: meta-analysis of randomized, placebo-controlled trials. American Journal of Geriatric Psychiatry 2006 14:191—210.

6. Rochon P, Normand S, Gomes T et al. Antipsychotic therapy and short-term serious events in older adults with dementia. Arch Intern Med 2008;168:1090-1096.

7.http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm053171.htm

8. The American Geriatrics Society. (2012). American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. Journal of American Geriatrics Society. New York. The American Geriatrics Society.

9. 3rd Canadian Consensus Conference on Diagnosis & Treatment of Dementia. (2007). Approved Recommendations. Montreal.

10. Scottish Intercollegiate Guidelines Network. (2006). Management of Patients with Dementia: A National Clinical Guideline. Scott Intercollegiate Guidelines Network.

Attachments: 3

Attachment A – SOM – Appendix P – Revision to Sample Selection for the Traditional Survey

Attachment B – SOM – Appendix PP – F309 – Interpretive Guidance for Care and Services of a Resident with Dementia; F329 – Interpretive Guidance for Drug Regimen Free from Unnecessary Drugs (includes only revised sections of F329, including Table 1, section on antipsychotic medications and the new severity example)

Attachment C – Surveyor Checklist for Review of Care and Services for a Resident with Dementia (This document is not considered a SOM revision or addition.)

For questions on this memorandum, please contact Michele Laughman at dnh_behavioralhealth@cms.hhs.gov.

Effective Date: This policy is in effect immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

Training: This policy should be shared with all appropriate survey and certification staff, their managers and the State/Regional Office training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal: Advanced Copy **Date:**

CHANGE REQUEST:

SUBJECT: National Partnership to Improve Dementia Care in Nursing Homes; Interim Changes to Appendix P State Operations Manual (SOM)

I. SUMMARY OF CHANGES: We are providing interim guidance related to surveyors' assessment for compliance with requirements related to nursing home residents with dementia and unnecessary drug use. These updates include sampling for the traditional survey process in Appendix P.

In Appendix P, we have made changes to the resident sampling process for the traditional survey (changes to QIS were included in the recent 10.1.3 release). The change is intended to ensure that the survey sample includes an adequate number of residents with dementia who are receiving an antipsychotic medication.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	App P/Revision to Sample Selection for the Traditional Survey/Task1/Off Site Preparation
R	App P/Revision to Sample Selection for the Traditional Survey/Task2/Entrance Conference/Onsite Preparatory Activities/A/Entrance Conference/3/The team coordinator should
R	App P/Revision to Sample Selection for the Traditional Survey/Task4/Revision to Sample Selection for Traditional Survey/D/Protocol/1/Phase 1 – Sample Selection

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service**

Appendix P - Revision to Sample Selection for the Traditional Survey*

Task 1 – Off Site Preparation

Use the Facility QM Report to pre-select concerns for any QM that is flagged at the 75th (or greater) national percentile.

NOTE: If either of the QM's for residents on antipsychotic medications are flagged, include the questions related to dementia care and antipsychotic medication use during the entrance conference (see Task 2 below).

Use the instructions identified in Task 2 and Task 4 in order to include a resident with dementia who is receiving an antipsychotic medication in the sample.

Task 2 – Entrance Conference/Onsite Preparatory Activities:

A. Entrance Conference

3. The team coordinator should:

- *Request a list of the names of residents who have a diagnosis of dementia and who are receiving, have received, or presently have PRN orders for antipsychotic medications over the past 30 days.*

- *If the facility population includes residents with dementia, ask the administrator or director of nursing to describe how the facility provides individualized care and services for residents with dementia and to provide policies related to the use of antipsychotic medications in residents with dementia.*

Task 4 –Sample Selection for Traditional Survey

Phase 1 - Sample Selection

- *Use the list of names of residents, who over the past 30 days, received, are presently receiving or have PRN orders for antipsychotic medications and have a diagnosis of dementia:*

    - *Compare this list to the off-site Phase 1 resident sample and determine if a resident from this list is already included in the Phase 1 sample; and*

    - *Ensure that, at a minimum, at least one of the residents on the list who is receiving an antipsychotic medication is in the Phase 1 sample for a comprehensive or focused record review.*

- *If the Phase 1 sample does not identify at least one resident that is on the facility provided list, the team should consider either replacing one resident from the Phase 1 sample with one resident from the facility provided list or adding a resident from the list to the sample. Consider the following:*

    1. If selecting a replacement resident, attempt to select a resident from the facility provided list that was noted to be included in the same QM conditions as the resident who was removed.

    2. When considering the addition of a resident from this list, attempt to select a resident who is representative of areas of concern, such as triggering QM's at or above the 75% percentile or other special factors.

    - *Reference the "Review of Care and Services for a Resident with Dementia Checklist" while conducting this review.*

Appendix P - Sample Selection for the Quality Indicator Survey (QIS)

For the QIS, surveyors will not have to make an adjustment to the sample selection as the software will automatically identify the required sample. NOTE: An electronic version of the CMS Review of Care and Services for a Resident with Dementia Checklist is available and may be used either electronically or the surveyor may print a copy of the checklist to guide the Phase 2 investigation of care provided to a resident with dementia.

*This is revised guidance for portions of Tasks 1, 2 and 4 – it does not replace existing guidance in Appendix P for other aspects of those tasks.

CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal: Advanced Copy **Date:**

CHANGE REQUEST:

SUBJECT: National Partnership to Improve Dementia Care in Nursing Homes; Interim Changes to Appendix PP in the State Operations Manual (SOM) for F309 – Quality of Care and F329 – Unnecessary Drugs

I. SUMMARY OF CHANGES: We are providing interim guidance related to surveyors' assessment for compliance with requirements related to nursing home residents with dementia and unnecessary drug use. These updates include Appendix PP F329 Table 1 and severity examples, as well as F309.

In Appendix PP, a new section of interpretative guidance at F309 related to the review of care and services for a resident with dementia has been added. At F329, new severity examples have been added at the end of the interpretative guidance and revisions to the antipsychotic medication section have been made to Table 1.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	App PP/§483.25/F309/Quality of Care
R	App PP/§483.25/F329/Table 1/Medication Issues of Particular Relevance/Antipsychotic Medications
R	App PP/§483.25/F329/Additional Example

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements

	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

F309

F309 – §483.25 Quality of Care

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Intent: §483.25

The facility must ensure that the resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process.

NOTE: Use guidance at F309 for review of quality of care not specifically covered by 42 CFR 483.25 (a)-(m). Tag F309 includes, but is not limited to, care such as *care of a resident with dementia,* end-of-life, diabetes, renal disease, fractures, congestive heart failure, non-pressure related skin ulcers, pain, and fecal impaction.

Review of Care and Services for a Resident with Dementia

Use this guidance for a resident with dementia. If the resident is receiving one or more psychopharmacological agents, also review the guidance at F329, Unnecessary Drugs.

*There is no specific investigative protocol for care of a resident with dementia. For the traditional survey, the surveyor may use the surveyor checklist titled, "**Review of Care and Services for a Resident with Dementia**" to assist in investigating the care and services provided to a resident with a diagnosis of dementia. For the QIS survey, the surveyor will use the general CE pathway and may use the checklist as a guide to completing that pathway.*

Definitions Related to Recognition and Management of Dementia

- *Behavioral interventions are individualized approaches (including direct care and activities) that are provided as part of a supportive physical and psychosocial environment, and are directed toward understanding, preventing, relieving, and/or accommodating a resident's distress or loss of abilities.*

- *Person-Centered or Person-Appropriate Care is care that is individualized by being tailored to all relevant considerations for that individual, including physical, functional, and psychosocial aspects. For example, activities should be relevant to the specific needs, interests, culture, background, etc. of the individual for whom they are developed and medical treatment should be tailored to an individual's risk factors, current conditions, past history, and details of any present symptoms.*

- *Behavioral or Psychological Symptoms of Dementia (BPSD) is a term used to describe behavior or other symptoms in individuals with dementia that cannot be attributed to a specific medical or psychiatric cause. The term "behaviors" is more*

general and may encompass BPSD or responses by individuals to a situation, the environment or efforts to communicate an unmet need.

Overview of Dementia and Behavioral Health

What is Behavior?

Human behavior is the response of an individual to a wide variety of factors. Behavior is generated through brain function, which is in turn influenced by input from the rest of the body. Specific behavioral responses depends on many factors, including personal experience and past learning, inborn tendencies and genetic traits, the environment and response to the actions and reactions of other people. A condition (such as dementia) that affects the brain and the body may affect behavior.

What is Dementia?

Dementia is not a specific disease. It is a descriptive term for a collection of symptoms that can be caused by a number of disorders that affect the brain. People with dementia have significantly impaired intellectual functioning that interferes with normal activities and relationships. They also lose their ability to solve problems and maintain emotional control, and they may experience personality changes and behavioral problems, such as agitation, delusions, and hallucinations. While memory loss is a common symptom of dementia, memory loss by itself does not mean that a person has dementia. Doctors diagnose dementia only if two or more brain functions - such as memory and language skills -- are significantly impaired without loss of consciousness.

Some of the diseases that can cause symptoms of dementia are Alzheimer's disease, vascular dementia, Lewy body dementia, fronto-temporal dementia, Huntington's disease, and Creutzfeldt-Jakob disease. Doctors have identified other conditions that can cause dementia or dementia-like symptoms including reactions to medications, metabolic problems and endocrine abnormalities, nutritional deficiencies, infections, poisoning, brain tumors, anoxia or hypoxia (conditions in which the brain's oxygen supply is either reduced or cut off entirely), and heart and lung problems. Although it is common in very elderly individuals, dementia is not a normal part of the aging process.[1]

Some individuals with dementia may have coexisting symptoms or psychiatric conditions such as depression or bipolar affective disorder, paranoia, delusions or hallucinations. Progressive dementia may exacerbate these and other symptoms.

Behavioral or psychological symptoms are often related to the brain disease in dementia; however behavior and other symptoms may also be caused or exacerbated by environmental triggers. Behavior often represents a person's attempt to communicate an unmet need, discomfort or thoughts that they can no longer articulate. Knowing detailed cultural, medical and psychosocial information about a person can help caregivers identify potential environmental or other triggers in order to prevent or reduce, to the extent possible, behavior or

other expressions of distress.[2] Because behavioral symptoms may be caused by medical conditions such as delirium, medication side effects, and psychiatric symptoms such as delusions or hallucinations, these should be considered as possible causes in addition to environmental triggers.

What is Delirium?

A resident may have undiagnosed delirium, which is an acute confusional state that includes symptoms very similar to those of dementia and psychiatric disorders. The diagnostic criteria for delirium include a fluctuating course throughout the day, inattention as evidenced by being easily distracted, cognitive changes, and perceptual disturbances[3].

Delirium develops rapidly over a short time period, such as hours or days, and is associated with an altered level of consciousness. Delirium has an underlying physiologic cause that can generally be identified through a diagnostic evaluation. Potential causes include, but are not limited to, infection, fluid/electrolyte imbalance, medication, or multiple factors. Specific diagnostic criteria are outlined in the DSM IV-TR or the Confusion Assessment Method[3,4].

Classic delirium is often characterized as hyperactive (e.g., extreme restlessness, climbing out of bed); but more commonly delirium is hypoactive often leading to the misdiagnosis of dementia or a psychiatric disorder. Delirium is particularly common post-hospitalization; signs and symptoms may be subtle and therefore are often missed. Although generally thought to be short lived, delirium can persist for months.

Delirium and dementia are now recognized as being related. Individuals with dementia are at higher risk for developing delirium and it now appears that delirium increases the risk of developing dementia over time[5]. Recognizing delirium is critical, as failure to act quickly to identify and treat the underlying causes may result in poor health outcomes, hospitalization or even death[6].

Therapeutic Interventions or Approaches

The use of any approach must be based on a careful, detailed assessment of physical, psychological and behavioral symptoms and underlying causes as well as potential situational or environmental reasons for the behaviors. Caregivers and practitioners are expected to understand or explain the rationale for interventions/approaches, to monitor the effectiveness of those interventions/approaches, and to provide ongoing assessment as to whether they are improving or stabilizing the resident's status or causing adverse consequences. Describing the details and possible consequences of resident behaviors helps to distinguish expressions such as restlessness or continual verbalization from potentially harmful actions such as kicking, biting or striking out at others. This description alone does not suggest that a specific intervention is or is not indicated; however, it is important information that may assist the care team (including the resident and/or family or representative) in decision-making and in matching selected interventions to the individual needs of each resident.

Identifying the frequency, intensity, duration and impact of behaviors, as well as the location, surroundings or situation in which they occur may help staff and practitioners identify individualized interventions or approaches to prevent or address the behaviors. Individualized, person-centered interventions must be implemented to address behavioral expressions of distress in persons with dementia. In many situations, medications may not be necessary; staff/practitioners should not automatically assume that medications are an appropriate treatment without a systematic evaluation of the resident. Examples of techniques or environmental modifications that may prevent certain behavior related to dementia may include (but are not limited to):

- *Arranging staffing to optimize familiarity with the resident (e.g., consistent caregiver assignment);*

- *Identifying, to the extent possible, factors that may underlie the resident's expressions of distress, as well as applying knowledge of lifelong patterns, preferences, and interests for daily activities to enhance quality of life and individualize routine care.*

- *Understanding that the resident with dementia may be responding predictably given the situation or surroundings. For example, being awakened at night in his/her bedroom by staff and not recognizing the staff could elicit an aggressive response; and*

- *Matching activities for a resident with dementia to his/her individual cognitive and other abilities and the specific behaviors in that individual based on the assessment.*

Medication Use in Dementia (see also F329)

It has been a common practice to use various types of psychopharmacological medications in nursing homes to try to address behavioral or psychological symptoms of dementia (BPSD)[7,8] without first determining whether there is an underlying medical, physical, functional, psychosocial, emotional, psychiatric, or environmental cause of the behaviors. Medications may be effective when they are used appropriately to address significant, specific underlying medical and psychiatric causes or new or worsening behavioral symptoms. However, medications may be ineffective and are likely to cause harm when given without a clinical indication, at too high a dose or for too long after symptoms have resolved and if the medications are not monitored. All interventions including medications need to be monitored for efficacy, risks, benefits and harm.

These agents must only be used if the steps in the care process below and as outlined in F329 have been followed.

When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling behavior of an unidentified cause, there is little chance that they will be effective, and they commonly cause complications such as movement disorders, falls, hip fractures, cerebrovascular adverse events (cerebrovascular accidents and transient ischemic events) and increased risk of death. [9,10,11,12] *The FDA Black Box*

Warning Regarding Atypical Antipsychotics in Dementia states, "Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo." The FDA issued a similar Black Box Warning for conventional antipsychotic drugs. (Additional information on the FDA black box warning is available at http://www.fda.gov/Drugs/default.htm.)

Recent studies suggest that certain antipsychotic medications may have greater risks than others in that same class of medications[13,14]. Other classes of psychopharmacological agents may carry significant risks as well.

NOTE: If a concern is identified during a survey that an antipsychotic medication may potentially be administered for discipline, convenience and/or is not being used to treat a medical symptom, consider reviewing F222 - 483.13(a) Restraints, for the right to be free from any chemical restraints.

Resident and/or Family/Representative Involvement:

CMS expects that the resident and family/representatives, to the extent possible, are involved in helping staff to understand the potential underlying causes of behavioral distress and to participate in the development and implementation of the resident's care plan. Residents have the right to be informed about their medical condition, care and treatment; they have the right to refuse treatment and the right to participate in the care plan process (See F154, F155, F242, F279, F280).

Facilities should be able to identify how they have involved residents/families/representatives in discussions about potential approaches to address behaviors and about the potential risks and benefits of a psychopharmacological medication (e.g., FDA black box warnings), the proposed course of treatment, expected duration of use of the medication, use of individualized approaches, plans to evaluate the effects of the treatment, and pertinent alternatives. The discussion should be documented in the resident's record (See F154).

NOTE: some states have specific laws/licensing rules regarding the provision of informed consent. The State Agency determines and directs the surveyors regarding the review for those provisions under their State licensing authority. If non-compliance with the State regulation is identified, the surveyors may only cite this non-compliance at F492 when the Federal, State or local authority having jurisdiction has both made a determination of non-compliance AND has taken a final adverse action.

The facility should document attempts to include the family/representative, to the extent possible, in the decision-making process. If the family/representative is unable to participate in person, were further attempts made to include the family/representative in the discussions/development of the care planning through alternative methods, such as by phone or electronic methods?

If the resident lacks decision-making capacity and lacks an effective family/representative support, contact the facility social worker to determine what type of social services or referrals have been attempted to assist the resident (See F250).

During interviews with the family/representative, surveyors should ask if families have observed staff implementing the individualized care plan interventions that were developed (See F282).

Care Process for a Resident with Dementia

Fundamental principles of care for persons with dementia include an interdisciplinary team approach that focuses holistically on the needs of the resident as well as the needs of the other residents in the nursing home. It is important for the facility to have systems and procedures in place to assure that assessments are timely and accurate; interventions are described, consistently implemented, monitored, and revised as appropriate in accordance with current standards of practice.

It is expected that a facility's approach to care for a resident with dementia follows a systematic care process in order to gather and analyze information necessary to provide appropriate care and services, and that the resident and/or family or representative is engaged throughout the process. It is expected that the resident's record reflects the implementation of the following care processes:

A. Recognition and Assessment;

B. Cause Identification and Diagnosis;

C. Development of Care Plan;

D. Individualized Approaches and Treatment;

E. Monitoring, Follow-up and Oversight; and

F. Quality Assessment and Assurance (QAA).

See Additional Resources section below for some suggested resources that facilities may consult in developing their dementia care policies.

The following guidance aggregates requirements in a number of other F-tags such as comprehensive assessment, activities, resident rights, unnecessary medications and others, bringing that guidance together into a framework for evaluating care of individuals with dementia.

A. Recognition and Assessment:

This step includes collecting detailed information about a resident. The resident's record should reflect comprehensive information about the person including, but not limited to: past life experiences, description of behaviors, preferences such as those for daily routines, food, music, exercise and others; oral health, presence of pain, medical conditions; cognitive status and related abilities and medications. When reviewing the comprehensive assessment (see F272), the Care Area Assessment (CAA) Resources, particularly those related to Activities and Behavioral Symptoms, found in the Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 3.0 may be helpful.

It is important to determine whether the record reflects the evaluation of, but is not limited to:

- *How the resident typically communicates physical needs such as pain, discomfort, hunger or thirst, as well as emotional and psychological needs such as frustration or boredom; or a desire to do or express something that he/she cannot articulate;*

- *The resident's usual and current cognitive patterns, mood and behavior, and whether these present a risk to the resident or others;*

- *How the resident typically displays personal distress such as anxiety or fatigue.*

This and other information enables an understanding of the individual and provides a basis for cause identification (based on knowing the whole person and how the situation and environment may trigger behaviors) and individualized interventions. If the resident expresses distress, staff should specifically describe the behavior (including potential underlying causes, onset, duration, intensity, precipitating events or environmental triggers, etc.) and related factors (such as appearance and alertness) in the medical record with enough detail of the actual situation to permit cause identification and individualized interventions (See F514). For example, noting that the resident is generally "violent," "agitated" or "aggressive" does not identify the specific behavior exhibited by the resident. Noting instead that the resident responds in crowded, busy group activities by yelling or throwing furniture reflects not only a potential safety issue but should result in the resident being provided alternative activities to meet his/her needs.

B. Cause Identification and Diagnosis:

This step uses the information collected about an individual to help identify the physical, functional, psychosocial, environmental, and other potential causes of behavior and related symptoms, including how they interact with each other. Staff, in collaboration with the practitioner, should identify possible risk and causal/contributing factors for behaviors, such as:

- *Presence of co-existing medical or psychiatric conditions, including acute/chronic pain, constipation, delirium and others, or worsening of mental function; and/or*

- *Adverse consequences related to the resident's current medications (See F329).*

Staff must make an ongoing effort to identify and document the new onset or worsening behavioral symptoms, including whether or not the behavior presents a significant risk for adverse consequences to the resident and/or others.

The attending physician is responsible for supervising each resident's medical care. In addition, the facility must immediately consult with the resident's physician when there is a significant change in the resident's physical, mental, or psychosocial status (See F157). If the behaviors observed represent a change or worsening from the baseline, the attending physician/practitioner and staff are expected to consider potential underlying medical, physical, psychosocial, or environmental causes of the behaviors (See F385). If the resident has experienced two or more areas of decline or improvement, including a change related to behavior, a Significant Change in Clinical Status Assessment (SCSA) should be considered (see F274).

If medical causes are ruled out, the facility should attempt to establish other root causes of behavior using individualized, holistic knowledge about the person and when possible, information from the resident, family or previous caregivers, and direct care staff. This includes conducting a systematic analysis and consideration of possible causes, including but not limited to:

- *Boredom; lack of meaningful activity or stimulation during customary routines and activities;*
- *Anxiety related to changes in routines such as shift changes, unfamiliar or different caregivers, change of (or relationship with) roommate, inability to communicate;*
- *Care routines (such as bathing) that are inconsistent with a person's preferences;*
- *Personal needs not being met appropriately or sufficiently, such as hunger, thirst, constipation;*
- *Fatigue, lack of sleep or change in sleep patterns which may make the person more likely to misinterpret environmental cues resulting in anxiety, aggression or confusion.*
- *Environmental factors, for example noise levels that could be causing or contributing to discomfort or misinterpretation of noises such as over-head pages, alarms, etc. causing delusions and/or hallucinations.*
- *Mismatch between the activities or routines selected and the resident's cognitive and other abilities to participate in those activities/routines. For example, a resident who has progressed from mid to later stages of dementia may become frustrated and upset if he/she is trying but unable to do things that she previously enjoyed, or unable to perform tasks such as dressing or grooming.*

C. Development of Care Plan:

This step identifies the approaches, interventions, therapies, medications, etc. for a specific resident. The care plan should include a well-defined problem-statement and should outline the goals of care. It should include measurable objectives and timetables for individualized interventions. It should also identify the responsibilities of various staff to implement the approaches effectively. The care plan should reflect:

- *Baseline and ongoing details (e.g., frequency, intensity, and duration) of common behavioral expressions and expected response to interventions (See F279);*

- *Specific goals for and monitoring of all interventions for effectiveness in responding to target behaviors/expressions of distress (See F279); and*

- *For any medications, indication/rationale for use, specific target behaviors and expected outcomes, dosage, duration, monitoring for efficacy and/or adverse consequences and (when applicable) plans for gradual dose reduction (GDR) if an antipsychotic medication is used (See F329).*

In developing the plan of care, the interdisciplinary team, in collaboration with the resident or family/representative, reviews the results of the assessment and cause identification above in order to develop individualized, person-centered interventions. Staff should determine, in collaboration with the practitioner, resident, and family/resident representative if and why behaviors should be addressed (e.g., severely distressing to resident and unrelieved by other approaches or interventions). Individualized, person-centered approaches should be implemented to address expressions of distress. These may include:

- *Non-pharmacological approaches. Section 483.25 (l)(2)(ii) - F329, requires that "Residents who use antipsychotic drugs receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs."*

  The guidance at F248, §483.15(f)(1), Activities, provides examples of non-pharmacological approaches for several types of distressed behavior such as constant walking, yelling, going through others' belongings, etc. Certain behavior may be anticipated and sometimes may be preventable based on understanding the underlying causes and possible triggers for each individual.

  Current published clinical guidelines[15,16,17,18,19] recommend use of non-pharmacological interventions for BPSD.

  Utilizing a consistent process to address behaviors that focuses on the resident's individual needs and tries to understand their behaviors as a form of communication may help to reduce behavioral expressions of distress in those residents.

Several techniques are also outlined in the CMS DVD series for nursing assistant training, "Hand in Hand," distributed to all U.S. nursing homes in 2012, and other materials available on the Advancing Excellence website: www.nhqualitycampaign.org.

NOTE: References to non-CMS sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

- *Pharmacological interventions: In certain cases, residents may benefit from the use of medications. For example, a person who has a persistent, frightening delusion that she has left her children unattended and that they are in danger is inconsolable most of the day or night despite a number of staff and family approaches to address this fear. If other potential causes are ruled out, the team may determine that a trial of a low dose antipsychotic medication is warranted.*

  If a psychopharmacologic medication is initiated or continued, review the guidance at F329, and interview staff about:

  - *What was the person trying to communicate through their behavior;*
  - *What were the possible reasons for the person's behavior that led to the initiation of the medication;*
  - *What other approaches and interventions were attempted prior to the use of the antipsychotic medication;*
  - *Was the family or representative contacted prior to initiating the medication;*
  - *Was the medication clinically indicated and/or necessary to treat a specific condition and target symptoms as diagnosed and documented in the record;*
  - *Was the medication adjusted to the lowest possible dosage to achieve the desired therapeutic effects;*
  - *Were gradual dose reductions planned and behavioral interventions, unless clinically contraindicated, provided in an effort to discontinue the medication;*
  - *Was the interdisciplinary team, including the primary care practitioner, involved in the care planning process; and*
  - *How does the staff monitor for the effectiveness and possible adverse consequences of the medication.*

If the resident experienced a decline in function, an increased or worsening behavior, or less than anticipated level of improvement in response to interventions, or refused or resisted the interventions, the care plan approaches should be reviewed and revised/updated as appropriate (See F280).

D. Individualized Approaches and Treatment:

This step implements the care plan interventions to address the needs of a resident with dementia. It includes addressing the causes and consequences of the resident's behavior and staff communication and interactions with residents and families to try to prevent potentially distressing behaviors or symptoms. It is important to conduct sufficient observations in order to determine if the care plan is being implemented as written. Observations should focus on whether staff:

- *Identify and document specific target behaviors, expressions of distress and desired outcomes (See F279 and F514); and*
- *Implement appropriate, individualized, person-centered interventions and document the results (See F240, F309, F329 and F514);*
- *Communicate and consistently implement the care plan, over time and across various shifts (See F282 and F498).*

Staffing and Staff Training

During observations, determine whether there are sufficient numbers of staff to consistently implement the care plan (See F353). The nursing home must provide staff, both in terms of quantity (direct care as well as supervisory staff) and quality to meet the needs of the residents as determined by resident assessments and individual plans of care. The facility must strive to staff in a way that optimizes familiarity with residents. The principles for quality include, but are not limited to, the facility ensuring that nursing assistants are able to demonstrate competency in skills and techniques necessary to care for residents' needs as identified through resident assessments, and as described in the plan of care (See F498). Surveyors should focus on observations of staff interactions with residents who have dementia to determine whether staff consistently applies basic principles for quality in the provision of care.

Nursing assistants must receive a performance review at least once every 12 months and receive regular in-service education based on the outcome of the reviews (See F497). In addition, the facility must provide training in care of individuals with dementia and related behaviors to nursing assistants when initially hired and annually thereafter.

Research on caregivers of people with dementia suggests that caregiver stress can have a significant impact on outcomes and behavioral expressions of distress in the individual with dementia. This may be true for family, community or institutional caregivers. Some facilities may have systems in place to assist their staff in identifying, addressing and supporting staff who may exhibit "caregiver stress." See the Additional Resources section here for an example of tools to assess caregiver stress.

Involvement of the Medical Team

During observations and record review, if potential medical causes of behavior or other symptoms (such as those indicating possible delirium or infection) were identified, determine whether the attending physician was contacted promptly and a workup and/or treatment were initiated (See F157 and F385). Residents who exhibit new or worsening BPSD should have an evaluation by the interdisciplinary team, including the physician and knowledgeable staff, in order to identify and address, to the extent possible, treatable medical, physical, emotional, psychiatric, psychological, functional, social, and environmental factors that may be contributing to behaviors, in order to develop a comprehensive plan of care to address expressions of distress. If a medication(s) was ordered, determine if the staff and practitioner identified and the medical record reflected documentation of the appropriate indication(s) for use (See F329, Table 1 and F428). For a resident who is receiving any type of psychopharmacologic medication, staff must attempt non-pharmacological interventions, unless clinically contraindicated (See F329 and F428).

None of the guidance to surveyors should be construed as evaluating the practice of medicine. Surveyors are instructed to evaluate the process of care, including the communication among the prescriber/practitioner, pharmacist, interdisciplinary team, resident or family/representative, and the review of the nursing home practice to prevent unnecessary use of psychopharmacological medications and to closely monitor those medications when they are used. Interviews with the attending physician or other primary care provider (e.g., NP, PA, CNS), medical director, behavioral health specialist and other team members help clarify the reasons for using a psychopharmacological medication or any other interventions for a specific resident. In addition, interviewing the medical director with regard to policies and procedures for behavioral health and psychopharmacological medication use is strongly encouraged.

F. Monitoring and Follow-up:

It is important that surveyors evaluate whether or not a facility used the steps identified above to develop the plan of care. To meet requirements related to monitoring and follow-up of care plan implementation, surveyors evaluate whether or not the interdisciplinary team reviewed a resident's progress towards defined goals, adjusted interventions as needed, and identified when care objectives were met. Monitoring and follow-up of care plan implementation includes, but is not limited to, the following:

- *Staff monitors and documents (See F514) the implementation of the care plan, identifies effectiveness of interventions relative to target behaviors and/or psychological symptoms and changes in a resident's level of distress or emergence of adverse consequences.*

- *In collaboration with the practitioner, staff adjusts the interventions based on the effectiveness and/or adverse consequences related to treatment (See F280, F329 and F428).*

- *If concerns are identified related to the effectiveness or potential or actual adverse consequences of a resident's medication regimen, staff must notify the physician and the physician must respond and, as necessary, initiate a change to the resident's care (F157, F385, F428);*

- *If the physician does not provide a timely and appropriate response to the notification, staff must contact the medical director for further review, and if the medical director was contacted, he/she must respond and intervene as needed (See F501).*

G. Quality Assessment and Assurance (QAA):

NOTE: Refer to F520 Quality Assessment and Assurance for guidance regarding information that is obtainable from the QAA committee.

This guidance addresses the evaluation of a facility's systemic approaches to deliver care and services for a resident with dementia. The medical director and the quality assessment and assurance committee can help the facility evaluate existing strategies for coordinating the care of a resident with dementia and ensure that facility policies and procedures are consistent with current standards of practice.

During interviews with the staff responsible for the QAA functions, determine whether the QAA committee has identified and corrected, as indicated, any quality deficiencies related to the care of residents with dementia. In addition, determine whether the QAA committee has monitored and overseen the following areas related to dementia care:

- *Whether resident care policies reflect the facility's overall approach to the care of residents with dementia including a clearly outlined process for their care (see also F501);*

- *How the facility monitors whether staff follow related policies and procedures in choosing and implementing individualized interventions for the care of each resident with dementia;*

- *Whether the facility has trained staff (such as nursing, dietary, therapy or rehabilitation staff, social workers) in how to communicate with and address behaviors in residents with dementia and were the trainings evaluated for effectiveness, including initial and annual dementia care training for CNAs (See F495 and F497);*

- *Whether there is sufficient staff to implement the care plan for residents with dementia, so that medication is not used instead of pertinent non-pharmacological interventions, unless clinically contraindicated (See F353 and F222);*

- *Whether staff collect and analyze data to monitor the pharmacological and non-pharmacological interventions used to care for residents with dementia; and*

- *How the committee helps the facility monitor responses to the issues and concerns identified through the consultant pharmacist medication regimen review (See F329 and F428).*

Criteria for Compliance (F309)

Compliance at F309, care for persons with dementia, is based upon a set of key principles. For a resident with dementia, the facility is in compliance with F309, care for persons with dementia, if they:

1. *Obtained details about the person's behaviors (nature, frequency, severity, and duration) and risks of those behaviors, and discussed potential underlying causes with the care team and (to the extent possible) resident, family or representative;*
2. *Excluded potentially remediable (medical, medication-related, psychiatric, physical, functional, psychosocial, emotional, environmental) causes of behaviors and determined if symptoms were severe, distressing or risky enough to adversely affect the safety of residents;*
3. *Implemented environmental and other approaches in an attempt to understand and address behavior as a form of communication and modified the environment and daily routines to meet the person's needs;*
4. *Implemented the care plan consistently and communicated across shifts and among caregivers and with the resident or family/representative (to the extent possible); and*
5. *Assessed the effects of the approaches, identified benefits and complications in a timely fashion, involved the attending physician and medical director as appropriate, and adjusted treatment accordingly.*

If not, cite F309.

(For residents with dementia for whom antipsychotic or other medications were prescribed, surveyors must also assess for compliance using guidance at F329, Unnecessary Medications).

DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F309 exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident. (Note: some of the examples here involving residents with dementia who receive an antipsychotic medication may also be cited at F329. Surveyors should evaluate compliance at each tag separately).

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

• Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and

• Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

***NOTE:** If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.*

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy
Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

***NOTE:** If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided.

*****

The following examples illustrate the differences among compliance and non-compliance at levels 4, 3 and 2 for F309 Review of a Resident with Dementia. This is only one example; surveyors must investigate each case as the specific situation will vary and may lead to different conclusions based on the evidence.

F309 – Review of a Resident with Dementia – Compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social worker's note, the nurses' notes and the care plan all included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method she was bathed was

"very important" and the resident's daughter stated she preferred sponge baths due to her fear of showers. The interventions in the care plan were implemented consistently across all shifts and levels of staff. The nurses and social workers documented ongoing discussions with family and reassessments to ensure the resident's needs were being met and that no new issues had been identified. The criteria for compliance were met.

F309 – Review of a Resident with Dementia - Level 4 Severity Non-compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social worker's note, the nurses' notes and the care plan all included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method the resident was bathed was "very important" and her daughter stated she preferred sponge baths due to her fear of showers.

In addition to the basic facts noted above in the level 4 severity non-compliance example:

- *The surveyor observed an occurrence of bathing for the resident described above during the survey. The resident displayed substantial distress and fearfulness, calling out "help me," crying, striking out and grabbing at the staff, and made repeated attempts to get out of the shower chair.*
- *The staff member present called for a second staff member to help her complete the shower. Despite the resident's cries for help, no other staff members intervened or attempted to determine whether or not her distress warranted a different approach to the bathing routine/schedule.*
- *Significant psychological distress was noted during the bathing and for the remainder of the day and was documented in the nurse's notes.*
- *The surveyor observed that no other staff members intervened to assess the resident's situation or consult the care plan during or after the bathing.*
- *The surveyor interviewed direct care staff and nurses on the unit. One licensed nurse stated, "That resident always yells out during her shower" and attributed this to her dementia. Neither CNA interviewed was aware that the resident had sustained a hip fracture during a shower prior to admission.*
- *The resident's fear of bathing was noted in the care plan; however during interviews/observations, direct care staff could not articulate this information about the resident.*
- *The staff admitted they had not considered alternative routines/approaches for bathing this resident, despite the fact that the family had reported the resident's fear of showers and despite repeated episodes of distress.*
- *In addition to the staff being unaware of the resident's fear of showers, they also failed to investigate for other causes of the behavior.*

- *Upon further investigation related to quality assurance, there was no evidence that a physician attends QA&A meetings regularly.*
- *In reviewing staff training records, it appears that nursing assistants have not received training on how to care for residents with dementia.*

What is the evidence for non-compliance?

- *Resident exhibits adverse reaction to showers with verbal distress, combative behavior, and continuous struggling to get out of the chair.*
- *Facility failed to consider and rule out possible causes such as pain related to hip fracture while sitting in a shower chair or possible discomfort with the approach being used to bathe. Facility also failed to recognize the risk of a fall or injury due to combative behavior that required two staff members.*
- *Facility failed to develop and attempt alternate interventions.*
- *No staff member intervened despite the staff member present calling for help and hearing resident's cries for help and her obvious distress.*
- *Facility failed to develop a care plan intervention related to trying to reduce or eliminate extreme reactions to showers;*
- *Staff had appropriate care plan but failed to communicate across shifts and caregivers; and/or*
- *Facility failed to assess the effects of the interventions and try to modify interventions based on those assessments.*

Why is this Immediate Jeopardy?

See Decision-Making Grid with Components of Immediate Jeopardy below. Based on the severity of the resident's reaction, there was evidence that the resident experienced actual psychological harm. In addition, there was immediacy since the repeated attempts at showering the resident resulted in resident-to-staff altercations and placed her at risk for serious physical harm.

Furthermore, there was no evidence of physician participation in the QA&A committee and no evidence that nurse aides received required training in caring for and communicating with residents with dementia. This suggests a lack of effective systems and processes for the assessment and treatment of a resident with dementia. If so, these systems failures place this and potentially other residents with dementia at risk for serious harm. The facility is culpable for a deficient practice that must be addressed immediately in order to prevent further harm to this and other residents (surveyors may wish to consider whether or not there is a need to expand the sample).

Components of Immediate Jeopardy

Harm	
a. Actual *- Was there an outcome of harm? Does the harm meet the definition of Immediate Jeopardy, e.g., has the provider's noncompliance caused serious injury, harm, impairment, or death to an individual?*	***Yes. Repeated, extreme reaction to attempts to bathe with visible anguish, crying and yelling out reflects actual psychological harm with no attempts to alter the care plan.***
b. Potential – *Is there a likelihood of potential harm? Does the potential harm meet the definition of Immediate Jeopardy; e.g., is the provider's noncompliance likely to cause serious injury, harm, impairment, or death to an individual?*	***Yes. Repeated risk of a serious fall on an already injured or vulnerable area due to the struggle related to attempted showering.***
Immediacy	
Is the harm or potential harm likely to occur in the very near future to this individual or others in the entity, if immediate action is not taken?	***Yes. Potential for subsequent harm (a fall or other injury, psychological harm) exists as the facility did not attempt to identify causes or modify alternate interventions related to showers. Other residents with dementia may also be at risk, as staff had not received training in caring for individuals with dementia including how to understand the communication efforts of residents with dementia. There was no evidence of physician participation with the QA&A committee.***
Culpability	
Did the facility know about the situation? If so when did the facility first become aware?	***Yes, it had happened repeatedly and the social worker and nurses had been informed on admission of the resident's fear and preferences. While the information was in the care plan, the team had not passed the information along to the direct care staff and staff did not review the care plan. Staff did not intervene during these episodes despite the resident's cries for help. These behaviors were attributed to her dementia and were not considered remediable.***
Should the facility have known about the situation?	***Yes. There were recurrent episodes and the family had reported similar behavior at home related to showers.***

F309 – Review of a Resident with Dementia - Level 3 Severity Non-compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. The social services note, the nurses' notes and the care plan all included information from the family: they had reported on admission that the resident was now very fearful of showers. The RAI indicated choosing the method she was bathed was "very important" and her daughter stated she preferred sponge baths due to her fear of showers.

In addition to the basic facts noted above in the level 3 severity non-compliance example:

- *The information about the resident's fear of bathing was in the care plan; however during interviews/observations, direct care staff could not articulate this information.*
- *The surveyor determined that the resident was taken to the shower room three times in the three weeks since admission. Staff interviews revealed that each time the staff attempted to provide her with a shower, the resident immediately started to call out, "help me, help me." With each of the three attempts, the shower was stopped, the staff member documented "shower was refused" and the resident was given a sponge bath instead. On those days, the resident was noted to be anxious and fretful, wringing her hands and crying on and off for the rest of the day. These behaviors are not noted on other days.*
- *No further investigation occurred after each incident. Neither the physician nor the family was involved in discussions regarding the resident's response to the shower and no change in the plan of care was evident after the attempts to shower the resident.*

Why is this Level 3 Severity?

There is evidence of actual psychosocial harm to this resident, with no attempts by the facility to identify the underlying cause of her expressions of distress. However this case does not meet the criteria for immediacy, since the staff did not attempt to actually place the resident into the shower once she started to resist. While staff failed to rule out underlying causes of the resident's behavior, they did provide an alternative when the resident resisted.

F309 – Review of a Resident with Dementia - Level 2 Severity Non-compliance Example

A resident with dementia was admitted after hospitalization for a hip fracture she sustained while showering at home. It was documented in the social service and nurses' notes that the family had reported on admission that the resident was now very fearful of showers and preferred sponge baths. However, this information was not communicated to other staff nor was it incorporated into the care plan. The care plan stated that the resident would receive weekly showers.

In addition to the basic facts noted above in the level 2 severity example:

- *The resident's daughter insisted on bathing her mother herself for a period of time after admission, and provided sponge baths to the resident several times a week. The staff did not attempt to provide showers to the resident for several weeks after admission.*
- *At the next care plan meeting, the daughter discovered that her mother's care plan included "provide weekly showers," and was upset that the information about her mother's fear of showers had not been identified and addressed in the care plan.*

Why is this Level 2 Severity?

There is potential for more than minimal harm since significant psychological distress was reported by the family to occur consistently with attempts to shower the resident. In addition, the potential for serious physical harm exists if showers are attempted and the resident resists by trying to get up out of the shower chair or becoming combative with staff. This is Level 2 because actual harm did not occur.

References

1. *http://www.ninds.nih.gov/disorders/dementias/dementia.htm*
2. *Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA 2012; 308(19): 2020-2029.*
3. *Diagnostic and Statistical Manual of Mental Disorders DSM IV-TR Fourth edition. 2000 American Psychiatric Association.*
4. *Wei, L. A., Fearing, M. A., Sternberg, E. J., & Inouye, S. K. (2008). The Confusion Assessment Method: A Systematic Review of Current Usage. Journal of the American Geriatrics Society, 56(5), 823-830.*
5. *http://www.ncbi.nlm.nih.gov/pubmed/22879644*
6. *http://ageing.oxfordjournals.org/content/28/6/551.abstract*

7. Briesacher BA, Limcangco MR, Simoni-Wastila L et al: The quality of antipsychotic drug prescribing in nursing homes. Arch Intern Med 2005; 165(June):1280-1285.

8. Levinson DR. Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents. Department of Health and Human Services Office of Inspector General Report (OEI-07-08-00150)05-04-2011 accessed at ***https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf***

9. Schneider L, Tariot P, Dagerman K. Effectiveness of atypical antipsychotic drugs in residents with Alzheimer's disease. N Engl J Med 2006; 355:1525-1538.

10. Ray WA, Chung CP, Murray KT, et al: Atypical antipsychotic drugs and the risk of sudden cardiac death. N Engl J Med 2009; 360:225—235.

11. Schneider LS, Dagerman K, Insel PS: Efficacy and adverse effects of atypical antipsychotics for dementia: meta-analysis of randomized, placebo-controlled trials. American Journal of Geriatric Psychiatry 2006 14:191-210.

12. Rochon P, Normand S, Gomes T et al. Antipsychotic therapy and short-term serious events in older adults with dementia. Arch Intern Med 2008; 168:1090-1096.

13. Huybrechts KF, Gerhard T, Crystal S, Olfson M, Avorn J, Levin R, Lucas JA, Schneeweiss S. Differential risk of death in older residents in nursing homes prescribed specific antipsychotic drugs: population based cohort study. BMJ. 2012 Feb 23; 344:e977. doi: 10.1136/bmj.e977

14. Jin, H, Shih BP, Golshan, S, Mudaliar, S, Henry, R, Glorioso, DK, Arndt, S, Kraemer, HC, Jeste, DV. Comparison of Longer-Term Safety and Effectiveness of 4 Atypical Antipsychotics in Patients over age 40: A trial Using Equipoise-Stratified Randomization. J Clin Psychiatry, 2012; November 27th 2012. doi:10.4088/JCP.12m08001.

15. http://www.americangeriatrics.org/files/documents/beers/2012BeersCriteria_JAGS.pdf

16. http://www.amda.com/tools/guidelines.cfm

17. http://www.cccdtd.ca/pdfs/Final_Recommendations_CCCDTD_2007.pdf

18. http://www.nice.org.uk/nicemedia/live/10998/30318/30318.pdf

19. http://www.sign.ac.uk/pdf/sign86.pdf

Additional Resources

NOTE: References to non-CMS sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

Some clinical resources that identify the challenges and basic principles of dementia care include, but are not limited to:

- *Advancing Excellence in America's Nursing Homes. www.nhqualitycampaign.org*

- *Diagnostic and Statistical Manual of Mental Disorders DSM IV-TR Fourth edition. 2000 American Psychiatric Association.*

- *Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA 2012; 308(19): 2020-2029.*

- *Hand in Hand. For information, to download the training modules or inquire about receiving a copy or replacement copies of the Hand in Hand Toolkit please visit http://www.cms-handinhandtoolkit.info/Index.aspx*

- *Lyketsos, C., Lipsey, J., Rabins, P., and Slavney, P. Psychiatric Aspects of Neurological Diseases. New York: Oxford University Press, 2008. Print*

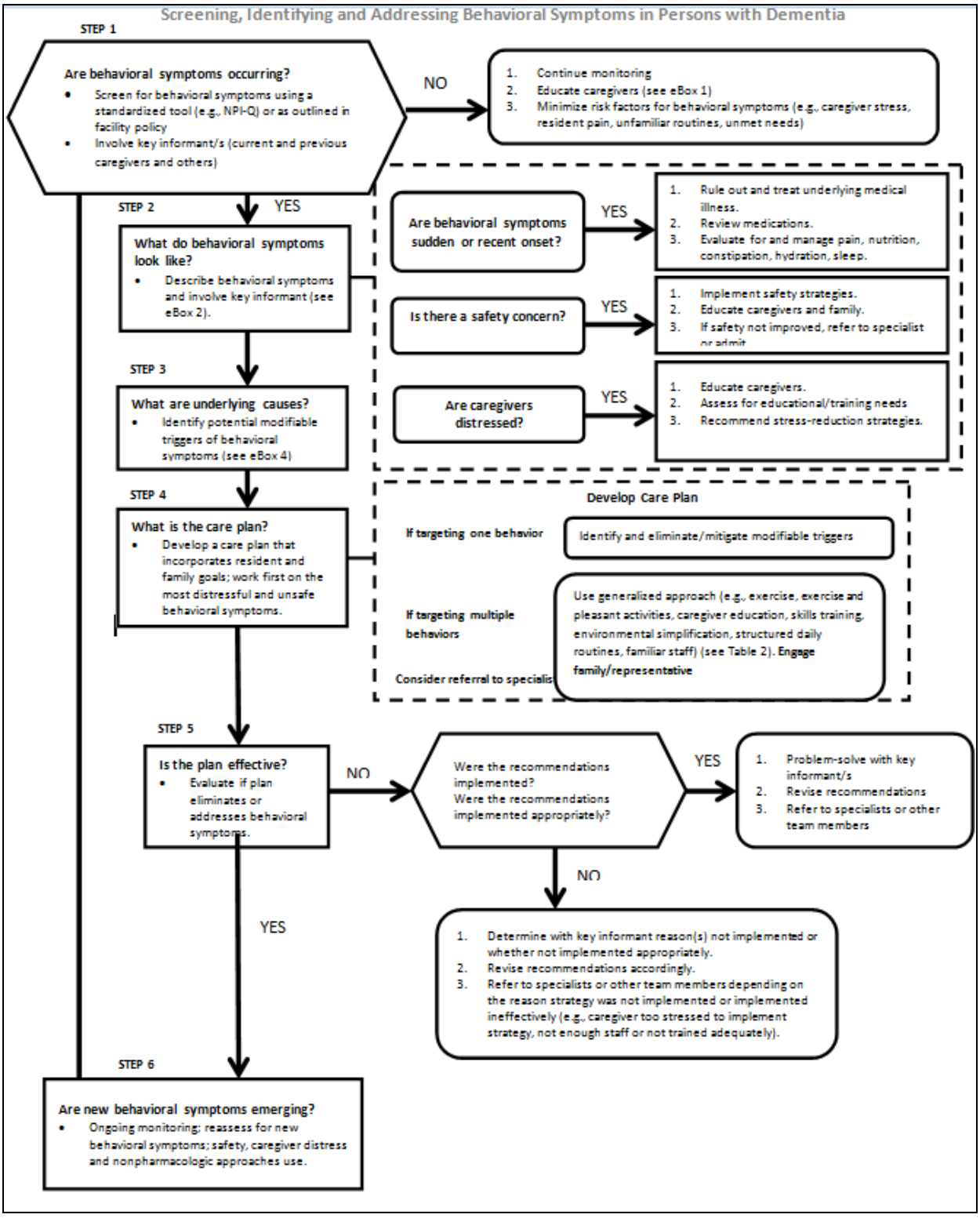
- *NINDS.NIH.gov. National Institute of Neurological Disorders and Stroke (NINDS), Dementia Information Page, n.d. Web. 29 AUG 2012. http://www.ninds.nih.gov/disorders/dementias/dementia.htm*

- *Power, G. Allen. Dementia Beyond Drugs. Baltimore, Maryland: Health Professions Press. 2010.*

- *Rabins, P. The 36-Hour Day. Baltimore: Johns Hopkins University Press, 2008. Print*

Additional Resources

- *Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 21, 2012; 308(19): 2020-2029.*



Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 21, 2012; 308(19): 2020-2029.

List of Boxes

***Box 1** – Key Considerations Caregivers Need to Know to Help Prevent Behavioral Symptoms*

- ❑ *Effectively communicate:*
  - *Use calm voice*
  - *Offer no more than two choices*
  - *Do not use open-ended questions*
  - *Keep it simple – do not over explain or discuss events happening in the future*
- ❑ *Attend to resident's nonverbal communications:*
  - *Grimacing may be a sign of pain*
  - *Ringing hands may be a sign of anxiety, feelings of insecurity*
- ❑ *Relax the rules - there is no right or wrong way to perform an activity if resident is safe*
- ❑ *Establish a structured daily routine for resident that is predictable*
- ❑ *Keep resident engaged in activities of interest and that match capabilities*
- ❑ *Use cueing strategies (e.g., touch, verbal directions) to help people with executive dysfunction initiate, sequence, and execute daily activities*
- ❑ *Understand behaviors are not intentional or done "in spite" but are a consequence of erosion in person's ability to initiate or comprehend steps of a task or its purpose*

Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 21, 2012; 308(19): 2020-2029.

- ❑ *Inform physician immediately of changes in behavior as they occur (e.g., sleep disruptions, withdrawal, increased confusion)*

- ❑ *Take care of self as a caregiver/team member:*

  - *Exercise regularly*
  - *Involve other staff and family/representative in care responsibilities as appropriate*
  - *Discuss stressful situations with colleagues and supervisors and brainstorm about potential solutions*
  - *Use stress reduction techniques (see Hand in Hand, CMS video series available in nursing home, or other resources for suggestions)*

Box 2 - *Informal Assessment: Brief Questions to Guide Describing Behavioral Symptoms*

- ❑ *What is the behavior? Can you describe the behavior?*
  - o *What did he/she do?*
  - o *What did he/she say?*
  - o *What did you do and say?*
- ❑ *Why is this behavior a problem? What about it really gets to you or makes you upset?*
- ❑ *When does the behavior occur?*
  - o *What time of day?*
  - o *What day(s) of the week?*
- ❑ *How often did the behavior happen in the past week? Past month?*
- ❑ *Where does the behavior occur?*
  - o *Is there a particular room/setting within the facility where the behavior occurs (e.g., during activities, in dining room, in person's own room with daily care routines)?*

Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 21, 2012; 308(19): 2020-2029.

- ❑ *Can you recognize any patterns?*
    - o *Does the behavior happen at the same time every day?*
- ❑ *What happens right before the behavior occurs?*
- ❑ *Who is around when the behavior occurs and how do they react?*
- ❑ *What is the environment like where the behavior occurs?*
    - o *Is there a lot of stimulation (television, noise, people)?*
- ❑ *How would you like this behavior to change? When would you consider the problem "solved"?*

Note: Adapted from randomized trials and the NIH Resources for Enhancing Alzheimer's Caregiver Health (REACH I and II).

***Box 3** – Checklist of Factors to Consider to Identify Potential Causes of Behavioral Symptoms*

1. Resident-based Factors

- ❑ *Altered emotional status (feelings of insecurity, sadness, anxiety, or loneliness)*
- ❑ *Lack of daily routines*
- ❑ *Sensory deficits (hearing, sight)*
- ❑ *Basic physical needs (hydration, constipation, body temperature)*
- ❑ *Interests and preferences not being met*
- ❑ *Level of stimulation (under or over) not appropriate*
- ❑ *Health issues (underlying infection)*
- ❑ *Impact of other illness or conditions*
- ❑ *Pain*

Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 21, 2012; 308(19): 2020-2029.

- ❑ *Medications (changes in, dosage, polypharmacy, failure to take, inappropriate medication administration)*
- ❑ *Ambulation and/or difficulty finding one's way (getting lost)*
- ❑ *Challenges performing daily activities of living (bathing, dressing, using the toilet, grooming, eating)*
- ❑ *Sleep cycle disruptions*

2. *Caregiver-based Factors*

- ❑ *Communications too complex*
- ❑ *Emotional tone is harsh*
- ❑ *High level of distress*
- ❑ *Lack of availability (staffing issues)*
- ❑ *Poor health status*
- ❑ *Expectations are too high or too low*
- ❑ *Cultural expectations and care values and beliefs that are not good fit with dementia care needs*
- ❑ *Style of caregiving not good fit*
- ❑ *Poor relationship with resident*
- ❑ *Lack of education about disease and behaviors*
- ❑ *Lack of supportive network or system within facility for dementia care*
- ❑ *Limited opportunities for respite*
- ❑ *Strained financial situation influencing work performance*

Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 21, 2012; 308(19): 2020-2029.

- ❑ *Employment and other family care responsibilities*

3. *Environmental-based factors*

- ❑ *Level of physical and/or social stimulation (too much or too little)*
- ❑ *Room arrangements*
    - o *Amount of clutter*
    - o *Needed items are out-of-sight or not in where person can see them*
- ❑ *Lack of appropriate visual cues*
- ❑ *Safety risk*
- ❑ *Too hot or too cold*
- ❑ *Lack of needed adaptive equipment (grab bars in bathroom)*
- ❑ *Poor lighting*

F329

Antipsychotic medications	
All classes, e.g., First generation (conventional) agents, e.g. • chlorpromazine • fluphenazine • haloperidol • loxapine • mesoridazine • molindone • perphenazine • promazine • thioridazine • thiothixene • trifluoperazine • trifluprom azine Second generation (atypical) agents, e.g. • *asenapine* • aripiprazole • clozapine • *iloperidone* • *lurasidone* • *olanzapine* • *paliperidone* • *quetiapine* • *risperidone* • *ziprasidone*	**Indications *for Use:*** ***A. Conditions Other than Dementia*** An antipsychotic medication should *generally* be used only for the following conditions/diagnoses as documented in the record and as meets the definition(s) in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Training Revision (DSM-IV TR) or subsequent editions): o Schizophrenia o Schizo-affective disorder o *Schizophreniform disorder* o *Delusional disorder* o *Mood disorders (e.g. bipolar disorder, severe depression refractory to other therapies and/or with psychotic features)* o Psychosis *in the absence of dementia* o *Medical illnesses with psychotic symptoms (e.g., neoplastic disease or delirium) and/or treatment related psychosis or mania (e.g., high-dose steroids)* o *Tourette's Disorder* o *Huntington disease* o *Hiccups (not induced by other medications)* o *Nausea and vomiting associated with cancer or chemotherapy* ***B. Behavioral or Psychological Symptoms of Dementia (BPSD)*** *(Use this guidance in conjunction with guidance at **§483.25** F309 Quality of Care, Review of Care and Services for a Resident with Dementia. Also consider **§483.10(d)(2)** F154, Right to be informed in advance*

	about care and treatment; F155, Right to refuse treatment; and ***§483.10(d)(3)*** *F280, Right to participate in planning care and treatment.)* *Antipsychotic medications are only appropriate for elderly residents in a small minority of circumstances (unless the antipsychotic is prescribed to treat previously diagnosed mental illness such as schizophrenia or possibly other conditions listed above). All antipsychotic medications carry a Food and Drug Administration (FDA) Black Box Warning. Since June 16, 2008, FDA warned healthcare professionals that both conventional and atypical antipsychotics are associated with an increased risk of death in elderly patients treated for dementia-related psychosis. Addition information is available at:* ***http://www.fda.gov/Drugs/default.htm.*** *(A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects. It is the strongest warning that the U.S. Food and Drug Administration can require a pharmaceutical company to place on the labeling of a prescription drug, or in the product literature describing it. The intent of 483.25(l) is that each resident's entire medication regimen be managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being.)* *Antipsychotic medications may be considered for elderly residents with dementia but only after medical, physical, functional, psychological, emotional psychiatric, social and environmental causes have been identified and addressed. Antipsychotic medications must be prescribed at the lowest possible dosage for the shortest period of time and are subject to gradual dose reduction and re-review.* ***Inadequate Indications:*** *Antipsychotic medications in persons with dementia should not be used if the only indication is one or more of the following:* • *wandering*

	• *poor self-care* • *restlessness* • *impaired memory* • *mild anxiety* • *insomnia* • *inattention or indifference to surroundings* • *sadness or crying alone that is not related to depression or other psychiatric disorders* • *fidgeting* • *nervousness* • *uncooperativeness (e.g. refusal of or difficulty receiving care).* ***Criteria:*** *All of the above highlight conditions/diagnoses where antipsychotic medications may possibly be appropriate, but diagnoses alone do not warrant the use of an antipsychotic unless the following criteria are also met**:*** o *The behavioral symptoms present a danger to the resident or others* *AND one or both of the following:* o *The symptoms are identified as being due to mania or psychosis (such as: auditory, visual, or other hallucinations; delusions, paranoia or grandiosity);* *OR* o *Behavioral interventions have been attempted and included in the plan of care, except in an emergency.* ***Additional Criteria:*** ***Acute Situations/Emergency***

	When an antipsychotic medication is being initiated or used to treat an *emergency situation (i.e., acute onset or exacerbation of symptoms or immediate threat to health or safety of resident or others)* related to one or more of the aforementioned conditions/diagnoses, *the use must meet the above criteria* and all of the following additional requirements: *1.* The acute treatment period is limited to seven days or less; AND *2. A clinician in conjunction with the interdisciplinary team must evaluate and document the situation within 7 days to identify and address any contributing and underlying causes of the acute condition and verify the continuing need for an antipsychotic medication.* *3. If the behaviors persist beyond the emergency situation, pertinent non-pharmacological interventions must be attempted, unless clinically contraindicated, and documented following the resolution of the acute psychiatric event.* ***Additional Criteria:*** ***Enduring Conditions*** Antipsychotic medications may be used to treat an enduring (i.e., non-acute; chronic or prolonged) condition, if the clinical condition/diagnosis meets the criteria in Section B above. *In addition, before initiating or increasing an antipsychotic medication for enduring conditions, the target behavior/s must be clearly and specifically identified and documented. Monitoring must ensure that the behavioral symptoms are:* 1. Not due to a medical condition or problem *(e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or polypharmacy)* that can be expected to improve or resolve as the underlying condition is treated *or the offending medication(s) are discontinued;*

	AND 2. *Not due to environmental stressors alone (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response), that can be addressed to improve the symptoms or maintain safety;* *AND* 3. *Not due to psychological stressors alone (e.g., loneliness, taunting, abuse), anxiety or fear stemming from misunderstanding related to his or her cognitive impairment (e.g., the mistaken belief that this is not where he/she lives or inability to find his or her clothes or glasses, unaddressed sensory deficits) that can be expected to improve or resolve as the situation is addressed;* *AND* 4. *Persistent. In this case, there must be clear documented evidence in the medical record that the situation or condition continues or recurs over time (persists) and that other approaches that have been attempted have failed to adequately address the behavioral/psychological symptoms and that the resident's quality of life is negatively affected by the behaviors/symptoms as described above.* ***New Admissions:*** *Many residents are admitted to a SNF/NF already on an antipsychotic medication. The medication may have been started in the hospital or the community, which can make it challenging for the facility and clinical team to identify the indication for use. However, the facility is responsible for:* • *Preadmission screening for mentally ill and intellectually disabled individuals, and;*

	• *Obtaining physician's orders for the resident's immediate care.* *This PASRR screening (F285) should provide pertinent information including appropriate clinical indications for the use of an antipsychotic.* *For residents who do not require PASRR screening and are admitted on an antipsychotic medication, the facility must re-evaluate the use of the antipsychotic medication at the time of admission and/or within two weeks of admission (at the time of the initial MDS assessment) and consider whether or not the medication can be reduced (tapered) or discontinued).*
	Dosage: *When dosing an antipsychotic, the treatment should be at the lowest possible dose to improve the target symptoms being monitored. It is important to note that doses for acute indications (e.g. delirium or acute psychosis) may differ from those used for long-term treatment of various conditions.* *The table below is provided only as a general guide for residents with dementia who have met **all** of the criteria outlined above. Orders for doses greater than those that appear in the table warrant closer review for adverse effects and risk/benefit evaluation. However, also note that in some cases, residents may require lower doses than those listed on the table. This is an individual, clinical decision based on a number of complex factors. Surveyors are strongly advised to speak with the practitioner/prescriber and/or consultant pharmacist in cases where an antipsychotic medication is prescribed for an elderly resident with dementia.*

Daily Dose Thresholds for Antipsychotic Medications Used *to Treat Residents with BPSD*

Generic *Name*	***Maximum Total Dosage (mg) per day***
First Generation or Typical Agents	
chlorpromazine	75
fluphenazine	4
haloperidol	2
loxapine	10
molindone	10
perphenazine	8
thioridazine	75 *
thiothixene	7
trifluoperazine	8
Second Generation *or Atypical*	
aripiprazole	10
clozapine	50
olanzapine	*5*
quetiapine	150
risperidone	2
ziprasidone	**
paliperidone	**
asenapine	**
iloperidone	**
lurasidone	**

** Due to additional black box warnings of QTC prolongation, its use should be avoided.*

*** No studies have been conducted or have results available to assess the drug's safety or efficacy in older adults with dementia.*

Duration*:*

Refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance.

Monitoring:

When monitoring antipsychotics, it is important to not only evaluate ongoing effectiveness and potential adverse consequences, as discussed below, but also to evaluate the use of any other psychopharmacological medications (e.g. mood stabilizers, benzodiazepines) being given to the resident. Specifically, surveyors should review the record to determine whether the facility can explain the rationale for adding, or switching from an antipsychotic to another category (or categories) of psychopharmacological agents; otherwise, both may potentially be unnecessary medications. Surveyors should investigate further in cases where more than one antipsychotic agent has been prescribed. Surveyors should investigate further in cases where more than one antipsychotic agent has been prescribed, or where an antipsychotic has been discontinued and a medication such as a mood stabilizer has been added.

Effectiveness:

After initiating or increasing the dose of an antipsychotic medication, the behavioral symptoms must be reevaluated periodically (at least during quarterly care plan review, but often more frequently, depending on the resident's response to the medication) to determine the effectiveness of the antipsychotic and the potential for reducing or discontinuing the dose based on target symptoms and any adverse effects or functional impairment.

Potential Adverse Consequences:

The facility assures that residents are being adequately monitored for adverse consequences such as:

- ***General**: anticholinergic effects (see Table II), falls, excessive sedation*
- ***Cardiovascular:** cardiac arrhythmias, orthostatic hypotension*
- ***Metabolic:** increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain*
- ***Neurologic:** akathisia, neuroleptic malignant*

	syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA)) in individuals with dementia *If the antipsychotic medication is identified as probably causing or contributing to adverse consequences as identified above, the facility must act upon this. In some cases, the benefits of treatment will still be considered to outweigh the risks or burdens of treatment, so the medication may be continued; however, the facility and prescriber must document the rationale for the decision and also that the resident, family member or legal representative is aware of and involved in the decision to continue the medication.*

F329

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F329 exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The key elements for severity determination for F329 are as follows:

1. Presence of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

Examples of actual or potential harm/negative outcomes for F329 may include, but are not limited to:

• Potential for life-threatening toxicity from excessive dose or lack of indication for the use of digoxin.

• Complications (such as diarrhea with life threatening fluid loss, nephrotoxicity, hearing loss, or anaphylactic shock) from use of an antibiotic when no clear indication for use has been established or response to the use has not been monitored.

• Fractures or falls with injury resulting from the continuing use of medications (e.g., hypnotics/sedatives, antipsychotics, antidepressants, antihypertensives) in the presence of predisposing risks or adverse consequences such as persistent dizziness or recurrent falling without intervening or reevaluating the need for and dose of the medication believed to be the cause of the gait instability.

2. Degree of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

• If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or

• If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required.

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F329. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

• Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and

• Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.
Examples may include, but are not limited to:
• Failure to assess or respond appropriately for a resident taking warfarin who had an elevated INR of 9 or greater with or without bleeding, or the elevated INR persisted without assessment/follow-up.
• Failure to monitor PT/INR for a resident on anticoagulant therapy in accordance with current standards of practice and to recognize and/or respond to a life threatening adverse consequence related to anticoagulation.
• Failure to recognize developing serotonin syndrome (e.g., confusion, motor restlessness, tremor) in a resident receiving a SSRI, leading to the addition of medications with additive serotonin effect or medication to suppress the symptoms.
• Failure to recognize and respond to signs and symptoms of neuroleptic malignant syndrome (NMS).
• In the presence of gastrointestinal bleeding, the failure to recognize medication therapies (such as NSAIDs or COX-2 inhibitors, bisphosphonates) as potentially causing or contributing to the gastrointestinal bleed, resulting in the continued administration of the medication, until the resident required hospitalization for severe bleeding.
NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.
Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy
Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:
• Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an INR greater than 4 and less than 9 for a resident who is
receiving warfarin until spontaneous bruising or frank bleeding occurs, resulting in the need to transfuse or hospitalize the resident.
• Facility failure to evaluate the medication regimen as a potential cause of seizure activity resulting in the addition of anticonvulsants to treat recent-onset seizures that can be adverse consequences of medications.
• Facility failure to implement a GDR that was not contraindicated in a resident receiving prolonged, continuous antipsychotic therapy resulting in functional decline, somnolence, lethargy, tremors, increased falling, or impaired ambulation.
NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.
Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy
Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:
• Facility failure to take appropriate action (e.g., change or suspend administration of the warfarin dose) for a resident who has an INR greater than 4 and less than 9 without any bleeding.

• Failure to monitor INR for a resident who has been stabilized on warfarin, but who has not had bleeding.
• Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash.
• Facility failure to monitor for response to therapy or for the emergence or presence of adverse consequences before the resident has experienced an adverse consequence or decline in function (e.g., monitoring periodically for symptoms of behavioral distress in someone receiving psychopharmacological medication; monitoring thyroid function at least annually in an individual receiving thyroid hormone replacement; and monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors, who had a change in mental status after the onset of diarrhea).

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide appropriate care and services to manage the resident's medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F329 - Additional Example under Investigative Protocol

The following example illustrates the differences between compliance, and non-compliance at severity levels 4, 3 and 2 related to the use of antipsychotic medication when circumstances and outcomes change:

F329 – Compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Upon readmission, diagnoses included pneumonia, CHF, and dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Upon readmission to the nursing home, the nurse practitioner contacted the hospitalist by telephone to review the case. They agreed that if the resident did not exhibit signs/symptoms of acute delirium over the next week, it would be reasonable to taper and discontinue the antipsychotic medication. The nurse practitioner communicated this information to the nursing staff and consultant pharmacist – the nursing staff included this information in the plan of care. After a week, no target behaviors were observed. The medication was tapered and discontinued, with ongoing monitoring in place for the potential recurrence of symptoms. The facility has met the criteria for compliance.

F329 - Level 4 Severity Non-compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Admitting diagnoses included pneumonia, CHF, and dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden

development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 4 months after nursing home readmission, the resident was still receiving the antipsychotic medication. Staff was monitoring for the identified target behaviors; however, documentation revealed that the resident had not exhibited any of the target behaviors for over 3 months. The facility failed to evaluate and/or consider gradual dose reductions, and had not attempted alternative approaches in an effort to discontinue the medication. The consultant pharmacist had recommended gradual dose reductions, but the physician had indicated that the medication was to be continued.

The record indicated that the resident was exhibiting orthostatic hypotension and was at high risk for falling. In addition, he was no longer attending group activities as he was sleeping off and on throughout the day. Staff had identified that the resident, who had been ambulatory with one staff person at admission, was no longer ambulating, was weaker and was in a recliner in his room during the day and evening. The resident had several areas on his hips and coccyx which were identified as Stage III pressure ulcers; he was losing weight due to decreased appetite and was drinking insufficient amounts of fluids.

When interviewed, staff stated that they believed the resident's decline was related to his dementia. They had not considered reducing or discontinuing the medication and failed to recognize that the medication had been initially ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

The facility failed to evaluate for the ongoing indication of use of the antipsychotic after symptoms were no longer present, had not monitored for the presence of adverse consequences, had not attempted gradual dose reductions nor implemented any behavioral interventions. The facility staff had not contacted the medical director to evaluate the resident's response and consider discussing the case with the attending physician. Following additional investigation, it was determined that the quality assessment and assurance (QAA) committee did not conduct any oversight or monitoring of residents who were receiving antipsychotics to assure that there were appropriate clinical indications for use and that behavioral interventions and gradual dose reductions were attempted.

Why is this Immediate Jeopardy?

This resident is now so compromised (he has developed pressure ulcers, has reduced food and fluid intake, is experiencing blood pressure fluctuations and is at risk for falls) that immediate action is required to prevent a serious illness or injury. While immediate jeopardy may exist when only one resident is affected, in this case the lack of systems and processes for review of psychopharmacological medications in residents with dementia indicates that other residents on these medications could potentially be at risk for serious harm as well.

F329 - Level 3 Severity Non-compliance Example

An 89 year old male was re-admitted to the nursing home from the hospital. Admitting diagnoses included pneumonia, heart failure, dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 3 months after nursing home readmission, the resident was still receiving the antipsychotic medication. The record indicated that the resident was now having difficulty with mobility and was more dependent on staff for ADLs such as bed mobility and transfers. Staff had identified that the resident was in a recliner in his room during the day and evening and was drowsy more often throughout the day. Staff documented that the resident had a small stage II pressure ulcer.

Staff was monitoring the identified target behaviors and documentation revealed the resident had not exhibited the target behaviors for the past 3 months. However, the facility failed to evaluate and/or consider gradual dose reductions, and had not attempted behavioral interventions in an effort to discontinue the medication. Staff failed to recognize that the medication had initially been ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

Why is this level 3 Severity?

The staff had not identified/evaluated the causal factors for the ongoing use of the medication, nor the potential that the medication could have been contributing to the resident's decline in ADLs, alertness and skin condition. Staff failed to recognize that the medication had initially been ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely. The facility failed to consider a gradual dose reduction. The resident had actual harm (ADL decline, stage II pressure ulcer) that could have been related to the medication. However, this is not a level 4 severity because the requirement for immediacy is not met.

Level 2 Severity

An 89 year old male was re-admitted to the nursing home sub-acute unit from the hospital. Admitting diagnoses included pneumonia, heart failure, dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The

resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident's infection stabilized, he was discharged back to the nursing home.

Approximately 3 months after admission, the resident was still receiving the antipsychotic medication and staff was monitoring for target behaviors and for the presence of adverse consequences. The record revealed that the resident had not had any adverse consequences and was no longer exhibiting the target behaviors. However, the facility failed to evaluate and/or consider gradual dose reductions, and had not attempted behavioral interventions in an effort to discontinue the medication. Staff failed to recognize that the medication had been initially ordered for delirium in the hospital, a condition that could potentially be time-limited and in many cases resolves completely.

Why is this level 2 Severity?
While the resident is at risk for potential for more than minimal harm from ongoing use of an antipsychotic medication without a clear clinical indication, the staff did not document any actual harm.

This is only one example. Specific evidence may differ in actual situations and surveyors should evaluate each situation individually as no one example applies to every situation.

Checklist

Review of Care and Services for a Resident with Dementia

(for use with the Interpretive Guidance at F309)

Assessment and Underlying Cause Identification

- ✓ Did staff describe behavior (onset, duration, intensity, possible precipitating events or environmental triggers, etc.) and related factors (appearance, alertness, etc.) in the medical record with enough specific detail of the actual situation to permit underlying cause identification to the extent possible?
- ✓ If the behaviors represent a sudden change or worsening from baseline, did staff contact the attending physician/practitioner immediately for a medical evaluation, as appropriate?
- ✓ If medical causes are ruled out, did staff attempt to establish other root causes of the behavior using individualized knowledge about the person and when possible, information from the resident, family, previous caregivers and/or direct care staff?
- ✓ As part of the comprehensive assessment did facility staff evaluate:
    - The resident's usual and current cognitive patterns, mood and behavior, and whether these present a risk to the resident or others?
    - How the resident typically communicates a need such as pain, discomfort, hunger, thirst or frustration?
    - Prior life patterns and preferences customary responses to triggers such as stress, anxiety or fatigue, as provided by family, caregivers, and others who are familiar with the resident before or after admission?
- ✓ Did staff, in collaboration with the practitioner, identify risk and causal/contributing factors for behaviors, such as:
    - Presence of co-existing medical or psychiatric conditions, or decline in cognitive function?
    - Adverse consequences related to the resident's current medications?

1. ***If the condition or risks were present at the time of the required comprehensive assessment, did the facility comprehensively assess the physical, mental and psychosocial needs of the resident with dementia to identify the risks and/or to determine underlying causes (to the extent possible) of the resident's behavioral and/or mental psychosocial symptoms, and needed adaptations, and the impact upon the resident's function, mood and cognition?***
   If No, cite F272

Care Planning

- ✓ Was the resident and/or family/representative involved (to the extent possible) in discussions about the potential use of any interventions, and was this documented in the medical record?
- ✓ Does the care plan reflect an individualized team approach with measureable goals, timetables and specific interventions for the management of behavioral and psychological symptoms?
- ✓ Does the care plan include:
    - Involvement of the resident/representative to the extent possible?
    - A description of and how to prevent targeted behaviors?
    - Why behaviors should be prevented or otherwise addressed (e.g., severely distressing to resident)?
    - Monitoring of the effectiveness of any/all interventions?
- ✓ If the resident or family/representative refused a recommended treatment or approach, was counseling on consequences and alternative approaches to address behavioral symptoms provided?

Note: If the resident lacks decisional capacity and lacks effective family/representative support, contact the facility social worker to determine what type of social services or referrals have been attempted to assist the resident.

2. ***Did the facility develop a plan of care with measurable goals and interventions to address the care and treatment for a resident with dementia related to the behavioral and/or mental/psychosocial symptoms, in accordance with the assessment, resident's wishes and current standards of practice? If No, cite F279***

Implementation of the Care Plan

Did staff:

Identify, document and communicate specific targeted behaviors and expressions of distress as well as desired outcomes?

- ✓ Implement individualized, person-centered interventions by qualified persons and document the results?
- ✓ Communicate and consistently implement the care plan, over time and across various shifts?
- ✓ If there is a sudden change in the resident's condition and medical causes of behavior or other symptoms (e.g., delirium or infection) are suspected, is the physician contacted immediately and treatment initiated?
- ✓ Is there a sufficient number of staff to consistently implement the care plan? (*Surveyors should focus on observations of staff interactions with residents who have dementia to determine whether staff consistently applies basic dementia care principles in the care of those individuals*).

3. ***Did the facility provide or arrange services to be provided by qualified persons in accordance with the resident's written plan of care? If No, cite F282***

Note: If during the survey a concern is identified that an antipsychotic medication is given by staff for purposes of discipline or convenience and not required to treat the resident's medical symptoms, review F222 – §483.13(a).

Care Plan Revision/Monitoring and Follow up

- ✓ Does staff, in collaboration with the practitioner, adjust the interventions based on the impact on behavior or other symptoms as well as any adverse consequences related to treatment?
- ✓ When concerns related to the effectiveness or adverse consequences of a resident's treatment regimen are identified:
    - Does staff modify the care plan and, if appropriate, notify the physician and does the physician respond and initiate a change to the resident's care as necessary?

4. ***Did the facility reassess the effectiveness of the interventions and review and revise the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident with dementia? If No, cite F280***

    - If the physician does not respond to the notification, does staff contact the medical director for further review? If the medical director was contacted, does he/she respond and intervene as needed?

5. ***Did the facility provide the necessary care and services for a resident with dementia to support his or her highest practicable level of physical, mental and psychosocial well-being in accordance with the comprehensive assessment and plan of care? If No, cite F309***

Quality Assessment and Assurance

Note: Please refer to F520 Quality Assessment and Assurance for guidance regarding the information that may be obtained from the QAA committee.

- ✓ Do resident care policies and procedures clearly outline a systematic process for the care of residents with dementia?
- ✓ Does the QAA Committee monitor for consistent implementation of the policies and procedures for the care of residents with dementia?
- ✓ Has the QAA committee corrected any identified quality deficiencies related to the care of residents with dementia?
- ✓ Has the QAA committee provided monitoring and oversight for the care and services for a resident with dementia?

CDPH L&C SNF Antipsychotic Use Survey Tool

Facility: _____ Date of Record Review: ____/____/____

Resident Name: _____ Unit/Room/Bed: _____

Resident Identifier: _____ DOB: ____/____/____ Age: ____ DOA: ____/____/____ □ Readmit

Event ID: _____

Antipsychotic Name:	Daily Dosage:	Order Date:	Behavioral Manifestation:

1. Which of the following represents the primary indication for use of the antipsychotic? (complete for each antipsychotic)	**Y**	**N**
1. Schizophrenia		
2. Schizo-affective disorder		
3. Delusional disorder		
4. Mood disorders (e.g., bipolar disorder, depression w/ psychotic features)		
5. Schizophreniform disorders		
6. Psychosis		
7. Atypical psychosis		
8. Brief psychotic disorder		
9. Dementing illnesses with associated behavioral symptoms		
10. Medical illnesses with psychotic symptoms (e.g., neoplastic disease) and/or treatment related psychosis or mania (e.g., high-dose steroids)		
11. Tourette's Disorder or Huntington disease		
12. Hiccups or nausea and vomiting associated with cancer or chemotherapy		
13. None of the above		

If "Y" to any indications 1 – 10 complete Sections 2 - 4;
If "Y" to indications 11 or 12 skip Sections 2-4 and continue with Section 5;
If "Y" to 13 cite at F329 (inadequate indication for use) or F222 (chemical restraints) and continue with Section 5.

2. Determine if resident's documented behavioral symptoms meet at least <u>one</u> of the following criteria:	**Y**	**N**
• The symptoms are due to mania or psychosis (such as auditory, visual, or other hallucinations; delusions); **OR**		
• The behavioral symptoms present a danger (documented) to the resident or to others; **OR**		
The symptoms are significant enough that the resident is experiencing one or more of the following:	**Y**	**N**
• Inconsolable or persistent distress (e.g., fear, continuously yelling, screaming, distress associated w/ end-of-life, or crying); **OR**		
• A significant decline in function; **OR**		
• Substantial difficulty receiving needed care (e.g., not eating resulting in weight loss; fear and not bathing leading to skin breakdown or infection).		

If "N" to all of the above, cite at F329 (inadequate indication for use) or F222 (chemical restraints).

3. If the antipsychotic is being used for long term behavioral management complete section 3A. If the antipsychotic is used to manage an acute situation complete section 3B to determine appropriateness.			
3A. Chronic Psychiatric Condition (N/A if resident admitted on an antipsychotic) The target behavior must be specifically identified and monitored objectively and quantitatively prior to its use to ensure the behavioral symptoms are:	**Y**	**N**	**N/A**
• Not due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, unrecognized hearing or visual impairment) that can be expected to improve or resolve as the underlying condition is treated; **AND**			
• Not due to environmental stressors (e.g., alteration in the resident's customary location or daily routine, unfamiliar care provider, hunger or thirst, excessive noise for that individual, inadequate or inappropriate staff response, physical barriers) that can be addressed to improve the symptoms or maintain safety; **AND**			
• Not due to psychological stressors (e.g., loneliness), or anxiety or fear stemming from misunderstanding related to his or her cognitive impairment that can be expected to improve or resolve as the situation is addressed; **AND**			
• Persistent; **AND**			
• Documented non-pharmacological interventions (e.g., psychological counseling, massage therapy, comfort-focused care) have been attempted but failed to resolve the cause of the behaviors.			

3B. Acute Psychiatric Situation/Emergency (must meet all of the following and be related to one or more clinical conditions in Section 1):	**Y**	**N**	**N/A**
• The acute treatment period is limited to 7 days or less; **AND**			
• A clinician in conjunction with the interdisciplinary team must evaluate and document the situation within 7 days, to identify and address any contributing and underlying causes of the acute psychiatric condition and verify the continuing need for antipsychotic medication; **AND**			
• Pertinent non-pharmacological interventions must be attempted, unless contraindicated, and documented following the resolution of the acute psychiatric situation.			

If "N" to any of the above, cite at F329 (inadequate indication for use) or F222 (chemical restraints). Additionally, if the facility failed to monitor the behaviors in an objective and quantitative manner, cite at F329 (for inadequate monitoring).

4. Dosage	**Y**	**N**	**N/A**
• If the antipsychotic is used to treat behavioral symptoms associated with a dementing illness, the daily dosage doesn't exceed that listed in F329 ("Table 1: Medication Issues of Particular Relevance" and also in attached supplemental guidance).			
• Resident is receiving one antipsychotic medication.			

If "N" to any of the above criteria cite at F329 (in excessive dosage or duplicate therapy) <u>unless</u> the prescriber has documented resident specific clinical rationale/justification demonstrating the benefit exceeds the associated risk.

5. Monitoring for Effectiveness	**Y**	**N**
Target behavior(s) are: • Identified in the resident's care plan.		
• Monitored objectively (behaviors are specifically identified and not generalized such as; "agitation, restlessness") and quantitatively (number of behavioral episodes		

exhibited over a specified course of time)		
• Consistent with the primary indication for use (e.g., schizophrenia as manifested by auditory hallucinations or dementia as manifested by hitting other residents during activities).		
Behavioral data are:	**Y**	**N**
• Made available to the prescriber in a consolidated manner at least monthly.		
• Sufficient to provide the prescriber with the necessary information to determine antipsychotic medication effectiveness/ineffectiveness as well as the presence of adverse consequences.		

If "N" to any of the above, consider deficiencies at F329 (inadequate monitoring) and/or F279 (care planning); or Title 22 72319(j)(2) and 72311(a)(1) for nursing care plan data that does not specify data to be collected for use in evaluating the effectiveness of the drugs and occurrence of adverse reactions; or Title 22 72319(j)(3) if consolidated monthly behavioral data not available to prescriber.

6. Monitoring for Adverse Consequences	**Y**	**N**
Adverse consequences to be monitored shall include at least the following: • Significant or severe consequences, such as those listed in FDA boxed warnings (manufacturer's package insert) and those that may be significant based on the resident's clinical condition.		
• Those listed in Table 1 of F329 and also in attached supplemental guidance.		
• The associated adverse consequences are identified in the resident's care plan		
If the resident has experienced possible or actual antipsychotic related adverse consequences the facility has documented such and taken action.		

If "N" to any of the above criteria cite at F329 (inadequate monitoring or presence of adverse consequences which indicate the dose should be reduced or discontinued).

7. Gradual Dose Reduction (GDR)	**Y**	**N**	**N/A**
If the antipsychotic was initiated within the last year the facility has attempted a GDR in two separate quarters (with at least one month between attempts).			
If the resident has been receiving the antipsychotic for more than one year the GDR has been attempted annually.			
If no antipsychotic GDR has been attempted the prescriber has documented a taper is clinically contraindicated (as defined in supplemental guidance).			

If "N" to any of the above criteria cite at F329 (for excessive duration/GDR).

8. Provision of Consultant Pharmacist Services	**Y**	**N**	**N/A**
Documentation is present the resident's clinical record was reviewed monthly by a consultant pharmacist.			
If non-compliances related to antipsychotic use were noted in Sections 1 – 7 the consultant pharmacist identified irregularities in writing to the attending physician and director of nursing.			
If the consultant pharmacist **did** identify (in the monthly Medication Regimen Review report) irregularities related to antipsychotic inappropriateness the facility acted on the report.			

If "N" to any of the above, cite at F428 (Drug Regimen Review).

9. Informed Consent **(Note: RP = Responsible Party)**	**Y**	**N**	**N/A**
If the antipsychotic was initiated **prior to** admission to the facility the clinical record contains documentation of previous informed consent; or verification of resident consent after admission. ***If "N" cite T22 Section 72528(c).***			
If the antipsychotic was initiated **after** admission to the facility the clinical record contains verification of resident informed consent. Exception is use for an emergency			

basis as defined in T22 Section 72528(e). ***If "N" cite T22 Section 72528(c).***			
If the antipsychotic dosage was increased the clinical record contains verification of resident informed consent. ***If "N" cite H&SC 1418.9.***			
Interview the resident (or RP if the resident does not have capacity) to determine if the following material information was provided prior to the use of the antipsychotic:	**Y**	**N**	**N/A**
(1) The reason for the treatment and the nature and seriousness of the resident's illness; and			
(2) The nature of the proposed treatment including frequency and duration; and			
(3) The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment; and			
(4) The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions; and			
(5) The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment; and			
(6) That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time. ***If "N" to any of the above cite the facility at T22 Section 72528(b)(1-6).***			
Determine the prescribing physician provided material information necessary (listed above) to obtain informed consent and received consent from the resident. ***If "N," cite the facility at T22 Section 72528(a) and/or H&SC 1418.9.***			
Prior to giving informed consent, the information provided was understood and questions were satisfactorily answered. ***If "N," cite at F156.***			
The resident/RP has been invited to participate in care planning as it relates to the use of the antipsychotic medication. ***If "N," cite F280 or T22 Section 72527(a)(3).***			

If the resident does **not** have capacity to give informed consent and has **no** designated RP/person with legal authority to make those decisions on behalf of the resident:	**Y**	**N**
• The attending physician has identified efforts (resident interview/family members consulted, etc.) no person with legal authority exists.		
• The facility IDT has documented review, assessment and care planning (unless in an emergency) of the proposed antipsychotic order in accordance with H&SC 1418.8 (e)(1) through (e)(6) prior to receipt of the medication.		
• In the case of an emergency antipsychotic medication intervention, the IDT has met within one week for an evaluation of the intervention.		
• The IDT has (at least quarterly or upon a significant change of condition) evaluated the antipsychotic therapy. ***If "N" to any of the above, cite at H&SC 1418.8.***		

Determine the following regarding informed consent policies and procedures:	**Y**	**N**
• The facility has written patients' rights policies and procedures related to psychotherapeutic informed consent.		
• Licensed nursing staff are familiar with written informed consent facility policies and procedures and are able to explain the process of verifying psychotherapeutic informed consent.		
• The resident's attending physician has verified (on interview) that antipsychotic		

informed consent was obtained in accordance with facility policies and procedures and regulatory requirements. ***If "N" to any of the above, cite at T22 Section 72527(a).***		

Consider issuance of a civil money citation for one or more of the following non-compliance(s):

- ***Resident/RP indicates (on interview) required material information (as defined in T22 Section 72528 (1-6)) was not received in order to make an informed decision prior to receipt of the antipsychotic medication.***
- ***Physician did not obtain informed consent from the resident (the process of informed consent was delegated to licensed nursing staff, ward clerk, etc.).***
- ***Facility failed to develop and implement patients' rights policies and procedures, in accordance with state laws and regulations, related to psychotherapeutic informed consent.***

10. Medical Director/Quality Assessment & Assurance (QAA)	**Y**	**N**	**N/A**
Medical Director has ensured resident care policies and procedures were developed and implemented regarding antipsychotic informed consent.			
Medical Director has addressed facility-identified clinically inappropriate use of antipsychotic medications in the context of regulatory requirements and current standards of practice.			
QAA has developed and implemented an action plan related to non-compliances with antipsychotic informed consent; appropriate antipsychotic use; or acting on consultant pharmacist MRR recommendations related to inappropriate antipsychotic use (note: facility not required to disclose QAA minutes).			

If "N" to any of the first three items, cite at F501 (Medical Director is responsible for implementation of resident care policies and/or the coordination of medical care in the facility); if "N" to the last item, cite at F520 (QAA committee develops and implements appropriate plans of action to correct identified quality deficiencies).

CDPH: Antipsychotic Use Survey Tool—Supplemental Guidance

Commonly prescribed antipsychotic medications (brand name and/or generic):

First generation (typical) antipsychotic:
chlorpromazine (generic only)
fluphenazine (generic only)
Haldol (haloperidol)
Loxitane (loxapine)
Moban (molindone)
Navane (thiothixene)
perphenazine (generic only)
thioridazine (generic only)
trifluoperazine (generic only)

Second generation (atypical) antipsychotic:
Abilify (aripiprazole)
Clozaril (clozapine)
Fanapt (iloperidone)
Geodon (ziprasidone)
Invega (paliperidone)
Risperdal (risperidone)
Seroquel (quetiapine)
Zyprexa (olanzapine)

Combination antidepressant and antipsychotic medication:
Symbyax (Prozac (fluoxetine) & Zyprexa)

F329 TABLE 1: ANTIPSYCHOTIC DOSAGE

If the resident has dementing illness, with associated behavioral symptoms, assess for the following total daily dose:

Medication	Total Daily Dosage
Abilify (aripiprazole)	10 mg
chlorpromazine (generic only)	75 mg
Clozaril (clozapine)	50 mg
Fanapt (iloperidone)	*
fluphenazine (generic only)	4 mg
Geodon (ziprasidone)	*
Haldol (haloperidol)	2 mg
Invega (paliperidone)	*
Loxitane (loxapine)	10 mg
Moban (molindone)	10 mg
Navane (thiothixene)	7 mg
perphenazine (generic only)	8 mg
Risperdal (risperidone)	2 mg
Seroquel (quetiapine)	150 mg
thioridazine (generic only)	75 mg
Trifluoperazine (generic only)	8 mg
Zyprexa (olanzapine)	7.5 mg

* Not customarily used for the treatment of dementia behavioral symptoms

MONITORING FOR ADVERSE CONSEQUENCES

Potential antipsychotic adverse effects:

- anticholinergic effects (dry mouth, constipation, blurred vision, drowsiness, dizziness, increased heart rate, urinary retention, delirium)
- increase in total cholesterol and triglycerides
- akathisia (inability to sit still, motor restlessness)

- parkinsonism (tremors, rigidity of movement, shuffling gait, droopy posture or masklike facies)
- neuroleptic malignant syndrome (hyperthermia with extrapyramidal and autonomic disturbances that may result in death)
- blood sugar elevation
- orthostatic hypotension
- falls
- weight change
- tardive dyskinesia (abnormal involuntary movements of the tongue, lips, face, trunk and extremities)
- lethargy/sedation

WARNINGS and PRECAUTIONS

Metabolic Changes

- Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

Weight Gain

- Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Antipsychotic FDA boxed warnings:

FDA ALERT [6/16/2008]: FDA is notifying healthcare professionals that both conventional and atypical antipsychotics are associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis.

In April 2005, FDA notified healthcare professionals that patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death. Since issuing that notification, FDA has reviewed additional information that indicates the risk is also associated with conventional antipsychotics.

Antipsychotics are not indicated for the treatment of dementia-related psychosis.

Source: **http://www.fda.gov/Drugs/default.htm**

Ziprasidone (Geodon®):

Ziprasidone use should be avoided in combination with other drugs that are known to prolong the QTc interval…. Additionally, clinicians should be alert to the identification of other drugs that have been consistently observed to prolong the QTc interval. Such drugs should not be prescribed with ziprasidone. Ziprasidone should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias.

Thioridazine (Mellaril®):

Mellaril® (thioridazine hcl) has been shown to prolong the qtc interval in a dose related manner, and drugs with this potential, including mellaril, have been associated with torsade de pointes-type arrhythmias and sudden death. Due to its potential for significant, possibly life-threatening, proarrhythmic effects, mellaril should be reserved for use in the treatment of schizophrenic patients who fail to show an acceptable response to adequate courses of treatment with other antipsychotic drugs, either because of insufficient effectiveness or the inability to achieve an effective dose due to intolerable adverse effects from those drugs.

Additional FDA boxed warning information relevant to antipsychotic medications available at the following link:

https://blackboxrx.com/

F222 (§483.13(a) Restraints)

The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

F329 (§483.25(l) Unnecessary Drugs)

1. General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

(i) In excessive dose (including duplicate therapy); or
(ii) For excessive duration; or
(iii) Without adequate monitoring; or
(iv) Without adequate indications for its use; or
(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
(vi) Any combination of the reasons above.

2. Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that:

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and
(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioural interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

F329: Antipsychotic Gradual Dose Reduction (GDR)

Clinically contraindicated is:
(A) For treatment of behavioral symptoms related to dementia, the GDR may be considered clinically contraindicated if:

- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; **AND**
- The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would likely impair the resident's function or increase distressed behavior.

(B) For treatment of a psychiatric disorder other than behavioral symptoms related to dementia the GDR may be considered contraindicated, if:

- ☐ The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would likely impair the resident's function or cause psychiatric instability by exacerbating an underlying psychiatric disorder; **OR**
- ☐ The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would likely impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

INFORMED CONSENT

T22 § 72527 Patients' Rights
(a) Patients have the rights enumerated in this section and the facility shall ensure that these rights are not violated. The facility shall establish and implement written policies and procedures which include these rights and shall make a copy of these policies available to the patient and to any representative of the patient. The policies shall be accessible to the public upon request. Patients shall have the right:
(3) To be fully informed by a physician of his or her total health status and to be afforded the opportunity to participate on an immediate and ongoing basis in the total plan of care including the identification of medical, nursing and psychosocial needs and the planning of related services.
(4) To consent to or refuse any treatment…
(5) To receive all information that is material of an individual patient's decision concerning whether to accept or refuse any proposed treatment or procedure. The disclosure of material information for administration of psychotherapeutic drugs or physical restraints or the prolonged use of a device that may lead to the inability to regain use of a normal bodily function shall include the disclosure of information listed in Section 72528(b).
(23) To be free from psychotherapeutic drugs…used for the purpose of patient discipline or staff convenience and to be free from psychotherapeutic drugs used as a chemical restraint…except in an emergency which threatens to bring immediate injury to the patient or others. If a chemical restraint is administered during an emergency, such medication shall be only that which is required to treat the emergency condition and shall be provided in ways that are least restrictive of the personal liberty of the patient and used only for a specified and limited period of time.
(e) Patients' rights policies and procedures established under this section concerning consent, informed consent and refusal or treatments or procedures shall include, but not be limited to the following:
(1) How the facility will verify that informed consent was obtained or a treatment or procedure was refused pertaining to the administration of psychotherapeutic drugs…

T22 § 72528 Informed Consent Requirements
(a) It is the responsibility of the attending licensed healthcare practitioner acting within the scope of his or her professional licensure to determine what information a reasonable person in the patient's condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure. Information that is commonly appreciated need not be disclosed. The disclosure of the material information and obtaining informed consent shall be the responsibility of the physician. The disclosure of the material information and obtaining informed consent shall be the responsibility of the licensed healthcare practitioner who, acting within the scope of his or her professional licensure, performs or orders the procedure or treatment for which informed consent is required.
(b) The information material to a decision concerning the administration of a psychotherapeutic drug or physical restraint, or the prolonged use of a device that may lead to the inability of the patient to regain use of a normal bodily function shall include at least the following:

(1) The reason for the treatment and the nature and seriousness of the patient's illness.
(2) The nature of the procedures to be used in the proposed treatment including their probable frequency and duration.
(3) The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment.
(4) The nature, degree, duration and probability of the side effects and significant risks, commonly known by the health professions.
(5) The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment.
(6) That the patient has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.
(c) Before initiating the administration of psychotherapeutic drugs, or physical restraints, or the prolonged use of a device that may lead to the inability to regain use of a normal bodily function, facility staff shall verify that the patient's health record contains documentation that the patient has given informed consent to the proposed treatment or procedure. The facility shall also ensure that all decisions concerning the withdrawal or withholding of life sustaining treatment are documented in the patient's health record.
(d) This section shall not be construed to require obtaining informed consent each time a treatment or procedure is administered unless material circumstances or risks change.
(e) There shall be no violation for initiating treatment without informed consent if there is documentation within the patient's health record that an emergency exists where there is an unanticipated condition in which immediate action is necessary for preservation of life or the prevention of serious bodily harm to the patient or others or to alleviate severe physical pain, and it is impracticable to obtain the required consent, and provided that the action taken is within the customary practice of physicians of good standing in similar circumstances.
(f) Notwithstanding Sections 72527(a)(5) and 72528(b)(4), disclosure of the risks of a proposed treatment or procedure may be withheld if there is documentation of one of the following in the patient's health record:
(1) That the patient or patient's representative specifically requested that he or she not be informed of the risk of the recommended treatment or procedure. This request does not waive the requirement for providing the other material information concerning the treatment or procedure.
(2) That the physician relied upon objective facts, as documented in the health record, that would demonstrate to a reasonable person that the disclosure would have so seriously upset the patient that the patient would not have been able to rationally weigh the risks of refusing to undergo the recommended treatment and that, unless inappropriate, a patient's representative gave informed consent as set forth herein.

H&SC 1418.8 Medical interventions requiring informed consent; resident lacking decision-making capacity; interdisciplinary team review (aka Epple Act regarding informed consent for an incapacitated resident):
(a) If the attending physician and surgeon of a resident in a skilled nursing facility or intermediate care facility prescribes or orders a medical intervention that requires that informed consent be obtained prior to administration of the medical intervention, but is unable to obtain informed consent because the physician and surgeon determines that the resident lacks capacity to make decisions concerning his or her health care and that there is no person with legal authority to make those decisions on behalf of the resident, the physician and surgeon shall inform the skilled nursing facility or intermediate care facility.
(b) For purposes of subdivision (a), a resident lacks capacity to make a decision regarding his or her health care if the resident is unable to understand the nature and consequences of the proposed medical intervention, including its risks and benefits, or is unable to express a preference regarding the intervention. To make the determination regarding capacity, the physician shall interview the patient, review the patient's medical records, and consult with skilled nursing or intermediate care facility staff, as appropriate, and family members and friends of the resident, if any have been identified.
(c) For purposes of subdivision (a), a person with legal authority to make medical treatment decisions on behalf of a patient is a person designated under a valid Durable Power of Attorney

for Health Care, a guardian, a conservator, or next of kin. To determine the existence of a person with legal authority, the physician shall interview the patient, review the medical records of the patient, and consult with skilled nursing or intermediate care facility staff, as appropriate, and with family members and friends of the resident, if any have been identified.
(d) The attending physician and the skilled nursing facility or intermediate care facility may initiate a medical intervention that requires informed consent pursuant to subdivision (e) in accordance with acceptable standards of practice.
(e) Where a resident of a skilled nursing facility or intermediate care facility has been prescribed a medical intervention by a physician and surgeon that requires informed consent and the physician has determined that the resident lacks capacity to make health care decisions and there is no person with legal authority to make those decisions on behalf of the resident, the facility shall, except as provided in subdivision (h), conduct an interdisciplinary team review of the prescribed medical intervention prior to the administration of the medical intervention. The interdisciplinary team shall oversee the care of the resident utilizing a team approach to assessment and care planning, and shall include the resident's attending physician, a registered professional nurse with responsibility for the resident, other appropriate staff in disciplines as determined by the resident's needs, and, where practicable, a patient representative, in accordance with applicable federal and state requirements. The review shall include all of the following:
(1) A review of the physician's assessment of the resident's condition.
(2) The reason for the proposed use of the medical intervention.
(3) A discussion of the desires of the patient, where known. To determine the desires of the resident, the interdisciplinary team shall interview the patient, review the patient's medical records, and consult with family members or friends, if any have been identified.
(4) The type of medical intervention to be used in the resident's care, including its probable frequency and duration.
(5) The probable impact on the resident's condition, with and without the use of the medical intervention.
(6) Reasonable alternative medical interventions considered or utilized and reasons for their discontinuance or inappropriateness.
(f) A patient representative may include a family member or friend of the resident who is unable to take full responsibility for the health care decisions of the resident, but who has agreed to serve on the interdisciplinary team, or other person authorized by state or federal law.
(g) The interdisciplinary team shall periodically evaluate the use of the prescribed medical intervention at least quarterly or upon a significant change in the resident's medical condition.
(h) In case of an emergency, after obtaining a physician and surgeon's order as necessary, a skilled nursing or intermediate care facility may administer a medical intervention that requires informed consent prior to the facility convening an interdisciplinary team review. If the emergency results in the application of physical or chemical restraints, the interdisciplinary team shall meet within one week of the emergency for an evaluation of the medical intervention.
(i) Physicians and surgeons and skilled nursing facilities and intermediate care facilities shall not be required to obtain a court order pursuant to Section 3201 of the Probate Code prior to administering a medical intervention which requires informed consent if the requirements of this section are met.
(j) Nothing in this section shall in any way affect the right of a resident of a skilled nursing facility or intermediate care facility for whom medical intervention has been prescribed, ordered, or administered pursuant to this section to seek appropriate judicial relief to review the decision to provide the medical intervention.
(k) No physician or other health care provider, whose action under this section is in accordance with reasonable medical standards, is subject to administrative sanction if the physician or health care provider believes in good faith that the action is consistent with this section and the desires of the resident, or if unknown, the best interests of the resident.
(l) The determinations required to be made pursuant to subdivisions (a), (e), and (g), and the basis for those determinations shall be documented in the patient's medical record and shall be made available to the patient's representative for review.

H&SC 1418.9 Order of antipsychotic medication; duties of attending physician and surgeon or resident; informed consent; notification requirements; definitions

(a) If the attending physician and surgeon of a resident in a skilled nursing facility prescribes, orders, or increases an order for an antipsychotic medication for the resident, the physician and surgeon shall do both of the following:

(1) Obtain the informed consent of the resident for purposes of prescribing, ordering, or increasing an order for the medication.

(2) Seek the consent of the resident to notify the resident's interested family member, as designated in the medical record. If the resident consents to the notice, the physician and surgeon shall make reasonable attempts, either personally or through a designee, to notify the interested family member, as designated in the medical record, within 48 hours of the prescription, order, or increase of an order.

(b) Notification of an interested family member is not required under paragraph (2) of subdivision (a) if any of the following circumstances exist:

(1) There is no interested family member designated in the medical record.

(2) The resident has been diagnosed as terminally ill by his or her physician and surgeon and is receiving hospice services from a licensed, certified hospice agency in the facility.

(3) The resident has not consented to the notification.

(c) As used in this section, the following definitions shall apply:

(1) "Resident" means a patient of a skilled nursing facility who has the capacity to consent to make decisions concerning his or her health care, including medications.

(2) "Designee" means a person who has agreed with the physician and surgeon to provide the notice required by this section.

(3) "Antipsychotic medication" means a medication approved by the United States Food and Drug Administration for the treatment of psychosis.

(4) "Increase of an order" means an increase of the dosage of the medication above the dosage range stated in a prior consent from the resident.

(d) This section shall not be construed to require consent from an interested family member for an attending physician and surgeon of a resident to prescribe, order, or increase an order for antipsychotic medication.

H & SC 1424. **Citations issued pursuant to this chapter shall be classified according to the nature of the violation and shall indicate the classification on the face thereof.**

(a) In determining the amount of the civil penalty, all relevant facts shall be considered, including, but not limited to, the following:

(1) The probability and severity of the risk that the violation presents to the patient's or resident's mental and physical condition.

(2) The patient's or resident's medical condition.

(3) The patient's or resident's mental condition and his or her history of mental disability or disorder.

(4) The good faith efforts exercised by the facility to prevent the violation from occurring.

(5) The licensee's history of compliance with regulations.

(b) Relevant facts considered by the department in determining the amount of the civil penalty shall be documented by the department on an attachment to the citation and available in the public record.

This requirement shall not preclude the department or a facility from introducing facts not listed on the citation to support or challenge the amount of the civil penalty in any proceeding set forth in Section 1428.

(c) Class "AA" violations are violations that meet the criteria for a class "A" violation and that the state department determines to have been a direct proximate cause of death of a patient or resident of a long-term health care facility. Except as provided in Section 1424.5, a class "AA" citation is subject to a civil penalty in the amount of not less than five thousand dollars ($5,000) and not exceeding twenty-five thousand dollars ($25,000) for each citation. In any action to enforce a citation issued under this subdivision, the state department shall prove all of the following:

(1) The violation was a direct proximate cause of death of a patient or resident.

(2) The death resulted from an occurrence of a nature that the regulation was designed to prevent.

(3) The patient or resident suffering the death was among the class of persons for whose protection the regulation was adopted. If the state department meets this burden of proof, the licensee shall have the burden of proving that the licensee did what might reasonably be expected of a long-term health care facility licensee, acting under similar circumstances, to comply with the regulation. If the licensee sustains this burden, then the citation shall be dismissed. Except as provided in Section 1424.5, for each class "AA" citation within a 12-month period that has become final, the state department shall consider the suspension or revocation of the facility's license in accordance with Section 1294. For a third or subsequent class "AA" citation in a facility within that 12-month period that has been sustained, the state department shall commence action to suspend or revoke the facility's license in accordance with Section 1294.

(d) Class "A" violations are violations which the state department determines present either (1) imminent danger that death or serious harm to the patients or residents of the long-term health care facility would result therefrom, or (2) substantial probability that death or serious physical harm to patients or residents of the long-term health care facility would result therefrom. A physical condition or one or more practices, means, methods, or operations in use in a long-term health care facility may constitute a class "A" violation. The condition or practice constituting a class "A" violation shall be abated or eliminated immediately, unless a fixed period of time, as determined by the state department, is required for correction. Except as provided in Section 1424**.**5, a class "A" citation is subject to a civil penalty in an amount not less than one thousand dollars ($1,000) and not exceeding ten thousand dollars ($10,000) for each and every citation.

If the state department establishes that a violation occurred, the licensee shall have the burden of proving that the licensee did what might reasonably be expected of a long-term health care facility licensee, acting under similar circumstances, to comply with the regulation. If the licensee sustains this burden, then the citation shall be dismissed.

(e) Except as provided in paragraph (4) of subdivision (a) of Section 1424.5, class "B" violations are violations that the state department determines have a direct or immediate relationship to the health, safety, or security of long-term health care facility patients or residents, other than class "AA" or "A" violations. Unless otherwise determined by the state department to be a class "A" violation pursuant to this chapter and rules and regulations adopted pursuant thereto, any violation of a patient's rights as set forth in Sections 72527 and 73523 of Title 22 of the California Code of Regulations, that is determined by the state department to cause or under circumstances likely to cause significant humiliation, indignity, anxiety, or other emotional trauma to a patient is a class "B" violation. A class "B" citation is subject to a civil penalty in an amount not less than one hundred dollars ($100) and not exceeding one thousand dollars ($1,000) for each and every citation. A class "B" citation shall specify the time within which the violation is required to be corrected. If the state department establishes that a violation occurred, the licensee shall have the burden of proving that the licensee did what might reasonably be expected of a long-term health care facility licensee, acting under similar circumstances, to comply with the regulation. If the licensee sustains this burden, then the citation shall be dismissed. In the event of any citation under this paragraph, if the state department establishes that a violation occurred, the licensee shall have the burden of proving that the licensee did what might reasonably be expected of a long-term health care facility licensee, acting under similar circumstances, to comply with the regulation. If the licensee sustains this burden, then the citation shall be dismissed.

Surveying to Antipsychotic Use in SNFs

July 19, 2012

Debra Brown, PharmD
Robert Menet, PharmD
Pharmaceutical Consultants II
California Department of Public Health
Center for Health Care Quality
Licensing & Certification Program

Goals and Objectives

- Be familiar with the CDPH-DHCS Antipsychotic Collaborative Executive Report
- Understand the national focus on antipsychotic medications and CDPH alignment with CMS initiatives
- Determine survey sample selection for residents receiving antipsychotic medications
- Understand and be able to implement the new CDPH "Antipsychotic Use Survey Tool" and supplemental guidance
- Discuss elements of SNF informed consent for antipsychotic medications
- Identify regulatory non-compliances related to SNF antipsychotic use and informed consent

Antipsychotic Use in SNFs

- Prescribing of antipsychotic drugs in nursing home residents:
  - More than one of every four Medicare beneficiaries in nursing homes (27.6%) received antipsychotics—the highest reported rate in nearly a decade.
  - Approximately 693,000, or 27.6%, of all Medicare beneficiaries in nursing homes received at least one antipsychotic during the study period. Of these:
    - Approximately 13% received duplicative drug therapy;
    - Over half (58.2%) of treated residents received antipsychotic therapy not in accordance with nursing home guidelines;
    - One in four patients (23.4%) had no appropriate indication for use;
    - Nearly one in five (17.2%) had daily doses exceeding recommended levels, and
    - 17.6% had both inappropriate indications for use and high dosing.

Briesacher BA, et al. The Quality of Antipsychotic Drug Prescribing in Nursing Homes. *Archives of Internal Medicine.* 2005; 163: 1280.

Antipsychotic Use in SNFs

CMS OSCAR data reflects NH antipsychotic use remains unchanged over 3 years: 24.2% (approximately one in four residents) receive these medications in CA

CMS Online Survey, Certification and Reporting (OSCAR) data 2010, 2011 and 2012; QIES link: https://web.qiesnet.org/qiestosuccess

CDPH/DHCS Antipsychotic Collaborative Executive Report

- Encompasses outcome of 42 NH antipsychotic collaborative investigations May 2010 – September 2011
  - Methodology:
    - DHCS Pharmacy Benefits Division shared Medi-Cal beneficiary antipsychotic utilization data with CDPH
    - CDPH conducted investigations through the complaint process utilizing a team of Pharmaceutical Consultants
- Identifies quality of care issues associated with NH antipsychotic use
- Posted to CDPH internet website 5/31/12: http://www.cdph.ca.gov/programs/LnC/Documents/AntipsychoticCollaborativeExecutiveReportFinalMay2012.pdf

CDPH/DHCS Antipsychotic Collaborative Executive Report

- Investigative findings revealed:
  - 29/42 (69%) of investigations resulted in regulatory deficiencies related to inappropriate antipsychotic use
  - Of those 29 investigations, 85% of the time the consultant pharmacist failed to identify the inappropriate antipsychotic use
  - In 18/29 investigations (62%), facilities received consultant pharmacist services below cost
  - In 16/29 investigations (55%), inadequate development of antipsychotic nursing care plans
  - In 14/29 investigations, inadequate adherence to informed consent (licensing) regulatory requirements

CDPH/DHCS Antipsychotic Collaborative Executive Report

- Investigative findings demonstrated opportunity for improvement as related to:
  - Provision of accurate/complete information during informed consent process
  - Ensuring consideration of non-pharmacologic alternatives and risk vs. benefit prior to initiating antipsychotics
  - Development and implementation of complete/accurate antipsychotic care plans
  - Provision of quality consultant pharmacist services
    - Under licensing and federal regulatory requirements the consultant pharmacist is retained to ensure quality of pharmaceutical services

CDPH/DHCS Antipsychotic Collaborative Executive Report

- Summary of recommendations for improving NH antipsychotic use:
  - Enforcement
    - Develop a survey tool to evaluate appropriate antipsychotic use
      - Including informed consent, care planning and provision of consultant pharmacist services
    - Develop/implement methodology for identifying facilities with high rate of antipsychotic use
  - Education
    - Antipsychotic collaborative findings have been shared with stakeholders and organizations
      - CMS Region IX and CO, CAHF, CANHR, HSAG, DOJ, BoP, CalTCM, DHCS, CPhA, ASCP and others
      - Next steps: CDPH working with stakeholders to develop educational materials (stakeholder workgroup)

National Focus on Antipsychotic Medications

- HHS-OIG report released 5/2011 entitled "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents"
- Study conducted 1/1/07 – 6/30/07
- Findings: 22% of atypical antipsychotics prescribed in LTCs not administered in accordance with CMS standards
- Findings: 83% of antipsychotics prescribed in LTCs for off-label indication (dementia)

National Focus on Antipsychotic Medications

- CMS National Initiative to improve dementia care -- rolled out May 2012
  - Reduce NH antipsychotic use by 15%
  - Target date: end of 2012
  - Focus on non-pharmacologic interventions
  - "Nursing Home Compare" website will post MDS 3.0 Quality Measure antipsychotic use data July 2012
    - Indicator: Psychoactive Medication Use in Absence of Psychotic or Related Condition (long stay residents)

Antipsychotic Use Survey Tool

- Reflects federal regulatory requirements at F222, F329, F428, F501, F520 and others
- Reflects licensing regulatory requirements under informed consent and care planning
  - Reminder: separate 2567 must be generated when licensing deficiencies are written
- To be implemented during federal re-certification surveys and complaint investigations
- Should be utilized (along with pertinent survey notes) to assess appropriateness of antipsychotic use

Antipsychotic Use Survey Tool – Sample Selection for Use

- CMS to provide MDS 3.0 QM data on "Nursing Home Compare" website by 7/19/12: (http://www.medicare.gov/NHCompare/Include/DataSection/Questions/ProximitySearch.asp?bhcp=1)
- Facilities triggering 30% percent or more under QM indicator "Psychoactive Medication Use in Absence of Psychotic or Related Condition" (long stay residents):
  - Pre-select two residents receiving antipsychotics for Phase 1 review and use the survey tool for Sub-Task 5C Resident Review
- All other re-certification surveys:
  - Use the survey tool for sampled residents receiving antipsychotics during Sub-Task 5C Resident Review
- Federal complaint investigations related to residents receiving antipsychotic medications:
  - Use the survey tool

Antipsychotic Use Survey Tool – Step by Step

- **Section 1**: Primary indication(s) from the clinical record related to use of the antipsychotic medication (items 1 – 13)

1. Schizophrenia
2. Schizo-affective disorder
3. Delusional disorder
4. Mood disorders (e.g., bipolar disorder, depression w/ psychotic features
5. Schizophreniform disorders
6. Psychosis
7. Atypical Psychosis
8. Brief psychotic disorder
9. Dementing illnesses with associated behavioral symptoms
10. Medical illnesses with psychotic symptoms (e.g., neoplastic disease) and/or treatment related psychosis or mania (e.g., high dose steroids)
11. Tourette's Disorder or Huntington's disease
12. Hiccups or nausea and vomiting associated with cancer or chemotherapy
13. None of the above
    - Guidance indicates: if "Y" to any indications 1-10 complete Sections 2 - 4; if "Y" to 11 or 12 skip Sections 2 - 4 and continue with Section 5; if "Y" to 13 cite F329 (inadequate indication for use) or F222 (chemical restraints) and continue with Section 5.

Antipsychotic Use Survey Tool – Step by Step

- **Section 2**: Behavioral symptoms (one criteria must be met)
  - The symptoms are due to mania or psychosis (such as auditory, visual or other hallucinations; delusions); **OR**
  - The behavioral symptoms present a danger (documented to the resident or to others; **OR**
  - The symptoms are significant enough that the resident is experiencing one or more of the following:
    - Inconsolable or persistent distress (e.g., fear, continuously yelling, screaming, distress associated w/ end-of-life, or crying); **OR**
    - A significant decline in function; **OR**
    - Substantial difficulty receiving needed care (e.g., not eating resulting in weight loss; fear and not bathing leading to skin breakdown or infection).
  - Guidance indicates: cite at F329 (inadequate indication for use) or F222 (chemical restraints) if "N" response to all of the above

Antipsychotic Use Survey Tool – Step by Step

- **Section 3**: Chronic or Acute Psychiatric Condition
  - **3A**: Chronic condition (N/A if resident admitted on an antipsychotic):
    - Target behavior must be specifically identified and monitored objectively and quantitatively prior to medication use to ensure behavioral symptoms are:
      - Not due to medical condition and environmental/psychological stressors; and are persistent; and documented non-pharmacological interventions have been attempted but failed to resolve cause of the behaviors.

Antipsychotic Use Survey Tool – Step by Step

- **Section 3 (cont'd)**: Chronic or Acute Psychiatric Condition
  - **3B**: Acute situation/emergency:
    - Must meet identified criteria and be related to one/more clinical conditions in Section 1.
    - Acute treatment period is limited to 7 days/less; and a clinician (w/ IDT) must evaluate condition to identify/address underlying causes of acute condition and verify continuing need for medication; and non-pharmacological interventions must be attempted, unless contraindicated, and documented following the resolution of the acute psychiatric situation.

    - Guidance indicates: cite at F329 (inadequate indication/monitoring) or F222 if "N" response to any criteria under 3A or 3B. Additionally, if the facility failed to monitor the behaviors in an objective and quantitative manner, cite at F329 (for inadequate monitoring).

Antipsychotic Use Survey Tool – Step by Step

- **Section 4**: Dosage
  - If the antipsychotic is used to treat behavior symptoms associated with a dementing illness, the dosage does not exceed that listed in F329 (Table 1).
    - See supplemental guidance document
  - Resident is receiving one antipsychotic medication
  - Guidance indicates: cite at F329 (in excessive dosage or duplicate therapy) if "N" response to either of the above unless the prescriber has documented resident specific clinical rationale/justification demonstrating the benefit exceeds the associated risk.

Antipsychotic Use Survey Tool – Step by Step

- **Section 5**: Monitoring for Effectiveness
  - Target behaviors (for the antipsychotic medication) are:
    - Identified in the resident's care plan; monitored objectively and quantitatively; and
    - Consistent with the primary indication for use.
  - Behavioral data are:
    - Made available to the prescriber in a consolidated manner monthly; and
    - Sufficient to provide the prescriber with the necessary information to determine antipsychotic medication effectiveness/ineffectiveness as well as the presence of adverse consequences.
  - Guidance indicates: cite at F329 (inadequate monitoring) and/or F279 (care planning) if "N" response to any of the above.
    - Cite at Title 22 Section 72319(j)(2) and 72311(a)(1) if nursing care plan does not specify data to the collected for use in evaluating effectiveness and occurrence of adverse reactions; and/or
    - Cite Title 22 Section 72319(j)(3) if consolidated monthly behavioral data not available to the prescriber.

Antipsychotic Use Survey Tool – Step by Step

- **Section 6**: Monitoring for Adverse Consequences:
  - Adverse consequences to be monitored shall include at least the following:
    - Significant/severe consequences such as those listed in FDA boxed warnings (manufacturer's package insert) and those that may be significant based on the resident's clinical condition.
      - See electronic URLs in supplemental guidance: **http://www.fda.gov/Drugs/default.htm** and **https://blackboxrx.com/**
    - Those listed in Table 1 of F329 (also in supplemental guidance)
    - The associated adverse consequences are identified in the resident's care plan.
  - If the resident has experienced any possible/actual antipsychotic- related consequences the facility has documented such and taken action.
  - Guidance indicates: cite at F329 (inadequate monitoring or presence of adverse consequences which indicate the dose should be reduced or discontinued) if "N" response to any of the above.

Antipsychotic Use Survey Tool – Step by Step

- **Section 7**: Gradual Dose Reduction:
  - If the antipsychotic was initiated within the last year the facility has attempted a GDR in two separate quarters.
    - Must be at least one month between attempts
  - If the resident has been receiving the antipsychotic for more than one year the GDR has been attempted annually.
  - If no antipsychotic GDR has been attempted the prescriber has documented a taper is clinically contraindicated.
    - F329 GDR language is included in supplemental guidance
  - Guidance indicates cite at F329 (for excessive duration/GDR) if "N" response to any of the above.

Antipsychotic Use Survey Tool – Step by Step

- **Section 8**: Provision of Consultant Pharmacist Services:
  - Documentation is present the resident's clinical record was reviewed monthly by a consultant pharmacist.
  - If non-compliances related to antipsychotic use were noted in Sections 1 – 7 the consultant pharmacist identified irregularities in writing to the attending physician and director of nursing.
  - If the consultant pharmacist **did** identify (in the monthly Medication Regimen Review report) irregularities related to antipsychotic inappropriateness the facility acted on the report.
  - Guidance indicates cite at F428 (Medication Regimen Review) if "N" response to any of the above.

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (RP = Responsible Party):
  - If the antipsychotic was initiated **prior** to admission to the facility the clinical record contains documentation of previous informed consent; or verification of resident consent after admission.
    - Guidance indicates cite T22 Section 72528(c) if "N" response
  - If the antipsychotic was initiated **after** admission to the facility the clinical record contains verification of resident informed consent. Exception is use for an emergency basis as defined in T22 Section 72528(e).
    - Guidance indicates cite T22 Section 72528(c) if "N" response
  - If the antipsychotic dosage was increased the clinical record contains verification of resident informed consent.
    - Guidance indicates cite H & SC Section 1418.9 if "N" response

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (continued):
  - Interview the resident (or RP if the resident does not have capacity) to determine if the prescribing physician provided the following material information prior to the use of the antipsychotic:

1. The reason for the treatment and the nature and seriousness of the resident's illness; and
2. The nature of the proposed treatment including frequency and duration; and
3. The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment; and
4. The nature, degree, duration and probability of side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions; and
5. The reasonable alternative treatments and risks, and why the health professional is recommending the particular treatment; and
6. That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

  - Guidance indicates cite T22 Section 72528(b)(1-6) if "N" response to any of the above.

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (continued):

  - Determine the prescribing physician provided material information necessary to obtain informed consent and received consent from the resident.
    - Guidance indicates cite T22 Section 72528(a) and/or H&SC 1418.9 if "N" response
  - Prior to giving informed consent, the information provided was understood and questions were satisfactorily answered.
    - Guidance indicates cite F156 if "N" response
  - The resident/RP has been invited to participate in care planning as it relates to the use of the antipsychotic medication.
    - Guidance indicates cite F280 or T22 Section 72527(a)(3) if "N" response

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (continued):
  - If the resident does **not** have capacity to give informed consent and has **no** designated RP/person with legal authority to make those decisions on behalf of the resident:
    - The attending physician has identified efforts (resident interview/family members consulted, etc.) no person with legal authority exists.
    - The facility IDT has documented review, assessment and care planning (unless in an emergency) of the proposed antipsychotic order in accordance with H&SC 1418.8(e)(1) through (e)(6) prior to receipt of the medication.
    - In the case of an emergency antipsychotic medication intervention, the IDT has met within one week for an evaluation of the intervention.
    - The IDT has (at least quarterly or upon a significant change of condition) evaluated the antipsychotic therapy.
  - Guidance indicates cite H&SC 1418.8 if "N" response.

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (continued):
  - Determine the following regarding informed consent policies and procedures:
    - The facility as written patients' rights policies and procedures related to psychotherapeutic informed consent.
    - Licensed nursing staff are familiar with written informed consent facility policies and procedures and are able to explain the process of verifying psychotherapeutic informed consent.
    - The resident's attending physician has verified (on interview) that antipsychotic informed consent was obtained in accordance with facility policies and procedures and regulatory requirements.
  - Guidance indicates cite T22 Section 72527(a) if "N" response to any of the above.

Antipsychotic Use Survey Tool – Step by Step

- **Section 9**: Informed Consent (continued):
  - The surveyor should consider issuance of a civil money citation for one or more of the following non-compliance(s):
    - Resident/RP indicates (on interview) required material information (as defined in T22 Section 72528 (1-6)) was not received in order to make an informed consent decision prior to receipt of the antipsychotic medication; and/or
    - Physician did not obtain informed consent from the resident (the process of informed consent was delegated to licensed nursing staff, ward clerk, etc.); and/or
    - Facility failed to develop and implement patients' rights policies and procedures, in accordance with state laws and regulations, related to psychotherapeutic informed consent.

Antipsychotic Use Survey Tool – Step by Step

- **Section 10**: Medical Director/Quality Assessment and Assurance (QAA):
  - Medical Director has ensured resident care policies and procedures were developed and implemented regarding antipsychotic informed consent.
  - Medical Director has addressed facility-identified clinically inappropriate use of antipsychotic medications in the context of regulatory requirements and current standards of practice.
  - QAA has developed and implemented an action plan related to non-compliances with antipsychotic informed consent; appropriate antipsychotic use; or acting on consultant pharmacist MRR recommendations related to inappropriate antipsychotic use (note: facility not required to disclose QAA minutes).
    - Guidance indicates cite F501 if "N" response to any of the first two items (Medical Director is responsible for implementation of resident care policies and/or the coordination of medical care in the facility); cite F520 if "N" response to the last item (QAA committee develops and implements appropriate plans of action to correct identified quality deficiencies).

Antipsychotic Use Survey Tool: In Summary

So what does this "Antipsychotic Survey Tool" help you do? It helps you determine the following:

1. Is there an appropriate indication for use of the antipsychotic (diagnosis and behavioral indication)?

2. Is there adequate monitoring related to antipsychotic use (effectiveness and adverse consequences)?

3. Is the dosage and duration of use appropriate?

4. Was informed consent obtained?

5. Is the consultant pharmacist actively involved in antipsychotic medication management?

6. Is the facility Medical Director overseeing the quality of care related to antipsychotic medication use?

7. Are there issues related to antipsychotic use which should be brought forward for the facility's Quality Assessment & Assurance (QAA) committee to address?

Contact Information

- If you have questions or comments related to the Antipsychotic Use Survey Tool or Supplemental Guidance, please contact:

Debra Brown, PharmD, Pharmaceutical Consultant II

– Licensing and Certification Program

- FAX (916) 552-8988
- Email: debra.brown@cdph.ca.gov
- Phone: (916) 319 - 9239

Thank you – questions?

Checklist

Review of Care and Services for a Resident with Dementia

(for use with the Interpretive Guidance at F309)

Assessment and Underlying Cause Identification

- ✓ Did staff describe behavior (onset, duration, intensity, possible precipitating events or environmental triggers, etc.) and related factors (appearance, alertness, etc.) in the medical record with enough specific detail of the actual situation to permit underlying cause identification to the extent possible?
- ✓ If the behaviors represent a sudden change or worsening from baseline, did staff contact the attending physician/practitioner immediately for a medical evaluation, as appropriate?
- ✓ If medical causes are ruled out, did staff attempt to establish other root causes of the behavior using individualized knowledge about the person and when possible, information from the resident, family, previous caregivers and/or direct care staff?
- ✓ As part of the comprehensive assessment did facility staff evaluate:
    - The resident's usual and current cognitive patterns, mood and behavior, and whether these present a risk to the resident or others?
    - How the resident typically communicates a need such as pain, discomfort, hunger, thirst or frustration?
    - Prior life patterns and preferences customary responses to triggers such as stress, anxiety or fatigue, as provided by family, caregivers, and others who are familiar with the resident before or after admission?
- ✓ Did staff, in collaboration with the practitioner, identify risk and causal/contributing factors for behaviors, such as:
    - Presence of co-existing medical or psychiatric conditions, or decline in cognitive function?
    - Adverse consequences related to the resident's current medications?

1. ***If the condition or risks were present at the time of the required comprehensive assessment, did the facility comprehensively assess the physical, mental and psychosocial needs of the resident with dementia to identify the risks and/or to determine underlying causes (to the extent possible) of the resident's behavioral and/or mental psychosocial symptoms, and needed adaptations, and the impact upon the resident's function, mood and cognition?***
   If No, cite F272

Care Planning

- ✓ Was the resident and/or family/representative involved (to the extent possible) in discussions about the potential use of any interventions, and was this documented in the medical record?
- ✓ Does the care plan reflect an individualized team approach with measureable goals, timetables and specific interventions for the management of behavioral and psychological symptoms?
- ✓ Does the care plan include:
    - Involvement of the resident/representative to the extent possible?
    - A description of and how to prevent targeted behaviors?
    - Why behaviors should be prevented or otherwise addressed (e.g., severely distressing to resident)?
    - Monitoring of the effectiveness of any/all interventions?
- ✓ If the resident or family/representative refused a recommended treatment or approach, was counseling on consequences and alternative approaches to address behavioral symptoms provided?

Note: If the resident lacks decisional capacity and lacks effective family/representative support, contact the facility social worker to determine what type of social services or referrals have been attempted to assist the resident.

2. ***Did the facility develop a plan of care with measurable goals and interventions to address the care and treatment for a resident with dementia related to the behavioral and/or mental/psychosocial symptoms, in accordance with the assessment, resident's wishes and current standards of practice? If No, cite F279***

Implementation of the Care Plan

Did staff:

Identify, document and communicate specific targeted behaviors and expressions of distress as well as desired outcomes?

- ✓ Implement individualized, person-centered interventions by qualified persons and document the results?
- ✓ Communicate and consistently implement the care plan, over time and across various shifts?
- ✓ If there is a sudden change in the resident's condition and medical causes of behavior or other symptoms (e.g., delirium or infection) are suspected, is the physician contacted immediately and treatment initiated?
- ✓ Is there a sufficient number of staff to consistently implement the care plan? (*Surveyors should focus on observations of staff interactions with residents who have dementia to determine whether staff consistently applies basic dementia care principles in the care of those individuals*).

3. ***Did the facility provide or arrange services to be provided by qualified persons in accordance with the resident's written plan of care? If No, cite F282***

Note: If during the survey a concern is identified that an antipsychotic medication is given by staff for purposes of discipline or convenience and not required to treat the resident's medical symptoms, review F222 – §483.13(a).

Care Plan Revision/Monitoring and Follow up

- ✓ Does staff, in collaboration with the practitioner, adjust the interventions based on the impact on behavior or other symptoms as well as any adverse consequences related to treatment?
- ✓ When concerns related to the effectiveness or adverse consequences of a resident's treatment regimen are identified:
    - Does staff modify the care plan and, if appropriate, notify the physician and does the physician respond and initiate a change to the resident's care as necessary?

4. ***Did the facility reassess the effectiveness of the interventions and review and revise the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident with dementia? If No, cite F280***

    - If the physician does not respond to the notification, does staff contact the medical director for further review? If the medical director was contacted, does he/she respond and intervene as needed?

5. ***Did the facility provide the necessary care and services for a resident with dementia to support his or her highest practicable level of physical, mental and psychosocial well-being in accordance with the comprehensive assessment and plan of care? If No, cite F309***

Quality Assessment and Assurance

Note: Please refer to F520 Quality Assessment and Assurance for guidance regarding the information that may be obtained from the QAA committee.

- ✓ Do resident care policies and procedures clearly outline a systematic process for the care of residents with dementia?
- ✓ Does the QAA Committee monitor for consistent implementation of the policies and procedures for the care of residents with dementia?
- ✓ Has the QAA committee corrected any identified quality deficiencies related to the care of residents with dementia?
- ✓ Has the QAA committee provided monitoring and oversight for the care and services for a resident with dementia?

SECTION A: IDENTIFICATION INFORMATION

Intent: The intent of this section is to obtain key information to uniquely identify each resident, the home in which he or she resides, and the reasons for assessment.

A0050: Type of Record

A0050. Type of Record	
Enter Code ☐	1. **Add new record** → Continue to A0100, Facility Provider Numbers 2. **Modify existing record** → Continue to A0100, Facility Provider Numbers 3. **Inactivate existing record** → Skip to X0150, Type of Provider

Coding Instructions for A0050, Type of Record

- Code 1, Add new record: if this is a **new record** that has not been previously submitted and accepted in the QIES ASAP system. If this item is **coded as 1**, continue to A0100 Facility Provider Numbers.

  If there is an existing database record for the same resident, the same facility, the same reasons for assessment/tracking, and the same date (assessment reference date, entry date, or discharge date), then the current record is a duplicate and not a new record. In this case, the submitted record will be rejected and not accepted in the QIES ASAP system and a "fatal" error will be reported to the facility on the Final Validation Report.

- Code 2, Modify existing record: if this is a **request to modify** the MDS items for a record that already has been submitted and accepted in the QIES ASAP system.

  If this item is coded as 2, continue to A0100, Facility Provider Numbers.

  When a modification request is submitted, the QIES ASAP System will take the following steps:

  1. The system will attempt to locate the existing record in the QIES ASAP database for this facility with the resident, reasons for assessment/tracking, and date (assessment reference date, entry date, or discharge date) indicated in subsequent Section X items.
  2. If the existing record is not found, the submitted modification record will be rejected and not accepted in the QIES ASAP system. A "fatal" error will be reported to the facility on the Final Validation Report.
  3. If the existing record is found, then the items in all sections of the submitted modification record will be edited. If there are any fatal errors, the modification record will be rejected and not accepted in the QIES ASAP system. The "fatal" error(s) will be reported to the facility on the Final Validation Report.
  4. If the modification record passes all the edits, it will replace the prior record being modified in the QIES ASAP database. The prior record will be moved to a history file in the QIES ASAP database.

A0050: Type of Record (cont.)

- Code 3, Inactivate existing record: if this is a **request to inactivate** a record that already has been submitted and accepted in the QIES ASAP system.

  If this item is **coded as 3**, skip to X0150, Type of Provider.

  When an inactivation request is submitted, the QIES ASAP system will take the following steps:

  1. The system will attempt to locate the existing record in the QIES ASAP system for this facility with the resident, reasons for assessment/tracking, and date (assessment reference date, entry date, or discharge date) indicated in subsequent Section X items.
  2. If the existing record is not found in the QIES ASAP database, the submitted inactivation request will be rejected and a "fatal" error will be reported to the facility on the Final Validation Report.
  3. All items in Section X of the submitted record will be edited. If there are any fatal errors, the current inactivation request will be rejected and no record will be inactivated in the QIES ASAP system.
  4. If the existing record is found, it will be removed from the active records in the QIES ASAP database and moved to a history file.

Identification of Record to be Modified/Inactivated

The Section X items from X0200 through X0700 identify the existing QIES ASAP database assessment or tracking record that is in error. In this section, reproduce the information **EXACTLY** as it appeared on the existing erroneous record, even if the information is incorrect. This information is necessary to locate the existing record in the database.

> **Example:** A MDS assessment for Joan L. Smith is submitted and accepted by the QIES ASAP system. A data entry error is then identified on the previously submitted and accepted record. When the encoder "data entered" the prior assessment for Joan L Smith, he typed "John" by mistake. To correct this data entry error, the facility will modify the erroneous record and complete the items in Section X including items under Identification of Record to be Modified/Inactivated. When completing X0200A, the Resident First Name, "John" will be entered in this item. This will permit the MDS system to locate the previously submitted assessment that is being corrected. If the correct name "Joan" were entered, the QIES ASAP system would not locate the prior assessment.

The correction to the name from "John" to "Joan" will be made by recording "Joan" in the "normal" A0500A, Resident First Name in the modification record. The modification record must include all items appropriate for that assessment, not just the corrected name. This modification record will then be submitted and accepted into the QIES ASAP system which causes the desired correction to be made.

A0100: Facility Provider Numbers

A0100. Facility Provider Numbers	
	A. National Provider Identifier (NPI): ☐☐☐☐☐☐☐☐☐☐ B. CMS Certification Number (CCN): ☐☐☐☐☐☐☐☐☐☐☐☐ C. State Provider Number: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Item Rationale

- Allows the identification of the nursing home submitting assessment.

Coding Instructions

- Nursing homes must have a National Provider Number (NPI) and a CMS Certified Number (CCN).
- Enter the nursing home provider numbers:
  - A. National Provider Identifier (NPI)
  - B. CMS Certified Number (CCN)
  - C. State Provider Number (optional)

DEFINITIONS

NATIONAL PROVIDER IDENTIFIER (NPI) A unique Federal number that identifies providers of health care services. The NPI applies to the long-term care hospital and all of its patients.

CMS CERTIFICATION NUMBER (CCN) Replaces the term "Medicare/Medicaid Provider Number" in survey, certification, and assessment-related activities.

STATE PROVIDER NUMBER Medicaid Provider Number established by a state.

A0200: Type of Provider

A0200. Type of Provider	
Enter Code ☐	Type of provider 1. Nursing home (SNF/NF) 2. Swing Bed

Item Rationale

- Allows designation of type of provider.

Coding Instructions

- Code 1, nursing home (SNF/NF): if a Medicare skilled nursing facility (SNF) or Medicaid nursing facility (NF).
- Code 2, swing bed: if a hospital with swing bed approval.

DEFINITION

SWING BED
A rural hospital with less than 100 beds that participates in the Medicare program that has CMS approval to provide post-hospital SNF care. The hospital may use its beds, as needed, to provide either acute or SNF care.

A0310: Type of Assessment

A0310. Type of Assessment	
Enter Code ☐☐	**A. Federal OBRA Reason for Assessment** 01. **Admission** assessment (required by day 14) 02. **Quarterly** review assessment 03. **Annual** assessment 04. **Significant change in status** assessment 05. **Significant correction** to **prior comprehensive** assessment 06. **Significant correction** to **prior quarterly** assessment 99. **None of the above**
Enter Code ☐☐	**B. PPS Assessment** **PPS Scheduled Assessments for a Medicare Part A Stay** 01. **5-day** scheduled assessment 02. **14-day** scheduled assessment 03. **30-day** scheduled assessment 04. **60-day** scheduled assessment 05. **90-day** scheduled assessment 06. **Readmission/return** assessment **PPS Unscheduled Assessments for a Medicare Part A Stay** 07. **Unscheduled assessment used for PPS** (OMRA, significant or clinical change, or significant correction assessment) **Not PPS Assessment** 99. **None of the above**
Enter Code ☐	**C. PPS Other Medicare Required Assessment - OMRA** 0. **No** 1. **Start of therapy** assessment 2. **End of therapy** assessment 3. **Both Start and End of therapy** assessment 4. **Change of therapy** assessment
Enter Code ☐	**D. Is this a Swing Bed clinical change assessment?** Complete only if A0200 = 2 0. **No** 1. **Yes**
Enter Code ☐	**E. Is this assessment the first assessment** (OBRA, Scheduled PPS, or Discharge) **since the most recent admission/entry or reentry?** 0. **No** 1. **Yes**
Enter Code ☐☐	**F. Entry/discharge reporting** 01. **Entry** tracking record 10. **Discharge** assessment-**return not anticipated** 11. **Discharge** assessment-**return anticipated** 12. **Death in facility** tracking record 99. **None of the above**
Enter Code ☐	**G. Type of discharge** - Complete only if A0310F = 10 or 11 1. **Planned** 2. **Unplanned**

For Comprehensive, Quarterly, and PPS Assessments, Entry and Discharge Records.

Item Rationale

- Allows identification of needed assessment content.

Coding Instructions for A0310, Type of Assessment

Enter the code corresponding to the reason or reasons for completing this assessment.

If the assessment is being completed for both Omnibus Budget Reconciliation Act (OBRA)–required clinical reasons (A0310A) and Prospective Payment System (PPS) reasons (A0310B and A0310C) all requirements for both types of assessments must be met. See Chapter 2 on assessment schedules for details of these requirements.

A0310: Type of Assessment (cont.)

Coding Instructions for A0310A, Federal OBRA Reason for Assessment

- Document the reason for completing the assessment, using the categories of assessment types. For detailed information on the requirements for scheduling and timing of the assessments, see Chapter 2 on assessment schedules.
- Enter the number corresponding to the OBRA reason for assessment. This item contains 2 digits. For codes 01-06, enter "0" in the first box and place the correct number in the second box. If the assessment is not coded 01-06, enter code "99".
  - 01. Admission assessment (required by day 14)
  - 02. Quarterly review assessment
  - 03. Annual assessment
  - 04. Significant change in status assessment
  - 05. Significant correction to prior comprehensive assessment
  - 06. Significant correction to prior quarterly assessment
  - 99. None of the above

Coding Tips and Special Populations

- If a nursing home resident elects the hospice benefit, the nursing home is required to complete an MDS significant change in status assessment. The nursing home is required to complete a SCSA when they come off the hospice benefit (revoke). See Chapter 2 for details on this requirement.
- It is a CMS requirement to have a significant change in status assessment completed EVERY time the hospice benefit has been elected, even if a recent MDS was done and the only change is the election of the hospice benefit.

Coding Instructions for A0310B, PPS Assessment

- Enter the number corresponding to the PPS reason for completing this assessment. This item contains 2 digits. For codes 01-07, enter "0" in the first box and place the correct number in the second box. If the assessment is not coded as 01-07, enter code "99".
- See Chapter 2 on assessment schedules for detailed information on the scheduling and timing of the assessments.

PPS Scheduled Assessments for a Medicare Part A Stay

- 01. 5-day scheduled assessment
- 02. 14-day scheduled assessment
- 03. 30-day scheduled assessment
- 04. 60-day scheduled assessment
- 05. 90-day scheduled assessment
- 06. Readmission/return assessment

DEFINITION

PROSPECTIVE PAYMENT SYSTEM (PPS)
Method of reimbursement in which Medicare payment is made based on the classification system of that service (e.g., resource utilization groups, RUGs, for skilled nursing facilities).

A0310: Type of Assessment (cont.)

PPS Unscheduled Assessments for Medicare Part A Stay

07. Unscheduled assessment used for PPS (OMRA, significant change, or significant correction assessment)
99. None of the above

Coding Instructions for A0310C, PPS Other Medicare Required Assessment—OMRA

- Code 0, no: if this assessment is not an OMRA.
- Code 1, Start of therapy assessment (OPTIONAL): with an assessment reference date (ARD) that is 5 to 7 days after the first day therapy services are provided (except when the assessment is used as a short stay assessment, see Chapter 6). No need to combine with the 5-day assessment except for short stay. Only complete if therapy RUG (index maximized), otherwise the assessment will be rejected.
- Code 2, End of therapy assessment: with an ARD that is 1 to 3 days after the last day therapy services were provided.
- Code 3, both the Start and End of therapy assessment: with an ARD that is both 5 to 7 days after the first day therapy services were provided and that is 1 to 3 days after the last day therapy services were provided (except when the assessment is used as a short stay assessment, see Chapter 6).
- Code 4, Change of therapy assessment: with an ARD that is Day 7 of the COT observation period.

Coding Instructions for A0310D, Is This a Swing Bed Clinical Change Assessment?

- Code 0, no: if this assessment is not a swing bed clinical change assessment.
- Code 1, yes: if this assessment is a swing bed clinical change assessment.

Coding Instructions for A0310E, Is This Assessment the First Assessment (OBRA, PPS, or Discharge) since the Most Recent Admission/Entry or Reentry?

- Code 0, no: if this assessment is not the first assessment since the most recent admission/entry or reentry.
- Code 1, yes: if this assessment is the first assessment since the most recent admission/entry or reentry.

Coding Tips and Special Populations

- A0310E = 0 for any tracking record (entry or death in facility) because tracking records are not considered assessments.

A0310: Type of Assessment (cont.)

Coding Instructions for A0310F, Federal OBRA & PPS Entry/Discharge Reporting

- Enter the number corresponding to the reason for completing this assessment or tracking record. This item contains 2 digits. For code 01, enter "0" in the first box and place "1" in the second box. If the assessment is not coded as "01" or "10 or "11" or "12," enter "99":

  01. Entry tracking record
  10. Discharge assessment-return not anticipated
  11. Discharge assessment-return anticipated
  12. Death in facility tracking record
  99. None of the above

Coding Instructions for A0310G, Type of Discharge

- Code 1: if type of discharge is a planned discharge.
- Code 2: if type of discharge is an unplanned discharge.

A0410: Submission Requirement

A0410. Submission Requirement	
Enter Code ☐	1. **Neither federal nor state required submission** 2. **State but not federal required submission** (FOR NURSING HOMES ONLY) 3. **Federal required submission**

Item Rationale

- There must be a federal and/or state authority to submit MDS assessment data to the MDS National Repository.
- Nursing homes must be certain they are submitting MDS assessments under the appropriate authority. With this item, the nursing home indicates the submission authority.

Steps for Assessment

1. Ask the nursing home administrator or representative which units in the nursing home are Medicare certified, if any, and which units are Medicaid certified, if any.
2. Identify all units in the nursing home that are not certified, if any.

   - If some or all of the units in the nursing home are neither Medicare nor Medicaid certified, ask the nursing home administrator or representative whether the State has authority to collect MDS information for residents on units that are neither Medicare nor Medicaid certified.

A0410: Submission Requirement (cont.)

Coding Instructions

- Code 1, neither federal nor state required submission: if the MDS record is for a resident on a unit that is neither Medicare nor Medicaid certified, and the state does not have authority to collect MDS information for residents on this unit. If the record is submitted, it will be rejected and all information from that record will be purged.
- Code 2, State but not federal required submission: if the MDS record is for a resident on a unit that is neither Medicare nor Medicaid certified, but the state has authority, under state licensure or other requirements, to collect MDS information for these residents.
- Code 3, Federal required submission: if the MDS record is for a resident on a Medicare and/or Medicaid certified unit. There is CMS authority to collect MDS information for residents on this unit.

A0500: Legal Name of Resident

A0500. Legal Name of Resident

A. First name: B. Middle initial:

C. Last name: D. Suffix:

Item Rationale

- Allows identification of resident
- Also used for matching each of the resident's records

DEFINITION

LEGAL NAME

Patient's name as it appears on the Medicare card. If the patient is not enrolled in the Medicare program, use the patient's name as it appears on a Medicaid card or other government-issued document.

Steps for Assessment

1. Ask resident, family, significant other, guardian, or legally authorized representative.
2. Check the resident's name on his or her Medicare card, or if not in the program, check a Medicaid card or other government-issued document.

Coding Instructions

Use printed letters. Enter in the following order:

A. First Name
B. Middle Initial (if the resident has no middle initial, leave Item A0500B blank; if the resident has two or more middle names, use the initial of the first middle name)
C. Last Name
D. Suffix (e.g., Jr./Sr.)

A0600: Social Security and Medicare Numbers

A0600. Social Security and Medicare Numbers

A. **Social Security Number:** ☐☐☐ – ☐☐ – ☐☐☐☐

B. **Medicare number** (or comparable railroad insurance number): ☐☐☐☐☐☐☐☐☐☐☐☐

Item Rationale

- Allows identification of the resident.
- Allows records for resident to be matched in system.

Coding Instructions

- Enter the Social Security Number (SSN) in A0600A, one number per space starting with the leftmost space. If no social security number is available for the resident (e.g., if the resident is a recent immigrant or a child) the item may be left blank.
- Enter Medicare number in A0600B exactly as it appears on the resident's documents.
- If the resident does not have a Medicare number, a Railroad Retirement Board (RRB) number may be substituted. These RRB numbers contain both letters and numbers. To enter the RRB number, enter the first letter of the code in the leftmost space followed by one letter/digit per space. If no Medicare number or RRB number is known or available, the item may be left blank.
- For PPS assessments (A0310B = 01, 02, 03, 04, 05, 06, and 07), either the SSN (A0600A) or Medicare number/RRB number (A0600B) must be present and both may not be blank.
- A0600B can only be a Medicare (HIC) number or a Railroad Retirement Board number.

DEFINITIONS

SOCIAL SECURITY NUMBER
A tracking number assigned to an individual by the U.S. Federal government for taxation, benefits, and identification purposes.

MEDICARE NUMBER (OR COMPARABLE RAILROAD INSURANCE NUMBER)
An identifier assigned to an individual for participation in national health insurance program. The Medicare Health Insurance identifier may be different from the resident's social security number (SSN), and may contain both letters and numbers. For example, many residents may receive Medicare benefits based on a spouse's Medicare eligibility.

A0700: Medicaid Number

A0700. Medicaid Number - Enter "+" if pending, "N" if not a Medicaid recipient

☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Item Rationale

- Assists in correct resident identification.

A0700: Medicaid Number (cont.)

Coding Instructions

- Record this number if the resident is a Medicaid recipient.
- Enter one number per box beginning in the leftmost box.
- Recheck the number to make sure you have entered the digits correctly.
- Enter a "+" in the leftmost box if the number is pending. If you are notified later that the resident does have a Medicaid number, just include it on the next assessment.
- If not applicable because the resident is not a Medicaid recipient, enter "N" in the leftmost box.

Coding Tips and Special Populations

- To obtain the Medicaid number, check the resident's Medicaid card, admission or transfer records, or medical record.
- Confirm that the resident's name on the MDS matches the resident's name on the Medicaid card.
- It is not necessary to process an MDS correction to add the Medicaid number on a prior assessment. However, a correction may be a State-specific requirement.

A0800: Gender

Item Rationale

- Assists in correct identification.
- Provides demographic gender specific health trend information.

Coding Instructions

- Code 1: if resident is male.
- Code 2: if resident is female.

Coding Tips and Special Populations

- Resident gender on the MDS should match what is in the Social Security system.

A0900: Birth Date

A0900: Birth Date (cont.)

Item Rationale

- Assists in correct identification.
- Allows determination of age.

Coding Instructions

- Fill in the boxes with the appropriate birth date. If the complete birth date is known, do not leave any boxes blank. If the month or day contains only a single digit, fill the first box in with a "0." For example: January 2, 1918, should be entered as 01-02-1918.
- Sometimes, only the birth year or the birth year and birth month will be known. These situations are handled as follows:
  - If only the birth year is known (e.g., 1918), then enter the year in the "year" portion of A0900, and leave the "month" and "day" portions blank. If the birth year and birth month are known, but the day of the month is not known, then enter the year in the "year" portion of A0900, enter the month in the "month" portion of A0900, and leave the "day" portion blank.

A1000: Race/Ethnicity

A1000. Race/Ethnicity	
↓ Check all that apply	
☐	A. American Indian or Alaska Native
☐	B. Asian
☐	C. Black or African American
☐	D. Hispanic or Latino
☐	E. Native Hawaiian or Other Pacific Islander
☐	F. White

Item Rationale

- This item uses the common uniform language approved by the Office of Management and Budget (OMB) to report racial and ethnic categories. The categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature.
- Provides demographic race/ethnicity specific health trend information.
- These categories are NOT used to determine eligibility for participation in any Federal program.

A1000: Race/Ethnicity (cont.)

Steps for Assessment: Interview Instructions

1. Ask the resident to select the category or categories that most closely correspond to his or her race/ethnicity from the list in A1000.
    - Individuals may be more comfortable if this and the preceding question are introduced by saying, "We want to make sure that all our residents get the best care possible, regardless of their race or ethnic background. We would like you to tell us your ethnic and racial background so that we can review the treatment that all residents receive and make sure that everyone gets the highest quality of care" (Baker et al., 2005).
2. If the resident is unable to respond, ask a family member or significant other.
3. Category definitions are provided to resident or family only if requested by them in order to answer the item.
4. Respondents should be offered the option of selecting one or more racial designations.
5. Only if the resident is unable to respond and no family member or significant other is available, observer identification or medical record documentation may be used.

Coding Instructions

Check all that apply.

- Enter the race or ethnic category or categories the resident, family or significant other uses to identify him or her.

DEFINITIONS

RACE/ETHNICITY

AMERICAN INDIAN OR ALASKA NATIVE

A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.

ASIAN

A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, Vietnam.

BLACK OR AFRICAN AMERICAN

A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black" or "African American."

HISPANIC OR LATINO

A person of Cuban, Mexican, Puerto Rican, South or Central American or other Spanish culture or origin regardless of race. The term "Spanish Origin" can be used in addition to "Hispanic" or "Latino."

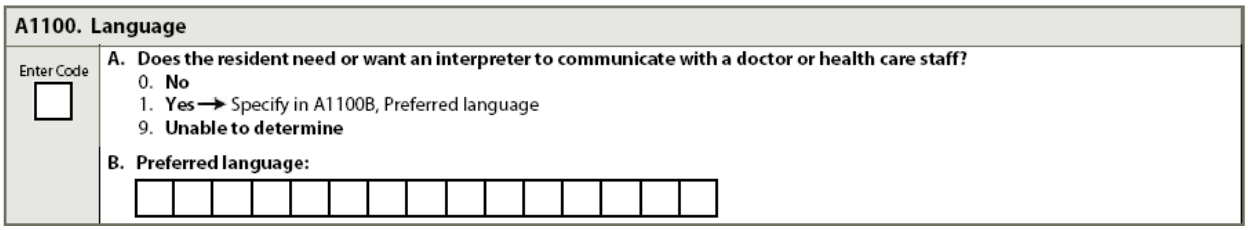
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER

A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

WHITE

A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

A1100: Language



Item Rationale

Health-related Quality of Life

- Inability to make needs known and to engage in social interaction because of a language barrier can be very frustrating and can result in isolation, depression, and unmet needs.
- Language barriers can interfere with accurate assessment.

Planning for Care

- When a resident needs or wants an interpreter, the nursing home should ensure that an interpreter is available.
- An alternate method of communication also should be made available to help to ensure that basic needs can be expressed at all times, such as a communication board with pictures on it for the resident to point to (if able).
- Identifies residents who need interpreter services in order to answer interview items or participate in consent process.

Steps for Assessment

1. Ask the resident if he or she needs or wants an interpreter to communicate with a doctor or health care staff.
2. If the resident is unable to respond, a family member or significant other should be asked.
3. If neither source is available, review record for evidence of a need for an interpreter.
4. If an interpreter is wanted or needed, ask for preferred language.
5. It is acceptable for a family member or significant other to be the interpreter if the resident is comfortable with it and if the family member or significant other will translate exactly what the resident says without providing his or her interpretation.

Coding Instructions for A1100A

- Code 0, no: if the resident (or family or medical record if resident unable to communicate) indicates that the resident does not want or need an interpreter to communicate with a doctor or health care staff.
- Code 1, yes: if the resident (or family or medical record if resident unable to communicate) indicates that he or she needs or wants an interpreter to communicate with a doctor or health care staff. Specify preferred language. Proceed to 1100B and enter the resident's preferred language.
- Code 9, unable to determine: if no source can identify whether the resident wants or needs an interpreter.

A1100: Language (cont.)

Coding Instructions for A1100B

- Enter the preferred language the resident primarily speaks or understands after interviewing the resident and family, observing the resident and listening, and reviewing the medical record.

Coding Tips and Special Populations

- An organized system of signing such as American Sign Language (ASL) can be reported as the preferred language if the resident needs or wants to communicate in this manner.

A1200: Marital Status

A1200. Marital Status	
Enter Code ☐	1. Never married 2. Married 3. Widowed 4. Separated 5. Divorced

Item Rationale

- Allows understanding of the formal relationship the resident has and can be important for care and discharge planning.
- Demographic information.

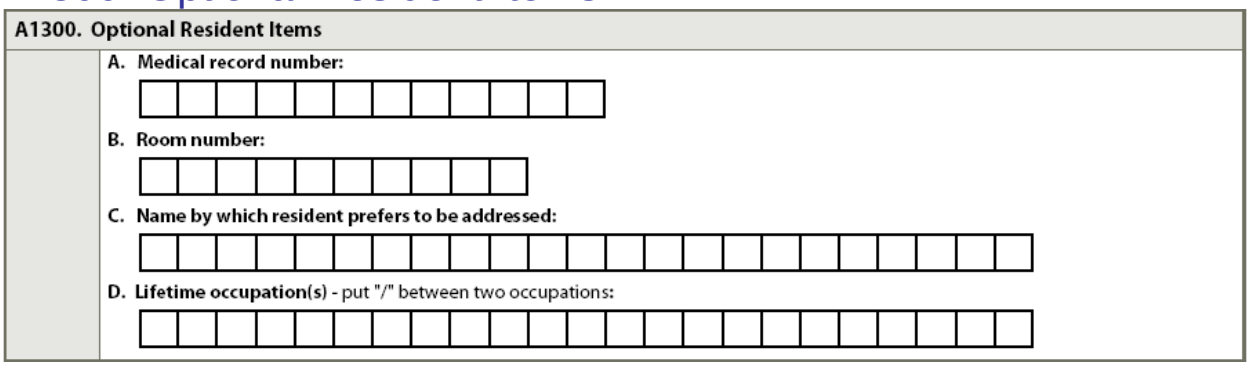
Steps for Assessment

1. Ask the resident about his or her marital status.
2. If the resident is unable to respond, ask a family member or other significant other.
3. If neither source can report, review the medical record for information.

Coding Instructions

- Choose the answer that best describes the current marital status of the resident and enter the corresponding number in the code box:
  1. Never Married
  2. Married
  3. Widowed
  4. Separated
  5. Divorced

A1300: Optional Resident Items



Item Rationale

- Some facilities prefer to include the nursing home medical record number on the MDS to facilitate tracking.
- Some facilities conduct unit reviews of MDS items in addition to resident and nursing home level reviews. The unit may be indicated by the room number.
- Preferred name and lifetime occupation help nursing home staff members personalize their interactions with the resident.
- Many people are called by a nickname or middle name throughout their life. It is important to call residents by the name they prefer in order to establish comfort and respect between staff and resident. Also, some cognitively impaired or hearing impaired residents might have difficulty responding when called by their legal name, if it is not the name most familiar to them.
- Others may prefer a more formal and less familiar address. For example, a physician might appreciate being referred to as "Doctor."
- Knowing a person's lifetime occupation is also helpful for care planning and conversation purposes. For example, a carpenter might enjoy pursuing hobby shop activities.
- These are optional items because they are not needed for CMS program function.

Coding Instructions for A1300A, Medical Record Number

- Enter the resident's medical record number (from the nursing home medical record, admission office or Health Information Management Department) if the nursing home chooses to exercise this option.

Coding Instructions for A1300B, Room Number

- Enter the resident's room number if the nursing home chooses to exercise this option.

Coding Instructions for A1300C, Name by Which Resident Prefers to Be Addressed

- Enter the resident's preferred name. This field captures a preferred nickname, middle name, or title that the resident prefers staff use.
- Obtained from resident self-report or family or significant other if resident is unable to respond.

A1300: Optional Resident Items (cont.)

Coding Instructions for A1300D, Lifetime Occupation(s)

- Enter the job title or profession that describes the resident's main occupation(s) before retiring or entering the nursing home. When two occupations are identified, place a slash (/) between each occupation.
- The lifetime occupation of a person whose primary work was in the home should be recorded as "homemaker." For a resident who is a child or a mentally retarded/developmentally delayed adult resident who has never had an occupation, record as "none."

A1500: Preadmission Screening and Resident Review (PASRR)

A1500. Preadmission Screening and Resident Review (PASRR)
Complete only if A0310A = 01, 03, 04, or 05

Enter Code ☐

Is the resident currently considered by the state level II PASRR process to have serious mental illness and/or intellectual disability ("mental retardation" in federal regulation) or a related condition?

0. **No** → Skip to A1550, Conditions Related to ID/DD Status
1. **Yes** → Continue to A1510, Level II Preadmission Screening and Resident Review (PASRR) Conditions
9. **Not a Medicaid-certified unit** → Skip to A1550, Conditions Related to ID/DD Status

Item Rationale

Health-related Quality of Life

- All individuals who are admitted to a Medicaid certified nursing facility must have a Level I PASRR completed to screen for possible mental illness (MI), intellectual disability (ID), ("mental retardation" (MR) in federal regulation), or related conditions regardless of the resident's method of payment (please contact your local State Medicaid Agency for details regarding PASRR requirements and exemptions).
- Individuals who have or are suspected to have MI/ID or related conditions may not be admitted to a Medicaid-certified nursing facility unless approved through Level II PASRR determination. Those residents covered by Level II PASRR process may require certain care and services provided by the nursing home, and/or specialized services provided by the State.
- A resident with MI or ID must have a Resident Review (RR) conducted when there is a significant change in the resident's physical or mental condition. Therefore, when a significant change in status MDS assessment is completed for a resident with MI or ID, the nursing home is required to notify the State mental health authority, intellectual disability or developmental delay disability authority (depending on which operates in their State) in order to notify them of the resident's change in status. Section 1919(e)(7)(B)(iii) of the Social Security Act requires the notification or referral for a significant change.[1]

[1] The statute may also be referenced as 42 USC 1396r(e)(7)(B)(iii). Note that as of this revision date the statute supersedes Federal regulations at 42 CFR 483.114(c), which still reads as requiring annual resident review. The regulation has not yet been updated to reflect the statutory change to resident review upon significant change in condition.

A1500: Preadmission Screening and Resident Review (PASRR) (cont.)

- Each State Medicaid agency might have specific processes and guidelines for referral, and which types of significant changes should be referred. Therefore, facilities should become acquainted with their own State requirements.
- Please see https://www.cms.gov/PASRR/01_Overview.asp for CMS information on PASRR.

Planning for Care

- The Level II PASRR determination and the evaluation report specify services to be provided by the nursing home and/or specialized services defined by the State.
- The State is responsible for providing specialized services to individuals with MI/ID. In some States specialized services are provided to residents in Medicaid-certified facilities (in other States specialized services are only provided in other facility types such as a psychiatric hospital). The nursing home is required to provide all other care and services appropriate to the resident's condition.
- The services to be provided by the nursing home and/or specialized services provided by the State that are specified in the Level II PASRR determination and the evaluation report should be addressed in the plan of care.
- Identifies individuals who are subject to Resident Review upon change in condition.

Steps for Assessment

1. Complete if A0310A = 01, 03, 04 or 05 (admission assessment, annual assessment, significant change in status assessment, significant correction to prior comprehensive assessment).
2. Review the Level I PASRR form to determine whether a Level II PASRR was required.
3. Review the PASRR report provided by the State if Level II screening was required.

Coding Instructions

- Code 0, no: and skip to A1550, Conditions Related to ID/DD Status, if any of the following apply:
  - — PASRR Level I screening did not result in a referral for Level II screening, or
  - — Level II screening determined that the resident does not have a serious mental illness and/or intellectual disability or related condition, or
  - — PASRR screening is not required because the resident was admitted from a hospital after requiring acute inpatient care, is receiving services for the condition for which he or she received care in the hospital, and the attending physician has certified before admission that the resident is likely to require less than 30 days of nursing home care.

A1500: Preadmission Screening and Resident Review (PASRR) (cont.)

- Code 1, yes: if PASRR Level II screening determined that the resident has a serious mental illness and/or intellectual disability or related condition, and continue to A1510, Level II Preadmission Screening and Resident Review (PASRR) Conditions.
- Code 9, not a Medicaid-certified unit: if bed is not in a Medicaid-certified nursing home. Skip to A1550, Conditions Related to ID/DD Status. The PASRR process does not apply to nursing home units that are not certified by Medicaid (unless a State requires otherwise) and therefore the question is not applicable.
  - Note that the requirement is based on the certification of the part of the nursing home the resident will occupy. In a nursing home in which some parts are Medicaid certified and some are not, this question applies when a resident is admitted, or transferred to, a Medicaid certified part of the building.

A1510: Level II Preadmission Screening and Resident Review (PASRR) Conditions

A1510. Level II Preadmission Screening and Resident Review (PASRR) Conditions Complete only if A0310A = 01, 03, 04, or 05	
↓ Check all that apply	
☐	A. Serious mental illness
☐	B. Intellectual Disability ("mental retardation" in federal regulation)
☐	C. Other related conditions

Steps for Assessment

1. Complete if A0310A = 01, 03, 04 or 05 (admission assessment, annual assessment, significant change in status assessment, significant correction to prior comprehensive assessment).
2. Check all that apply.

Coding Instructions

- Code A, Serious mental illness: if resident has been diagnosed with a serious mental illness.
- Code B, Intellectual Disability ("mental retardation" in federal regulation): if resident has been diagnosed with intellectual disability (or "mental retardation").
- Code C, Other related conditions: if resident has been diagnosed with other related conditions.

A1550: Conditions Related to Intellectual Disability/Developmental Delay (ID/DD) Status

A1550. Conditions Related to ID/DD Status If the resident is 22 years of age or older, complete only if A0310A = 01 If the resident is 21 years of age or younger, complete only if A0310A = 01, 03, 04, or 05	
↓ **Check all conditions that are related to ID/DD status** that were manifested before age 22, and are likely to continue indefinitely	
	ID/DD With Organic Condition
☐	**A. Down syndrome**
☐	**B. Autism**
☐	**C. Epilepsy**
☐	**D. Other organic condition related to ID/DD**
	ID/DD Without Organic Condition
☐	**E. ID/DD with no organic condition**
	No ID/DD
☐	**Z. None of the above**

Item Rationale

- To document conditions associated with intellectual or developmental delay disabilities.

Steps for Assessment

1. If resident is 22 years of age or older on the assessment reference date, complete only if A0310A = 01 (admission assessment).
2. If resident is 21 years of age or younger on the assessment reference date, complete if A0310A = 01, 03, 04, or 05 (admission assessment, annual assessment, significant change in status assessment, significant correction to prior comprehensive assessment).

Coding Instructions

- Check all conditions related to ID /DD status that were present before age 22.
- When age of onset is not specified, assume that the condition meets this criterion AND is likely to continue indefinitely.
- Code A: if Down syndrome is present.
- Code B: if autism is present.
- Code C: if epilepsy is present.
- Code D: if other organic condition related to ID/DD is present.

DEFINITIONS

DOWN SYNDROME

A common genetic disorder in which a child is born with 47 rather than 46 chromosomes, resulting in developmental delays, intellectual disability, low muscle tone, and other possible effects.

AUTISM

A developmental disorder that is characterized by impaired social interaction, problems with verbal and nonverbal communication, and unusual, repetitive, or severely limited activities and interests.

EPILEPSY

A common chronic neurological disorder that is characterized by recurrent unprovoked seizures.

A1550: Conditions Related to Intellectual Disability/Developmental Delay (ID/DD) Status (cont.)

- Code E: if an ID/DD condition is present but the resident does not have any of the specific conditions listed.
- Code Z: if ID/DD condition is not present.

DEFINITION

OTHER ORGANIC CONDITION RELATED TO ID/DD

Examples of diagnostic conditions include congenital syphilis, maternal intoxication, mechanical injury at birth, prenatal hypoxia, neuronal lipid storage diseases, phenylketonuria (PKU), neurofibromatosis, microcephalus, macroencephaly, meningomyelocele, congenital hydrocephalus, etc.

A1600: Entry Date (date of this admission/entry or reentry into the facility)

A1600. Entry Date (date of this admission/entry or reentry into the facility)	
	☐☐-☐☐-☐☐☐☐ Month Day Year

Item Rationale

- To document the date of admission/entry or reentry into the nursing home.

DEFINITION

ENTRY DATE

The initial date of admission to the nursing facility, or the date the resident most recently returned to your nursing facility after being discharged.

Coding Instructions

- Enter the most recent date of admission/entry or reentry to this nursing home. Use the format: Month-Day-Year: XX-XX-XXXX. For example, October 12, 2010, would be entered as 10-12-2010.

A1700: Type of Entry

A1700. Type of Entry	
Enter Code ☐	1. Admission 2. Reentry

Item Rationale

- Captures whether date in A1600 is an admission/entry or reentry date.

Coding Instructions

- Code 1, admission/entry: when one of the following occurs:

A1700: Type of Entry (cont.)

1. resident has never been admitted to this facility before; OR
2. resident has been in this facility previously and was discharged prior to completion of the OBRA admission assessment; OR
3. resident has been in this facility previously and was discharged return not anticipated; OR
4. resident has been in this facility previously and was discharged return anticipated and did not return within 30 days of discharge.

- Code 2, reentry: when all 3 of the following occurred prior to the this entry, the resident was:
  1. admitted to this nursing home (i.e., OBRA admission assessment was completed), AND
  2. discharged return anticipated, AND
  3. returned to facility within 30 days of discharge.

Coding Tips and Special Populations

- Swing bed facilities will always code the resident's entry as an admission, '1', since an OBRA Admission assessment must have been completed to code as a reentry. OBRA Admission assessments are not completed for swing bed residents.
- In determining if a resident returns to the facility within 30 days, the day of discharge from the facility is not counted in the 30 days. For example, a resident is discharged return anticipated on December 1 would need to return to the facility by December 31 to meet the "within 30 day" requirement.

A1800: Entered From

A1800. Entered From

Enter Code

01. **Community** (private home/apt., board/care, assisted living, group home)
02. **Another nursing home or swing bed**
03. **Acute hospital**
04. **Psychiatric hospital**
05. **Inpatient rehabilitation facility**
06. **ID/DD facility**
07. **Hospice**
09. **Long Term Care Hospital** (LTCH)
99. **Other**

Item Rationale

- Understanding the setting that the individual was in immediately prior to nursing home admission informs care planning and may also inform discharge planning and discussions.
- Demographic information.

Steps for Assessment

1. Review transfer and admission records.
2. Ask the resident and/or family or significant others.

A1800: Entered From (cont.)

Coding Instructions

Enter the 2-digit code that corresponds to the location or program the resident was admitted from for this admission.

- Code 01, community (private home/apt, board/care, assisted living, group home): if the resident was admitted from a private home, apartment, board and care, assisted living facility or group home.
- Code 02, another nursing home or swing bed: if the resident was admitted from an institution (or a distinct part of an institution) that is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care or rehabilitation services for injured, disabled, or sick persons. Includes swing beds.
- Code 03, acute hospital: if the resident was admitted from an institution that is engaged in providing, by or under the supervision of physicians for inpatients, diagnostic services, therapeutic services for medical diagnosis, and the treatment and care of injured, disabled, or sick persons.
- Code 04, psychiatric hospital: if the resident was admitted from an institution that is engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill residents.
- Code 05, inpatient rehabilitation facility (IRF): if the resident was admitted from an institution that is engaged in providing, under the supervision of physicians, services for the rehabilitation of injured, disabled or sick persons. Includes IRFs that are units within acute care hospitals.
- Code 06, ID/DD facility: if the resident was admitted from an institution that is engaged in providing, under the supervision of a physician, any health and rehabilitative services for individuals who have intellectual or developmental delay disabilities.
- Code 07, hospice: if the resident was admitted from a program for terminally ill persons where an array of services is necessary for the palliation and management of terminal illness and related conditions. The hospice must be licensed by the State as a hospice provider and/or certified under the Medicare program as a hospice provider. Includes community-based or inpatient hospice programs.
- Code 09, long term care hospital (LTCH): if the patient was admitted from a hospital that is certified under Medicare as a short-term, acute-care hospital which has been excluded from the Inpatient Acute Care Hospital Prospective Payment System (IPPS) under §1886(d)((1)(B)(iv) of the Social Security Act. For the purpose of Medicare

DEFINITION

DEFINITIONS PRIVATE HOME OR APARTMENT Any house, condominium, or apartment in the community whether owned by the resident or another person. Also included in this category are retirement communities and independent housing for the elderly.

BOARD AND CARE/ ASSISTED LIVING/ GROUP HOME A non-institutional community residential setting that includes services of the following types: home health services, homemaker/personal care services, or meal services.

A1800: Entered From (cont.)

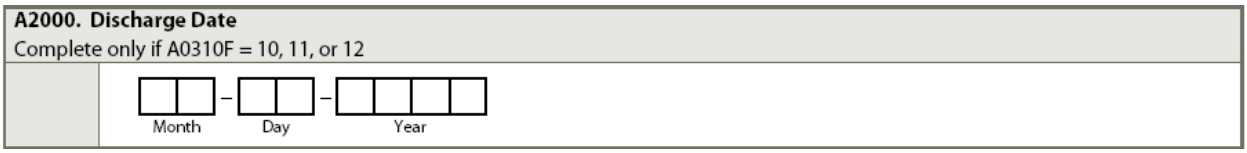
payment, LTCHs are defined as having an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.

- Code 99, other: if the resident was admitted from none of the above.

Coding Tips and Special Populations

- If an individual was enrolled in a home-based hospice program enter 07, Hospice, instead of 01, Community.

A2000: Discharge Date



Item Rationale

- Closes case in system.

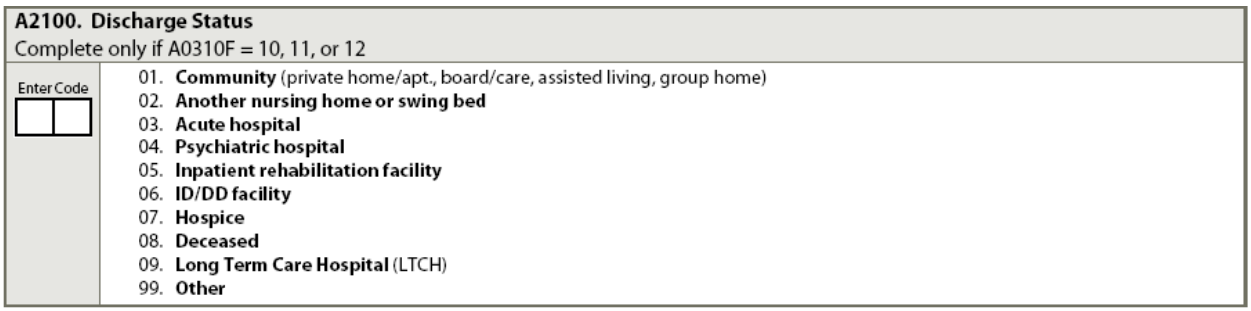
Coding Instructions

- Enter the date the resident was discharged (whether or not return is anticipated). This is the date the resident leaves the facility.
- For discharge assessments, the discharge date (A2000) and ARD (A2300) must be the same date.
- Do not include leave of absence or hospital observational stays less than 24 hours unless admitted to the hospital.
- Obtain data from the medical, admissions or transfer records.

Coding Tips and Special Populations

- If a resident was receiving services under SNF Part A PPS, the discharge date may be later than the end of Medicare stay date (A2400C).

A2100: Discharge Status



A2100: Discharge Status (cont.)

Item Rationale

- Demographic and outcome information.

Steps for Assessment

1. Review the medical record including the discharge plan and discharge orders for documentation of discharge location.

Coding Instructions

Select the 2-digit code that corresponds to the resident's discharge status.

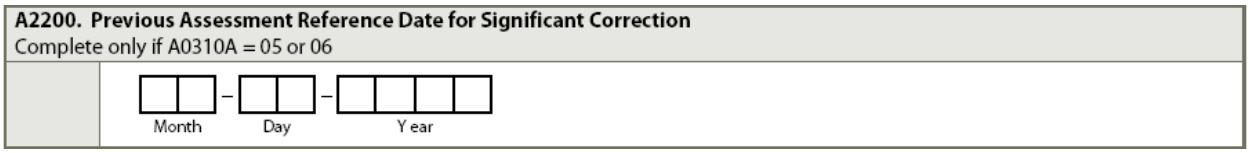
- Code 01, community (private home/apt., board/care, assisted living, group home): if discharge location is a private home, apartment, board and care, assisted living facility, or group home.
- Code 02, another nursing home or swing bed: if discharge location is an institution (or a distinct part of an institution) that is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care or rehabilitation services for injured, disabled, or sick persons. Includes swing beds.
- Code 03, acute hospital: if discharge location is an institution that is engaged in providing, by or under the supervision of physicians for inpatients, diagnostic services, therapeutic services for medical diagnosis, and the treatment and care of injured, disabled, or sick persons.
- Code 04, psychiatric hospital: if discharge location is an institution that is engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill residents.
- Code 05, inpatient rehabilitation facility: if discharge location is an institution that is engaged in providing, under the supervision of physicians, rehabilitation services for the rehabilitation of injured, disabled or sick persons. Includes IRFs that are units within acute care hospitals.
- Code 06, ID/DD facility: if discharge location is an institution that is engaged in providing, under the supervision of a physician, any health and rehabilitative services for individuals who have intellectual or developmental delay disabilities.
- Code 07, hospice: if discharge location is a program for terminally ill persons where an array of services is necessary for the palliation and management of terminal illness and related conditions. The hospice must be licensed by the State as a hospice provider and/or certified under the Medicare program as a hospice provider. Includes community-based (e.g., home) or inpatient hospice programs.
- Code 08, deceased: if resident is deceased.
- Code 09, long term care hospital (LTCH): if the patient was discharged from a hospital that is certified under Medicare as a short-term, acute-care hospital which has

A2100: Discharge Status (cont.)

been excluded from the Inpatient Acute Care Hospital Prospective Payment System (IPPS) under §1886(d)((1)(B)(iv) of the Social Security Act. For the purpose of Medicare payment, LTCHs are defined as having an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.

- Code 99, other: if discharge location is none of the above.

A2200: Previous Assessment Reference Date for Significant Correction



Item Rationale

- To identify the ARD of a previous comprehensive or quarterly assessment (A0310A = 05 or 06) in which a significant error is discovered.

Coding Instructions

- Complete only if A0310A = 05 (Significant correction to prior comprehensive assessment) or A0310A = 06 (Significant correction to prior quarterly assessment).
- Enter the ARD of the prior comprehensive or quarterly assessment in which a significant error has been identified and a correction is required.

A2300: Assessment Reference Date

Item Rationale

- Designates the end of the look-back period so that all assessment items refer to the resident's status during the same period of time.

  As the last day of the look-back period, the ARD serves as the reference point for determining the care and services captured on the MDS assessment. Anything that happens after the ARD will not be captured on that MDS. For example, for a MDS item with a 7-day look-back period, assessment information is collected for a 7-day period ending on and including the ARD which is the 7th day of this look-back period. For an item with a 14-day look-back period, the information is collected for a 14-day period ending on and including the ARD. The look-back period includes observations and events through the end of the day (midnight) of the ARD.

A2300: Assessment Reference Date (cont.)

Steps for Assessment

1. Interdisciplinary team members should select the ARD based on the reason for the assessment and compliance with all timing and scheduling requirements outlined in Chapter 2.

Coding Instructions

- Enter the appropriate date on the lines provided. Do not leave any spaces blank. If the month or day contains only a single digit, enter a "0" in the first space. Use four digits for the year. For example, October 2, 2010, should be entered as: 10-02-2010.
- For detailed information on the timing of the assessments, see Chapter 2 on assessment schedules.
- For discharge assessments, the discharge date item (A2000) and the ARD item (A2300) must contain the same date.

Coding Tips and Special Populations

- When the resident dies or is discharged prior to the end of the look-back period for a required assessment, the ARD must be adjusted to equal the discharge date.
- The look-back period may not be extended simply because a resident was out of the nursing home during part of the look-back period (e.g., a home visit, therapeutic leave, or hospital observation stay less than 24 hours when resident is not admitted). For example, if the ARD is set at day 13 and there is a 2-day temporary leave during the look-back period, the 2 leave days are still considered part of the look-back period.
- When collecting assessment information, data from the time period of the leave of absence is captured as long as the particular MDS item permits. For example, if the family takes the resident to the physician during the leave, the visit would be counted in Item O0600, **Physician Examination** (if criteria are otherwise met).

  This requirement applies to all assessments, regardless of whether they are being completed for clinical or payment purposes.

DEFINITIONS

ASSESSMENT REFERENCE DATE (ARD)
The specific end-point for the look-back periods in the LTCH CARE Data Set assessment process. Almost all LTCH CARE Data Set items refer to the patient's status over a designated time period referring back in time from the Assessment Reference Date (ARD). Most frequently, this look-back period, also called the observation or assessment period, is a XX-day period ending on the ARD. Look-back periods may cover the XX days ending on this date, xx days ending on this date, etc.

A2400: Medicare Stay

A2400. Medicare Stay

Enter Code ☐

A. Has the resident had a Medicare-covered stay since the most recent entry?

0. **No** → Skip to B0100, Comatose
1. **Yes** → Continue to A2400B, Start date of most recent Medicare stay

B. Start date of most recent Medicare stay:

☐☐ – ☐☐ – ☐☐☐☐
Month Day Year

C. End date of most recent Medicare stay - Enter dashes if stay is ongoing:

☐☐ – ☐☐ – ☐☐☐☐
Month Day Year

A2400: Medicare Stay (cont.)

Item Rationale

- Identifies when a resident is receiving services under the scheduled PPS.
- Identifies when a resident's Medicare Part A stay begins and ends.
- The end date is used to determine if the resident's stay qualifies for the short stay assessment.

Coding Instructions for A2400A, Has the Resident Had a Medicare-covered Stay since the Most Recent Entry?

- Code 0, no: if the resident has not had a covered Medicare Part A covered stay since the most recent admission/entry or reentry. Skip to B0100, Comatose.
- Code 1, yes: if the resident has had a Medicare Part A covered stay since the most recent admission/entry or reentry. Continue to A2400B.

Coding Instructions for A2400B, Start of Most Recent Medicare Stay

- Code the date of day 1 of this Medicare stay if A2400A is coded 1, yes.

Coding Instructions for A2400C, End Date of Most Recent Medicare Stay

- Code the date of last day of this Medicare stay if A2400A is coded 1, yes.
- If the Medicare Part A stay is ongoing there will be no end date to report. Enter dashes to indicate that the stay is ongoing.
- The end of Medicare date is coded as follows, whichever occurs first:
  - — Date SNF benefit exhausts (i.e., the 100th day of the benefit); or
  - — Date of last day covered as recorded on the effective date from the Generic Notice or
  - — The last paid day of Medicare A when payer source changes to another payer (regardless if the resident was moved to another bed or not); or
  - — Date the resident was discharged from the facility (see Item A2000, Discharge Date).

DEFINITIONS

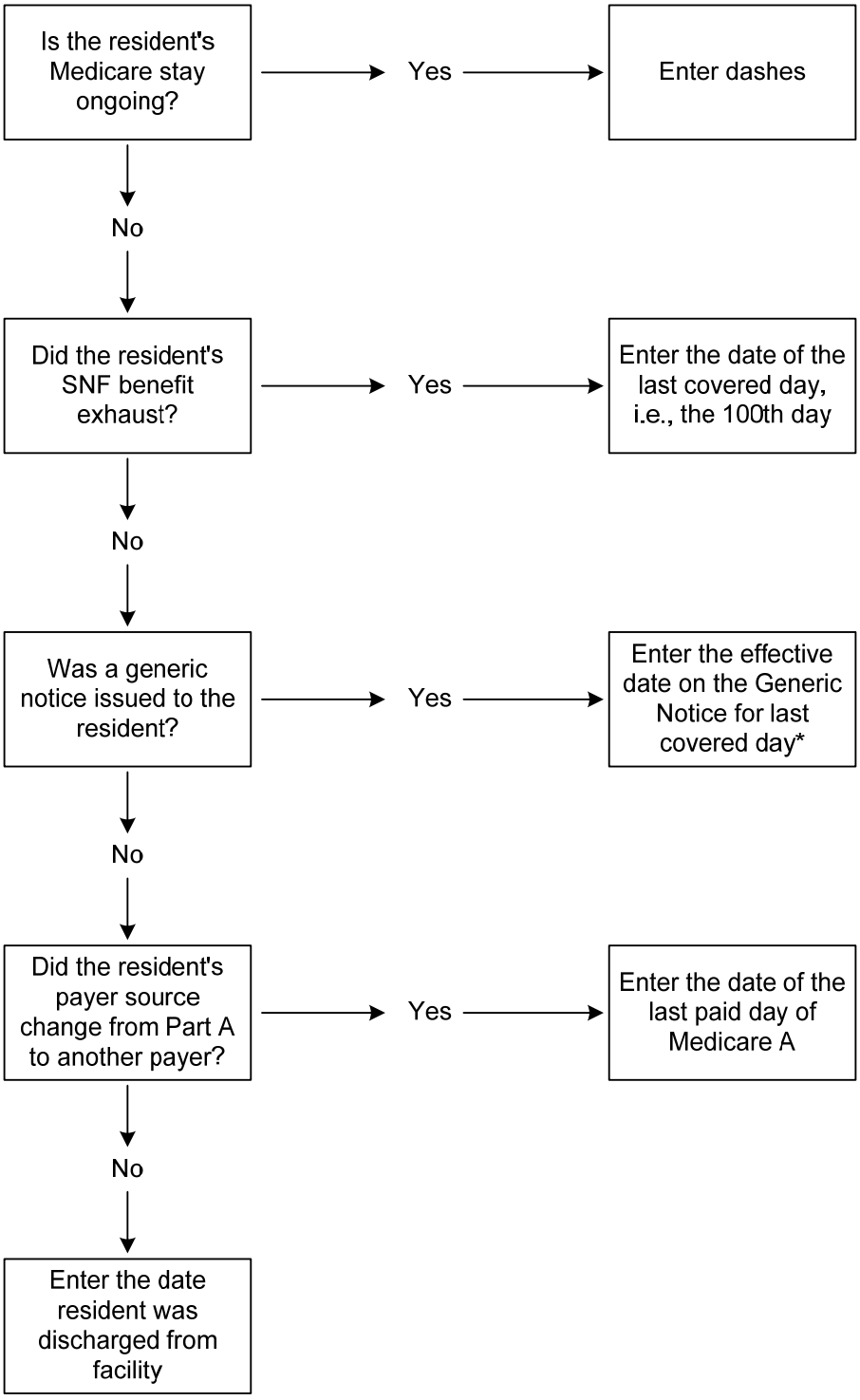
MOST RECENT MEDICARE STAY
This is a Medicare Part A covered stay that has started on or after the most recent admission/entry or reentry to the nursing facility.

MEDICARE-COVERED STAY
Skilled Nursing Facility stays billable to Medicare Part A. Does not include stays billable to Medicare Advantage HMO plans.

CURRENT MEDICARE STAY
NEW ADMISSION:
Day 1 of Medicare Part A stay.

READMISSION:
Day 1 of Medicare Part A coverage after readmission following a discharge.

Medicare Stay End Date Algorithm
A2400C



*if resident leaves facility prior to last covered day as recorded on the generic notice, enter date resident left facility.

A2400: Medicare Stay (cont.)

Coding Tips and Special Populations

- When a resident on Medicare Part A returns following a therapeutic leave of absence or a hospital observation stay of less than 24 hours (without hospital admission), this is a continuation of the Medicare Part A stay, not a new Medicare Part A stay.
- The end date of the Medicare stay may be earlier than actual discharge date from the facility (Item A2000).

Examples

1. Mrs. G. began receiving services under Medicare Part A on October 14, 2010. Due to her stable condition and ability to manage her medications and dressing changes, the facility determined that she no longer qualified for Part A SNF coverage and issued an ABN with the last day of coverage as November 23, 2010. Mrs. G. was discharged from the facility on November 24, 2010. Code the following on her discharge assessment:
    - A2000 = 11-24-2010
    - A2400A = 1
    - A2400B = 10-14-2010
    - A2400C = 11-23-2010
2. Mr. N began receiving services under Medicare Part A on December 11, 2010. He was sent to the ER on December 19, 2010 at 8:30pm and was not admitted to the hospital. He returned to the facility on December 20, 2010, at 11:00 am. The facility completed his 14-day PPS assessment with an ARD of December 23, 2010. Code the following on his 14-day PPS assessment:
    - A2400A = 1
    - A2400B = 12-11-2010
    - A2400C = ----------
3. Mr. R. began receiving services under Medicare Part A on October 15, 2010. He was discharged return anticipated on October 20, 2010, to the hospital. Code the following on his discharge assessment:
    - A2000 = 10-20-2010
    - A2400A = 1
    - A2400B = 10-15-2010
    - A2400C = 10-20-2010

SECTION I: ACTIVE DIAGNOSES

Intent: The items in this section are intended to code diseases that have a direct relationship to the resident's current functional status, cognitive status, mood or behavior status, medical treatments, nursing monitoring, or risk of death. One of the important functions of the MDS assessment is to generate an updated, accurate picture of the resident's current health status.

Active Diagnoses in the Last 7 Days

Active Diagnoses in the last 7 days - Check all that apply Diagnoses listed in parentheses are provided as examples and should not be considered as all-inclusive lists	
	Cancer
☐	**I0100. Cancer** (with or without metastasis)
	Heart/Circulation
☐	**I0200. Anemia** (e.g., aplastic, iron deficiency, pernicious, and sickle cell)
☐	**I0300. Atrial Fibrillation or Other Dysrhythmias** (e.g., bradycardias and tachycardias)
☐	**I0400. Coronary Artery Disease (CAD)** (e.g., angina, myocardial infarction, and atherosclerotic heart disease (ASHD))
☐	**I0500. Deep Venous Thrombosis (DVT), Pulmonary Embolus (PE), or Pulmonary Thrombo-Embolism (PTE)**
☐	**I0600. Heart Failure** (e.g., congestive heart failure (CHF) and pulmonary edema)
☐	**I0700. Hypertension**
☐	**I0800. Orthostatic Hypotension**
☐	**I0900. Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD)**
	Gastrointestinal
☐	**I1100. Cirrhosis**
☐	**I1200. Gastroesophageal Reflux Disease (GERD) or Ulcer** (e.g., esophageal, gastric, and peptic ulcers)
☐	**I1300. Ulcerative Colitis, Crohn's Disease, or Inflammatory Bowel Disease**
	Genitourinary
☐	**I1400. Benign Prostatic Hyperplasia (BPH)**
☐	**I1500. Renal Insufficiency, Renal Failure, or End-Stage Renal Disease (ESRD)**
☐	**I1550. Neurogenic Bladder**
☐	**I1650. Obstructive Uropathy**
	Infections
☐	**I1700. Multidrug-Resistant Organism (MDRO)**
☐	**I2000. Pneumonia**
☐	**I2100. Septicemia**
☐	**I2200. Tuberculosis**
☐	**I2300. Urinary Tract Infection (UTI) (LAST 30 DAYS)**
☐	**I2400. Viral Hepatitis** (e.g., Hepatitis A, B, C, D, and E)
☐	**I2500. Wound Infection** (other than foot)
	Metabolic
☐	**I2900. Diabetes Mellitus (DM)** (e.g., diabetic retinopathy, nephropathy, and neuropathy)
☐	**I3100. Hyponatremia**
☐	**I3200. Hyperkalemia**
☐	**I3300. Hyperlipidemia** (e.g., hypercholesterolemia)
☐	**I3400. Thyroid Disorder** (e.g., hypothyroidism, hyperthyroidism, and Hashimoto's thyroiditis)
	Musculoskeletal
☐	**I3700. Arthritis** (e.g., degenerative joint disease (DJD), osteoarthritis, and rheumatoid arthritis (RA))
☐	**I3800. Osteoporosis**
☐	**I3900. Hip Fracture** - any hip fracture that has a relationship to current status, treatments, monitoring (e.g., sub-capital fractures, and fractures of the trochanter and femoral neck)
☐	**I4000. Other Fracture**
	Neurological
☐	**I4200. Alzheimer's Disease**
☐	**I4300. Aphasia**
☐	**I4400. Cerebral Palsy**
☐	**I4500. Cerebrovascular Accident (CVA), Transient Ischemic Attack (TIA), or Stroke**
☐	**I4800. Non-Alzheimer's Dementia** (e.g. Lewy body dementia, vascular or multi-infarct dementia; mixed dementia; frontotemporal dementia such as Pick's disease; and dementia related to stroke, Parkinson's or Creutzfeldt-Jakob diseases)
	Neurological Diagnoses continued on next page

I: Active Diagnoses in the Last 7 Days (cont.)

Active Diagnoses in the last 7 days - Check all that apply
Diagnoses listed in parentheses are provided as examples and should not be considered as all-inclusive lists

Neurological - Continued

- ☐ I4900. **Hemiplegia or Hemiparesis**
- ☐ I5000. **Paraplegia**
- ☐ I5100. **Quadriplegia**
- ☐ I5200. **Multiple Sclerosis (MS)**
- ☐ I5250. **Huntington's Disease**
- ☐ I5300. **Parkinson's Disease**
- ☐ I5350. **Tourette's Syndrome**
- ☐ I5400. **Seizure Disorder or Epilepsy**
- ☐ I5500. **Traumatic Brain Injury (TBI)**

Nutritional

- ☐ I5600. **Malnutrition** (protein or calorie) or at risk for malnutrition

Psychiatric/Mood Disorder

- ☐ I5700. **Anxiety Disorder**
- ☐ I5800. **Depression** (other than bipolar)
- ☐ I5900. **Manic Depression** (bipolar disease)
- ☐ I5950. **Psychotic Disorder** (other than schizophrenia)
- ☐ I6000. **Schizophrenia** (e.g., schizoaffective and schizophreniform disorders)
- ☐ I6100. **Post Traumatic Stress Disorder (PTSD)**

Pulmonary

- ☐ I6200. **Asthma, Chronic Obstructive Pulmonary Disease (COPD), or Chronic Lung Disease** (e.g., chronic bronchitis and restrictive lung diseases such as asbestosis)
- ☐ I6300. **Respiratory Failure**

Vision

- ☐ I6500. **Cataracts, Glaucoma, or Macular Degeneration**

None of Above

- ☐ I7900. **None of the above active diagnoses** within the last 7 days

Other

I8000. **Additional active diagnoses**
Enter diagnosis on line and ICD code in boxes. Include the decimal for the code in the appropriate box.

A. _____ ☐☐☐☐☐☐☐☐
B. _____ ☐☐☐☐☐☐☐☐
C. _____ ☐☐☐☐☐☐☐☐
D. _____ ☐☐☐☐☐☐☐☐
E. _____ ☐☐☐☐☐☐☐☐
F. _____ ☐☐☐☐☐☐☐☐
G. _____ ☐☐☐☐☐☐☐☐
H. _____ ☐☐☐☐☐☐☐☐
I. _____ ☐☐☐☐☐☐☐☐
J. _____ ☐☐☐☐☐☐☐☐

I: Active Diagnoses in the Last 7 Days (cont)

Item Rationale

Health-Related Quality of Life

- Disease processes can have a significant adverse affect on an individual's health status and quality of life.

Planning for Care

- This section identifies active diseases and infections that drive the current plan of care.

Steps for Assessment

There are two look-back periods for this section:

- Diagnosis identification (Step 1) is a 60-day look-back period.
- Diagnosis status: Active or Inactive (Step 2) is a 7-day look-back period (except for Item I2300 UTI, which does not use the active 7-day look-back period).

1. **Identify diagnoses:** The disease conditions in this section require a physician-documented diagnosis (or by a nurse practitioner, physician assistant, or clinical nurse specialist if allowable under state licensure laws) in the **last 60 days.**

   Medical record sources for physician diagnoses include progress notes, the most recent history and physical, transfer documents, discharge summaries, diagnosis/problem list, and other resources as available. If a diagnosis/problem list is used, only diagnoses confirmed by the physician should be entered.

   - Although open communication regarding diagnostic information between the physician and other members of the interdisciplinary team is important, it is also essential that diagnoses communicated verbally be documented in the medical record by the physician to ensure follow-up.
   - Diagnostic information, including past history obtained from family members and close contacts, must also be documented in the medical record by the physician to ensure validity and follow-up.

2. **Determine whether diagnoses are active:** Once a diagnosis is identified, it must be determined if the diagnosis is **active.** Do not include conditions that have been resolved or have no **longer** affected the resident's current functioning or plan of care, or that the resident has adjusted to as their "new normal," during the last 7 days. Item I2300 UTI, has specific coding criteria and does not use the active 7-day look-back. Please refer to Page I-8 for specific coding instructions for Item I2300 UTI.

DEFINITIONS

ACTIVE DIAGNOSES

Physician-documented diagnoses in the last 60 days that have a direct relationship to the resident's current functional status, cognitive status, mood or behavior, medical treatments, nursing monitoring, or risk of death during the 7-day look-back period..

FUNCTIONAL LIMITATIONS

Loss of range of motion, contractures, muscle weakness, fatigue, decreased ability to perform, ADLs, paresis, or paralysis.

NURSING MONITORING

Nursing Monitoring includes clinical monitoring by a licensed nurse (e.g. serial blood pressure evaluations, medication management, etc.).

I: Active Diagnoses in the Last 7 Days (cont)

- **Active** diagnoses have a **direct** relationship to the resident's functional status, cognitive status, mood or behavior, medical treatments, nursing monitoring, or risk of death during the look-back period.
- Check the following information sources in the medical record for the last 7 days to identify "active" diagnoses: transfer documents, physician progress notes, recent history and physical, recent discharge summaries, nursing assessments, nursing care plans, medication sheets, doctor's orders, consults and official diagnostic reports, and other sources as available.

Coding Instructions

Code diseases that have a documented diagnosis in the last 60 days and have a direct relationship to the resident's current functional status, cognitive status, mood or behavior status, medical treatments, nursing monitoring, or risk of death during the 7-day look-back period (except Item I2300 UTI, which does not use the active diagnosis 7-day look-back. Please refer to Item I2300 UTI, Page I-8 for specific coding instructions).

- Document active diagnoses on the MDS as follows:
  - — Diagnoses are listed by major disease category: Cancer; Heart/Circulation; Gastrointestinal; Genitourinary; Infections; Metabolic; Musculoskeletal; Neurological; Nutritional; Psychiatric/Mood Disorder; Pulmonary; and Vision.
  - — Examples of diseases are included for some disease categories. Diseases to be coded in these categories are not meant to be limited to only those listed in the examples. For example, **I0200, Anemia,** includes anemia of any etiology, including those listed (e.g., aplastic, iron deficiency, pernicious, sickle cell).
- Check off each active disease. Check all that apply.
- If a disease or condition is **not** specifically listed, check the "Other" box (I8000) and write in the ICD code and name for that diagnosis.
- Computer specifications are written such that the ICD code should be automatically justified. The important element is to insure that the ICD code's decimal point is in it's own box and should be right justified (aligned with the right margin so that any unused boxes and on the left.)
- If a diagnosis is a V-code, another diagnosis for the related primary medical condition should be checked in items I0100-I7900 or entered in I8000.

Cancer

- I0100, cancer (with or without metastasis)

Heart/Circulation

- I0200, anemia (e.g., aplastic, iron deficiency, pernicious, sickle cell)
- I0300, atrial fibrillation or other dysrhythmias (e.g., bradycardias, tachycardias)
- I0400, coronary artery disease (CAD) (e.g., angina, myocardial infarction, atherosclerotic heart disease [ASHD])

I: Active Diagnoses in the Last 7 Days (cont.)

- I0500, deep venous thrombosis (DVT), pulmonary embolus (PE), or pulmonary thrombo-embolism (PTE)
- I0600, heart failure (e.g., congestive heart failure [CHF], pulmonary edema)
- I0700, hypertension
- I0800, orthostatic hypotension
- I0900, peripheral vascular disease or peripheral arterial disease

Gastrointestinal

- I1100, cirrhosis
- I1200, gastroesophageal reflux disease (GERD) or ulcer (e.g., esophageal, gastric, and peptic ulcers)
- I1300, ulcerative colitis or Crohn's disease or inflammatory bowel disease

Genitourinary

- I1400, benign prostatic hyperplasia (BPH)
- I1500, renal insufficiency, renal failure, or end-stage renal disease (ESRD)
- I1550, neurogenic bladder
- I1650, obstructive uropathy

Infections

- I1700, multidrug resistant organism (MDRO)
- I2000, pneumonia
- I2100, septicemia
- I2200, tuberculosis
- I2300, urinary tract infection (UTI) (last 30 days)
- I2400, viral hepatitis (e.g., hepatitis A, B, C, D, and E)
- I2500, wound infection (other than foot)

Metabolic

- I2900, diabetes mellitus (DM) (e.g., diabetic retinopathy, nephropathy, neuropathy)
- I3100, hyponatremia
- I3200, hyperkalemia
- I3300, hyperlipidemia (e.g., hypercholesterolemia)
- I3400, thyroid disorder (e.g., hypothyroidism, hyperthyroidism, Hashimoto's thyroiditis)

I: Active Diagnoses in the Last 7 Days (cont.)

Musculoskeletal

- I3700, arthritis (e.g., degenerative joint disease [DJD], osteoarthritis, rheumatoid arthritis [RA])
- I3800, osteoporosis
- I3900, hip fracture (any hip fracture that has a relationship to current status, treatments, monitoring (e.g., subcapital fractures and fractures of the trochanter and femoral neck)
- I4000, other fracture

Neurological

- I4200, Alzheimer's disease
- I4300, aphasia
- I4400, cerebral palsy
- I4500, cerebrovascular accident (CVA), transient ischemic attack (TIA), or stroke
- I4800, dementia (e.g., Lewy-Body dementia; vascular or multi-infarct dementia; mixed dementia; frontotemporal dementia, such as Pick's disease; and dementia related to stroke, Parkinson's disease or Creutzfeldt-Jakob diseases)
- I4900, hemiplegia or hemiparesis
- I5000, paraplegia
- I5100, quadriplegia
- I5200, multiple sclerosis (MS)
- I5250, Huntington's disease
- I5300, Parkinson's disease
- I5350, Tourette's syndrome
- I5400, seizure disorder or epilepsy
- I5500, traumatic brain injury (TBI)

Nutritional

- I5600, malnutrition (protein or calorie) or at risk for malnutrition

Psychiatric/Mood Disorder

- I5700, anxiety disorder
- I5800, depression (other than bipolar)
- I5900, manic depression (bipolar disease)
- I5950, psychotic disorder (other than schizophrenia)
- I6000, schizophrenia (e.g., schizoaffective and schizophreniform disorders)
- I6100, post-traumatic stress disorder (PTSD)

I: Active Diagnoses in the Last 7 Days (cont.)

Pulmonary

- I6200, asthma, chronic obstructive pulmonary disease (COPD), or chronic lung disease (e.g., chronic bronchitis and restrictive lung diseases, such as asbestosis)
- I6300, respiratory failure

Vision

- I6500, cataracts, glaucoma, or macular degeneration

None of Above

- I7900, none of the above active diagnoses within the past 7 days

Other

- I8000, additional active diagnoses

Coding Tips

The following indicators may assist assessors in determining whether a diagnosis should be coded as active in the MDS.

- **There may be specific documentation in the medical record by a physician, nurse practitioner, physician assistant, or clinical nurse specialist of active diagnosis.**
  - The physician may specifically indicate that a condition is active. Specific documentation may be found in progress notes, most recent history and physical, transfer notes, hospital discharge summary, etc.
  - For example, the physician documents that the resident has inadequately controlled hypertension and will modify medications. This would be sufficient documentation of active disease and would require no additional confirmation.
- **In the absence of specific documentation that a disease is active, the following indicators may be used to confirm active disease:**
  - Recent onset or acute exacerbation of the disease or condition indicated by a positive study, test or procedure, hospitalization for acute symptoms and/or recent change in therapy in the last 7 days. Examples of a recent onset or acute exacerbation include the following: new diagnosis of pneumonia indicated by chest X-ray; hospitalization for fractured hip; or a blood transfusion for a hematocrit of 24. Sources may include radiological reports, hospital discharge summaries, doctor's orders, etc.
  - Symptoms and abnormal signs indicating ongoing or decompensated disease in the last 7 days. For example, intermittent claudication (lower extremity pain on exertion) in conjunction with a diagnosis of peripheral vascular disease would indicate active disease. Sometimes signs and symptoms can be nonspecific and could be caused by several disease processes. Therefore, a symptom must be specifically attributed to the disease. For example, a productive cough would confirm a diagnosis of pneumonia if specifically noted as such by a physician. Sources may include radiological reports, nursing assessments and care plans, progress notes, etc.

I: Active Diagnoses in the Last 7 Days (cont.)

- Listing a disease/diagnosis (e.g., arthritis) on the resident's medical record problem list is not sufficient for determining active or inactive status. To determine if arthritis, for example, is an "active" diagnosis, the reviewer would check progress notes (including the history and physical) during the 7-day look-back period for notation of treatment of symptoms of arthritis, doctor's orders for medications for arthritis, and documentation of physical or other therapy for functional limitations caused by arthritis.
- Ongoing therapy with medications or other interventions to manage a condition that requires monitoring for therapeutic efficacy or to monitor potentially severe side effects in the last 7 days. A medication indicates active disease if that medication is prescribed to manage an ongoing condition that requires monitoring or is prescribed to decrease active symptoms associated with a condition. This includes medications used to limit disease progression and complications. If a medication is prescribed for a condition that requires regular staff monitoring of the drug's effect on that condition (therapeutic efficacy), then the prescription of the medication would indicate active disease.

- **It is expected that nurses monitor all medications for adverse effects as part of usual nursing practice.** For coding purposes, this monitoring relates to management of pharmacotherapy and not to management or monitoring of the underlying disease.
- **Item I2300 Urinary tract infection (UTI):**
  - The UTI has a look-back period of 30 days for active disease instead of 7 days.
  - **Code only if all the following are met**
    1. Physician, nurse practitioner, physician assistant, or clinical nurse specialist or other authorized licensed staff as permitted by state law diagnosis of a UTI in last 30 days,
    2. Sign or symptom attributed to UTI, which may or may not include but not be limited to: fever, urinary symptoms (e.g., peri-urethral site burning sensation, frequent urination of small amounts), pain or tenderness in flank, confusion or change in mental status, change in character of urine (e.g. pyuria),
    3. "Significant laboratory findings" (The attending physician should determine the level of significant laboratory findings and whether or not a culture should be obtained), and
    4. Current medication or treatment for a UTI in the last 30 days.

  In response to questions regarding the resident with colonized MRSA, we consulted with the Centers for Disease Control (CDC) who provided the following information:

  A physician often prescribes empiric antimicrobial therapy for a suspected infection **after a culture is obtained, but prior to receiving the culture results**. The confirmed diagnosis of UTI will depend on the culture results and other clinical assessment to determine appropriateness and continuation of antimicrobial therapy. This should not be any different, even if the resident is known to be colonized with an antibiotic resistant

I: Active Diagnoses in the Last 7 Days (cont.)

organism. An appropriate culture will help to ensure the diagnosis of infection is correct, and the appropriate antimicrobial is prescribed to treat the infection. The CDC does not recommend routine antimicrobial treatment for the purposes of attempting to eradicate colonization of MRSA or any other antimicrobial resistant organism.

The CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) has released infection prevention and control guidelines that contain recommendations that should be applied in all healthcare settings. At this site you will find information related to UTI's and many other issues related to infections in LTC.
http://www.cdc.gov/ncidod/dhqp/gl_longterm_care.html

Examples of Active Disease

1. A resident is prescribed hydrochlorothiazide for hypertension. The resident requires regular blood pressure monitoring to determine whether blood pressure goals are achieved by the current regimen. Physician progress note documents hypertension.

   Coding: **Hypertension** item (I0700), would be checked.
   Rationale: This would be considered an active diagnosis because of the need for ongoing monitoring to ensure treatment efficacy.

2. Warfarin is prescribed for a resident with atrial fibrillation to decrease the risk of embolic stroke. The resident requires monitoring for change in heart rhythm, for bleeding, and for anticoagulation.

   Coding: **Atrial fibrillation** item (I0300), would be checked.
   Rationale: This would be considered an active diagnosis because of the need for ongoing monitoring to ensure treatment efficacy as well as to monitor for side effects related to the medication.

3. A resident with a past history of healed peptic ulcer is prescribed a non-steroidal anti-inflammatory (NSAID) medication for arthritis. The physician also prescribes a proton-pump inhibitor to decrease the risk of peptic ulcer disease (PUD) from NSAID treatment.

   Coding: **Arthritis** item (I3700), would be checked.
   Rationale: Arthritis would be considered an active diagnosis because of the need for medical therapy. Given that the resident has a history of a healed peptic ulcer without current symptoms, the proton-pump inhibitor prescribed is preventive and therefore PUD would not be coded as an active disease.

4. The resident had a stroke 4 months ago and continues to have left-sided weakness, visual problems, and inappropriate behavior. The resident is on aspirin and has physical therapy and occupational therapy three times a week. The physician's note 25 days ago lists stroke.

   Coding: **Cerebrovascular Vascular Accident (CVA), Transient Ischemic Attack (TIA), or Stroke** item (I4500), would be checked.

I: Active Diagnoses in the Last 7 Days (cont.)

Rationale: The physician note within the last 30 days indicates stroke, and the resident is receiving medication and therapies to manage continued symptoms from stroke.

Examples of Inactive Diagnoses (do not code)

1. The admission history states that the resident had pneumonia 2 months prior to this admission. The resident has recovered completely, with no residual effects and no continued treatment during the 7-day look back period.

   Coding: **Pneumonia** item (I2000), would not be checked**.**
   Rationale: The pneumonia diagnosis would not be considered active because of the resident's complete recovery and the discontinuation of any treatment during the look-back period.

2. The problem list includes a diagnosis of coronary artery disease (CAD). The resident had an angioplasty 3 years ago, is not symptomatic, and is not taking any medication for CAD.

   Coding: **CAD** item (I0400), would not be checked**.**
   Rationale: The resident has had no symptoms and no treatment during the 7-day look-back period; thus, the CAD would be considered inactive.

3. Mr. J fell and fractured his hip 2 years ago. At the time of the injury, the fracture was surgically repaired. Following the surgery, the resident received several weeks of physical therapy in an attempt to restore him to his previous ambulation status, which had been independent without any devices. Although he received therapy services at that time, he now requires assistance to stand from the chair and uses a walker. He also needs help with lower body dressing because of difficulties standing and leaning over.

   Coding: **Hip Fracture** item (I3900), would not be checked**.**
   Rationale: Although the resident has mobility and self-care limitations in ambulation and ADLs due to the hip fracture, he has not received therapy services during the 7-day look-back period; thus, Hip Fracture would be considered inactive.

SECTION N: MEDICATIONS

Intent: The intent of the items in this section is to record the number of days, during the last 7 days (or since admission/reentry if less than 7 days) that any type of injection (subcutaneous, intramuscular or intradermal), insulin, and/or select medications were received by the resident.

N0300: Injections

N0300. Injections	
Enter Days ☐	**Record the number of days that injections of any type** were received during the last 7 days or since admission/entry or reentry if less than 7 days. If 0 → Skip to N0410, Medications Received

Item Rationale

Health-related Quality of Life

- Frequency of administration of medication via injection can be an indication of stability of a resident's health status and/or complexity of care needs.

Planning for Care

- Monitor for adverse effects of injected medications.
- Although antigens and vaccines are not considered to be medications per se, it is important to track when they are given to monitor for localized or systemic reactions.

Steps for Assessment

1. Review the resident's medication administration records for the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
2. Review documentation from other health care locations where the resident may have received injections while a resident of the nursing home (e.g., flu vaccine in a physician's office, in the emergency room – as long as the resident was not admitted).
3. Determine if any medications were received by the resident via injection. If received, determine the number of days during the look-back period they were received.

Coding Instructions

Record the number of days during the 7-day look-back period (or since admission/entry or reentry if less than 7 days) that the resident received any type of medication, antigen, vaccine, etc., by subcutaneous, intramuscular, or intradermal injection.

Insulin injections are counted in this item as well as in Item N0350.

- Count the number of days that the resident received any type of injection (subcutaneous, intramuscular, or intradermal) while a resident of the nursing home.
- Record the number of days that any type of injection (subcutaneous, intramuscular, or intradermal) was received in Item N0300.

N0300: Injections (cont.)

Coding Tips and Special Populations

- For subcutaneous pumps, code only the number of days that the resident actually required a subcutaneous injection to restart the pump.
- If an antigen or vaccination is provided on one day, and another vaccine provided on the next day, the number of days the resident received injections would be **coded as 2 days.**
- If two injections were administered on the same day, the number of days the resident received injections would be **coded as 1 day.**

Examples

1. During the 7-day look-back period, Mr. T. received an influenza shot on Monday, a PPD test (for tuberculosis) on Tuesday, and a Vitamin B_{12} injection on Wednesday.

   Coding: N0300 would be coded 3.
   Rationale: The resident received injections on 3 separate days during the 7-day look-back period.

2. During the 7-day look-back period, Miss C. received both an influenza shot and her vitamin B_{12} injection on Thursday.

   Coding: N0300 would be coded 1.
   Rationale: The resident received injections on one day during the 7-day look-back period.

N0350: Insulin

N0350. Insulin	
Enter Days ☐	**A. Insulin injections - Record the number of days that insulin injections** were received during the last 7 days or since admission/entry or reentry if less than 7 days
Enter Days ☐	**B. Orders for insulin - Record the number of days the physician (or authorized assistant or practitioner) changed the resident's insulin orders** during the last 7 days or since admission/entry or reentry if less than 7 days

Item Rationale

Health-related Quality of Life

- Insulin is a medication used to treat diabetes mellitus (DM).
- Individualized meal plans should be created with the resident's input to ensure appropriate meal intake. Residents are more likely to be compliant with their DM diet if they have input related to food choices.

N0350: Insulin (cont.)

Planning for Care

- Orders for insulin may have to change depending on the resident's condition (e.g., fever or other illness) and/or laboratory results.
- Ensure that dosage and time of injections take into account meals, activity, etc., based on individualized resident assessment.
- Monitor for adverse effects of insulin injections (e.g., hypoglycemia).
- Monitor HbA1c and blood glucose levels to ensure appropriate amounts of insulin are being administered.

Steps for Assessment

1. Review the resident's medication administration records for the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
2. Determine if the resident received insulin injections during the look-back period.
3. Determine if the physician (or nurse practitioner, physician assistant, or clinical nurse specialist if allowable under state licensure laws and Medicare) changed the resident's insulin orders during the look-back period.
4. Count the number of days insulin injections were received and/or changed.

Coding Instructions for N0350A

- Enter in Item N0350A, the number of days during the 7-day look-back period (or since admission/entry or reentry if less than 7 days) that insulin injections were received.

Coding Instructions for N0350B

- Enter in Item N0350B, the number of days during the 7-day look-back period (or since admission/entry or reentry if less than 7 days) that the physician (nurse practitioner, physician assistant, or clinical nurse specialist if allowable under state licensure laws and Medicare) changed the resident's insulin orders.

Coding Tips and Special Populations

- A sliding scale dosage schedule that is written to cover different dosages depending on lab values **does not** count as an order change simply because a different dose is administered based on the sliding scale guidelines.
- If the sliding scale order is new, discontinued, or is the first sliding scale order for the resident, these days **can** be counted and coded.
- For subcutaneous insulin pumps, code only the number of days that the resident actually required a subcutaneous injection to restart the pump.

N0410: Medications Received

N0410. Medications Received	
Indicate the number of DAYS the resident received the following medications during the last 7 days or since admission/entry or reentry if less than 7 days. Enter "0" if medication was not received by the resident during the last 7 days	
Enter Days ☐	**A. Antipsychotic**
Enter Days ☐	**B. Antianxiety**
Enter Days ☐	**C. Antidepressant**
Enter Days ☐	**D. Hypnotic**
Enter Days ☐	**E. Anticoagulant** (warfarin, heparin, or low-molecular weight heparin)
Enter Days ☐	**F. Antibiotic**
Enter Days ☐	**G. Diuretic**

Item Rationale

Health-related Quality of Life

- Medications are an integral part of the care provided to residents of nursing homes. They are administered to try to achieve various outcomes, such as curing an illness, diagnosing a disease or condition, arresting or slowing a disease's progress, reducing or eliminating symptoms, or preventing a disease or symptom.
- Residents taking medications in these drug classes are at risk of side effects that can adversely affect health, safety, and quality of life.
- While assuring that only those medications required to treat the resident's assessed condition are being used, it is important to reduce the need for or maximize the effectiveness of medications for all residents. Therefore, as part of all medication management, it is important for the interdisciplinary team to consider non-pharmacological approaches. Educating the nursing home staff and providers about non-pharmacological approaches in addition to and/or in conjunction with the use of medication may minimize the need for medications or reduce the dose and duration of those medications.

DEFINITIONS

ADVERSE CONSEQUENCE

An unpleasant symptom or event that is caused by or associated with a medication, impairment or decline in an individual's physical condition, mental, functional or psychosocial status. It may include various types of adverse drug reactions (ADR) and interactions (e.g., medication-medication, medication-food, and medication-disease).

NON-PHARMACOLOGICAL INTERVENTION

Approaches that do not involve the use of medication to address a medical condition.

N0410: Medications Received (cont.)

Planning for Care

- The indications for initiating, withdrawing, or withholding medication(s), as well as the use of non-pharmacological interventions, are determined by assessing the resident's underlying condition, current signs and symptoms, and preferences and goals for treatment. This includes, where possible, the identification of the underlying cause(s), since a diagnosis alone may not warrant treatment with medication.
- Target symptoms and goals for use of these medications should be established for each resident. Progress toward meeting the goals should be evaluated routinely.
- Possible adverse effects of drugs in each of these drug groups should be well understood by nursing staff. Educate nursing home staff to be observant for these adverse effects.
- Implement systematic monitoring of each resident taking any of these medications to identify adverse consequences early.

Steps for Assessment

1. Review the resident's medical record for documentation that any of these medications were received by the resident during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
2. Review documentation from other health care settings where the resident may have received any of these medications while a resident of the nursing home (e.g., valium given in the emergency room).

DEFINITIONS

DOSE

The total amount/strength/ concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/ concentration received at each administration. The amount received over a 24-hour period may be referred to as the "daily dose."

MONITORING

The ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline and current data in order to ascertain the individual's response to treatment and care, including progress or lack of progress toward a goal. Monitoring can detect any improvements, complications or adverse consequences of the condition or of the treatments; and support decisions about adding, modifying, continuing, or discontinuing, any interventions.

Coding Instructions

- Check A, antipsychotic: if antipsychotic medication was received by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days)
- Check B, antianxiety: if anxiolytic medication was received by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- Check C, antidepressant: if antidepressant medication was received by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).

N0410: Medications Received (cont.)

- Check D, hypnotic: if hypnotic medication was received by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- Check E, anticoagulant (e.g., warfarin, heparin, or low- molecular weight heparin): if anticoagulant medication was received by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days). Do not code antiplatelet medications such as aspirin/extended release, dipyridamole, or clopidogrel here.
- Check F, antibiotic: if antibiotics were received by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- Check G, diuretic: if diuretics were received by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- Check Z, none of the above were received: if none of the medications in Item N0410 were received during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).

Coding Tips and Special Populations

- Code medications according to a drug's pharmacological classification, not how it is used. For example, oxazepam may be used as a hypnotic, but it is classified as an antianxiety medication. It would be coded as an antianxiety medication.
- Include any of these medications given to the resident by any route (e.g., PO, IM, or IV) in any setting (e.g., at the nursing home, in a hospital emergency room) while a resident of the nursing home.
- Code a medication even if it was given only once during the look-back period.
- Count long-acting medications, such as fluphenazine decanoate or haloperidol decanoate, that are given every few weeks or monthly **only** if they are given during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- Combination medications should be coded in all categories that constitute the combination. For example, if the resident receives a single tablet that combines an antipsychotic and an antidepressant, then both antipsychotic and antidepressant should be coded.
- Over-the-counter sleeping medications are not coded as hypnotics, as they are not classified as hypnotic drugs.
- When residents are having difficulty sleeping, nursing home staff should explore non-pharmacological interventions (e.g., sleep hygiene approaches that individualize the sleep and wake times to accommodate the person's wishes and prior customary routine) to try to improve sleep prior to initiating pharmacologic interventions. If residents are currently on sleep-enhancing medications, nursing home staff can try non-pharmacologic interventions to help reduce the need for these medications or eliminate them.

DEFINITIONS

SLEEP HYGIENE
Practices, habits and environmental factors that promote and/or improve sleep patterns.

N0410: Medications Received (cont.)

- Many psychoactive medications increase confusion, sedation, and falls. For those residents who are already at risk for these conditions, nursing home staff should develop plans of care that address these risks.
- Adverse drug reaction (ADR) is a form of adverse consequence. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.
- Doses of psychopharmacologic drugs differ in acute and long-term treatment. Doses should always be the lowest possible to achieve the desired therapeutic effects and be deemed necessary to maintain or improve the resident's function, well-being, safety, and quality of life. Duration of treatment should also be in accordance with pertinent literature, including clinical practice guidelines.
- Since medication issues continue to evolve and new medications are being approved regularly, it is important to refer to a current authoritative source for detailed medication information, such as indications and precautions, dosage, monitoring, or adverse consequences.
- During the first year in which a resident on a psychopharmacological medication is admitted, or after the nursing home has initiated such medication, nursing home staff should attempt to taper the medication or perform gradual dose reduction (GDR) as long as it is not medically contraindicated. Information on GDR and tapering of medications can be found in the **State Operations Manual, Appendix PP, Guidance to Surveyors for Long Term Care Facilities** (the **State Operations Manual** can be found at http://www.cms.gov/Manuals/IOM/list.asp).
- Prior to discontinuing a psychoactive drug, residents may need a GDR or tapering to avoid withdrawal syndrome (e.g., selective serotonin reuptake inhibitors [SSRIs], tricyclic antidepressants [TCAs]).

DEFINITION

GRADUAL DOSE REDUCTION (GDR) Step-wise tapering of a dose to determine whether or not symptoms, conditions, or risks can be managed by a lower dose or whether or not the dose or medication can be discontinued.

DEFINITION

MEDICATION INTERACTION

The impact of medication or other substance (such as nutritional supplements including herbal products, food, or substances used in diagnostic studies) upon another medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

N0410: Medications Received (cont.)

- Residents who are on antidepressants should be closely monitored for worsening of depression and/or suicidal ideation/behavior, especially during initiation or change of dosage in therapy. Stopping antidepressants abruptly puts one at higher risk of suicidal ideation and behavior.
- Anticoagulants must be monitored with dosage frequency determined by clinical circumstances, duration of use, and stability of monitoring results (e.g., Prothrombin Time [PT]/International Normalization Ratio [INR]).
  - Multiple medication interactions exist with use of anticoagulants (information on common medication-medication interactions can be found in the **State Operations Manual, Appendix PP, Guidance to Surveyors for Long Term Care Facilities** [the **State Operations Manual** can be found at http://www.cms.gov/Manuals/IOM/list.asp]), which may
    - significantly increase PT/INR results to levels associated with life-threatening bleeding, or
    - decrease PT/INR results to ineffective levels, or increase or decrease the serum concentration of the interacting medication.
- Herbal and alternative medicine products are considered to be dietary supplements by the Food and Drug Administration (FDA). They are not regulated by the FDA (e.g., they are not reviewed for safety and effectiveness like medications) and their composition is not standardized (e.g., the composition varies among manufacturers). Therefore, they should not be counted as medications (e.g. chamomile, valerian root). Keep in mind that, for clinical purposes, it is important to document a resident's intake of such substances elsewhere in the medical record and to monitor their potential effects as they can interact with other medications. For more information consult the FDA website http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm#what.

Example

1. The Medication Administration Record for Mrs. P. reflects the following:

- Resperidone 0.5 mg PO BID PRN: Received once a day on Monday, Wednesday, and Thursday.
- Lorazepam 1 mg PO QAM: Received every day.
- Temazepam 15 mg PO QHS PRN: Received at bedtime on Tuesday and Wednesday only.

Coding: Medications in N0410, would be checked as follows: A. antipsychotic, resperidone is an antipsychotic drug, B. antianxiety, lorazepam is an antianxiety drug, and D. hypnotic, temazepam is a hypnotic drug. Please note: if a resident is receiving drugs in all three classes simultaneously there must be a clear clinical indication for the use of these drugs. Administration of these types of drugs, particularly in this combination, could be interpreted as chemically restraining the resident. Adequate documentation is essential in justifying their use.

N0410: Medications Received (cont.)

Additional information on psychopharmacologic medications can be found in the **Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition** (**DSM-IV**) (or subsequent editions) (http://www.psychiatryonline.com/resourceTOC.aspx?resourceID=1), and the **State Operations Manual, Appendix PP, Guidance to Surveyors for Long Term Care Facilities** [the **State Operations Manual** can be found at (http://www.cms.gov/Manuals/IOM/list.asp)].

Additional information on medications can be found in:

The Orange Book, http://www.fda.gov/cder/ob/default.htm

The National Drug Code Directory, http://www.fda.gov/cder/ndc/database/Default.htm

APPENDIX C

CARE AREA ASSESSMENT (CAA) RESOURCES

Chapter 4 of this manual provides information on specific care areas triggered and the CAA process. This appendix contains both specific and general resources that nursing homes may choose to use to further assess care areas triggered from the MDS 3.0 resident assessment instrument. The resources include the care area specific tools beginning in this section and the general resource list at the end of this appendix.

It is important to note that the resources provided in this appendix are provided solely as a courtesy for use by nursing homes, should they choose to, in completing the RAI CAA process. **It is also important to reiterate that CMS does not mandate, nor does it endorse, the use of any particular resource(s), including those provided in this appendix.** However, nursing homes should ensure that the resource(s) used are current, evidence-based or expert-endorsed research and clinical practice guidelines/resources.

DISCLAIMER: **The list of resources in this appendix is neither prescriptive nor all-inclusive. References to non-U.S. Department of Health and Human Services (HHS) sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or HHS. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.**

CARE AREA SPECIFIC RESOURCES

The specific resources or tools contained on the next several pages are provided by care area. The general instructions for using them include:

Step 1: After completing the MDS, review all MDS items and responses to determine if any care areas have been triggered.

Step 2: For any triggered care area(s), conduct a thorough assessment of the resident using the care area-specific resources.

Step 3: Check the box in the left column if the item is present for this resident. ***Some of this information will be on the MDS - some will not.***

Step 4: In the right column the facility can provide a summary of supporting documentation regarding the basis or reason for checking a particular item or items. This could include the location and date of that information, symptoms, possible causal and contributing factor(s) for item(s) checked, etc.

Step 5: Obtain and consider input from resident and/or family/resident's representative regarding the care area.

Step 6: Analyze the findings in the context of their relationship to the care area and standards of practice. This should include a review of indicators and supporting documentation, including symptoms and causal and contributing factors, related to this care area. Draw conclusions about the causal/contributing factors and effect(s) on the resident, and document these conclusions in the Analysis of Findings section.

Step 7: Decide whether referral to other disciplines is warranted and document this decision.

Step 8: In the Care Plan Considerations section, document whether a care plan for the triggered care area will be developed and the reason(s) why or why not.

Step 9: Information in the *Supporting Documentation* column can be used to populate the *Location and Date of CAA Documentation* column in Section V, Item V0200A (CAA Results) – for e.g. "See Delirium CAA 4/30/11, H&P dated 4/18/11."

NOTE: *An optional Signature/Date line has been added to each checklist. This was added if the facility wants to document the staff member who completed the checklist and date completed.*

DISCLAIMER: **The checklists of care area specific resources in this appendix are not mandated, prescriptive, or all-inclusive and are provided as a service to facilities. They do not constitute or imply endorsement by CMS or HHS.**

TABLE OF CONTENTS

1. DELIRIUM

Review of Indicators of Delirium

✓	Changes in vital signs compared to baseline	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	Temperatures 2.4^{0}F higher than baseline or a temperature of 100.4^{0}F (38^{0}C) on admission prior to establishment of baseline. (J1550A)	
☐	Pulse rate less than 60 or greater than 100 beats per minute	
☐	Respiratory rate over 25 breaths per minute or less than 16 per minute (J1100)	
☐	Hypotension or a significant decrease in blood pressure: (I0800)	
☐	• Systolic blood pressure of less than 90 mm Hg, OR	
☐	• Decline of 20 mm Hg or greater in systolic blood pressure from person's usual baseline, OR	
☐	• Decline of 10 mm Hg or greater in diastolic blood pressure from person's usual baseline, OR	
☐	Hypertension - a systolic blood pressure above 160 mm Hg, OR a diastolic blood pressure above 95 mm Hg (I0700)	

✓	**Abnormal laboratory values** (from clinical record)	
☐	• Electrolytes, such as sodium	
☐	• Kidney function	
☐	• Liver function	
☐	• Blood sugar	
☐	• Thyroid function	
☐	• Arterial blood gases	
☐	• Other	

✓	**Pain**	
☐	• Pain CAA triggered (J0100, J0200) [review findings for relationship to delirium (C1300)]	
☐	• Pain frequency, intensity, and characteristics (time of onset, duration, quality) (J0400, J0600, J0800, J0850 and clinical record) indicate possible relationship to delirium (C1300)	
☐	• Adverse effect of pain on function (J0500A, J0500B) may be related to delirium (C1300)	

✓	**Diseases and conditions** (diagnosis/signs/symptoms)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Circulatory/Heart — Anemia (I0200) — Cardiac dysrhythmias (I0300) — Angina, Myocardial Infarction (MI) (I0400) — Atherosclerotic Heart Disease (ASHD) (I0400) — Congestive Heart Failure (CHF) pulmonary edema (I0600) — Cerebrovascular Accident (CVA) (I4500) — Transient Ischemic Attack (TIA) (I4500)	
☐	• Respiratory — Asthma (I6200) — Emphysema/Chronic Obstructive Pulmonary Disease (COPD) (I6200) — Shortness of breath (J1100) — Ventilator or respirator (O0100F) — Respiratory Failure (I6300)	
☐	• Infectious — Infections (I1700-I2500) — Wound infection other than on foot or lower extremity (M) (I2500) — Isolation or quarantine for active infectious disease (O0100M)	
☐	• Metabolic — Diabetes (I2900) — Thyroid disease (I3400) — Hyponatremia (I3100)	
☐	• Gastrointestinal bleed (clinical record)	
☐	• Renal disease (I1500), Dialysis (O0100J)	
☐	• Hospice care (O0100K)	
☐	• Cancer (I0100)	
☐	• Dehydration (J1550C, clinical record)	

✓	**Signs of Infection** (from observation, clinical record)	
☐	• Fever (J1550A)	
☐	• Cloudy or foul smelling urine	
☐	• Congested lungs or cough	
☐	• Dyspnea (J1100)	
☐	• Diarrhea	
☐	• Abdominal pain	
☐	• Purulent wound drainage	
☐	• Erythema (redness) around an incision	

✓	Indicators of Dehydration	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Dehydration CAA triggered, indicating signs or symptoms of dehydration are present (J1550C)	
☐	• Recent decrease in urine volume or more concentrated urine than usual (I and O) (clinical record)	
☐	• Recent decrease in eating habits – skipping meals or leaving food uneaten, weight loss (K0300)	
☐	• Nausea, vomiting (J1550B), diarrhea, or blood loss	
☐	• Receiving intravenous drugs (O0100H)	
☐	• Receiving diuretics or drugs that may cause electrolyte imbalance (medication administration record)(N0410G)	

✓	**Functional Status**	
☐	• Recent decline in ADL status (Section G0110) (may be related to delirium) (C1300)	
☐	• Increased risk for falls (J1700) (may be related to delirium) (See Falls CAA)	

✓	**Medications** (that may contribute to delirium)	
☐	• New medication(s) or dosage increase(s)	
☐	• Drugs with anticholinergic properties (for example, some antipsychotics (N0410A), antidepressants (N0410C), antiparkinsonian drugs, antihistamines)	
☐	• Opioids (narcotic pain drug)	
☐	• Benzodiazepines, especially long-acting agents (N0410B)	
☐	• Analgesics, cardiac and GI medications, anti-inflammatory drugs	
☐	• Recent abrupt discontinuation, omission, or decrease in dose of a short or long acting benzodiazepines (N0410B)	
☐	• Drug interactions (pharmacist review may be required)	
☐	• Resident taking more than one drug from a particular class of drugs	
☐	• Possible drug toxicity, especially if the person is dehydrated (J1550C) or has renal insufficiency (I1500). Check serum drug levels	

✓	Associated or progressive signs and symptoms	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Sleep disturbances (for example, up and awake at night/asleep during the day) (D0100C, D0500C)	
☐	• Agitation and inappropriate movements (for example, unsafe climbing out of bed or chair, pulling out tubes) (E0500)	
☐	• Hypoactivity (for example, low or lack of motor activity, lethargy or sluggish responses) (D0200D, D0500D)	
☐	• Perceptual disturbances such as hallucinations (E0100A) and delusions (E0100B)	

✓	Other Considerations	
☐	Psychosocial • Recent change in mood; sad or anxious (for example, crying, social withdrawal) (D0200, D0500) • Recent change in social situation (for example, isolation, recent loss of family member or friend) • Use of restraints (P0100, clinical record)	
☐	Physical or environmental factors • Hearing or vision impairment (B0200, B1000) - may have an impact on ability to process information (directions, reminders, environmental cues) • Lack of frequent reorientation, reassurance, reminders to help make sense of things • Recent change in environment (for example, a room or unit change, new admission, or return from hospital) (A1700) • Interference with resident's ability to get enough sleep (for example, light, noise, frequent disruptions) • Noisy or chaotic environment (for example, calling out, loud music, constant commotion, frequent caregiver changes)	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

2. COGNITIVE LOSS/DEMENTIA

Review of Indicators of Cognitive Loss/Dementia

✓	Reversible causes of cognitive loss	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Delirium (C1300) CAA triggered (Immediate follow-up required. Perform the Delirium CAA to determine possible causes, contributing factors, etc., and go directly to care planning for those issues. Then continue below.)	

✓	Neurological factors	
☐	• Mental Retardation/Developmental Disability (A1550)	
☐	• Alzheimer's Disease or other dementias (I4200, I4800)	
☐	• Parkinson's Disease (I5300)	
☐	• Traumatic brain injury (I5500)	
☐	• Brain tumor (clinical record)	
☐	• Normal pressure hydrocephalus	
☐	• Other (clinical record, I8000)	

✓	**Observable characteristics and extent** of this resident's cognitive loss	
☐	• Analyze component of Brief Interview for Mental Status (BIMS) (C0200-C0500) (V0100D)	
☐	• If unable to complete BIMS, analyze components of Staff Assessment for Mental Status (C0700, C0800, C0900,C1000)	
☐	• Identify components of Delirium assessment (C1300) that are present and not new onset or worsening	
☐	• Confusion, disorientation, forgetfulness (observation, clinical record) (C0200, C0300, C0400, C0500,C0700, C0800, C0900, C1300, C1600)	
☐	• Decreased ability to make self understood (B0700) or to understand others (B0800)	
☐	• Impulsivity (observation, clinical record)	
☐	• Other (observation, clinical record)	

✓	Mood and behavior	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Mood State (D0100) CAA triggered. Analysis of Findings indicates possible impact on cognition – important to consider when drawing conclusions about cognitive loss	
☐	• Behavioral Symptoms (E0200) CAA triggered: Analysis of Findings points to cause(s), contributing factors, etc. – important to consider when drawing conclusions about cognitive loss	

✓	**Medical problems** that can impact cognition	
☐	• Constipation (H0600), fecal impaction, diarrhea	
☐	• Diabetes (I2900)	
☐	• Thyroid Disorder (I3400)	
☐	• Congestive heart failure (I0600)/other cardiac diseases (I0300, I0400)	
☐	• Respiratory problems (I6200, I6300, I2000, I2200, I8000)/decreased oxygen saturation	
☐	• Cancer (I0100)	
☐	• Liver disease (I1100, I2400, I8000, clinical record)	
☐	• Renal failure (I1500)	
☐	• Psychiatric or mood disorder (I5700-I6100)	
☐	• Electrolyte imbalance (clinical record)	
☐	• Poor nutrition (I5600) or hydration status (J1550C) (clinical record)	
☐	• End of life (Hospice O0100K and clinical record)	
☐	• Alcoholism (I8000)	
☐	• Failure to thrive (I8000)	

✓	**Pain** and its relationship to cognitive loss and behavior	
☐	• Indications that pain is present (J0100, J0300, J0400, J0500, J0600 , J0700, J0800, J0850)	
☐	• Pain CAA triggered. Determine relationship between pain and cognitive status via observation and assessment.	

✓	**Functional status** and its relationship to cognitive loss	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Activities of Daily Living (ADL) status (Section G) — ADL Care Area triggered (G0110). Analysis of Findings provides important information about relationship of ADL decline to cognitive loss (C0500, C0700, C0800, C0900, C1000, V0100D) — Resident has potential for more independence with cueing, restorative nursing program, and/or task segmentation or other programs (G0600, O0100 – O0500)	
☐	• Decline in continence (H0300, H0400, clinical record)	
☐	• Impaired daily decision-making (C1000, clinical record)	
☐	• Participates better in small group programs (F0800P, observation, clinical record)	
☐	• Staff and/or resident believe resident is capable of doing more (G0900)	

✓	**Other Considerations**	
☐	• Cognitive decline occurred slowly over time (V0100D)	
☐	• Unexplainable behavior may be attempt at communication about pain, toileting needs, uncomfortable position, etc.	
☐	• Use of physical restraints (P0100)	
☐	• Hearing or vision impairment (B0200, B0300, B1000, B1200) - may have an impact on ability to process information (directions, reminders, environmental cues)	
☐	• Lack of frequent reorientation, reassurance, reminders to help make sense of things (C0900, C1300)	
☐	• Interference with the resident's ability to get enough sleep (noise, light, etc.) (D0200C, D0500C)	
☐	• Noisy or chaotic environment (for example, calling out, loud music, constant commotion, frequent caregiver changes)	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

3. VISUAL FUNCTION

Review of Indicators of Visual Function

✓	**Diseases and conditions** of the eye (diagnosis OR signs/symptoms present)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Cataracts, Glaucoma, or Macular Degeneration (I6500)	
☐	• Diabetic retinopathy (I2900)	
☐	• Blindness (B1000 = 3 or 4)	
☐	• Decreased visual acuity (B1000, B1200 = 1)	
☐	• Visual field deficit (B1200 = 1)	
☐	• Eye pain (J0800)	
☐	• Blurred vision	
☐	• Double vision	
☐	• Sudden loss of vision	
☐	• Itching/burning eye	
☐	• Indications of eye infection (I8000)	

✓	**Diseases and conditions** that can cause visual disturbances	
☐	• Cerebrovascular accident or transient ischemic attack (I4500)	
☐	• Alzheimer's Disease and other dementias (I4200, I4800)	
☐	• Myasthenia gravis (I8000, clinical record)	
☐	• Multiple sclerosis (I5200)	
☐	• Cerebral palsy (I4400)	
☐	• Mood ((I5800, I5900, I5950, I6000, I6100, D0300 or D0600) or anxiety disorder (I5700)	
☐	• Traumatic brain injury (I5500)	
☐	• Other (I8000)	

✓	**Functional limitations related to vision problems** (from clinical record, resident and staff interviews, direct observation)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Peripheral vision or other visual problem that impedes ability to eat, walk, or interact with others (B1000 = 3, 4)	
☐	• Ability to recognize staff limited by vision problem (B1000 = 3, 4)	
☐	• Difficulty negotiating the environment due to vision problem (B1000 = 3, 4)	
☐	• Balance problems (G0300) exacerbated by vision problem (B1000, B1200)	
☐	• Participation in self-care limited by vision problem (B1000)	
☐	• Difficulty seeing television, reading material of interest, or participating in activities of interest because of vision problem (B1000 = 2, 3, 4)	
☐	• Increased risk for falls due to vision problems or due to bifocals or trifocals (B1200 = 1)	

✓	**Environment**	
☐	• Is resident's environment adapted to his or her unique needs, such as availability of large print books, high wattage reading lamp, night light, etc.?	
☐	• Are there aspects the facility's environment that should be altered to enhance vision, such as low-glare floors, low glare tables and surfaces, large print signs marking rooms, etc.?	

✓	**Medications** that can impair vision (consultant pharmacist review of medication regimen can be very helpful)	
☐	• Narcotics	
☐	• Antipsychotics (N0410A)	
☐	• Antidepressants (N0410C)	
☐	• Anticholinergics	
☐	• Hypnotics (N0410D)	
☐	• Other	

✓	**Use of visual appliances** (B1200)	
☐	• Reading glasses	
☐	• Distance glasses	
☐	• Contact lenses	
☐	• Magnifying glass	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

4. COMMUNICATION

Review of Indicators of Communication

✓	**Diseases and conditions** that may be related to communication problems	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Alzheimer's Disease or other dementias (I4200, I4800, I8000)	
☐	• Aphasia (I4300) following a cerebrovascular accident (I4500)	
☐	• Parkinson's disease (I5300)	
☐	• Mental health problems (I5700 – I6100)	
☐	• Conditions that can cause voice production deficits, such as	
☐	— Asthma (I6200)	
☐	— Emphysema/COPD (I6200)	
☐	— Cancer (I0100) — Poor-fitting dentures (L0200)	
☐	• Transitory conditions, such as	
☐	— Delirium (C1300, I8000, clinical record)	
☐	— Infection (I1700 – I2500) — Acute illness (I8000, clinical record)	
☐	• Other (I8000, clinical record)	

✓	**Medications** (consultant pharmacist review of medication regimen can be very helpful)	
☐	• Narcotic analgesics (medication administration record)	
☐	• Antipsychotics (N0410A)	
☐	• Antianxiety (N0410B)	
☐	• Antidepressants (N0410C)	
☐	• Parkinson's medications (medication administration record)	
☐	• Hypnotics (N0410D)	
☐	• Gentamycin (N0410F) (medication administration record)	
☐	• Tobramycin(N0410F) (medication administration record)	
☐	• Aspirin (medication administration record)	
☐	• Other (clinical record)	

✓	**Characteristics of the communication impairment** (from clinical record)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Expressive communication (B0700)	
☐	— Speaks different language (A1100)	
☐	— Disruption in ability to speak (B0600, clinical record)	
☐	— Problem with voice production, low volume (B0600, clinical record)	
☐	— Word-finding problems (clinical record)	
☐	— Difficulty putting sentence together (B0700, C1300B, clinical record)	
☐	— Problem describing objects and events (B0700, clinical record)	
☐	— Pronouncing words incorrectly (B0600, clinical record)	
☐	— Stuttering (B0700, clinical record)	
☐	— Hoarse or distorted voice (clinical record)	
☐	• Receptive communication (B0800)	
☐	— Does not understand English (A1100)	
☐	— Hearing impairment (B0200, B0300 = 1, B0800)	
☐	— Speech discrimination problems (clinical record)	
☐	— Decreased vocabulary comprehension (clinical record) (A1100A-B)	
☐	— Difficulty reading and interpreting facial expressions (clinical record, direct observation)	
☐	• Communication is more successful with some individuals than with others. Identify and build on the successful approaches (clinical record, interviews, observation)	
☐	• Limited opportunities for communication due to social isolation or need for communication devices (clinical record, interviews)	
☐	• Communication problem may be mistaken as cognitive impairment	

✓	**Confounding problems** that may need to be resolved before communication will improve	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Decline in cognitive status (clinical record) and BIMS decline (C0500, V0100D)	
☐	• Mood problem, increase in PHQ-9 score (D0300, D0600, V0100E)	
☐	• Increased dependence in Activities of Daily Living (ADLs) (clinical record, changes in G0110, G0120)	
☐	• Deterioration in respiratory status (clinical record)	
☐	• Oral motor function problems, such as swallowing, clarity of voice production (B0600, K0100, clinical record)	

✓	**Use of communication devices** (from clinical record, observation)	
☐	• Hearing aid (B0300)	
☐	• Written communication	
☐	• Sign language	
☐	• Braille	
☐	• Signs, gestures, sounds	
☐	• Communication board	
☐	• Electronic assistive devices	
☐	• Other	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

5. ACTIVITIES OF DAILY LIVING (ADLs) – FUNCTIONAL STATUS/REHABILITATION POTENTIAL

Review of Indicators of ADLs - Functional Status/Rehabilitation Potential

✓	**Possible underlying problems** that may affect function. Some may be reversible.	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Delirium (C1300) (clinical record and Delirium CAA)	
☐	• Acute episode or flare-up of chronic condition (I8000, clinical record)	
☐	• Changing cognitive status (C0100) (see Cognitive Loss CAA)	
☐	• Mood decline (D0100)(clinical record and Mood State CAA)	
☐	• Daily behavioral symptoms/decline in behavior(E0200) (see Behavioral Symptoms CAA)	
☐	• Use of physical restraints(P0100) (See Physical Restraints CAA)	
☐	• Pneumonia (I2000)	
☐	• Fall(J1700) (from record and Falls CAA)	
☐	• Hip fracture (I3900)	
☐	• Recent hospitalization (clinical record) (A1700, A1800= 3, 4)	
☐	• Fluctuating ADLs (G0110A-J, G0120, G0300A-E, G0900) (observation, clinical record)	
☐	• Nutritional problems (K0510A1, K0510A2) (clinical record and Nutrition CAA)	
☐	• Pain(J0700) (See Pain CAA)	
☐	• Dizziness	
☐	• Communication problems (B0200, B0700, B0800) (clinical record and Communication CAA)	
☐	• Vision problems(B1000) (observation, interview, clinical record, and Vision CAA)	

✓	**Abnormal laboratory values** (from clinical record)	
☐	• Electrolytes	
☐	• Complete blood count	
☐	• Blood sugar	
☐	• Thyroid function	
☐	• Arterial blood gases	
☐	• Other	

✓	**Medications** that can contribute to functional decline	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Psychoactive medications (N0410A-D)	
☐	• Other medications – ask consultant pharmacist to review medication regimen to identify these medications	

✓	**Limiting factors** resulting in need for assistance with any of the ADLs (observation, interview, clinical record)	
☐	• Mental errors such as sequencing problems, incomplete performance, or anxiety limitations	
☐	• Physical limitations such as weakness (G0110A–J.1 = 2,3, 4) (G0110 A-J.2 = 2, 3), limited range of motion (G0400A = 1, 2, G0400B = 1, 2), poor coordination, poor balance (G0300A-E =2), visual impairment (B1000 = 1-4), or pain (J0300 = 1, J0700 =1)	
☐	• Facility conditions such as policies, rules, or physical layout	

✓	**Problems resident is at risk for** because of functional decline (from observation, assessment, clinical record)	
☐	• Falls (J1700)	
☐	• Weight loss (K0300)	
☐	• Unidentified pain (J0700)	
☐	• Social isolation	
☐	• Restraint use (P0100)	
☐	• Depression(D0100)	
☐	• Complications of immobility, such as — Pressure ulcers (M0210) — Muscular atrophy — Contractures (G0400 A, B = 1, 2) — Incontinence (H0300, H0400) — Urinary (I2300) and respiratory infections	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

Where rehabilitation goals are envisioned, use of the ***ADL Supplement*** will help care planners to focus on those areas that might be improved, allowing them to choose from among a number of basic tasks in designated areas. Part 1 of the supplement can assist in the evaluation of all residents that trigger this care area. Part 2 of the supplement can be helpful for residents with rehabilitation potential (ADL Triggers A), to help plan a treatment program.

ADL SUPPLEMENT
(Attaining maximum possible Independence)

PART 1: ADL Problem Evaluation INSTRUCTIONS: For those triggered - In areas physical help provided, indicate reason(s) for this help.	DRESSING	BATHING	TOILETING	LOCOMOTION	TRANSFER	EATING
Mental Errors: Sequencing problems, incomplete performance, anxiety limitations, etc. **Physical Limitations:** Weakness, limited range of motion, poor coordination, visual impairment, pain, etc. **Facility Conditions:** Policies, rules, physical layout, etc.						

PART 2: Possible ADL Goals INSTRUCTIONS: For those considered for rehabilitation or decline prevention treatment -				If wheelchair, check: ☐		
Indicate specific type of ADL activity that might require: 1. Maintenance to prevent decline. 2. Treatment to achieve highest practical self-sufficiency (selecting ADL abilities that are just above those the resident can now perform or participate in).	Locates/ selects/ obtains clothes	Goes to tub/ shower	Goes to toilet (include commode/ urinal at night)	Walks in room/ nearby ☐	Positions self in preparation	Opens/ pours/ unwraps/ cuts etc.
	Grasps/puts on upper lower body	Turns on water/ adjusts temperature	Removes/ opens clothes in preparation	Walks on unit ☐	Approaches chair/bed	Grasps utensils and cups
	Manages snaps, zippers, etc.	Lathers body (except back)	Transfers/ positions self	Walks throughout building (uses elevator) ☐	Prepares chair/bed (locks pad, moves covers)	Scoops/ spears food (uses fingers when necessary)
	Puts on in correct order	Rinses body	Eliminates into toilet	Walks outdoors ☐	Transfers (stands/sits/ lifts/turns)	Chews, drinks, swallows
	Grasps, removes each item	Dries with towel	Tears/uses paper to clean self	Walks on uneven surfaces ☐	Repositions/ arranges self	Repeats until food consumed
	Replaces clothes properly	Other	Flushes	Other ☐	Other	Uses napkins, cleans self
	Other		Adjusts clothes, washes hands			Other

6. URINARY INCONTINENCE AND INDWELLING CATHETER

Review of Indicators of Urinary Incontinence and Indwelling Catheter

✓	**Modifiable factors** contributing to transitory urinary incontinence	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Delirium (C1300) (See Delirium CAA)	
☐	• Urinary Tract Infection (I2300)	
☐	• Atrophic vaginitis in postmenopausal women (I8000)	
☐	• Medications (see below)	
☐	• Psychological or psychiatric problems (I5700-I6100)	
☐	• Constipation/impaction (H0600, clinical record)	
☐	• Caffeine use	
☐	• Excessive fluid intake	
☐	• Pain (J0300)	
☐	• Environmental factors	
☐	— Restricted mobility (G0110.1.A-F. = 2, 3,4)(G0110.2.A-F.=2, 3) (See ADL CAA)	
☐	— Lack of access to a toilet	
☐	— Other environmental barriers (such as pads or briefs)	
☐	— Restraints (P0100)	

✓	**Other factors** that contribute to incontinence or catheter use	
☐	• Excessive or inadequate urine output	
☐	• Urinary urgency AND need for assistance in toileting (G0110.1.I = 2, 3, 4)	
☐	• Bladder cancer (I0100) or stones (I8000)	
☐	• Spinal cord or brain lesions (I8000)	
☐	• Tabes dorsalis (I8000)	
☐	• Neurogenic bladder (I1550)	

✓	**Laboratory tests**	
☐	• High serum calcium	
☐	• High blood glucose	
☐	• Low B12	
☐	• High BUN or creatinine	

✓	Diseases and conditions	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Benign prostatic hypertrophy (I1400)	
☐	• Congestive Heart Failure (CHF), pulmonary edema (I0600)	
☐	• Cerebrovascular Accident (CVA) (I4500)	
☐	• Transient Ischemic Attack (TIA) (I4500)	
☐	• Diabetes (I2900)	
☐	• Depression (I5800)	
☐	• Parkinson's disease (I5300)	
☐	• Prostate cancer (I0100)	

✓	Type of incontinence	
☐	• Stress (occurs with coughing, sneezing, laughing, lifting heavy objects, etc.)	
☐	• Urge (overactive or spastic bladder)	
☐	• Mixed (stress incontinence with urgency)	
☐	• Overflow (due to blocked urethra or weak bladder muscles)	
☐	• Transient (temporary/occasional related to a potentially improvable/reversible cause)	
☐	• Functional (can't get to toilet in time due to physical disability, external obstacles, or problems thinking or communicating)	

✓	**Medications** (from medication administration record and preadmission records if new admission; review by consultant pharmacist)	
☐	• Diuretics(N0410G)– can cause urge incontinence	
☐	• Sedative hypnotics (N0410B, N0410D)	
☐	• Anticholinergics – can lead to overflow incontinence — Parkinson's medications (except Sinemet and Deprenyl) — Disopyramide — Antispasmodics — Antihistamines — Antipsychotics (N0410A) — Antidepressants (N0410C) — Narcotics	
☐	• Drugs that stimulate or block sympathetic nervous system	
☐	• Calcium channel blockers	

✓	**Use of indwelling catheter (H0100 is checked)**: (Presence of situation in which catheter use ***may*** be appropriate intervention after consideration of risks/benefits and after efforts to avoid catheter use have been unsuccessful	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Coma (B0100)	
☐	• Terminal illness (O0100K)	
☐	• Stage 3 or 4 pressure ulcer in area affected by incontinence	
☐	• Need for exact measurement of urine output	
☐	• History of inability to void after catheter removal	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

7. PSYCHOSOCIAL WELL-BEING

Review of Indicators of Psychosocial Well-Being

✓	**Modifiable factors for relationship problems** (from resident, family, staff interviews and clinical record)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Resident says or indicates he or she feels lonely — Recent decline in social involvement and associated loneliness can be sign of acute health complications and depression	
☐	• Resident indicates he or she feels distressed because of decline in social activities	
☐	• Over the past few years, resident has experienced absence of daily exchanges with relatives and friends	
☐	• Resident is uneasy dealing with others	
☐	• Resident has conflicts with family, friends, roommate, other residents, or staff	
☐	• Resident appears preoccupied with the past and unwilling to respond to needs of the present	
☐	• Resident seems unable or reluctant to begin to establish a social role in the facility; may be grieving lost status or roles	
☐	• Recent change in family situation or social network, such as death of a close family member or friend	

✓	**Customary lifestyle** (from resident, family, staff interviews and clinical record) (Section F)	
☐	• Was lifestyle more satisfactory to the resident prior to admission to the nursing home?	
☐	• Are current psychosocial/relationship problems consistent with resident's long-standing lifestyle or is this relatively new for the resident?	
☐	• Has facility care plan to date been as consistent as possible with resident's prior lifestyle, preferences, and routines (F0400, F0600, F0800)?	

✓	**Diseases and conditions** that may impede ability to interact with others	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Delirium (C1300, C1600 = 1, Delirium CAA)	
☐	• Mental retardation/developmental disability (A1550)	
☐	• Alzheimer's disease (I4200)	
☐	• Aphasia (I4300)	
☐	• Other dementia (I4800)	
☐	• Depression (I5800)	

✓	**Health status factors** that may inhibit social involvement	
☐	• Decline in activities of daily living (G0110)	
☐	• Health problem, such as falls (J1700, J1800), pain (J0300, J0800), fatigue, etc.	
☐	• Mood (D0200A1, D0300, D0500A1, D0600) or behavior (E0200) problem that impacts interpersonal relationships or that arises because of social isolation (See Mood State and Behavioral Symptoms CAAs)	
☐	• Change in communication (B0700, B0800), vision (B1000), hearing (B0200), cognition (C0100, C0600)	
☐	• Medications with side effects that interfere with social interactions, such as incontinence, diarrhea, delirium, or sleepiness	

✓	**Environmental factors** that may inhibit social involvement	
☐	• Use of physical restraints (P0100)	
☐	• Change in residence leading to loss of autonomy and reduced self-esteem (A1700)	
☐	• Change in room assignment or dining location or table mates	
☐	• Living situation limits informal social interaction, such as isolation precautions (O0100M)	

✓	**Strengths** to build upon (from resident, family, staff interviews and clinical record)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Activities in which resident appears especially at ease interacting with others	
☐	• Certain situations appeal to resident more than others, such as small groups or 1:1 interactions rather than large groups	
☐	• Certain individuals who seem to bring out a more positive, optimistic side of the resident	
☐	• Positive traits that distinguished the resident as an individual prior to his or her illness	
☐	• What gave the resident a sense of satisfaction earlier in his or her life?	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

8. MOOD STATE

Review of Indicators of Mood

✓	Psychosocial changes	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Personal loss	
☐	• Recent move into or within the nursing home (A1700)	
☐	• Recent change in relationships, such as illness or loss of a relative or friend	
☐	• Recent change in health perception, such as perception of being seriously ill or too ill to return home (Q0300 - Q0600)	
☐	• Clinical or functional change that may affect the resident's dignity, such as new or worsening incontinence, communication, or decline	

✓	**Clinical issues** that can cause or contribute to a mood problem	
☐	• Relapse of an underlying mental health problem (I5700 – I6100)	
☐	• Psychiatric disorder (anxiety, depression, manic depression, schizophrenia, post-traumatic stress disorder) (I5700 – I6100)	
☐	• Alzheimer's disease (I4200)	
☐	• Delirium (C1600)	
☐	• Delusions (E0100B)	
☐	• Hallucinations (E0100A)	
☐	• Communication problems (B0700, B0800)	
☐	• Decline in Activities of Daily Living (ADLs) (G0110, clinical record)	
☐	• Infection (I1700 – I2500, clinical record)	
☐	• Pain (J0300 or J0800)	
☐	• Cardiac disease (I0200 – I0900)	
☐	• Thyroid abnormality (I3400)	
☐	• Dehydration (J1550C, clinical record)	
☐	• Metabolic disorder (I2900 – I3400)	
☐	• Neurological disease (I4200 – I5500)	
☐	• Recent cerebrovascular accident (I4500)	
☐	• Dementia, cognitive decline (I4800, clinical record)	
☐	• Cancer (I0100)	
☐	• Other (I8000)	

✓	**Medications** (from medication administration record and preadmission records if new admission)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Antibiotics (N0410F)	
☐	• Anticholinergics	
☐	• Antihypertensives	
☐	• Anticonvulsants	
☐	• Antipsychotics (N0410A)	
☐	• Cardiac medications	
☐	• Cimetidine	
☐	• Clonidine	
☐	• Chemotherapeutic agents	
☐	• Digitalis	
☐	• Other	
☐	• Glaucoma medications	
☐	• Guanethidine	
☐	• Immuno-suppressive medications	
☐	• Methyldopa	
☐	• Narcotics	
☐	• Nitrates	
☐	• Propranolol	
☐	• Reserpine	
☐	• Steroids	
☐	• Stimulants	

✓	**Laboratory tests**	
☐	• Serum calcium	
☐	• Thyroid function	
☐	• Blood glucose	
☐	• Potassium	
☐	• Porphyria	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

9. BEHAVIORAL SYMPTOMS

Review of Indicators of Behavioral Symptoms

✓	**Seriousness of the behavioral symptoms (E0300, E0800, E0900, E1100)**	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Resident is immediate threat to self – IMMEDIATE INTERVENTION REQUIRED (D0200I.1=1, D0500I.1=1, E1000 = 1)	
☐	• Resident is immediate threat to others – IMMEDIATE INTERVENTION REQUIRED (E0600A)	

✓	**Nature of the behavioral disturbance** (resident interview, if possible; staff observations)	
☐	• Provoked or unprovoked	
☐	• Offensive or defensive	
☐	• Purposeful	
☐	• Occurs during specific activities, such as bath or transfers	
☐	• Pattern, such as certain times of the day, or varies over time	
☐	• Others in the vicinity are involved	
☐	• Reaction to a particular action, such as being physically moved	
☐	• Resident appears to startle easily	

✓	**Medication side effects** that can cause behavioral symptoms (from medication records)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• New medication	
☐	• Change in dosage	
☐	• Antiparkinsonian drugs - may cause hypersexuality, socially inappropriate behavior	
☐	• Sedatives, centrally active antihypertensives, some cardiac drugs, anticholinergic agents can cause paranoid delusions, delirium	
☐	• Bronchodilators or other respiratory drugs, which can increase agitation and cause difficulty sleeping	
☐	• Caffeine	
☐	• Nicotine	
☐	• Medications that impair impulse control, such as benzodiazepines, sedatives, alcohol (or any product containing alcohol, such as some cough medicine)	

✓	**Illness or conditions** that can cause behavior problems	
☐	• Long-standing mental health problem associated with the behavioral disturbances, such as schizophrenia, bipolar disorder, depression, anxiety disorder, post-traumatic stress disorder (I5700 – I6100)	
☐	• New or acute physical health problem or flare-up of a known chronic condition (I8000)	
☐	• Delusions (E0100B)	
☐	• Hallucinations (E0100A)	
☐	• Paranoia (from record)	
☐	• Constipation (H0600)	
☐	• Congestive heart failure (I0600)	
☐	• Infection (I1700 – I2500)	
☐	• Head injury (I5500, clinical record)	
☐	• Diabetes (I2900)	
☐	• Pain (J0300, J0800)	
☐	• Fever (J1550A, clinical record)	
☐	• Dehydration (J1550C, clinical record; see Dehydration CAA)	

✓	**Factors that can cause or exacerbate the behavior** (from observation, interview, record)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Frustration due to problem communicating discomfort or unmet need	
☐	• Frustration, agitation due to need to urinate or have bowel movement	
☐	• Fear due to not recognizing caregiver	
☐	• Fear due to not recognizing the environment or misinterpreting the environment or actions of others	
☐	• Major unresolved sources of interpersonal conflict between the resident and family members, other residents, or staff (see Psychosocial Well-Being CAA)	
☐	• Recent change, such as new admission (A1700) or a new unit, assignment of new care staff, or withdrawal from a treatment program	
☐	• Departure from normal routines	
☐	• Sleep disturbance (D0500C = 1)	
☐	• Noisy, crowded area	
☐	• Dimly lit area	
☐	• Sensory impairment, such as hearing or vision problem (B0200, B1000)	
☐	• Restraints (P0100)	
☐	• Fatigue (D0500D = 1)	
☐	• Need for repositioning (M1200)	

✓	**Cognitive status problems** (also see Cognitive Loss CAT/CAA)	
☐	• Delirium (C1300), clinical record (Delirium CAT)	
☐	• Dementia (I4800)	
☐	• Recent cognitive loss (clinical record, interviews with family, etc.)	
☐	• Alzheimer's disease (I4200)	
☐	• Effects of cerebrovascular accident (I4500)	

✓	Other Considerations	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• May be communicating discomfort, personal needs, preferences, fears, feeling ill	
☐	• Persons exhibiting long-standing problem behaviors related to psychiatric conditions may place others in danger of physical assault, intimidation, or embarrassment and place themselves at increased risk of being stigmatized, isolated, abused, and neglected by loved ones or care givers	
☐	• The actions and responses of family members and caregivers can aggravate or even cause behavioral outbursts	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

10. ACTIVITIES

Review of Indicators of Activities

✓	**Activity preferences prior to admission** (from interviews and clinical record)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Passive	
☐	• Active	
☐	• Outside the home	
☐	• Inside the home	
☐	• Centered almost entirely on family activities	
☐	• Centered almost entirely on non-family activities	
☐	• Group (F0500E) activities	
☐	• Solitary activities	
☐	• Involved in community service, volunteer activities	
☐	• Athletic	
☐	• Non-athletic	

✓	**Current activity pursuits** (from interviews and clinical record)	
☐	• Resident identifies leisure activities of interest	
☐	• Self-directed or done with others and/or planned by others	
☐	• Activities resident pursues when visitors are present	
☐	• Scheduled programs in which resident participates	
☐	• Activities of interest not currently available or offered to the resident	

✓	**Health issues** that result in reduced activity participation	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Indicators of depression or anxiety (D0200, D0300, D0500, D0600)	
☐	• Use of psychoactive medications (N0410A-N0410D)	
☐	• Functional/mobility (G0110) or balance (G0300) problems; physical disability (G0300, G0400)	
☐	• Cognitive deficits (C0500, C0700-C1000), including stamina, ability to express self (B0700), understand others (B0800), make decisions (C1000)	
☐	• Unstable acute/chronic health problem (clinical record, O0100, J0100, J1100, J0700, J1400, J1550, I8000, M1040, M1200)	
☐	• Chronic health conditions, such as incontinence (H0300, H0400) or pain (J0300)	
☐	• Embarrassment or unease due to presence of equipment (O0100D, E, F), such as tubes, oxygen tank (O0100C), or colostomy bag (H0100) (observation, clinical record)	
☐	• Receives numerous treatments (O0100, O0400) that limit available time/energy (clinical record)	
☐	• Performs tasks slowly due to reduced energy reserves (observation, clinical record)	

✓	**Environmental or staffing issues** that hinder participation	
☐	• Physical barriers that prevent the resident from gaining access to the space where the activity is held (observation)	
☐	• Need for additional staff responsible for social activities (observation)	
☐	• Lack of staff time to involve residents in current activity programs (observation)	
☐	• Resident's fragile nature results in feelings of intimidation by staff responsible for the activity (from observation, interviews, clinical record)	

✓	**Unique skills or knowledge** the resident has that he or she could pass on to others (from interviews and clinical record)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Games	
☐	• Complex tasks such as knitting, or computer skills	
☐	• Topic that might interest others	

✓	**Issues** that result in reduced activity participation	
☐	• Resident is new to facility or has been in facility long enough to become bored with status quo (interview, clinical record)	
☐	• Psychosocial well-being issues, such as shyness, initiative, and social involvement	
☐	• Socially inappropriate behavior (E0200)	
☐	• Indicators of psychosis (E0100A-E0100C)	
☐	• Feelings of being unwelcome, due to issues such as those already involved in an activity drawing boundaries that are difficult to cross (observation, interview, clinical record)	
☐	• Limited opportunities for resident to get to know others through activities such as shared dining, afternoon refreshments, monthly birthday parties, reminiscence groups (observation, facility activity calendar)	
☐	• Available activities do not correspond to resident's values, attitudes, expectations (interview, clinical record) (F0500, F0800)	
☐	• Long history of unease in joining with others (interview, clinical record)	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

11. FALL(S)

Review of Indicators of Fall Risk

✓	History of falling (J1700, J1800, J1900)	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Time of day, exact hour of the fall(s)	
☐	• Location of the fall(s), such as bedroom, bathroom, hallway, stairs, outside, etc.	
☐	• Related to specific medication	
☐	• Proximity to most recent meal	
☐	• Responding to bowel or bladder urgency	
☐	• Doing usual/unusual activity	
☐	• Standing still or walking	
☐	• Reaching up or reaching down	
☐	• Identify the conclusions about the root cause(s), contributing factors related to previous falls	

✓	Physical performance limitations: balance, gait, strength, muscle endurance (G0300A-G0300E)	
☐	• Difficulty maintaining sitting balance	
☐	• Need to rock body or push off on arms of chair when standing up from chair	
☐	• Difficulty maintaining standing position	
☐	• Impaired balance during transitions (G0300A-G0300E)	
☐	• Gait problem, such as unsteady gait, even with mobility aid or personal assistance, slow gait, takes small steps, takes rapid steps, or lurching gait	
☐	• One leg appears shorter than the other	
☐	• Musculoskeletal problem, such as kyphosis, weak hip flexors from extended bed rest, or shortening of a leg	

✓	Medications	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Antipsychotics (N0410A)	
☐	• Antianxiety agents (N0410B)	
☐	• Antidepressants (N0410C)	
☐	• Hypnotics (N0410D)	
☐	• Cardiovascular medications (from medication administration record)	
☐	• Diuretics (N0410G) (from medication administration record)	
☐	• Narcotic analgesics (from medication administration record)	
☐	• Neuroleptics (from medication administration record)	
☐	• Other medications that cause lethargy or confusion (from medication administration record)	

✓	**Internal risk factors** (from diagnosis list and clinical indicators)	
☐	• Circulatory/Heart — Anemia (I0200) — Cardiac Dysrhythmias (I0300) — Angina, Myocardial Infarction (MI), Atherosclerotic Heart Disease (ASHD) (I0400) — Congestive Heart Failure (CHF) pulmonary edema (I0600) — Cerebrovascular Accident (CVA) (I4500) — Transient Ischemic Attack (TIA) (I4500) — Postural/Orthostatic hypotension (I0800)	

(continued)

✓	**Internal risk factors** (from diagnosis list and clinical indicators) (continued)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Neuromuscular/functional — Cerebral palsy (I4400) — Loss of arm or leg movement (G0400) — Decline in functional status (G0110) — Incontinence (H0300, H0400) — Hemiplegia/Hemiparesis (I4900) — Parkinson's disease (I5300) — Seizure disorder (I5400) — Paraplegia (I5000) — Multiple sclerosis (I5200) — Traumatic brain injury (I5500) — Syncope — Chronic or acute condition resulting in instability — Peripheral neuropathy — Muscle weakness	
☐	• Orthopedic — Joint pain — Arthritis (I3700) — Osteoporosis (I3800) — Hip fracture (I3900) — Missing limb(s) (G0600D)	
☐	• Perceptual — Visual impairment (B1000) — Hearing impairment (B0200) — Dizziness/vertigo	
☐	• Psychiatric or cognitive — Impulsivity or poor safety awareness — Delirium (C1300) — Wandering (E0900) — Agitation behavior (E0200) – describe the specific verbal or motor activity- e.g. screaming, babbling, cursing, repetitive questions, pacing, kicking, scratching, etc. — Cognitive impairment (C0500, C0700-C1000) — Alzheimer's disease (I4200) — Other dementia (I4800) — Anxiety disorder (I5700) — Depression (I5800) — Manic depression (I5900) — Schizophrenia (I6000)	

(continued)

✓	**Internal risk factors** (from diagnosis list and clinical indicators) (continued)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Infection (I1700 – I2500)	
☐	• Low levels of physical activity	
☐	• Pain (J0300)	
☐	• Headache	
☐	• Fatigue, weakness	
☐	• Vitamin D deficiency	

✓	**Laboratory tests**	
☐	• Hypo- or hyperglycemia	
☐	• Electrolyte imbalance	
☐	• Dehydration (J1550C)	
☐	• Hemoglobin and hematocrit	

✓	**Environmental factors** (from review of facility environment)	
☐	• Poor lighting	
☐	• Glare	
☐	• Patterned carpet	
☐	• Poorly arranged furniture	
☐	• Uneven surfaces	
☐	• Slippery floors	
☐	• Obstructed walkway	
☐	• Poor fitting or slippery shoes	
☐	• Proximity to aggressive resident	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

12. NUTRITIONAL STATUS

Review of Indicators of Nutritional Status

✓	**Current eating pattern** – resident leaves significant proportion of meals, snacks, and supplements daily for even a few days	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Food offered or available is not consistent with the resident's food choices/needs — Food preferences not consistently honored — Resident has allergies or food intolerance (for example, needs lactose-free) — Food not congruent with religious or cultural needs — Resident complains about food quality (for example, not like what spouse used to prepare, food lacks flavor) — Resident doesn't eat processed foods — Food doesn't meet other special diet requirements	
☐	• Pattern re: food left uneaten (for example, usually leaves the meat or vegetables)	
☐	• Intervals between meals may be too long or too short	
☐	• Unwilling to accept food supplements or to eat more than three meals per day	

✓	**Functional problems** that affect ability to eat	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Swallowing problem (K0100)	
☐	• Arthritis (I3700)	
☐	• Contractures (G0400)	
☐	• Functional limitation in range of motion (G0400)	
☐	• Partial or total loss of arm movement (G0400A)	
☐	• Hemiplegia/hemiparesis (I4900)(G0400 A and B = 1)	
☐	• Quadriplegia/paraplegia (I5100/I5000) (G0400 A and/or B =2)	
☐	• Inability to perform ADLs without significant physical assistance (G0110)	
☐	• Inability to sit up (G0300)	
☐	• Missing limb(s) (G0600D)	
☐	• Vision problems (B1000)	
☐	• Decreased ability to smell or taste food	
☐	• Need for special diet or altered consistency which might not appeal to resident	
☐	• Recent decline in Activities of Daily Living (ADLs) (G0110-G0600)	

✓	**Cognitive, mental status, and behavior problems** that can interfere with eating	
☐	• Review Cognitive Loss CAA	
☐	• Alzheimer's Disease (I4200)	
☐	• Other dementia (I4800)	
☐	• Mental retardation/developmental disability (A1550)	
☐	• Paranoid fear that food is poisoned	
☐	• Requires frequent/constant cueing	
☐	• Disruptive behaviors (E0200)	
☐	• Indicators of psychosis (E0100)	
☐	• Wandering (E0900)	
☐	• Pacing (E0200)	
☐	• Throwing food (E0200C)	
☐	• Resisting care (E0800)	
☐	• Very slow eating	
☐	• Short attention span	
☐	• Poor memory (C0500, C0700-C0900)	
☐	• Anxiety problems (I5700)	

✓	Communication problems	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Review Communication CAA	
☐	• Comatose (B0100)	
☐	• Difficulty making self understood (B0700)	
☐	• Difficulty understanding others (B0800)	
☐	• Aphasia (I4300)	

✓	**Dental/oral problems** (from Section L and physical assessment)	
☐	• See Dental Care CAA	
☐	• Broken or fractured teeth (L0200D)	
☐	• Toothache (L0200F)	
☐	• Bleeding gums (L0200E)	
☐	• Loose dentures, dentures causing sores (L0200A)	
☐	• Lip or mouth lesions (for example, cold sores, fever blisters, oral abscess) (L0200C)	
☐	• Mouth pain (L0200F)	
☐	• Dry mouth	

✓	**Other diseases and conditions** that can affect appetite or nutritional needs	
☐	• Anemia (I0200)	
☐	• Arthritis (I3700)	
☐	• Burns (M1040F)	
☐	• Cancer (I0100)	
☐	• Cardiovascular disease (I0300-I0900)	
☐	• Cerebrovascular accident (I4500)	
☐	• Constipation (H0600)	
☐	• Delirium (C1600)	
☐	• Depression (I5800)	
☐	• Diabetes (I2900)	
☐	• Diarrhea	
☐	• Gastrointestinal problem (I1100-I1300)	
☐	• Hospice care (O0100K)	
☐	• Liver disease (I8000)	
☐	• Pain (J0300)	
☐	• Parkinson's disease (I5300)	
☐	• Pressure ulcers (M0300)	

(continued)

✓	**Other diseases and conditions** that can affect appetite or nutritional needs (continued)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Radiation therapy (O0100B)	
☐	• Recent acute illness (I8000)	
☐	• Recent surgical procedure (I8000) (M1200F)	
☐	• Renal disease (I1500)	
☐	• Respiratory disease (I6200)	
☐	• Thyroid problem (I3400)	
☐	• Weight loss (K0300)	
☐	• Weight gain (K0310)	

✓	**Abnormal laboratory values** (from clinical record)	
☐	• Electrolytes	
☐	• Pre-albumin level	
☐	• Plasma transferrin level	
☐	• Others	

✓	**Medications** (from medication administration record and preadmission records if new admission)	
☐	• Antipsychotics (N0410A)	
☐	• Chemotherapy (O0100A)	
☐	• Cardiac drugs	
☐	• Diuretics (N0410G)	
☐	• Anti-inflammatory drug	
☐	• Anti-Parkinson's drugs	
☐	• Laxatives	
☐	• Antacids	
☐	• Start of a new drug	

✓	**Environmental factors** (from direct observation and clinical record)	
☐	• Sufficient eating assistance	
☐	• Availability of adaptive equipment	
☐	• Dining environment fosters pleasant social experience	
☐	• Appropriate lighting	
☐	• Sufficient personal space during meals	
☐	• Proper positioning in wheelchair/chair for dining	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

13. FEEDING TUBE(S)

Review of Indicators of Feeding Tubes

✓	Reason for tube feeding	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Unable to swallow or to eat food and unlikely to eat within a few days due to — Physical problems in chewing or swallowing (for example, stroke or Parkinson's disease) (L0200F, K0100D) — Mental problems (I5700 – I6100) (for example, Alzheimer's (I4200), depression (I5800))	
☐	• Normal caloric intake is substantially impaired due to endotracheal tube or a tracheostomy (O0100E)	
☐	• Prevention of meal-induced hypoxemia (insufficient oxygen to blood), in resident with COPD (I6200) or other pulmonary problems that interfere with eating (I6200)	

✓	Complications of tube feeding	
☐	• Diagnostic conditions — Delirium (C1600) — Repetitive physical movements — Anxiety (I5700, clinical record) — Depression (I5800) — Lung aspiration, pneumonia (I2000, clinical record) — Infection at insertion site — Shortness of breath (J1100)	
☐	• Bleeding around insertion site	
☐	• Constipation (H0600)	
☐	• Abdominal distension or abdominal pain	
☐	• Diarrhea or cramping	
☐	• Nausea, vomiting (J1550B)	
☐	• Tube dislodgement, blockage, leakage	
☐	• Bowel perforation	
☐	• Dehydration (J1550C) or fluid overload	
☐	• Self-extubation	
☐	• Use of physical restraints (P0100)	

✓	**Psychosocial issues** related to tube feeding	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Signs of depression ((D0300, D0600, I5800); see Mood State CAA)	
☐	• Ways to socially engage the resident with a feeding tube	
☐	• Emotional and social support from social workers, other members of the healthcare team	

✓	**Periodic evaluations and consultations**	
☐	• Weight check at least monthly (K0300, K0310)	
☐	• Lab tests to monitor electrolytes, serum albumin, hematocrit	
☐	• Periodic evaluations by nutritionist or dietitian	
☐	• Periodic evaluation of possibility of resuming oral feeding	
☐	• Regular changing and replacement of PEG tubes and J-tubes, per physician order and facility protocol (K0510B1, K0510B2)	

✓	**Factors that may impede removal of feeding tube**	
☐	• Comatose (B0100)	
☐	• Failure to eat and resists assistance in eating (E0800)	
☐	• Cerebrovascular accident (I4500)	
☐	• Gastric ulcers, gastric bleeding, or other stomach disorder (I1200, I1300)	
☐	• Chewing problems unresolvable (L0200F)	
☐	• Swallowing problems (K0100) unresolvable	
☐	• Mouth pain (L0200F)	
☐	• Anorexia (I8000)	
☐	• Lab values indicating compromised nutritional status	
☐	• Significant weight loss (K0300)	
☐	• Significant weight gain (K0310)	
☐	• Prolonged illness	
☐	• Neurological disorder (I4200 – I5500)	
☐	• Cancer or side effects of cancer treatment (I0100, clinical record)	
☐	• Advanced dementia (I4800)	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

14. DEHYDRATION/FLUID MAINTENANCE

Review of Indicators of Dehydration/Fluid Maintenance

✓	Symptoms of dehydration	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Dizziness on sitting or standing	
☐	• Confusion or change in mental status (delirium) (C1600, V0100D)	
☐	• Lethargy (C1300C)	
☐	• Recent decrease in urine volume or more concentrated urine than usual	
☐	• Decreased skin turgor, dry mucous membranes (J1550)	
☐	• Newly present constipation (H0600), fecal impaction	
☐	• Fever (J1550A)	
☐	• Functional decline (G0110)	
☐	• Increased risk for falls (J1700)	
☐	• Fluid and electrolyte disturbance	

✓	**Abnormal laboratory values** (from clinical record)	
☐	• Hemoglobin	
☐	• Hematocrit	
☐	• Potassium chloride	
☐	• Sodium	
☐	• Albumin	
☐	• Blood urea nitrogen	
☐	• Urine specific gravity	

✓	**Cognitive, communication, and mental status** issues that can interfere with intake	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Depression (I5800, D0300, D0600) or anxiety (I5700)	
☐	• Behavioral disturbance that interferes with intake (E0200, clinical record)	
☐	• Recent change in mental status (C1600)	
☐	• Alzheimer's or other dementia that interferes with eating due to short attention span, resisting assistance, slow eating/drinking, etc. (I4200, I4800)	
☐	• Difficulty making self understood (B0700)	
☐	• Difficulty understanding others (B0800)	

✓	**Diseases and conditions** that predispose to limitations in maintaining normal fluid balance	
☐	• Infection (I1700 – I2500)	
☐	• Fever (J1550A)	
☐	• Diabetes (I2900)	
☐	• Congestive heart failure (I0600)	
☐	• Swallow problem (K0100)	
☐	• Renal disease (I1500)	
☐	• Weight loss (K0300)	
☐	• Weight gain (K0310)	
☐	• New cerebrovascular accident (clinical record, I4500)	
☐	• Unstable acute or chronic condition (clinical record, I8000)	
☐	• Nausea or vomiting (J1550B)	
☐	• Diarrhea (clinical record)	
☐	• Excessive sweating (clinical record)	
☐	• Recent surgery (clinical record, I8000)	
☐	• Recent decline in activities of daily living (G0110), including body control or hand control problems, inability to sit up (G0300), etc. (observation, interview, clinical record)	
☐	• Parkinson's or other neurological disease that requires unusually long time to eat (I4200 – I5500)	
☐	• Abdominal pain, with or without diarrhea, nausea, or vomiting (clinical record, (J1550B)	

(continued)

✓	**Diseases and conditions** that predispose to limitations in maintaining normal fluid balance (continued)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Newly taking a diuretic or recent increase in diuretic dose (N0410G) (medication records)	
☐	• Takes excessive doses of a laxative (interview, clinical record)	
☐	• Hot weather (increases risk for elderly in absence of increased fluid intake)	

✓	**Oral intake** (from observation and clinical record)	
☐	• Recent change in oral intake	
☐	• Skips meals or consumes less than 25 percent of meals	
☐	• Fluid restriction	
☐	• Newly prescribed diet	
☐	• Decreased perception of thirst	
☐	• Limited fluid-drinking opportunities	
☐	• Fluid intake limited to try to control incontinence	
☐	• Dependence on staff for fluid intake	
☐	• Excessive output compared to fluid intake	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

15. DENTAL CARE

Review of Indicators of Oral/Dental Condition/Problem

✓	**Cognitive problems** that contribute to oral/dental problems	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Needs reminders to clean teeth	
☐	• Cannot remember steps to complete oral hygiene	
☐	• Decreased ability to understand others (B0800) or to perform tasks following demonstration	
☐	• Cognitive deficit (C0500, C0700 – C1000)	

✓	**Functional impairment** limiting ability to perform personal hygiene	
☐	• Loss of voluntary arm movement (G0400A)	
☐	• Impaired hand dexterity (G0400A)	
☐	• Functional limitation in upper extremity range of motion (G0400A)	
☐	• Decreased mobility (G0110)	
☐	• Resists assistance with activities of daily living (E0800)	
☐	• Lacks motivation or knowledge regarding adequate oral hygiene, dental care	
☐	• Requires adaptive equipment for oral hygiene	

✓	**Dry mouth** causing buildup of oral bacteria	
☐	• Dehydration (see Dehydration/Fluid Maintenance CAA)	
☐	• Medications (from MDS and medication administration record) — Antipsychotics (N0410A) — Antidepressants (N0410C) — Antianxiety agents (N0410B) — Sedatives/hypnotics (N0410D) — Diuretics (N0410G) — Antihypertensives — Antiparkinsons medications — Narcotics — Anticonvulsants — Antihistamines — Decongestants — Antiemetics	
☐	• Antineoplastics	

✓	**Diseases and conditions** that may be related to poor oral hygiene, oral infection	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Recurrent pneumonia related to aspiration of saliva contaminated due to poor oral hygiene (I2000)	
☐	• Unstable diabetes related to oral infection (I2900)	
☐	• Endocarditis related to oral infection (I8000)	
☐	• Sores in mouth related to poor-fitting dentures (L0200C)	
☐	• Poor nutrition (I5600) (See Nutrition CAA)	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

16. PRESSURE ULCER(S)

Review of Indicators of Pressure Ulcer(s)

✓	**Existing pressure ulcer(s)** (M0100)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Assess location, size, stage, presence and type of drainage, presence of odors, condition of surrounding skin (M0610) — Note if eschar or slough is present (M0300F, M0700 = 4) — Assess for signs of infection, such as the presence of a foul odor, increasing pain, surrounding skin is reddened (erythema) or warm, or there is a presence of purulent drainage — Note whether granulation tissue (required for healing) is present and the wound is healing as expected (M0700 = 2)	
☐	• If the ulcer does not show signs of healing despite treatment, consider complicating factors — Elevated bacterial level in the absence of clinical infection — Presence of exudate, necrotic debris or slough in the wound, too much granulation tissue, or odor in the wound bed — Underlying osteomyelitis (bone infection)	

✓	**Extrinsic risk factors**	
☐	• Pressure — Requires staff assistance to move sufficiently to relieve pressure over any one site — Confined to a bed or chair all or most of the time — Needs special mattress or seat cushion to reduce or relieve pressure (M1200A, M1200B) — Requires regular schedule of turning (M1200C)	
☐	• Friction and shear — Slides down in the bed — Moved by sliding rather than lifting	
☐	• Maceration — Persistently wet, especially from fecal incontinence, wound drainage, or perspiration — Moisture associated skin damage (M1040H)	

✓	Intrinsic risk factors	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Immobility (G0110)	
☐	• Altered mental status — Delirium limits mobility (see Delirium CAA) — Cognitive loss (C0500, C0700-C1000) limits mobility (see Cognitive Loss CAA)	
☐	• Incontinence (H0300, H0400, M1040H) (see Incontinence CAA)	
☐	• Poor nutrition (see Nutrition CAA)	

✓	**Medications** that increase risk for pressure ulcer development	
☐	• Antipsychotics (N0410A)	
☐	• Antianxiety agents (N0410B)	
☐	• Antidepressants (N0410C)	
☐	• Hypnotics (N0410D)	
☐	• Steroids	
☐	• Narcotics	

✓	**Diagnoses and conditions** that present complications or increase risk for pressure ulcers	
☐	• Delirium (C1600)	
☐	• Comatose (B0100)	
☐	• Cancer (I0100)	
☐	• Peripheral Vascular Disease (I0900)	
☐	• Diabetes (I2900)	
☐	• Alzheimer's disease (I4200)	
☐	• Cerebrovascular Accident (I4500)	
☐	• Other dementia (I4800)	
☐	• Hemiplegia/hemiparesis (I4900)	
☐	• Paraplegia (I5000), Quadriplegia (I5100)	
☐	• Multiple sclerosis (I5200)	
☐	• Depression (D0300, D0600, I5800)	
☐	• Edema	
☐	• Severe pulmonary disease (I6200)	
☐	• Sepsis (I2100)	
☐	• Terminal illness (O0100K)	

(continued)

✓	**Diagnoses and conditions** that present complications or increase risk for pressure ulcers (continued)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Chronic or end-stage renal (I1500) , liver, or heart disease (I0400, I0600)	
☐	• Pain (J0300)	
☐	• Dehydration (J1500C, I8000)	
☐	• Shortness of breath (J1100)	
☐	• Recent weight loss (K0300)	
☐	• Recent weight gain (K0310)	
☐	• Malnutrition (I5600)	
☐	• Decreased sensory perception	
☐	• Recent decline in Activities of Daily Living (ADLs) (G0110-G0600)	

✓	**Treatments and other factors** that cause complications or increase risk	
☐	• Newly admitted or readmitted (A1700)	
☐	• History of healed pressure ulcer(s) (M0900)	
☐	• Chemotherapy (O0100A)	
☐	• Radiation therapy (O0100B)	
☐	• Ventilator or respirator (O0100F)	
☐	• Renal dialysis (O0100J)	
☐	• Functional limitation in range of motion (G0400)	
☐	• Head of bed elevated most or all of the time	
☐	• Physical restraints (P0100)	
☐	• Devices that can cause pressure, such as oxygen (O0100C) or indwelling catheter (H0100A) tubing, TED hose, casts, or splints	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____

_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

17. PSYCHOTROPIC MEDICATION USE

Review of Indicators of Psychotropic Drug Use

✓	**Class(es) of medication** this resident is taking	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Antipsychotic (N0410A)	
☐	• Antianxiety (N0410B)	
☐	• Antidepressant (N0410C)	
☐	• Sedative/Hypnotic (N0410D)	

✓	**Unnecessary drug evaluation** (from clinical record)	
☐	• Excessive dose, including duplicate medications	
☐	• Excessive duration and/or without gradual dose reductions	
☐	• Inadequate monitoring for effectiveness and/or adverse consequences	
☐	• Inadequate or inappropriate indications for use	
☐	• In presence of adverse consequences of the drug	

✓	**Treatable/reversible reasons for use** of psychotropic drug	
☐	• Environmental stressors such as excessive heat, noise, overcrowding, etc. (observation, clinical record)	
☐	• Psychosocial stressors such as abuse, taunting, not following resident's customary routine, etc. (observation, clinical record) (F0300 – F0800)	
☐	• Treatable medical conditions, such as heart disease (I0200 – I0900) , diabetes (I2900), or respiratory disease (from medical evaluation) (I6200, I6300)	

✓	**Adverse consequences of ANTIDEPRESSANTS** exhibited by this resident	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Worsening of depression and/or suicidal behavior or thinking (D0350, D0650, V0100E, V0100F, clinical record)	
☐	• Delirium unrelated to medical illness or severe depression (C1600, clinical record)	
☐	• Hallucinations (E0100A)	
☐	• Dizziness (clinical record)	
☐	• Nausea (clinical record)	
☐	• Diarrhea (clinical record)	
☐	• Anxiety (I5700, clinical record)	
☐	• Nervousness, fidgety or restless (clinical record)	
☐	• Insomnia (clinical record)	
☐	• Somnolence (clinical record)	
☐	• Weight gain (K0310, clinical record)	
☐	• Anorexia or increased appetite (clinical record)	
☐	• Increased risk for falls (clinical record), falls (J1700-J1900)	
☐	• Seizures (I5400)	
☐	• Hypertensive crisis if combined with certain foods, cheese, wine (MAO inhibitors)	
☐	• Anticholinergic (tricyclics), such as constipation, dry mouth, blurred vision, urinary retention, etc. (clinical record)	
☐	• Postural hypotension (tricyclics) (I0800, clinical record)	

✓	**Adverse consequences of ANTIPSYCHOTICS** exhibited by this resident	
☐	• Anticholinergic effects, such as constipation, dry mouth, blurred vision, urinary retention, etc. (clinical record)	
☐	• Increase in total cholesterol and triglycerides (clinical record)	
☐	• Akathisia (inability to sit still) (clinical record)	
☐	• Parkinsonism (any combination of tremors, postural unsteadiness, muscle rigidity, pill-rolling of hands, shuffling gait, etc.) (clinical record)	

(continued)

✓	**Adverse consequences of ANTIPSYCHOTICS** exhibited by this resident	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Neuroleptic malignant syndrome (high fever with severe muscular rigidity) (clinical record)	
☐	• Blood sugar elevation (clinical record)	
☐	• Cardiac arrhythmias (I0300)	
☐	• Orthostatic hypotension (I0800, clinical record)	
☐	• Cerebrovascular accident or transient ischemic attack (I4500)	
☐	• Falls (J1700-J1900)	
☐	• Tardive dyskinesia (persistent involuntary movements such as tongue thrusting, lip movements, chewing or puckering movements, abnormal limb movements, rocking or writhing trunk movements) (clinical record)	
☐	• Lethargy (D0200D, clinical record)	
☐	• Excessive sedation (clinical record)	
☐	• Depression (D0300, D0600, I5800)	
☐	• Hallucinations (E0100A)	
☐	• Delirium unrelated to medical illness or severe depression (C1600, clinical record)	

✓	**Adverse consequences of ANXIOLYTICS** exhibited by this resident	
☐	• Sedation manifested by short-term memory loss (C0500, C0700), decline in cognitive abilities, slurred speech (B0600), drowsiness, little/no activity involvement (clinical record)	
☐	• Delirium unrelated to medical illness or severe depression (C1600, clinical record)	
☐	• Hallucinations (E0100A)	
☐	• Depression (D0300, D0600, I5800)	
☐	• Disturbances of balance, gait, positioning ability (G0300, G0110C, G0110D, G0110A, clinical record)	

✓	**Adverse consequences of SEDATIVES/HYPNOTICS** exhibited by this resident	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• May increase the metabolism of many medications (for example, anticonvulsants, antipsychotics), which may lead to decreased effectiveness and subsequent worsening of symptoms or decreased control of underlying illness (clinical record)	
☐	• Hypotension (I0800, clinical record)	
☐	• Dizziness, lightheadedness (clinical record)	
☐	• "Hangover" effect (interview, clinical record)	
☐	• Drowsiness (observation, clinical record)	
☐	• Confusion, delirium unrelated to acute illness or severe depression (C1600, clinical record)	
☐	• Mental depression (I5800, I5900)	
☐	• Unusual excitement (clinical record)	
☐	• Nervousness (clinical record)	
☐	• Headache (interview, clinical record)	
☐	• Insomnia (clinical record)	
☐	• Nightmares (interview, clinical record)	
☐	• Hallucinations (E0100A)	
☐	• Falls (J1700-J1900)	

✓	**Drug-related discomfort** requiring treatment and/or prevention	
☐	• Dehydration (J1550C, I8000)	
☐	• Reduced dietary bulk (from observation of food intake)	
☐	• Lack of exercise (observation, clinical record)	
☐	• Constipation/fecal impaction (H0600, clinical record)	
☐	• Urinary retention (clinical record)	
☐	• Dry mouth (interview, clinical record)	

✓	**Overall status change** for relationship to psychotropic drug use (from clinical record)	
☐	• Major differences in a.m./p.m. performance	
☐	• Decline in cognition/communication (V0100D)	
☐	• Decline in mood (V0100E, V0100F)	
☐	• Decline in behavior	
☐	• Decline in Activities of Daily Living (ADLs) (G0110)	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

18. PHYSICAL RESTRAINTS

Review of Indicators of Physical Restraints

✓	**Evaluation of current restraint use** (based on chart documentation, including care plan)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Does not meet regulatory definition of restraint (stop here and check accuracy of MDS item that triggered this CAA)	
☐	• Evidence of informed consent not evident on chart	
☐	• Medical symptom not identified for treatment via restraints	
☐	• Used for staff convenience	
☐	• Used for discipline purposes	
☐	• Multiple restraints in use	
☐	• Non-restraint interventions not attempted prior to restraining	
☐	• Less restrictive devices not attempted	
☐	• No regular schedule for removing restraints	
☐	• No schedule for frequency by hour of the day for checking on resident's well-being	
☐	• No plan for reducing/eliminating restraints	

✓	**Medical conditions/treatments that may lead to restraint use**	
☐	• Indwelling catheter (H0100A), external catheter (H0100B), or ostomy (H0100C)	
☐	• Parenteral/IV feeding (K0510A1, K0510A2)	
☐	• Feeding tube (K0510B1, K0510B2)	
☐	• Pressure ulcer (M0210) or pressure ulcer care (M1200E)	
☐	• Other skin ulcers, wounds, skin problems (M1040) or wound care (M1200F-M1200I)	
☐	• Oxygen therapy (O0100C)	
☐	• Tracheostomy (O0100E, clinical record)	
☐	• Ventilator or respirator (O0100F)	
☐	• IV medications (O0100H)	
☐	• Transfusions (O0100I)	
☐	• Functional decline, decreased mobility (clinical record)	
☐	• Other medical problem or equipment associated with restraint use (clinical record)	

✓	**Cognitive impairment/behavioral symptoms that may lead to restraint use** (also see Cognitive Loss and Behavior CAAs)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Inattention, easily distracted (C1300A)	
☐	• Disorganized thinking (C1300B)	
☐	• Fidgety, restless	
☐	• Agitation behavior (E0200) – describe the specific verbal or motor activity- e.g. screaming, babbling, cursing, repetitive questions, pacing, kicking, scratching, etc.	
☐	• Confusion (C0100, C0600)	
☐	• Psychosis (E0100A, E0100B)	
☐	• Physical symptoms directed toward others (E0200A)	
☐	• Verbal behavioral symptoms directed toward others (E0200B)	
☐	• Rejection of care (E0800)	
☐	• Wandering (E0900)	
☐	• Delirium (C1600), including side effects of medications (clinical record)	
☐	• Alzheimer's disease (I4200) or other dementia (I4800)	
☐	• Traumatic brain injury (I5500)	
☐	• Psychiatric disorder (I5700-I6100)	

✓	**Risk for falls that may lead to restraint use** (also see Falls CAA)	
☐	• Poor safety awareness, impulsivity (clinical record)	
☐	• Urinary urgency (clinical record)	
☐	• Incontinence of bowel and/or bladder (H0300, H0400)	
☐	• Side effect of medication, such as dizziness, postural/orthostatic hypotension (I0800), sedation, etc. (clinical record)	
☐	• Insomnia, fatigue (D0200D, D0500D)	
☐	• Need for assistance with mobility (G0110)	
☐	• Balance problem (G0300)	
☐	• Postural/orthostatic hypotension (I0800, clinical record)	
☐	• Hip or other fracture (I3900, I4000)	
☐	• Hemiplegia/hemiparesis (I4900), paraplegia (I5000), quadriplegia (I5100)	
☐	• Other neurological disorder (for example, Cerebral Palsy (I4400), Multiple Sclerosis (I5200), Parkinson's Disease (I5300))	
☐	• Respiratory problems (J1100, I6200, I6300, clinical record)	
	• History of falls (J1700 – J1900)	

✓	Adverse reaction to restraint use	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Skin breakdown (Section M)	
☐	• Incontinence or increased incontinence (H0300, H0400, clinical record)	
☐	• Moisture associated skin damage (M1040H)	
☐	• Constipation (H0600)	
☐	• Increased agitation behavior (E0200, clinical record) – describe the specific verbal or motor activity- e.g. screaming, babbling, cursing, repetitive questions, pacing, kicking, scratching, etc.	
☐	• Depression, withdrawal, diminished dignity, social isolation (I5800, I5900, clinical record)	
☐	• Loss of muscle mass, contractures, lessened mobility (G0110, G0300, G0400) and stamina (clinical record)	
☐	• Infections, such as UTI or pneumonia (I1700 – I2500)	
☐	• Frequent attempts to get out of the restraints (P0100), falls (J1700 – J1900, clinical record)	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

19. PAIN

Review of Indicators of Pain

✓	**Diseases and conditions that may cause pain** (diagnosis OR signs/symptoms present)	**Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)**
☐	• Cancer (I0100)	
☐	• Circulatory/heart — Angina, Myocardial Infarction (MI), Atherosclerotic Heart Disease (ASHD) (I0400) — Deep Vein Thrombosis (I0500) — Peripheral Vascular Disease (I0900)	
☐	• Skin/Wound — Pressure ulcer (section M) — Other ulcers, wounds, incision, skin problems (M1040) — Moisture associated skin damage (M1040H)	
☐	• Infections — Urinary tract infection (I2300) — Pneumonia (I2000)	
☐	• Neurological (I4200 – I5500) — Head trauma (clinical record) — Headache — Neuropathy — Post-stroke syndrome	
☐	• Gastrointestinal — Gastroesophageal Reflux Disease/Ulcer (I1200) — Ulcerative Colitis/Crohn's Disease/Inflammatory Bowel Disease (I1300) — Constipation (H0600, clinical record, resident interview)	
☐	• Hospice care (O0100K)	
☐	• Musculoskeletal — Arthritis (I3700) — Osteoporosis (I3800) — Hip fracture (I3900) — Other fracture (I4000) — Back problems (I8000) — Amputation (O0500) — Other (I8000)	
☐	• Dental problems (section L) (L0200)	

✓	Characteristics of the pain	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Location	
☐	• Type (constant, intermittent, varies over time, etc.)	
☐	• What makes it better	
☐	• What makes it worse	
☐	• Words that describe it (for example, aching, soreness, dull, throbbing, crushing) — Burning, pins and needles, shooting, numbness (neuropathic) — Cramping, crushing, throbbing, stabbing (musculoskeletal) — Cramping, tightness (visceral)	

✓	**Frequency and intensity of the pain** (J0400, J0600, J0850)	
☐	• How often it occurs	
☐	• Time or situation of onset	
☐	• How long it lasts	

✓	**Non-verbal indicators of pain** (particularly important if resident is stoic)	
☐	• Facial expression (frowning, grimacing, etc.) (J0800A, J0800C)	
☐	• Vocal behaviors (signing, moaning, groaning, crying, etc.) (J0800A, J0800B)	
☐	• Body position (guarding, distorted posture, restricted limb movement, etc.) (J0800D)	
☐	• Restlessness	

✓	**Pain effect on function**	
☐	• Disturbs sleep (J0500A)	
☐	• Decreases appetite (clinical record)	
☐	• Adversely affects mood (D0200, D0500, clinical record)	
☐	• Limits day-to-day activities (J0500B) (social events, eating in dining room, etc.)	
☐	• Limits independence with at least some Activities of Daily Living (ADLs) (G0110)	

✓	Associated signs and symptoms	Supporting Documentation (Basis/reason for checking the item, including the location, date, and source (if applicable) of that information)
☐	• Agitation or new or increased behavior problems (E0200) – describe the specific verbal or motor activity- e.g. screaming, babbling, cursing, repetitive questions, pacing, kicking, scratching, etc.	
☐	• Delirium (C1600)	
☐	• Withdrawal	

✓	Other Considerations	
☐	• Improper positioning (M1200C)	
☐	• Contractures (G0400)	
☐	• Immobility (G0110)	
☐	• Use of restraints (P0100)	
☐	• Recent change in pain (characteristics, frequency, intensity, etc.) (J0400, J0600)	
☐	• Insufficient pain relief (from resident/staff interview, clinical record, direct observation) (J0100 – J0850)	
☐	• Pain relief occurs, but duration is not sufficient, resulting in breakthrough pain (J0100 – J0850)	

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

20. RETURN TO COMMUNITY REFERRAL

Review of Return to Community Referral

✓	Steps in the Process
☐	1. Document in the care plan whether the individual indicated a desire to talk to someone about the possibility of returning to the community or not (Q0500B).
☐	2. Discuss with the individual and his or her family to identify potential barriers to transition planning. The care planning/discharge planning team should have additional discussions with the individual and family to develop information that will support the individual's smooth transition to community living. (Q0100)
☐	3. Other factors to consider regarding the individual's discharge assessment and planning for community supports include: • Cognitive skills for decision making (C1000) and Cognitive deficits (C0500, C0700-C1000) • Functional/mobility (G0110) or balance (G0300) problems • Need for assistive devices and/or home modifications if considering a discharge home
☐	4. Inform the discharge planning team and other facility staff of the individual's choice.
☐	5. Look at the previous care plans of this individual to identify their previous responses and the issues or barriers they expressed. Consider the individual's overall goals of care and discharge planning from previous items responses (Q0300 and Q0400B). Has the individual indicated that his or her goal is for end-of-life-care (palliative or hospice care)? Or does the individual expect to return home after rehabilitation in your facility? (Q0300, Q0400)
☐	6. Initiate contact with the State-designated local contact agency within approximately 10 business days, and document (Q0600). Follow-up is expected in a "reasonable" amount of time, 10 business days is a recommendation and not a requirement.
☐	7. If the local contact agency does not contact the individual by telephone or in person within approximately 10 business days, make another follow-up call to the designated local contact agency as necessary. The level and type of response needed by a particular individual is determined on a resident-by-resident basis, so timeframes for response may vary depending on the needs of the resident and the supports available within the community.
☐	8. Communicate and collaborate with the State-designated local contact agency on the discharge process. Identify and address challenges and barriers facing the individual in their discharge process. Develop solutions to these challenges in the discharge/transition plan.
☐	9. Communicate findings and concerns with the facility discharge planning team, the individual's support circle, the individual's physician and the local contact agency in order to facilitate discharge/transition planning.

Input from resident and/or family/representative regarding the care area. (Questions/Comments/Concerns/Preferences/Suggestions)

Analysis of Findings		**Care Plan Considerations**
Review indicators and supporting documentation, and draw conclusions. Document: • Description of the problem; • Causes and contributing factors; and • Risk factors related to the care area.	Care Plan Y/N	Document reason(s) care plan will/ will not be developed.

Referral(s) to another discipline(s) is warranted (to whom and why): _____
_____

Information regarding the CAA transferred to the CAA Summary (Section V of the MDS):
☐ Yes ☐ No

Signature/Title:_____ Date:_____

CARE AREA GENERAL RESOURCES

The general resources contained on this page are not specific to any particular care area. Instead, they provide a general listing of known clinical practice guidelines and tools that may be used in completing the RAI CAA process.

***NOTE**: This list of resources is neither prescriptive nor all-inclusive. References to non-U.S. Department of Health and Human Services (HHS) sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or HHS. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.*

- Advancing Excellence in America's Nursing Homes Resources: http://www.nhqualitycampaign.org/star_index.aspx?controls=resImplementationGuides;
- Agency for Health Care Research and Quality – Clinical Information, Evidence-Based Practice: http://www.ahrq.gov/clinic/;
- Alzheimer's Association Resources: http://www.alz.org/professionals_and_researchers_14899.asp#professional;
- American Dietetic Association – Individualized Nutrition Approaches for Older Adults in Health Care Communities (PDF Version): http://www.eatright.org/About/Content.aspx?id=8373;
- American Geriatrics Society Clinical Practice Guidelines and Tools: http://www.americangeriatrics.org/health_care_professionals/clinical_practice/featured_programs_products/;
- American Medical Directors Association (AMDA) Clinical Practice Guidelines and Tools: http://www.amda.com/tools;
- American Pain Society: http://www.ampainsoc.org/pub/cp_guidelines.htm;
- American Society of Consultant Pharmacists Practice Resources: http://www.ascp.com/articles/professional-development/clinical-practice-resources;
- Association for Professionals in Infection Control and Epidemiology Practice Resources: http://www.apic.org/AM/Template.cfm?Section=Practice;
- Centers for Disease Control and Prevention: Infection Control in Long-Term Care Facilities Guidelines: http://www.cdc.gov/HAI/settings/ltc_settings.html;
- CMS Pub. 100-07 State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care Facilities (federal regulations noted throughout; resources provided in endnotes): http://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf;
- Emerging Solutions in Pain Tools: http://www.emergingsolutionsinpain.com/;
- Hartford Institute for Geriatric Nursing Access to Important Geriatric Tools: http://www.hartfordign.org/resources;
- Hartford Institute for Geriatric Nursing Evidence-Based Geriatric Content: http://www.hartfordign.org/practice/consultgerirn/;
- Improving Nursing Home Culture (CMS Special Study): http://www.healthcentricadvisors.org/images/stories/documents/inhc.pdf
- Institute for Safe Medication Practices: http://www.ismp.org/;
- Quality Improvement Organizations: http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1144767874793

CARE AREA GENERAL RESOURCES (cont.)

- University of Missouri's Geriatric Examination Tool Kit: http://web.missouri.edu/~proste/tool/; and
- U.S. Department of Health and Human Services Agency for Healthcare Research and Quality's National Guideline Clearinghouse: http://www.guideline.gov/;

MDS 3.0 Quality Measures

USER'S MANUAL

(v8.0 04-15-2013)

Prepared for:
The Centers for Medicare & Medicaid Services
under Contract No. HSM-500-2008-00021I.
(RTI Project Number 0211942.001.100.004)

QUALITY MEASURES (QM) USER'S MANUAL

CONTENTS

Chapter 1

QM Sample and Record Selection Methodology

The purpose of this chapter is to describe the methodology that is used to select the short and long stay samples as well as the key records that are used to compute the QMs for each of those samples. The first section below will present definitions that are used to describe the selection methodology. The second section describes the selection of the two samples. The third and fourth sections describe the selection of the key records within each of the two samples. Section 5 presents issues to date.

The logic presented below depends upon the concepts of stays and episodes. Detailed specifications for the identification of stays and episodes are presented in a separate document[1].

Section 1: Definitions

Target period. The span of time that defines the QM reporting period (e.g., a calendar quarter).

Stay. The period of time between a resident's entry into a facility and either (a) a discharge, or (b) the end of the target period, whichever comes first. A stay is also defined as a set of contiguous days in a facility. The start of a stay is either:

- An admission entry (A0310F = [01] and A1700 = [1]), OR
- A reentry (A0310F = [01] and A1700 = [2]).

The end of a stay is the earliest of the following:

- Any discharge assessment (A0310F = [10, 11]), OR
- A death in facility tracking record (A0310F = [12]), OR
- The end of the target period.

Episode. A period of time spanning one or more stays. An episode begins with an admission (defined below) and ends with either (a) a discharge, or (b) the end of the target period, whichever comes first. An episode starts with:

- An admission entry (A0310F = [01] and A1700 = [1]).

The end of an episode is the earliest of the following:

- A discharge assessment with return not anticipated (A0310F = [10]), OR
- A discharge assessment with return anticipated (A0310F = [11]) but the resident did not return (A0310F = [10]) within 30 days of discharge, OR
- A death in facility tracking record (A0310F = [12]), OR
- The end of the target period.

[1] See *Appendix C: MDS 3.0 Episode and Stay Determination Logic*.

Admission. An admission entry record (A0310F = [01] and A1700 = [1]) is required when ***any one*** of the following occurs:

- resident has never been admitted to this facility before; OR
- resident has been in this facility previously and was discharged return not anticipated; OR
- resident has been in this facility previously and was discharged return anticipated and did not return within 30 days of discharge.

Reentry. A reentry record (A0310F = [01] and A1700 = [2]) is required when ***all of the following*** occurred prior to this entry, the resident was:

- discharged return anticipated, AND
- returned to facility within 30 days of discharge.

Cumulative days in facility (CDIF). The total number of days within an episode during which the resident was in the facility. It is the sum of the number of days within each stay included in an episode. If an episode consists of more than one stay separated by periods of time outside the facility (e.g., hospitalizations), only those days within the facility would count towards CDIF. Any days outside of the facility (e.g., hospital, home, etc.) would not count towards the CDIF total. The following rules are used when computing CDIF:

- When counting the number of days until the end of the episode, counting stops with (a) the last record in the target period if that record is a discharge assessment (A0310F = [10, 11]), (b) the last record in the target period if that record is a death in facility (A0310F = [12]), or (c) the end of the target period is reached, whichever is earlier.
- When counting the duration of each stay within an episode, include the day of entry (A1600) but not the day of discharge (A2000) unless the entry and discharge occurred on the same day in which case the number of days in the stay is equal to 1.
- While death in facility records (A0310F = [12]) end CDIF counting, these records are not used as target records because they contain only tracking information and do not include clinical information necessary for QM calculation.
- **Special rules for the MDS 2.0/MDS 3.0 transition.** The MDS 3.0 QMs will be based entirely on MDS 3.0 data; no MDS 2.0 data will be used for these measures. Therefore, special rules must be used when constructing episodes and counting days that could span the MDS 3.0 implementation date of 10/1/2010.
    - When computing an episode's CDIF, work backwards from the end of the episode, counting CDIF. If CDIF exceeds 100 before reaching 10/1/2010, stop: the resident is long stay.
    - If an admission entry record is encountered before reaching 10/1/2010, stop and classify the resident as long or short stay depending upon the number of days accumulated.
    - If 10/1/2010 is encountered, stop counting CDIF. If 101 or more days have been accumulated, then resident is long stay. If CDIF is less than or equal to 100, then the episode is undetermined, and the episode is excluded from analysis.

Short stay. An episode with CDIF less than or equal to 100 days as of the end of the target period.

Long stay. An episode with CDIF greater than or equal to 101 days as of the end of the target period.

Target date. The event date for an MDS record, defined as follows:

- For an entry record (A0310F = [01]), the target date is equal to the entry date (A1600).
- For a discharge record (A0310F = [10, 11]) or death-in-facility record (A0310F = [12]), the target date is equal to the discharge date (A2000).
- For all other records, the target date is equal to the assessment reference date (A2300).

Section 2: Selecting the QM Samples

Two resident samples are selected for computing the QMs: a short-stay sample and a long-stay sample. These samples are selected using the following steps:

1. Select all residents whose latest episode either ends during the target period or is ongoing at the end of the target period. This latest episode is selected for QM calculation.

2. For each episode that is selected, compute the cumulative days in the facility (CDIF).

3. If the CDIF is less than or equal to 100 days, the resident is included in the short-stay sample.

4. If the CDIF is greater than or equal to 101 days, the resident is included in the long-stay sample.

Note that all residents who are selected in Step 1 above will be placed in either the short- or long-stay sample and that the two samples are mutually exclusive. If a resident has multiple episodes within the target period, only the latest episode is used.

Within each sample, certain key records are identified which are used for calculating individual measures. These records are defined in the following sections.

Section 3: Short Stay Record Definitions

ASSESSMENT SELECTED	PROPERTY	SELECTION SPECIFICATIONS
Target assessment	Selection period	Most recent 6 months (the short stay target period).
	Qualifying RFAs	A0310A = [01, 02, 03, 04, 05, 06] or A0310B = [01, 02, 03, 04, 05, 06] or A0310F = [10, 11]
	Selection logic	Latest assessment that meets the following criteria: (a) it is contained within the resident's selected episode, (b) it has a qualifying RFA, and (c) its target date is no more than 120 days[1] before the end of the episode.
	Rationale	Records with a qualifying RFA contain all of the items needed to define the QMs. The target assessment need not have a target date within the target period, but it must occur within 120 days before the end of the resident's selected episode (either the target date of a discharge assessment or death in facility record that is the last record in the target period or the end of the target period if the episode is ongoing). 120 days allows 93 days between quarterly assessments plus an additional 27 days to allow for late assessments. The target assessment represents the resident's status at the end of the episode.
Initial assessment	Selection period	First assessment following the admission entry record at the beginning of the resident's selected episode.
	Qualifying RFAs	A0310A = [01] or A0310B = [01, 06] or A0310F = [10, 11]
	Selection logic	Earliest assessment that meets the following criteria: (a) it is contained within the resident's selected episode, (b) it has a qualifying RFA, (c) it has the earliest target date that is greater than or equal to the admission entry date starting the episode, and (d) its target date is no more than 130 days prior to the target date of the target record. The initial assessment cannot be the same as the target assessment. If the same assessment qualifies as both the initial and target assessments, it is used as the target assessment and the initial assessment is considered to be missing.
	Rationale	Records with a qualifying RFA contain all of the items needed to define the QMs. The initial assessment need not have a target date within the target period. The initial assessment represents the resident's status as soon as possible after the admission that marks the beginning of the episode. If the initial assessment is more than 130 days prior to the target assessment, it is not used and the initial record is considered to be missing. This prevents the use of an initial assessment for a short stay in which a large portion of the resident's episode was spent outside the facility. 130 days allows for as many as 30 days of a 100-day stay to occur outside of the facility.

(continued)

[1] A short stay episode can span more than 100 calendar days because days outside of the facility are not counted in defining a 100-day or less short stay episode.

Short Stay Record Definitions (continued)

ASSESSMENT SELECTED	PROPERTY	SELECTION SPECIFICATIONS
Look-back Scan	Selection period	Scan all assessments within the current episode.
	Qualifying RFAs	A0310A = [01, 02, 03, 04, 05, 06] or A0310B = [01, 02, 03, 04, 05, 06] or A0310F = [10, 11]
	Selection logic	Include the target assessment and qualifying earlier assessments in the scan. Include an earlier assessment in the scan if it meets all of the following conditions: (a) it is contained within the resident's episode, (b) it has a qualifying RFA, and (c) its target date is on or before the target date for the target assessment. The target assessment and qualifying earlier assessments are scanned to determine whether certain events or conditions occurred during the look-back period. These events and conditions are specified in the definitions of measures that utilize the look-back scan.
	Rationale	Some measures utilize MDS items that record events or conditions that occurred since the prior assessment was performed. The purpose of the look-back scan is to determine whether such events or conditions occurred during the look-back period. All assessments with target dates within the episode are examined to determine whether the event or condition of interest occurred at any time during the episode.

[1] RFA: reason for assessment.

[2] A short stay episode can span more than 100 calendar days because days outside of the facility are not counted in defining a 100-day or less short stay episode.

Section 4: Long Stay Record Definitions

ASSESSMENT SELECTED	PROPERTY	SELECTION SPECIFICATIONS
Target assessment	Selection period	Most recent 3 months (the long stay target period)
	Qualifying RFAs	A0310A = [01, 02, 03, 04, 05, 06] or A0310B = [01, 02, 03, 04, 05, 06] or A0310F = [10, 11]
	Selection logic	Latest assessment that meets the following criteria: (a) it is contained within the resident's selected episode, (b) it has a qualifying RFA, and (c) its target date is no more than 120 before the end of the episode.
	Rationale	Records with a qualifying RFA contain all of the items needed to define the QMs. The target assessment need not have a target date within the target period, but it must occur within 120 days of the end of the resident's episode (either the last discharge in the target period or the end of the target period if the episode is ongoing). 120 days allows 93 days between quarterly assessments plus an additional 27 days to allow for late assessments. The target assessment represents the resident's status at the end of the episode.
Prior assessment	Selection period	Latest assessment that is 46 to 165 days before the target assessment.
	Qualifying RFAs	A0310A = [01, 02, 03, 04, 05, 06] or A0310B = [01, 02, 03, 04, 05, 06] or A0310F = [10, 11]
	Selection logic	Latest assessment that meets the following criteria: (a) it is contained within the resident's episode, (b) it has a qualifying RFA, and (c) its target date is contained in the window that is 46 days to 165 days preceding the target date of the target assessment. If no qualifying assessment exists, the prior assessment is considered missing.
	Rationale	Records with a qualifying RFA contain all of the items needed to define the QMs. The prior assessment need not have a target date within the target period, but it must occur within the defined window. The window covers 120 days, which allows 93 days between quarterly assessments plus an additional 27 days to allow for late assessments. Requiring a 45 day gap between the prior assessment and the target assessment insures that the gap between the prior and target assessment will not be small (gaps of 45 days or less are excluded).

(continued)

Long Stay Record Definitions (continued)

ASSESSMENT SELECTED	PROPERTY	SELECTION SPECIFICATIONS
Look-back Scan	Selection period	Scan all assessments within the current episode that have target dates no more than 275 days prior to the target assessment.
	Qualifying RFAs	A0310A = [01, 02, 03, 04, 05, 06] or A0310B = [01, 02, 03, 04, 05, 06] or A0310F = [10, 11]
	Selection logic	Include the target assessment and all qualifying earlier assessments in the scan. Include an earlier assessment in the scan if it meets all of the following conditions: (a) it is contained within the resident's episode, (b) it has a qualifying RFA, (c) its target date is on or before the target date for the target assessment, and (d) its target date is no more than 275 days prior to the target date of the target assessment. The target assessment and qualifying earlier assessments are scanned to determine whether certain events or conditions occurred during the look-back period. These events and conditions are specified in the definitions of measures that utilize the look-back scan.
	Rationale	Some measures utilize MDS items that record events or conditions that occurred since the prior assessment was performed. The purpose of the look-back scan is to determine whether such events or conditions occurred during the look-back period. These measures trigger if the event or condition of interest occurred any time during a one year period. A 275 day time period is used to include up to three quarterly OBRA assessments. The earliest of these assessments would have a look-back period of up to 93 days which would cover a total of about one year. All assessments with target dates in this time period are examined to determine whether the event or condition of interest occurred at any time during the time interval.

Chapter 2

MDS 3.0 Quality Measures Logical Specifications

Section 1: Short Stay Quality Measures

MDS 3.0 Measure: Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N001.01 **NQF: 0676** **This measure captures the percent of short stay residents, with at least one episode of moderate/severe pain or horrible/excruciating pain of any frequency, in the last 5 days.**	***Numerator*** Short-stay residents with a selected target assessment where the target assessment meets ***either*** *or* ***both*** of the following two conditions: 1. Condition #1: resident reports daily pain with at least one episode of moderate/severe pain. ***Both*** of the following conditions must be met: 1.1. Almost constant or frequent pain (J0400=[1,2]) ***and*** 1.2. At least one episode of moderate to severe pain (J0600A=[05,06,07,08,09] OR J0600B=[2,3]). 2. Condition #2: resident reports very severe/horrible pain of any frequency (J0600A=[10] OR J0600B=[4]). ***Denominator*** All short-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** If the resident is not included in the numerator (the resident did not meet the pain symptom conditions for the numerator) AND ***any*** of the following conditions are true: 1. The pain assessment interview was not completed (J0200=[0,-,^]). 2. The pain presence item was not completed (J0300=[9,-,^]). 3. For residents with pain or hurting at any time in the last 5 days (J0300 = [1]), any of the following are true: 3.1. The pain frequency item was not completed (J0400=[9,-,^]). 3.2. Neither of the pain intensity items was completed (J0600A=[99,^, -] and J0600B=[9,^,-]). 3.3. The numeric pain intensity item indicates no pain (J0600A=[00]).	Not applicable.

MDS 3.0 Measure: Percent of Residents With Pressure Ulcers That Are New or Worsened (Short Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N002.01 **NQF: 0678** **This measure captures the percentage of short-stay residents with new or worsening Stage II-IV pressure ulcers.**	***Numerator*** Short-stay residents for which a look-back scan indicates one or more new or worsening Stage II-IV pressure ulcers Where on any assessment in the look-back scan: 1. Stage II (M0800A) > [0] and M0800A < = M0300B1, OR 2. Stage III (M0800B) > [0] and M0800B < = M0300C1, OR 3. Stage IV (M0800C) > [0] and M0800C < = M0300D1. ***Denominator*** All residents with one or more assessments that are eligible for a look-back scan, except those with exclusions. ***Exclusions*** Residents are excluded if none of the assessments that are included in the look-back scan has a usable response for M0800A, M0800B, or M0800C. This situation is identified as follows: 1. Examine each assessment that is included in the look-back scan. For each assessment, do the following: 1.1 The response to M0800A is usable if either of the following conditions are true: 1.1.1. M0300B1 = [0, 1, 2, 3, 4, 5, 6, 7, 8, 9] and M0800A = [0, 1, 2, 3, 4, 5, 6, 7, 8, 9] and M0800A ≤ M0300B1. 1.1.2. M0300B1 = [^] and M0800A = [^]. 1.2 The response to M0800B is usable if either of the following conditions are true: 1.2.1. M0300C1 = [0, 1, 2, 3, 4, 5, 6, 7, 8, 9] and M0800B = [0, 1, 2, 3, 4, 5, 6, 7, 8, 9] and M0800B ≤ M0300C1. 1.2.2. M0300C1 = [^] and M0800B = [^]. 1.3 The response to M0800C is usable if either of the following conditions are true: 1.3.1. M0300D1 = [0, 1, 2, 3, 4, 5, 6, 7, 8, 9] and M0800C = [0, 1, 2, 3, 4, 5, 6, 7, 8, 9] and M0800C ≤ M0300D1. 1.3.2. M0300D1 = [^] and M0800C = [^]. 1.4 If ***none*** of the three items M0800A, M0800B, and M0800C is usable, then the assessment is not usable and is discarded. 2. If all of the assessments that are eligible for the look-back scan are discarded and no usable assessments remain, then the resident is excluded from the numerator and the denominator.	1. Indicator of requiring limited or more assistance in bed mobility self-performance on the initial assessment: Covariate = [1] if G0110A1 = [2, 3, 4, 7, 8] Covariate = [0] if G0110A1 = [0, 1, -] 2. Indicator of bowel incontinence at least occasionally on the initial assessment: Covariate = [1] if H0400 = [1, 2, 3] Covariate = [0] if H0400 = [0, 9, - , ^] 3. Have diabetes or peripheral vascular disease on initial assessment: Covariate = [1] if any of the following are true: a. I0900 = [1] (checked) b. I2900 = [1] (checked) c. I8000A through I8000J contains any of the following peripheral vascular disease diagnosis codes: [250.7, 440.20, 440.21, 440.22, 440.23, 440.24, 440.29, 440.31, 440.32, 443.81, 443.9][1]. Covariate = [0] if I0900 = [0, -, missing[2]] AND I2900 = [0, -]AND I8000A through I8000J do not contain any of the peripheral vascular disease diagnosis codes listed above. 4. Indicator of Low Body Mass Index, based on Height (K0200A) and Weight (K0200B) on the initial assessment: Covariate = [1] if BMI ≥ [12.0] AND ≤ [19.0] Covariate = [0] if BMI > [19.0] AND ≤ [40.0] Where: BMI = (weight * 703 / height^2) = ((K0200B) * 703) / (K0200A^2) and the resulting value is rounded to one decimal. Covariate = missing if K0200A = [0,-] OR K0200B = [0,-] OR BMI < [12.0] OR BMI > [40.0]. 5. All covariates are missing if no initial assessment is available.

[1] Condition 3c (scanning I8000A through I8000J for a peripheral vascular disease diagnosis codes) will be discontinued for all assessments with a target date on or after April 1, 2012. Scanning will occur only for assessments with target dates on or before March 31, 2012.

MDS 3.0 Measure: Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N003.01 **NQF: 0680** **The measure reports the percent of short-stay residents who are given, appropriately, the influenza vaccination during the current or most recent influenza season.**	***Numerator*** Residents meeting any of the following criteria on the selected target assessment: 1. resident received the influenza vaccine during the current or most recent influenza season, either in the facility (O0250A = [1]) or outside the facility (O0250C = [2]); or 2. resident was offered and declined the influenza vaccine (O0250C = [4]); or 3. resident was ineligible due to contraindication(s) (O0250C = [3]) (e.g., anaphylactic hypersensitivity to eggs or other components of the vaccine, history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination, bone marrow transplant within the past 6 months). ***Denominator*** All short-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. O0250C = [1] (resident not in facility during the current or most recent influenza season). 2. Resident's age on target date of selected target assessment is 179 days or less.	Not applicable.

[2] Item I0900 can be "missing" on assessments with target dates prior to 4/1/2012 where the item subset code is equal to NP or NQ. The item was not active on those assessments.

MDS 3.0 Measure: Percent of Residents Who Received the Seasonal Influenza Vaccine (Short Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N004.01 **NQF: 0680A** **The measure reports the percent of short-stay residents who received the influenza vaccination during the current or most recent influenza season.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. resident received the influenza vaccine during the current or most recent influenza season, either in the facility (O0250A = [1]) or outside the facility (O0250C = [2]). ***Denominator*** All short-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. O0250C = [1] (resident not in facility during the current or most recent influenza season). 2. Resident's age on target date of selected target assessment is 179 days or less.	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Were Offered and Declined the Seasonal Influenza Vaccine (Short Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N005.01 **NQF: 0680B** **The measure reports the percent of short-stay residents who are offered and declined the influenza vaccination during the current or most recent influenza season.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. resident was offered and declined the influenza vaccine (O0250C = [4]). ***Denominator*** All short-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. O0250C = [1] (resident not in facility during the current or most recent influenza season). 2. Resident's age on target date of selected target assessment is 179 days or less.	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Did Not Receive, Due to Medical Contraindication, the Seasonal Influenza Vaccine (Short Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N006.01 **NQF: 0680C** **The measure reports the percent of short-stay residents who did not receive, due to medical contraindication, the influenza vaccination during the current or most recent influenza season.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. resident was ineligible due to contraindication(s) (O0250C = [3]) (e.g., anaphylactic hypersensitivity to eggs or other components of the vaccine, history of Guillian-Barré Syndrome within 6 weeks after a previous influenza vaccination, bone marrow transplant within the past 6 months). ***Denominator*** All short-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. O0250C = [1] (resident not in facility during the current or most recent influenza season). 2. Resident's age on target date of selected target assessment is 179 days or less.	Not applicable.

MDS 3.0 Measure: Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N007.01 **NQF: 0682** **This measure reports the percent of short-stay residents whose pneumococcal vaccine status is up to date during the 12-month reporting period.**	***Numerator*** Residents meeting any of the following criteria on the selected target assessment: 1. Pneumococcal vaccine status is up to date (O0300A = [1]); or 2. were offered and declined the vaccine (O0300B = [2]); or 3. were ineligible due to medical contraindication(s) (O0300B = [1]) (e.g., anaphylactic hypersensitivity to components of the vaccine; bone marrow transplant within the past 12 months; or receiving a course of chemotherapy within the past two weeks). ***Denominator*** All short-stay residents with a selected target assessment. ***Exclusions*** Resident's age on target date of selected target assessment is less than 5 years (i.e., resident has not yet reached 5th birthday on target date).	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Received the Pneumococcal Vaccine (Short Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N008.01 **NQF: 0682A** **This measure reports the percent of short-stay residents who received the pneumococcal polysaccharide vaccine during the 12-month reporting period.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. Pneumococcal vaccine status is up to date (O0300A = [1]). ***Denominator*** All short-stay residents with a selected target assessment. ***Exclusions*** Resident's age on target date of selected target assessment is less than 5 years (i.e., resident has not yet reached 5th birthday on target date).	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Were Offered and Declined the Pneumococcal Vaccine (Short Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N009.01 **NQF: 0682B** **This measure reports the percent of short-stay residents who were offered and declined the pneumococcal polysaccharide vaccine during the 12-month reporting period.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. were offered and declined the vaccine (O0300B = [2]). ***Denominator*** All short-stay residents with a selected target assessment. ***Exclusions*** Resident's age on target date of selected target assessment is less than 5 years (i.e., resident has not yet reached 5th birthday on target date).	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Did Not Receive, Due to Medical Contraindication, the Pneumococcal Vaccine (Short Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N010.01 **NQF: 0682C** **This measure reports the percent of short-stay residents who did not receive, due to medical contraindication, the pneumococcal polysaccharide vaccine during the 12-month reporting period.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. were ineligible due to medical contraindication(s) (O0300B = [1]) (e.g., anaphylactic hypersensitivity to components of the vaccine; bone marrow transplant within the past 12 months; or receiving a course of chemotherapy within the past two weeks). ***Denominator*** All short-stay residents with a selected target assessment. ***Exclusions*** Resident's age on target date of selected target assessment is less than 5 years (i.e., resident has not yet reached 5th birthday on target date).	Not applicable.

MDS 3.0 Measure: Percent of Short-Stay Residents Who Newly Received an Antipsychotic Medication[3]

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N011.01 **NQF: none** **This measure reports the percentage of short-stay residents who are receiving an antipsychotic medication during the target period but not on their initial assessment.**	***Numerator*** Short-stay residents for whom one or more assessments in a look-back scan (*not including* the initial assessment) indicates that antipsychotic medication was received: • For assessments with target dates on or before 03/31/2012: N0400A = [1]. • For assessments with target dates on or after 04/01/2012: N0410A=[1,2,3,4,5,6,7]. Note that residents are excluded from this measure if their initial assessment indicates antipsychotic medication use or if antipsychotic medication use is unknown on the initial assessment (see exclusion #3, below). ***Denominator*** All short-stay residents who do not have exclusions and who meet all of the following conditions: • The resident has a target assessment, and • The resident has an initial assessment, and • The target assessment is not the same as the initial assessment. ***Exclusions*** 1. The following is true for ***all*** assessments in the look-back scan (excluding the initial assessment): 1.1. For assessments with target dates on or before 03/31/2012: N0400A = [-]. 1.2. For assessments with target dates on or after 04/01/2012: N0410A=[-]. 2. ***Any*** of the following related conditions are present on ***any*** assessment in a look-back scan: 2.1. Schizophrenia (I6000 = [1]). 2.2. Tourette's Syndrome (I5350 = [1]). 2.3. Huntington's Disease (I5250 = [1]). 3. The resident's initial assessment indicates antipsychotic medication use or antipsychotic medication use is unknown: 3.1. For initial assessments with target dates on or before 03/31/2012: N0400A = [1,-]. 3.2. For initial assessments with target dates on or after 04/01/2012: N0410A=[1,2,3,4,5,6,7,-].	Not applicable.

[3] This measure has not been submitted to NQF for approval.

Section 2: Long Stay Quality Measures

MDS 3.0 Measure: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N013.01 **NQF: 0674** **This measure reports the percent of long-stay residents who have experienced one or more falls with major injury reported in the target period or look-back period.**	***Numerator*** Long-stay residents with one or more look-back scan assessments that indicate one or more falls that resulted in major injury (J1900C = [1, 2]). ***Denominator*** All long-stay nursing home residents with a one or more look-back scan assessments except those with exclusions. ***Exclusions*** Resident is excluded if one of the following is true for ***all*** of the look-back scan assessments: 1. The occurrence of falls was not assessed (J1800 = [-]), OR 2. The assessment indicates that a fall occurred (J1800 = [1]) AND the number of falls with major injury was not assessed (J1900C = [-]).	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Self-Report Moderate to Severe Pain (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N014.01 **NQF: 0677** **This measure captures the percent of long-stay residents who report either (1) almost constant or frequent moderate to severe pain in the last 5 days or (2) any very severe/horrible in the last 5 days.**	***Numerator*** Long-stay residents with a selected target assessment where the target assessment meets ***either*** *or* ***both*** of the following two conditions: 1. Condition #1: resident report almost constant or frequent moderate to severe pain in the last 5 days. ***Both*** of the following conditions must be met: 1.1. Almost constant or frequent pain (J0400=[1,2]), ***and*** 1.2. At least one episode of moderate to severe pain: (J0600A=[05,06,07,08,09] OR J600B=[2,3]). 2. Condition #2: resident reports very severe/horrible pain of any frequency (J0600A=[10] OR J0600B=[4]). ***Denominator*** All long-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. The target assessment is an admission assessment, a PPS 5-day assessment, or a PPS readmission/return assessment (A0310A=[01] or A0310B=[01,06]). 2. The resident is not included in the numerator (the resident did not meet the pain symptom conditions for the numerator) AND any of the following conditions are true: 2.1. The pain assessment interview was not completed (J0200=[0,-,^]). 2.2. The pain presence item was not completed (J0300=[9,-,^]). 2.3. For residents with pain or hurting at any time in the last 5 days (J0300 = [1]), ***any*** of the following are true: 2.3.1. The pain frequency item was not completed (J0400=[9,-,^]). 2.3.2. Neither of the pain intensity items was completed (J0600A=[99,^, -] and J0600B=[9,^,-]). 2.3.3. The numeric pain intensity item indicates no pain (J0600A=[00]).	Independence or modified independence in daily decision making on the prior assessment Covariate = 1 if C1000 = [0, 1] ***or*** if (C0500 ≥ [13] and C0500 ≤ [15]) Covariate = 0 if C1000 = [2, 3] ***or*** if (C0500 ≥ [00] and C0500 ≤ [12]). Covariate = missing if ***either*** of the following are true: 1. C0500 = [99,-,^] ***and*** C1000 = [-,^]. 2. No prior assessment is available.

MDS 3.0 Measure: Percent of High-Risk Residents With Pressure Ulcers (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N015.01 **NQF: 0679** **This measure captures the percentage of long-stay, high-risk residents with Stage II-IV pressure ulcers.**	***Numerator*** All long-stay residents with a selected target assessment that meets ***both*** of the following conditions: 1. Condition #1: There is a high risk for pressure ulcers, where "high-risk" is defined in the denominator definition below. 2. Condition #2: Stage II-IV pressure ulcers are present, as indicated by ***any*** of the following three conditions: 2.1 M0300B1 = [1, 2, 3, 4, 5, 6, 7, 8, 9] ***or*** 2.2. M0300C1 =[1, 2, 3, 4, 5, 6, 7, 8, 9] ***or*** 2.3. M0300D1 = [1, 2, 3, 4, 5, 6, 7, 8, 9]. ***Denominator*** All long-stay residents with a selected target assessment who meet the definition of high risk, except those with exclusions. Residents are defined as high-risk if they meet ***one or more*** of the following three criteria on the target assessment: 1. Impaired bed mobility or transfer indicated, by ***either or both*** of the following: 1.1. Bed mobility, self-performance (G0110A1) = [3, 4, 7, 8]. 1.2. Transfer, self-performance (G0110B1) = [3, 4, 7, 8]. 2. Comatose (B0100 = [1]) 3. Malnutrition or at risk of malnutrition (I5600 = [1]) (checked). ***Exclusions*** 1. Target assessment is an admission assessment (A0310A = [01]) or a PPS 5-day or readmission/return assessment (A0310B = [01, 06]). 2. If the resident is not included in the numerator (the resident did not meet the pressure ulcer conditions for the numerator) AND ***any*** of the following conditions are true: a. M0300B1 = [-] b. M0300C1 = [-] c. M0300D1 = [-].	Not applicable.

MDS 3.0 Measure: Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N016.01 **NQF: 0681** **The measure reports the percent of long-stay residents who are given, appropriately, the influenza vaccination during the current or most recent influenza season.**	***Numerator*** Residents meeting **any** of the following criteria on the selected target assessment: 1. Resident received the influenza vaccine during the current or most recent influenza season, either in the facility (O0250A = [1]) or outside the facility (O0250C = [2]); or 2. Resident was offered and declined the influenza vaccine (O0250C = [4]); or 3. Resident was ineligible due to contraindication(s) (O0250C = [3]) (e.g., anaphylactic hypersensitivity to eggs or other components of the vaccine, history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination, bone marrow transplant within the past 6 months). ***Denominator*** All long-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** Resident was not in facility during the current or most recent influenza season (O0250C = [1]).	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Received the Seasonal Influenza Vaccine (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N017.01 **NQF: 0681A** **The measure reports the percent of long-stay residents who received the influenza vaccination during the current or most recent influenza season.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. resident received the influenza vaccine during the current or most recent influenza season, either in the facility (O0250A = [1]) or outside the facility (O0250C = [2]). ***Denominator*** All long-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. O0250C = [1] (resident not in facility during the current or most recent influenza season).	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Were Offered and Declined the Seasonal Influenza Vaccine (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N018.01 **NQF: 0681B** **The measure reports the percent of long-stay residents who are offered and declined the influenza vaccination during the current or most recent influenza season.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. resident was offered and declined the influenza vaccine (O0250C = [4]). ***Denominator*** All long-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. O0250C = [1] (resident not in facility during the current or most recent influenza season).	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Did Not Receive, Due to Medical Contraindication, the Seasonal Influenza Vaccine (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N019.01 **NQF: 0681C** **The measure reports the percent of long-stay residents who did not receive, due to medical contraindication, the influenza vaccination during the current or most recent influenza season.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. resident was ineligible due to contraindication(s) (O0250C = [3]) (e.g., anaphylactic hypersensitivity to eggs or other components of the vaccine, history of Guillian-Barré Syndrome within 6 weeks after a previous influenza vaccination, bone marrow transplant within the past 6 months). ***Denominator*** All long-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. O0250C = [1] (resident not in facility during the current or most recent influenza season).	Not applicable.

MDS 3.0 Measure: Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N020.01 **NQF: 0683** **This measure reports the percent of long-stay residents whose pneumococcal polysaccharide vaccine status is up to date.**	***Numerator*** Residents meeting any of the following criteria on the selected target assessment: 1. Have an up to date PNEUMOCOCCAL VACCINE status (O0300A = [1]); or 2. Were offered and declined the vaccine (O0300B = [2]); or 3. Were ineligible due to medical contraindication(s) (e.g., anaphylactic hypersensitivity to components of the vaccine; bone marrow transplant within the past 12 months; or receiving a course of chemotherapy within the past two weeks) (O0300B = [1]). ***Denominator*** All long-stay residents with a selected target assessment.	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Received the Pneumococcal Vaccine (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N021.01 **NQF: 0683A** **This measure reports the percent of long-stay residents who received the pneumococcal polysaccharide vaccine during the 12-month reporting period.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. PNEUMOCOCCAL VACCINE status is up to date (O0300A = [1]). ***Denominator*** All long-stay residents with a selected target assessment.	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Were Offered and Declined the Pneumococcal Vaccine (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N022.01 **NQF: 0683B** **This measure reports the percent of long-stay residents who were offered and declined the pneumococcal polysaccharide vaccine during the 12-month reporting period.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. were offered and declined the vaccine (O0300B = [2]). ***Denominator*** All long-stay residents with a selected target assessment.	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Did Not Receive, Due to Medical Contraindication, the Pneumococcal Vaccine (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N023.01 **NQF: 0683C** **This measure reports the percent of long-stay residents who did not receive, due to medical contraindication, the pneumococcal polysaccharide vaccine during the 12-month reporting period.**	***Numerator*** Residents meeting the following criteria on the selected target assessment: 1. were ineligible due to medical contraindication(s) (O0300B = [1]) (e.g., anaphylactic hypersensitivity to components of the vaccine; bone marrow transplant within the past 12 months; or receiving a course of chemotherapy within the past two weeks). ***Denominator*** All long-stay residents with a selected target assessment.	Not applicable.

MDS 3.0 Measure: Percent of Residents With a Urinary Tract Infection (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N024.01 **NQF: 0684** **The measure reports the percentage of long stay residents who have a urinary tract infection**	***Numerator*** Long-stay residents with a selected target assessment that indicates urinary tract infection within the last 30 days (I2300 = [1]). ***Denominator*** All long-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. Target assessment is an admission assessment (A0310A = [01]) or a PPS 5-day or readmission/return assessment (A0310B = [01, 06]). 2. Urinary tract infection value is missing (I2300 = [-]).	Not applicable.

MDS 3.0 Measure: Percent of Low Risk Residents Who Lose Control of Their Bowel or Bladder (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N025.01 **NQF: 0685** **The measure reports the percent of long-stay residents who frequently lose control of their bowel or bladder.**	***Numerator*** Long-stay residents with a selected target assessment that indicates frequently or always incontinence of the bladder (H0300 = [2, 3]) or bowel (H0400 = [2, 3]). ***Denominator*** All long-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. Target assessment is an admission assessment (A0310A = [01]) or a PPS 5-day or readmission/return assessment (A0310B = [01, 06]). 2. Resident is not in numerator and H0300 = [-] OR H0400 = [-]. 3. Residents who have **any** of the following high risk conditions: a. Severe cognitive impairment on the target assessment as indicated by (C1000 = [3] and C0700 = [1]) OR (C0500 ≤ [7]). b. Totally dependent in bed mobility self-performance (G0110A1 = [4, 7, 8]). c. Totally dependent in transfer self-performance (G0110B1 = [4, 7, 8]). d. Totally dependent in locomotion on unit self-performance (G0110E1 = [4, 7, 8]). 4. Resident does not qualify as high risk (see #3 above) and ***both*** of the following two conditions are true for the target assessment: a. C0500 = [99, ^, -], ***and*** b. C0700 = [^, -] ***or*** C1000 = [^, -]. 5. Resident does not qualify as high risk (see #3 above) and ***any*** of the following three conditions are true: a. G0110A1 = [-] b. G0110B1 = [-] c. G0110E1 = [-]. 6. Resident is comatose (B0100 = [1]) or comatose status is missing (B0100 = [-]) on the target assessment. 7. Resident has an indwelling catheter (H0100A = [1]) or indwelling catheter status is missing (H0100A = [-]) on the target assessment. 8. Resident has an ostomy (H0100C = [1]) or ostomy status is missing (H0100C = [-]) on the target assessment.	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N026.01 **NQF: 0686** **This measure reports the percentage of residents who have had an indwelling catheter in the last 7 days.**	***Numerator*** Long-stay residents with a selected target assessment that indicates the use of indwelling catheters (H0100A = [1]). ***Denominator*** All long-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. Target assessment is an admission assessment (A0310A = [01]) or a PPS 5-day or readmission/return assessment (A0310B = [01, 06]). 2. Target assessment indicates that indwelling catheter status is missing (H0100A = [-]). 3. Target assessment indicates neurogenic bladder (I1550 = [1]) or neurogenic bladder status is missing (I1550 = [-]). 4. Target assessment indicates obstructive uropathy (I1650 = [1]) or obstructive uropathy status is missing (I1650 = [-]).	1. Frequent bowel incontinence on prior assessment (H0400 = [2, 3]). Covariate = [1] if H0400 = [2, 3] Covariate = [0] if H0400 = [0, 1, 9, -]. 2. Pressure ulcers at stages II, III, or IV on prior assessment: Covariate = [1] if any of the following are true: a. M0300B1 = [1, 2, 3, 4, 5, 6, 7, 8, 9], ***or*** b. M0300C1 = [1, 2, 3, 4, 5, 6, 7, 8, 9], ***or*** c. M0300D1 = [1, 2, 3, 4, 5, 6, 7, 8, 9] Covariate = [0] if M0300B1 = [0, ^] ***and*** M0300C1 = [0, ^] ***and*** M0300D1 = [0, ^]. Covariate = missing if M0300B1 = [-] AND M0300C1 = [-] AND M0300D1 = [-]. 3. All covariates are missing if no prior assessment is available.

MDS 3.0 Measure: Percent of Residents Who Were Physically Restrained (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N027.01 **NQF: 0687** **This measure reports the percent of long-stay nursing facility residents who are physically restrained on a daily basis.**	***Numerator*** Long-stay residents with a selected target assessment that indicates daily physical restraints, where: trunk restraint used in bed (P0100B = [2]), OR limb restraint used in bed (P0100C = [2]), OR trunk restraint used in chair or out of bed (P0100E = [2]), OR limb restraint used in chair or out of bed (P0100F = [2]), OR chair prevents rising used in chair or out of bed (P0100G) = [2]). ***Denominator*** All long-stay residents with a target assessment, except those with exclusions. ***Exclusions*** Resident is not in numerator and any of the following is true: P0100B = [-], OR P0100C = [-], OR P0100E = [-], OR P0100F = [-], OR P0100G = [-].	Not applicable.

MDS 3.0 Measure: Percent of Residents Whose Need for Help with Activities of Daily Living Has Increased (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N028.01 **NQF: 0688** **This measure reports the percent of long-stay residents whose need for help with late-loss Activities of Daily Living (ADLs) has increased when compared to the prior assessment.**	***Numerator*** Long-stay residents with selected target and prior assessment assessments that indicate the need for help with late-loss Activities of Daily Living (ADLs) has increased when the selected assessments are compared. The four late-loss ADL items are self-performance bed mobility (G0110A1), self-performance transfer (G0110B1), self-performance eating (G0110H1), and self-performance toileting (G0110I1). An increase is defined as an increase in two or more coding points in one late-loss ADL item or one point increase in coding points in two or more late-loss ADL items. Note that for each of these four ADL items, if the value is equal to [7, 8] on either the target or prior assessment, then recode the item to equal [4] to allow appropriate comparison.. Residents meet the definition of increased need of help with late-loss ADLs if either of the following are true **1.** ***At least* two** of the following are true (note that in the notation below, [t] refers to the target assessment, and [t-1] refers to the prior assessment): 1. Bed mobility: [Level at target assessment (G0110A1[t]] - [Level at prior assessment (G0110A1[t-1])] > [0], or 2. Transfer: [Level at target assessment (G0110B1[t]] - [Level at prior assessment (G0110B1[t-1])] > [0], or 3. Eating: [Level at target assessment (G0110H1[t]] - [Level at prior assessment (G0110H1[t-1])] > [0], or 4. Toileting: [Level at target assessment (G0110I1[t]] - [Level at prior assessment (G0110I1[t-1])] > [0]. ***2. At least one*** of the following is true: 1. Bed mobility: [Level at target assessment (G0110A1[t]] - [Level at prior assessment (G0110A1[t-1])] > [1], or 2. Transfer: [Level at target assessment (G0110B1[t]] - [Level at prior assessment (G0110B1[t-1])] > [1], or 3. Eating: [Level at target assessment (G0110H1[t]] - [Level at prior assessment (G0110H1[t-1])] > [1], or 4. Toileting: [Level at target assessment (G0110I1[t]] - [Level at prior assessment (G0110I1[t-1])] > [1].	Not applicable.

(continued)

MDS 3.0 Measure: Percent of Residents Whose Need for Help with Activities of Daily Living Has Increased (Long Stay) (continued)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
	Denominator All long-stay residents with a selected target and prior assessment except those with exclusions. ***Exclusions*** 1. All four of the late-loss ADL items indicate total dependence on the prior assessment, as indicated by: Bed Mobility (G0110A1) = [4, 7, 8] AND Transferring (G0110B1) = [4, 7, 8] AND Eating (G0110H1) = [4, 7, 8] AND Toileting (G0110I1) = [4, 7, 8]. 2. Three of the late-loss ADLs indicate total dependence on the prior assessment, as in #1 AND the fourth late-loss ADL indicates extensive assistance (value 3) on the prior assessment. 3. If resident is comatose (B0100 = [1, -]) on the target assessment. 4. Prognosis of life expectancy is less than 6 month (J1400 = [1, -]) on the target assessment. 5. Hospice care (O0100K2 = [1, -]) on the target assessment. 6. The resident is not in the numerator AND Bed Mobility (G0110A1) = [-] on the prior or target assessment, OR Transferring (G0110B1) = [-] on the prior or target assessment, OR Eating (G0110H1) = [-] on the prior or target assessment, OR Toileting (G0110I1) = [-] on the prior or target assessment].	

MDS 3.0 Measure: Percent of Residents Who Lose Too Much Weight (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N029.01 **NQF: 0689** **The measure captures the percentage of long-stay residents who had a weight loss of 5% or more in the last month or 10% or more in the last two quarters who were not on a physician prescribed weight-loss regimen noted in an MDS assessment during the selected quarter.**	***Numerator*** Long-stay nursing home residents with a selected target assessment which indicates a weight loss of 5% or more in the last month or 10% or more in the last 6 months who were not on a physician prescribed weight-loss regimen (K0300 = [2]. ***Denominator*** Long-stay nursing home residents with a selected target assessment except those with exclusions. ***Exclusions*** 1. Target assessment is an OBRA admission assessment (A0310A = [01]) OR a PPS 5-day or readmission/return assessment (A0310B = [01, 06]). 2. Weight loss item is missing on target assessment (K0300 = [-].	Not applicable.

MDS 3.0 Measure: Percent of Residents Who Have Depressive Symptoms (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N030.01 **NQF: 0690** **The measure reports the percentage of long-stay residents who have had symptoms of depression during the 2-week period preceding the MDS 3.0 target assessment date.**	***Numerator*** Long-stay residents with a selected target assessment where the target assessment meets ***either*** of the following two conditions: *CONDITION A* (The resident mood interview must meet Part 1 ***and*** Part 2 below) PART 1: • Little interest or pleasure in doing things half or more of the days over the last two weeks (D0200A2 = [2, 3]) ***OR*** • Feeling down, depressed, or hopeless half or more of the days over the last two weeks (D0200B2 = [2, 3]) PART 2: The resident interview total severity score indicates the presence of depression (D0300 ≥ [10] and D0300 ≤ [27]). *CONDITION B*: (The staff assessment of resident mood must meet Part 1 ***and*** Part 2 below) PART 1: • Little interest or pleasure in doing things half or more of the days over the last two weeks (D0500A2 = [2, 3]) ***OR*** • Feeling or appearing down, depressed, or hopeless half or more of the days over the last two weeks (D0500B2 = [2, 3]) PART 2: The staff assessment total severity score indicates the presence of depression (D0600 ≥ [10] and D0600 ≤ [30]).	Not applicable.

(continued)

MDS 3.0 Measure: Percent of Residents Who Have Depressive Symptoms (Long Stay) (continued)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
	Denominator All long-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. Resident is comatose or comatose status is missing (B0100 = [1, -]). 2. Resident is not included in the numerator (the resident did not meet the depression symptom conditions for the numerator) AND both of the following are true: a. D0200A2 = [^, -] OR D0200B2 = [^, -] OR D0300=[99, -, ^]. b. D0500A2 = [^, -] OR D0500B2 = [^, -] OR D0600=[-, ^].	

MDS 3.0 Measure: Percent of Long-Stay Residents Who Received An Antipsychotic Medication [4]

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N031.02 **NQF: none** **This measure reports the percentage of long-stay residents who are receiving antipsychotic drugs in the target period.**	***Numerator*** Long-stay residents with a selected target assessment where the following condition is true: antipsychotic medications received. This condition is defined as follows: • For assessments with target dates on or before 03/31/2012: N0400A = [1]. • For assessments with target dates on or after 04/01/2012: N0410A=[1,2,3,4,5,6,7]. ***Denominator*** All long-stay residents with a selected target assessment, except those with exclusions. ***Exclusions*** 1. The resident did not qualify for the numerator and any of the following is true: 1.1. For assessments with target dates on or before 03/31/2012: N0400A = [-]. 1.2. For assessments with target dates on or after 04/01/2012: N0410A=[-]. 2. ***Any*** of the following related conditions are present on the target assessment (unless otherwise indicated): 2.1. Schizophrenia (I6000 = [1]). 2.2. Tourette's Syndrome (I5350 = [1]). 2.3. Tourette's Syndrome (I5350 = [1]) on the prior assessment if this item is not active on the target assessment and if a prior assessment is available. 2.4. Huntington's Disease (I5250 = [1]).	Not applicable.

[4] This measure has not been submitted to NQF for approval. The measure will appear on Nursing Home Compare beginning in Summer, 2012 and will appear in the CASPER reports at a later time. When it appears on CASPER, it will replace the surveyor measure: Prevalence of Psychoactive Medication Use, in the Absence of Psychotic or Related Conditions (Long Stay).

MDS 3.0 Quality Measures

USER'S MANUAL

APPENDIX A

Technical Details

(v8.0 04-15-2013)

Prepared for:
The Centers for Medicare & Medicaid Services
under Contract No. HSM-500-2008-00021I.
(RTI Project Number 0211942.001.100.004)

Quality Measures (QM) Technical Details

List of Contents:

Section 1
Introduction

This appendix presents technical details regarding the calculation of the nursing home quality measures (QMs), including the methodology used for risk adjustment.

Overview of QM Calculations

The QMs are created from counts of nursing facility long stay residents or short stay residents who have certain conditions or problems (e.g., falls resulting in major injury). For example, facility-level scores for the long stay falls QM are computed by: 1) counting residents in the facility who had a fall resulting in major injury and 2) computing the percent of residents in the facility who had valid MDS data and who experienced such a fall. The detailed logic for defining the resident-level outcomes for each QM is presented in the QM Sample and Record Selection Methodology section and in the Quality Measure Logic Specifications section of this manual. This logic is listed under the "Numerator" entry for each QM.

A Note on Risk Adjustment

Risk adjustment refines raw QM scores to better reflect the prevalence of problems that facilities should be able to address. Two complementary approaches to risk adjustment are applied to the QMs.

One approach involves exclusion of residents whose outcomes are not under nursing facility control (e.g., outcome is evidenced on admission to the facility) or the outcome may be unavoidable (e.g., the resident has end-stage disease or is comatose). All of the QMs, except the vaccination QMs, are shaped by one or more exclusions. For each QM, the prevalence of the outcome across all residents in a nursing facility, after exclusions, is the *facility-level observed QM score*.

A second approach involves adjusting QM scores directly, using logistic regression. This method of adjustment employs *resident-level covariates* that are found to increase the risks of an outcome. Detailed specifications for resident-level covariates are presented in the Quality Measure Logical Specifications section of this manual. This approach involves the following steps:

- First, resident-level covariates were used in a logistic regression model to calculate a *resident-level expected QM score* (the probability that the resident will evidence the outcome, given the presence or absence of characteristics measured by the covariates). Section 3 of this Appendix presents the details for calculating expected scores for residents.

- Then, an average of all resident-level expected QM scores for the nursing facility was calculated to create a *facility-level expected QM score.*

- The final *facility-level adjusted QM score* was based on a calculation which combines the *facility-level expected score* and the *facility-level observed score*. The details for

calculating facility-level adjusted scores are presented in Section 4 of this Appendix. The parameters used for each release of the QMs are presented in Appendix B.

Only three of the QMs are adjusted using resident level covariates for public reporting:

- N002.01: Percent of Residents With Pressure Ulcers That Are New or Worsened (Short Stay)
- N014.01: Percent of Residents Who Self-Report Moderate to Severe Pain (Long Stay)
- N026.01: Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (Long Stay)

The remaining QMs are not adjusted using resident-level covariates. For these measures, facility-level observed QM scores are reported.

Section 2
Steps Used In National QM Calculation

Introduction

This section outlines the processing steps used to calculate QMs. The description below uses the Q3 2011 as the target period. The dates associated with these steps would be updated, as appropriate, for subsequent quarterly releases of the QMs. It is important to note two items that recurred throughout the process:

Every step in file construction and QM calculation proceeded in parallel for two samples of residents and facilities: a "Long stay" (LS) sample and a "Short stay" (SS) sample.

- Two "target periods" were defined:
  - a "Current Period" which was one quarter, Q3 2011, for LS residents and two quarters, Q2 and Q3 2011, for SS patients. Data from the current periods were used as the target period for final QM reporting;
  - a "Current Year", Q4 2010 through Q3 2011, data from which were used to estimate logistic regressions for risk adjustment.

Processing Steps:

1. ***MDS Selection.*** All MDS records for U.S. nursing facilities in Q4 2010 through Q3 2011 were selected.

2. ***Episode Creation.*** Using the definitions contained elsewhere in this document, episodes were created from the available data. Each episode was classified as either long or short stay depending upon the number of cumulative days in the facility. Only the latest episode was retained for each resident.

3. ***Sampling for LS QMs.*** Nursing facilities and residents were sampled to provide data for LS QM and covariate calculations.
   a. "Current Period" LS resident sample: residents were included in this sample if they had a long stay episode that ended within the last quarter of the target period (i.e., Q2 2011).
   b. "Current Year" LS resident sample: residents were included in this sample if they had a long stay episode in the target period Q4 2010 through Q3 2011).

4. ***Sampling for SS QMs.*** Nursing facilities and residents were sampled to provide data for SS QM and covariate calculations.

    a. "Current Period" SS resident sample: residents were included in this sample if they had a short stay episode that ended within the last two quarters of the target period (i.e., Q2 2011 or Q3 2011).

    b. "Current Year" SS resident sample: residents were included in this sample if they had a short stay episode in the target period Q4 2010 through Q3 2011).

5. ***Resident-level QM Calculation Files.*** At this point, resident-level QM calculation files were created, separately for LS residents and SS residents, for the two target periods, using the specified target, prior, and initial assessments for each resident record, if available.

6. ***Resident-level QM and Covariate Calculation Files.*** Next, resident-level QM scores were calculated (and covariate values were calculated for the risk-adjusted QMs), separately for each LS resident and SS resident.

    a. Resident-level QM calculation (all QMs):

        i. Resident exclusions: For each QM, excluded residents were assigned a missing value for that QM. Residents with missing covariate values were also assigned a missing value for that QM.

        ii. QM values: does the resident "trigger" the QM?

            1. If "Yes", then store a value of 1 for that QM in the resident-level QM calculation record appropriate to that resident for a target period.

            2. If "No", then store a value of 0 for that QM in the resident-level QM calculation record appropriate to that resident for a target period.

    b. Resident-level covariate calculation (risk-adjusted QMs):

        i. Resident exclusions: For each QM, excluded residents were assigned a missing value for that QM. Residents with missing covariate values were also assigned a missing value for that QM.

        ii. Covariate: does the resident "trigger" the covariate?

            1. If "Yes", then store a value of 1 for that covariate in the resident-level QM calculation record appropriate to that resident for a target period.

            2. If "No", then store a value of 0 for that covariate in the resident-level QM calculation record appropriate to that resident for a target period.

7. ***Logistic Regressions.*** With the resident-level files complete, and all relevant exclusions applied, logistic regressions for the risk-adjusted QMs were estimated using the Current Year LS and SS samples (Q4 2010 to Q3 2011).

    a. Input: LS or SS resident-level file.

b. Dependent variable: was the QM triggered? (yes = 1, no = 0).

c. Predictors: resident-level covariates.

d. Calculation of logistic regressions: (See Section 3 in this Appendix).

e. Output values: logistic regression constant term and resident-level covariate coefficients for each of the risk-adjusted QMs. The resulting values are given in Table B.1 of Appendix B.

8. ***Resident-level Expected QM Scores.*** For the QMs that were risk adjusted, resident-level expected QM scores were calculated for each resident for the Current Period LS and SS samples. (See Section 3 in this Appendix for calculation formulas).

   a. Input: logistic regression constant term and resident-level covariate coefficients from the previous step for each adjusted QM.

   b. Output values: resident-level expected QM scores for each resident, for each of the risk-adjusted QMs.

9. ***National Mean QMs.*** National mean observed QMs were needed for calculating the facility-level adjusted QM scores below. The overall national mean observed QM scores for the Current Period LS and SS samples were calculated, for each risk adjusted QM:

   a. Numerator: for each QM, count the total number or residents that triggered the QM and sum for the nation.

   b. Denominator: for each QM, count the total number of residents retained after exclusions and sum for the nation. Note that the sample will include only those residents with non-missing data for the component covariates.

   c. Overall national mean observed QM score: divide the numerator by the denominator.

10. ***Facility-level Observed QM Scores.*** For all QMs, the facility-level observed QM scores were calculated for the Current Period LS and SS samples -- for the QMs that were not risk adjusted, these are the measures that will be publicly reported.

    a. Numerator: for each QM, count the total number of residents who triggered the QM in each facility and sum for the nursing facility.

    b. Denominator: for each QM, count the total number of residents retained after exclusions for each facility and sum for the nursing facility. Note that the sample will include only those residents with non-missing data for the component covariates.

    c. Facility-level observed QM scores: divide the numerator by the denominator for each QM and nursing facility.

11. ***Facility-level Expected QM Scores.*** For the risk-adjusted QMs, the facility-level expected QM scores are calculated for the Current Period LS and SS samples. This is done by averaging the resident-level expected QM scores for each QM within each nursing facility. Note that the sample will include only those residents with non-missing data for the component covariates.

12. ***Facility-level Adjusted QM Scores.*** Finally, for the risk-adjusted QMs, the facility-level adjusted QM scores were calculated for the Current Period LS and SS samples.

    a. Input -- for each of the risk-adjusted QMs

        i. Facility-level observed QM scores

        ii. Facility-level expected QM scores

        iii. National mean observed QM scores

    b. Calculation: (See Section 4 of this Appendix for calculation formulas)

    c. Output: Facility-level adjusted QM scores for the five risk-adjusted QMs

13. ***Final Facility-level Output File.*** The final facility-level output files for the Current Period LS and SS QMs contained the following:

    a. For all QMs:

        i. Facility numerator counts

        ii. Facility denominator counts

        iii. Facility-level observed QM scores (publicly reported for the unadjusted QMs)

    b. For the risk-adjusted QMs: Facility-level adjusted QM scores (publicly reported scores)

Section 3
Calculation of the Expected QM Score

For the QMs adjusted with resident-level covariates, the resident-level expected QM score was calculated as an intermediate step to obtaining an adjusted QM score for the facility. This section describes the technical details referred to in Section 2 of this Technical Appendix.

Calculating Resident-level Expected QM Scores

The resident-level expected score for a QM is an estimate of the risk that a resident will trigger the QM. This estimate is based on consideration of the resident-level covariates associated with the QM.

For each of the risk-adjusted QMs, a resident-level logistic regression was estimated. Data came from the short stay and long stay samples described in the prior section of this appendix. The resident-level observed QM score was the dependent variable. The predictor variables were one or more resident-level covariates associated with the QM. Calculation of the QM and covariate scores is described in Section 2 (Step 5) of this Appendix.

Each logistic regression had the following form:

[1] QM triggered (yes = 1, no = 0) = $B_0 + B_1*COV_A + B_2*COV_B + \ldots + B_N*COV_N$

where B_0 is the logistic regression constant, B_1 is the logistic regression coefficient for the first covariate, COV_A is the resident-level score for the first covariate, B_2 is the logistic regression coefficient for the second covariate (where applicable), and COV_B is the resident-level score for the second covariate (where applicable), and so on.

Each resident's expected QM score could then be calculated with the following formula:

[2] Resident-level expected QM score = $1/ [1+e^{-X}]$

where e is the base of natural logarithms and X is a linear combination of the constant and the logistic regression coefficients times the covariate scores (from Formula [1], above). A covariate score will be 1 if the covariate is triggered for that resident, and 0 if not.

As an example, consider the actual calculation used for the expected score for the LS "Percent of residents who have moderate to severe pain" QM (N014.01). The covariate for that QM is an indicator of independence in daily decision-making on the prior assessment. The equation used for this QM (with the parameters from Table B.1 for Q3 2011) is:

[3] N014.01.01 Score = $1/ [1+e^{-(B_0 + B_1 * IndpDec)}]$

where B_0 is the logistic regression constant, B_1 is the logistic regression coefficient for IndpDec, and IndpDec is the resident-level covariate indicating independence in daily decision-making.

The N014.01 score for a resident who triggers the independence in decision making covariate (covariate score = 1) is expected to be:

[4] $0.2006 = 1/[1+e^{-(-2.426281 + 1.044019*1)}]$

For a resident who does not trigger the independence in decision making covariate (covariate score = 0), the N014.01 score is expected to be:

[5] $0.0812 = 1/[1+e^{-(-2.426281 + 1.044019*0)}]$

Thus a resident who is independent in decision making (i.e. covariate = 1) is over twice as likely to report severe pain (20.06 percent, compared to 8.12 percent for a resident who is not independent in decision making).

The parameters used for calculating the resident-level expected QM scores are presented in Table B.1 of Appendix B.

Calculating Facility-level Expected QM Scores

Once an expected QM score has been calculated for all residents at risk, the facility-level expected QM score is simply the average of all resident-level scores for each of the risk-adjusted QMs.

Section 4
Calculation of the Adjusted QM Score

The risk-adjusted QM score is a facility-level QM score adjusted for the specific risk for that QM in the nursing facility. The risk-adjusted QM score can be thought of as an estimate of what the nursing facility's QM rate would be if the facility had residents with average risk.

The facility-level adjusted score is calculated on the basis of

- The facility-level observed QM score,
- The facility-level average expected QM score, and
- The national average observed QM score.

The actual calculation of the adjusted score uses the following equation:

$$[6]\ Adj = 1/\ [1 + e^{-y}]$$

where

Adj is the facility-level adjusted QM score, and

$$y = (Ln(Obs/(1\text{-}Obs) - Ln(Exp/1\text{-}Exp)) + Ln(Nat/(1\text{-}Nat))$$

Obs is the facility-level observed QM rate,
Exp is the facility-level expected QM rate,
Nat is the national observed QM rate, and
Ln indicates a natural logarithm.

e is the base of natural logarithms

Note that the adjusted QM rate (Adj) is calculated differently in two special cases:

1. When Obs equals 0.00, then Adj is set to 0.00 (without using the equation).
2. When Obs equals 1.00, then Adj is set to 1.00 (without using the equation).

The adjusted QM score equation will produce adjusted scores in the range of 0 to 1. These adjusted scores can then be converted to percentages for ease of interpretation.

These adjusted score calculations are applied to QMs that use expected scores based on resident-level covariates (See Section 3 of this Appendix). The national average observed QM rates, required for these calculations, are presented in Appendix B.

MDS 3.0 Quality Measures

USER'S MANUAL

APPENDIX B

Parameters Used for Each Quarter

(v8.0 04-15-2013)

Prepared for:
The Centers for Medicare & Medicaid Services
under Contract No. HSM-500-2008-00021I.
(RTI Project Number 0211942.001.100.004)

Introduction

This appendix presents the model parameters that were estimated for the risk adjusted QMs. for the following time period:

- The period ending September 30, 2011, referred to as Q3 2011.

The purpose of this document is to present the logistic regression coefficients used in the risk adjustment calculations that were applied to the risk-adjusted QMs. For details regarding the use of these parameters, please refer to Appendix A.

Logistic Regression Coefficients

Three QMs are risk adjusted. The logistic regression coefficients used are presented in Table B.1. Where risk adjustment involves the use of more than one resident-level covariate, coefficients are listed in the order presented in the LS and SS matrices that are presented in the MDS 3.0 Quality Measures Logical Specifications section of this manual.

Table B.1. Logistic Regression Coefficients

QM	Constant (Intercept)	Resident-Level Covariates
N002.01	-5.157683	1. (Covariate 1) 0.994473 2. (Covariate 2) 0.874906 3. (Covariate 3) 0.358582 4. (Covariate 4) 0.386363
N014.01	-2.426281	1. (Covariate 1) 1.044019
N026.01	-3.645993	1. (Covariate 1) 0.545108 2. (Covariate 2) 1.967017

National Observed Means

The national observed QM means are updated for each quarterly release. Table B.2 presents these means for Q3 2011, as an example.

Table B.2. National Observed QM Means

QM	Q3 2011
N002.01	0.020956
N014.01	0.119092
N026.01	0.042446

MDS 3.0 Quality Measures

USER'S MANUAL

APPENDIX C

Episode and Stay Determination Logic

(v8.0 04-15-2013)

Prepared for:
The Centers for Medicare & Medicaid Services
under Contract No. HSM-500-2008-00021I.
(RTI Project Number 0211942.001.100.004)

MDS 3.0 Episode and Stay Determination Logic

Introduction

Several CMS applications are based upon the identification of stays and episodes using MDS 3.0 data. This document provides definitions and detailed logic that can be used by these applications.

This document begins with definitions of key terms and concepts. It then explains how stays and episodes are identified in a well-defined assessment data stream (i.e., when all assessment completion and submission rules are followed). It concludes with detailed logic that handles exceptional cases (e.g., missing entry or discharge records).

Definitions

An episode consists of one or more stays, and a stay is defined as a set of contiguous days in a facility. Because an episode is built from a set of one or more stays, the episode can be identified if the stays have been built properly. Therefore, this section will describe how to build stays.

Three properties of each stay must be determined:

- The starting date.
- The ending date.
- The stay type (admission or reentry).

The starting date is the date the resident entered the facility (either for the first time or after a previous discharge). The ending date is either (a) the discharge date, or (b) the end of the target period, whichever is earlier. The stay type is defined as follows:

Admission. An admission occurs when ***any one*** of the following conditions apply:

- the resident has never been admitted to this facility before; OR
- the resident has been in this facility previously and was discharged return not anticipated; OR
- the resident has been in this facility previously and was discharged return anticipated and did not return within 30 days of discharge.

Reentry. A reentry occurs when ***both of the following*** conditions apply:

- the resident has a discharge return anticipated, AND
- the resident returned to the facility within 30 days of discharge.

Rules for a Well Constructed Data Stream

In a well constructed data stream (where all records are submitted and correctly coded), the following logic will correctly determine the starting date, ending date, and type for each stay. This logic assumes that the resident's records have been sorted in reverse chronological order (see the end of this section for sorting details). Stays and episodes must be contained within a single facility, so the following logic applies to the records for a single facility.

1. If the first (latest) record that is on or before the end of the reporting period is a discharge (A0310F = [10, 11, 12]), then the **stay end date** is equal to the discharge date (A2000). Otherwise, the stay is ongoing and the **stay end date** is equal to the end of the reporting period.

2. If the **stay end date** of the resident's latest stay chronologically precedes the beginning of the target period[1], then the episode is not included in the sample. If the stay is ongoing or if the discharge occurs within the target period, then continue.

3. Scan backwards chronologically until an entry record (A0310F = [01]) is encountered. The **stay start date** is equal to the entry date (A1600) on the entry record.

4. Look at the chronologically preceding record. The stay type is defined as follows:

    4.1. If a chronologically preceding record is found and if it is a discharge return anticipated (A0310F = [11]) and if the discharge date of the discharge record is within 30 days of the stay start date defined above, then the stay type is a reentry. Otherwise, the stay type is an admission. Admissions occur under any of the following conditions:

        4.1.1. No chronologically preceding record is found.

        4.1.2. A chronologically preceding record is found and it is a discharge return not anticipated (A0310F = 10).

        4.1.3. A chronologically preceding record is found and it is a discharge return anticipated (A0310F = 11) and the discharge date is 31 days or more before the stay start date.

5. If the stay was classified as an admission stay, then scanning would stop because this would mark the beginning of the episode. If the stay was a reentry, then the scan logic would continue with the stay that ended with the record found in Step #4 (if any). Stays would continue to be scanned and classified until one of the following conditions occurred:

    5.1. An admission stay was identified, or

---

[1] The span of time that defines the application's reporting period (e.g., a calendar quarter).

5.2. No more records were found for the same resident and facility, or

5.3. An application-specific rule was met. For example, for Quality Measures (QMs), processing stops when the number of cumulative days in the facility (CDIF) exceeded 100 days (CDIF is the sum of the number of days within each of the stays that are contained in the episode).

Handling Missing Records

Exceptions to the rules will occur when entry and/or discharge records are missing from a resident's data stream. When this occurs, starting and/or ending dates must be imputed and the stay type must be determined as accurately as possible. The following rules will describe how these situations are handling. This discussion will refer to three types of records:

- Entry record (where A0310F = [01]).
- Discharge record (where A0310F = [10, 11, 12]).
- A normal assessment (where A0310F = [99]).

Missing Entry Records

In the scan logic described above, if a normal assessment is immediately preceded chronologically by a discharge record or if there is no chronologically preceding record, then an entry record is missing. In this case the stay start date and type must be imputed. The imputation rules are as explained below. In these rules, the assessment that is preceded chronologically by a discharge or that has no preceding record is termed the "problem assessment".

The table below is used to impute the entry date when there is a missing entry record.

Table C1: Possible Entry Dates When Entry Record is Missing

Type of Assessment	Reasons for Assessment	Possible Entry Dates	
		Earliest Date	Latest Date
5-day PPS	A0310B=[01]	A2300 - 7 days	A2300
14-day PPS	A0310B=[02]	A2300 - 18 days	A2300 - 10 days
30-day PPS	A0310B=[03]	A2300 - 33 days	A2300 - 20 days
60-day PPS	A0310B=[04]	A2300 - 63 days	A2300 - 49 days
90-day PPS	A0310B=[05]	A2300 - 93 days	A2300 – 79 days
PPS readmission/ return	A0310B=[06]	A2300 - 7 days	A2300
OBRA admission	A0310A=[01]	A2300 - 13 days	A2300
Other OBRA	A0310A=[02,03,04,05,06]	A2300 - 106 days	A2300
OMRA	A0310B=[07]	A2300 - 7 days	A2300
Discharge	A0310F=[10,11,12]	A1600	A1600

The table above lists various types of assessments and shows the earliest and latest possible entry dates that are associated with each one. The following steps explain how to use this table to impute an entry date and stay type when a problem assessment is chronologically preceded by a discharge assessment or where no record precedes the problem assessment.

1. Use the table above to classify the problem assessment. Classify the assessment using the reason for assessment items indicated in the table. If the problem assessment qualifies for more than one of the rows in the table, use the first (topmost) row for which it qualifies.

2. Determine the earliest and latest entry date associated with the selected row.

3. Determine the entry date (A1600) that is reported on the problem assessment.

4. Determine a tentative entry date, as follows:

    4.1. If the entry date (A1600) on the problem assessment falls between the earliest and latest entry date in the table, set the tentative entry date equal to this value of A1600.

    4.2. Otherwise, set the tentative entry date equal to the date that is listed in the "earliest date" column of the table.

5. Determine a final imputed entry date, as follows:

    5.1. If the problem assessment is chronologically preceded by a discharge record, add one day to the tentative entry date and compare the resulting entry date with the discharge date (A2000) on the discharge record. Set the final imputed entry date equal to the later of these two dates.

    5.2. If there is no record that chronologically precedes the problem assessment, then set the final imputed entry date equal to the tentative entry date.

6. Determine the stay type, as follows:

    6.1. If the problem assessment is chronologically preceded by a discharge record, determine the stay type using the normal logic described above.

    6.2. If there is no record that chronologically precedes the problem assessment, then set the stay type as an admission stay.

Missing Discharge Records

In the scan logic described above, if an entry record is immediately preceded chronologically by a normal assessment, then a discharge record is missing. In this case, the end date of the chronologically preceding stay and the stay type of the current stay must be imputed. The imputation rules are as follows. In these rules, the assessment that chronologically precedes the entry record is termed the "ending index assessment". The "current stay" is the stay that begins with the entry record. The "chronologically preceding stay" is the stay that contains the ending index assessment.

1. The end date of the chronologically preceding stay is set equal to the assessment reference date that is recorded on the ending index assessment.

2. Set the stay type of the current stay as follows:

   2.1. Determine the value of A1700 that is recorded on the entry record of the current stay.

   2.2. If A1700 is equal to [1] (admission), then set the stay type for the current stay to "admission".

   2.3. If A1700 is equal to [2] (reentry), then set the stay type for the current stay to "reentry".

Multiple Entry Records

If there are two or more entry records which are adjacent to one another in the resident's data stream, keep the latest entry record and ignore the earlier adjacent entry record(s).

Multiple Discharge Records

If there are two or more discharge records which are adjacent to one another in the resident's data stream, keep the latest discharge record and ignore the earlier adjacent discharge record(s).

Sorting Rules

As noted above, stays are identified from the records for a given resident and facility that are sorted in reverse chronological order. Sorting criteria must be applied to handle the case where there is more than one record on a given target date. The exact sorting criteria are as follows:

State ID +
Facility internal ID +
Resident internal ID +
Target date (descending) +
Record type (descending) +
Assessment internal ID (descending)

Note that record type (record_type) is defined as follows:

1. If A0310F = 01 (the record is an entry record), then record_type = 1.

2. Else if A0310F = 99 (the record is not an entry or discharge), then:

   a. If the item subset code[2] is equal to NC (comprehensive assessment), then record_type = [7].

   b. Else if the item subset code is equal to NQ (quarterly assessment), then record_type = [6].

[2] The item subset code is contained in the field ITM_SBST_CD.

c. Else if the item subset code is equal to NP (PPS assessment), then record_type = [5].

d. Else if the item subset code is equal to NO ("other" OMRA assessment), then record type = [4].

e. Else if the item subset code is equal to NS (start-of-therapy OMRA assessment), then record_type =[3].

f. Else record_type = [2] (this condition should not occur).

3. Else if A0310F = [10] (discharge, return not anticipated), then record_type = [8].

4. Else if A0310F = [11] (discharge, return anticipated), then record_type = [9].

5. Else if A0310F = [12] (death in facility), then record_type = [10].

Also note that the assessment internal ID is used as the final tie-breaker on the assumption that records that should be later in the sort sequence will be submitted and processed later than the other records. The record processing timestamp would be a slightly better field to use for this purpose. However, it is available only to users who have direct access to the ASAP database. The assessment internal ID was therefore adopted as a reasonable substitute for the timestamp so that all users would have access to the same sorting fields.

MDS 3.0 Quality Measures

USER'S MANUAL

APPENDIX D

Measures Withdrawn from NQF Submission

(v8.0 04-15-2013)

Prepared for:
The Centers for Medicare & Medicaid Services under
Contract No. HSM-500-2008-00021I.
(RTI Project Number 0211942.001.100.004)

Measures Withdrawn from NQF Submission

The following measures were previously approved or given time limited endorsement by the National Quality Forum (NQF) but have been withdrawn from NQF submission.

MDS 3.0 Measure: The Percentage of Residents on a Scheduled Pain Medication Regimen on Admission Who Self-Report a Decrease in Pain Intensity or Frequency (Short Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N012.01 **NQF: 0675-withdrawn** **This measure captures the percentage of short-stay residents who can self-report pain, are on a scheduled pain medication regimen at their initial assessment, and who report lowered levels of pain on their target assessment.**	***Numerator*** Short-stay residents with both an initial assessment and a subsequent target assessment, AND who can self-report on pain (J0200 = [1]) on both the initial assessment and the target assessment. AND who are on a scheduled pain medication regimen on their initial assessment (J0100A = [1]) , AND who report reduced pain on their target assessment when compared with their initial assessment as indicated by ***any*** of the following: 1. Resolution of pain with J0300 = [1] (pain present) on the initial assessment AND J0300 = [0] (no pain) on the target assessment. 2. Decrease in pain frequency indicated by J0400=[1,2,3,4] on both the initial and target assessments and J0400 on the target assessment > J0400 on the initial assessment. A score of [1] on J0400 indicates the most frequent pain and a score of [4] indicates the least frequent. 3. Reduced intensity of pain indicated by J0600A=[00,01,02,03,04,05,06,07,08,09,10] on both the initial and target assessments and J0600A on the target assessment < J0600A on the initial assessment. A score of [10] on J0600A indicates the most intense pain and a score of [00] indicates no pain. 4. Reduced intensity of pain indicated by J0600B=[1,2,3,4] on both the initial and target assessments and J0600B on the target assessment < J0600B on the initial assessment. A score of [4] on J0600B indicates the most intense pain and a score of [1] indicates the least intense pain. ***Denominator*** Short-stay residents with both an initial assessment and a subsequent target assessment, AND who can self-report on pain (J0200 = [1]) on both the initial assessment and the target assessment. AND who are on a scheduled pain medication regimen (J0100A = [1]) on the initial assessment, except those who meet the exclusion criteria.	Not applicable.

(continued)

MDS 3.0 Measure: The Percentage of Residents on a Scheduled Pain Medication Regimen on Admission Who Self-Report a Decrease in Pain Intensity or Frequency (Short Stay) (continued)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
	Exclusions Residents are excluded in any of the following cases: 1. The resident is not included in the numerator AND the value for J0300 or J0400 is [9] or dash [-] indicating not assessed on either the initial or target assessment. 2. The resident is not included in the numerator AND a valid comparison could not be made between the initial and target assessment on either J0600A or J0600B. In order for a valid comparison to be made, ***at least one*** of the following must be true: 2.1 Item J0600A must have a value of [00] through [10] on both the initial and target assessments. 2.2. Item J0600B must have a value of [1] through [4] on both the initial and target assessments. 3. There was no opportunity for the pain levels to improve because pain levels were at their lowest level possible on the initial assessment. This will occur if one of the following is true for the ***initial assessment***: 3.1. J0300 = [0] (the resident reports no pain) 3.2. ***Both*** the following conditions are true: 3.2.1 J0400 = [4] (pain occurs rarely) ***AND*** 3.2.2. J0600A = [00, -, ^] (no pain reported) ***OR*** J0600B = [1, 9, ^] (no pain reported).	

MDS 3.0 Quality Measures

USER'S MANUAL

APPENDIX E

Surveyor Quality Measures

(v8.0 04-15-2013)

Prepared for:
The Centers for Medicare & Medicaid Services
under Contract No. HSM-500-2008-00021I.
(RTI Project Number 0211942.001.100.004)

Surveyor Quality Measures

Quality measure reports are available to State surveyors and facility staff through CMS's CASPER reporting system. These reports contain a subset of the measures that are documented in the main body of this user's guide plus several additional measures that are available only on the CASPER reports.

The table below lists the measures that are contained on the CASPER QM reports and indicates whether each measure is documented above (in the main body of this user guide) or within this appendix. The first column of the table shows the label for the measure that is used on the CASPER reports. The next column shows whether the measure uses the short- or long-stay sample. The third column indicates the unique CMS identification number. The fourth column shows the NQF ID for the measure, if available. The final column indicates whether the measure is defined in the main body of this manual ("above") or whether it is defined in this appendix (Appendix E). The specifications for the measures that are unique to the CASPER reports appear after the table.

Table E1: Measures Listed on CASPER QM Reports

Measure Label	Short/Long Stay	CMS ID	NQF ID	Specs Definition
SR Mod/Severe Pain (S)	Short	N001.01	0676	Above
SR Mod/Severe Pain (L)	Long	N014.01	0677	Above
Hi-risk Pres Ulcer (L)	Long	N015.01	0679	Above
New/worse Pres Ulcer (S)	Short	N002.01	0678	Above
Phys restraints (L)	Long	N027.01	0687	Above
Falls (L)	Long	N032.01		Appendix E
Falls w/Maj Injury (L)	Long	N013.01	0674	Above
Antipsych Med (S)	Short	N011.01		Above
Antipsych Med (L)	Long	N031.02		Above
Antianxiety/Hypnotic (L)	Long	N033.01		Appendix E
Behav Sx affect Others (L)	Long	N034.01		Appendix E
Depress Sx (L)	Long	N030.01	0690	Above
UTI (L)	Long	N024.01	0684	Above
Cath Insert/Left Bladder (L)	Long	N026.01	0686	Above
Lo-Risk Lose B/B Con (L)	Long	N025.01	0685	Above
Excess Wt Loss (L)	Long	N029.01	0689	Above
Incr ADL Help (L)	Long	N028.01	0688	Above

MDS 3.0 QM Measure: Prevalence of Falls (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N032.01 **NQF: none** **This measure reports the percentage of long-stay residents who have had a fall during their episode of care.**	***Numerator*** Long-stay residents with one or more look-back assessments that indicate the occurrence of a fall (J1800 = [1]). ***Denominator*** All long-stay nursing home residents with one or more look-back scan assessments except those with exclusions. ***Exclusions*** Resident is excluded if the following is true for all of the look-back scan assessments: The occurrence of falls was not assessed (J1800 = [-]),	Not applicable.

MDS 3.0 Measure: Prevalence of Antianxiety/Hypnotic Use (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N033.01 **NQF: none** **This measure reports the percentage of long-stay residents who are receiving antianxiety medications or hypnotics but do not have evidence of psychotic or related conditions in the target period.**	***Numerator*** Long-stay residents with a selected target assessment where any of the following conditions are true: 1. For assessments with target dates on or before 03/31/2012: 1.1. Antianxiety medications received (N0400B = [1]), or 1.2. Hypnotic medications received (N0400D = [1]). 2. For assessments with target dates on or after 04/01/2012: 2.1. Antianxiety medications received (N0410B = [1,2,3,4,5,6,7]), or 2.2. Hypnotic medications received (N0410D = [1,2,3,4,5,6,7]). ***Denominator*** All long-stay residents with a selected target assessment, except those with exclusions.. ***Exclusions*** 1. The resident did not qualify for the numerator and **any** of the following is true :: 1.1. For assessments with target dates on or before 03/31/2012: N0400B = [-] **or** N0400D = [-] 1.2. For assessments with target date on or after 04/01/2012: N0410B = [-] **or** N0410D = [-]. 2. **Any** of the following related conditions are present on the target assessment (unless otherwise indicated): 2.1. Schizophrenia (I6000 = [1]). 2.2. Psychotic disorder (I5950 = [1]). 2.3. Manic depression (bipolar disease) (I5900 = [1]). 2.4. Tourette's Syndrome (I5350 = [1]). 2.5. Tourette's Syndrome (I5350 = [1]) on the prior assessment if this item is not active on the target assessment and if a prior assessment is available. 2.6. Huntington's Disease (I5250 = [1]). 2.7. Hallucinations (E0100A = [1]). 2.8. Delusions (E0100B = [1]). 2.9. Anxiety disorder (I5700 = [1]). 2.10. Post traumatic stress disorder (I6100 = [1]). 2.11. Post traumatic stress disorder (I6100 = [1]) on the prior assessment if this item is not active on the target assessment and if a prior assessment is available.	Not applicable.

MDS 3.0 Measure: Prevalence of Behavior Symptoms Affecting Others (Long Stay)

MEASURE DESCRIPTION	MEASURE SPECIFICATIONS	COVARIATES
CMS: N034.01 **NQF: none** **This measure reports the percentage of long-stay residents who have behavior symptoms that affect others during the target period.**	***Numerator*** Long-stay residents with a selected target assessment where any of the following conditions are true: 1. The presence of physical behavioral symptoms directed towards others (E0200A = [1,2,3]), or 2. The presence of verbal behavioral symptoms directed towards others (E0200B = [1,2,3]), or 3. The presence of other behavioral symptoms not directed towards others (E0200C = [1,2,3]), or 4. Rejection of care (E0800 = [1,2,3]), or 5. Wandering (E0900 = [1,2,3]). ***Denominator*** All residents with a selected target assessment, except those with exclusions. ***Exclusions*** Resident is not in numerator and any of the following is true: 1. The target assessment is a discharge (A0310F=[10,11]. 2. E0200A is equal to [-,^]. 3. E0200B is equal to [-,^]. 4. E0200C is equal to [-,^]. 5. E0800 is equal to [-,^]. 6. E0900 is equal to [-,^].	Not applicable.

MDS 3.0 Quality Measures

USER'S MANUAL

APPENDIX F

Specifications for the Facility Characteristics Report

(v8.0 04-15-2013)

Prepared for:
The Centers for Medicare & Medicaid Services
under Contract No. HSM-500-2008-00021I.
(RTI Project Number 0211942.001.100.004)

Specifications for Facility Characteristics Report

Record Selection

The Facility Characteristic Report is populated using data from records selected using the standard QM episode and record selection logic as given in the QM User's Manual. The Facility Characteristics measures can be processed with the QM measures. Each Facility Characteristic measure is computed for both short-stay and long-stay residents.

Most of the Facility Characteristic measures are populated using data from a look-back scan of the assessment records selected for each resident. For each resident, the look-back scan begins with the target assessment selected for QM processing. The resident's records are scanned in reverse chronological order (by ARD) and all data items required for the Facility Characteristics report are populated from data that are available from each assessment. As assessments are scanned, each required item is initially populated with the item value from the target assessment. If the value from the target assessment is a valid (non-missing) value, then the scan for that item stops. If the value for the target assessment is not a valid value (a missing value), then the scan continues with the earlier assessments in reverse chronological order. Once a valid value is found for an item, that value is used for the report (i.e., the value is not changed if additional values are present in earlier records).

A "valid value" is any value that is one of the "normal" responses to an item. Missing non-valid values are:

1. A dash ("-") indicating that the item was not assessed.
2. A caret ("^") indicating that the item was skipped.
3. A null (.) indicating that the item is inactive.

Note that the diagnosis code items (I8000A through I8000J) are not used in the measure specifications below and are therefore not included in the look-back scan.

For each resident, the look-back scan continues until any of the following conditions is satisfied:

- All required items have been populated with valid values, as defined above, OR
- All selected records for a resident have been scanned.

Note that scanning stops for a resident as soon as ***either*** of these conditions is satisfied.

Measure Specifications

The definitions in the following table are applied to a look-back scan of the records selected for a resident as described in the prior section on *Record Selection*. Counts of the number of residents within each facility that meet the numerator criteria for each measure below are used as the numerator to produce facility percentages for the report.

The denominator used to produce the facility percentages in the report will vary for different measures, depending on missing data. If missing data precludes determination of the status for a

measure as indicated in the "Exclusions" section, then the resident is excluded from both the numerator and denominator in the facility percentage.

Table F1: Facility Characteristics Report Measure Definitions

Measure	Description and Definition
Gender	
Male	**Description:** Resident is included if Item A0800 (Gender) is equal to **1** (Male). Records with dashes (not assessed) in A0800 are excluded from the male/female counts. **Numerator:** A0800 = 1 (Male). **Exclusions:** A0800 missing
Female	**Description:** Resident is included if Item A0800 (Gender) is equal to **2** (Female). Records with dashes (not assessed) in A0800 are excluded from the male/female counts. **Numerator:** A0800 = 2 (Female). **Exclusions:** A0800 missing
Age	
	Calculation of Age, based on Items A0900 (Birth Date) and A2300 (Assessment Reference Date ARD): IF (MONTH(A2300) > MONTH(A0900)) OR (MONTH(A2300) = MONTH(A0900) AND DAY(A2300) >= DAY(A0900)) THEN Age = YEAR(A2300)-YEAR(A0900) ELSE Age = YEAR(A2300)-YEAR(A0900)-1
<25 years old	**Description:** Age less than 25 years old. **Numerator:** Record triggers if age < 25.
25-54 years old	**Description:** Age of 25 through 54 years old. **Numerator:** Record triggers if age >= 25 and <= 54.
55-64 years old	**Description:** Age of 55 through 64 years old. **Numerator:** Record triggers if age >= 55 and <= 64.
65-74 years old	**Description:** Age of 65 to 74 years old. **Numerator:** Record triggers if age >= 65 and <= 74.
75-84 years old	**Description:** Age of 75 through 84 years old. **Numerator:** Record triggers if age >= 75 and <= 84.

Measure	Description and Definition
85+ years old	**Description:** Age of 85 years of age or older. **Numerator:** Record triggers if age >= 85.
Diagnostic Characteristics	
Psychiatric Diagnosis	**Description:** Resident is included as having a psychiatric diagnosis if any of the following is true: • any psychiatric mood disorders are checked in items I5700 through I6100, OR • item I5350 (Tourette's Syndrome) is checked, OR • item I5250 (Huntington's Disease) is checked. **Numerator:** • Any of the following items are checked: I5250, I5350, I5700 through I6100. **Exclusions:** No value I5250, I5350, I5700 through I6100 = 1 and any value I5250, I5350, I5700 through I6100 missing
Intellectual Disability (ID) (Mental retardation as defined at 483.45(a)) or Developmental Disability (DD)	**Description:** Resident is counted as having ID/DD if any of the following items are checked: • A1550A (Down syndrome) • A1550B (Autism) • A1550C (Epilepsy) • A1550D (Other organic condition related to ID/DD) • A1550E (ID/DD with no organic condition) **Numerator:** A1550A, B, C, D, or E is checked. **Exclusions:** No value A1550A, B, C, D, or E = 1 and any value A1550A, B, C, D, or E missing
Hospice	**Description:** Resident is included if Item O0100K2 (Hospice care) is checked. **Numerator:** O0100K2 is checked. **Exclusions:** O0100K2 missing
Prognosis	
Life expectancy of less than 6 months	**Description:** Resident is included if item J1400 (Prognosis) is coded **1** (Yes). **Numerator:** J1400 = 1 (Yes). **Exclusions:** J1400 missing

Measure	Description and Definition
Discharge Plan	
Discharge planning IS NOT already occurring for the resident to return to the community.	**Description:** Resident is included if Item Q0400A (Discharge Plan) is coded **0** (No). **Numerator:** Q0400A = 0 (No). **Exclusions:** Q0400A missing
Discharge planning IS already occurring for the resident to return to the community.	**Description:** Resident is included if Item Q0400A (Discharge Plan) is coded **1** (Yes). **Numerator:** Q0400A = 1 (Yes). **Exclusions:** Q0400A missing
Referral	
Referral not needed.	**Description:** Resident is included if Item Q0600 (Referral) is coded **0** (No - Referral not needed). **Numerator:** Q0600 = 0 (No - Referral not needed). **Exclusions:** Q0600 missing
Referral is or may be needed, but has not been made.	**Description:** Resident is included if Item Q0600 (Referral) is coded **1** (Yes – Referral is or may be needed). **Numerator:** Q0600 = 1 (No - Referral is or may be needed). **Exclusions:** Q0600 missing
Referral has been made.	**Description:** Resident is included if Item Q0600 (Referral) is coded **2** (Yes - Referral made). **Numerator:** Q0600 = 2 (Yes - Referral made). **Exclusions:** Q0600 missing
Type of Entry	
Admission	**Description:** Resident is included if Item A1700 (Type of Entry) is coded **1**, (Admission). **Numerator:** A1700 = 1 (Admission). **Exclusions:** A1700 missing
Reentry	**Description:** Resident is included if Item A1700 (Type of Entry) is coded **2**, (Reentry). **Numerator:** A1700 = 2 (Reentry). **Exclusions:** A1700 missing

Measure	Description and Definition
Entered Facility From	
Community (private home/apartment board/care, assisted living, group home)	**Description:** Resident is included if Item A1800 (Entered From) is coded **01** (Community). **Numerator:** A1800 = 01 (Community). **Exclusions:** A1800 missing
Another nursing home or swing bed	**Description:** Resident is included if Item A1800 (Entered From) is coded **02** (Another nursing home or swing bed). **Numerator:** A1800 = 02 (Another nursing home or swing bed). **Exclusions:** A1800 missing
Acute hospital	**Description:** Resident is included if Item A1800 (Entered From) is coded **03** (Acute hospital). **Numerator:** A1800 = 03 (Acute hospital). **Exclusions:** A1800 missing
Psychiatric hospital	**Description:** Resident is included if Item A1800 (Entered From) is coded **04** (Psychiatric hospital). **Numerator:** A1800 = 04 (Psychiatric hospital). **Exclusions:** A1800 missing
Inpatient rehabilitation facility	**Description:** Resident is included if Item A1800 (Entered From) is coded **05** (Inpatient rehabilitation facility). **Numerator:** A1800 = 05 (Inpatient rehabilitation facility). **Exclusions:** A1800 missing
ID/DD facility	**Description:** Resident is included if Item A1800 (Entered From) is coded **06** (ID/DD facility). **Numerator:** A1800 = 06 (ID/DD facility). **Exclusions:** A1800 missing
Hospice	**Description:** Resident is included if Item A1800 (Entered From) is coded **07** (Hospice). **Numerator:** A1800 = 07 (Hospice). **Exclusions:** A1800 missing
Long Term Care Hospital (LTCH)	**Description:** Resident is included if Item A1800 (Entered From) is coded **09** (Long Term Care Hospital (LTCH)). **Numerator:** A1800 = 09 (Long Term Care Hospital (LTCH)). **Exclusions:** A1800 missing

Measure	Description and Definition
Other	**Description:** Resident is included if Item A1800 (Entered From) is coded **99** (Other). **Numerator:** A1800 = 99 (Other). **Exclusions:** A1800 missing

Sample Psychotropic Medication Policy and Procedure

Shared with Permission of Karyn Leible, RN, MD, CMD

Policy:

Physicians and mid level providers will use psychotropic medications appropriately working with the interdisciplinary team to ensure appropriate use, evaluation and monitoring.

Standards:

1. The facility will make every effort to comply with state and federal regulations related to the use of psychopharmacological medications in the long term care facility to include regular review for continued need, appropriate dosage, side effects, risks and/or benefits.
2. The facility supports the appropriate use of psychopharmacologic medications that are therapeutic and enabling for residents suffering from mental illness.
3. The facility supports the goal of determining the underlying cause of behavioral symptoms so the appropriate treatment of environmental, medical, and/or behavioral interventions, as well as psychopharmacological medications can be utilized to meet the needs of the individual resident.
4. The facility supports the goal of determining the underlying cause of residents having difficulty sleeping so the appropriate treatment of environmental or medical interventions can be utilized prior to psychopharmacologic medication use.
5. Efforts to reduce dosage or discontinue of psychopharmacological medications will be ongoing, as appropriate, for the clinical situation.
6. Psychopharmacological medications will never be used for the purpose of discipline or convenience.
7. Psychotropic medications include: anti-anxiety/hypnotic, antipsychotic and antidepressant classes of drugs.

Responsible Party – Actions Required:

Primary care physician, PA or APN

1. Orders for psychotropic medication only for the treatment of specific medical and/ or psychiatric conditions or when the medication meets the needs of the resident to alleviate significant distress for the resident not met by the use of non pharmacologic approaches.
2. Documents rationale and diagnosis for use and identifies target symptoms.
3. Documents discussion with the resident and/or responsible party regarding the risk versus benefit of the use of these medications included in the discussion and documentation must be the presence of any black box warning or off label use of the medication affecting the prescribing of the medication to the resident.

4. Evaluates with the interdisciplinary team, effects and side effects of psychoactive medications within one month of initiating, increasing, or decreasing dose and during routine visits thereafter.
5. Monitors the resident for lack of drug efficacy clinically and in discussions with the interdisciplinary team within one month of initiating and during routine visits.
6. Attempt a gradual dose reduction (GDR) decrease or discontinuation of psychotropic medications after no more than 3 months unless clinically contraindicated. Gradual dose reduction must be attempted for 2 separate quarters (with at least one month between attempts). Gradual dose reduction must be attempted annually thereafter or as the resident's clinical condition warrants.
7. Sedative/ hypnotics will be reviewed quarterly for gradual dose reduction. GDR must be attempted quarterly unless clinically contraindicated.
8. Orders for PRN psychotropic medications will be time limited (i.e., times 2 weeks) and only for specific clearly documented circumstances.
9. Obtains psychiatric consultation as resident's clinical condition requires.

Psychiatrist/mental health (When available to a facility)

1. May assist the facility in establishing appropriate guidelines for use, dosage and monitoring of psychotropic medications.
2. Uses the above standards (1-9) in recommendations to physicians.
3. Provides in service training to nursing, medical, and other staff as appropriate.
4. Is available for consultation.
5. Helps develop behavior management plans.

Nursing

1. Monitors psychotropic drug use daily noting any adverse effects such as increased somnolence or functional decline.
2. Will monitor for the presence of target behaviors on a daily basis charting by exception (i.e., charting only when the behaviors are present).
3. Reviews the use of the medication with the physician and the interdisciplinary team on a quarterly basis to determine the continued presence of target behaviors and or the presence of any adverse effects of the medication use.
4. AIMS will be performed on any resident on and antipsychotic on a quarterly basis changes will be reported to the physician.
5. May develop behavioral care plans.

Social Services

1. Maintains a list of residents in the facility on psychoactive medications.
2. Coordinates the interdisciplinary team resident reviews of psychoactive medications.
3. May develop behavioral care plans.

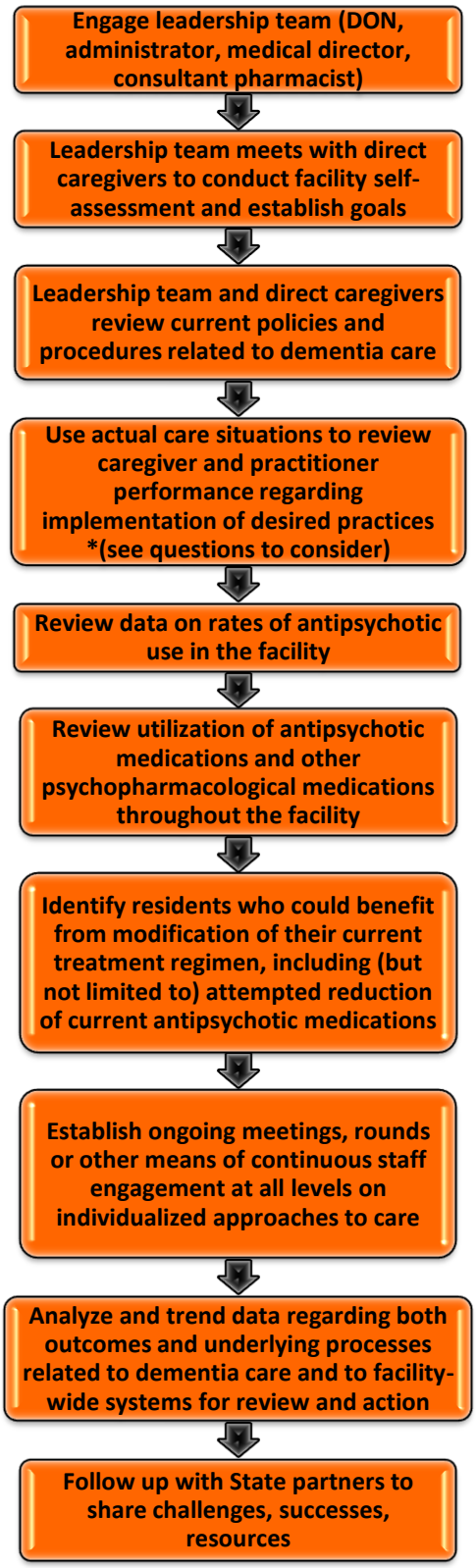
Pharmacist and/or consulting pharmacist

1. Monitors psychotropic drug use in the facility to ensure that medications are not used in excessive doses or for excessive duration.
2. Participates in the interdisciplinary quarterly review of resident's on psychoactive medications.
3. Notifies the physician and the nursing unit if whenever a psychotropic medication is past due for review.

Medical Director

1. Reviews psychotropic medication policy with the interdisciplinary team at least annually.
2. Monitors the overall use of these medications in the facility through the QAPI process.
3. Identifies any resident care or potential regulatory issues with the use of psychotropic medications in the facility and discusses with the medical staff as appropriate.
4. Participates in the interdisciplinary quarterly review of resident's on psychoactive medications and facilitates communications with attending physicians of any recommendations from the IDT.

PARTNERSHIP TO IMPROVE DEMENTIA CARE IN NURSING HOMES
Provider Implementation Flow Diagram



Partnership to Improve Dementia Care in Nursing Homes
State Coalition Provider Question Worksheet
(Self-Assessment Tool)

Appropriate dementia care includes more than managing individuals with dementia-related behavior. It also requires minimizing and managing the various factors that maintain overall health and physical stability and optimize function in residents who are often complex and may suffer from multiple chronic conditions. How do caregivers collaborate with practitioners to properly assess behavior carefully and systematically, to help rule out critical underlying causes, including (but not limited to) environmental, functional, and other possibly correctable causes or serious medical conditions such as delirium? Does the facility have detailed process guidance for staff regarding the assessment, documentation, and reporting of all symptoms and changes in condition, including behavior? Are they reviewing and addressing staff performance in these areas, based on individual cases?

Direct Caregivers

1. How does staff address behavioral responses by persons with dementia in your facility, such as anxiousness or aggressiveness?

2. Do you know if your facility has policies and procedures in place that you are supposed to follow when a resident with dementia exhibits certain behaviors, or those behaviors worsen?

3. What training have you received about how to care for persons with dementia?
    a. Who provides the training?
    b. Do you know what materials are used?
    c. Does the training give you a chance to practice how you would respond?

4. When a resident with dementia demonstrates certain behaviors such as anxiety or aggression, is he or she given a medication to treat them?
    a. Do you know whether the team at your facility is trying to reduce the use of these drugs?

5. Are residents and families given information about care options for persons with dementia, including those that do or do not use medications?

Leadership- (Nursing Home Administrator, Director of Nursing, Medical Director)

1. How will your facility measure success in improving dementia care and reducing or optimizing antipsychotic drug use?

2. What do you see as the major barriers to accomplishing this?

3. Are you currently reviewing data related to antipsychotic drug use for all residents, including residents that are returning or were recently discharged from an acute care setting?

4. Are there tools/resources/support that would assist you in analyzing and interpreting data?
   For example, telephone or in-person support from:
   a. A member of your state nursing home association;
   b. A consultant;
   c. A quality improvement organization;
   d. Other state-based nursing home specialist?

5. If your facility is part of a corporation, does the corporation provide educational materials, clinical support or data analysis related to dementia care and/or antipsychotic drug use?

6. Is staff in all departments educated on person-centered care for individuals with dementia?

7. How is the Consultant Pharmacist involved in the overall care of residents?
   For example, does the Consultant Pharmacist routinely engage in:
   a. Data analysis;
   b. Staff education;
   c. Routine interaction with residents and/or families?

8. How is the Medical Director involved in the overall care of residents with dementia?

Partnership to Improve Dementia Care in Nursing Homes Suggestions for Provider Checklist

% of residents in facility on atypical antipsychotics: __ Quality Measure State Percentile Rank – antipsychotics: __

	YES	NO
Staff in all departments, are trained in person-centered care and how to respond effectively to behaviors (access sample training programs on Advancing Excellence website; Hand in Hand).		
In addition to medical and psychiatric history, recent changes in behavior or cognition and other standard clinical evaluations, at admission information is obtained from the resident, family, and/or caregivers on the resident's preferences, routines, pre-dementia personality, social patterns, responses to stress and effective interventions.		
The information obtained on during the admission process is conveyed to direct caregivers.		
This admission information is integrated into the care plan and may be revised over time as the resident's condition and needs change.		
Interviews with staff demonstrate that they have implemented and are following the care plan, continue to seek input from family members or care givers for unresolved issues, and communicate with practitioners regarding change in condition or new or persistent symptoms.		
If a resident is placed on an antipsychotic medication, there is documentation in the record that the resident or appropriate legal representative was involved in the decision.		
Facility has consistent staff assignments (same Certified Nursing Assistant to same resident 5 days/week).		
Certified Nursing Assistant to Resident Ratio 1st shift/2nd shift/3rd shift		
Senior leadership (Nursing Home Administrator, Director of Nursing, Medical Director) attend care plan meetings periodically for residents with unresolved behavioral or psychological symptoms of dementia.		
Interdisciplinary team seeks input at care plan meetings from the Medical Director, Consultant Pharmacist and Certified Nursing Assistants for residents with behavioral or psychological symptoms.		
Providers conduct outreach and education to the resident's family and strongly encourage their participation in care plan meetings (offering to flex the schedule or use conference calls when the family cannot physically be in attendance).		
Nursing Home Administrators and Directors of Nursing review quality measures (e.g., monthly) and use the Quality Measures report to identify residents who may need alternative interventions and oversee their implementation.		
Each month, Nursing Home Administrators and Directors of Nursing review Quality Measures report, along with the Pharmacy Consultant report, to identify residents appropriate for possible reduction/elimination of antipsychotics. The review of aggregate data should be combined with real-time, case-based information and input from practitioners.		
Nursing Home Administrators and Directors of Nursing review Pharmacy Consultant's report quarterly with Consultant Pharmacist and Medical Director to track and trend data.		
Direct caregivers (Certified Nursing Assistants), together with the family and care plan team, is involved in the process of developing and implementing effective, person-specific interventions to address behavioral symptoms.		
If any resident is admitted on an antipsychotic or is started on an antipsychotic after admission, the Consultant Pharmacist, along with the practitioner, reviews that resident's care plan, including all medications, within 24-48 hours.		
A documented process is in place and is utilized when initiating an antipsychotic prescription (e.g., standard order set, decision support algorithm, routine monitoring recommendations, etc.).		

"Yes" answers require supporting documentation and visual confirmation by quality improvement personnel.

Pain Assessment in Advanced Dementia Scale (PAINAD)

Instructions: Observe the patient for five minutes before scoring his or her behaviors. Score the behaviors according to the following chart. Definitions of each item are provided on the following page. The patient can be observed under different conditions (e.g., at rest, during a pleasant activity, during caregiving, after the administration of pain medication).

Behavior	0	1	2	Score
Breathing Independent of vocalization	• Normal	• Occasional labored breathing • Short period of hyperventilation	• Noisy labored breathing • Long period of hyperventilation • Cheyne-Stokes respirations	
Negative vocalization	• None	• Occasional moan or groan • Low-level speech with a negative or disapproving quality	• Repeated troubled calling out • Loud moaning or groaning • Crying	
Facial expression	• Smiling or inexpressive	• Sad • Frightened • Frown	• Facial grimacing	
Body language	• Relaxed	• Tense • Distressed pacing • Fidgeting	• Rigid • Fists clenched • Knees pulled up • Pulling or pushing away • Striking out	
Consolability	• No need to console	• Distracted or reassured by voice or touch	• Unable to console, distract, or reassure	
			TOTAL SCORE	

(Warden et al., 2003)

Scoring:

The total score ranges from 0-10 points. A possible interpretation of the scores is: 1-3=mild pain; 4-6=moderate pain; 7-10=severe pain. These ranges are based on a standard 0-10 scale of pain, but have not been substantiated in the literature for this tool.

Source:

Warden V, Hurley AC, Volicer L. Development and psychometric evaluation of the Pain Assessment in Advanced Dementia (PAINAD) scale. *J Am Med Dir Assoc*. 2003;4(1):9-15.

PAINAD Item Definitions

(Warden et al., 2003)

Breathing

1. *Normal breathing* is characterized by effortless, quiet, rhythmic (smooth) respirations.
2. *Occasional labored breathing* is characterized by episodic bursts of harsh, difficult, or wearing respirations.
3. *Short period of hyperventilation* is characterized by intervals of rapid, deep breaths lasting a short period of time.
4. *Noisy labored breathing* is characterized by negative-sounding respirations on inspiration or expiration. They may be loud, gurgling, wheezing. They appear strenuous or wearing.
5. *Long period of hyperventilation* is characterized by an excessive rate and depth of respirations lasting a considerable time.
6. *Cheyne-Stokes respirations* are characterized by rhythmic waxing and waning of breathing from very deep to shallow respirations with periods of apnea (cessation of breathing).

Negative Vocalization

1. *None* is characterized by speech or vocalization that has a neutral or pleasant quality.
2. *Occasional moan or groan* is characterized by mournful or murmuring sounds, wails, or laments. Groaning is characterized by louder than usual inarticulate involuntary sounds, often abruptly beginning and ending.
3. *Low level speech with a negative or disapproving quality* is characterized by muttering, mumbling, whining, grumbling, or swearing in a low volume with a complaining, sarcastic, or caustic tone.
4. *Repeated troubled calling out* is characterized by phrases or words being used over and over in a tone that suggests anxiety, uneasiness, or distress.
5. *Loud moaning or groaning* is characterized by mournful or murmuring sounds, wails, or laments in much louder than usual volume. Loud groaning is characterized by louder than usual inarticulate involuntary sounds, often abruptly beginning and ending.
6. *Crying* is characterized by an utterance of emotion accompanied by tears. There may be sobbing or quiet weeping.

Facial Expression

1. *Smiling or inexpressive*. Smiling is characterized by upturned corners of the mouth, brightening of the eyes, and a look of pleasure or contentment. Inexpressive refers to a neutral, at ease, relaxed, or blank look.
2. *Sad* is characterized by an unhappy, lonesome, sorrowful, or dejected look. There may be tears in the eyes.
3. *Frightened* is characterized by a look of fear, alarm, or heightened anxiety. Eyes appear wide open.
4. *Frown* is characterized by a downward turn of the corners of the mouth. Increased facial wrinkling in the forehead and around the mouth may appear.
5. *Facial grimacing* is characterized by a distorted, distressed look. The brow is more wrinkled, as is the area around the mouth. Eyes may be squeezed shut.

Body Language

1. *Relaxed* is characterized by a calm, restful, mellow appearance. The person seems to be taking it easy.
2. *Tense* is characterized by a strained, apprehensive, or worried appearance. The jaw may be clenched. (Exclude any contractures.)
3. *Distressed pacing* is characterized by activity that seems unsettled. There may be a fearful, worried, or disturbed element present. The rate may be faster or slower.
4. *Fidgeting* is characterized by restless movement. Squirming about or wiggling in the chair may occur. The person might be hitching a chair across the room. Repetitive touching, tugging, or rubbing body parts can also be observed.
5. *Rigid* is characterized by stiffening of the body. The arms and/or legs are tight and inflexible. The trunk may appear straight and unyielding. (Exclude any contractures.)
6. *Fists clenched* is characterized by tightly closed hands. They may be opened and closed repeatedly or held tightly shut.
7. *Knees pulled up* is characterized by flexing the legs and drawing the knees up toward the chest. An overall troubled appearance. (Exclude any contractures.)
8. *Pulling or pushing away* is characterized by resistiveness upon approach or to care. The person is trying to escape by yanking or wrenching him- or herself free or shoving you away.
9. *Striking out* is characterized by hitting, kicking, grabbing, punching, biting, or other form of personal assault.

Consolability

1. *No need to console* is characterized by a sense of well-being. The person appears content.
2. *Distracted or reassured by voice or touch* is characterized by a disruption in the behavior when the person is spoken to or touched. The behavior stops during the period of interaction, with no indication that the person is at all distressed.
3. *Unable to console, distract, or reassure* is characterized by the inability to soothe the person or stop a behavior with words or actions. No amount of comforting, verbal or physical, will alleviate the behavior.

NAME _____ AGE_____ SEX_____ DATE _____

Cornell Scale for Depression in Dementia

Ratings should be based on symptoms and signs occurring during the week before interview. No score should be given if symptoms result from physical disability or illness.

SCORING SYSTEM

a = Unable to evaluate 0 = Absent
1 = Mild to Intermittent 2 = Severe

Score greater than 12 = Probable Depression

	a	0	1	2
A. MOOD-RELATED SIGNS				
1. Anxiety; anxious expression, rumination, worrying				
2. Sadness; sad expression, sad voice, tearfulness				
3. Lack of reaction to pleasant events				
4. Irritability; annoyed, short tempered				
B. BEHAVIORAL DISTURBANCE				
5. Agitation; restlessness, hand wringing, hair pulling				
6. Retardation; slow movements, slow speech, slow reactions				
7. Multiple physical complaints *(score 0 if gastrointestinal symptoms only)*				
8. Loss of interest; less involved in usual activities *(score 0 only if change occurred acutely, i.e., in less than one month)*				
C. PHYSICAL SIGNS				
9. Appetite loss; eating less than usual				
10. Weight loss *(score 2 if greater than 5 pounds in one month)*				
11. Lack of energy; fatigues easily, unable to sustain activities				
D. CYCLIC FUNCTIONS				
12. Diurnal variation of mood; symptoms worse in the morning				
13. Difficulty falling asleep; later than usual for this individual				
14. Multiple awakenings during sleep				
15. Early morning awakening; earlier than usual for this individual				
E. IDEATIONAL DISTURBANCE				
16. Suicidal; feels life is not worth living				
17. Poor self-esteem; self-blame, self-depreciation, feelings of failure				
18. Pessimism; anticipation of the worst				
19. Mood congruent delusions; delusions of poverty, illness or loss				

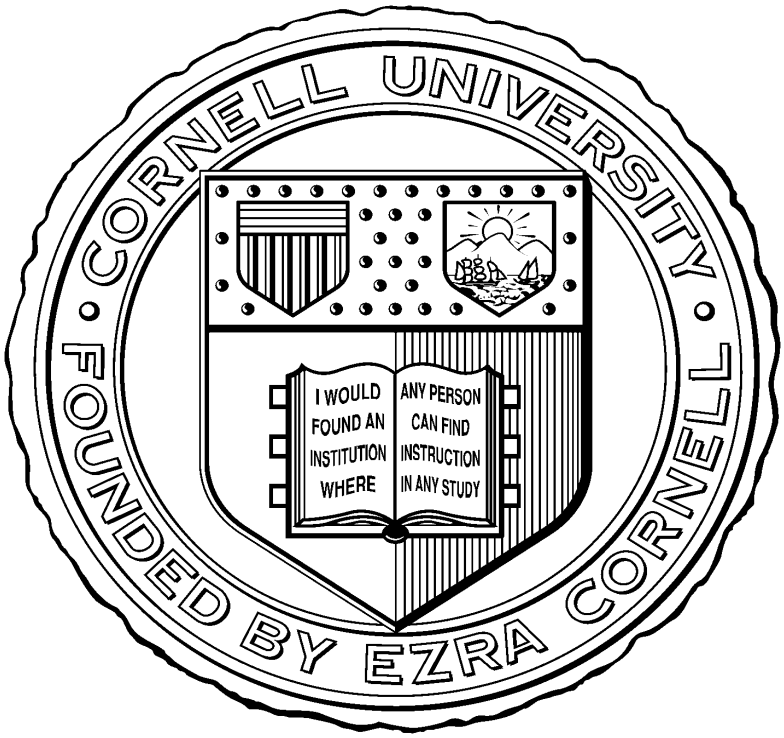
NOTES/CURRENT MEDICATIONS:

ASSESSOR:

Score

Instruction for use: (Cornell Dementia Depression Assessment Tool)

1. The same CNA (certified nursing assistant) should conduct the interviewed each time to assure consistency in the response.
2. The assessment should be based on the patient's normal weekly routine.
3. If uncertain of answers, questioning other caregivers may further define the answer.
4. Answer all questions by placing a check in the column under the appropriately numbered answer. (a=unable to evaluate, 0=absent, 1=mild to intermittent, 2=severe).
5. Add the total score for all numbers checked for each question.
6. Place the total score in the "SCORE" box and record any subjective observation notes in the "Notes/Current Medications" section.
7. Scores totaling twelve (12) points or more indicate probable depression.



The Cornell Scale for Depression in Dementia

ADMINISTRATION & SCORING GUIDELINES

George S. Alexopoulos, M.D.
Cornell Institute of Geriatric Psychiatry
Weill Medical College of Cornell University
21 Bloomingdale Road
White Plains, NY 10605

The Cornell Scale for Depression in Dementia
Administration & Scoring

The Cornell Scale for Depression in Dementia (CSDD) was specifically developed to assess signs and symptoms of major depression in patients with dementia. Because some of these patients may give unreliable reports, the CSDD uses a comprehensive interviewing approach that derives information from the patient and the informant. Information is elicited through two semi-structured interviews; an interview with an informant and an interview with the patient. Based on these interviews, the interviewer can score the CSDD by assigning a preliminary score to each item of the scale on the basis of the informant's report in the "Informant" column. The next step is for the rater to interview the patient using the Cornell scale items as a guide. The interviews focus on depressive symptoms and signs occurring during the week preceding the interview. Many of the items during the patient interview can be filled after direct observation of the patient. If there are discrepancies in ratings generated from the informant and the patient interviews, the rater should re-interview both the informant and the patient to resolve the discrepancies. The final ratings of the CSDD items represent the rater's clinical impression rather than the responses of the informant or the patient. The CSDD takes approximately 20 minutes to administer.

Each item is rated for severity on a scale of 0-2 (0=absent, 1=mild or intermittent, 2=severe). The item scores are added. Scores above 10 indicate a probable major depression. Scores above 18 indicate a definite major depression. Scores below 6 as a rule are associated with absence of significant depressive symptoms.

INTERVIEW WITH THE INFORMANT

Who qualifies as an Informant? Informants should know and have frequent contact with the patient. Reliable informants can include nursing staff for patients in the hospital and nursing homes or a family member for outpatients.

The informant interview should be conducted first. The interviewer should ask about any change in symptoms of depression over the prior week. The rater should complete each item on the scale. The rater can expand on the descriptions of the symptoms in order to help the informant understand each item.

Interview Instructions: I am going to ask you questions about how your relative has been feeling **during the past week**. I am interested in changes you have noticed and the duration of these changes.

A. Mood Related Signs

1. **Anxiety:** *(anxious expression, ruminations, worrying)* Has your relative been feeling anxious this past week? Has s/he been worrying about things s/he may not ordinarily worry about, or ruminating over things that may not be that important? Has your relative had an anxious, tense, distressed or apprehensive expression?

2. **Sadness:** *(sad expression, sad voice, tearfulness)* Has your relative been feeling down, sad, or blue this past week? Has s/he been crying at all? How many days out of the past week has s/he been feeling like this? For how long each day?

3. **Lack of reactivity to pleasant events:** If a pleasant event were to occur today (i.e., going out with spouse, friends, seeing grandchildren), would your relative be able to enjoy it fully, or might his/her mood get in the way of his/her interest in the event or activity? Does your relative's mood affect any of the following:
    - his/her ability to enjoy activities that used to give him/her pleasure?
    - his/her surroundings?
    - his/her feelings for family and friends?

4. **Irritability:** *(easily annoyed, short tempered)* Has your relative felt short-tempered or easily annoyed this past week? Has s/he been feeling irritable, impatient, or angry this week?

B. Behavioral Disturbance

5. **Agitation:** *(restlessness, handwringing, hairpulling)* Has your relative been so fidgety or restless this past week that s/he was unable to sit still for at least an hour? Was your relative so physically agitated that you or others noticed it? Agitation may include such behaviors as playing with one's hands, hair, hand-wringing, hair-pulling, and/or lip-biting: have you observed any such behavior in your relative during the past week?

6. **Retardation:** *(slow movements, slow speech, slow reactions)* Has your relative been talking or moving more slowly than is normal for him/her? This may include:
    - slowness of thoughts and speech
    - delayed response to your questions
    - decreased motor activity and/or reactions.

7. **Multiple physical complaints:** In the past week, has your relative had any of the following physical symptoms? (in excess of what is normal for him/her):
    - indigestion?
    - constipation?
    - diarrhea?
    - stomach cramps?
    - belching?
    - joint pain?
    - backaches?
    - muscles aches?
    - frequent urination?
    - sweating?
    - headaches?
    - heart palpitations?
    - hyperventilation (shortness of breath)?

If you have observed any of these physical symptoms, how much have these things been bothering your relative? How severe have the symptoms gotten? How often have they occurred in the past week?

Rating guideline: *Do not rate symptoms that are side effects from medications or those symptoms that are only related to gastrointestinal ailments.*

8. **Acute Loss of interest:** *(less involved in usual activities)* How has your relative been spending his/her time this past week (not including work and chores)? Has your relative felt interested in his/her usual activities and hobbies? Has your relative spent any *less* time engaging in these activities?

   If s/he is ***not*** as interested, or has not been that engaged in activities during the past week: Has your relative had to push him/herself to do the things s/he normally enjoys? Has your relative *stopped* doing anything s/he used to do? Can s/he look forward to anything or has s/he lost interest in many of the hobbies from which s/he used to derive pleasure?

   Rating guideline: *Ratings of this item should be based on loss of interest during the past week. This item should be rated 0 if the loss of interest is long-standing (longer than 1 month) and there has been no worsening during the past month. This item should be rated 0 if the patient has not been engaged in activities because of physical illness or disability, or if the patient has persistent apathy associated with dementia.*

C. Physical Signs

9. **Appetite loss:** *(eating less than usual)* How has your relative's appetite been this past week compared to normal? Has it decreased at all? Has your relative felt less hungry or had to remind him/herself to eat? Have others had to urge or force him/her to eat?

   Rating guideline: *Rate 1 if there is appetite loss but still s/he is eating on his/her own. Rate 2 if eats only with others' encouragement or urging.*

10. **Weight loss:** Has your relative lost any weight in the past month that s/he has not meant to or been trying to lose? (If not sure: are your relative's clothes any looser on him/her?) If weight loss is associated with present illness (i.e., not due to diet or exercise): how many pounds has s/he lost?

    Rating guideline: *Rate 2 if weight loss is greater than 5 lbs. in past month.*

11. **Lack of energy:** *(fatigues easily, unable to sustain activities – score only if change occurred acutely, or in less than one month)* How has your relative's energy been this past week compared to normal? Has s/he been tired all the time? Has s/he asked to take naps because of fatigue? This week, has your relative had any of the following symptoms due to lack of energy only (***not*** due to physical problems):
    - heaviness in limbs, back, or head?
    - felt like s/he is dragging through the day?

    Has your relative been fatigued more easily this week?

Rating guideline: *Ratings of this item should be based on lack of energy during the week prior to the interview. This item should be rated 0 if the lack of energy is long-standing (longer than 1 month) and there has been no worsening during the past month.*

D. Cyclic Functions

12. Diurnal variation of mood: *(symptoms worse in the morning)* Regarding your relative's mood (his/her feelings and symptoms of depression), is there any part of the day in which s/he usually feels better or worse? (or does it not make any difference, or vary according to the day or situation?)

If ***yes*** to a difference in mood during the day: Is your relative's depression worse in the morning or the evening?

If worse in the morning: Is this a mild or a very noticeable difference?

Rating guideline: *Diurnal variation of mood is only rated for symptoms that are worse in the morning. Variation of mood in the evening can be related to sundowning in patients with dementia and should not be rated.*

13. Difficulty falling asleep: *(later than usual for this individual)* Has your relative had any trouble falling asleep this past week? Does it take him/her longer than usual to fall asleep once s/he gets into bed (i.e., more than 30 min)?

Rating guideline: *Rate 1 if patient only had trouble falling asleep a few nights in the past week. Rate 2 if s/he has had difficulty falling asleep every night this past week.*

14. Multiple awakenings during sleep: Has your relative been waking up in the middle of the night this past week? How long is s/he awake?
If ***yes***: does s/he get out of bed? Is this just to go to the bathroom and then s/he goes back to sleep?

Rating guideline: *Do not rate if waking is only to go to the bathroom and then is able to fall right back asleep. Rate 1 if sleep has only been restless and disturbed occasionally in the past week, and has not gotten out of bed (besides going to the bathroom). Rate 2 if s/he gets out of bed in the middle of the night (for reasons other than voiding), and/or has been waking up every night in the past week.*

15. Early morning awakenings: *(earlier than usual for this individual)* Has your relative been waking up any earlier this week than s/he normally does (without an alarm clock or someone waking him/her up)?
If ***yes***: how much earlier is s/he waking up than is normal for him/her? Does your relative get out of bed when s/he wakes up early, or does s/he stay in bed and/or go back to sleep?

Rating guideline: *Rate 1 if s/he wakes up on his/her own but then goes back to sleep. Rate 2 if s/he wakes earlier than usual and then gets out of bed for the day (i.e., s/he cannot fall back asleep).*

E. Ideational Disturbance

16. Suicide: *(feels life is not worth living, has suicidal wishes, or makes suicide attempt)* During the past week, has your relative had any thoughts that life is not worth living or that s/he would be better off dead? Has s/he had any thoughts of hurting or even killing him/herself?

Rating guideline: *Rate 1 for passive suicidal ideation (i.e., feels life isn't worth living but has no plan). Rate 2 for active suicidal wishes, and/or any recent suicide attempts, gestures, or plans. History of suicide attempt without current passive or active suicidal ideation is not scored.*

17. Self-depreciation: *(self-blame, poor self-esteem, feelings of failure)* How has your relative been feeling about him/herself this past week? Has s/he been feeling especially critical of him/herself, feeling that s/he has done things wrong or let others down? Has s/he been feeling guilty about anything s/he has or has not done? Has s/he been comparing him/herself to others, or feeling worthless, or like a failure? Has s/he described him/herself as "no good" or "inferior"?

Rating guideline: *Rate 1 for loss of self-esteem or self-reproach. Rate 2 for feelings of failure, or statements that s/he is "worthless", "inferior", or "no good".*

18. Pessimism: *(anticipation of the worst)* Has your relative felt pessimistic or discouraged about his/her future this past week? Can your relative see his/her situation improving? Can your relative be reassured by others that things will be okay or that his/her situation will improve?

Rating guideline: *Rate 1 if s/he feels pessimistic, but can be reassured by self or others. Rate 2 if feels hopeless and cannot be reassured that his/her future will be okay.*

19. Mood congruent delusions: *(delusions of poverty, illness, or loss)* Has your relative been having ideas that others may find strange? Does your relative think his/her present illness is a punishment, or that s/he has brought it on him/herself in some irrational way? Does your relative think s/he has less money or material possessions than s/he really does?

INTERVIEW WITH THE PATIENT

Ratings of some patient interview items should be based principally on direct observation, i.e. anxiety, sadness, irritability, agitation, retardation. Questions to the patient can provide additional information on these items. The remaining items are scored based on the interview behavior and the patient's response to direct inquiry. **Interview Instructions:** I am going to ask you some questions about how you have been feeling **during the past week**.

A. Mood Related Signs:

1. **Anxiety:** *(anxious expression, ruminations, worrying)* Does the subject have an anxious, tense, distressed or apprehensive expression?

   Ask the patient: Have you been feeling anxious this past week? Have you been worrying about things you may not ordinarily worry about, or ruminating over things that may not be that important?

2. **Sadness:** *(sad expression, sad voice, tearfulness)* Does the patient have a sad expression or sad voice? Is the patient tearful?

   Ask the patient: Have you been feeling down, sad, or blue this past week? Have you been crying at all? How many days out of the past week have you been feeling like this? For how long each day?

3. **Lack of reactivity to pleasant events:** Is the patient able to respond to friendly or supportive remarks or to humor?

   Ask the patient: If a pleasant event were to occur today (i.e., going out with your spouse, friends, seeing your grandchildren), would you be able to enjoy it fully, or might your mood get in the way of your interest in the event or activity? Does your mood affect any of the following:

   - your ability to enjoy activities that used to give you pleasure?
   - your surroundings?
   - your feelings for your family and friends?

4. **Irritability:** *(easily annoyed, short tempered)* Observe whether the patient is easily annoyed and short-tempered during the interview.

   Ask the patient: Have you felt short-tempered or easily annoyed this past week? Have you been feeling irritable, impatient, or angry this week?

B. Behavioral Disturbance

5. **Agitation:** *(restlessness, handwringing, hairpulling):* Observe the patient for behaviors such as playing with his/her hands, hair, hand-wringing, hair-pulling, and/or lip-biting.

   Ask the patient: Have you been fidgety or restless this past week? Have you been unable to sit still for at least an hour? Were you so physically agitated to the point that others noticed it?

6. **Retardation:** *(slow movements, slow speech, slow reactions)* This item should be scored *exclusively on the basis of the rater's observations*. Retardation is characterized by:
   - slow speech
   - delayed response to questions
   - decreased motor activity and/or reactions.

7. **Multiple physical complaints:** In the past week, have you had any of the following physical symptoms in excess to what is normal for you:
   - indigestion?
   - constipation?
   - diarrhea?
   - stomach cramps?
   - belching?
   - joint pain?
   - backaches?
   - muscles aches?
   - frequent urination?
   - sweating?
   - headaches?
   - heart palpitations?
   - hyperventilation (shortness of breath)?

   If ***yes*** to any of the above: How much have these things been bothering you? How bad have they gotten and how often have they occurred in the past week?

   Rating guideline: *Do not rate symptoms that are side effects from taking medications or those that are only related to gastrointestinal ailments.*

8. **Loss of interest:** *(less involved in usual activities – score only if change occurred acutely, or in less than one month)* How have you been spending your time this past week (not including work and chores)? Have you felt interested in what you usually like to do? Have you spent any *less* time engaging in these activities?

   If ***not*** as interested, or has not been engaged in activities during the past week: Have you had to push yourself to do the things you normally enjoy? Have you *stopped* doing anything you used to do? Can you look forward to anything or have you lost interest in many of the hobbies from which you used to derive pleasure?

   Rating guideline: *Ratings of this item should be based on loss of interest during the past week. This item should be rated 0 if the loss of interest is long-standing (longer than 1 month) and there has been no worsening during the past month. This item should be rated 0 if the patient has not been engaged in activities because of physical illness or disability or if the patient has persistent apathy associated with his/her dementia.*

C. Physical Signs

9. **Appetite Loss:** *(eating less than usual)* How has your appetite been this past week compared to normal? Has it decreased at all? Have you felt less hungry or had to remind yourself to eat? Have others had to urge or force you to eat?

   Rate 1 if appetite loss but still eating on his/her own. Rate 2 if eats only with others' encouragement or urging.

10. **Weight Loss:** Have you lost any weight in the past month that you have not been trying to lose? (If not sure: are your clothes any looser on you?) If weight loss is associated with present illness (i.e., not due to diet or exercise): how many pounds have you lost?

    Rating guideline: *Rate 2 if weight loss is greater than 5 lbs. in past month.*

11. **Lack of energy:** *(fatigues easily, unable to sustain activities – score only if change occurred acutely, or in less than one month)* Does the patient appear fatigued or drained of energy?

    Ask the patient: How has your energy been this past week compared to normal? Have you been tired all the time? Have you needed to take naps because of fatigue? Have you had any of the following symptoms due to lack of energy only (*not* due to physical problems):

    - heaviness in limbs, back, or head?
    - felt like you are dragging through the day?

    Rating guideline: *Ratings of this item should be based on lack of energy during the week prior to the interview. This item should be rated 0 if the lack of energy is long-standing (longer than 1 month) and there has been no worsening during the past month.*

D. Cyclic Functions

12. **Diurnal variation of mood:** *(symptoms worse in the morning)* Regarding your mood (feelings and symptoms of depression), is there any part of the day in which you usually feel better or worse? (Or does it not make any difference, or vary according to the day or situation?)

    If ***yes*** to a difference in mood during the day: Is your depression worse in the morning or the evening? If worse in the morning: is this a mild or a very noticeable difference?

    Rating guideline: *Diurnal variation of mood is only rated for symptoms that are worse in the morning. Variation of mood in the evening can be related to sundowning inpatients with dementia and should not be rated.*

13. **Difficulty falling asleep:** *(later than usual for this individual)* Have you had any trouble falling asleep this past week? Does it take you longer than usual to fall asleep once you get into bed (i.e., more than 30 min)?

    Rating guideline: *Rate 1 if only the subject had trouble falling asleep a few nights in the past week. Rate 2 if s/he has had difficulty falling asleep every night this past week.*

14. **Multiple awakenings during sleep:** Have you been waking up in the middle of the night this past week more than usual? If ***yes***: do you get out of bed? Is this just to go to the bathroom and then you go back to sleep?

    Rating guideline: *Do not rate if waking is only to go to the bathroom and then is able to fall right back asleep. Rate 1 if sleep has only been restless and disturbed occasionally in the past week, and has not gotten out of bed (besides going to the bathroom). Rate 2 if s/he gets out of bed in the middle of the night (for reasons other than voiding), and/or has been waking up every night in the past week.*

15. **Early morning awakenings:** *(earlier than usual for this individual)* Have you been waking up any earlier this week than you normally do (without an alarm clock or someone waking you up)? If ***yes***: how much earlier are you waking up than is normal for you? Do you get out of bed when you wake up early, or do you stay in bed and/or go back to sleep?

    Rating guideline: *Rate 1 if s/he wakes up on his/her own but then goes back to sleep. Rate 2 if s/he wakes earlier than usual and then gets out of bed for the day (i.e., s/he cannot fall back asleep).*

E. Ideational Disturbance

16. **Suicide:** *(feels life is not worth living, has suicidal wishes, or makes suicide attempt)* During the past week, have you had any thoughts that life is not worth living or that you would be better off dead? Have you had any thoughts of hurting or even killing yourself?

    Rating guideline: *Rate 1 for passive suicidal ideation (i.e., feels life isn't worth living). Rate 2 for active suicidal wishes, and/or any recent suicide attempts, gestures, or plans. History of suicide attempt in a subject with no passive or active suicidal ideation does not in itself justify a score.*

17. **Self-depreciation:** *(self-blame, poor self-esteem, feelings of failure)* How have you been feeling about yourself this past week? Have you been feeling especially critical of yourself, feeling that you have done things wrong or let others down? Have you been feeling guilty about anything you have or have not done? Have you been comparing yourself to others, or feeling worthless, or like a failure? Have you felt "no good" or "inferior"?

    Rating guideline: *Rate 1 for loss of self-esteem or self-reproach. Rate 2 for feelings of failure, or statements that s/he is "worthless", "inferior", or "no good".*

18. **Pessimism:** *(anticipation of the worst)* Have you felt pessimistic or discouraged about your future this past week? How do you think things will work out for yourself? Can you see your situation improving? Can you be reassured by others that things will be okay or that your situation will improve?

    Rating guideline: *Rate 1 if s/he feels pessimistic, but can be reassured by self or others. Rate 2 if feels hopeless and cannot be reassured that his/her future will be okay.*

19. **Mood congruent delusions:** *(delusions of poverty, illness, or loss)* Have you been seeing or hearing things that others do not see or hear? Has your imagination been playing tricks on you in any way, or have you been having ideas that others may not understand? Do you think that your present illness is a punishment, or that you have brought it on yourself in some way? Do you think you have a lot less money or material possessions than others say that you have?

References

Alexopoulos GA, Abrams RC, Young RC & Shamoian CA: Cornell scale for depression in dementia. Biol Psych, 1988, 23:271-284.

Alexopoulos GS, Abrams RC, Young RC, Shamoian CA: Use of the Cornell scale in nondemented patients. J Amer Geriatr Soc 36:230-236, 1988.

MULTIDISCIPLINARY MEDICATION MANAGEMENT COMMITTEE

ANTIPSYCHOTIC USE IN DEMENTIA ASSESSMENT

RESIDENT NAME: _____ **ROOM:** _____ **PHYSICIAN:** _____

ASSESSMENT DATE: _____ □ Initial assessment □ Continuation assessment
PHQ-9 Score/date: _____ BIMS/CPS Score/date: _____

A. ANTIPSYCHOTIC (name/dosage/directions): _____

- Start Date: _____ Last Dosage Change: _____ (Decrease/Increase)

B. OTHER CONCURRENT CLINICAL CONCERNS:

❑ *Pain*	❑ *Infection*	❑ *Constipation*	❑ *Weight loss*
❑ *Falls*	❑ *Parkinson's*	❑ *Depression*	❑ *Insomnia*
❑ *Other:*			

C. REASON FOR ANTIPSYCHOTIC INITIATION:

- ❑ *Dementing Illness with associated behavioral symptoms*
- ❑ *Dementia alone*
- ❑ *Other:* _____
- ❑ *No Indication Identified*

D. TARGETED SYMPTOMS OR BEHAVIORS (why was it started):

_____
_____

E. NONPHARMACOLOGICAL INTERVENTIONS:

_____
_____

F. BEHAVIORAL TRENDS SINCE LAST ASSESSMENT (In Documentation**):**

❑ Behavioral symptoms Decreased	❑ Behavioral symptoms Increased
❑ No Change in Behavioral symptoms	

***SUMMARY*:** _____

G. ADVERSE EFFECT MONITORING (changes from baseline functioning) [**AIMS=** _____ date_____]

❑ *Drowsiness, sedation or confusion*	❑ *Dizziness or loss of balance*	❑ *Falls*	❑ *Constipation*
❑ *Muscle spasm, tremor, shaking*	❑ *Uncontrolled movements*	❑ *Tardive dyskinesia*	❑ *Vision changes*
❑ *Swallowing difficulty*	❑ *Speech difficulty*	❑ *Headache*	❑ *Weight gain*
❑ *Dry mouth*	❑ *Drooling*	❑ *Increased skin sensitivity*	❑ *Restlessness or anxiety*
Other:	*Other:*	❑ *NO Apparent ADR's reported*	

M3 COMMITTEE SUMMARY OF BEHAVIORAL TRENDS & ANTIPSYCHOTIC USAGE:

_____
_____
_____

ANTIPSYCHOTIC USE IN DEMENTIA ASSESSMENT

H. **M3 COMMITTEE RECOMMENDATION** (Date: _____):

[*Always consider a dose reduction even if it may have failed in the past*]

☐ ***Gradual Dosage Reduction at this Time:***

- Recommended dose reduction (write new orders):
  _____

☐ ***Gradual Dosage Reduction NOT indicated due to (BOTH requirements must be met):***

- Previous attempt at GDR resulted in reoccurrence of behavioral symptoms (documented date: _____) ; **AND**
- Clinical rationale why an attempt at GDR would likely impair this resident's function or increase their distressed behavior:
  _____
  _____

☐ ***Recent Dosage Change*** *(<60 days)*: _____

☐ ***Will Consider GDR when Resident is Clinically Stable:***

- Clinical Rationale: _____

☐ ***Recommend Additional Clinician Assessment of Behavioral Symptoms with Follow-up Report at Next Scheduled Meeting***

M3 Committee Members:

Medical Director: _____ Executive Director: _____ D.O.N.: _____

Consultant Pharmacist: _____ Social Services: _____ Nurse Manager: _____

I. **ATTENDING PHYSICIAN ASSESSMENT** (Date: _____):

☐ ***I Agree with M3 Committee's recommendation (follow recommendation above)***

☐ ***I Agree with M3 Committee's recommendations*, but with these orders:**

- _____

☐ ***I Disagree with M3 Committee's recommendations because (specific clinical rationale for this resident required):***

- _____
  _____
  _____

PHYSICIAN SIGNATURE: _____ **Date:** _____

ORDERS CONFIRMED BY: _____ Date: _____

Psychopharmacologic Interdisciplinary Medication Review

Shared with Permission of Karyn Leible, RN, MD, CMD

Resident:_____ Date of review:_____

Reason for Review: ____Initiation ____Dose reduction consideration
____Dose reduction review ____ Change in condition

Diagnosis for psychopharmacologic medication use:_____

Other diagnosis: _____

Medication to be reviewed: _____

Date started_____ Last review_____ Last GDR attempt_____

Other Medications:_____

Target behavior/symptom_____

____Decline in frequency ____No longer present ____ No change

Target symptom/behavior non-pharm interventions present in care plan_____

Documentation of effectiveness_____

Evidence of adverse effects or functional decline: ____Falls ____ Increased assistance for ADLs
____Weight loss ____Decreased oral intake (fluids) ____Somnolence
____Insomnia ____Restlessness ____Decreased mobility
Other: _____

Recent Pain Assessment_____

Recent sleep study (if indicated) _____

AIMS _____Date _____Score **BIMS** _____ Date _____Score **PHQ 9** _____ Date ____Score

Pertinent laboratory studies:_____

Risk/ benefit discussion with resident or MDPOA documented at initiation of medication_____
Date_____

Committee Recommendations:

Response:

Practitioner Signature and date:

Committee Members:

Anti-psychotrophic Reality Reductions

Presented by:
Kathie J. Gately, BSW, SLTCO

Real Medical Medication Need

- *Appropriate* use for anti-psychotic medications

PSYCHIATRIC DIAGNOSES

- **Schizophrenia**
- **Schizo-affective disorder**
- **Delusional disorder**
- **Psychotic mood disorders (mania and depression with psychotic features)**
- **Acute psychotic episodes**
- **Brief reactive psychosis**
- **Schizophreniform disorder**
- **Atypical psychosis**
- **Tourette's disorder**
- **Huntington's disease**
- **Short term (7 days) treatment of hiccups, nausea, vomiting, or pruritus**

Real Not so Needed

- *Inappropriate* use for antipsychotic medication
- **Wandering**
- **Poor self care**
- **Restlessness**
- **Impaired memory**
- **Anxiety**
- **Depression (without psychotic features)**
- **Insomnia**
- **Unsociability**
- **Indifference to surroundings**
- **Fidgeting**
- **Uncooperativeness**
- **Agitated behavior which does not represent danger to resident or others**

Our Reality - Anger

- Do you ever get angry?
- What makes you angry?
- How do you express your anger?
- Reaction from others when you are angry?
- Most importantly……
- What anti-psychotics are you taking due to your anger?

Our Reality – So you had a bad day…

- Do you ever get sad?
- What makes you sad?
- Simple sadness
- Life review sadness

- …. And your anti-depressant is?

Our Reality – Oh Happy Day….

- Woke up on the right side of the bed?
- Good news!
- Love?
- Accomplishments?
- …and your medication of choice is?

Real Team

- Physician
- Nurse
- CNA
- Housekeeper
- Social Worker
- Dietary
- Activities Director
- Maintenance
- Family
- Visitors
- Clergy
- Volunteers
- Office Workers
- Therapist

Home Thermostat

- Where?
- When?
- What's happening?

Real Physical Assessment

- Medical related
- Pain
- Non-verbal cry for assistance

Real Resident Knowledge

- Interview who?
- Observe who?
- Monitoring change – do we change?

Real Behavior Interventions

Music

RAP, Country Western, Rock, religious, elevator

How long?

Massage

Neck, Hand, Elbow, Foot

Individual Activities, Self-Time and Outside.

Real Group Support

- Life Loss Issues
- Reminisce
- Behavior
- Active
- Gentlemen Talk
- Ladies Chatter
- Keeping up with the Times

Ms. Zelma's Real World

Come into my world

Validation Therapy

Does it work?
Is it worth the time?
What is the beneficial outcome?

Real Time Up!

Thanks to all of you for what you are doing to ensure that individuals (including yourself one day) receive the right medications, interventions and liberties to select their mood of the day!

"To be angry, sad, and happy all in one day.....assures me that I am not unstable and not just alive, but that I am living and not just existing."

Kathie J. Gately

ahca American Health Care Association

ncal National Center for Assisted Living

A PERSPECTIVE ON CMS'S ANTIPSYCHOTIC REDUCTION INITIATIVE

DAVID GIFFORD MD MPH
SR VP QUALITY & REGULATORY AFFAIRS

ASCP

National Harbor MD November 8th, 2012

Faculty Disclosure

- Dr Gifford has no financial, other relationship or other support from the pharmaceutical industry related to antipsychotic medications
- Dr Gifford will be discussing the evidence related to the off-label use of antipsychotic medications

Learning Objectives

- Able to describe the magnitude of the risks and benefits of antipsychotics for individuals with dementia residing in nursing homes
- Interpret and use the CMS quality measures on the use of antipsychotic medication in your practice
- Strategies to safely reduce the use of these medications in long term care setting

National Priority

- CMS is making the reduction of off-label use of antipsychotic medications a national priority
- Don Berwick, Director of CMS has asked professional associations to work together and with CMS to reduce the off-label use of antipsychotic medications in nursing homes

Antipsychotic Medications

- Conventional
  - Compazine
  - Haldol
  - Loxitane
  - Mellaril
  - Moban
  - Navane
  - Orap
  - Prolixin
  - Stelazine
  - Thorazine
  - Trilafon
- Atypical
  - Aripiprazole
  - Asenapine
  - Clozapine
  - Iloperidon
  - Olanzapine
  - Paliperidone
  - Quetiapine
  - Risperidone
  - Ziprasidone

FDA approved diagnoses

- Schizophrenia
- Bi-polar Disorder
- Irritability associated with Autistic Disorder (Aripiprazole & Risperidone)
- Treatment Resistant Depression (Olanzapine)
- Major Depressive Disorder (Quetiapine)
- Tourettes (Orap)

When prescribed to a patient without an FDA approved diagnosis; the prescription is considered as an “off-label use”, which is allowed by FDA and Medical Boards

Common Off-label uses

- Dementia with behavior difficulties
  - Agitation
  - Abusive, violent
  - Wandering
- Acute Delirium
- Obsessive-compulsive disorder
- Psychotic symptoms (e.g. hallucinations, delusions) with neurological diseases
  - Parkinson's disease
  - Stroke

Effectiveness in Dementia

- Antipsychotic effect takes 3-7 days to start working
  - Very sedating medication so acute effect is most likely due to sedating effect not the antipsychotic effect
- Randomized controlled trial (RCTs) is the gold standard method to evaluate the effectiveness of medications
  - RCTs randomized dementia patients to either receive an antipsychotic or a placebo and clinicians are blinded to who gets the meds when rating outcomes
- Meta-analysis is method that combines the results from multiple RCTs

Scales to assess Behavior in Dementia

- **Cohen-Mansfield Agitation Inventory (CMAI) scale**
  - Assesses 29 types of agitated behavior (pacing, verbal or physical aggression, performing repetitious mannerisms, screaming, and general restlessness.) on a seven-point scale.
- **Behavior Pathology in Alzheimer's Disease Rating Scale (BEHAVE-AD)**
  - Assesses seven clusters of behavior: paranoid/delusional ideation; aggressiveness; hallucinations; activity symptoms; diurnal rhythm symptoms; affective symptoms; and anxieties and phobias using 25 questions rated on a four-point scale.
- **NeuroPsychitatric inventory (NPI)**
  - Assess 12 behaviors: delusions, hallucinations, agitation/aggression, depression, anxiety, euphoria, apathy, disinhibition, irritability, aberrant motor behavior, sleep, easting disorders scored on a4 point scale.
- **Clinical Global Impression of Change (CGI-C)**
  - Assesses overall patients change in condition on a seven point scale (1 – very much improved; 4 - no change; 7 - very much worse)

Effectiveness in Dementia is weak Meta-Analysis (JAMA 2011)

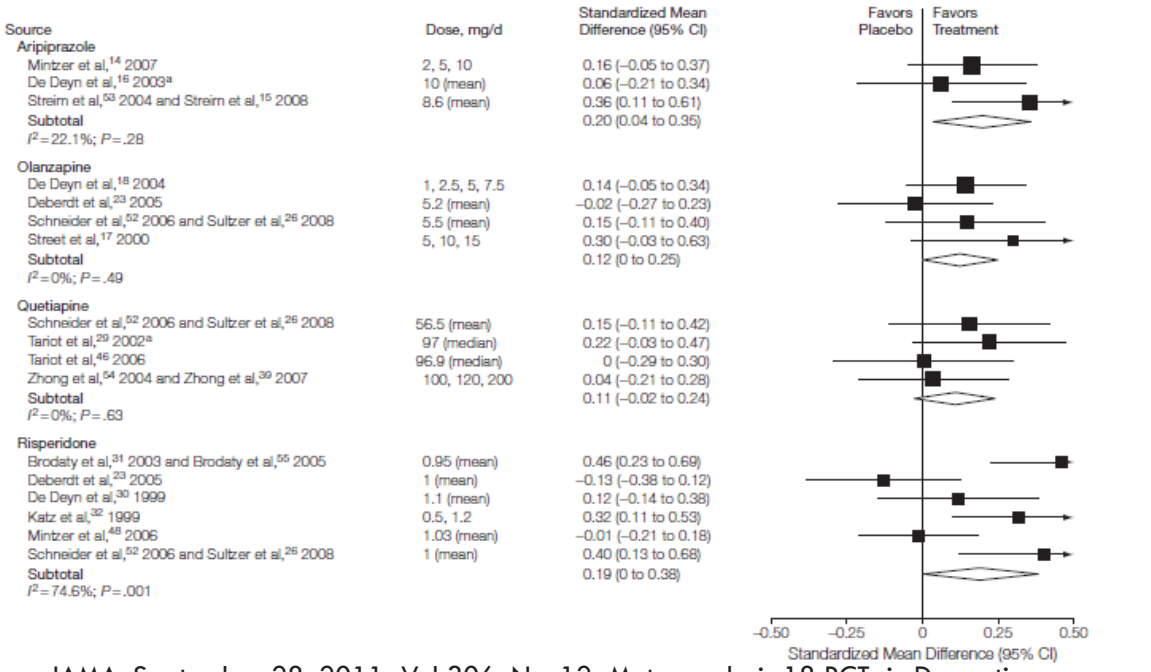
- Olanzapine, Risperidone and Aripiprazole, had a small but statistically significant effect (12 – 20% got better) when compared to placebo
- Quetiapine did not have a statistically significant effect
- Antipsychotics led to an average change/difference on the NeuroPsychiatric Inventory (NPI) of
  - 35% from a patient's baseline
  - 3.41 point difference from placebo group

  (note: a 30% change and 4.0 difference is the minimum threshold needed for a clinically meaningful result)
- No conclusive evidence was found regarding the comparative effectiveness of different antipsychotics

Source: JAMA 306:1359-69 2011; Meta-analysis 38 RCTs in dementia

Antipsychotic vs Placebo Results

Figure 1. Controlled Trials of Patients Taking Atypical Antipsychotic Medications vs Placebo



Source: JAMA, September 28, 2011; Vol 306, No. 12; Meta-analysis 18 RCTs in Dementia

Effectiveness in Treating Aggression in Dementia (Cocharane Review 2012)

Evaluated 16 randomized controlled trials with atypical antipsychotics vs placebo although only 9 had sufficient data to include in meta-analysis.

Conclusions:

- Statistically significant improvement in aggression with risperidone and olanzapine when compared to placebo
- Statistically significant improvement in psychosis with risperidone
- Significant increase in drop-outs in risperidone (2 mg) and olanzapine (5-10 mg) treated patients

Source: Cohcrane Review 2012; Meta-analysis 16 RCTs in dementia

Effectiveness of Antipsychotics in Dementia

Drug	% improvement in symptom scale	% treatment discontinuation
olanzapine	32%	24%
quetiapine	26%	16%
risperidone	29%	18%
placebo	21% (p=0.22 for trend)	5% (p=0.009 for trend)

Source: Scheurer D. Antipsychotic use in Primary care: limited benefit, sizable risk Independent Drug Information Service (IDIS) 2012.

Associated with adverse outcomes

- Off-label use of antipsychotics in nursing facility residents are associated with an increase in:
  - Death
  - Hospitalization
  - Falls & fractures
  - Venothrombolic events
- Conventional antipsychotics are worse than atypical antipsychotics

Dose for Antipsychotics Used in Dementia

Medication	Low Dose	Normal Dose
Aripiprazole	<2 mg/d	2-15 mg/d
Olanzapine	<5 mg/d	5-10 mg/d
Quetiapine	<50 mg/d	50-100 mg/d
Risperidone	<1 mg/d	1-2 mg/d

Effectiveness with Low Dose

- Low dose Resperidone <1 mg/d) has small positive effective but also has increase risk of adverse events
- Low dose Olanzapine (5 mg/d) has no positive effect but does have increase risk of adverse events
- Low dose Aripiprazole and Quetiapine effectiveness are unknown but Quetiapine at normal dose ineffective

Source: Cochrane Review 2012; Meta-analysis 16 RCTs in dementia

Odds of having an adverse event after receiving an Respiridone 1 mg/d compared to placebo

Adverse Event	Odd Ratio	95% Confidence Interval
Mortality	**1.25**	0.73 to 2.16
Somnolence	**2.40**	1.70 to 3.20
Falls	**0.84**	0.63 to 1.14
Extrapyramidal disorder	**1.78**	1.00 to 3.17
UTI	**1.40**	0.92 to 2.13
Edema	**2.75**	1.51 to 5.03
Abnormal Gait	**5.31**	2.24 to 12.62
Urinary Incontinence	**13.6**	1.81 to 101
CVA	**3.64**	1.72 to 7.69
Drop out (had to stop meds)	**1.43**	1.01 to 2.03

Source: Cochrane Review 2012; Meta-analysis 4 RCTs in dementia

Odds of having an adverse event after receiving an Olanzapine 5-10 mg/d compared to placebo

Adverse Event	Odd Ratio	95% Confidence Interval
Mortality	**2.31**	0.66 to 8.13
Somnolence	**3.72**	1.90 to 7.25
Falls	**1.52**	0.79 to 2.91
Abnormal Gait	**4.76**	1.67 to 13.57
Urinary Incontinence	**9.60**	1.27 to 72.85
CVA	**5.24**	0.29 to 95.69
Drop outs	**3.34**	1.69 to 6.59

Source: Cochrane Review 2012; Meta-analysis 3 RCTs in dementia

Net effectiveness

"For every 100 patients with dementia treated with an antipsychotic medication, only 9 to 25 will benefit and 1 will die"

Drs Avorn, Choudhry & Fishcher

Harvard Medical School

Dr Scheurer

Medical University of South Carolina

Source: Independent Drug Information Service (IDIS) Restrained Use of antipsychotic medications: rational management of irrationality. 2012

FDA Black Box Warning

- Issued in 2005
- Warning: Increased Mortality in Elderly Patients with Dementia-Related Psychosis
  - Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at and increased risk of death. [Name of Antipsychotic] is not approved for the treatment of patients with dementia-related psychosis.

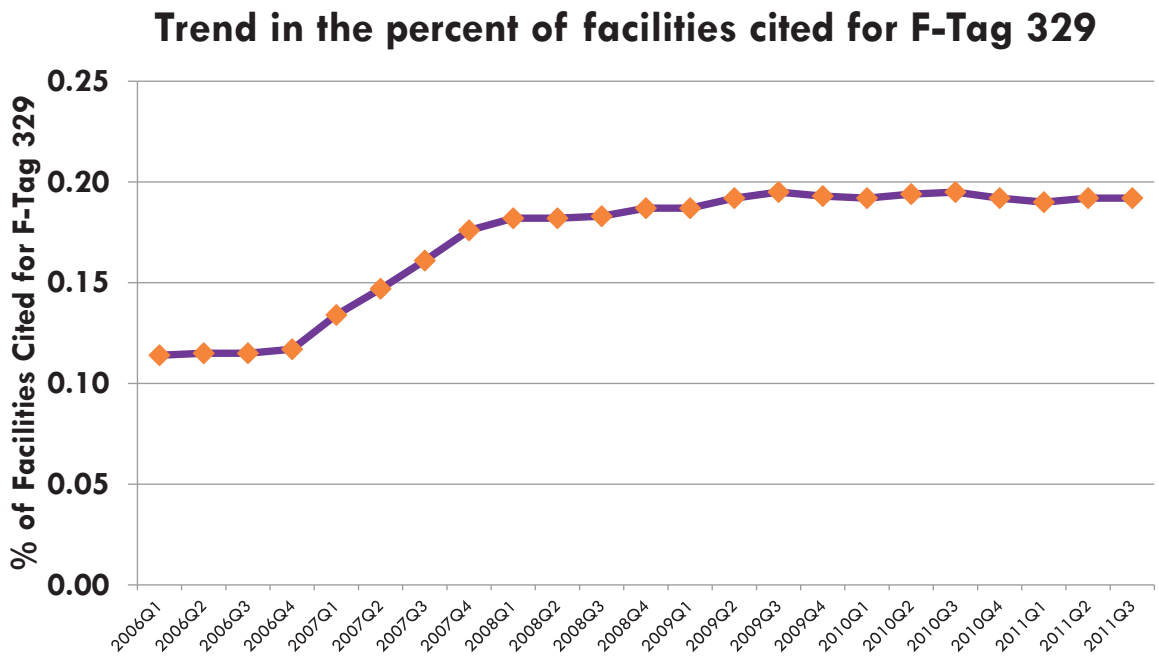
WARNING

Increased Mortality in Elderly Patients with Dementia-Related Psychosis — Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. [this drug] is not approved for the treatment of patients with dementia-related psychosis.

F-Tag associated with off-label use

- F-Tag 329: Unnecessary Drugs
  - Residents should have drug regimens that are free of unnecessary drugs defined as
    - There in an excessive dose including duplicate therapy
    - There is an excessive duration of being on the drug
    - There is inadequate monitoring of the drug
    - There is inadequate indication for the use of the drug
    - There are adverse consequences
    - A combination of the reasons above
  - Specific conditions for antipsychotic drugs
    - The facility must ensure that residents have not used antipsychotics previously, are not given these drugs unless the drug therapy is necessary, and recorded in the clinical record
    - In an effort to decrease the use of antipsychotics residents must receive gradual dose reduction and alternate therapies, unless they are counter-indicated

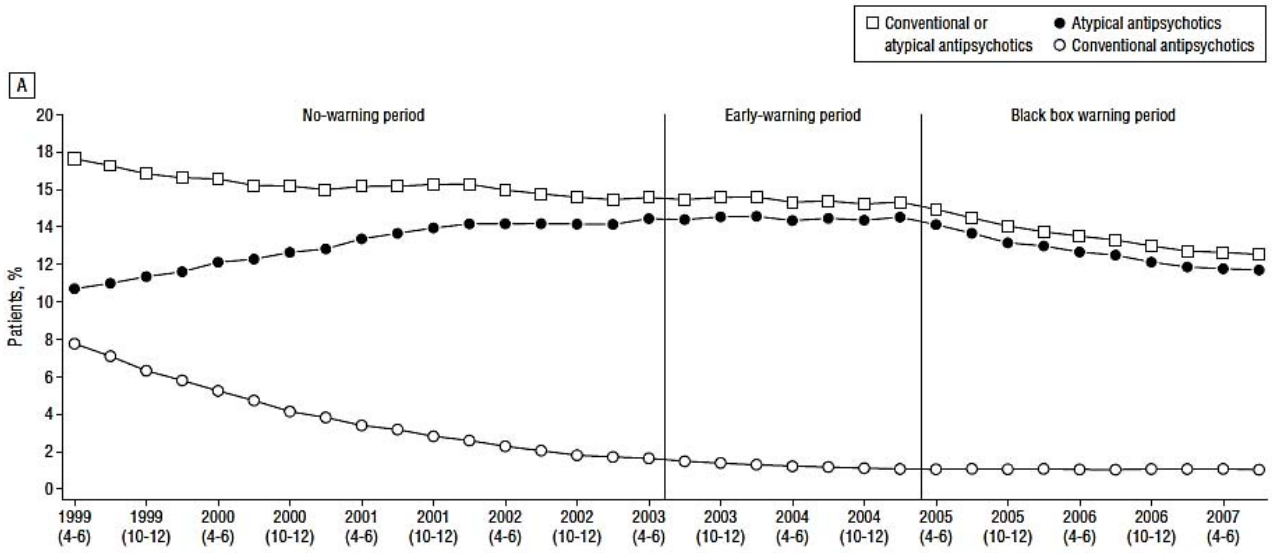
Trends in F-Tag 329 unnecessary Meds



Trends in use following FDA Black Box

- 1990s there was a shift from conventional to atypical antipsychotics
  - Atypical antipsychotics have lower rates of Parkinsonism and Tardive Dyskinesia
- The outpatient use of antipsychotics started to decrease before the FDA black box warning
- 5% increase in the use of antidepressants, anxiolytics, and anticonvulsants after the FDA black box warning

Patients with dementia which outpatient antipsychotic use



Helen C. Kales; Kara Zivin; Hyungjin Myra Kim; Marcia Valenstein; Claire Chiang; Rosalinda V. Ignacio; Dara Ganoczy; Francesca Cunningham; Lon S. Schneider; Frederic C. Blow. **Trends in Antipsychotic Use in Dementia 1999-2007**.*Arch Gen Psychiatry*. 2011;68(2):190-197.

OIG Report 2011

- OIG report
  - Reviewed 600 medical records
  - Medicare claims data for Part B and Part D and MDS data from January 1st to July 31st, 2007 was used to identify payments for atypical antipsychotic drug use for elderly nursing home residents
- Major Findings
  - 14% of elderly nursing home residents had Medicare claims for atypical antipsychotic drugs
    - Off-label conditions accounted for 83% of these claims
  - Over ½ of the Medicare claims for antipsychotic drugs for elderly nursing home resident were incorrect
  - Medicare reimbursement criteria was not met for 726,000 of the 1.4 million claims
  - 22% of the atypical antipsychotic drugs were not administered in accordance with CMS standards

CMS quality measures

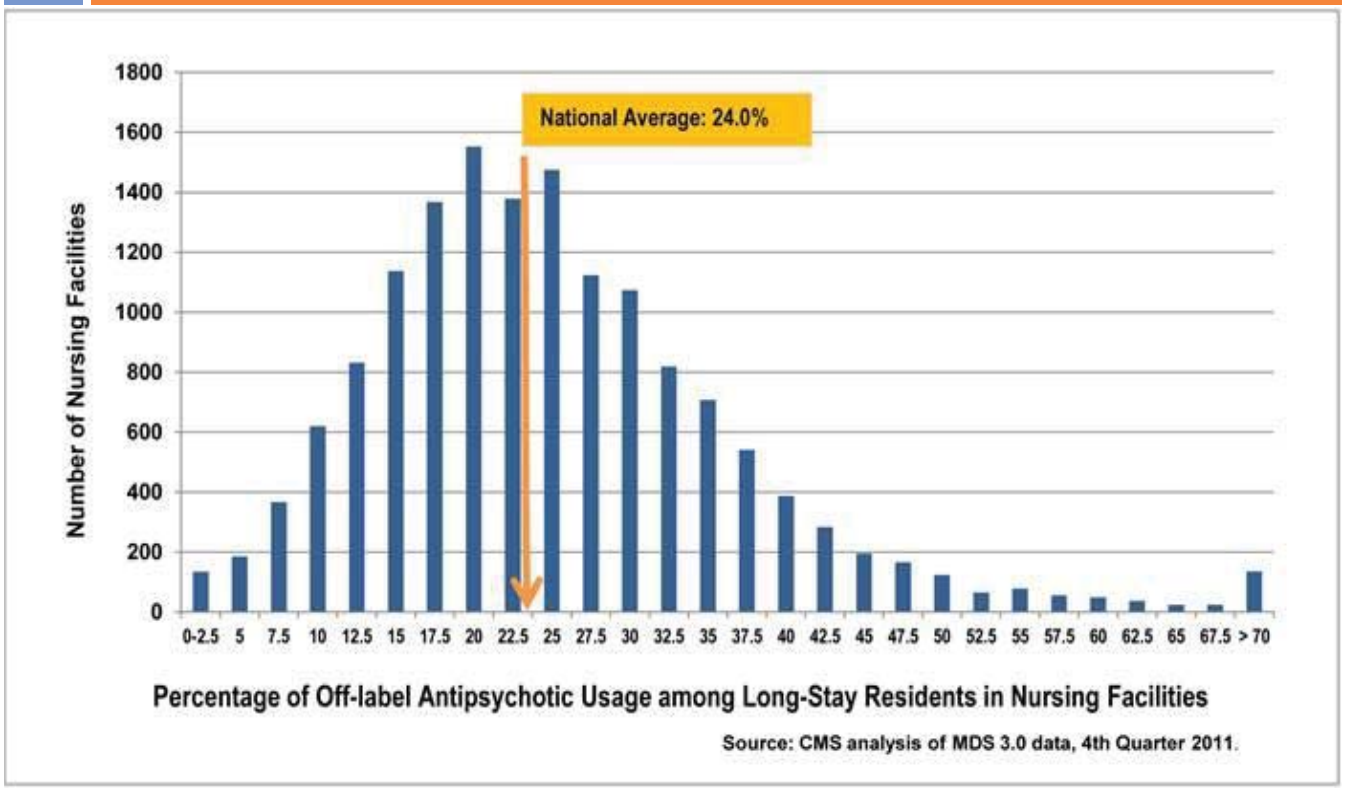
- % started on medication following admission
  - % of individuals in a facility for $\leq$100 days who were not admitted on the medication but who have it started during their 100 day stay excluding individuals with schizophrenia, Tourette's and Huntington's disease
- % long stay residents who receive the medication
  - % of individuals in a facility for > 100 days who are receiving the medication excluding individuals with schizophrenia, Tourette's and Huntington's disease

CMS measures

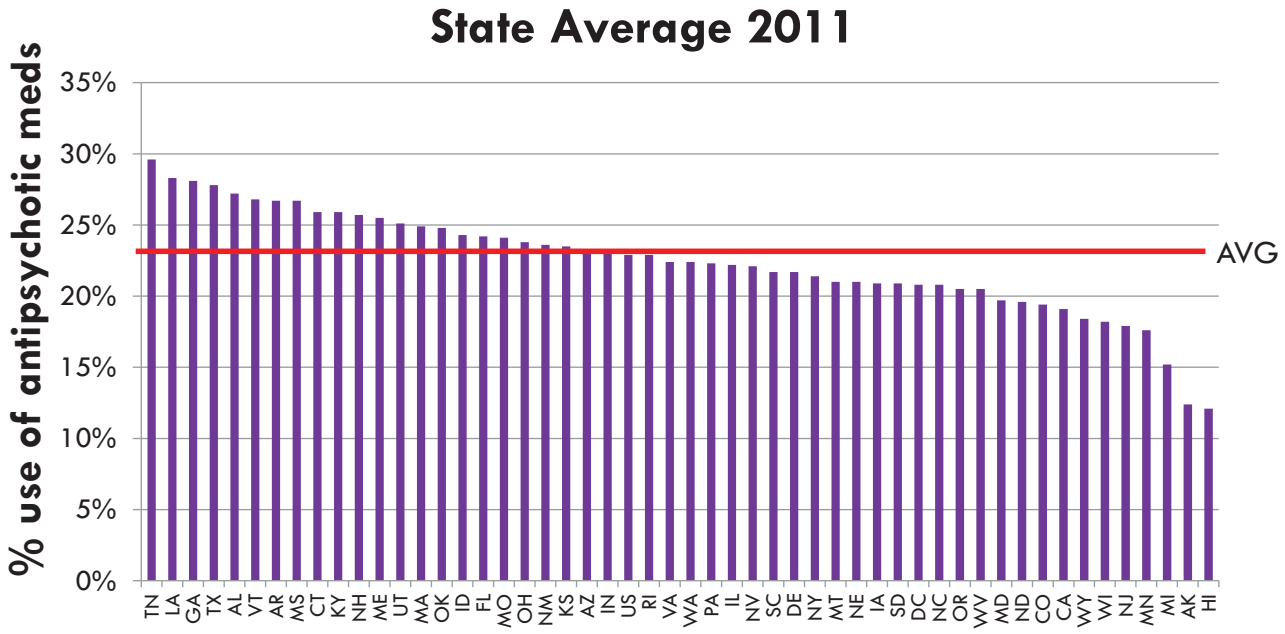
- Failure to include other FDA approved diagnoses such a bipolar disorder
- % Started during 100 days[1] = 3%
- % Receiving medication long stay[1] = 24%
- % Receiving medication on admission[2] = 12%

[1]Source: CMS Nursing home compare reported July 2012 using data from 4th Quarter 2011
[2]Source: MDS 2.0 data 2010 analysis of admission assessments excluding schizophrenia and bipolar disorder

Off-Label Use of Antipsychotic Meds



Off-Label Use of Antipsychotics



AHCA Quality Initiative Goals

- ***Reduce Hospital Readmissions***
  - By March 2, 2015 at 12:00 p.m., reduce the number of hospital readmissions within 30 days during a SNF stay by 15 percent
- ***Increase Staff Stability:***
  - By March 2, 2015 at 12:00 p.m., reduce turnover among clinical staff (RN, LVN, CNA) by 15 percent
- ***Reduce the Off-Label Use of Antipsychotics:***
  - By December 31, 2012 at 12:00 p.m., reduce the off-label use of antipsychotics by 15 percent
- ***Increase Resident Satisfaction:***
  - By March 2, 2015 at 12:00 p.m., increase the number of customers who would recommend the facility to others up to 90%

AHCA Strategies to reduce use of antipsychotics in nursing facilities

- Phase I: immediate steps facilities can take that will show results in the near term
  - Focus on withdrawal or gradual dose reduction of antipsychotics
- Strategies
  - Identify residents with off-label use of antipsychotics
  - Review records to assure compliance with CMS SOM
  - Use evidence based approaches for gradual dose reduction (GDR) to discontinue patients from antipsychotics
    - Work with the medical director and consultant pharmacist to guide the GDR process and promote GDR to physicians, staff and families.
  - Educate families about prevalence of dementia, use of antipsychotics and alternate treatment options

Immediate steps to reduce antipsychotics

- No role for PRN only antipsychotic medications
- Evaluate the need for continuing antipsychotics at admission & those on very low doses
- Evaluate need for antipsychotics started on residents during the evening/night shift or over the weekend
- Look at discontinue or gradual dose reduction for residents on medications for greater than 12 weeks (3 months), particularly those with no change in dose or frequency

Can you stop antipsychotics safely?

2. If individuals with dementia on low dose antipsychotics were randomized to either continue their meds or switched to a placebo, would the placebo group's behaviors compared to continued meds group be?

a. a lot worse

b. somewhat worse

c. no different

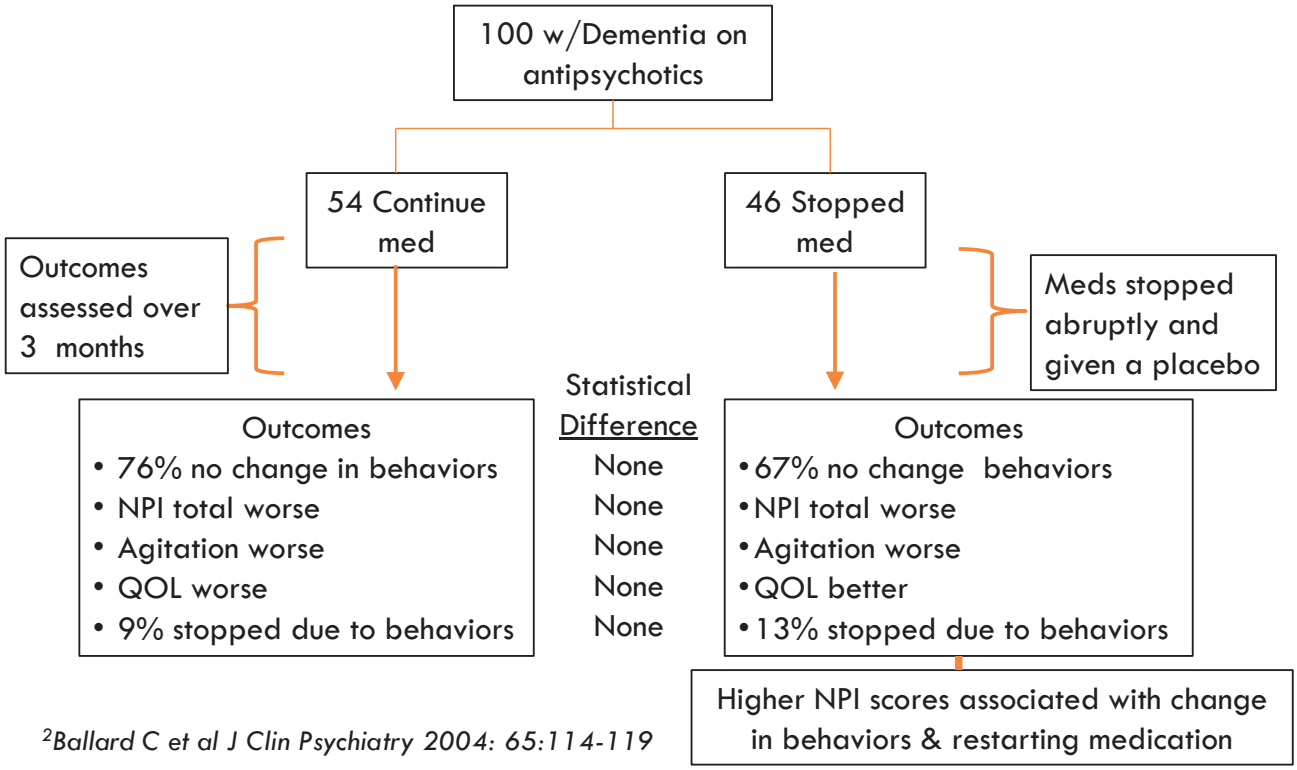
d. somewhat better

e. a lot better

Evidence based for Discontinuing Meds at lose dose

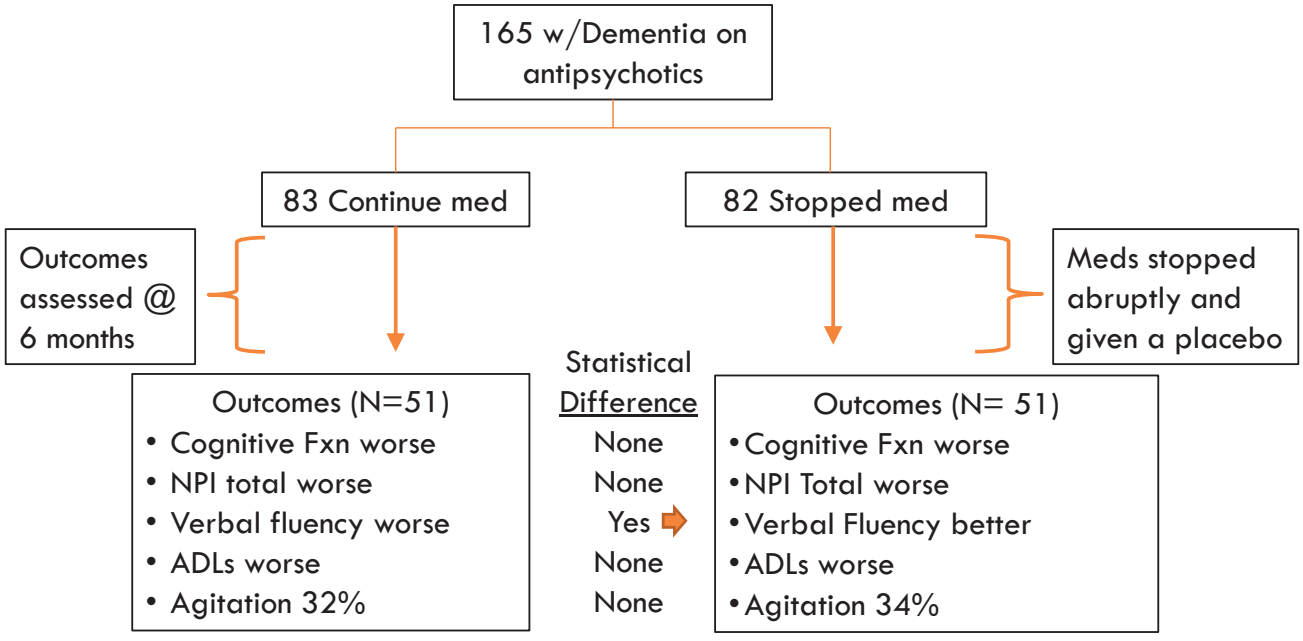
- RCTs comparing withdrawal of medication to continuing antipsychotics show
  - No difference in outcomes between placebo group and continued medication group
  - About 75% people remain off the drug after the trial
    - Less than 25% need to be restarted on antipsychotic
  - Placebo group (drug withdrawal) have fewer adverse events

RCT to withdraw antipsychotics[2]



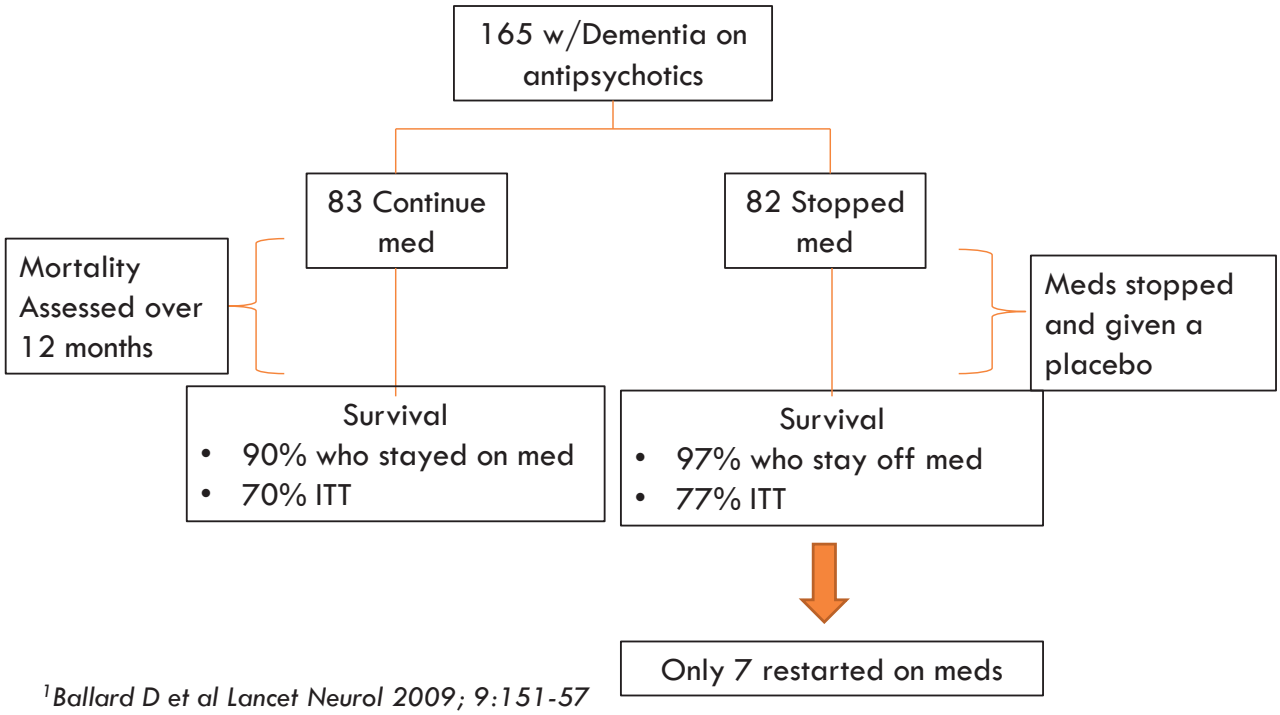
[2]*Ballard C et al J Clin Psychiatry 2004: 65:114-119*

RCT to withdraw antipsychotics[3]



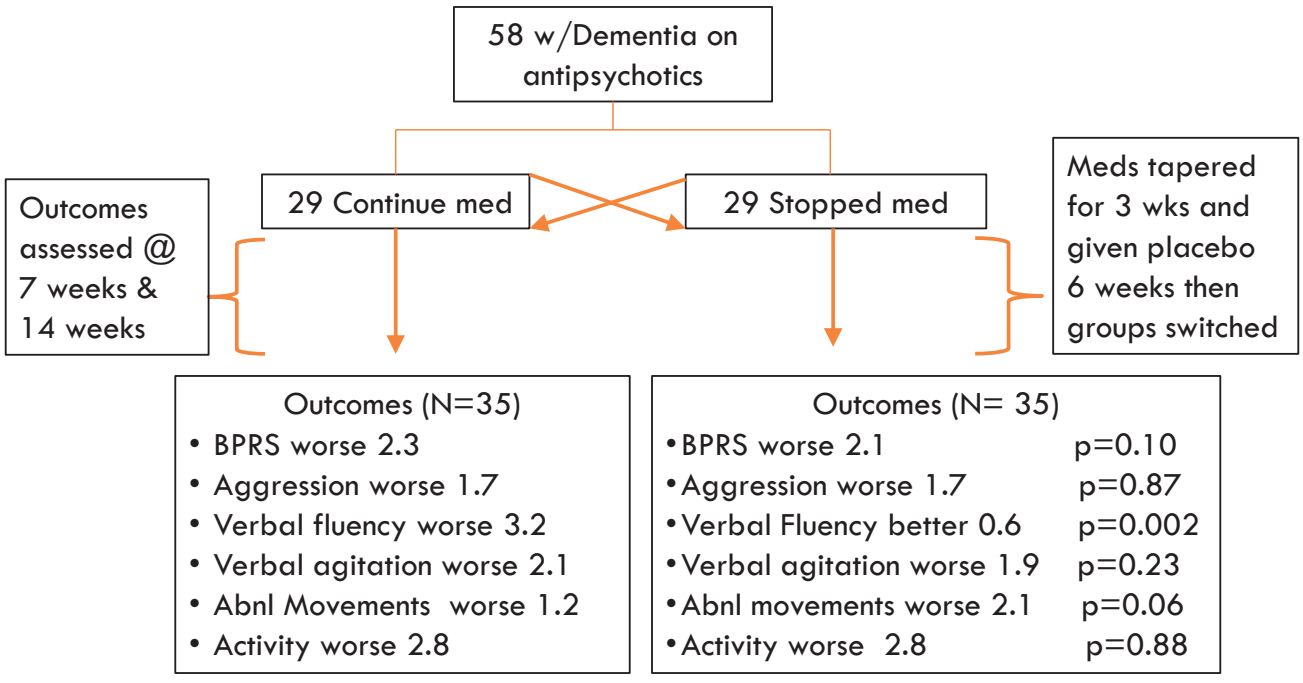
[3]*Ballard C et al Plos Medicine 2008; 5:e76: 587-599*

RCT to withdraw antipsychotics[1]



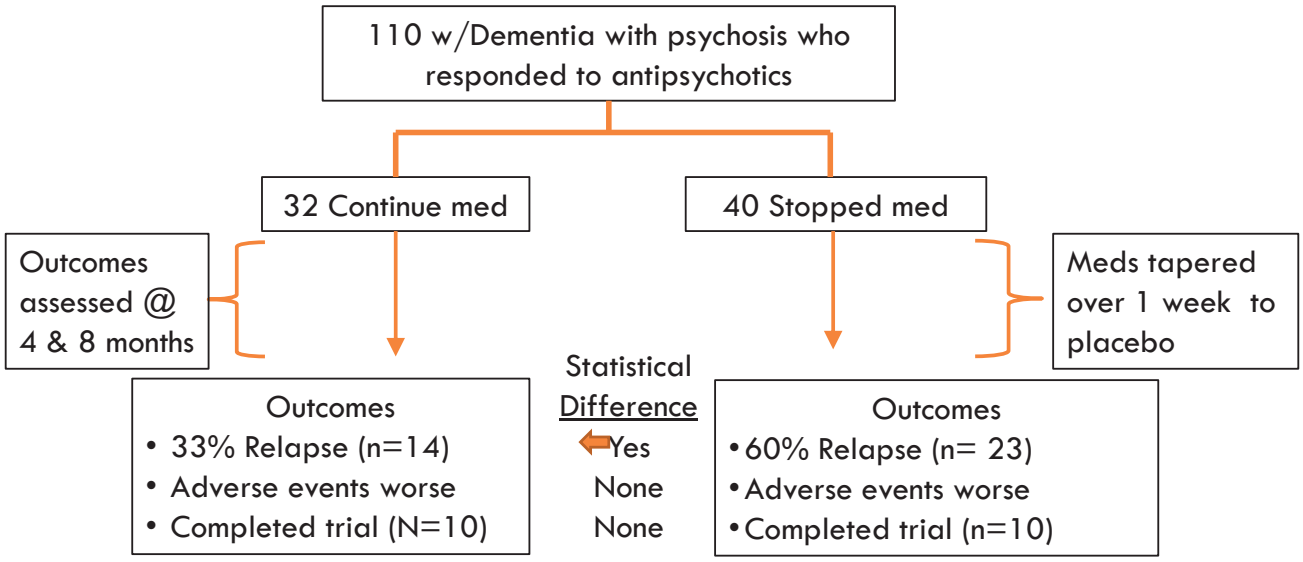
[1]*Ballard D et al Lancet Neurol 2009; 9:151-57*

RCT to withdraw antipsychotics[4]



[4]*Cohen-Mansfield et al Arch Int Med 1999; 159:1733-1740*

RCT to withdraw antipsychotics[4]



[4]*Devandand DP et al NEJM 2012; 367:1497-1507*

Clinical Practice Tools

- See ASCP, AMDA, AHCA, Advancing Excellence
- AHCA Tools to facilitate GDR/discontinuation:
  - Nursing Process
  - SBAR
- University of Iowa/Iowa Geriatric Education Center resources:
  - Videos
  - Pocket guides to evidence-based practices
  - Decision algorithms
  - Fact sheets for professionals & families

Primary Challenge is Changing Beliefs

- Most health care professionals and families believe

  (1) dementia "behaviors" are abnormal & need to be treated

  (2) antipsychotics medications are effective

Strategies to reduce use of antipsychotics in nursing facilities

- Phase II: steps that will take longer to implement but need to be started now
  - Focus on implementing programs to minimize the off-label use of antipsychotics by promoting
    - Non-pharmacologic strategies to manage individuals with dementia
    - Changes to how we view dementia behaviors as attempts to communicate unmet needs
- Strategies
  - Staff training on interacting with individuals with dementia
  - Adopt policy on minimal use of medications with dementia residents
    - Educate families about this policy
  - Implement consistent assignment
  - Compare facility off-label antipsychotic use to others
    - Learn from other facilities

Dementia re-examined

- Experiencing the world in a different way
- What are "behaviors"?
  - Medical symptoms?
  - Predictable human responses to the situation perceived?
- Key questions to ask:
  - What is this person trying to tell me?
  - What is distressing this person?
  - What does he or she need to be in well-being?

Questions to ask for new Rxs

- What did you do to try and figure out why the resident was doing <fill in the blank>?
- What is resident trying to communicate to us about their <fill in blank>?
- What is reason for resident doing <fill in blank>?
  - Unacceptable answer (Dementia or sun-downing)
- What did you try before requesting medications?

Contact Information

David Gifford MD MPH

SR VP for Quality & Regulatory Affairs

American Health Care Association

120 L St. NW

Washington DC 20005

Dgifford@ahca.org

202-898-3161

www.ahcancal.org

ahca American Health Care Association

ncal National Center for Assisted Living

Antipsychotic Medication Reference*

User Guide

- Usual dosage ranges represent treatment of schizophrenia in healthy adults unless otherwise indicated. Dosage adjustments are often required based on patient age, renal and hepatic function, etc.
- Side effects in bold type represent those listed in "Warnings and Precautions" section of product information
- Side effects/adverse effects are not necessarily listed in order of severity or frequency
- Not all side effects/adverse effects are represented. Consult full prescribing information for complete list and frequency of side effects
- Off-label uses identified by one or more references/compendia do not imply appropriate use

Drug Name	FDA-Approved Indications	Other FDA-Approved Indications	Age Group for Which Approved	Off Label Uses	Side Effects/Adverse Effects
1st generation antipsychotics					
Chlorpromazine (Thorazine®): usual oral dosage range for acute treatment of schizophrenia – 300-1000mg/day in divided doses[1]	• Management of manifestations of psychotic disorders[2] • Treatment of schizophrenia[2] • Control the manifestations of the manic type of manic-depressive illness[2] • Treatment of severe behavioral problems in children marked by combativeness and/or explosive hyperexcitable behavior[2] • Short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders consisting of some or all of the following symptoms: impulsivity, difficulty sustaining attention, aggressivity, mood lability and poor frustration tolerance[2]	• To control nausea and vomiting[2] • For relief of restlessness and apprehension before surgery[2] • For acute intermittent porphyria[2] • As an adjunct in the treatment of tetanus[2] • For relief of intractable hiccups[2]	Adults and Children (6 months-12 years)[2]	• Behavioral symptoms associated with dementia (elderly); psychosis/ agitation related to Alzheimer's dementia[3] • Treatment of migraine in adults (intramuscular/ intravenous) [4]	**Drowsiness**, **extrapyramidal symptoms (dystonia, motor restlessness, pseudo-parkinsonism, tardive dyskinesia), neuroleptic malignant syndrome, lowering of seizure threshold, hyperprolactinemia,** jaundice, hematologic disorders, agranulocytosis, hypotensive effects, ECG changes, convulsive seizures, allergic reactions, endocrine disorders, autonomic reactions, changes in skin pigmentation, ocular changes, increase in appetite, peripheral edema, lupus-like syndrome, weight changes, hyperpyrexia[2]
Fluphenazine (Prolixin®): usual oral dosage range for acute treatment of schizophrenia – 5-20mg/day in divided doses[1]	Management of manifestations of psychotic disorders[5]		Adults[5]	• Psychosis/ agitation related to Alzheimer's dementia[6] • Postherpetic neuralgia • Antiemetic[7]	**Extrapyramidal symptoms, neuroleptic malignant syndrome, hyperprolactinemia,** drowsiness, lethargy, nausea, loss of appetite, salivation, polyuria, perspiration, dry mouth, headache, constipation, hypertension, fluctuations in blood pressure, blurred vision, glaucoma, bladder paralysis, fecal impaction, paralytic ileus, tachycardia, nasal congestion, metabolic and endocrine (weight change, peripheral edema, abnormal lactation, gynecomastia, menstrual irregularities, impotence), allergic reactions, hematologic changes, jaundice, lupus-like syndrome, hypotension severe enough to cause fatal cardiac arrest, altered electrocardiographic and electroencephalographic tracings, altered cerebrospinal fluid proteins, cerebral edema, asthma, laryngeal edema, and angioneurotic edema[5]
Haloperidol (Haldol®): usual oral dosage range for treatment of acute schizophrenia – 1-20mg/day in divided doses[1,8]	• Management of manifestations of psychotic disorders[9] • Tourette's Syndrome[9]		Adults and Children (3-12 years)[9]	• Treatment of non-schizophrenia psychosis • May be used for the emergency sedation of severely-agitated or delirious patients • Adjunctive treatment of ethanol dependence • Postoperative nausea and vomiting (alternative therapy) • Psychosis/agitation related to Alzheimer's dementia[8] • Hiccups • Obsessive-compulsive disorder • Prevention of chemotherapy-induced nausea and vomiting • Phencyclidine psychosis (improving phencyclidine-induced aggression, combativeness, and schizophreniform symptoms like hallucinations, delusions, and disorganized thinking)[10]	**Cardiovascular effects (arrhythmias, QT prolongation, torsades de points, sudden death, tachycardia), tardive dyskinesia, dystonia, neuroleptic malignant syndrome, hyperprolactinemia,** extrapyramidal symptoms, hypotension, hypertension, insomnia, restlessness, anxiety, euphoria, agitation, drowsiness, depression, lethargy, headache, confusion, vertigo, grand mal seizures, exacerbation of psychotic symptoms including hallucinations and catatonic-like behavioral states, hematologic effects, jaundice, dermatologic reactions, endocrine disorders, gastrointestinal effects, autonomic reactions (dry mouth, blurred vision, urinary retention, diaphoresis), respiratory effects (laryngospasm, bronchospasm), cataracts, retinopathy, visual disturbances[9]

Drug Name	FDA-Indications	Other FDA-Indications	Age Group for Which Approved	Off Label Uses	Side-Effects/Adverse Effects
Loxapine (Loxitane®): usual oral dosage range for acute treatment of schizophrenia – 30-100mg/day in divided doses[1]	Treatment of schizophrenia[11]		Adults[11]		**Tardive dyskinesia, neuroleptic malignant syndrome, hematologic effects,** extrapyramidal symptoms, tachycardia, hypotension, hypertension, orthostatic hypotension, lightheadedness, syncope, EKG changes, anticholinergic effects, dermatologic effects, hematologic effects, gastrointestinal side effects, weight gain, weight loss, dyspnea, ptosis, hyperpyrexia, flushing, headache, paresthesia, and polydipsia, galactorrhea, amenorrhea, gynecomastia, and menstrual irregularity[11]
Perphenazine (Trilafon®): usual oral dosage range for acute treatment of schizophrenia – 16-64mg/day in divided doses[1]	Treatment of schizophrenia[12]	Control of severe nausea and vomiting[12]	Adults and Children ≥ 12 years[12]		**Tardive dyskinesia, neuroleptic malignant syndrome, hypotension (if pressor needed, use norepinephrine), hyperprolactinemia,** extrapyramidal symptoms, convulsive seizures, jaundice, sedation, dry mouth or salivation, nausea, vomiting, diarrhea, anorexia, constipation, obstipation, fecal impaction, urinary retention, frequency or incontinence, bladder paralysis, polyuria, nasal congestion, pallor, myosis, mydriasis, blurred vision, glaucoma, perspiration, hypertension, change in pulse rate, allergic reactions, endocrine effect, cardiovascular effects (tachycardia, bradycardia, ECG changes), hematological effects, ocular changes[12]
Pimozide (Orap®): usual oral dosage range for treatment of Tourette's Syndrome – 1-10mg/day in divided doses[13]	Suppression of motor and phonic tics in patients with Tourette's Syndrome who have failed to respond satisfactorily to standard treatment[14]		Adults and Children ≥ 12 years[14]	Parasitosis (delusional)[15]	**Tardive dyskinesia, sudden death, neuroleptic malignant syndrome, hematologic effects,** extrapyramidal symptoms, ECG changes, hyperpyrexia, asthenia, chest pain, periorbital edema, postural hypotension, hypotension, hypertension, tachycardia, palpitations, increased salivation, nausea, vomiting, anorexia, GI distress, loss of libido, weight gain, weight loss, dizziness, tremor, parkinsonism, fainting, dyskinesia[14]
Prochlorperazine (Compazine®): usual oral dosage range for acute treatment of schizophrenia – 50-150mg/day in divided doses[1]	• Treatment of schizophrenia[16] • Short-term treatment of generalized non-psychotic anxiety[16]	Control of severe nausea and vomiting[16]	Adults and Children ≥ 20 pounds and ≥ 2 years[16]		**Tardive dyskinesia, neuroleptic malignant syndrome, hypotension,** extrapyramidal symptoms, drowsiness, dizziness, amenorrhea, blurred vision, skin reactions, leukopenia, agranulocytosis, jaundice[16]
Thioridazine (Mellaril®): usual oral dosage range for acute treatment of schizophrenia – 300-800mg/day in divided doses[1]	Management of schizophrenic patients who fail to respond adequately to treatment with other antipsychotic drugs[17]		Adults and pediatric patients with schizophrenia who are unresponsive to other agents[17]	Management of agitation and psychotic events in patients with dementia and Alzheimer's disease[18]	**Proarrhythmic effects (prolongation of QT interval), orthostatic hypotension, neuroleptic malignant syndrome, extrapyramidal symptoms, hyperprolactinemia,** drowsiness, nocturnal confusion, lethargy, dry mouth, blurred vision, constipation, nausea, vomiting, diarrhea, dermatitis, skin eruptions, endocrine effects[17]
Thiothixene (Navane®): usual oral dosage range for acute treatment of schizophrenia – 6-50mg/day in divided doses[1,19]	Management of schizophrenia[19]		Adults and Children ≥ 12 years[19]	Nonpsychotic patient, dementia behavior (elderly); psychosis/agitation related to Alzheimer's dementia[20]	**Tardive dyskinesia, extrapyramidal symptoms, sudden death, hyperprolactinemia, seizures, hematologic effects, neuroleptic malignant syndrome, hepatic effects,** dry mouth, blurred vision, nasal congestion, constipation, increased sweating, increased salivation, tachycardia, hypotension, light-headedness, syncope, drowsiness, restlessness, agitation, insomnia, impotence, allergic reaction, jaundice, endocrine effects, hyperpyrexia, anorexia, nausea, vomiting, diarrhea, increase in appetite and weight, weakness or fatigue, polydipsia, and peripheral edema[19]
Trifluoperazine (Stelazine®): usual oral dosage range for acute treatment of schizophrenia – 4-40mg/day in divided doses[1]	• Management of schizophrenia[21] • Short-term treatment of generalized non-psychotic anxiety[21]		Adults and Children 6-12 years[21]		**Extrapyramidal symptoms,** drowsiness, dizziness, skin reactions, rash, dry mouth, insomnia, amenorrhea, fatigue, muscular weakness, anorexia, lactation, blurred vision, hematologic effects[21]

Drug Name	FDA-Indications	Other FDA-Indications	Age Group for Which Approved	Off Label Uses	Side-Effects/Adverse Effects
2nd generation (atypical) antipsychotics					
Aripiprazole (Abilify®): usual oral immediate release dosage range for monotherapy for treatment of schizophrenia – 15-30mg/day[22] (see full prescribing information for dosages for other indications)	• Autistic disorder - Psychomotor agitation[23] • Bipolar disorder - Psychomotor agitation[23] • Bipolar I disorder, Adjunctive therapy with lithium or valproate[23] • Bipolar I disorder, Monotherapy, manic or mixed episodes[23] • Major depressive disorder, Adjunctive treatment in patients receiving antidepressant[23] • Schizophrenia - Psychomotor agitation[23] • Schizophrenia[23]		Can be used in children 6 and older, however, recommended ages differ for the various indications.[23]	• Cocaine dependence[24] • Restless legs syndrome[24] • Trichotillomania[24] • Psychosis/agitation related to Alzheimer's dementia[25]	**Suicide, increased mortality in elderly patients with dementia-related psychosis, neuroleptic malignant syndrome, orthostatic hypotension, tardive dyskinesia,** commonly observed adverse reactions (incidence ≥ 5% and at least twice placebo): • Adult schizophrenia: akathisia. • Adult (monotherapy) bipolar mania: akathisia, sedation, restlessness, tremor, and extrapyramidal disorder. Adult (adjunctive therapy with lithium or valproate) bipolar mania: akathisia, insomnia, and extrapyramidal disorder. • Adult major depressive disorder (adjunctive treatment to antidepressant therapy): akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision. • Adult agitation associated with schizophrenia or bipolar mania: nausea.[23]
Asenapine (Saphris®): usual oral dosage range for treatment of schizophrenia – 10-20mg/day in divided doses[22]	• Schizophrenia – acute treatment[26] • Schizophrenia – maintenance treatment[26] • Bipolar mania or mixed – monotherapy[26] • Bipolar mania or mixed – as an adjunct to lithium or valproate[26]		Safety and efficacy have not been established in children.[26]		**Neuroleptic malignant syndrome, tardive dyskinesia, cerebrovascular events, QT prolongation, suicide,** commonly observed adverse reactions (incidence ≥5% and at least twice placebo): • Schizophrenia: akathisia, oral hypoesthesia, and somnolence. • Bipolar Disorder (Monotherapy): somnolence, dizziness, extrapyramidal symptoms other than akathisia, and weight increase. • Bipolar Disorder (Adjunctive): somnolence and oral hypoesthesia.[26]
Clozapine (Clozaril®, FazaClo® ODT): usual oral immediate release dosage range for treatment of schizophrenia – 50-500mg/day in divided doses[22]	• Schizophrenia, Treatment-resistant[27] • Recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorders[27]		Safety and efficacy has not been established in children[27]	• Parkinson's disease - Psychotic disorder[28] • Schizoaffective disorder[29] • Acute manic episodes associated with bipolar disorder; treatment of refractory bipolar mania[28] • Obsessive-compulsive disorders[28] • May be effective in the treatment of tardive dyskinesia[28] • Psychosis/agitation related to Alzheimer's dementia[28]	**Increased mortality In elderly patients with dementia-related psychosis, agranulocytosis (mandatory monitoring, fatal if not detected early and therapy interrupted), seizures, myocarditis,** adverse events observed in incidence of >5%: • Central nervous system complaints including drowsiness/sedation, dizziness/vertigo, headache and tremor • Autonomic nervous system complaints including salivation, sweating, dry mouth and visual disturbances • Cardiovascular findings including tachycardia, hypotension and syncope • Gastrointestinal complaints including constipation and nausea; fever.[27]
Iloperidone (Fanapt®): usual oral dosage range for treatment of schizophrenia – 2-24mg/day in divided doses[22] (must titrate slowly from a low starting dose to avoid orthostatic hypotension due to alpha-adrenergic blocking properties)	Schizophrenia[30]		Safety and effectiveness in pediatric patients has not been established.[30]		**Increased mortality in elderly patients with dementia-related psychosis, neuroleptic malignant syndrome, QT prolongation, tardive dyskinesia.** commonly observed adverse reactions (incidence ≥5% and at least twice placebo): dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, and weight increase.[30]
Lurasidone (Latuda®): usual oral dosage range for treatment of schizophrenia 40-160mg/day[31]	Schizophrenia[31]		Safety and effectiveness in pediatric patients has not been established.[31]		**Increased mortality in elderly patients with dementia-related psychosis, neuroleptic malignant syndrome, tardive dyskinesia, metabolic changes,** commonly observed adverse reactions (incidence ≥5% and at least twice placebo): somnolence, akathisia, nausea, and parkinsonism.[31]

Drug Name	FDA-Indications	Other FDA-Indications	Age Group for Which Approved	Off Label Uses	Side-Effects/Adverse Effects
Olanzapine (Zyprexa®, Zyprexa® Zydis®, Zyprexa® Relprevv®): usual oral immediate release dosage range for schizophrenia 10-20mg/day[22]	• Agitation - Bipolar I disorder[32] • Agitation - Schizophrenia[32] • Bipolar I disorder, Acute mixed or manic episodes[32] • Bipolar I disorder - adjunct therapy with lithium or valproate[32] • Bipolar I disorder, Maintenance therapy[32] • Schizophrenia[32] • Depressed bipolar I disorder[32] • Depression, Treatment-resistant; Adjunct[32] • Bipolar disorder, depressed phase[32] • Major depressive disorder (treatment resistant)[32]		Adults and Children >13 years old[32]	• Agitation, acute - Dementia[33,34] • Delirium[34] • Obsessive-compulsive disorder - adjunct therapy, treatment resistant[33,35] • Severe major depression with psychotic features[35] • Chronic pain; prevention of chemotherapy-associated delayed nausea or vomiting[34] • Tourette's syndrome[35] • Stuttering[35] • Parasitosis (delusional)[35] • Insomnia (elderly)[35]	**Increased mortality in elderly patients with dementia-related psychosis, suicide, neuroleptic malignant syndrome, metabolic changes,** commonly observed adverse reactions oral olanzapine (incidence ≥5% and at least twice placebo): postural hypotension, constipation, weight gain, dizziness, personality disorder, akathisia, asthenia, dry mouth, dyspepsia, increased appetite, somnolence, and tremor.[32]
Olanzapine/fluoxetine (Symbyax®): usual oral dosage range for bipolar and major depressive disorders 6/25-12/50 mg/day[36]	• Bipolar disorder, depressed phase[36] • Major depressive disorder (treatment resistant)[36]		Safety and effectiveness in children and adolescent patients has not been established.[36]		**Suicide, increased mortality in elderly patients with dementia-related psychosis, neuroleptic malignant syndrome, metabolic changes,** commonly observed adverse reactions (incidence ≥5% and at least twice placebo): disturbance in attention, dry mouth, fatigue, hypersomnia, increased appetite, peripheral edema, sedation, somnolence, tremor, vision blurred, and weight increased. Adverse reactions reported in clinical trials of olanzapine and fluoxetine in combination are generally consistent with treatment-emergent adverse reactions during olanzapine or fluoxetine monotherapy.[36]
Paliperidone (Invega®): usual oral immediate release dosage range for schizophrenia 3-9mg/day Invega® Sustenna® 39-234mg/month IM[22]	• Schizoaffective disorder[37] • Schizophrenia[37]		Adults >18 years old[37]	Psychosis/agitation related to Alzheimer's dementia[38]	**Increased mortality in elderly patients with dementia-related psychosis, QT prolongation, neuroleptic malignant syndrome, tardive dyskinesia,** commonly observed adverse reactions (incidence ≥ 5% and at least twice placebo): • Schizophrenia: extrapyramidal symptoms, tachycardia, akathisia. • Schizoaffective disorder: extrapyramidal symptoms, somnolence, dyspepsia, constipation, weight increase and nasopharyngitis.[37]
Quetiapine (Seroquel®, Seroquel® XR): usual oral immediate release dosage range for schizophrenia 250-500mg/day in divided doses[22]	• Bipolar disorder, depressed phase[39] • Bipolar disorder (maintenance) as an adjunct to lithium or divalproex[39] • Acute treatment of manic episodes associated with bipolar I disorder, as monotherapy)[39] • Acute treatment of manic as an adjunct to lithium or divalproex[39] • Schizophrenia[39] • Adjunctive treatment of major depressive disorders (XR only-with antidepressants)[41,42]		Adults and children >13 years old[39]	• Autism[40] • Psychosis/agitation related to Alzheimer's dementia[41] • Insomnia, adjunct therapy in elderly[41] • Treatment resistant obsessive-compulsive disorder[33,41] • Alcohol dependence[41] • Psychosis in Parkinson's disease[41] • Trichotillomania[41]	**Suicide; increased mortality in elderly patients with dementia-related psychosis, neuroleptic malignant syndrome, metabolic changes, QT prolongation,** commonly observed adverse reactions (incidence ≥ 5% and at least twice placebo): somnolence, dry mouth, dizziness, constipation, asthenia, abdominal pain, postural hypotension, pharyngitis, weight gain, lethargy, ALT increased, dyspesia.[39]

Drug Name	FDA-Approved Indications	Other FDA-Approved Indications	Age Group for Which Approved	Off Label Uses	Side Effects/Adverse Effects
Risperidone (Risperdal®): usual oral immediate release dosage range for schizophrenia 2-8mg/day in divided doses Risperdal® Consta® 25-50 mg every 2 weeks IM[22]	• Schizophrenia[43] • Autistic disorder - Irritability[43] • Bipolar I disorder - short term of acute manic or mixed episodes, in combination with lithium or valproate[43]		Adults and children >5 years old, however, recommended ages differ for the various indications.[43]	• Stuttering[44] • Insomnia (elderly)[44] • Tardive dyskinesias[44] • Psychosis in Parkinson's disease[44] • Management of agitation and psychotic events in patients with dementia and Alzheimer's disease[44] • Tourette's syndrome[44] • Psychosis/agitation related to Alzheimer's dementia[33,44] • Obsessive-compulsive disorder-adjunct therapy[33] • Post-traumatic stress disorder (PTSD)[33,45] • Delirium in the critically-ill patient[45]	**Increased mortality in elderly patients with dementia-related psychosis, neuroleptic malignant syndrome, tardive dyskinesia, metabolic changes, orthostatic hypotension,** common adverse reactions in clinical trials (≥10%): somnolence, increased appetite, fatigue, insomnia, sedation, parkinsonism, akathisia, vomiting, cough, constipation, nasopharyngitis, drooling, rhinorrhea, dry mouth, abdominal pain-upper, dizziness, nausea, anxiety, headache, nasal congestion, rhinitis, tremor and rash.[43]
Ziprasidone (Geodon®): usual oral dosage range 40-160 mg/day[22]	• Bipolar I disorder, acute manic or mixed episodes, monotherapy[46] • Schizophrenia[46] • Acute agitation in schizophrenic patients[46]		Safety and effectiveness for pediatric patients has not been established[46]	• Psychosis/agitation related to Alzheimer's dementia[47] • Autism[48] • Tourette's syndrome[48]	**Increased mortality in elderly patients with dementia-related psychosis, neuroleptic malignant syndrome, tardive dyskinesia, hyperglycemia and diabetes mellitus, rash,** commonly observed adverse reactions (incidence ≥ 5% and at least twice placebo): • Somnolence, respiratory tract infection, extrapyramidal symptoms (extrapyramidal syndrome, hypertonia, dystonia, dyskinesia, hypokinesia, tremor, paralysis and twitching. • None of these adverse reactions occurred individually at an incidence greater than 10% in bipolar mania trials, dizziness (dizziness and lightheadedness), akathisia, abnormal vision, asthenia, vomiting, headache.[46]

References

[1]Lehman AF, Kreyenbuhl J, Buchanan RW et al. The Schizophrenia Patient Outcomes Research Team (PORT). Updated Treatment Recommendations 2003. Schizophrenia Bulletin. 2004; 30(2): 193-217. [2]Chlorpromazine [prescribing information]. Indianapolis, IN: Upsher-Smith Laboratories, Inc. [3]Chlorpromazine. In: Lexi-Drugs Online [Internet Database]. Hudson, OH: Lexi-Comp, Inc. Updated 2012 May 17. [4]Chlorpromazine. In: Facts & Comparisons Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health. Updated 2012 February. [5]Fluphenazine [prescribing information]. Spring Valley, IN: Par Pharmaceuticals, Inc.; 2005. [6]Fluphenazine. In: Lexi-Drugs Online [Internet Database]. Hudson, OH: Lexi-Comp, Inc. Updated 2012 May 30. [7]Fluphenazine. In: Facts & Comparisons Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health. Updated 2012 January. [8]Haloperidol. In: Lexi-Drugs Online [Internet Database]. Hudson, OH: Lexi-Comp, Inc. Updated 2012 May 07. [9]Haloperidol [prescribing information]. Morgantown, IN: Mylan Pharmaceuticals Inc.; 2011. [10]Haloperidol. In: Facts & Comparisons Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health. Updated 2010 March. [11]Loxapine [prescribing information]. Philadelphia, IN: Lannett Company Inc.; 2011. [12]Perphenazine [prescribing information]. Huntsville, IN: Qualitest Pharmaceuticals. [13]Pimozide. In Facts & Comparisons Online [Internet Database] Indianapolis, IN: Wolters Kluwer Health. Updated 2011 Sept. [14]Pimozide [prescribing information]. Sellersville. IN: Gate Pharmaceuticals; 2011. [15]Pimozide. In: Facts & Comparisons Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health. Updated 2011 October. [16]Prochlorperazine [prescribing information]. Rockford, IN: UDL Laboratories, Inc. [17]Thioridazine [prescribing information]. Morgantown, IN: Mylan Pharmaceuticals Inc. [18]Thioridazine. In: Facts & Comparisons Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health. Updated 2012 January. [19]Thiothixene [prescribing information]. Morgantown, IN: Mylan Pharmaceuticals Inc.; 2011. [20]Thiothixene. In: Lexi-Drugs Online [Internet Database]. Hudson, OH: Lexi-Comp, Inc. Updated 2012 May 07. [21]Trifluoperazine [prescribing information]. Morgantown, IN: Mylan Pharmaceuticals Inc.; 2010. [22]Crismon L, Argo TR, Buckley PF. Chapter 76. Schizophrenia. In: Talbert RL, DiPiro JT, Matzke GR, Posey LM, Wells BG, Yee GC, eds. Pharmacotherapy: A Pathophysiologic Approach. 8th ed. New York: McGraw-Hill; 2011. http://www.accesspharmacy.com/content.aspx?aID=7987911. Accessed June 4, 2012. [23]Abilify [prescribing information]. Tokyo, Japan: Otsuka Pharmaceutical Co, Ltd.; 2012. [24]Aripiprazole. In: Facts & Comparisons Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health. Updated 2012 March. [25]Aripiprazole. In: Lexi-Drugs Online [Internet Database]. Hudson, OH: Lexi-Comp, Inc. Updated 2012 June 07. [26]Saphris [prescribing information]: Whitehouse Station, NJ: Merck & Co., Inc.; 2011. [27]Clozaril [prescribing information]: East Hanover, NJ: Novartis Pharmaceuticals Co.; 2011. [28]Clozapine. In: Facts & Comparisons Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health. Updated 2011 Jan. [29]Clozapine In: Lexi-Drugs Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health Updated 2012 July. [30]Fanapt [prescribing information]: East Hanover, NJ: Novartis Pharmaceuticals Co.; 2011. [31]Latuda [prescribing information]: Marlborough, MA: Sunovion Pharmaceuticals Inc.; 2012. [32]Zyprexa [prescribing information]: Indianapolis, IN: Eli Lilly & Company; 2011. [33]Maglione M, Ruelaz Maher A, Hu J, et al. Off-Label Use of Atypical Antipsychotics: An Update. Comparative Effectiveness Review No. 43. (Prepared by the Southern California Evidence-based Practice Center under Contract No. HHSA290-2007-10062 – 1.) Rockville, MD: Agency for Healthcare Research and Quality. September 2011. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm. [34]Olanzapine. In: Lexi-Drugs Online [Internet Database]. Hudson, OH: Lexi-Comp, Inc. Updated 2012 June 20. [35]Olanzapine. In: Facts & Comparisons Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health. Updated 2010 Aug. [36]Symbyax [prescribing information]: Indianapolis, IN: Eli Lilly & Company; 2012. [37]Invega [prescribing information]: Titusville, NJ: Janssen Pharmaceuticals; 2011. [38]Paliperidone. In: Lexi-Drugs Online [Internet Database]. Hudson, OH: Lexi-Comp, Inc. Updated 2012 June 18. [39]Seroquel [prescribing information]: Wilmington, DE: AstraZeneca Pharmaceuticals LP.; 2012. [40]Quetiapine. In: Lexi-Drugs Online [Internet Database]. Hudson, OH: Lexi-Comp, Inc. Updated 2012 June 18. [41]Quetiapine. In: Facts & Comparisons Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health. Updated 2010 March. [42]Seroquel (Quetiapine) XR. [prescribing information]: Wilmington, DE: AstraZeneca Pharmaceuticals LP.; 2012. [43]Risperdal [prescribing information]: Titusville, NJ: Ortho-McNeil-Janssen Pharmaceuticals, Inc.; 2011. [44]Risperdone. In: Facts & Comparisons Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health. Updated 2011 Sept. [45]Risperidone. In: Lexi-Drugs Online [Internet Database]. Hudson, OH: Lexi-Comp, Inc. Updated 2012 June 18. [46]Geodon [prescribing information]: NY, NY: Roerig, division of Pfizer, Inc.; 2009. [47]Ziprasidone In: Lexi-Drugs Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health Updated 2012 July. [48]Ziprasidone. In: Facts & Comparisons Online [Internet Database]. Indianapolis, IN: Wolters Kluwer Health. Updated 2012 March.

HQSI and Delmarva Foundation would like to thank the following students for their assistance in the creation of this reference: Bhavini Parikh, PharmD Candidate 2013, and Judy Sim, PharmD Candidate 2013.

* This document is intended for educational purposes only as a quick reference guide to commonly used antipsychotic drugs. Information contained herein is condensed and incomplete. Please refer to full prescribing information and additional reference materials for detailed information on a specific drug or drug use, dosing in special populations and drug use in patients with specific medical conditions. Promethazine and droperidol may be prescribed as antiemetic agents; however these agents have the same cautions as 1st generation antipsychotics. HQSI and DFMC are not responsible for any omissions or errors. This document is not intended to override a clinician's judgment in individual patient management.

Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES

DFMC DELMARVA FOUNDATION Maryland

DFDC DELMARVA FOUNDATION District of Columbia

HQSI Healthcare Quality Strategies, Inc.

This material was prepared jointly by Healthcare Quality Strategies, Inc., Delmarva Foundation – Maryland, and Delmarva Foundation – District of Columbia, the Medicare Quality Improvement Organizations for New Jersey, Maryland, and the District of Columbia, under contract with the Centers for Medicare & Medicaid Services (CMS), and agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. 10SOW-NJ-C.7.3-12-10. 10/2012

Monitoring Guidelines and Adverse Effects[1]

Assessments to monitor physical status and detect concomitant physical conditions		
Assessment	**Initial or Baseline**	**Follow-Up**
Vital signs	Pulse, blood pressure, temperature	As clinically indicated, particularly as medication doses are titrated
Hematology	CBC	If clinically indicated, including assessment of patients treated with clozapine
Blood chemistries	Electrolytes, renal function tests (BUN/creatinine ratio), liver function tests, thyroid function tests	Annually and as clinically indicated
Infectious diseases	Test for syphilis, hepatitis C and HIV, if clinically indicated	
Pregnancy	Consider pregnancy test for women of childbearing potential	
Toxicology	Drug toxicology/screen, heavy metal screen, if clinically indicated	Drug toxicology screen, if clinically indicated
Imaging/EEG	EEG, brain imaging (CT or MRI, with MRI being preferred), if clinically indicated	
Practice Guideline for the Treatment of Patients with Schizophrenia Second Edition, American Psychiatric Association, 2010; 1-184.		

Table 76-7 Relative Side-Effect Incidence of Commonly Used Antipsychotics[a,b]						
	Sedation	**EPS**	**Anticholinergic**	**Orthostasis**	**Weight Gain**	**Prolactin**
Aripiprazole	+	+	+	+	+	+
Asenapine	+	++	+/–	++	+	+
Chlorpromazine	++++	+++	+++	++++	++	+++
Clozapine	++++	+	++++	++++	++++	+
Fluphenazine	+	++++	+	+	+	++++
Haloperidol	+	++++	+	+	+	++++
Iloperidone	+	+/–	++	+++	++	+
Olanzapine	++	++	++	++	++++	+
Paliperidone	+	++	+	++	++	++++
Perphenazine	++	++++	++	+	+	++++
Quetiapine	++	+	+	++	++	+
Risperidone	+	++	+	++	++	++++
Thioridazine	++++	+++	++++	++++	+	+++
Thiothixene	+	++++	+	+	+	++++
Ziprasidone	++	++	+	+	+	+

EPS, extrapyramidal side effects; Relative side-effect risk: ±, negligible; +, low; ++, moderate; +++, moderately high; ++++, high.
[a]Side effects shown are relative risk based on doses within the recommended therapeutic range.
[b]Individual patient risk varies depending on patient-specific factors.

Second-Generation Antipsychotic Monitoring Guide							
	Baseline	**4 Weeks**	**8 Weeks**	**12 Weeks**	**Quarterly**	**Annually**	**Every 5 years**
Personal Family History[+]	✓					✓	
Weight & Height (BMI)	✓	✓	✓	✓	✓		
Waist Circumference	✓					✓	
Blood Pressure	✓			✓		✓	
Fasting Plasma Glucose	✓			✓		✓	✓
Fasting Plasma Lipids	✓			✓			✓

[+]Family history of obesity, diabetes, dyslipidemia, hypertension, and/or cardiovascular disease
Adapted from American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, North American Association for the Study of Obesity. Consensus development conference on antipsychotic drugs and obesity and diabetes. Diabetes Care 2004; 27(2):596-601.

Antipsychotic Medication Reference

Definitions of Select Adverse Effects

1. **Tardive Dyskinesia:** involuntary, repetitive body movements such as lip smacking, tongue protrusion, and grimacing
2. **Parkinsonism:** tremor, decreased bodily movement, rigidity and postural instability
3. **Anticholinergic Effects:** dry mouth, dry eyes, difficulty urinating, constipation, blurred vision, confusion, memory impairment, drowsiness, nervousness, agitation, rapid heart rate, weakness
4. **Extrapyramidal Symptoms (EPS):** various movement disorders such as acute, sustained muscle contractions causing twisting and repetitive movements or abnormal postures (dystonic reactions), pseudoparkinsonism, and inability to initiate movement (akinesia) and/or inability to remain motionless (akathisia)

Warnings and Precautions[2]

- **Elderly Patients with Dementia-Related Psychosis:** increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack, including fatalities)
- **Suicide/Suicidality and Antidepressants:** increased risk of suicidality in children, adolescents, and young adults with major depressive disorder; closely supervise high-risk patients
- **Neuroleptic Malignant Syndrome:** manage with immediate discontinuation and close monitoring
- **Tardive Dyskinesia:** discontinue if clinically appropriate
- **Metabolic Changes:** atypical antipsychotic drugs have been associated with metabolic changes that include hyperglycemia/diabetes mellitus, dyslipidemia, and body weight gain
- **Hyperglycemia/Diabetes Mellitus:** monitor glucose regularly in patients with and at risk for diabetes
- **Dyslipidemia:** undesirable alterations in lipid levels have been observed in patients treated with atypical antipsychotics
- **Weight Gain:** weight gain has been observed with atypical antipsychotic use – monitor weight
- **Hyperprolactinemia:** prolactin elevations occur and persist during chronic administration. Prolactin is a hormone which may cause breast enlargement (gynecomastia) and sexual dysfunction.
- **Orthostatic Hypotension:** use with caution in patients with known cardiovascular or cerebrovascular disease
- **Leukopenia, Neutropenia, and Agranulocytosis** has been reported with antipsychotics. Patients with a history of a clinically significant low white blood cell count (WBC) or a drug-induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and discontinuation of drug should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors
- **Seizures/Convulsions:** use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold
- **Potential for Cognitive and Motor Impairment:** use caution when operating machinery
- **QT Prolongation:** increases in QT interval; avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval

Black Box Warning

Prescribing information for many antipsychotic medications contains the following "black box" warning cautioning against the use of these drugs in elderly dementia patients:

"Antipsychotic medications are not approved for the treatment of patients with dementia-related psychoses (see Boxed Warning)."

WARNING

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infections (e.g., pneumonia) in nature.

Observational studies suggest that similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patient is not clear.

[1] This document is intended for educational purposes only as a quick reference guide to commonly used antipsychotic drugs. Information contained herein is condensed and incomplete. Please refer to full prescribing information and additional reference materials for detailed information on a specific drug or drug use, dosing in special populations and drug use in patients with specific medical conditions. Promethazine and droperidol may be prescribed as antiemetic agents; however these agents have the same cautions as 1st generation antipsychotics. HQSI and DFMC are not responsible for any omissions or errors. This document is not intended to override a clinician's judgment in individual patient management.

[2] Antipsychotic Agents. In: Facts & Comparisons Online [Internet Database], Indianapolis, IN: Wolters Kluwer Health. Updated 2012 Jan.

Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES
DFMC DELMARVA FOUNDATION Maryland
DFDC DELMARVA FOUNDATION District of Columbia
HQSI Healthcare Quality Strategies, Inc.

This material was prepared jointly by Healthcare Quality Strategies, Inc., Delmarva Foundation – Maryland, and Delmarva Foundation – District of Columbia, the Medicare Quality Improvement Organizations for New Jersey, Maryland, and the District of Columbia, under contract with the Centers for Medicare & Medicaid Services (CMS), and agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy.
10SOW-NJ-C.7.3-12-10. 10/2012

Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES

Reducing Inappropriate Use of Antipsychotics in Nursing Homes

Adrienne Mims, MD MPH
Alliant | GMCF
Medicare Quality Improvement

Pharmacological Treatment

- In 2005 the FDA issued a black box warning on antipsychotics and the increased risk of cardiovascular mortality when used in the elderly for behavioral symptoms in dementia
- Antipsychotics are not FDA approved for behavioral symptoms in dementia
- No psychotropic medications are FDA approved for behavioral symptoms
- There is some evidence supporting cautious use of antipsychotics at low doses

AHCA

- 2011- HHS Inspector General found that 14% of NH residents were prescribed antipsychotics, but eight to 10% were off-label, and, thus, not for treatment of mental illness
- Goal - Reduce avoidable antipsychotic use by 15% by 12/31/12 (*18,400 fewer individuals will receive antipsychotic medications per year)*

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Measure

Measure 1

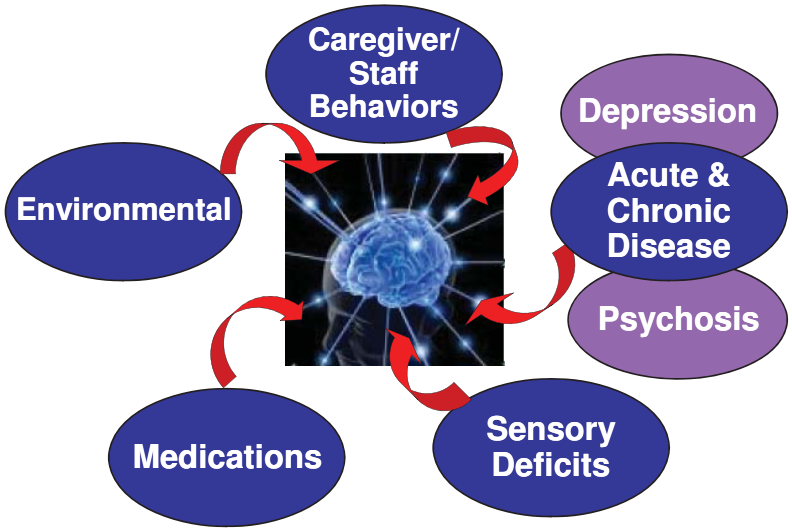
- ***Incidence****:* % of individuals who have an antipsychotic drug initiated for an off-label use within the first 90 days of a nursing facility stay (regardless of payer source or length of stay)
- **Exclusions:**
  (1) Antipsychotic use identified on the initial assessment ***OR***
  (2) Diagnosis of: bipolar or schizophrenia

Measure 2

- ***Prevalence****:* % of long-stay residents with off-label use of an antipsychotic drug
- **Exclusions:**
  Diagnosis of bipolar or schizophrenia.

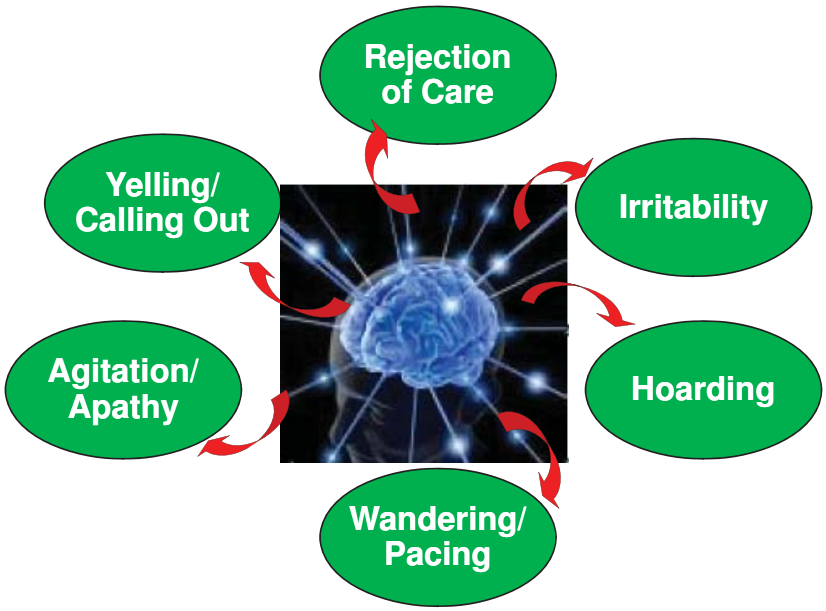
ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Triggers



ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Behavioral Symptoms



ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Preferred Staff Reaction

- STOP & LISTEN
- What is the Target behavior?
- How often is it occurring & timing
- What are the circumstances?
- What may have precipitated behavior?
- What has already been done to modify the behavior?

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Modifiable Causes of Behavioral Symptoms

- **Medical / Physical**: PAIN, infection, hunger, thirst, hypoxia, sleep disturbance, constipation
- **Medications**: that cause anti-cholinergic reactions (including psychosis), delirium, depression, sleep disturbance
- **Communication**: Inability to communicate perceptions or expectations

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Modifiable Causes of Behavioral Symptoms

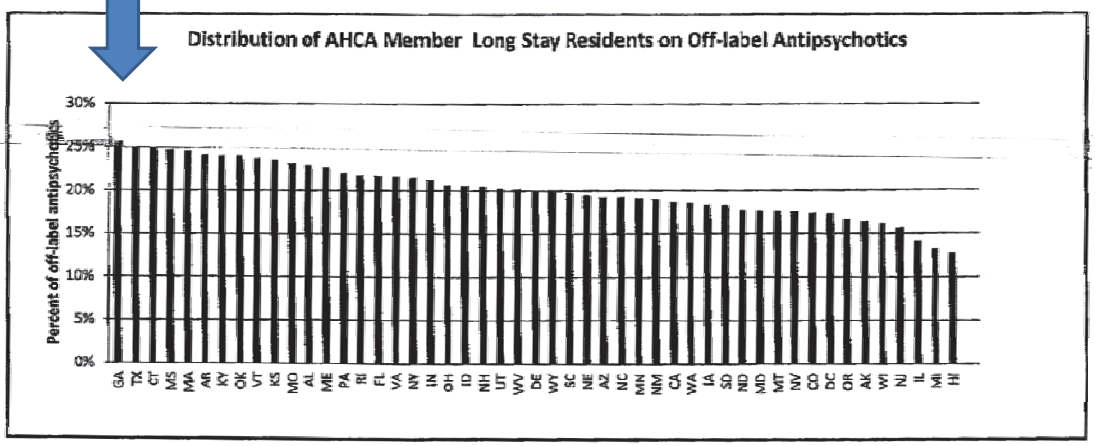
- **Environmental**: Noise, physical barriers, visual barriers, temperature
- **Cognitive impairment**: Lack of understanding (agnosia), inability to communicate perceptions or expectations
- **Psychiatric conditions**: Depression, Anxiety, Psychosis

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Draft 3/8/2012

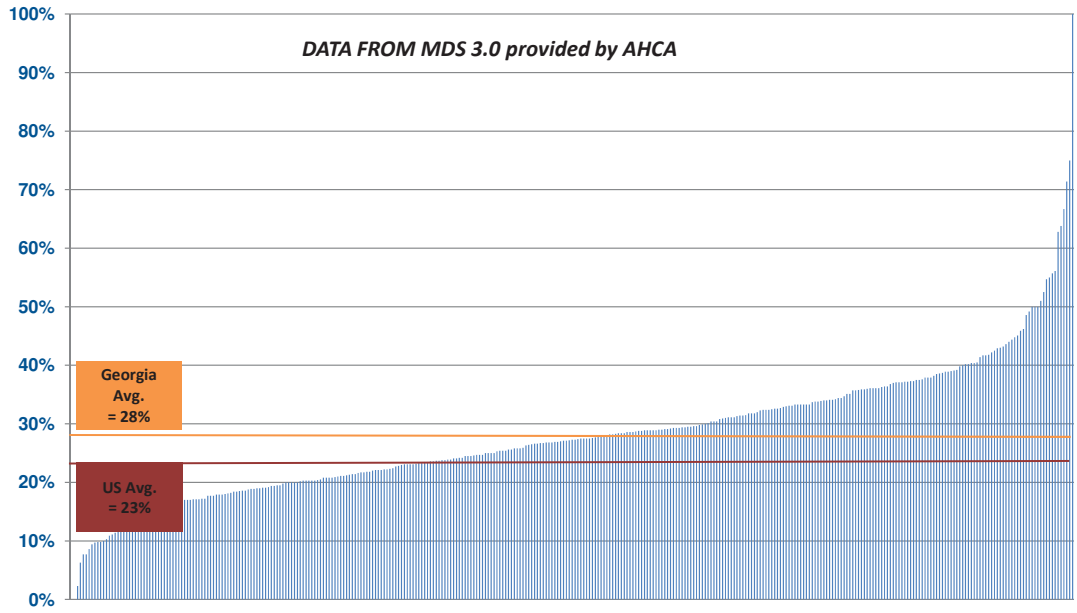
Georgia

Off-Label Antipsychotics[3]



[3] Source: AHCA analysis of Brown University Center for Gerontology and Health Care Research data.
Note: Preliminary data. Measure specifications and the target are likely to change, 2009.

Off-Label Anti-Psychotic Use in Georgia LTC



Strategy

1) Obtain Leadership Commitment – build the will to work on this and develop the buy- in to understand, taking a thoughtful approach, use QA&A (or QAPI) review
2) Convene a local interdisciplinary committee for oversight
3) Review Baseline data - the nation, state, facility data to determine the issue (pull own data, understand the numbers, follow regularly)
   a) Rate of use of antipsychotics for all reasons; rate of off-label use; rate and pattern of PRN use
   b) Behaviors that trigger use of medications
   c) Initial patient list of impacted individuals

Strategy *(continued)*

4) Assess current practices – i.e., consistent assignment, CNA meetings, environmental assessment, culture change processes, pharmacy processes, Medical Director and staff MD involvement
5) Education of CNAs to increase skills and give new tools
6) After the above – (months into project) – ask CNAs which residents could benefit from this new approach
7) Routine monitoring of facility MDS 3.0 data

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Potential Impact

- Culture change of family, staff and clinicians
- Fewer accidents and injury rates
- Fewer residents on antipsychotics
- Lower doses of antipsychotics
- Improved staff satisfaction
- Avoid future potential penalties

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Next Steps?

- Alliant | GMCF is ready to partner with you
  - Identify and tailor educational tools
  - Host webinars / facilitate presentations
  - Data interpretation and analysis
  - Pilot projects
  - Targeted Quality Improvement support
- What can you do?

This material was prepared by Alliant | GMCF, the Medicare Quality Improvement Organization for Georgia, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. Publication No. 10SOW-GA-IIPC-12-123

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES

Reducing Inappropriate Use of Antipsychotics in Nursing Homes

Adrienne Mims, MD MPH
Alliant | GMCF
Medicare Quality Improvement

Presentation Outline/ Questions To Think On

- Why is this initiative important?
- What resources are there to address this concern?
- What are my next steps?

Polling Question #1

Who is represented in the room today?

1. Nursing Home Administrators
2. Director of Nursing / Nursing Leadership
3. MDS Coordinators / other nursing
4. Physicians
5. Pharmacy
6. Industry / Corporations
7. Other

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Polling Question #2

Who has already started work on this initiative?

GREEN	Have a team identified and meetings begun
YELLOW	Committed but not yet started
RED	Interested by not sure this is for us

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Polling Question #3

Who has a Medical Director already interested in this initiative?

GREEN	Have had discussions and is on board
YELLOW	Not sure of their interest
RED	May be reluctant to work on this

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

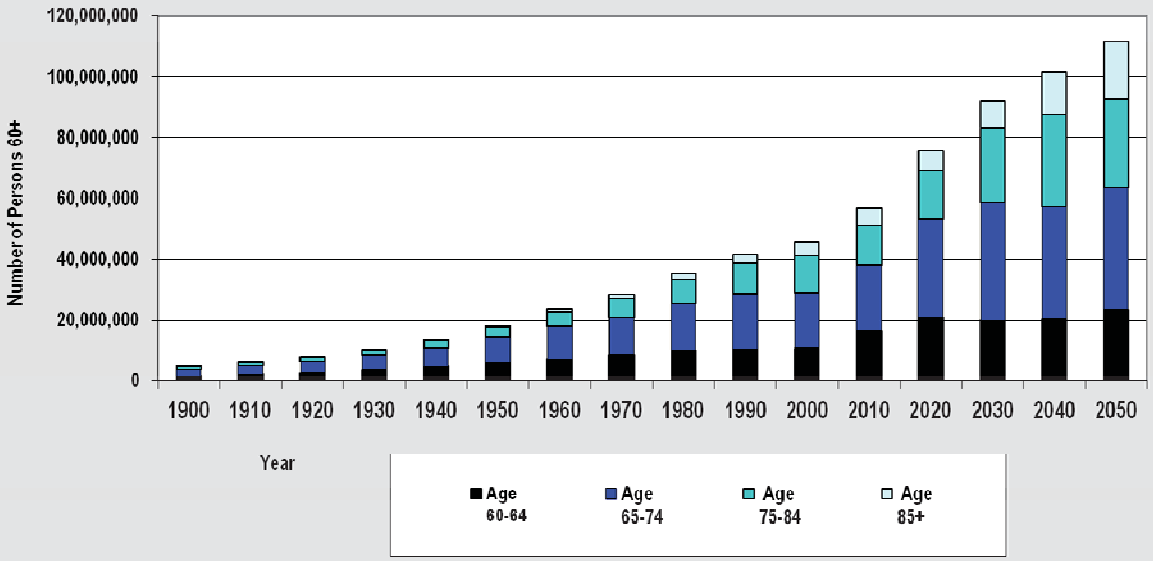
Polling Question #4

Who has access to pharmacy data for this initiative?

GREEN	Have seen the data
YELLOW	I think I have it but have not seen it
RED	I don't think / am not sure if we get this

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Population by Age: 1900 – 2050

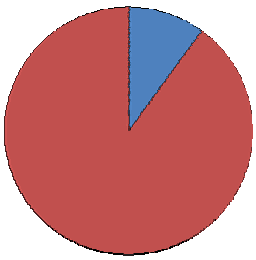


http://www.aoa.gov/AoARoot/Aging_Statistics/future_growth/future_growth.aspx#gender

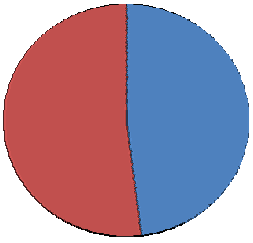
ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Prevalence of Alzheimer's Disease

- Most people with dementia do not complain of memory loss
- Cognitively impaired older persons are at ↑ risk for accidents, delirium, medical non-adherence, and disability



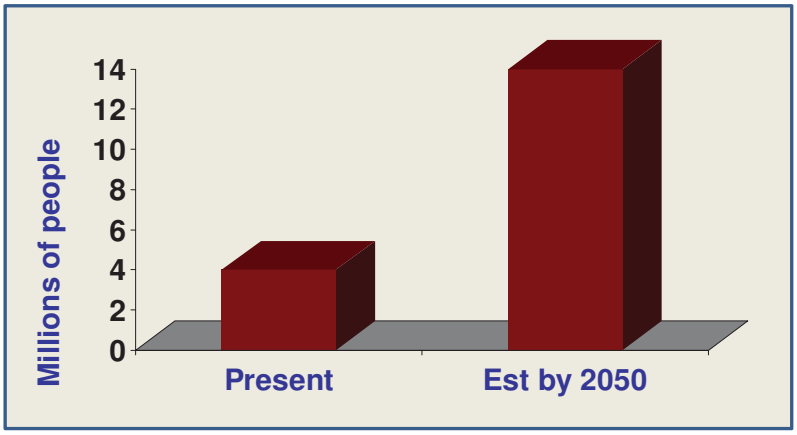
10% of those aged 65+



Nearly 50% of those aged 85+

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

The Prevalence of ALZHEIMER'S DISEASE



- 4 million in U.S. currently – 14 million in U.S. by 2050
- Life expectancy of 8 -10 years after symptoms begin

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

DSM-IV Diagnostic Criteria for Alzheimer's Disease

- Development of cognitive deficits manifested by:
  - Impaired memory ***and***
  - Aphasia, apraxia, agnosia, disturbed executive function
- Significantly impaired social, occupational function
- Gradual onset, continuing decline
- Not due to CNS or other physical conditions (e.g., PD, delirium)
- Not due to an Axis I disorder (e.g., schizophrenia)

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Psychotic Symptoms

- As many as 80% - 90% of patients with dementia develop at least one psychotic symptom or behavioral disturbance over the course of their illness
- Behavioral disturbances or psychotic symptoms in dementia often precipitate nursing home placement
- Disturbances are potentially treatable, so it is vital to recognize them early

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

CLINICAL FEATURES: AGITATION (1 of 2)

- Reflects loss of ability to modulate behavior in a socially acceptable way
- May involve verbal outbursts, physical aggression, resistance to bathing or other care needs, and restless motor activity such as pacing or rocking
- Often occurs concomitantly with psychotic symptoms such as paranoia, delusional thinking or hallucinations

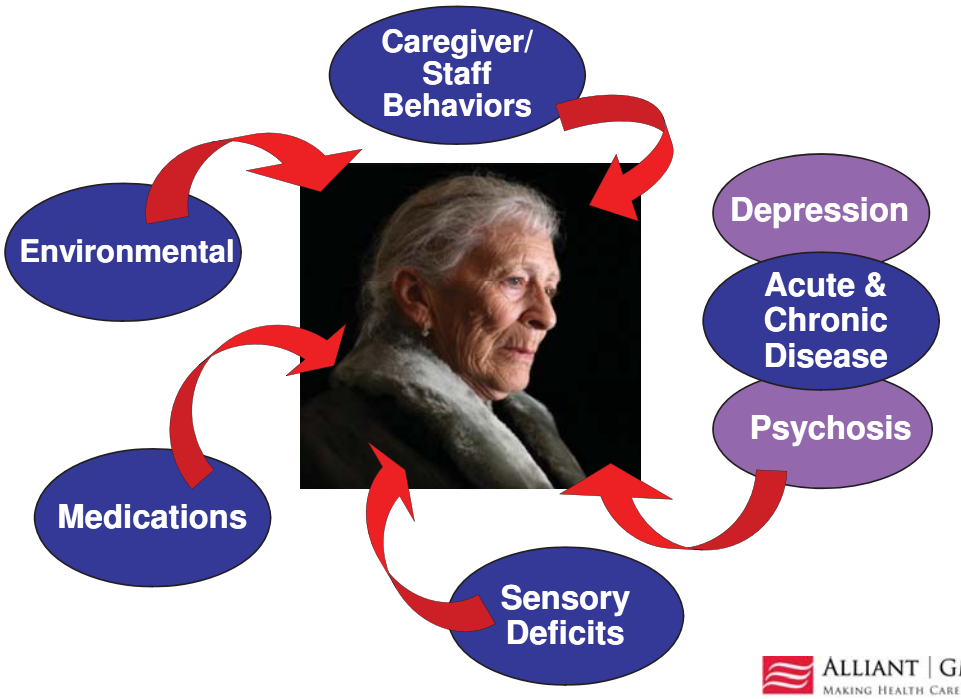
ALLIANT | GMCF
MAKING HEALTH CARE BETTER

CLINICAL FEATURES: AGITATION (2 of 2)

- Caregivers, both professional and family, may use the word *agitation* to describe a variety of behaviors and psychologic symptoms
- The clinician must consider agitation to be a nonspecific complaint and pursue further history of the problem
- Overt resistance to care is most often seen in later stages of dementia, but it may be a first sign of incipient cognitive decline in earlier stages as well

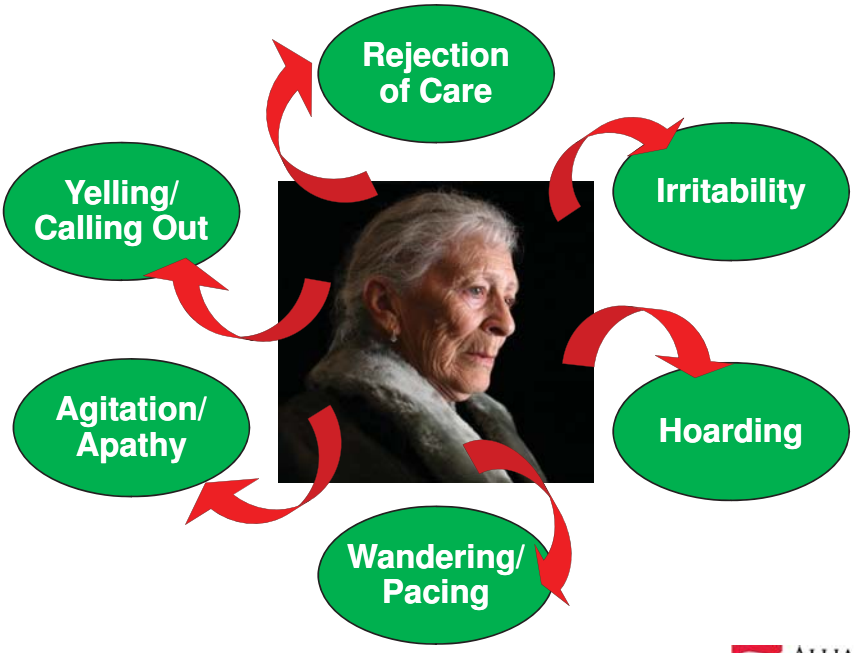
ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Triggers



ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Behavioral Symptoms



ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Modifiable Causes of Behavioral Symptoms

- **Medical / Physical**: PAIN, infection, hunger, thirst, hypoxia, sleep disturbance, constipation
- **Medications**: that cause anti-cholinergic reactions (including psychosis), delirium, depression, sleep disturbance
- **Communication**: Inability to communicate perceptions or expectations

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Modifiable Causes of Behavioral Symptoms

- **Environmental**: Noise, physical barriers, visual barriers, temperature
- **Cognitive impairment**: Lack of understanding (agnosia), inability to communicate perceptions or expectations
- **Psychiatric conditions**: Depression, Anxiety, Psychosis

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Pharmacological Treatment

- In 2005 the FDA issued a black box warning on antipsychotics and the increased risk of cardiovascular mortality when used in the elderly for behavioral symptoms in dementia
- Antipsychotics are not FDA approved for behavioral symptoms in dementia
- No psychotropic medications are FDA approved for behavioral symptoms
- There is some evidence supporting cautious use of antipsychotics at low doses

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

The Problem

~22% of antipsychotic prescriptions in nursing homes are problematic per Centers for Medicare and Medicaid Services (CMS) standards

Problem per CMS standards	% of claims
Excessive dose	10.4%
Excessive duration	9.4%
Without adequate indication	8.0%
Without adequate monitoring	7.7%
In the presence of adverse effects that indicate the dose should be reduced or discontinued	4.7%

http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Number of Medicare Claims and Amount for Each Atypical Antipsychotic Drug (January 1 through June 30, 2007)

Generic Drug Name	Claims	Amount
Quetiapine	627,661	$85,847,131
Risperidone	536,600	$87,161,507
Olanzapine	356,695	$94,055,067
Aripiprazole	83,756	$29,565,887
Ziprasidone	44,681	$10,067,477
Clozapine	27,294	$1,691,718
Olanzapine/Fluoxetine	1,521	$431,799
Paliperidone	666	$207,731
Total	**1,678,874**	**$309,028,317**

ANTIPSYCHOTIC AGENTS (1 of 3)
selected agents used off-label for treatment of psychosis in dementia

Drug	Daily Dose	Adverse Effects	Comments
Aripiprazole (Abilify)	5 -15 mg	Mild sedation, mild hypotension	Warning about increased cerebrovascular events in dementia, possible hyperglycemia
Clozapine (Clozaril)	12.5 - 200 mg	Sedation, hypotension, anticholinergic effects, hyperglycemia, agranulocytosis	Weekly CBC required; poorly tolerated by older adults; reserve for treatment of refractory cases

ANTIPSYCHOTIC AGENTS (2 of 3)

Drug	Daily Dose	Adverse Effects	Comments
Olanzapine (Zyprexia)	2.5 -10 mg	Sedation, falls, gait disturbance	Warning about hyperglycemia and cerebrovascular events in patients with dementia
Quetiapine (Seroquel)	25 - 200 mg	Sedation, hypotension	Warning about hyperglycemia; ophthalmologic exam recommended every 6 months

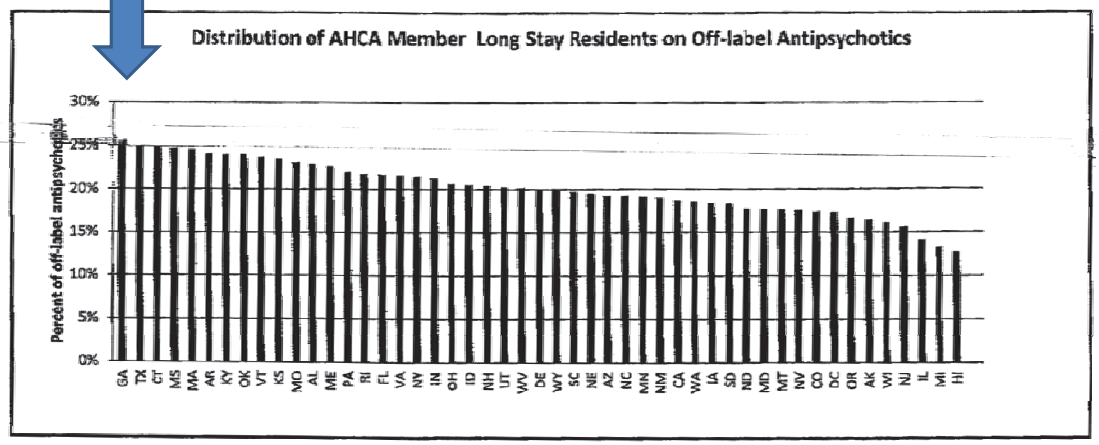
ANTIPSYCHOTIC AGENTS (3 of 3)

Drug	Daily Dose	Adverse Effects	Comments
Risperidone (Risperdal)	0.5 - 2 mg	Sedation, hypotension, extrapyramidal symptoms with |doses > 1 mg/day	Warning about cerebrovascular events in patients with dementia, hyperglycemia warning
Ziprasidone (Geodon)	40 -160 mg	Higher risk of prolonged QTc interval, hyperglycemia	Little published information on use in older adults

Draft 3/8/2012

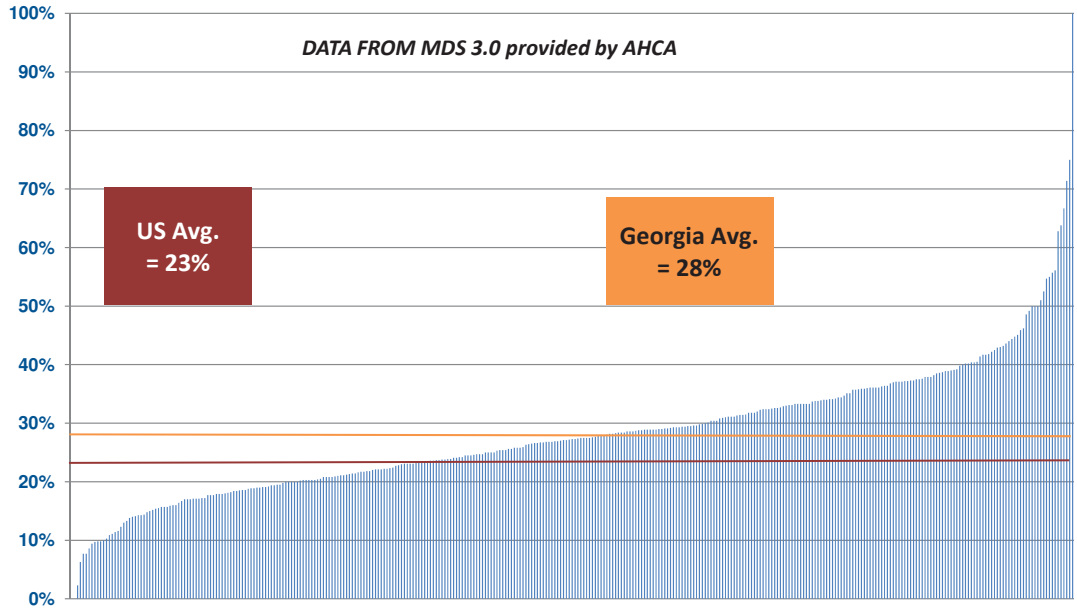
Off-Label Antipsychotics[3]

Georgia



[3] Source: AHCA analysis of Brown University Center for Gerontology and Health Care Research data.
Note: Preliminary data. Measure specifications and the target are likely to change. 2009.

Off-Label Anti-Psychotic Use in Georgia LTC



AHCA

- 2011- HHS Inspector General found that 14% of NH residents were prescribed antipsychotics, but eight to 10% were off-label and thus, not for treatment of mental illness
- Goal - Reduce avoidable antipsychotic use by 15% by 12/31/12 (nationally, 1*8,400 fewer individuals will receive antipsychotic medications per year).*
- Move from 23% to 19.6%

The QUALITY INITIATIVE

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

GHCA

- Goal - Reduce avoidable antipsychotic use by 15% by 12/31/12
- Move from 28% to an average of 23.8%

ghca Georgia Health Care Association

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Measure #1

- ***Incidence:*** % of individuals who have an antipsychotic drug initiated for an off-label use within the first 90 days of a nursing facility stay (regardless of payer source or length of stay)
- ***Calculation:***
  - # of short-stay individuals (100 or less cumulative days in the facility) with antipsychotic drug use indicated on an MDS assessment in the target quarter
  - # of short-stay individuals (100 or less cumulative days in facility) with one or more MDS assessments in the target quarter
- ***Exclusions*:**

  (1) Antipsychotic use identified on the initial assessment ***OR***

  (2) Diagnosis of: bipolar or schizophrenia

http://www.ahcancal.org/quality_improvement/qualityinitiative/Documents/Goal%204%20-%20Measurement%20Summary.pdf

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Measure #2

- ***Prevalence:*** % of long-stay residents with off-label use of an antipsychotic drug
- ***Calculation:***
  - # of long-stay residents (those with >100 cumulative days in the facility) with antipsychotic drug use indicated on one or more MDS assessments in the target quarter
  - # of long-stay residents (those with >100 cumulative days in the facility) with one or more MDS assessments in the target quarter.
- **Exclusions:**

  Diagnosis of bipolar or schizophrenia.

http://www.ahcancal.org/quality_improvement/qualityinitiative/Documents/Goal%204%20-%20Measurement%20Summary.pdf

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Table Discussion

Turn to your neighbor and describe those behaviors occurring in your setting in patients with dementia.

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Polling of Behaviors

GREEN A rare occurrence or seldom drug use

YELLOW Monthly occurrence w/medication use

RED Weekly occurrence w/medication use

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Preferred Staff Reaction

- STOP & LISTEN
- What is the Target behavior?
- How often is it occurring & timing
- What are the circumstances?
- What may have precipitated behavior?
- What has already been done to modify the behavior?

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Tools to Support Staff Behavior Change

- Resources on AHCA website: http://www.ahcancal.org/quality_improvement/qualityinitiative/Pages/ResourcesByGoal.aspx#4
- Dementia Beyond Drugs (book) http://www.healthpropress.com/store/power-29562/
- Improving Antipsychotic Appropriateness in Dementia Patients (IA-ADAPT) https://www.healthcare.uiowa.edu/igec/IAADAPT
- Quality of Life Outcomes for People with Alzheimer's Disease and Related Dementia https://www.healthcare.uiowa.edu/IGEC/IAAdapt/

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Change in Perspective About Behaviors

Behavior in "old" language	New language for behavior
► Agitation	► Energetic/Assertive
► Rummaging or "Shopping"	► Seeking
► Wandering	► Exploring
► Egress or Elopement	► Assertive / Focused / Showing Initiative
► Refusing Personal Care	► Cautious
► Repetitive Crying Out	► Assertive

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Strategies to Manage Behaviors

- Start with Consistent Assignment
- Sooth the anxiety – determine the cause – (noise, constipation, dehydration, hungry)
- Leave if they are escalating
- Let patient make a call to a family or friend – short list for day or night
- Switch TV or radio to a calming show

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Communication Techniques

- Talk slow
- Get their attention
- Listen
- Calm tone
- Yes or no questions
- Orient to task
- Use touch
- Don't argue
- Repeat rephrase and repair
- Smile and laugh
- Reinforce positive moments
- Affirmations
- Use humor
- Watch your language

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Alternative Medicine Approaches

- Chamomile tea or milk
- Magnesium 250-500mg
- Familiar or comfort foods
- Essential oils – lavender, rose, rosemary – tiny amounts
- Favorite cologne, aftershave, perfume
- Colored lights – pink, blue, outside sunlight
- Pets
- Small children
- Acupressure / shiatsu / swaddling
- Exercise
- Foot bath, shoulder massage / hydro therapy
- Neutral temperature bath
- Music

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

F329 - Unnecessary Medications

Victoria L. Walter, Director
Healthcare Facility Regulation/Nursing Home Section

Georgia Department of Community Health
email: vlwalter@dhr.state.ga.us

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Getting to Know Your Resident

- Activity – Interview your neighbor and determine what you can about them from the ages 15-25.

.....

- What did you learn that could be helpful if they were now in their 80s living in your nursing home with dementia and become…

The Best Friends™ Approach to Alzheimer's Care
http://www.healthpropress.com/sos/BestFriends_Overview.pdf

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Reducing Off-label Antipsychotics

Requires Change:

- Systems
- Process
- Personal behavior changes
- Workflow

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Potential Impact

- Culture change of family, staff and clinicians
- Fewer accidents and injury rates
- Fewer residents on antipsychotics
- Lower doses of antipsychotics
- Improved staff satisfaction
- Avoid future potential penalties

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Strategy - FOCUS

F ind a process to improve

O rganize a team

C larify current knowledge

U nderstand the variation

S elect the process changes

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

FOCUS

Find a process to improve

- ***Identify*** a care/service process that is "**KEY**" to your success
- ***Select*** the **AIM** of your improvement
- ***Determine*** if there is a **BEST PRACTICE** internally or externally
- ***Establish*** if there is a **POLICY** or **REGULATION** that is prescriptive

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

FOCUS

Organize a team

- Include Key Stakeholders
  - Stakeholders have the most knowledge about the process
  - Stakeholders are key to making successful and sustainable improvements

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

FOCUS

Clarify current knowledge

- Identify how the process is currently taking place (the real practice)
- Generate a Process Map to represent the sequential order of each step
- Collect/Gather Baseline Data about the current process

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

FOCUS

Understand the variation

- Compare the current process steps to the steps in the process that you would like to model
  - *This could be based on Policy, Regulations or a Best Practice Model*
- Understand the differences between the two practices and determine where non-value added steps exist
- Analyze Baseline Data compared to Best Practice Data if available

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

FOCUS

Select the process changes

- Using the Baseline Date, determine the improvement actions you need to take
- Prioritize the list through Rank Order of importance

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Strategy

1) Obtain Leadership Commitment – build the will to work on this and develop the buy-in to understand, taking a thoughtful approach, use QA&A (or QAPI) review
2) Convene a local interdisciplinary committee for oversight
3) Review Baseline data – the nation, state, facility data to determine the issue (pull own data, understand the numbers, follow regularly)
   a) Rate of use of antipsychotics for all reasons; rate of off-label use; rate and pattern of PRN use
   b) Behaviors that trigger use of medications
   c) Initial patient list of impacted individuals

Strategy *(continued)*

4) Assess current practices – i.e., consistent assignment, CNA meetings, environmental assessment, culture change processes, pharmacy processes, Medical Director and staff MD involvement
5) Education of CNAs to increase skills and give new tools
6) After the above – (months into project) – ask CNAs which residents could benefit from this new approach
7) Routine monitoring of facility MDS 3.0 data

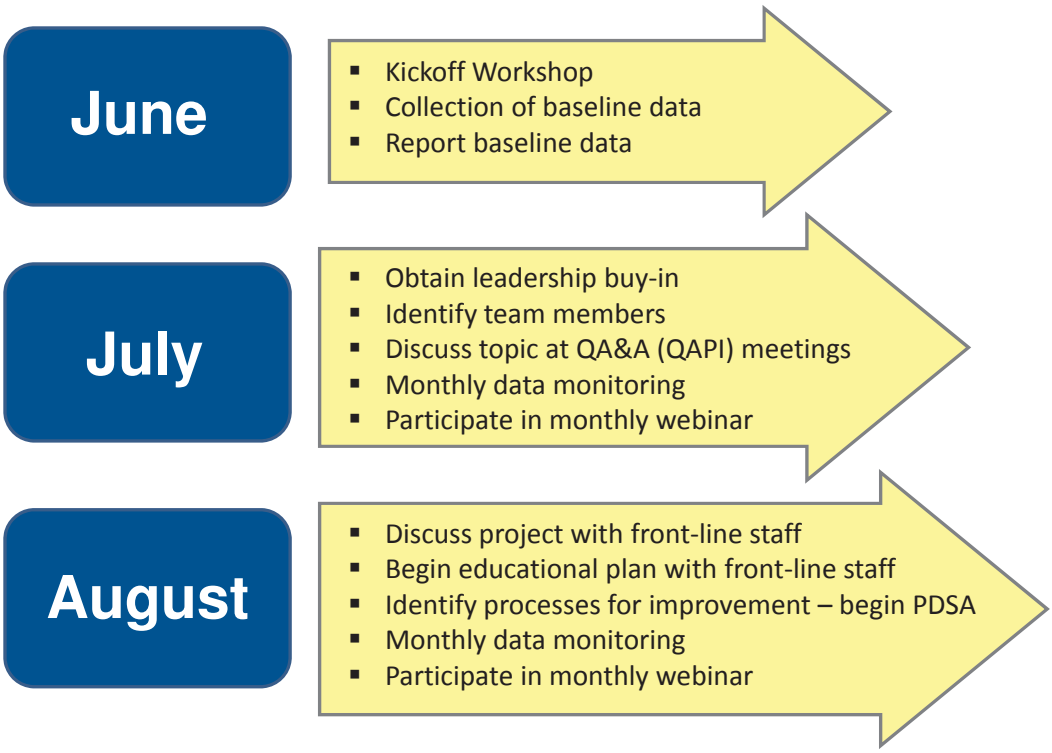
ALLIANT | GMCF
MAKING HEALTH CARE BETTER

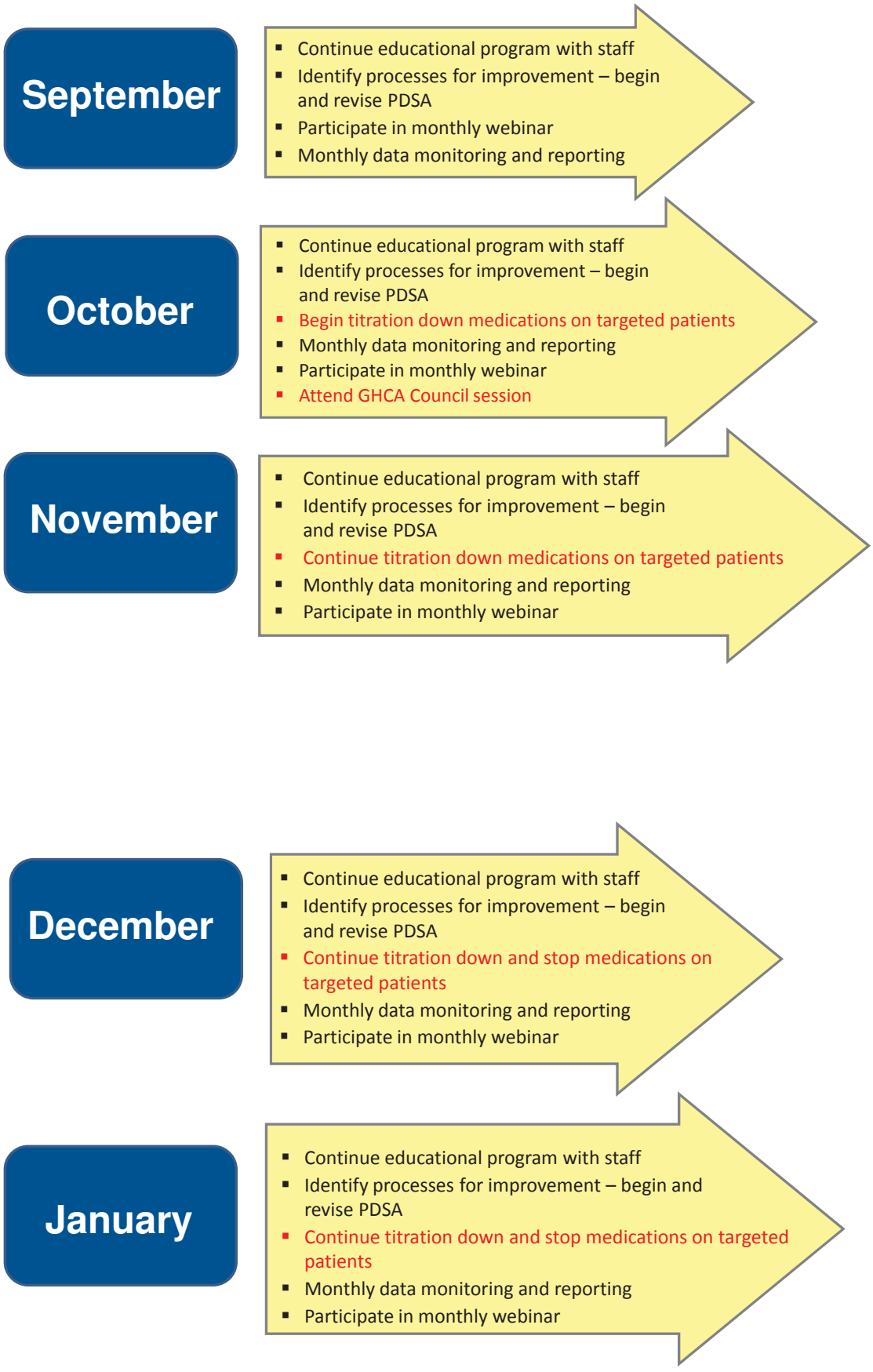
Next Steps

- Alliant | GMCF is ready to partner with you
  - Identify and tailor educational tools
    - AHCA website, CMS or other videos
  - Host webinars
    - Monthly 30-minute educational sessions
    - Monthly 30-minute project tracking and support sessions
  - Data interpretation and analysis
    - Assist you in tracking your blinded data

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

Timeline





Celebrate Improvement!

In Closing

Questions

Commitment Signing

Photo

This material was prepared by Alliant | GMCF, the Medicare Quality Improvement Organization for Georgia, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. Publication No. 10SOW-GA-IIPC-12-147

ALLIANT | GMCF
MAKING HEALTH CARE BETTER

SBAR Antipsychotic Medication Reduction

Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES

HSAG HEALTH SERVICES ADVISORY GROUP

SBAR: Communication and Progress Note for Antipsychotics

Before calling the attending physician, nurse practitioner, or physician assistant:

☐ Evaluate the resident and document in the SBAR form.

☐ Review chart: recent progress notes, labs, orders.

☐ Have relevant information available when reporting (e.g., identify needs-driven expressions, behaviors, falls, medications, disease, adverse drug reactions, interdisciplinary team recommendations, etc.).

S — SITUATION

The symptom I'm calling about is:
☐ Violent/self-destructive behavior
☐ Unpleasant hallucinations
☐ Suicidal ideations/attempts
☐ Physically abusive
☐ Other: _____
_____

The symptom/why the call was initiated:
_____
What are the contributing factors that make it worse?
_____
What are the contributing factors that make it better?
_____
What are other things that have occurred with this change?
_____
This symptom has gotten ☐ **worse** ☐**better** ☐ **stayed** the same since it started.

B — BACKGROUND

Primary diagnosis and/or reason for antipsychotic medication use: _____
Pertinent history: _____
Vital signs: BP___/___ HR ____ RR _____ Temp _____ Pulse oximetry:___% on O2 at __L/min via_____ (NC, mask)
Change in function or mobility: _____
Medication changes or new orders in the last two weeks: _____
Side effects or adverse drug reactions: _____
Mental status changes: (e.g., confusion/agitation/lethargy) _____ **Recent infections**: _____
GI/GU changes: ☐ Nausea ☐ Vomiting ☐ Diarrhea ☐ Impaction ☐ Distension ☐ Decreased urinary output ☐ Other_____ **Numeric pain level/location of pain**: _____
Change in intake/hydration: _____ **Labs**: _____
Allergies: _____ **Any pertinent information**: _____

A — ASSESSMENT

What do you think is going on with the resident? (e.g., cardiac, infection, respiratory, urinary, dehydration, mental status change, medication side effects or adverse reaction?)_____
The resident appears: _____
The interdisciplinary team (IDT) met and recommended:_____
Alternatives tried include: ☐ Align resident past preferences with care plan ☐ Provide companionship and supervision ☐ Changing or eliminating bothersome approaches ☐ Frequent reorientation to surroundings ☐ Offering person-centered activities (social HX) ☐ Schedule checks for pain, food, or comfort ☐ Anticipate resident voiding needs ☐ Modify environment ☐ Other: _____

R — REQUEST

I suggest or request (check all that apply):
☐ Comprehensive facility IDT evaluation ☐ Provider visit (MD/NP/PA) ☐ Monitor vital signs and observe ☐ Lab work, X-rays, EKG, other tests ☐ Physical therapy evaluation ☐ Speech therapy evaluation ☐ Occupational therapy evaluation ☐ Pharmacy medication review ☐ Social consultant review ☐ Activity consultant review ☐ Psychiatric evaluation ☐ Other _____

Nurse's name and signature: _____RN/LVN

MD/NP/PA notified. Name: _____ (MD/NP/PA) Date____/____/____ Time _____a.m./p.m.

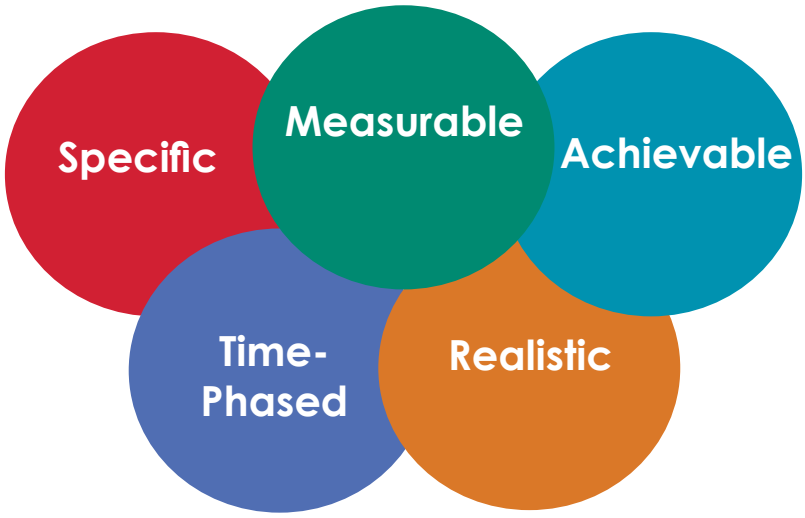
Resident name: _____ Room number: _____

Source: The SBAR technique was developed by Michael Leonard, MD, Doug Bonacum, and Suzanne Graham at Kaiser Permanente of Colorado.

This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. Publication No. CA-10SOW-7.2-110113-02.

SMART Objectives

SMART Objectives are valuable tools that your organization can use to establish meaningful mileposts as you work toward specific goals.



Objectives are more immediate than goals and should be based on the strategies you have selected to meet your goals.

Because strategies are implemented through objectives and quality improvement activities, multiple objectives are generally needed to address a single strategy. Objectives are the basis for monitoring the implementation of your strategies and progressing toward achieving your goals. Objectives also help set targets for accountability.

SMART Objectives are:

1. **Specific:**
   - Provide the who and what of quality improvement activities.
   - Use only one action verb, since objectives with more than one verb imply that more than one activity or behavior is being measured.
   - Avoid verbs that have vague meanings to describe intended outcomes, since it may be difficult to measure them.

     -*Vague*: "CNA will understand proper turning technique."

     - *Specific*: "CNA will list three appropriate ways to turn residents and use these techniques daily."
   - Remember, the more specific it is, the more measureable it is.
2. **Measurable:**
   - Quantify the amount of change expected. The objective provides a reference point from which a change in the target population can be clearly measured.
   - Remember, it is impossible to determine whether objectives have been met unless they can be measured.
3. **Achievable:**
   - Be sure that objectives are attainable within a given time frame and with available program resources.

(continued on next page)

SMART Objectives *(continued)*

4. **Realistic:**
   - Accurately address the scope of the problem and establish steps that can be implemented within a specific time frame.
   - Be sure that objectives directly relate to the program goal.
5. **Time-phased:**
   - Provide a time frame in which the objective will be measured or met. This will help you plan and evaluate your quality improvement strategy.

Examples:

Non-Smart Objective

- *CNAs will be trained on the selected evidence-based pressure ulcer curriculum.*

This objective is not SMART because it is not specific, measurable, or time-phased.

Smart Objective

- *By the end of 2012, the DON and other nursing staff will have trained 75 percent of CNAs on the selected evidence-based pressure ulcer curriculum.*

This objective is SMART because it indicates who is responsible for training, how many will be trained, who will receive the training, and when the trainings will be completed.

Non-Smart Objective

- *Ninety percent of residents' family members will participate in training on effective communication with nursing home staff.*

This objective is not SMART because it is not specific or time-phased.

Smart Objective

- *By the end of the first quarter of 2013, AAA staff will have delivered training to 90 percent of residents' family members on effective communication with nursing home staff as part of a formal new resident orientation program.*

This objective is SMART because it specifically indicates who will conduct the training, who will participate in the training, a target number to be trained, and a completion date.

Additional Resources:

More information on writing SMART objectives can be found at:
http://www.cdc.gov/HealthyYouth/evaluation/resources.htm.

Criteria to Assess SMART Objectives

1. Is the objective SMART?

Specific:
Who is doing what? List person completing the activity and the target population, followed by a description of the activity.

Measurable:
Can you count it or observe it?

Achievable:
Can this realistically be accomplished given our internal and external resources?

Realistic:
Does this objective work toward the facility's mission, goals, and values?

Time-Phased:
Provides the timeline.

2. Can you answer the questions who, what, where, when, and how?

3. How and when do you plan to evaluate the outcome?

This material was adapted and is distributed by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization (QIO) for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services, from material originally created by the Department of Health and Human Services, Centers for Disease Control and Prevention. The contents presented do not necessarily reflect CMS policy. Publication No. CA-10SOW-7.2-010912-01

PARTNERSHIP TO IMPROVE DEMENTIA CARE IN NURSING HOMES
*Questions to Consider in Interdisciplinary Team Review of Individual Dementia Care Cases

- If the behavioral symptoms represent a change or worsening, was a medical work up performed to rule out underlying medical or physical causes of the behaviors, if appropriate?
- Were current medications considered as potential causes of the behaviors (i.e., those with significant anticholinergic or other side effects)?
- If a medical cause (e.g., UTI) was identified, was treatment (if indicated) initiated in a timely manner?
- If medical causes were ruled out, did the staff attempt to establish the root causes of the behaviors, using a careful and systematic process and individualized knowledge about the resident when possible? Were family caregivers or others who knew the resident prior to his/her dementia consulted about prior life patterns, responses to stress, etc.?
- Was the initial clinical indication for the medication valid?
- Were non-pharmacologic, person-centered interventions tried before medications (other than in an emergency)? Were the results documented?

- Were specific target behaviors identified and desired outcomes related to those behaviors documented? Were caregivers aware of the target behaviors and desired results of the medication?
- Was the resident or appropriate legal representative consulted about the decision to use an antipsychotic medication and was that discussion documented?
- If a drug is continued for more than a few weeks, is the original clinical indication still valid (are the behaviors still present)?
- Is appropriate monitoring in place and is the team aware of the potential side effects?
- If new symptoms or changes in condition occurred after an antipsychotic medication was started, was medication use considered as a potential cause of a change or symptom?
- If on a medication, did the pharmacist perform a medication regimen review and identify related signs and symptoms, or did the staff inform the pharmacist if symptoms occurred after the last pharmacist visit?

Antipsychotic Medication Reduction Care Plan

Facility Name: _____

Resident Name:		Medical Record #:	Physician:	Room #:
Date	**Problem**	**Goal and Target Date**	**Interventions**	**Discipline**

This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. Publication No. CA-10SOW-7.2-110113-03.

101 Non-Pharmacological Interventions

1. Vacuum
2. Iron
3. Bake cookies
4. Read paper
5. Invite children to visit
6. Read a letter out loud
7. Listen to music
8. Parachute game
9. Color/Paint
10. Make lemonade
11. Wipe off table
12. Weed the garden
13. Make Pigs-in-a-Blanket
14. Spelling bee
15. Readers Digest
16. Fold clothes
17. Pet visit
18. Cut out cards
19. Wash silverware
20. Bake bread
21. Sort objects
39. Sort poker chips
40. Count things
41. Fold towels
42. Afternoon Tea
43. Reminisce/Inventions
44. Play a game
45. Paint
46. Cut out paper dolls
47. Identify states and capitols
48. Make a family tree
49. Color American Flag
50. Cook hot dogs
51. Grow magic rocks
52. Water house plants
53. Reminisce - first kiss
54. Play horseshoes
55. Dance
56. Sing a hymn
57. Make ice cream
58. Plant bulbs
59. Make cards
60. Sort cards by suit
61. Write a letter
75. Sand wood
76. Rub on hand lotion
77. Decorate place mats
78. Arrange fresh flowers in a vase
79. Remember famous people
80. Rake leaves
81. Make a fruit salad
82. Sweep the patio or room
83. Talk about famous events
84. Nursery Rhymes. You start
85. Make sandwiches
86. Dust furniture
87. Cut up paper/ Tear paper
88. Take care of bird cage/fish tank.
89. Trace/cut leaves

22. Sing Christmas songs 23. Life Review 24. Put silver away 25. Make a Valentine's collage 26. Sing songs 27. Take a ride 28. Make a pie 29. Read a poem 30. Dye Easter eggs 31. Sort socks 32. Take a walk 33. String fruit loops 34. String cranberries 35. Sensory Stimulation 36. Look at photos 37. Reminisce 38. Clip coupons	62. Dress in team colors 63. Pop popcorn 64. Name the U.S. Presidents 65. Give a manicure 66. Music, Movement & Props 67. Plant a tree 68. Make a may basket 70. Finish a famous saying 71. Feed the ducks 72. Mold dough 73. Picture books 74. Put a simple puzzle together	90. Simple trivia questions 91. Finish Bible quotes 92. Paint with string 93. Cut out pictures 94. Read/listen to a short story 95. Put coins in a jar 96. Sew sewing cards 97. Put seed in bird feeder 98. Clean out pumpkin 99. Roll yarn 100. Reminisce about vacation 101. Make a Cake

Royal College of Nursing

Alzheimer's Society | Leading the fight against dementia

This is me

This leaflet will help you support me in an unfamiliar place.

Please place a photograph of yourself in the space provided.

My full name

_____

photo

For someone with dementia, changes such as moving to an unfamiliar place or meeting new people who contribute to their care can be unsettling or distressing. **This is me** provides information about the person at the time the document is completed. It can help health and social care professionals build a better understanding of who the person really is.

This is me should be completed by the individual(s) who know the person best and, wherever possible, with the person with dementia. It should be updated as necessary. It is not a medical document.

On the back page you will find more detailed guidance notes to help you complete **This is me**, including examples of the kind of information to include. You might find it helpful to read through these notes before you begin to fill in the form.

Name I like to be called

Where I live (list your area, not your full address)

Carer/the person who knows me best

I would like you to know

My life so far (family, home, background and treasured possessions)

Current and past interests, jobs and places I have lived

The following routines are important to me

Things that may worry or upset me

What makes me feel better if I am anxious or upset

Royal College of Nursing

Alzheimer's Society | Leading the fight against dementia

My hearing and eyesight

How we can communicate

My mobility

My sleep

My personal care

How I take my medication

My eating and drinking

Other notes about me

Date completed

By whom

Relationship to person

I agree that the information in this leaflet may be shared with health and social care professionals.

Guidance notes to help you to complete **This is me**

Name I like to be called: Enter your full name on the front and the name you like to be called inside.

Where I live: The area (not the address) where you live and how long you have lived there.

Carer/the person who knows me best: This may be a spouse, relative, friend or carer.

I would like you to know: Include anything you feel is important and will help staff to get to know and care for you, eg I have dementia, I have never been in hospital before, I prefer female carers, I am left-handed, I am allergic to …, other languages I can speak.

My life so far (family, home, background and treasured possessions): Include place of birth, education, marital status, children, grandchildren, friends and pets. Any religious or cultural considerations.

Current and past interests, jobs and places I have lived: Include career history, voluntary experience, clubs and memberships, sports or cultural interests.

The following routines are important to me: What time do you usually get up/go to bed? Do you have a regular nap or enjoy a snack or walk at a particular time of the day? Do you have a hot drink before bed, carry out personal care activities in a particular order, or like to watch the news at 6pm? What time do you prefer to have breakfast, lunch, evening meal?

Things that may worry or upset me: Include anything you may find troubling, eg family concerns, being apart from a loved one, or physical needs such as being in pain, constipated, thirsty or hungry. List environmental factors that may also make you feel anxious, eg open doors, loud voices or the dark.

What makes me feel better if I am anxious or upset: Include things that may help if you become unhappy or distressed, eg comforting words, music or TV. Do you like company and someone sitting and talking with you or do you prefer quiet time alone?

My hearing and eyesight: Can you hear well or do you need a hearing aid? How is it best to approach you? Is the use of touch appropriate? Do you wear glasses or need any other vision aids?

How we can communicate: How do you usually communicate, eg verbally, using gestures, pointing or a mixture of both? Can you read and write and does writing things down help? How do you indicate pain, discomfort, thirst or hunger? Include anything that may help staff identify your needs.

My mobility: Are you fully mobile or do you need help? Do you need a walking aid? Is your mobility affected by surfaces? Can you use stairs? Can you stand unaided from a sitting position? Do you need handrails? Do you need a special chair or cushion, or do your feet need raising to make you comfortable? What physical activity do you take?

My sleep: Include usual sleep patterns and bedtime routine. Do you like a light left on or do you find it difficult to find the toilet at night? Do you have a favoured position in bed, special mattress or pillow?

My personal care: List your usual practices, preferences and level of assistance required in the bath, shower or other. Do you prefer a male or female carer? Do you have preferences for brands of continence aids, soaps, cosmetics, toiletries, shaving, teeth cleaning or dentures? Do you have particular care or styling requirements for your hair?

How I take my medication: Do you need help to take medication? Do you prefer to take liquid medication?

My eating and drinking: Do you need assistance to eat or drink? Can you use cutlery or do you prefer finger foods? Do you need adapted aids such as cutlery or crockery to eat and drink? Does food need to be cut into pieces? Do you wear dentures to eat or do you have swallowing difficulties? What texture of food is required to help – soft or liquidised? Do you require thickened fluids? List any special dietary requirements or preferences including being vegetarian, and religious or cultural needs. Include information about your appetite and whether you need help to choose food from a menu.

Other notes about me: Include additional details about you that are not listed above and help to show who you are, eg favourite TV programmes or places, favourite meals or food you dislike, significant events in your past, expectations and aspirations you have.

Indicate any advance plans that you have made, including the person you have appointed as your attorney, and where health and social care professionals can find this information.

To order further copies please call 01628 529240.

Phone the National Dementia Helpline on 0300 222 11 22 or visit alzheimers.org.uk

1553 Dedicated to the memory of Ken Ridley, a much valued member of the Northumberland Acute Care and Dementia Group.

DOT.COM
Dementia Oversight Team.Care Options Meeting
Pre-Admission Person-Centered Care Approach Tool

Resident's Name: _____ **Today's Date:** _____

Key considerations in caring for your loved one:

1. **When your loved one is upset, you should (choose all that apply):**
   - ◯ Speak in a calm voice.
   - ◯ Offer no more than two choices.
   - ◯ Use yes/no questions.
   - ◯ Keep it simple—do not over explain or discuss events happening in the future.
   - ◯ Validate what he/she believes is happening in that moment.
   - ◯ Not argue with him/her, but agree and provide support for his/her current feelings.

2. **What does your loved one do when trying to communicate a need?**
   - ◯ Grimaces (may be a sign of pain)
   - ◯ Wrings hands (may be a sign of anxiety or feeling of insecurity)
   - ◯ Paces
   - ◯ Rocks
   - ◯ Yells
   - ◯ Displays physical aggression
   - ◯ Other _____

3. **What are your loved one's preferences for routine care practices?**
   a. Waking (time, method) _____
   b. Bathing (morning or evening) _____
   c. Dressing (describe routine) _____
   d. Meals (where they sit and with whom) _____
   e. Activities _____
   f. Bedtime (time, method, relaxation techniques) _____

4. **What are your loved one's historical preferences regarding activities?**
   a. What interests him/her on a daily basis? _____
   _____
   b. What activities comfort him/her when he/she is distressed? _____
   _____
   c. What activities have you tried that he/she does not respond well to? _____
   _____
   d. What did he/she do for a living? _____

5. **Is there a person or persons that your loved one is more comfortable with than others?**
   Name and relation of person(s) _____
   Sex of person(s) they respond to better: M F

Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 21, 2012; 308(19): 2020-2029.

This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services, from material originally appearing in JAMA, 2012 American Medical Association. The contents presented do not necessarily reflect CMS policy.
Publication No. CA-10SOW-7.2-082913-01

DOT.COM
Dementia Oversight Team.Care Options Meeting
Resident Review: Describing Needs-Driven Behavior (NDB) Expressions

Resident's Name: _____ **Date of Review:** _____

1. **What is/are the NDB(s)?** _____

2. **Describe the NDB(s):**
   a. What did he/she do?_____
   b. What did he/she say? _____
   c. What did you do and say before and after the NDB? _____
   _____

3. **Why is this NDB a problem? (Choose all that apply.)**
   ◯ Safety of this resident
   ◯ Safety of other residents
   ◯ Safety of caregivers
   ◯ Resident family/interested party has recognized a change in mood or behavior
   ◯ Other _____

4. **When does the NDB occur? Is it documented? Yes No (Circle choice)**
   a. What time(s) of day? _____
   b. What day(s) of the week? _____
   c. When trying to provide assistance with activities of daily living (Describe)_____
   _____

5. **How often did the resident try to communicate an unmet need? Is it documented? Yes No**
   a. How many times in the past week? _____
   b. How many times the past month? _____

6. **Where does the NDB occur? Is there a particular room/setting within the facility? Is it documented? Yes No**
   ◯ During activities
   ◯ Dining room
   ◯ Own room
   ◯ Other location(s) that may trigger a NDB (Describe) _____
   _____

7. **Do you recognize any patterns in the NDB? (Choose all that apply.)**
   ◯ The NDB frequently happens at the same time of day.
   ◯ The NDB frequently happens in the same location.
   ◯ The NDB frequently happens with the same caregiver.
   ◯ The NDB frequently happens *before/ during/after* family members/other parties visit. (Circle choice)
   ◯ Other _____
   _____

8. **Describe what happens right before the NDB occurs:** _____

9. How do staff members react when the NDB occurs?

- ◯ They perceive the NDB is not able to be determined/helped.
- ◯ They do not respond to the NDB at all—they have become desensitized to the communication attempt.
- ◯ They attempt to redirect the resident immediately by reacting with care approaches not consistent with the care plan.
- ◯ They refer to the care plan for guidance on appropriate care approaches developed by the interdisciplinary team.
- ◯ They collaborate with other staff members for assistance.
- ◯ Other _____

10. What is the environment like where the NDB occurs?

- ◯ There is a lot of stimulation (television, noise, people).
- ◯ There is no/very limited stimulation.
- ◯ We changed this resident's room/environment recently.
- ◯ Other (Describe) _____
- ◯ Changes we propose to the environment to meet the resident's needs: _____
  _____

11. Does the activity programming match the resident's prior daily home routine and social history?

- ◯ Yes (Explain) _____
- ◯ No (Explain) _____
- ◯ This resident could benefit from reviewing *101 Activities for Residents with Dementia* and matching preferences more closely based on social and professional history.

Source material: Adapted from randomized trials and the NIH Resources for Enhancing Alzheimer's Caregiver Health (REACH I and II).

This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services, from material originally appearing in JAMA, 2012 American Medical Association. The contents presented do not necessarily reflect CMS policy.
Publication No. CA-10SOW-7.2-082913-02

DOT.COM
Dementia Oversight Team.Care Options Meeting
Identifying Potential Causes of Needs-Driven Behavioral (NDB) Expression Symptoms

Resident's Name: _____ **Today's Date:** _____

1. Resident-based factors and issues: (Choose all that apply.)

- ◯ Resident pain assessments indicate alternate plan is needed to address pain.
- ◯ Medications overview—resident has recently experienced:
  - ☐ Changes in dosage
  - ☐ Polypharmacy
  - ☐ Failure to take
  - ☐ Inappropriate medication administration
  - ☐ Last date medications were reviewed: _____
- ◯ Altered emotional status that the resident could be experiencing due to adjustments or changes in routine, family structure, etc.:
  - ☐ Insecurity
  - ☐ Sadness
  - ☐ Anxiety
  - ☐ Loneliness
  - ☐ Other _____
- ◯ Sensory deficits/proper functioning of devices—the resident has trouble with:
  - ☐ Hearing (Describe) _____
  - ☐ Vision (Describe) _____
- ◯ What basic physical needs might the resident be having trouble with?
  - ☐ Hydration
  - ☐ Hunger
  - ☐ Constipation
  - ☐ Body temperature
  - ☐ Other _____
- ◯ What is the resident's preference with: (Choose all that apply.)
  - ☐ Bathing time _____
  - ☐ Waking up and going to bed times _____
  - ☐ Meal times and food preferences _____
  - ☐ Activity programming _____
  - ☐ Clothing choices _____
  - ☐ Male or female caregivers _____
- ◯ Level of stimulation (under or over) where the NDB occurs that is **not** appropriate for this resident:
  - ☐ The room is too *noisy/active* or too *quiet/calm.* (Circle choice.)
  - ☐ The room is too *bright* or too *dark*. (Circle choice.)
- ◯ Health issues that the resident may be experiencing:
  - ☐ History of infections that may be resurfacing
  - ☐ Other _____
- ◯ Impact of other illnesses or conditions _____

- ◯ If the resident is experiencing confusion while ambulating (wandering), we could:
  - ☐ Use calm reorientation methods
  - ☐ Explain surroundings as if it was the first time for the resident in that location
  - ☐ Utilize memory boxes outside the room
- ◯ The resident is feeling frustrated or depressed about activities of daily living decline with:
  - ☐ Bathing
  - ☐ Dressing
  - ☐ Using the toilet
  - ☐ Grooming
  - ☐ Eating
  - ☐ Other _____
- ◯ The resident is experiencing sleep-cycle disruptions.

2. Caregivers for this resident need help with: (Choose all that apply.)

- ◯ Using specialized communication techniques
- ◯ Using a more appropriate emotional tone
- ◯ Appropriate care techniques when the resident tries to communicate a need
- ◯ Getting to know the resident based on his/her personal history
- ◯ Education to understand the individual resident's condition
- ◯ Understanding facility protocol for providing good dementia care
- ◯ Managing a personal situation that affects caregiving approaches
- ◯ Social services, so that they may develop a bio-sketch of the resident's history

3. Environmental-based factors and issues that affect this resident: (Choose all that apply)

- ◯ Level of physical and/or social stimulation
  - ☐ Too much
  - ☐ Too little
- ◯ Room arrangements
  - ☐ There is too much clutter in the room
  - ☐ Needed items are out-of-sight or not where the resident can see them
  - ☐ Other _____
- ◯ Lack of appropriate visual cues to assist with orientation
- ◯ Safety risk (describe) _____
- ◯ Too hot
- ◯ Too cold
- ◯ Lack of necessary adaptive equipment
  - ☐ Grab bars in bathroom
  - ☐ Walker or wheelchair
  - ☐ Other _____
- ◯ Poor lighting. Too dark in the room.
- ◯ Other _____

Excerpt adapted from: Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic Management of Behavioral Symptoms in Dementia. JAMA, November 21, 2012; 308(19): 2020-2029.

This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services, from material originally appearing in JAMA, 2012 American Medical Association. The contents presented do not necessarily reflect CMS policy.
Publication No. AZ-10SOW-7.2-070000-00, CA-10SOW-7.2-082913-03

Resident History and Profile and Who am I

It is important to get as much background and history about all the resident's we work with. Aiming to see a person as an individual, rather than focus on their illness or behaviors they exhibit, is the quality path to person centered care. Person-centered care considers the whole person, taking into account each individual's history/past, likes, dislikes, preferences, and needs.

These two tools can be an easy and beneficial way to provide person-centered care.

Resident History and Profile

1. Give this tool to family/loved ones upon the admission of the resident to your facility. It can be distributed through the admission packet, physically handed to the family/loved one, and/or mailed to them.

2. Once the form is completed and returned, the IDT should schedule a meeting to review the information. Can be integrated with care-plan/IDT meeting process.

3. The IDT should discuss how the information can be utilized and implemented into the plan of care.

4. Complete the "Who Am I" form with personalized information about the resident.

Who Am I

1. The IDT will utilize the information from the completed Resident History/Profile to complete all areas of the "Who Am I Form".

2. The IDT will then determine the best method to communicate this information to all facility staff.

3. All facility staff must be trained on where to find this information and how to utilize with their role in caring for the resident.

4. Ideas for communication of resident information to the staff
   -Post inside the closet of the resident in their room
   -Put information in Care Tracker System
   -Put in "Get to know me" binder at Nurses Station

   ****Here is a good idea to ensure staff is reviewing information provided**
   1. Train staff where the "Who Am I" information is located and encourage staff to read the personalized information about each resident.
   2. Have DSD periodically ask staff to tell them one thing about their resident from "Who Am I" form". If the staff can give one personal fact about the resident they will receive a raffle ticket.
   3. At end of month the facility can have a raffle to reward the people who have earned tickets from knowing more about who they are caring for.

WHO AM I?

MY NAME PREFERENCE IS_____

I WAS BORN IN_____I LIVED MOSTLY IN_____

I WENT TO SCHOOL AT? HIGH SCHOOL_____COLLEGE_____

I WORKED MOST OF LIFE AS? _____ I SPEAK_____

I MARRIED _____ WE HAVE___CHILDREN

THERE NAMES ARE_____

OTHER IMPORTANT PEOPLE IN MY LIFE ARE _____

MY MOST FREQUENT VISITORS ARE:

Name	Relationship	How Often They Visit

MY FAVORITE ACTIVITIES/ PAST TIMES?

_____

_____

I LOVE (FOODS, TV SHOWS, BOOKS, MUSIC, HOBBIES, PETS, SOCIALIZATION)

_____

I DISLIKE_____

WHEN I AM (List Behavioral Symptoms)_____

I LIKE YOU TO (Interventions)_____

I LIKE TO GO TO BED (Circle Choice) EARLY LATE I LIKE TO GET UP (Circle Choice) EARLY LATE

Created by: Laurie Kjar, CTRS, Actiity Consultant and Educator

RESIDENT PROFILE

Name: First_____ Middle_____ Last_____ Nickname_____

Birth Date _____ Place of Birth_____ Location of Residence_____

Occupation_____ Education_____Name of College_____

Family

Current Marital Status? M W S D Married To (Name)? _____
Years of Marriage____

If Spouse Living? Will he/she be visiting? Yes No Frequency? _____

Children? Yes No Number of Children? ____ ____Son(s) ___Daughter(s)

Name/Relationship Location Visit Frequency_

_____
_____
_____
_____
_____
_____
_____
_____

Brothers/Sisters/Family Members of Resident

Name Relationship/Living (Yes/No) Location

_____
_____
_____
_____
_____
_____

Other Family Information/History

_____
_____
_____
_____

Created by: Laurie Kjar, CTRS, Activity Consultant and Educator

Favorite Activities/Hobbies/Past times?

__Pets? Cats, Dogs, Birds, Fish
Owned? Y N Allergies to Pets? _____
__Reading_____
__TV _____
__Music_____
__Gardening_____
__Cooking_____
__Outdoor Act._____

__Spiritual/Religion_____
__Hobbies_____
__Crafts_____
__Clubs/Organizations_____
_____
__Travel/Favorite Destinations_____
__Cards/Games_____
__Exercise/Sports_____
(Include Spectator/favorite teams and Participating)

Do they like or dislike the following?

Food? ___Like ___Dislike_____
Flowers? ___Like ___Dislike _____
Animals? ___Like ___Dislike_____
Being around
Large groups? ___Like ___Dislike_____

Things They Like and Things They Dislike

_____

_____

Personality

__Enjoys being with others
__Loner/Likes being by self
__Generally happy/pleasant
__Sense of Humor
__Serious
__Outgoing
__Likes to be in Charge
__Negative

Sleep Habits

__Goes to bed early
__Night owl-Stays up late
__Likes to get up early
__Likes to sleep in late in AM
__Takes naps during day
__Has difficulty sleeping at night

Daily Routines

_____

_____

Behavioral Symptoms in recent past? (I.e. Crying, Anxious, Wandering, Yelling, Insomnia)

_____

_____

Interventions that have been successful to decrease behavioral episodes?

_____

Other Comments___

_____

_____

Created by: Laurie Kjar, CTRS, Activity Consultant and Educator

Antipsychotic (An-tie-sy-COT-ick) Medicines for People with Dementia

When you have a loved one with dementia, it can be hard to make choices about their care. This hand-out can help you decide about using certain medicines for them.

What is dementia* (de-MEN-shuh)?

Dementia is an illness that makes it harder and harder for a person to remember things and live normally. There are many kinds of dementia. Alzheimer's (ALTZ-hi-merz) is one kind. People with dementia may also:

- See or hear things that are not there. These are called hallucinations* (huh-loo-sin-AY-shuns).
- Believe something that isn't true, even when told otherwise. This is called a delusion* (duh-LOO-zhun).
- Get angry for no clear reason, or for a small problem.

These things can be very upsetting for people with dementia and their caregivers. It is important to comfort and support people with dementia. But sometimes medicines are needed.

What are antipsychotic* (an-tie-sy-COT-ick) medicines?

These medicines can help when people see or hear things, or believe things that are not true. But they can also have side effects (things that come from taking a medicine but are not part of the treatment). These medicines may cause a small increase in the risk of death. So it's important to only use them when needed. And only if they help. Sometimes there are other ways to handle problems with dementia. They should be tried first.

What can these medicines help?

Antipsychotic medicines can help:

- **Aggressive behavior**, like hitting, kicking, or biting.
- **Hallucinations**, like hearing voices when there are none, or seeing people in the room who aren't there.
- **Delusions**, like being suspicious (suh-SPI-shus) or thinking people are trying to hurt them. This is called being paranoid (PAIR-uh-noyd).
- **Other things** that can cause danger to the person or other people, or make it very hard to take care of the person.

What will these medicines NOT help?

Antipsychotic medicines do not help these problems:

- **Not being social**—when a person doesn't want to be friendly to others
- **Not taking care of their self**
- **Memory problems**
- **Not paying attention or caring** about what is going on around them
- **Yelling or repeating questions** over and over
- **Being restless**—when it's hard for a person to sit still

There may be other medicines or ways to help. So talk to the health care team.

What are the possible benefits of antipsychotic medicines?

They may help aggressive behavior, hallucinations, or delusions. This can make a person with dementia feel better. It might also make it safer for the person or others.

*Words to Know

Antipsychotic medicine – helps when people see or hear things, or believe things that are not true.
Delusion – believing something that is not true, even when told otherwise.
Dementia – an illness that makes it harder and harder for a person to remember things and live normally.
Hallucination – seeing or hearing things that are not there.

What are the possible side effects of antipsychotic medicines?

They can cause a small increase in some side effects in people with dementia. Here is information about this:

- **Death:** Research shows that if 100 people with dementia take an antipsychotic medicine, 1 of them may die sooner because of the medicine. The chance of dying is small. If someone dies, it is hard to tell if the antipsychotic medicine had anything to do with it. And there is no way to tell who might die while taking this medicine.

- **Stroke:** Research shows that if 100 people take an antipsychotic medicine, 1 could have a stroke because of the medicine. Some kinds of antipsychotic medicines might have a lower risk for stroke. But we don't know for sure.

- **Movement Side Effects:** In some people, these medicines can affect the part of the brain that controls how muscles move. The chance of this is different for each kind of antipsychotic medicine. It doesn't happen as much with low doses. Most of the time, these go away if the medicine is stopped, or the dose is lowered. Sometimes a different kind of medicine can be used. Here are some movement side effects to watch for. Tell the doctor right away if you see:
  - ✓ The person's muscles getting tight, like in Parkinson's Disease. This is Parkinsonism (PARK-in-sun-izm). It can make their steps short so they shuffle when they walk. Their hands or arms may shake. This is called a tremor.
  - ✓ Restlessness or needing to walk around a lot. Sometimes their face can twitch. Rarely, a person can get very stiff and ill, with a very high fever. If this happens, call a doctor or take the person to the emergency room right away!

- **Things that affect overall health**, like gaining weight, high blood sugar, and high cholesterol. Some antipsychotic medicines cause these more than others. It might be okay to try a different kind.

- **Very low blood pressure** when a person stands up quickly. It can make them dizzy or fall.

- **Swelling**, usually around the ankles.

- **Changes in Thinking:**
  - ✓ Being sleepy or groggy because of a drug. This is called sedation (suh-DAY-shun).
  - ✓ Confusion – This can be part of dementia. But antipsychotic and other medicines can sometimes make this worse.

- **Other Side Effects:**
  - ✓ Constipation (con-sti-PAY-shun) (trouble pooping)
  - ✓ Problems urinating (YUR-in-ate-ing) (trouble peeing)
  - ✓ Falling down

How do we know if antipsychotic medicines are helping?

- **Get a clear picture of the problems**.
  - ✓ Before the medicine starts, write down exactly what problems are happening, and how often.
  - ✓ Do this every week, after the medicine starts.
  - ✓ If the problems are not as bad or don't happen as often, the medicine might be helping. But these problems can get better or worse, whether or not medicine is given.
  - ✓ After being on the medicine awhile, a person may have less of the problems. Or the problem may not get better. Talk to the person prescribing the medicine about a lower dose or stopping the medicine.

- **Watch for Side Effects.**
  - ✓ You and the health care team should watch and check for things like:
    - Odd movements
    - Tight muscles
    - Shaking
    - Trouble eating
    - Choking
    - Dizziness
    - Falling
    - Sleepiness
    - Confusion
    - Swelling in the legs
    - Trouble pooping or peeing
    - High or very low blood pressure
    - High blood sugar
    - High cholesterol
  - ✓ If these happen, talk to the doctor or health care team. If it looks like the medicine is causing a problem, things can be tried to help, like:
    - Lowering the dose.
    - Changing to a different kind.
    - Stopping it.

- **Talk to the person's doctor and the rest of the health care team.**

How do I decide if an antipsychotic medicine is right for my loved one?

- **First, check for other things that might be causing problems.** Talk to the doctor or health care team to help figure this out. They might have other ways to help problem behaviors. Here are some things that can cause aggressive behavior, hallucinations, or delusions.
  - ✓ Medicines, especially new ones
  - ✓ Health problems
  - ✓ Constipation
  - ✓ Dehydration (not enough water in the body)
  - ✓ Pain
  - ✓ Mouth sores from dentures or other things
  - ✓ Trouble seeing or hearing
  - ✓ Depression
  - ✓ Stress or fear
  - ✓ Being bored

- **Making the Choice:** Sometimes, no matter what you do, a person with dementia may be aggressive or have bad hallucinations or delusions. Medicine may be needed if the person is acting dangerous or is very upset, and can't be helped in other ways. It may help the person feel better, even if there are risks. Think about things like:
  - ✓ What would the person have wanted before they got dementia?
  - ✓ What would they want if they knew they were biting, kicking, or hitting people?
  - ✓ If the person is having scary hallucinations or seeing people who aren't there, would they want it to stop if a medicine might help?

Many people would want to stop these things if possible, even if there are risks.

Deciding to use an antipsychotic medicine is hard. There are risks. Not everyone is helped. But many people can take them and not get side effects.

We can't cure dementia. When it is getting worse, you can think about whether using an antipsychotic medicine makes a person's comfort and quality of life better, even if there are risks.

What are the names of antipsychotic medicines?

There are 5 kinds that research shows might help people with dementia who act in ways that make it hard to take care of them. Here is a list, and an example brand name:

Name	Example
Aripiprazole (air-uh-PIP-ruh-zol)	Abilify
Haloperidol (hal-oh-PEAR-uh-dol)	Haldol
Risperidone (ri-SPARE-uh-dohn)	Risperdal
Olanzapine (oh-LAN-zuh-peen)	Zyprexa
Quetiapine (kwe-TIE-uh-peen)	Seroquel

Notes:

Name of Antipsychotic Medicine:

_____

Strength of Medicine: _____

How often it is given:

_____

Watch for these things. If you see them, write when it happened, and how often:

- Odd movements _____
- Tight muscles _____
- Shaking _____
- Trouble eating _____
- Choking _____
- Dizziness _____
- Falling _____
- Sleepiness _____
- Confusion _____
- Swelling in the legs _____
- Trouble pooping or peeing _____

_____

Other things: _____

_____

_____

_____

Questions You Want to Ask

_____

_____

_____

_____

_____

_____

Mental Health Medications

National Institute of Mental Health

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES • National Institutes of Health

Contents

Mental Health Medications

Medications are used to treat the symptoms of mental disorders such as schizophrenia, depression, bipolar disorder (sometimes called manic-depressive illness), anxiety disorders, and attention deficit-hyperactivity disorder (ADHD). Sometimes medications are used with other treatments such as psychotherapy. This guide describes:

- Types of medications used to treat mental disorders
- Side effects of medications
- Directions for taking medications
- Warnings about medications from the U.S. Food and Drug Administration (FDA).

This booklet does not provide information about diagnosing mental disorders. Choosing the right medication, medication dose, and treatment plan should be based on a person's individual needs and medical situation, and under a doctor's care.

Information about medications is frequently updated. Check the FDA website (http://www.fda.gov) for the latest information on warnings, patient medication guides, or newly approved medications. Throughout this document you will see two names for medications—the generic name and in parenthesis, the trade name. An example is fluoxetine (Prozac). See the end of this document for a complete alphabetical listing of medications.

What are psychiatric medications?

Psychiatric medications treat mental disorders. Sometimes called psychotropic or psychotherapeutic medications, they have changed the lives of people with mental disorders for the better. Many people with mental disorders live fulfilling lives with the help of these medications. Without them, people with mental disorders might suffer serious and disabling symptoms.

How are medications used to treat mental disorders?

Medications treat the symptoms of mental disorders. They cannot cure the disorder, but they make people feel better so they can function.

Medications work differently for different people. Some people get great results from medications and only need them for a short time. For example, a person with depression may feel much better after taking a medication for a few months, and may never need it again. People with disorders like schizophrenia or bipolar disorder, or people who have long-term or severe depression or anxiety may need to take medication for a much longer time.

Some people get side effects from medications and other people don't. Doses can be small or large, depending on the medication and the person. Factors that can affect how medications work in people include:

- Type of mental disorder, such as depression, anxiety, bipolar disorder, and schizophrenia
- Age, sex, and body size
- Physical illnesses
- Habits like smoking and drinking
- Liver and kidney function
- Genetics
- Other medications and herbal/vitamin supplements
- Diet
- Whether medications are taken as prescribed.

What medications are used to treat schizophrenia?

Antipsychotic medications are used to treat schizophrenia and schizophrenia-related disorders. Some of these medications have been available since the mid-1950's. They are also called conventional "typical" antipsychotics. Some of the more commonly used medications include:

- Chlorpromazine (Thorazine)
- Haloperidol (Haldol)
- Perphenazine (generic only)
- Fluphenazine (generic only).

In the 1990's, new antipsychotic medications were developed. These new medications are called second generation, or "atypical" antipsychotics.

One of these medications was clozapine (Clozaril). It is a very effective medication that treats psychotic symptoms, hallucinations, and breaks with reality, such as when a person believes he or she is the president. But clozapine can sometimes cause a serious problem called agranulocytosis, which is a loss of the white blood cells that help a person fight infection. Therefore, people who take clozapine must get their white blood cell counts checked every week or two. This problem and the cost of blood tests make treatment with clozapine difficult for many people. Still, clozapine is potentially helpful for people who do not respond to other antipsychotic medications.

Other atypical antipsychotics were developed. All of them are effective, and none cause agranulocytosis. These include:

- Risperidone (Risperdal)
- Olanzapine (Zyprexa)
- Quetiapine (Seroquel)
- Ziprasidone (Geodon)
- Aripiprazole (Abilify)
- Paliperidone (Invega).

The antipsychotics listed here are some of the medications used to treat symptoms of schizophrenia. Additional antipsychotics and other medications used for schizophrenia are listed in the chart at the end.

Note: The FDA issued a Public Health Advisory for atypical antipsychotic medications. The FDA determined that death rates are higher for elderly people with dementia when taking this medication. A review of data has found a risk with conventional antipsychotics as well. Antipsychotic medications are not FDA-approved for the treatment of behavioral disorders in patients with dementia.

What are the side effects?

Some people have side effects when they start taking these medications. Most side effects go away after a few days and often can be managed successfully. People who are taking antipsychotics should not drive until they adjust to their new medication. Side effects of many antipsychotics include:

- Drowsiness
- Dizziness when changing positions
- Blurred vision
- Rapid heartbeat
- Sensitivity to the sun
- Skin rashes
- Menstrual problems for women.

Atypical antipsychotic medications can cause major weight gain and changes in a person's metabolism. This may increase a person's risk of

getting diabetes and high cholesterol.[1] A person's weight, glucose levels, and lipid levels should be monitored regularly by a doctor while taking an atypical antipsychotic medication.

Typical antipsychotic medications can cause side effects related to physical movement, such as:

- Rigidity
- Persistent muscle spasms
- Tremors
- Restlessness.

Long-term use of typical antipsychotic medications may lead to a condition called tardive dyskinesia (TD). TD causes muscle movements a person can't control. The movements commonly happen around the mouth. TD can range from mild to severe, and in some people the problem cannot be cured. Sometimes people with TD recover partially or fully after they stop taking the medication.

Every year, an estimated 5 percent of people taking typical antipsychotics get TD. The condition happens to fewer people who take the new, atypical antipsychotics, but some people may still get TD. People who think that they might have TD should check with their doctor before stopping their medication.

How are antipsychotics taken and how do people respond to them?

Antipsychotics are usually pills that people swallow, or liquid they can drink. Some antipsychotics are shots that are given once or twice a month.

Symptoms of schizophrenia, such as feeling agitated and having hallucinations, usually go away within days. Symptoms like delusions usually go away within a few weeks. After about six weeks, many people will see a lot of improvement.

However, people respond in different ways to antipsychotic medications, and no one can tell beforehand how a person will respond. Sometimes a person needs to try several medications before finding the right one. Doctors and patients can work together to find the best medication or medication combination, and dose.

Some people may have a relapse—their symptoms come back or get worse. Usually, relapses happen when people stop taking their medication, or when they only take it sometimes. Some people stop taking the medication because they feel better or they may feel they don't need it anymore. **But no one should stop taking an antipsychotic medication without talking to his or her doctor.** When a doctor says it is okay to stop taking a medication, it should be gradually tapered off, never stopped suddenly.

How do antipsychotics interact with other medications?

Antipsychotics can produce unpleasant or dangerous side effects when taken with certain medications. For this reason, all doctors treating a patient need to be aware of all the medications that person is taking. Doctors need to know about prescription and over-the-counter medicine, vitamins, minerals, and herbal supplements. People also need to discuss any alcohol or other drug use with their doctor.

To find out more about how antipsychotics work, the National Institute of Mental Health (NIMH) funded a study called CATIE (Clinical Antipsychotic Trials of Intervention Effectiveness). This study compared the effectiveness and side effects of five antipsychotics used to treat people with schizophrenia. In general, the study found that the older medication perphenazine worked as well as the newer, atypical medications. But because people respond differently to different medications, it is important that treatments be designed carefully for each person. You can find more information at http://www.nimh.nih.gov/trials/practical/catie/index.shtml.

What medications are used to treat depression?

Depression is commonly treated with antidepressant medications. Antidepressants work to balance some of the natural chemicals in our brains. These chemicals are called neurotransmitters, and they affect our mood and emotional responses. Antidepressants work on neurotransmitters such as serotonin, norepinephrine, and dopamine.

The most popular types of antidepressants are called selective serotonin reuptake inhibitors (SSRIs). These include:

- Fluoxetine (Prozac)
- Citalopram (Celexa)
- Sertraline (Zoloft)
- Paroxetine (Paxil)
- Escitalopram (Lexapro).

Other types of antidepressants are serotonin and norepinephrine reuptake inhibitors (SNRIs). SNRIs are similar to SSRIs and include venlafaxine (Effexor) and duloxetine (Cymbalta). Another antidepressant that is commonly used is bupropion (Wellbutrin). Bupropion, which works on the neurotransmitter dopamine, is unique in that it does not fit into any specific drug type.

SSRIs and SNRIs are popular because they do not cause as many side effects as older classes of antidepressants. Older antidepressant medications include tricyclics, tetracyclics, and monoamine oxidase inhibitors (MAOIs). For some people, tricyclics, tetracyclics, or MAOIs may be the best medications.

What are the side effects?

Antidepressants may cause mild side effects that usually do not last long. **Any unusual reactions or side effects should be reported to a doctor immediately.**

The most common side effects associated with SSRIs and SNRIs include:

- Headache, which usually goes away within a few days.
- Nausea (feeling sick to your stomach), which usually goes away within a few days.
- Sleeplessness or drowsiness, which may happen during the first few weeks but then goes away. Sometimes the medication dose needs to be reduced or the time of day it is taken needs to be adjusted to help lessen these side effects.
- Agitation (feeling jittery).
- Sexual problems, which can affect both men and women and may include reduced sex drive, and problems having and enjoying sex.

Tricyclic antidepressants can cause side effects, including:

- Dry mouth.
- Constipation.
- Bladder problems. It may be hard to empty the bladder, or the urine stream may not be as strong as usual. Older men with enlarged prostate conditions may be more affected.
- Sexual problems, which can affect both men and women and may include reduced sex drive, and problems having and enjoying sex.

- Blurred vision, which usually goes away quickly.
- Drowsiness. Usually, antidepressants that make you drowsy are taken at bedtime.

People taking MAOIs need to be careful about the foods they eat and the medicines they take. Foods and medicines that contain high levels of a chemical called tyramine are dangerous for people taking MAOIs. Tyramine is found in some cheeses, wines, and pickles. The chemical is also in some medications, including decongestants and over-the-counter cold medicine.

Mixing MAOIs and tyramine can cause a sharp increase in blood pressure, which can lead to stroke. People taking MAOIs should ask their doctors for a complete list of foods, medicines, and other substances to avoid. An MAOI skin patch has recently been developed and may help reduce some of these risks. A doctor can help a person figure out if a patch or a pill will work for him or her.

How should antidepressants be taken?

People taking antidepressants need to follow their doctors' directions. The medication should be taken in the right dose for the right amount of time. It can take three or four weeks until the medicine takes effect. Some people take the medications for a short time, and some people take them for much longer periods. People with long-term or severe depression may need to take medication for a long time.

Once a person is taking antidepressants, it is important not to stop taking them without the help of a doctor. Sometimes people taking antidepressants feel better and stop taking the medication too soon, and the depression may return. When it is time to stop the medication, the doctor will help the person slowly and safely decrease the dose. It's important to give the body time to adjust to the change. People don't get addicted, or "hooked," on the medications, but stopping them abruptly can cause withdrawal symptoms.

If a medication does not work, it is helpful to be open to trying another one. A study funded by NIMH found that if a person with difficult-to-treat depression did not get better with a first medication, chances of getting better increased when the person tried a new one or added a second medication to his or her treatment. The study was called STAR*D (Sequenced Treatment Alternatives to Relieve Depression).[2,3] For more information, visit http://www.nimh.nih.gov/trials/practical/stard/index.shtml.

Are herbal medicines used to treat depression?

The herbal medicine St. John's wort has been used for centuries in many folk and herbal remedies. Today in Europe, it is used widely to treat mild-to-moderate depression. In the United States, it is one of the top-selling botanical products.

The National Institutes of Health conducted a clinical trial to determine the effectiveness of treating adults who have major depression with St. Johns wort. The study included 340 people diagnosed with major depression. One-third of the people took the herbal medicine, one-third took an SSRI, and one-third took a placebo, or "sugar pill." The people did not know what they were taking. The study found that St. John's wort was no more effective than the placebo in treating major depression.[4] A study currently in progress is looking at the effectiveness of St. John's wort for treating mild or minor depression.

Other research has shown that St. John's wort can dangerously interact with other medications, including those used to control HIV. On February

10, 2000, the FDA issued a Public Health Advisory letter stating that the herb appears to interfere with certain medications used to treat heart disease, depression, seizures, certain cancers, and organ transplant rejection. Also, St. Johns wort may interfere with oral contraceptives.

Because St. John's wort may not mix well with other medications, people should always talk with their doctors before taking it or any herbal supplement.

FDA warning on antidepressants

Antidepressants are safe and popular, but some studies have suggested that they may have unintentional effects, especially in young people. In 2004, the FDA looked at published and unpublished data on trials of antidepressants that involved nearly 4,400 children and adolescents. They found that 4 percent of those taking antidepressants thought about or tried suicide (although no suicides occurred), compared to 2 percent of those receiving placebos (sugar pill).

In 2005, the FDA decided to adopt a "black box" warning label—the most serious type of warning—on all antidepressant medications. The warning says there is an increased risk of suicidal thinking or attempts in children and adolescents taking antidepressants. In 2007, the FDA proposed that makers of all antidepressant medications extend the warning to include young adults up through age 24. The warning also says that patients of all ages taking antidepressants should be watched closely, especially during the first few weeks of treatment. Possible side effects to look for are depression that gets worse, suicidal thinking or behavior, or any unusual changes in behavior such as trouble sleeping, agitation, or withdrawal from normal social situations. Families and caregivers should report any changes to the doctor. The latest information from the FDA can be found at http://www.fda.gov.

Results of a comprehensive review of pediatric trials conducted between 1988 and 2006 suggested that the benefits of antidepressant medications likely outweigh their risks to children and adolescents with major depression and anxiety disorders.[5] The study was funded in part by NIMH.

Finally, the FDA has warned that combining the newer SSRI or SNRI antidepressants with one of the commonly-used "triptan" medications used to treat migraine headaches could cause a life-threatening illness called "serotonin syndrome." A person with serotonin syndrome may be agitated, have hallucinations (see or hear things that are not real), have a high temperature, or have unusual blood pressure changes. Serotonin syndrome is usually associated with the older antidepressants called MAOIs, but it can happen with the newer antidepressants as well, if they are mixed with the wrong medications.

What medications are used to treat bipolar disorder?

Bipolar disorder, also called manic-depressive illness, is commonly treated with mood stabilizers. Sometimes, antipsychotics and antidepressants are used along with a mood stabilizer.

Mood stabilizers

People with bipolar disorder usually try mood stabilizers first. In general, people continue treatment with mood stabilizers for years. Lithium is a very effective mood stabilizer. It was the first mood stabilizer approved by the FDA in the 1970's for treating both manic and depressive episodes.

Anticonvulsant medications also are used as mood stabilizers. They were originally developed to treat seizures, but they were found to help control moods as well. One anticonvulsant commonly used as a mood stabilizer is valproic acid, also called divalproex sodium (Depakote). For some people, it may work better than lithium.[6] Other anticonvulsants used as mood stabilizers are carbamazepine (Tegretol), lamotrigine (Lamictal) and oxcarbazepine (Trileptal).

Atypical antipsychotics

Atypical antipsychotic medications are sometimes used to treat symptoms of bipolar disorder. Often, antipsychotics are used along with other medications.

Antipsychotics used to treat people with bipolar disorder include:

- Olanzapine (Zyprexa), which helps people with severe or psychotic depression, which often is accompanied by a break with reality, hallucinations, or delusions[7]
- Aripiprazole (Abilify), which can be taken as a pill or as a shot
- Risperidone (Risperdal)
- Ziprasidone (Geodon)
- Clozapine (Clorazil), which is often used for people who do not respond to lithium or anticonvulsants.[8]

Antidepressants

Antidepressants are sometimes used to treat symptoms of depression in bipolar disorder. Fluoxetine (Prozac), paroxetine (Paxil), or sertraline (Zoloft) are a few that are used. However, people with bipolar disorder should not take an antidepressant on its own. Doing so can cause the person to rapidly switch from depression to mania, which can be dangerous.[9] To prevent this problem, doctors give patients a mood stabilizer or an antipsychotic along with an antidepressant.

Research on whether antidepressants help people with bipolar depression is mixed. An NIMH-funded study found that antidepressants were no more effective than a placebo to help treat depression in people with bipolar disorder. The people were taking mood stabilizers along with

the antidepressants. You can find out more about this study, called STEP-BD (Systematic Treatment Enhancement Program for Bipolar Disorder),[10] at http://www.nimh.nih.gov/trials/practical/step-bd/index.shtml.

What are the side effects?

Treatments for bipolar disorder have improved over the last 10 years. But everyone responds differently to medications. If you have any side effects, tell your doctor right away. He or she may change the dose or prescribe a different medication.

Different medications for treating bipolar disorder may cause different side effects. Some medications used for treating bipolar disorder have been linked to unique and serious symptoms, which are described below.

Lithium can cause several side effects, and some of them may become serious. They include:

- Loss of coordination
- Excessive thirst
- Frequent urination
- Blackouts
- Seizures
- Slurred speech
- Fast, slow, irregular, or pounding heartbeat
- Hallucinations (seeing things or hearing voices that do not exist)
- Changes in vision
- Itching, rash
- Swelling of the eyes, face, lips, tongue, throat, hands, feet, ankles, or lower legs.

If a person with bipolar disorder is being treated with lithium, he or she should visit the doctor regularly to check the levels of lithium in the blood, and make sure the kidneys and the thyroid are working normally.

Some possible side effects linked with valproic acid/divalproex sodium include:

- Changes in weight
- Nausea
- Stomach pain
- Vomiting
- Anorexia
- Loss of appetite.

Valproic acid may cause damage to the liver or pancreas, so people taking it should see their doctors regularly.

Valproic acid may affect young girls and women in unique ways. Sometimes, valproic acid may increase testosterone (a male hormone) levels in teenage girls and lead to a condition called polycystic ovarian syndrome (PCOS).[11,12] PCOS is a disease that can affect fertility and make the menstrual cycle become irregular, but symptoms tend to go away after valproic acid is stopped.[13] It also may cause birth defects in women who are pregnant.

Lamotrigine can cause a rare but serious skin rash that needs to be treated in a hospital. In some cases, this rash can cause permanent disability or be life-threatening.

In addition, valproic acid, lamotrigine, carbamazepine, oxcarbazepine and other anticonvulsant medications (listed in the chart at the end of this document) have an FDA warning. The warning states that their use may increase the risk of suicidal thoughts and behaviors. People taking anticonvulsant medications for bipolar or other illnesses should be closely monitored for new or worsening symptoms of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior. People taking these medications should not make any changes without talking to their health care professional.

Other medications for bipolar disorder may also be linked with rare but serious side effects. Always talk with the doctor or pharmacist about any potential side effects before taking the medication.

For information on side effects of antipsychotics, see the section on medications for treating schizophrenia.

For information on side effects and FDA warnings of antidepressants, see the section on medications for treating depression.

How should medications for bipolar disorder be taken?

Medications should be taken as directed by a doctor. Sometimes a person's treatment plan needs to be changed. When changes in medicine are needed, the doctor will guide the change. **A person should never stop taking a medication without asking a doctor for help.**

There is no cure for bipolar disorder, but treatment works for many people. Treatment works best when it is continuous, rather than on and off. However, mood changes can happen even when there are no breaks in treatment. Patients should be open with their doctors about treatment. Talking about how treatment is working can help it be more effective.

It may be helpful for people or their family members to keep a daily chart of mood symptoms, treatments, sleep patterns, and life events. This chart can help patients and doctors track the illness. Doctors can use the chart to treat the illness most effectively.

Because medications for bipolar disorder can have serious side effects, it is important for anyone taking them to see the doctor regularly to check for possibly dangerous changes in the body.

What medications are used to treat anxiety disorders?

Antidepressants, anti-anxiety medications, and beta-blockers are the most common medications used for anxiety disorders.

Anxiety disorders include:

- Obsessive compulsive disorder (OCD)
- Post-traumatic stress disorder (PTSD)
- Generalized anxiety disorder (GAD)
- Panic disorder
- Social phobia.

Antidepressants

Antidepressants were developed to treat depression, but they also help people with anxiety disorders. SSRIs such as fluoxetine (Prozac), sertraline (Zoloft), escitalopram (Lexapro), paroxetine (Paxil), and citalopram (Celexa) are commonly prescribed for panic disorder, OCD, PTSD, and social phobia. The SNRI venlafaxine (Effexor) is commonly used to treat GAD. The antidepressant bupropion (Wellbutrin) is also sometimes used. When treating anxiety disorders, antidepressants generally are started at low doses and increased over time.

Some tricyclic antidepressants work well for anxiety. For example, imipramine (Tofranil) is prescribed for panic disorder and GAD. Clomipramine (Anafranil) is used to treat OCD. Tricyclics are also started at low doses and increased over time.

MAOIs are also used for anxiety disorders. Doctors sometimes prescribe phenelzine (Nardil), tranylcypromine (Parnate), and isocarboxazid (Marplan). People who take MAOIs must avoid certain food and medicines that can interact with their medicine and cause dangerous increases in blood pressure. For more information, see the section on medications used to treat depression.

Benzodiazepines (anti-anxiety medications)

The anti-anxiety medications called benzodiazepines can start working more quickly than antidepressants. The ones used to treat anxiety disorders include:

- Clonazepam (Klonopin), which is used for social phobia and GAD
- Lorazepam (Ativan), which is used for panic disorder
- Alprazolam (Xanax), which is used for panic disorder and GAD.

Buspirone (Buspar) is an anti-anxiety medication used to treat GAD. Unlike benzodiazepines, however, it takes at least two weeks for buspirone to begin working.

Clonazepam, listed above, is an anticonvulsant medication. See FDA warning on anticonvulsants under the bipolar disorder section.

Beta-blockers

Beta-blockers control some of the physical symptoms of anxiety, such as trembling and sweating. Propranolol (Inderal) is a beta-blocker usually used to treat heart conditions and high blood pressure. The medicine also helps people who have physical problems related to anxiety. For example, when a person with social phobia must face a stressful situation, such as giving a speech, or attending an important meeting, a doctor may prescribe a beta-blocker. Taking the medicine for a short period of time can help the person keep physical symptoms under control.

What are the side effects?

See the section on antidepressants for a discussion on side effects.

The most common side effects for benzodiazepines are drowsiness and dizziness. Other possible side effects include:

- Upset stomach
- Blurred vision
- Headache
- Confusion
- Grogginess
- Nightmares.

Possible side effects from buspirone (BuSpar) include:

- Dizziness
- Headaches
- Nausea
- Nervousness
- Lightheadedness
- Excitement
- Trouble sleeping.

Common side effects from beta-blockers include:

- Fatigue
- Cold hands
- Dizziness
- Weakness.

In addition, beta-blockers generally are not recommended for people with asthma or diabetes because they may worsen symptoms.

How should medications for anxiety disorders be taken?

People can build a tolerance to benzodiazepines if they are taken over a long period of time and may need higher and higher doses to get the same effect. Some people may become dependent on them. To avoid these problems, doctors usually prescribe the medication for short periods, a practice that is especially helpful for people who have substance abuse problems or who become dependent on medication easily. If people suddenly stop taking benzodiazepines, they may get withdrawal symptoms, or their anxiety may return. Therefore, they should be tapered off slowly.

Buspirone and beta-blockers are similar. They are usually taken on a short-term basis for anxiety. Both should be tapered off slowly. Talk to the doctor before stopping any anti-anxiety medication.

What medications are used to treat ADHD?

Attention deficit/hyperactivity disorder (ADHD) occurs in both children and adults. ADHD is commonly treated with stimulants, such as:

- Methylphenidate (Ritalin, Metadate, Concerta, Daytrana)
- Amphetamine (Adderall)
- Dextroamphetamine (Dexedrine, Dextrostat).

In 2002, the FDA approved the nonstimulant medication atomoxetine (Strattera) for use as a treatment for ADHD. In February 2007, the FDA approved the use of the stimulant lisdexamfetamine dimesylate (Vyvanse) for the treatment of ADHD in children ages 6 to 12 years.

What are the side effects?

Most side effects are minor and disappear when dosage levels are lowered. The most common side effects include:

- Decreased appetite. Children seem to be less hungry during the middle of the day, but they are often hungry by dinnertime as the medication wears off.
- Sleep problems. If a child cannot fall asleep, the doctor may prescribe a lower dose. The doctor might also suggest that parents give the medication to their child earlier in the day, or stop the afternoon or evening dose. To help ease sleeping problems, a doctor may add a prescription for a low dose of an antidepressant or a medication called clonidine.
- Stomachaches and headaches.
- **Less common side effects.** A few children develop sudden, repetitive movements or sounds called tics. These tics may or may not be noticeable. Changing the medication dosage may make tics go away. Some children also may appear to have a personality change, such as appearing "flat" or without emotion. Talk with your child's doctor if you see any of these side effects.

How are ADHD medications taken?

Stimulant medications can be short-acting or long-acting, and can be taken in different forms such as a pill, patch, or powder. Long-acting, sustained and extended release forms allow children to take the medication just once a day before school. Parents and doctors should decide together which medication is best for the child and whether the child needs medication only for school hours or for evenings and weekends too.

ADHD medications help many children and adults who are hyperactive and impulsive. They help people focus, work, and learn. Stimulant medication also may improve physical coordination. However, different people respond differently to medications, so children taking ADHD medications should be watched closely.

Are ADHD medications safe?

Stimulant medications are safe when given under a doctor's supervision. Some children taking them may feel slightly different or "funny."

Some parents worry that stimulant medications may lead to drug abuse or dependence, but there is little evidence of this. Research shows that teens with ADHD who took stimulant medications were less likely to abuse drugs than those who did not take stimulant medications.[14]

FDA warning on possible rare side effects

In 2007, the FDA required that all makers of ADHD medications develop Patient Medication Guides. The guides must alert patients to possible heart and psychiatric problems related to ADHD medicine. The FDA required the Patient Medication Guides because a review of data found that ADHD patients with heart conditions had a slightly higher risk of strokes, heart attacks, and sudden death when taking the medications. The review also found a slightly higher risk (about 1 in 1,000) for medication-related psychiatric problems, such as hearing voices, having hallucinations, becoming suspicious for no reason, or becoming manic. This happened to patients who had no history of psychiatric problems.

The FDA recommends that any treatment plan for ADHD include an initial health and family history examination. This exam should look for existing heart and psychiatric problems.

The non-stimulant ADHD medication called atomoxetine (Strattera) carries another warning. Studies show that children and teenagers with ADHD who take atomoxetine are more likely to have suicidal thoughts than children and teenagers with ADHD who do not take atomoxetine. If your child is taking atomoxetine, watch his or her behavior carefully. A child may develop serious symptoms suddenly, so it is important to pay attention to your child's behavior every day. Ask other people who spend a lot of time with your child, such as brothers, sisters, and teachers, to tell you if they notice changes in your child's behavior. Call a doctor right away if your child shows any of the following symptoms:

- Acting more subdued or withdrawn than usual
- Feeling helpless, hopeless, or worthless
- New or worsening depression
- Thinking or talking about hurting himself or herself
- Extreme worry
- Agitation
- Panic attacks
- Trouble sleeping
- Irritability
- Aggressive or violent behavior
- Acting without thinking
- Extreme increase in activity or talking
- Frenzied, abnormal excitement
- Any sudden or unusual changes in behavior.

While taking atomoxetine, your child should see a doctor often, especially at the beginning of treatment. Be sure that your child keeps all appointments with his or her doctor.

Which groups have special needs when taking psychiatric medications?

Psychiatric medications are taken by all types of people, but some groups have special needs, including:

- Children and adolescents
- Older adults
- Women who are pregnant or may become pregnant.

Children and adolescents

Most medications used to treat young people with mental illness are safe and effective. However, many medications have not been studied or approved for use with children. Researchers are not sure how these medications affect a child's growing body. Still, a doctor can give a young person an FDA-approved medication on an "off-label" basis. This means that the doctor prescribes the medication to help the patient even though the medicine is not approved for the specific mental disorder or age.

For these reasons, it is important to watch young people who take these medications. Young people may have different reactions and side effects than adults. Also, some medications, including antidepressants and ADHD medications, carry FDA warnings about potentially dangerous side effects for young people. See the sections on antidepressants and ADHD medications for more information about these warnings.

More research is needed on how these medications affect children and adolescents. NIMH has funded studies on this topic. For example, NIMH funded the Preschoolers with ADHD Treatment Study (PATS), which involved 300 preschoolers (3 to 5 years old) diagnosed with ADHD. The study found that low doses of the stimulant methylphenidate are safe and effective for preschoolers. However, children of this age are more sensitive to the side effects of the medication, including slower growth rates. Children taking methylphenidate should be watched closely.[15,16,17]

In addition to medications, other treatments for young people with mental disorders should be considered. Psychotherapy, family therapy, educational courses, and behavior management techniques can help everyone involved cope with the disorder. For more information on child and adolescent mental health research, visit http://www.nimh.nih.gov/health/topics/child-and-adolescent-mental-health/index.shtml.

Older adults

Because older people often have more medical problems than other groups, they tend to take more medications than younger people, including prescribed, over-the-counter, and herbal medications. As a result, older people have a higher risk for experiencing bad drug interactions, missing doses, or overdosing.

Older people also tend to be more sensitive to medications. Even healthy older people react to medications differently than younger people because their bodies process it more slowly. Therefore, lower or less frequent doses may be needed.

Sometimes memory problems affect older people who take medications for mental disorders. An older adult may forget his or her regular dose and take too much or not enough. A good way to keep track of medicine is to use a seven-day pill

box, which can be bought at any pharmacy. At the beginning of each week, older adults and their caregivers fill the box so that it is easy to remember what medicine to take. Many pharmacies also have pillboxes with sections for medications that must be taken more than once a day.

Women who are pregnant or may become pregnant

The research on the use of psychiatric medications during pregnancy is limited. The risks are different depending on what medication is taken, and at what point during the pregnancy the medication is taken.

Research has shown that antidepressants, especially SSRIs, are safe during pregnancy. Birth defects or other problems are possible, but they are very rare.[18,19]

However, antidepressant medications do cross the placental barrier and may reach the fetus. Some research suggests the use of SSRIs during pregnancy is associated with miscarriage or birth defects, but other studies do not support this.[20] Studies have also found that fetuses exposed to SSRIs during the third trimester may be born with "withdrawal" symptoms such as breathing problems, jitteriness, irritability, trouble feeding, or hypoglycemia (low blood sugar).

Most studies have found that these symptoms in babies are generally mild and short-lived, and no deaths have been reported. On the flip side, women who stop taking their antidepressant medication during pregnancy may get depression again and may put both themselves and their infant at risk.[20,21]

In 2004, the FDA issued a warning against the use of certain antidepressants in the late third trimester. The warning said that doctors may want to gradually taper pregnant women off antidepressants in the third trimester so that the baby is not affected.[22] After a woman delivers, she should consult with her doctor to decide whether to return to a full dose during the period when she is most vulnerable to postpartum depression.

Some medications should not be taken during pregnancy. Benzodiazepines may cause birth defects or other infant problems, especially if taken during the first trimester. Mood stabilizers are known to cause birth defects. Benzodiazepines and lithium have been shown to cause "floppy baby syndrome," which is when a baby is drowsy and limp, and cannot breathe or feed well.

Research suggests that taking antipsychotic medications during pregnancy can lead to birth defects, especially if they are taken during the first trimester. But results vary widely depending on the type of antipsychotic. The conventional antipsychotic haloperidol has been studied more than others, and has been found not to cause birth defects.[23,24]

After the baby is born, women and their doctors should watch for postpartum depression, especially if they stopped taking their medication during pregnancy. In addition, women who nurse while taking psychiatric medications should know that a small amount of the medication passes into the breast milk. However, the medication may or may not affect the baby. It depends on the medication and when it is taken. Women taking psychiatric medications and who intend to breastfeed should discuss the potential risks and benefits with their doctors.

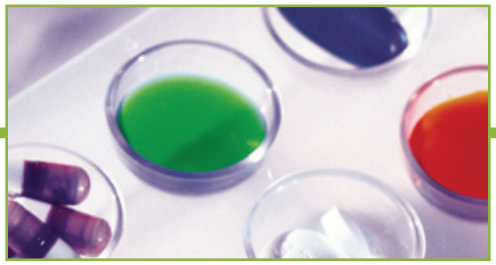
Decisions on medication should be based on each woman's needs and circumstances. Medications should be selected based on available scientific research, and they should be taken at the lowest possible dose. Pregnant women should be watched closely throughout their pregnancy and after delivery.

What should I ask my doctor if I am prescribed a psychiatric medication?

You and your family can help your doctor find the right medications for you. The doctor needs to know your medical history; family history; information about allergies; other medications, supplements or herbal remedies you take; and other details about your overall health. You or a family member should ask the following questions when a medication is prescribed:

- What is the name of the medication?
- What is the medication supposed to do?
- How and when should I take it?
- How much should I take?
- What should I do if I miss a dose?
- When and how should I stop taking it?
- Will it interact with other medications I take?
- Do I need to avoid any types of food or drink while taking the medication? What should I avoid?
- Should it be taken with or without food?
- Is it safe to drink alcohol while taking this medication?
- What are the side effects? What should I do if I experience them?
- Is the Patient Package Insert for the medication available?

After taking the medication for a short time, tell your doctor how you feel, if you are having side effects, and any concerns you have about the medicine.



Alphabetical List of Medications

This section identifies antipsychotic medications, antidepressant medications, mood stabilizers, anticonvulsant medications, anti-anxiety medications, and ADHD medications. Some medications are marketed under trade names, not all of which can be listed in this publication.

The first chart lists the medications by trade name; the second chart lists the medications by generic name. If your medication does not appear in this section, refer to the FDA website (http://www.fda.gov). Also, ask your doctor or pharmacist for more information about any medication.

Medications Organized by Trade Name

Trade Name	Generic Name	FDA Approved Age
Combination Antipsychotic and Antidepressant Medication		
Symbyax (Prozac & Zyprexa)	fluoxetine & olanzapine	18 and older
Antipsychotic Medications		
Abilify	aripiprazole	10 and older for bipolar disorder, manic, or mixed episodes; 13 to 17 for schizophrenia and bipolar
Clozaril	clozapine	18 and older
Fanapt	iloperidone	18 and older
fluphenazine (generic only)	fluphenazine	18 and older
Geodon	ziprasidone	18 and older
Haldol	haloperidol	3 and older
Invega	paliperidone	18 and older
Loxitane	loxapine	18 and older
Moban	molindone	18 and older
Navane	thiothixene	18 and older
Orap (for Tourette's syndrome)	pimozide	12 and older
perphenazine (generic only)	perphenazine	18 and older
Risperdal	risperidone	13 and older for schizophrenia; 10 and older for bipolar mania and mixed episodes; 5 to 16 for irritability associated with autism
Seroquel	quetiapine	13 and older for schizophrenia; 18 and older for bipolar; 10 to 17 for treatment of manic and mixed episodes of bipolar disorder
Stelazine	trifluoperazine	18 and older
thioridazine (generic only)	thioridazine	2 and older
Thorazine	chlorpromazine	18 and older
Zyprexa	olanzapine	18 and older; ages 13 to 17 as second line treatment for manic or mixed episodes of bipolar disorder and schizophrenia

Trade Name	Generic Name	FDA Approved Age
Antidepressant Medications (also used for anxiety disorders)		
Anafranil (tricyclic)	clomipramine	10 and older (for OCD only)
Asendin	amoxapine	18 and older
Aventyl (tricyclic)	nortriptyline	18 and older
Celexa (SSRI)	citalopram	18 and older
Cymbalta (SNRI)	duloxetine	18 and older
Desyrel	trazodone	18 and older
Effexor (SNRI)	venlafaxine	18 and older
Elavil (tricyclic)	amitriptyline	18 and older
Emsam	selegiline	18 and older
Lexapro (SSRI)	escitalopram	18 and older; 12 to 17 (for major depressive disorder)
Ludiomil (tricyclic)	maprotiline	18 and older
Luvox (SSRI)	fluvoxamine	8 and older (for OCD only)
Marplan (MAOI)	isocarboxazid	18 and older
Nardil (MAOI)	phenelzine	18 and older
Norpramin (tricyclic)	desipramine	18 and older
Pamelor (tricyclic)	nortriptyline	18 and older
Parnate (MAOI)	tranylcypromine	18 and older
Paxil (SSRI)	paroxetine	18 and older
Pexeva (SSRI)	paroxetine-mesylate	18 and older
Pristiq (SNRI)	desvenlafaxine	18 and older
Prozac (SSRI)	fluoxetine	8 and older
Remeron	mirtazapine	18 and older
Sarafem (SSRI)	fluoxetine	18 and older for premenstrual dysphoric disorder (PMDD)
Sinequan (tricyclic)	doxepin	12 and older
Surmontil (tricyclic)	trimipramine	18 and older
Tofranil (tricyclic)	imipramine	6 and older (for bedwetting)
Tofranil-PM (tricyclic)	imipramine pamoate	18 and older
Vivactil (tricyclic)	protriptyline	18 and older
Wellbutrin	bupropion	18 and older
Zoloft (SSRI)	sertraline	6 and older (for OCD only)

Trade Name	Generic Name	FDA Approved Age
Mood Stabilizing and Anticonvulsant Medications		
Depakote	divalproex sodium (valproic acid)	2 and older (for seizures)
Eskalith	lithium carbonate	12 and older
Lamictal	lamotrigine	18 and older
lithium citrate (generic only)	lithium citrate	12 and older
Lithobid	lithium carbonate	12 and older
Neurontin	gabapentin	18 and older
Tegretol	carbamazepine	any age (for seizures)
Topamax	topiramate	18 and older
Trileptal	oxcarbazepine	4 and older
Anti-anxiety Medications (All of these anti-anxiety medications are benzodiazepines, except BuSpar)		
Ativan	lorazepam	18 and older
BuSpar	buspirone	18 and older
Klonopin	clonazepam	18 and older
Librium	chlordiazepoxide	18 and older
oxazepam (generic only)	oxazepam	18 and older
Tranxene	clorazepate	18 and older
Valium	diazepam	18 and older
Xanax	alprazolam	18 and older

Trade Name	Generic Name	FDA Approved Age
ADHD Medications (All of these ADHD medications are stimulants, except Intuniv and Straterra.)		
Adderall	amphetamine	3 and older
Adderall XR	amphetamine (extended release)	6 and older
Concerta	methylphenidate (long acting)	6 and older
Daytrana	methylphenidate patch	6 and older
Desoxyn	methamphetamine	6 and older
Dexedrine	dextroamphetamine	3 and older
Dextrostat	dextroamphetamine	3 and older
Focalin	dexmethylphenidate	6 and older
Focalin XR	dexmethylphenidate (extended release)	6 and older
Intuniv	guanfacine	6 and older
Metadate ER	methylphenidate (extended release)	6 and older
Metadate CD	methylphenidate (extended release)	6 and older
Methylin	methylphenidate (oral solution and chewable tablets)	6 and older
Ritalin	methylphenidate	6 and older
Ritalin SR	methylphenidate (extended release)	6 and older
Ritalin LA	methylphenidate (long-acting)	6 and older
Strattera	atomoxetine	6 and older
Vyvanse	lisdexamfetamine dimesylate	6 and older

Medications Organized by Generic Name

Generic Name	Trade Name	FDA Approved Age
Combination Antipsychotic and Antidepressant Medication		
fluoxetine & olanzapine	Symbyax (Prozac & Zyprexa)	18 and older
Antipsychotic Medications		
aripiprazole	Abilify	10 and older for bipolar disorder, manic, or mixed episodes; 13 to 17 for schizophrenia and bipolar
chlorpromazine	Thorazine	18 and older
clozapine	Clozaril	18 and older
fluphenazine (generic only)	fluphenazine	18 and older
haloperidol	Haldol	3 and older
iloperidone	Fanapt	18 and older
loxapine	Loxitane	18 and older
molindone	Moban	18 and older
olanzapine	Zyprexa	18 and older; ages 13 to 17 as second line treatment for manic or mixed episodes of bipolar disorder and schizophrenia
paliperidone	Invega	18 and older
perphenazine (generic only)	perphenazine	18 and older
pimozide (for Tourette's syndrome)	Orap	12 and older
quetiapine	Seroquel	13 and older for schizophrenia; 18 and older for bipolar; 10 to 17 for treatment of manic and mixed episodes of bipolar disorder
risperidone	Risperdal	13 and older for schizophrenia; 10 and older for bipolar mania and mixed episodes; 5 to 16 for irritability associated with autism
thioridazine (generic only)	thioridazine	2 and older
thiothixene	Navane	18 and older
trifluoperazine	Stelazine	18 and older
ziprasidone	Geodon	18 and older

Generic Name	Trade Name	FDA Approved Age
Antidepressant Medications (also used for anxiety disorders)		
amitriptyline (tricyclic)	Elavil	18 and older
amoxapine	Asendin	18 and older
bupropion	Wellbutrin	18 and older
citalopram (SSRI)	Celexa	18 and older
clomipramine (tricyclic)	Anafranil	10 and older (for OCD only)
desipramine (tricyclic)	Norpramin	18 and older
desvenlafaxine (SNRI)	Pristiq	18 and older
doxepin (tricyclic)	Sinequan	12 and older
duloxetine (SNRI)	Cymbalta	18 and older
escitalopram (SSRI)	Lexapro	18 and older; 12 to 17 (for major depressive disorder)
fluoxetine (SSRI)	Prozac	8 and older
fluoxetine (SSRI)	Sarafem	18 and older for premenstrual dysphoric disorder (PMDD)
fluvoxamine (SSRI)	Luvox	8 and older (for OCD only)
imipramine (tricyclic)	Tofranil	6 and older (for bedwetting)
imipramine pamoate (tricyclic)	Tofranil-PM	18 and older
isocarboxazid (MAOI)	Marplan	18 and older
maprotiline (tricyclic)	Ludiomil	18 and older
mirtazapine	Remeron	18 and older
nortriptyline (tricyclic)	Aventyl, Pamelor	18 and older
paroxetine (SSRI)	Paxil	18 and older
paroxetine mesylate (SSRI)	Pexeva	18 and older
phenelzine (MAOI)	Nardil	18 and older
protriptyline (tricyclic)	Vivactil	18 and older
selegiline	Emsam	18 and older
sertraline (SSRI)	Zoloft	6 and older (for OCD only)
tranylcypromine (MAOI)	Parnate	18 and older
trazodone	Desyrel	18 and older
trimipramine (tricyclic)	Surmontil	18 and older
venlafaxine (SNRI)	Effexor	18 and older

Generic Name	Trade Name	FDA Approved Age
Mood Stabilizing and Anticonvulsant Medications		
carbamazepine	Tegretol	any age (for seizures)
divalproex sodium (valproic acid)	Depakote	2 and older (for seizures)
gabapentin	Neurontin	18 and older
lamotrigine	Lamictal	18 and older
lithium carbonate	Eskalith, Lithobid	12 and older
lithium citrate (generic only)	lithium citrate	12 and older
oxcarbazepine	Trileptal	4 and older
topiramate	Topamax	18 and older
Anti-anxiety Medications (All of these anti-anxiety medications are benzodiazepines, except buspirone.)		
alprazolam	Xanax	18 and older
buspirone	BuSpar	18 and older
chlordiazepoxide	Librium	18 and older
clonazepam	Klonopin	18 and older
clorazepate	Tranxene	18 and older
diazepam	Valium	18 and older
lorazepam	Ativan	18 and older
oxazepam (generic only)	oxazepam	18 and older

Generic Name	Trade Name	FDA Approved Age
ADHD Medications (All of these ADHD medications are stimulants, except atomoxetine and guanfacine.)		
amphetamine	Adderall	3 and older
amphetamine (extended release)	Adderall XR	6 and older
atomoxetine	Strattera	6 and older
dexmethylphenidate	Focalin	6 and older
dexmethylphenidate (extended release)	Focalin XR	6 and older
dextroamphetamine	Dexedrine, Dextrostat	3 and older
guanfacine	Intuniv	6 and older
lisdexamfetamine dimesylate	Vyvanse	6 and older
methamphetamine	Desoxyn	6 and older
methylphenidate	Ritalin	6 and older
methylphenidate (extended release)	Metadate CD, Metadate ER, Ritalin SR	6 and older
methylphenidate (long-acting)	Ritalin LA, Concerta	6 and older
methylphenidate patch	Daytrana	6 and older
methylphenidate (oral solution and chewable tablets)	Methylin	6 and older

Citations

1. Lieberman JA, Stroup TS, McEvoy JP, Swartz MS, Rosenheck RA, Perkins DO, Keefe RS, Davis SM, Davis CE, Lebowitz BD, Severe J, Hsiao JK; Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE). Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. *New England Journal of Medicine*. 2005 Sep 22;353(12):1209-1223.

2. Rush JA, Trivedi MH, Wisniewski SR, Stewart JW, Nierenberg AA, Thase ME, Ritz L, Biggs MM, Warden D, Luther JF, Shores-Wilson K, Niederehe G, Fava M. Bupropion-SR, sertraline, or venlafaxine-XR after failure of SSRIs for depression. *New England Journal of Medicine*. 2006 Mar 23; 354(12):1231-1242.

3. Trivedi MH, Fava M, Wisniewski SR, Thase ME, Quitkin F, Warden D, Ritz L, Nierenberg AA, Lebowitz BD, Biggs MM, Luther JF, Shores-Wilson K, Rush JA. Medication augmentation after the failure of SSRIs for depression. *New England Journal of Medicine*. 2006 Mar 23; 354(12): 1243-1252.

4. Hypericum Depression Trial Study Group. Effect of Hypericum perforatum (St. John's wort) in major depressive disorder: a randomized controlled trial. *Journal of the American Medical Association*. 2002; 287(14): 1807-1814.

5. Bridge JA, Iyengar S, Salary CB, Barbe RP, Birmaher B, Pincus HA, Ren L, Brent DA. Clinical response and risk for reported suicidal ideation and suicide attempts in pediatric antidepressant treatment, a meta-analysis of randomized controlled trials. *Journal of the American Medical Association*. 2007; 297(15): 1683-1696.

6. Bowden CL, Calabrese JR, McElroy SL, Gyulai L, Wassef A, Petty F, Pope HG, Jr., Chou JC, Keck PE, Jr., Rhodes LJ, Swann AC, Hirschfeld RM, Wozniak PJ, Group DMS. A randomized, placebo-controlled 12-month trial of divalproex and lithium in treatment of outpatients with bipolar I disorder. *Archives of General Psychiatry*. 2000 May; 57(5):481-489.

7. Rothschild AJ, Bates KS, Boehringer KL, Syed A. Olanzapine response in psychotic depression. *Journal of Clinical Psychiatry*. 1999 Feb; 60(2):116-118.

8. Suppes T, Webb A, Paul B, Carmody T, Kraemer H, Rush AJ. Clinical outcome in a randomized 1-year trial of clozapine versus treatment as usual for patients with treatment-resistant illness and a history of mania. *American Journal of Psychiatry*. 1999 Aug;156(8): 1164-1169.

9. Thase ME, Sachs GS. Bipolar depression: pharmacotherapy and related therapeutic strategies. *Biological Psychiatry*. 2000 Sep 15;48(6):558-572.

10. Sachs G, Nierenberg AA, Calabrese JR, Marangell LB, Wisniewski SR, Gyulai L, Friedman ES, Bowden CL, Fossey MD, Ostacher MJ, Ketter TA, Patel J, Hauser P, Rapport D, Martinez JM, Allen MH, Miklowitz DJ, Otto MW, Dennehy EB, Thase ME. Effectiveness of adjunctive antidepressant treatment for bipolar depression: a double-blind placebo-controlled study. *New England Journal of Medicine*. Epub 28 Mar 2007; 356(17): 1771-1773.

11. Vainionpaa LK, Rattya J, Knip M, Tapanainen JS, Pakarinen AJ, Lanning P, Tekay A, Myllyla VV, Isojarvi JI. Valproate-induced hyperandrogenism during pubertal maturation in girls with epilepsy. *Annals of Neurology*. 1999 Apr;45(4):444-450.

12. Joffe H, Cohen LS, Suppes T, McLaughlin WL, Lavori P, Adams JM, Hwang CH, Hall JE, Sachs GS. Valproate is associated with new-onset oligoamenorrhea with hyperandrogenism in women with bipolar disorder. *Biological Psychiatry*. 2006 Jun 1;59(11):1078-1086.

13. Joffe H, Cohen LS, Suppes T, Hwang CH, Molay F, Adams JM, Sachs GS, Hall JE. Longitudinal follow-up of reproductive and metabolic features of valproate-associated polycystic ovarian syndrome features: A preliminary report. *Biological Psychiatry*. 2006 Dec 15;60(12):1378-1381.

14. Wilens TC, Faraone, SV, Biederman J, Gunawardene S. Does stimulant therapy of attention-deficit/hyperactivity disorder beget later substance abuse? A meta-analytic review of the literature. *Pediatrics*. 2003; 111(1):179-185.

15. Swanson J, Greenhill L, Wigal T, Kollins S, Stehli A, Davies M, Chuang S, Vitiello B, Skroballa A, Posner K, Abikoff H, Oatis M, McCracken J, McGough J, Riddle M, Ghouman J, Cunningham C, Wigal S. Stimulant-related reductions in growth rates in the PATS. *Journal of the Academy of Child and Adolescent Psychiatry*. 2006 Nov; 45(11): 1304-1313.

16. Greenhill L, Kollins S, Abikoff H, McCracken J, Riddle M, Swanson J, McGough J, Wigal S, Wigal T, Vitiello B, Skroballa A, Posner K, Ghuman J, Cunningham C, Davies M, Chuang S, Cooper T. Efficacy and safety of immediate-release methylphenidate treatment for preschoolers with attention-deficit/hyperactivity disorder. *Journal of the Academy of Child and Adolescent Psychiatry*. 2006 Nov; 45(11):1284-1293.

17. Wigal T, Greenhill L, Chuang S, McGough J, Vitiello B, Skrobala A, Swanson J, Wigal S, Abikoff H, Kollins S, McCracken J, Riddle M, Posner K, Ghuman J, Davies M, Thorp B, Stehli A. Safety and tolerability of methylphenidate in preschool children with attention-deficit/hyperactivity disorder. *Journal of the Academy of Child and Adolescent Psychiatry*. 2006 Nov; 45(11): 1294-1303.

18. Alwan S, Reefhuis J, Rasmussen S, Olney R, Friedman J for the National Birth Defects Prevention Study. Use of selective serotonin-reuptake inhibitors in pregnancy and the risk of birth defects. *New England Journal of Medicine*. 2007 Jun 28; 356(26):2684-2692.

19. Louik C, Lin An, Werler M, Hernandez S, Mitchell A. First-trimester use of selective serotonin-reuptake inhibitors and the risk of birth defects. *New England Journal of Medicine*. 2007 Jun 28; 356(26):2675-2683.

20. Austin M. To treat or not to treat: maternal depression, SSRI use in pregnancy and adverse neonatal effects. *Psychological Medicine*. 2006 Jul 25; 1-8.

21. Cohen L, Altshuler L, Harlow B, Nonacs R, Newport DJ, Viguera A, Suri R, Burt V, Hendrick AM, Loughead A, Vitonis AF, Stowe Z. Relapse of major depression during pregnancy in women who maintain or discontinue antidepressant treatment. *Journal of the American Medical Association*. 2006 Feb 1; 295(5): 499-507.

22. U.S. Food and Drug Administration (FDA). FDA Medwatch drug alert on Effexor and SSRIs, 2004 Jun 3. Available at www.fda.gov/medwatch/safety/2004/safety04.htm#effexor.

23. Jain AE, Lacy T. Psychotropic drugs in pregnancy and lactation. *Journal of Psychiatric Practice*. 2005 May; 11(3): 177-191.

24. Ward RK, Zamorski MA. Benefits and risks of psychiatric medications during pregnancy. *American Family Physician*. 15 Aug. 2002; 66(4): 629-636.

For More Information on Medications:

Visit the National Library of Medicine's MedlinePlus
http://www.nlm.nih.gov/medlineplus

En Español
http://medlineplus.gov/spanish

For information on Clinical Trials
http://www.nimh.nih.gov/trials/index.shtml

National Library of Medicine Clinical Trials Database
http://www.clinicaltrials.gov

Information from NIMH is available in multiple formats. You can browse online, download documents in PDF, and order paper brochures through the mail. If you would like to have NIMH publications, you can order them online at http://www.nimh.nih.gov. If you do not have Internet access and wish to have information that supplements this publication, please contact the NIMH Information Resource Center at the numbers listed below.

National Institute of Mental Health
Science Writing, Press & Dissemination Branch
6001 Executive Boulevard
Room 8184, MSC 9663
Bethesda, MD 20892-9663
Phone: 301-443-4513 or
1-866-615-NIMH (6464) toll-free
TTY: 301-443-8431 or
866-415-8051 toll-free
FAX: 301-443-4279
E-mail: **nimhinfo@nih.gov**
Website: **http://www.nimh.nih.gov**

Reprints

NIMH publications are in the public domain and may be reproduced or copied without the permission from the National Institute of Mental Health. NIMH encourages you to reproduce them and use them in your efforts to improve public health. Citation of the National Institute of Mental Health as a source is appreciated. However, using government materials inappropriately can raise legal or ethical concerns, so we ask you to use these guidelines:

- NIMH does not endorse or recommend any commercial products, processes, or services, and publications may not be used for advertising or endorsement purposes.
- NIMH does not provide specific medical advice or treatment recommendations or referrals; these materials may not be used in a manner that has the appearance of such information.
- NIMH requests that non-Federal organizations not alter publications in a way that will jeopardize the integrity and "brand" when using publications.
- Addition of non-Federal Government logos and Web site links may not have the appearance of NIMH endorsement of any specific commercial products or services or medical treatments or services.
- Images used in publications are of models and are used for illustrative purposes only. Use of some images is restricted.

If you have questions regarding these guidelines and use of NIMH publications, please contact the NIMH Information Resource Center at 1-866-615-6464 or e-mail **nimhinfo@nih.gov**.

NIMH
National Institute
of Mental Health

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
NIH Publication No. 12–3929
Revised 2010
Reprinted 2012

THE UNIVERSITY OF IOWA

IOWA GERIATRIC EDUCATION CENTER

INFO-CONNECT

Family Involvement in Care

For Persons with Dementia in Long-Term Care Facilities

The Facts . . .

⇒ 50 to 70 percent of persons living in nursing homes have dementia.

⇒ Although family members seek assistance for care of their relatives, they maintain an interest in quality of caregiving.

⇒ Long-term care staff as well as families report many difficulties sharing the caregiving role.

Family Involvement in Care Intervention

The Family Involvement in Care (FIC) intervention refers to a strategy that partners family caregiver(s) and long-term care facility staff to provide the best possible care for a person with dementia.

One key to the FIC intervention is for both parties to continually negotiate and clarify their expectations to establish mutually satisfactory roles and relationships.

Another key is for staff to help family members choose the type and frequency of activities in which they want to participate.

Benefits of FIC Intervention

Benefits can be seen from the FIC intervention for family and staff, as well as for persons with dementia.

For Family and Staff

- Improved staff attitudes about families
- Decreased family caregiver guilt and burden
- Improved communication between family and staff

For Persons with Dementia

- Improved quality of interaction with families
- Increased therapeutic and diversional activities
- Increased preservation of individual identity

Risk Factors in Care Relationships

Both the person with dementia and the family caregiver(s) are at risk for unsatisfactory relationships and care. Families may experience conflict with staff over competing priorities. Without family involvement in care, long-term care facility staff may unintentionally neglect aspects of caregiving that are important to both the family and the resident.

Situations that put the person with dementia or their families at risk include:

- Family caregiver's assumption of a new role once staff becomes the primary caregiver
- Change in the type of care services or resources available
- Change from care in a familiar environment to care in an unfamiliar institution
- Change in care providers
- Deteriorating mental or physical capacity of the person with dementia
- Deteriorating physical or mental capacity of the family caregiver(s)
- Traditional expectations of staff that families are visitors and, therefore, minimally involved in caregiving
- Institutional barriers (e.g. lack of staffing, policy, procedures, or environmental structures)
- Resident and family's negative feelings about the new care environment

Information to Share

For families and staff to form successful family involvement in care partnerships, the following information should be shared about the person with dementia, the family caregivers, and the formal care provider.

Person with Dementia

- Date of admission to new care situation
- Cognitive function status
- Usual behaviors and activities
- Basic and instrumental activities of daily living
- Medical and nursing diagnoses
- Plan of care

Family Caregivers

- Date of admission to new care situation
- Reason for change in care situation
- Filial relationship of family member to person with dementia
- Primary caregiver at home
- Employment status
- Degree of family support
- Other social support
- Other family roles/obligations
- Feelings about new care situation
- Frequency of caregiving
- Care provided
- Ability to provide care (physical/emotional)
- Problems encountered in providing care
- Expectations for continuing participation in caregiving
- Expected frequency of contact
- Major concerns about new care situation

Formal Care Provider

- Type of setting
- Plan of care for person with dementia
- Philosophy of care of persons with dementia
- Policies regarding visitation
- Policies regarding family participation in caregiving
- Presence of family support group
- Attitudes about family participation in caregiving
- Expectations of staff for family participation in caregiving
- Staff knowledge about dementia and care of persons with dementia

For Additional Information about the FIC Intervention

Maas, M. *et. al*. (1994, November/December). "The caring partnership: Staff and families of persons institutionalized with Alzheimer's disease." *The American Journal of Alzheimer's Care and Related Disorders & Research*, 21-30.

Kelley, L., Specht, J., & Maas, M. (1999). "Research-Based protocol: Family involvement in care for persons with dementia." In M. Titler (Series Ed.) *Series on Evidence-Based Practice for Older Adults.* Iowa City, IA: The University of Iowa College of Nursing Gerontological Nursing Interventions Research Center, Research Dissemination Core.

Specht, J., Kelley, L., *et al*. (2000). "Who's the boss? Family/staff partnership in care of persons with dementia." *Nursing Administration Quarterly, 24*(3), 64-77.

Kelley, L., Specht, J., & Maas, M. (2000, February). "Family involvement in care for individuals with dementia protocol." *Journal of Gerontological Nursing*, 13-21.

A Service of:

Iowa Geriatric Research Center

University of Iowa

2153 Westlawn

Iowa City, IA 52242

(319) 353-5756

Grant funded by the Department of Health Resources and Services Administration (HRSA)

Visit us at:

http://www.medicine.uiowa.edu/igec

Content provided by:

Janet Specht, PhD, RN
Associate Professor, College of Nursing
University of Iowa

Meridean Maas, PhD, RN, FAAN
Professor and Chair, Adult and Gerontology Area
Director of Doctoral Studies
College of Nursing
University of Iowa

Lisa Skemp Kelley, MA, RN
Doctoral Candidate, College of Nursing
University of Iowa

(Work funded by grant NR01 NR01689-03A2
M. Maas, PhD, RN, FAAN Principal Investigator;
E. Swanson, PhD., RN Co-Principal Investigator; and
D. Reed, PhD, Project Director.)

Editorial review by:

Margo Schilling, MD
Assistant Professor of Clinical Medicine
Division of General Internal Medicine
University of Iowa

Implementing the *FIC* Intervention

The FIC intervention is accomplished by establishing and implementing a Partnership Agreement which consists of four key phases:

- Orientation of family and staff;
- Education of all care providers;
- Negotiation and formation of the Partnership Agreement; and
- Ongoing evaluation and renegotiation of the Partnership Agreement.

Orientation

The purpose of the orientation phase is to establish a foundation of the FIC intervention. There are three important steps in this phase:

- A formal care provider who will act as nurse care manager (NCM) is identified.
- The NCM visits with family to identify primary family caregiver(s).
- The family caregiver(s) is taken on a tour of the care environment, reviewing philosophies and policies and discussing expectations and concerns.

Education

The purpose of the education phase is to educate family and staff regarding general principles of caregiving as well as the more specific principles associated with caring for someone with dementia. The following are suggested components of this education:

- Communication and visitation strategies
- Role adjustments required for family members and staff
- Therapeutic approaches to facilitate quality of care in a new care situation
- Negotiation and partnership information
- Negotiation skills for formation, maintenance and termination of partnership
- Role playing to practice negotiation and partnership agreement

Negotiation and Formation

Family members and staff review, discuss, agree upon, and document the goals and approaches for care of the person with dementia.

The negotiated Partnership Agreement specifically documents the plan for both family member and staff care provider involvement, as well as the frequency and anticipated length of time for each of the activities.

Ongoing Evaluation and Renegotiation

The care setting influences the frequency of evaluation and renegotiation. For example, in the nursing home setting, this is achieved by discussions between the NCM and the family member at least each week. If the family member does not initiate this weekly contact, the NCM contacts the family by phone.

A quarterly care conference is an ideal time to formally evaluate family, resident, and staff satisfaction with the FIC intervention. Although the length of time for these conferences is often brief, frequent communications provide a critical time for the NCM to solicit feedback and suggestions from family and staff.

EXAMPLES OF PARTNERSHIP ACTIVITIES

⇒ Family member constructs a photo life story book or room bulletin board.

- Photo life story book can be used during visits.
- Family member shares life story book with new staff.
- Staff uses life story book to reminisce with the resident on days when the family does not visit.

⇒ Family member supplies staff with information about the person's life experiences, personality, and accomplishments.

- Family member prepares a tape for all staff to listen to.
- Family member participates in resident care conferences.

⇒ Family member assists in physical care (e.g. bathing, exercise, and grooming).

- Wife assists with bathing on Monday and Thursday evenings.
- Daughter feeds father lunch on Monday, Wednesday and Fridays.
- Son trims mother's fingernails every other week.
- Daughter-in-law monitors physical care by observing cleanliness of resident and reporting any problems to a designated person.

FAMILY AND STAFF PARTNERSHIP ACTIVITIES AGREEMENT

Staff and family have agreed that they are partners in planning, providing, and evaluating care for

_____ (Resident)

Family member(s) will do the following activities (Please include frequency and amount of time for each activity):

_____

_____

_____

_____

Staff will do the following activities (Please include frequency and amount of time for each activity):

_____

_____

_____

_____

Comments and Explanations:

Family Member(s) Signature(s)

_____

_____

Facility Staff Signatures

_____

_____

ANTIDEPRESSANT MEDICATIONS

MEDICATION INFORMATION

Depression is commonly treated with antidepressant medications. Antidepressants work to balance some of the natural chemicals in our brains. These chemicals are called neurotransmitters, and they affect our mood and emotional responses. Antidepressants work on neurotransmitters such as serotonin, norepinephrine, and dopamine.

The most popular types of antidepressants are called selective serotonin reuptake inhibitors (SSRIs). These include:

- Fluoxetine (Prozac)
- Citalopram (Celexa)
- Sertraline (Zoloft)
- Paroxetine (Paxil)
- Escitalopram (Lexapro)

Other types of antidepressants are serotonin and norepinephrine reuptake inhibitors (SNRIs). SNRIs are similar to SSRIs and include venlafaxine (Effexor) and duloxetine (Cymbalta). Another antidepressant that is commonly used is bupropion (Wellbutrin). Bupropion, which works on the neurotransmitter dopamine, is unique in that it does not fit into any specific drug type.

SSRIs and SNRIs are popular because they do not cause as many side effects as older classes of antidepressants. Older antidepressant medications include tricyclics, tetracyclics, and monoamine oxidase inhibitors (MAOIs). For some people, tricyclics, tetracyclics, or MAOIs may be the best medications.

HOW SHOULD ANTIDEPRESSANTS BE TAKEN

People taking antidepressants need to follow their doctors' directions. The medication should be taken in the right dose for the right amount of time. It can take three or four weeks until the medicine takes effect. Some people take the medications for a short time, and some people take them for much longer periods. People with long-term or severe depression may need to take medication for a long time.

Once a person is taking antidepressants, it is important not to stop taking them without the help of a doctor. Sometimes people taking antidepressants feel better and stop taking the medication too soon, and the depression may return. When it is time to stop the medication, the doctor will help the person slowly and safely decrease the dose. It's important to give the body time to adjust to the change. People don't get addicted, or "hooked," on the medications, but stopping them abruptly can cause withdrawal symptoms.

Source of Information: http://www.nimh.nih.gov/health/publications/mental-health-medications/nimh-mental-health-medications.pdf

IF YOU HAVE ANY QUESTIONS REGARDING YTHIS INFORMATION OR THE RESIDENT'S PLAN OF CARE, PLEASE CONTACT: **MIRA JENSEN, MSN RN NP**

ENSIGN FACILITY SERVICES
(949) 487- 9500

WHAT ARE THE SIDE EFFECTS?

Antidepressants may cause mild side effects that usually do not last long. **Any unusual reactions or side effects should be reported to a doctor immediately.**

The most common side effects associated with SSRIs and SNRIs include:

- Headache, which usually goes away within a few days
- Nausea (feeling sick to your stomach), which usually goes away within a few days
- Sleeplessness or drowsiness, which may happen during the first few weeks but then goes away Sometimes the medication dose needs to be reduced or the time of day it is taken needs to be adjusted to help lessen these side effects
- Agitation (feeling jittery)
- Sexual problems, which can affect both men and women and may include reduced sex drive, and problems having and enjoying sex

Tricyclic antidepressants can cause side effects, including:

- Dry mouth
- Constipation
- Bladder problems. It may be hard to empty the bladder, or the urine stream may not be as strong as usual. Older men with enlarged prostate conditions may be more affected.
- Sexual problems, which can affect both men and women and may include reduced sex drive, and problems having and enjoying sex
- Blurred vision, which usually goes away quickly
- Drowsiness Usually, antidepressants that make you drowsy are taken at bedtime

People taking MAOIs need to be careful about the foods they eat and the medicines they take. Foods and medicines that contain high levels of a chemical called tyramine are dangerous for people taking MAOIs. Tyramine is found in some cheeses, wines, and pickles. The chemical is also in some medications, including decongestants and over-the-counter cold medicine.

Mixing MAOIs and tyramine can cause a sharp increase in blood pressure, which can lead to stroke. People taking MAOIs should ask their doctors for a complete list of foods, medicines, and other substances to avoid. An MAOI skin patch has recently been developed and may help reduce some of these risks. A doctor can help a person figure out if a patch or a pill will work for him or her.

FDA Warning on Antidepressants

Antidepressants are safe and popular, but some studies have suggested that they may have unintentional effects, especially in young people. In 2004, the FDA looked at published and unpublished data on trials of antidepressants that involved nearly 4,400 children and adolescents. They found that 4 percent of those taking antidepressants thought about or tried suicide (although no suicides occurred), compared to 2 percent of those receiving placebos (sugar pill).

In 2005, the FDA decided to adopt a "black box" warning label—the most serious type of warning—on all antidepressant medications. The warning says there is an increased risk of suicidal thinking or attempts in children and adolescents taking antidepressants. In 2007, the FDA proposed that makers of all antidepressant medications extend the warning to include young adults up through age 24.

The warning also says that patients of all ages taking antidepressants should be watched closely, especially during the first few weeks of treatment Possible side effects to look for are depression that gets worse, suicidal thinking or behavior, or any unusual changes in behavior such as trouble sleeping, agitation, or withdrawal from normal social situations Families and caregivers should report any changes to the doctor The latest information from the FDA can be found at http://www fda gov.

ANTIPSYCHOTIC MEDICATIONS

MEDICATION INFORMATION

WHAT ARE THE SIDE EFFECTS?

Some people have side effects when they start taking these medications. Most side effects go away after a few days and often can be managed successfully. People who are taking antipsychotics should not drive until they adjust to their new medication. Side effects of many antipsychotics include:

- Drowsiness
- Dizziness when changing positions
- Blurred vision
- Rapid heartbeat
- Sensitivity to the sun
- Skin rashes
- Menstrual problems for women

Atypical antipsychotic medications can cause major weight gain and changes in a person's metabolism. This may increase a person's risk of getting diabetes and high cholesterol. A person's weight, glucose levels, and lipid levels should be monitored regularly by a doctor while taking an atypical antipsychotic medication.

Typical antipsychotic medications can cause side effects related to physical movement, such as:

- Rigidity
- Persistent muscle spasms
- Tremors
- Restlessness

Note: The FDA issued a Public Health Advisory for atypical antipsychotic medications The FDA determined that death rates are higher for elderly people with dementia when taking this medication A review of data has found a risk with conventional antipsychotics as well Antipsychotic medications are not FDA-approved for the treatment of behavioral disorders in patients with dementia.

Long-term use of typical antipsychotic medications may lead to a condition called **tardive dyskinesia** (TD).

TD causes muscle movements a person can't control. The movements commonly happen around the mouth. TD can range from mild to severe, and in some people the problem cannot be cured. Sometimes people with TD recover partially or fully after they stop taking the medication.

Every year, an estimated 5 percent of people taking typical antipsychotics get TD. The condition happens to fewer people who take the new, atypical antipsychotics, but some people may still get TD. People who think that they might have TD should check with their doctor before stopping their medication.

Antipsychotic medications have been available since the mid- 1950's. The older types are called conventional or "typical" antipsychotics. Some of the more commonly used typical medications include:

- **Chlorpromazine (Thorazine)**
- **Haloperidol (Haldol)**
- **Perphenazine (Etrafon, Trilafon)**
- **Fluphenazine (Prolixin)**

In the 1990's, new antipsychotic medications were developed. These new medications are called second generation, or "atypical" antipsychotics. Examples include:

- **Aripiprazole (Abilify)**
- **Asenapine Maleate (Saphris)**
- **Clozapine (Clozaril)**
- **Iloperidone (Fanapt)**
- **Lurasidone (Latuda)**
- **Olanzapine (Zyprexa)**
- **Olanzapine/Fluoxetine (Symbyax)**
- **Paliperidone (Invega)**
- **Quetiapine (Seroquel)**
- **Risperidone (Risperdal)**
- **Ziprasidone (Geodon)**

HOW ARE ANTIPSYCHOTICS TAKEN AND HOW DO PEOPLE RESPOND TO THEM?

Antipsychotics are usually pills that people swallow, or liquid they can drink. Some antipsychotics are shots that are given once or twice a month.

Symptoms of schizophrenia, such as feeling agitated and having hallucinations, usually go away within days. Symptoms like delusions usually go away within a few weeks. After about six weeks, many people will see a lot of improvement.

However, people respond in different ways to antipsychotic medications, and no one can tell beforehand how a person will respond. Sometimes a person needs to try several medications before finding the right one. Doctors and patients can work together to find the best medication or medication combination, and dose.

Some people may have a relapse—their symptoms come back or get worse. Usually, relapses happen when people stop taking their medication, or when they only take it sometimes. Some people stop taking the medication because they feel better or they may feel they don't need it anymore. **But no one should stop taking an antipsychotic medication without talking to his or her doctor.** When a doctor says it is okay to stop taking a medication, it should be gradually tapered off, never stopped suddenly.

Source of Information:

http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm094303.htm

http://www.nimh.nih.gov/health/publications/mental-health-medications/nimh-mental-health-medications.pdf

If you have any questions regarding this information or the resident's plan of care, please contact:

Mira Jensen, MSN RN NP
Director of Clinical Services
Ensign Facility Services
(949) 487- 9500
mjensen@ensigngroup.net

FAST FACTS: What You Need to Know About Antipsychotic Drugs for Persons Living with Dementia

The AHCA/NCAL Quality Initiative

What is an antipsychotic drug?

An antipsychotic (an-tie-sy-COT-ick) drug is a medicine that works in the brain, which may help to block certain chemicals that can cause symptoms of psychosis, such as hallucinations or delusions.

- Hallucinations are when a person sees or hears things that are not there.
- Delusions are when a person believes something that isn't true, even after being told.

Some people with some mental illnesses like schizophrenia and bipolar disorder often have these symptoms.

What are common antipsychotics?

- Haldol
- Quetiapine (Seroquel)
- Olanzapine (Zyprexa)
- Aripiprazole (Abilify)
- Risperidone (Risperdal)

Why are these drugs used in people with Dementia?

These drugs can help for some people with dementia who do have psychosis. However, most of the time these drugs are used when a person acts in way that is challenging or disturbing to others, such as

- hitting, yelling, screaming
- refusing care, walking around
- crying, banging, throwing things

Some people think that these drugs may help with these behaviors however; studies show that many of these behaviors in people with dementia are normal reactions to something they find scary, upsetting or uncomfortable. Or, their actions may also be telling us that they need something such as:

- food because they are hungry,
- water or juice to drink because they are thirsty,
- to take a nap because they are tired,
- to go to the bathroom, or
- something to do because they are bored.

In these cases, drugs will not help.

Do these drugs work in people with dementia?

For people with dementia who have hallucinations or delusions, these drugs can help. However, most people with dementia don't have hallucinations or delusions. For many people, these drugs slow them down, making them drowsy or groggy. These drugs don't get to the heart of the reason for the person's actions. Scientific studies show that for only a small number of people with dementia these drugs will help a little bit. Overall, most people do not get better. Of those who get better, it is those with psychosis and hallucination.

What can these drugs NOT do?

These drugs do not help:

- Stop yelling or repeating questions over and over;
- Calm being restless, fidgety or uneasy,
- Stop memory problems;
- Persons do more for themselves;
- Persons interact better with others; or
- Stop inappropriate things being said.

Why am I hearing so much about them?

Recent scientific studies from both universities and government agencies have found:

1. That these drugs are often used too much in people with dementia
2. That these drugs do not work as well as people first believed in people with dementia.

What are the risks?

People with dementia who are given these drugs are more likely to:

- be unsteady when they walk
- fall
- break their bones
- have incontinence ("pee in their pants")
- have a stroke
- die sooner

Because of these dangers, the US Food and Drug Administration (FDA) requires a warning on the label of all antipsychotic drugs. Such "black box" warnings are only required for drugs with serious risks. The warning includes the following:

Warning: Increased Mortality in Elderly Patients with Dementia-Related Psychosis. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. [Name of Antipsychotic] is not approved for the treatment of patients with dementia-related psychosis

Is it safe to stop these drugs?

Studies in nursing homes show that it is very safe to try stopping these drugs in people who:

- are taking a low dose;
- did not have any actions recently; or
- did not have hallucinations before starting the drugs.

In studies of people already on an antipsychotic drug that was then replaced with a fake pill, doctors and nurses could not tell the difference between who stopped the drug and who took the drug. This shows that stopping these drugs is safe.

Many experts suggest trying a lower dose or stopping these drugs because

- in nursing homes, staff watch to see if there is a reason to keep using these drugs;
- many of the actions these drugs are used for are about unmet needs and cannot be fixed by drugs; and
- about one out of three people will still act in challenging ways, whether the drug is continued or not.

Why do people with dementia behave in ways that can be challenging?

They may have a need they cannot express or be in a situation they don't understand. For example, when it's time to get undressed for bed or a bath, some people with dementia may hit or try to stop their care giver. This can be because they don't understand why someone is taking off their clothes. A person with dementia can't always tell us how they feel. They may get upset when they need to go to the bathroom. They may get angry when they are tired or hungry. Skilled care givers do their best to predict the needs of people with dementia. Sometimes, they can take steps to meet those needs and keep the person from getting upset. Skilled care givers look at what is going on physically, emotionally, and environmentally that might be causing the person to react.

- Are they cold, hungry, tired, thirsty, or in pain?
- Are they bored; scared, stressed out, upset by too much noise or another person's actions?
- Are they missing their family or friends?
- Do they find a task they are trying to do, like dressing or bathing, too hard?

These kinds of things can all upset a person. However, drugs do not help with these kinds of needs.

What should I do?

If your loved one is already taking these drugs, ask:

- What type of drug is my loved one on?
- What caused the drug to be prescribed?
- How has the care team tried to help solve the problem without drugs?
- What is the plan to decrease or stop the drug?

If your loved one is not currently on an antipsychotic, BEFORE any are prescribed, ask:

- What is causing the drug to be prescribed?
- What has the care team tried to respond to my loved one's challenging behaviors?
- How will they track the behaviors once the drug is started?
- What is the plan to decrease or stop the drug?

How can I help?

Staff will never know all that you know! You can help by providing answers to questions such as:

- How does your family member express themself when they are scared, angry, anxious, and hungry?
- What, in the past, has comforted them?
- What is their typical daily routine?
- Are there any behaviors that you have found more difficult to respond to than others?
- What have you tried to prevent them?
- Stay involved in your loved ones care and attend care plan meetings.

Antipsychotic (An-tie-sy-COT-ick) Medicines for People with Dementia

When you have a loved one with dementia, it can be hard to make choices about their care. This hand-out can help you decide about using certain medicines for them.

What is dementia* (de-MEN-shuh)?

Dementia is an illness that makes it harder and harder for a person to remember things and live normally. There are many kinds of dementia. Alzheimer's (ALTZ-hi-merz) is one kind. People with dementia may also:

- See or hear things that are not there. These are called hallucinations* (huh-loo-sin-AY-shuns).
- Believe something that isn't true, even when told otherwise. This is called a delusion* (duh-LOO-zhun).
- Get angry for no clear reason, or for a small problem.

These things can be very upsetting for people with dementia and their caregivers. It is important to comfort and support people with dementia. But sometimes medicines are needed.

What are antipsychotic* (an-tie-sy-COT-ick) medicines?

These medicines can help when people see or hear things, or believe things that are not true. But they can also have side effects (things that come from taking a medicine but are not part of the treatment). These medicines may cause a small increase in the risk of death. So it's important to only use them when needed. And only if they help. Sometimes there are other ways to handle problems with dementia. They should be tried first.

What can these medicines help?

Antipsychotic medicines can help:

- **Aggressive behavior**, like hitting, kicking, or biting.
- **Hallucinations**, like hearing voices when there are none, or seeing people in the room who aren't there.
- **Delusions**, like being suspicious (suh-SPI-shus) or thinking people are trying to hurt them. This is called being paranoid (PAIR-uh-noyd).
- **Other things** that can cause danger to the person or other people, or make it very hard to take care of the person.

What will these medicines NOT help?

Antipsychotic medicines do not help these problems:

- **Not being social**—when a person doesn't want to be friendly to others
- **Not taking care of their self**
- **Memory problems**
- **Not paying attention or caring** about what is going on around them
- **Yelling or repeating questions** over and over
- **Being restless**—when it's hard for a person to sit still

There may be other medicines or ways to help. So talk to the health care team.

What are the possible benefits of antipsychotic medicines?

They may help aggressive behavior, hallucinations, or delusions. This can make a person with dementia feel better. It might also make it safer for the person or others.

*Words to Know

Antipsychotic medicine – helps when people see or hear things, or believe things that are not true.
Delusion – believing something that is not true, even when told otherwise.
Dementia – an illness that makes it harder and harder for a person to remember things and live normally.
Hallucination – seeing or hearing things that are not there.

What are the possible side effects of antipsychotic medicines?

They can cause a small increase in some side effects in people with dementia. Here is information about this:

- **Death:** Research shows that if 100 people with dementia take an antipsychotic medicine, 1 of them may die sooner because of the medicine. The chance of dying is small. If someone dies, it is hard to tell if the antipsychotic medicine had anything to do with it. And there is no way to tell who might die while taking this medicine.

- **Stroke:** Research shows that if 100 people take an antipsychotic medicine, 1 could have a stroke because of the medicine. Some kinds of antipsychotic medicines might have a lower risk for stroke. But we don't know for sure.

- **Movement Side Effects:** In some people, these medicines can affect the part of the brain that controls how muscles move. The chance of this is different for each kind of antipsychotic medicine. It doesn't happen as much with low doses. Most of the time, these go away if the medicine is stopped, or the dose is lowered. Sometimes a different kind of medicine can be used. Here are some movement side effects to watch for. Tell the doctor right away if you see:
  - ✓ The person's muscles getting tight, like in Parkinson's Disease. This is Parkinsonism (PARK-in-sun-izm). It can make their steps short so they shuffle when they walk. Their hands or arms may shake. This is called a tremor.
  - ✓ Restlessness or needing to walk around a lot. Sometimes their face can twitch. Rarely, a person can get very stiff and ill, with a very high fever. If this happens, call a doctor or take the person to the emergency room right away!

- **Things that affect overall health**, like gaining weight, high blood sugar, and high cholesterol. Some antipsychotic medicines cause these more than others. It might be okay to try a different kind.

- **Very low blood pressure** when a person stands up quickly. It can make them dizzy or fall.

- **Swelling**, usually around the ankles.

- **Changes in Thinking:**
  - ✓ Being sleepy or groggy because of a drug. This is called sedation (suh-DAY-shun).
  - ✓ Confusion – This can be part of dementia. But antipsychotic and other medicines can sometimes make this worse.

- **Other Side Effects:**
  - ✓ Constipation (con-sti-PAY-shun) (trouble pooping)
  - ✓ Problems urinating (YUR-in-ate-ing) (trouble peeing)
  - ✓ Falling down

How do we know if antipsychotic medicines are helping?

- **Get a clear picture of the problems**.
  - ✓ Before the medicine starts, write down exactly what problems are happening, and how often.
  - ✓ Do this every week, after the medicine starts.
  - ✓ If the problems are not as bad or don't happen as often, the medicine might be helping. But these problems can get better or worse, whether or not medicine is given.
  - ✓ After being on the medicine awhile, a person may have less of the problems. Or the problem may not get better. Talk to the person prescribing the medicine about a lower dose or stopping the medicine.

- **Watch for Side Effects.**
  - ✓ You and the health care team should watch and check for things like:
    - Odd movements
    - Tight muscles
    - Shaking
    - Trouble eating
    - Choking
    - Dizziness
    - Falling
    - Sleepiness
    - Confusion
    - Swelling in the legs
    - Trouble pooping or peeing
    - High or very low blood pressure
    - High blood sugar
    - High cholesterol
  - ✓ If these happen, talk to the doctor or health care team. If it looks like the medicine is causing a problem, things can be tried to help, like:
    - Lowering the dose.
    - Changing to a different kind.
    - Stopping it.

- **Talk to the person's doctor and the rest of the health care team.**

How do I decide if an antipsychotic medicine is right for my loved one?

- **First, check for other things that might be causing problems.** Talk to the doctor or health care team to help figure this out. They might have other ways to help problem behaviors. Here are some things that can cause aggressive behavior, hallucinations, or delusions.
  - ✓ Medicines, especially new ones
  - ✓ Health problems
  - ✓ Constipation
  - ✓ Dehydration (not enough water in the body)
  - ✓ Pain
  - ✓ Mouth sores from dentures or other things
  - ✓ Trouble seeing or hearing
  - ✓ Depression
  - ✓ Stress or fear
  - ✓ Being bored

- **Making the Choice:** Sometimes, no matter what you do, a person with dementia may be aggressive or have bad hallucinations or delusions. Medicine may be needed if the person is acting dangerous or is very upset, and can't be helped in other ways. It may help the person feel better, even if there are risks. Think about things like:
  - ✓ What would the person have wanted before they got dementia?
  - ✓ What would they want if they knew they were biting, kicking, or hitting people?
  - ✓ If the person is having scary hallucinations or seeing people who aren't there, would they want it to stop if a medicine might help?

Many people would want to stop these things if possible, even if there are risks.

Deciding to use an antipsychotic medicine is hard. There are risks. Not everyone is helped. But many people can take them and not get side effects.

We can't cure dementia. When it is getting worse, you can think about whether using an antipsychotic medicine makes a person's comfort and quality of life better, even if there are risks.

What are the names of antipsychotic medicines?

There are 5 kinds that research shows might help people with dementia who act in ways that make it hard to take care of them. Here is a list, and an example brand name:

Name	Example
Aripiprazole (air-uh-PIP-ruh-zol)	Abilify
Haloperidol (hal-oh-PEAR-uh-dol)	Haldol
Risperidone (ri-SPARE-uh-dohn)	Risperdal
Olanzapine (oh-LAN-zuh-peen)	Zyprexa
Quetiapine (kwe-TIE-uh-peen)	Seroquel

Notes:

Name of Antipsychotic Medicine:

_____

Strength of Medicine: _____

How often it is given:

_____

Watch for these things. If you see them, write when it happened, and how often:

- Odd movements _____
- Tight muscles _____
- Shaking _____
- Trouble eating _____
- Choking _____
- Dizziness _____
- Falling _____
- Sleepiness _____
- Confusion _____
- Swelling in the legs _____
- Trouble pooping or peeing _____

_____

Other things: _____

_____

_____

_____

Questions You Want to Ask

_____

_____

_____

_____

_____

_____

Mental Health Medications

National Institute of Mental Health

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES • National Institutes of Health

Contents

Mental Health Medications

Medications are used to treat the symptoms of mental disorders such as schizophrenia, depression, bipolar disorder (sometimes called manic-depressive illness), anxiety disorders, and attention deficit-hyperactivity disorder (ADHD). Sometimes medications are used with other treatments such as psychotherapy. This guide describes:

- Types of medications used to treat mental disorders
- Side effects of medications
- Directions for taking medications
- Warnings about medications from the U.S. Food and Drug Administration (FDA).

This booklet does not provide information about diagnosing mental disorders. Choosing the right medication, medication dose, and treatment plan should be based on a person's individual needs and medical situation, and under a doctor's care.

Information about medications is frequently updated. Check the FDA website (http://www.fda.gov) for the latest information on warnings, patient medication guides, or newly approved medications. Throughout this document you will see two names for medications—the generic name and in parenthesis, the trade name. An example is fluoxetine (Prozac). See the end of this document for a complete alphabetical listing of medications.

What are psychiatric medications?

Psychiatric medications treat mental disorders. Sometimes called psychotropic or psychotherapeutic medications, they have changed the lives of people with mental disorders for the better. Many people with mental disorders live fulfilling lives with the help of these medications. Without them, people with mental disorders might suffer serious and disabling symptoms.

How are medications used to treat mental disorders?

Medications treat the symptoms of mental disorders. They cannot cure the disorder, but they make people feel better so they can function.

Medications work differently for different people. Some people get great results from medications and only need them for a short time. For example, a person with depression may feel much better after taking a medication for a few months, and may never need it again. People with disorders like schizophrenia or bipolar disorder, or people who have long-term or severe depression or anxiety may need to take medication for a much longer time.

Some people get side effects from medications and other people don't. Doses can be small or large, depending on the medication and the person. Factors that can affect how medications work in people include:

- Type of mental disorder, such as depression, anxiety, bipolar disorder, and schizophrenia
- Age, sex, and body size
- Physical illnesses
- Habits like smoking and drinking
- Liver and kidney function
- Genetics
- Other medications and herbal/vitamin supplements
- Diet
- Whether medications are taken as prescribed.

What medications are used to treat schizophrenia?

Antipsychotic medications are used to treat schizophrenia and schizophrenia-related disorders. Some of these medications have been available since the mid-1950's. They are also called conventional "typical" antipsychotics. Some of the more commonly used medications include:

- Chlorpromazine (Thorazine)
- Haloperidol (Haldol)
- Perphenazine (generic only)
- Fluphenazine (generic only).

In the 1990's, new antipsychotic medications were developed. These new medications are called second generation, or "atypical" antipsychotics.

One of these medications was clozapine (Clozaril). It is a very effective medication that treats psychotic symptoms, hallucinations, and breaks with reality, such as when a person believes he or she is the president. But clozapine can sometimes cause a serious problem called agranulocytosis, which is a loss of the white blood cells that help a person fight infection. Therefore, people who take clozapine must get their white blood cell counts checked every week or two. This problem and the cost of blood tests make treatment with clozapine difficult for many people. Still, clozapine is potentially helpful for people who do not respond to other antipsychotic medications.

Other atypical antipsychotics were developed. All of them are effective, and none cause agranulocytosis. These include:

- Risperidone (Risperdal)
- Olanzapine (Zyprexa)
- Quetiapine (Seroquel)
- Ziprasidone (Geodon)
- Aripiprazole (Abilify)
- Paliperidone (Invega).

The antipsychotics listed here are some of the medications used to treat symptoms of schizophrenia. Additional antipsychotics and other medications used for schizophrenia are listed in the chart at the end.

Note: The FDA issued a Public Health Advisory for atypical antipsychotic medications. The FDA determined that death rates are higher for elderly people with dementia when taking this medication. A review of data has found a risk with conventional antipsychotics as well. Antipsychotic medications are not FDA-approved for the treatment of behavioral disorders in patients with dementia.

What are the side effects?

Some people have side effects when they start taking these medications. Most side effects go away after a few days and often can be managed successfully. People who are taking antipsychotics should not drive until they adjust to their new medication. Side effects of many antipsychotics include:

- Drowsiness
- Dizziness when changing positions
- Blurred vision
- Rapid heartbeat
- Sensitivity to the sun
- Skin rashes
- Menstrual problems for women.

Atypical antipsychotic medications can cause major weight gain and changes in a person's metabolism. This may increase a person's risk of

getting diabetes and high cholesterol.[1] A person's weight, glucose levels, and lipid levels should be monitored regularly by a doctor while taking an atypical antipsychotic medication.

Typical antipsychotic medications can cause side effects related to physical movement, such as:

- Rigidity
- Persistent muscle spasms
- Tremors
- Restlessness.

Long-term use of typical antipsychotic medications may lead to a condition called tardive dyskinesia (TD). TD causes muscle movements a person can't control. The movements commonly happen around the mouth. TD can range from mild to severe, and in some people the problem cannot be cured. Sometimes people with TD recover partially or fully after they stop taking the medication.

Every year, an estimated 5 percent of people taking typical antipsychotics get TD. The condition happens to fewer people who take the new, atypical antipsychotics, but some people may still get TD. People who think that they might have TD should check with their doctor before stopping their medication.

How are antipsychotics taken and how do people respond to them?

Antipsychotics are usually pills that people swallow, or liquid they can drink. Some antipsychotics are shots that are given once or twice a month.

Symptoms of schizophrenia, such as feeling agitated and having hallucinations, usually go away within days. Symptoms like delusions usually go away within a few weeks. After about six weeks, many people will see a lot of improvement.

However, people respond in different ways to antipsychotic medications, and no one can tell beforehand how a person will respond. Sometimes a person needs to try several medications before finding the right one. Doctors and patients can work together to find the best medication or medication combination, and dose.

Some people may have a relapse—their symptoms come back or get worse. Usually, relapses happen when people stop taking their medication, or when they only take it sometimes. Some people stop taking the medication because they feel better or they may feel they don't need it anymore. **But no one should stop taking an antipsychotic medication without talking to his or her doctor.** When a doctor says it is okay to stop taking a medication, it should be gradually tapered off, never stopped suddenly.

How do antipsychotics interact with other medications?

Antipsychotics can produce unpleasant or dangerous side effects when taken with certain medications. For this reason, all doctors treating a patient need to be aware of all the medications that person is taking. Doctors need to know about prescription and over-the-counter medicine, vitamins, minerals, and herbal supplements. People also need to discuss any alcohol or other drug use with their doctor.

To find out more about how antipsychotics work, the National Institute of Mental Health (NIMH) funded a study called CATIE (Clinical Antipsychotic Trials of Intervention Effectiveness). This study compared the effectiveness and side effects of five antipsychotics used to treat people with schizophrenia. In general, the study found that the older medication perphenazine worked as well as the newer, atypical medications. But because people respond differently to different medications, it is important that treatments be designed carefully for each person. You can find more information at http://www.nimh.nih.gov/trials/practical/catie/index.shtml.

What medications are used to treat depression?

Depression is commonly treated with antidepressant medications. Antidepressants work to balance some of the natural chemicals in our brains. These chemicals are called neurotransmitters, and they affect our mood and emotional responses. Antidepressants work on neurotransmitters such as serotonin, norepinephrine, and dopamine.

The most popular types of antidepressants are called selective serotonin reuptake inhibitors (SSRIs). These include:

- Fluoxetine (Prozac)
- Citalopram (Celexa)
- Sertraline (Zoloft)
- Paroxetine (Paxil)
- Escitalopram (Lexapro).

Other types of antidepressants are serotonin and norepinephrine reuptake inhibitors (SNRIs). SNRIs are similar to SSRIs and include venlafaxine (Effexor) and duloxetine (Cymbalta). Another antidepressant that is commonly used is bupropion (Wellbutrin). Bupropion, which works on the neurotransmitter dopamine, is unique in that it does not fit into any specific drug type.

SSRIs and SNRIs are popular because they do not cause as many side effects as older classes of antidepressants. Older antidepressant medications include tricyclics, tetracyclics, and monoamine oxidase inhibitors (MAOIs). For some people, tricyclics, tetracyclics, or MAOIs may be the best medications.

What are the side effects?

Antidepressants may cause mild side effects that usually do not last long. **Any unusual reactions or side effects should be reported to a doctor immediately.**

The most common side effects associated with SSRIs and SNRIs include:

- Headache, which usually goes away within a few days.
- Nausea (feeling sick to your stomach), which usually goes away within a few days.
- Sleeplessness or drowsiness, which may happen during the first few weeks but then goes away. Sometimes the medication dose needs to be reduced or the time of day it is taken needs to be adjusted to help lessen these side effects.
- Agitation (feeling jittery).
- Sexual problems, which can affect both men and women and may include reduced sex drive, and problems having and enjoying sex.

Tricyclic antidepressants can cause side effects, including:

- Dry mouth.
- Constipation.
- Bladder problems. It may be hard to empty the bladder, or the urine stream may not be as strong as usual. Older men with enlarged prostate conditions may be more affected.
- Sexual problems, which can affect both men and women and may include reduced sex drive, and problems having and enjoying sex.

- Blurred vision, which usually goes away quickly.
- Drowsiness. Usually, antidepressants that make you drowsy are taken at bedtime.

People taking MAOIs need to be careful about the foods they eat and the medicines they take. Foods and medicines that contain high levels of a chemical called tyramine are dangerous for people taking MAOIs. Tyramine is found in some cheeses, wines, and pickles. The chemical is also in some medications, including decongestants and over-the-counter cold medicine.

Mixing MAOIs and tyramine can cause a sharp increase in blood pressure, which can lead to stroke. People taking MAOIs should ask their doctors for a complete list of foods, medicines, and other substances to avoid. An MAOI skin patch has recently been developed and may help reduce some of these risks. A doctor can help a person figure out if a patch or a pill will work for him or her.

How should antidepressants be taken?

People taking antidepressants need to follow their doctors' directions. The medication should be taken in the right dose for the right amount of time. It can take three or four weeks until the medicine takes effect. Some people take the medications for a short time, and some people take them for much longer periods. People with long-term or severe depression may need to take medication for a long time.

Once a person is taking antidepressants, it is important not to stop taking them without the help of a doctor. Sometimes people taking antidepressants feel better and stop taking the medication too soon, and the depression may return. When it is time to stop the medication, the doctor will help the person slowly and safely decrease the dose. It's important to give the body time to adjust to the change. People don't get addicted, or "hooked," on the medications, but stopping them abruptly can cause withdrawal symptoms.

If a medication does not work, it is helpful to be open to trying another one. A study funded by NIMH found that if a person with difficult-to-treat depression did not get better with a first medication, chances of getting better increased when the person tried a new one or added a second medication to his or her treatment. The study was called STAR*D (Sequenced Treatment Alternatives to Relieve Depression).[2,3] For more information, visit http://www.nimh.nih.gov/trials/practical/stard/index.shtml.

Are herbal medicines used to treat depression?

The herbal medicine St. John's wort has been used for centuries in many folk and herbal remedies. Today in Europe, it is used widely to treat mild-to-moderate depression. In the United States, it is one of the top-selling botanical products.

The National Institutes of Health conducted a clinical trial to determine the effectiveness of treating adults who have major depression with St. Johns wort. The study included 340 people diagnosed with major depression. One-third of the people took the herbal medicine, one-third took an SSRI, and one-third took a placebo, or "sugar pill." The people did not know what they were taking. The study found that St. John's wort was no more effective than the placebo in treating major depression.[4] A study currently in progress is looking at the effectiveness of St. John's wort for treating mild or minor depression.

Other research has shown that St. John's wort can dangerously interact with other medications, including those used to control HIV. On February

10, 2000, the FDA issued a Public Health Advisory letter stating that the herb appears to interfere with certain medications used to treat heart disease, depression, seizures, certain cancers, and organ transplant rejection. Also, St. Johns wort may interfere with oral contraceptives.

Because St. John's wort may not mix well with other medications, people should always talk with their doctors before taking it or any herbal supplement.

FDA warning on antidepressants

Antidepressants are safe and popular, but some studies have suggested that they may have unintentional effects, especially in young people. In 2004, the FDA looked at published and unpublished data on trials of antidepressants that involved nearly 4,400 children and adolescents. They found that 4 percent of those taking antidepressants thought about or tried suicide (although no suicides occurred), compared to 2 percent of those receiving placebos (sugar pill).

In 2005, the FDA decided to adopt a "black box" warning label—the most serious type of warning—on all antidepressant medications. The warning says there is an increased risk of suicidal thinking or attempts in children and adolescents taking antidepressants. In 2007, the FDA proposed that makers of all antidepressant medications extend the warning to include young adults up through age 24. The warning also says that patients of all ages taking antidepressants should be watched closely, especially during the first few weeks of treatment. Possible side effects to look for are depression that gets worse, suicidal thinking or behavior, or any unusual changes in behavior such as trouble sleeping, agitation, or withdrawal from normal social situations. Families and caregivers should report any changes to the doctor. The latest information from the FDA can be found at http://www.fda.gov.

Results of a comprehensive review of pediatric trials conducted between 1988 and 2006 suggested that the benefits of antidepressant medications likely outweigh their risks to children and adolescents with major depression and anxiety disorders.[5] The study was funded in part by NIMH.

Finally, the FDA has warned that combining the newer SSRI or SNRI antidepressants with one of the commonly-used "triptan" medications used to treat migraine headaches could cause a life-threatening illness called "serotonin syndrome." A person with serotonin syndrome may be agitated, have hallucinations (see or hear things that are not real), have a high temperature, or have unusual blood pressure changes. Serotonin syndrome is usually associated with the older antidepressants called MAOIs, but it can happen with the newer antidepressants as well, if they are mixed with the wrong medications.

What medications are used to treat bipolar disorder?

Bipolar disorder, also called manic-depressive illness, is commonly treated with mood stabilizers. Sometimes, antipsychotics and antidepressants are used along with a mood stabilizer.

Mood stabilizers

People with bipolar disorder usually try mood stabilizers first. In general, people continue treatment with mood stabilizers for years. Lithium is a very effective mood stabilizer. It was the first mood stabilizer approved by the FDA in the 1970's for treating both manic and depressive episodes.

Anticonvulsant medications also are used as mood stabilizers. They were originally developed to treat seizures, but they were found to help control moods as well. One anticonvulsant commonly used as a mood stabilizer is valproic acid, also called divalproex sodium (Depakote). For some people, it may work better than lithium.[6] Other anticonvulsants used as mood stabilizers are carbamazepine (Tegretol), lamotrigine (Lamictal) and oxcarbazepine (Trileptal).

Atypical antipsychotics

Atypical antipsychotic medications are sometimes used to treat symptoms of bipolar disorder. Often, antipsychotics are used along with other medications.

Antipsychotics used to treat people with bipolar disorder include:

- Olanzapine (Zyprexa), which helps people with severe or psychotic depression, which often is accompanied by a break with reality, hallucinations, or delusions[7]
- Aripiprazole (Abilify), which can be taken as a pill or as a shot
- Risperidone (Risperdal)
- Ziprasidone (Geodon)
- Clozapine (Clorazil), which is often used for people who do not respond to lithium or anticonvulsants.[8]

Antidepressants

Antidepressants are sometimes used to treat symptoms of depression in bipolar disorder. Fluoxetine (Prozac), paroxetine (Paxil), or sertraline (Zoloft) are a few that are used. However, people with bipolar disorder should not take an antidepressant on its own. Doing so can cause the person to rapidly switch from depression to mania, which can be dangerous.[9] To prevent this problem, doctors give patients a mood stabilizer or an antipsychotic along with an antidepressant.

Research on whether antidepressants help people with bipolar depression is mixed. An NIMH-funded study found that antidepressants were no more effective than a placebo to help treat depression in people with bipolar disorder. The people were taking mood stabilizers along with

the antidepressants. You can find out more about this study, called STEP-BD (Systematic Treatment Enhancement Program for Bipolar Disorder),[10] at http://www.nimh.nih.gov/trials/practical/step-bd/index.shtml.

What are the side effects?

Treatments for bipolar disorder have improved over the last 10 years. But everyone responds differently to medications. If you have any side effects, tell your doctor right away. He or she may change the dose or prescribe a different medication.

Different medications for treating bipolar disorder may cause different side effects. Some medications used for treating bipolar disorder have been linked to unique and serious symptoms, which are described below.

Lithium can cause several side effects, and some of them may become serious. They include:

- Loss of coordination
- Excessive thirst
- Frequent urination
- Blackouts
- Seizures
- Slurred speech
- Fast, slow, irregular, or pounding heartbeat
- Hallucinations (seeing things or hearing voices that do not exist)
- Changes in vision
- Itching, rash
- Swelling of the eyes, face, lips, tongue, throat, hands, feet, ankles, or lower legs.

If a person with bipolar disorder is being treated with lithium, he or she should visit the doctor regularly to check the levels of lithium in the blood, and make sure the kidneys and the thyroid are working normally.

Some possible side effects linked with valproic acid/divalproex sodium include:

- Changes in weight
- Nausea
- Stomach pain
- Vomiting
- Anorexia
- Loss of appetite.

Valproic acid may cause damage to the liver or pancreas, so people taking it should see their doctors regularly.

Valproic acid may affect young girls and women in unique ways. Sometimes, valproic acid may increase testosterone (a male hormone) levels in teenage girls and lead to a condition called polycystic ovarian syndrome (PCOS).[11,12] PCOS is a disease that can affect fertility and make the menstrual cycle become irregular, but symptoms tend to go away after valproic acid is stopped.[13] It also may cause birth defects in women who are pregnant.

Lamotrigine can cause a rare but serious skin rash that needs to be treated in a hospital. In some cases, this rash can cause permanent disability or be life-threatening.

In addition, valproic acid, lamotrigine, carbamazepine, oxcarbazepine and other anticonvulsant medications (listed in the chart at the end of this document) have an FDA warning. The warning states that their use may increase the risk of suicidal thoughts and behaviors. People taking anticonvulsant medications for bipolar or other illnesses should be closely monitored for new or worsening symptoms of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior. People taking these medications should not make any changes without talking to their health care professional.

Other medications for bipolar disorder may also be linked with rare but serious side effects. Always talk with the doctor or pharmacist about any potential side effects before taking the medication.

For information on side effects of antipsychotics, see the section on medications for treating schizophrenia.

For information on side effects and FDA warnings of antidepressants, see the section on medications for treating depression.

How should medications for bipolar disorder be taken?

Medications should be taken as directed by a doctor. Sometimes a person's treatment plan needs to be changed. When changes in medicine are needed, the doctor will guide the change. **A person should never stop taking a medication without asking a doctor for help.**

There is no cure for bipolar disorder, but treatment works for many people. Treatment works best when it is continuous, rather than on and off. However, mood changes can happen even when there are no breaks in treatment. Patients should be open with their doctors about treatment. Talking about how treatment is working can help it be more effective.

It may be helpful for people or their family members to keep a daily chart of mood symptoms, treatments, sleep patterns, and life events. This chart can help patients and doctors track the illness. Doctors can use the chart to treat the illness most effectively.

Because medications for bipolar disorder can have serious side effects, it is important for anyone taking them to see the doctor regularly to check for possibly dangerous changes in the body.

What medications are used to treat anxiety disorders?

Antidepressants, anti-anxiety medications, and beta-blockers are the most common medications used for anxiety disorders.

Anxiety disorders include:

- Obsessive compulsive disorder (OCD)
- Post-traumatic stress disorder (PTSD)
- Generalized anxiety disorder (GAD)
- Panic disorder
- Social phobia.

Antidepressants

Antidepressants were developed to treat depression, but they also help people with anxiety disorders. SSRIs such as fluoxetine (Prozac), sertraline (Zoloft), escitalopram (Lexapro), paroxetine (Paxil), and citalopram (Celexa) are commonly prescribed for panic disorder, OCD, PTSD, and social phobia. The SNRI venlafaxine (Effexor) is commonly used to treat GAD. The antidepressant bupropion (Wellbutrin) is also sometimes used. When treating anxiety disorders, antidepressants generally are started at low doses and increased over time.

Some tricyclic antidepressants work well for anxiety. For example, imipramine (Tofranil) is prescribed for panic disorder and GAD. Clomipramine (Anafranil) is used to treat OCD. Tricyclics are also started at low doses and increased over time.

MAOIs are also used for anxiety disorders. Doctors sometimes prescribe phenelzine (Nardil), tranylcypromine (Parnate), and isocarboxazid (Marplan). People who take MAOIs must avoid certain food and medicines that can interact with their medicine and cause dangerous increases in blood pressure. For more information, see the section on medications used to treat depression.

Benzodiazepines (anti-anxiety medications)

The anti-anxiety medications called benzodiazepines can start working more quickly than antidepressants. The ones used to treat anxiety disorders include:

- Clonazepam (Klonopin), which is used for social phobia and GAD
- Lorazepam (Ativan), which is used for panic disorder
- Alprazolam (Xanax), which is used for panic disorder and GAD.

Buspirone (Buspar) is an anti-anxiety medication used to treat GAD. Unlike benzodiazepines, however, it takes at least two weeks for buspirone to begin working.

Clonazepam, listed above, is an anticonvulsant medication. See FDA warning on anticonvulsants under the bipolar disorder section.

Beta-blockers

Beta-blockers control some of the physical symptoms of anxiety, such as trembling and sweating. Propranolol (Inderal) is a beta-blocker usually used to treat heart conditions and high blood pressure. The medicine also helps people who have physical problems related to anxiety. For example, when a person with social phobia must face a stressful situation, such as giving a speech, or attending an important meeting, a doctor may prescribe a beta-blocker. Taking the medicine for a short period of time can help the person keep physical symptoms under control.

What are the side effects?

See the section on antidepressants for a discussion on side effects.

The most common side effects for benzodiazepines are drowsiness and dizziness. Other possible side effects include:

- Upset stomach
- Blurred vision
- Headache
- Confusion
- Grogginess
- Nightmares.

Possible side effects from buspirone (BuSpar) include:

- Dizziness
- Headaches
- Nausea
- Nervousness
- Lightheadedness
- Excitement
- Trouble sleeping.

Common side effects from beta-blockers include:

- Fatigue
- Cold hands
- Dizziness
- Weakness.

In addition, beta-blockers generally are not recommended for people with asthma or diabetes because they may worsen symptoms.

How should medications for anxiety disorders be taken?

People can build a tolerance to benzodiazepines if they are taken over a long period of time and may need higher and higher doses to get the same effect. Some people may become dependent on them. To avoid these problems, doctors usually prescribe the medication for short periods, a practice that is especially helpful for people who have substance abuse problems or who become dependent on medication easily. If people suddenly stop taking benzodiazepines, they may get withdrawal symptoms, or their anxiety may return. Therefore, they should be tapered off slowly.

Buspirone and beta-blockers are similar. They are usually taken on a short-term basis for anxiety. Both should be tapered off slowly. Talk to the doctor before stopping any anti-anxiety medication.

What medications are used to treat ADHD?

Attention deficit/hyperactivity disorder (ADHD) occurs in both children and adults. ADHD is commonly treated with stimulants, such as:

- Methylphenidate (Ritalin, Metadate, Concerta, Daytrana)
- Amphetamine (Adderall)
- Dextroamphetamine (Dexedrine, Dextrostat).

In 2002, the FDA approved the nonstimulant medication atomoxetine (Strattera) for use as a treatment for ADHD. In February 2007, the FDA approved the use of the stimulant lisdexamfetamine dimesylate (Vyvanse) for the treatment of ADHD in children ages 6 to 12 years.

What are the side effects?

Most side effects are minor and disappear when dosage levels are lowered. The most common side effects include:

- Decreased appetite. Children seem to be less hungry during the middle of the day, but they are often hungry by dinnertime as the medication wears off.
- Sleep problems. If a child cannot fall asleep, the doctor may prescribe a lower dose. The doctor might also suggest that parents give the medication to their child earlier in the day, or stop the afternoon or evening dose. To help ease sleeping problems, a doctor may add a prescription for a low dose of an antidepressant or a medication called clonidine.
- Stomachaches and headaches.
- **Less common side effects.** A few children develop sudden, repetitive movements or sounds called tics. These tics may or may not be noticeable. Changing the medication dosage may make tics go away. Some children also may appear to have a personality change, such as appearing "flat" or without emotion. Talk with your child's doctor if you see any of these side effects.

How are ADHD medications taken?

Stimulant medications can be short-acting or long-acting, and can be taken in different forms such as a pill, patch, or powder. Long-acting, sustained and extended release forms allow children to take the medication just once a day before school. Parents and doctors should decide together which medication is best for the child and whether the child needs medication only for school hours or for evenings and weekends too.

ADHD medications help many children and adults who are hyperactive and impulsive. They help people focus, work, and learn. Stimulant medication also may improve physical coordination. However, different people respond differently to medications, so children taking ADHD medications should be watched closely.

Are ADHD medications safe?

Stimulant medications are safe when given under a doctor's supervision. Some children taking them may feel slightly different or "funny."

Some parents worry that stimulant medications may lead to drug abuse or dependence, but there is little evidence of this. Research shows that teens with ADHD who took stimulant medications were less likely to abuse drugs than those who did not take stimulant medications.[14]

FDA warning on possible rare side effects

In 2007, the FDA required that all makers of ADHD medications develop Patient Medication Guides. The guides must alert patients to possible heart and psychiatric problems related to ADHD medicine. The FDA required the Patient Medication Guides because a review of data found that ADHD patients with heart conditions had a slightly higher risk of strokes, heart attacks, and sudden death when taking the medications. The review also found a slightly higher risk (about 1 in 1,000) for medication-related psychiatric problems, such as hearing voices, having hallucinations, becoming suspicious for no reason, or becoming manic. This happened to patients who had no history of psychiatric problems.

The FDA recommends that any treatment plan for ADHD include an initial health and family history examination. This exam should look for existing heart and psychiatric problems.

The non-stimulant ADHD medication called atomoxetine (Strattera) carries another warning. Studies show that children and teenagers with ADHD who take atomoxetine are more likely to have suicidal thoughts than children and teenagers with ADHD who do not take atomoxetine. If your child is taking atomoxetine, watch his or her behavior carefully. A child may develop serious symptoms suddenly, so it is important to pay attention to your child's behavior every day. Ask other people who spend a lot of time with your child, such as brothers, sisters, and teachers, to tell you if they notice changes in your child's behavior. Call a doctor right away if your child shows any of the following symptoms:

- Acting more subdued or withdrawn than usual
- Feeling helpless, hopeless, or worthless
- New or worsening depression
- Thinking or talking about hurting himself or herself
- Extreme worry
- Agitation
- Panic attacks
- Trouble sleeping
- Irritability
- Aggressive or violent behavior
- Acting without thinking
- Extreme increase in activity or talking
- Frenzied, abnormal excitement
- Any sudden or unusual changes in behavior.

While taking atomoxetine, your child should see a doctor often, especially at the beginning of treatment. Be sure that your child keeps all appointments with his or her doctor.

Which groups have special needs when taking psychiatric medications?

Psychiatric medications are taken by all types of people, but some groups have special needs, including:

- Children and adolescents
- Older adults
- Women who are pregnant or may become pregnant.

Children and adolescents

Most medications used to treat young people with mental illness are safe and effective. However, many medications have not been studied or approved for use with children. Researchers are not sure how these medications affect a child's growing body. Still, a doctor can give a young person an FDA-approved medication on an "off-label" basis. This means that the doctor prescribes the medication to help the patient even though the medicine is not approved for the specific mental disorder or age.

For these reasons, it is important to watch young people who take these medications. Young people may have different reactions and side effects than adults. Also, some medications, including antidepressants and ADHD medications, carry FDA warnings about potentially dangerous side effects for young people. See the sections on antidepressants and ADHD medications for more information about these warnings.

More research is needed on how these medications affect children and adolescents. NIMH has funded studies on this topic. For example, NIMH funded the Preschoolers with ADHD Treatment Study (PATS), which involved 300 preschoolers (3 to 5 years old) diagnosed with ADHD. The study found that low doses of the stimulant methylphenidate are safe and effective for preschoolers. However, children of this age are more sensitive to the side effects of the medication, including slower growth rates. Children taking methylphenidate should be watched closely.[15,16,17]

In addition to medications, other treatments for young people with mental disorders should be considered. Psychotherapy, family therapy, educational courses, and behavior management techniques can help everyone involved cope with the disorder. For more information on child and adolescent mental health research, visit http://www.nimh.nih.gov/health/topics/child-and-adolescent-mental-health/index.shtml.

Older adults

Because older people often have more medical problems than other groups, they tend to take more medications than younger people, including prescribed, over-the-counter, and herbal medications. As a result, older people have a higher risk for experiencing bad drug interactions, missing doses, or overdosing.

Older people also tend to be more sensitive to medications. Even healthy older people react to medications differently than younger people because their bodies process it more slowly. Therefore, lower or less frequent doses may be needed.

Sometimes memory problems affect older people who take medications for mental disorders. An older adult may forget his or her regular dose and take too much or not enough. A good way to keep track of medicine is to use a seven-day pill

box, which can be bought at any pharmacy. At the beginning of each week, older adults and their caregivers fill the box so that it is easy to remember what medicine to take. Many pharmacies also have pillboxes with sections for medications that must be taken more than once a day.

Women who are pregnant or may become pregnant

The research on the use of psychiatric medications during pregnancy is limited. The risks are different depending on what medication is taken, and at what point during the pregnancy the medication is taken.

Research has shown that antidepressants, especially SSRIs, are safe during pregnancy. Birth defects or other problems are possible, but they are very rare.[18,19]

However, antidepressant medications do cross the placental barrier and may reach the fetus. Some research suggests the use of SSRIs during pregnancy is associated with miscarriage or birth defects, but other studies do not support this.[20] Studies have also found that fetuses exposed to SSRIs during the third trimester may be born with "withdrawal" symptoms such as breathing problems, jitteriness, irritability, trouble feeding, or hypoglycemia (low blood sugar).

Most studies have found that these symptoms in babies are generally mild and short-lived, and no deaths have been reported. On the flip side, women who stop taking their antidepressant medication during pregnancy may get depression again and may put both themselves and their infant at risk.[20,21]

In 2004, the FDA issued a warning against the use of certain antidepressants in the late third trimester. The warning said that doctors may want to gradually taper pregnant women off antidepressants in the third trimester so that the baby is not affected.[22] After a woman delivers, she should consult with her doctor to decide whether to return to a full dose during the period when she is most vulnerable to postpartum depression.

Some medications should not be taken during pregnancy. Benzodiazepines may cause birth defects or other infant problems, especially if taken during the first trimester. Mood stabilizers are known to cause birth defects. Benzodiazepines and lithium have been shown to cause "floppy baby syndrome," which is when a baby is drowsy and limp, and cannot breathe or feed well.

Research suggests that taking antipsychotic medications during pregnancy can lead to birth defects, especially if they are taken during the first trimester. But results vary widely depending on the type of antipsychotic. The conventional antipsychotic haloperidol has been studied more than others, and has been found not to cause birth defects.[23,24]

After the baby is born, women and their doctors should watch for postpartum depression, especially if they stopped taking their medication during pregnancy. In addition, women who nurse while taking psychiatric medications should know that a small amount of the medication passes into the breast milk. However, the medication may or may not affect the baby. It depends on the medication and when it is taken. Women taking psychiatric medications and who intend to breastfeed should discuss the potential risks and benefits with their doctors.

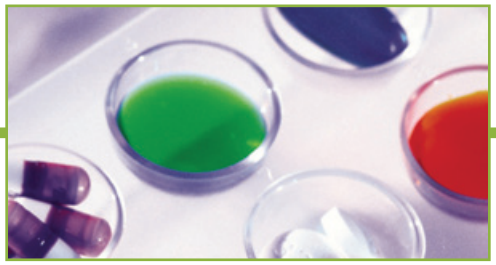
Decisions on medication should be based on each woman's needs and circumstances. Medications should be selected based on available scientific research, and they should be taken at the lowest possible dose. Pregnant women should be watched closely throughout their pregnancy and after delivery.

What should I ask my doctor if I am prescribed a psychiatric medication?

You and your family can help your doctor find the right medications for you. The doctor needs to know your medical history; family history; information about allergies; other medications, supplements or herbal remedies you take; and other details about your overall health. You or a family member should ask the following questions when a medication is prescribed:

- What is the name of the medication?
- What is the medication supposed to do?
- How and when should I take it?
- How much should I take?
- What should I do if I miss a dose?
- When and how should I stop taking it?
- Will it interact with other medications I take?
- Do I need to avoid any types of food or drink while taking the medication? What should I avoid?
- Should it be taken with or without food?
- Is it safe to drink alcohol while taking this medication?
- What are the side effects? What should I do if I experience them?
- Is the Patient Package Insert for the medication available?

After taking the medication for a short time, tell your doctor how you feel, if you are having side effects, and any concerns you have about the medicine.



Alphabetical List of Medications

This section identifies antipsychotic medications, antidepressant medications, mood stabilizers, anticonvulsant medications, anti-anxiety medications, and ADHD medications. Some medications are marketed under trade names, not all of which can be listed in this publication.

The first chart lists the medications by trade name; the second chart lists the medications by generic name. If your medication does not appear in this section, refer to the FDA website (http://www.fda.gov). Also, ask your doctor or pharmacist for more information about any medication.

Medications Organized by Trade Name

Trade Name	Generic Name	FDA Approved Age
Combination Antipsychotic and Antidepressant Medication		
Symbyax (Prozac & Zyprexa)	fluoxetine & olanzapine	18 and older
Antipsychotic Medications		
Abilify	aripiprazole	10 and older for bipolar disorder, manic, or mixed episodes; 13 to 17 for schizophrenia and bipolar
Clozaril	clozapine	18 and older
Fanapt	iloperidone	18 and older
fluphenazine (generic only)	fluphenazine	18 and older
Geodon	ziprasidone	18 and older
Haldol	haloperidol	3 and older
Invega	paliperidone	18 and older
Loxitane	loxapine	18 and older
Moban	molindone	18 and older
Navane	thiothixene	18 and older
Orap (for Tourette's syndrome)	pimozide	12 and older
perphenazine (generic only)	perphenazine	18 and older
Risperdal	risperidone	13 and older for schizophrenia; 10 and older for bipolar mania and mixed episodes; 5 to 16 for irritability associated with autism
Seroquel	quetiapine	13 and older for schizophrenia; 18 and older for bipolar; 10 to 17 for treatment of manic and mixed episodes of bipolar disorder
Stelazine	trifluoperazine	18 and older
thioridazine (generic only)	thioridazine	2 and older
Thorazine	chlorpromazine	18 and older
Zyprexa	olanzapine	18 and older; ages 13 to 17 as second line treatment for manic or mixed episodes of bipolar disorder and schizophrenia

Trade Name	Generic Name	FDA Approved Age
Antidepressant Medications (also used for anxiety disorders)		
Anafranil (tricyclic)	clomipramine	10 and older (for OCD only)
Asendin	amoxapine	18 and older
Aventyl (tricyclic)	nortriptyline	18 and older
Celexa (SSRI)	citalopram	18 and older
Cymbalta (SNRI)	duloxetine	18 and older
Desyrel	trazodone	18 and older
Effexor (SNRI)	venlafaxine	18 and older
Elavil (tricyclic)	amitriptyline	18 and older
Emsam	selegiline	18 and older
Lexapro (SSRI)	escitalopram	18 and older; 12 to 17 (for major depressive disorder)
Ludiomil (tricyclic)	maprotiline	18 and older
Luvox (SSRI)	fluvoxamine	8 and older (for OCD only)
Marplan (MAOI)	isocarboxazid	18 and older
Nardil (MAOI)	phenelzine	18 and older
Norpramin (tricyclic)	desipramine	18 and older
Pamelor (tricyclic)	nortriptyline	18 and older
Parnate (MAOI)	tranylcypromine	18 and older
Paxil (SSRI)	paroxetine	18 and older
Pexeva (SSRI)	paroxetine-mesylate	18 and older
Pristiq (SNRI)	desvenlafaxine	18 and older
Prozac (SSRI)	fluoxetine	8 and older
Remeron	mirtazapine	18 and older
Sarafem (SSRI)	fluoxetine	18 and older for premenstrual dysphoric disorder (PMDD)
Sinequan (tricyclic)	doxepin	12 and older
Surmontil (tricyclic)	trimipramine	18 and older
Tofranil (tricyclic)	imipramine	6 and older (for bedwetting)
Tofranil-PM (tricyclic)	imipramine pamoate	18 and older
Vivactil (tricyclic)	protriptyline	18 and older
Wellbutrin	bupropion	18 and older
Zoloft (SSRI)	sertraline	6 and older (for OCD only)

Trade Name	Generic Name	FDA Approved Age
Mood Stabilizing and Anticonvulsant Medications		
Depakote	divalproex sodium (valproic acid)	2 and older (for seizures)
Eskalith	lithium carbonate	12 and older
Lamictal	lamotrigine	18 and older
lithium citrate (generic only)	lithium citrate	12 and older
Lithobid	lithium carbonate	12 and older
Neurontin	gabapentin	18 and older
Tegretol	carbamazepine	any age (for seizures)
Topamax	topiramate	18 and older
Trileptal	oxcarbazepine	4 and older
Anti-anxiety Medications (All of these anti-anxiety medications are benzodiazepines, except BuSpar)		
Ativan	lorazepam	18 and older
BuSpar	buspirone	18 and older
Klonopin	clonazepam	18 and older
Librium	chlordiazepoxide	18 and older
oxazepam (generic only)	oxazepam	18 and older
Tranxene	clorazepate	18 and older
Valium	diazepam	18 and older
Xanax	alprazolam	18 and older

Trade Name	Generic Name	FDA Approved Age
ADHD Medications (All of these ADHD medications are stimulants, except Intuniv and Straterra.)		
Adderall	amphetamine	3 and older
Adderall XR	amphetamine (extended release)	6 and older
Concerta	methylphenidate (long acting)	6 and older
Daytrana	methylphenidate patch	6 and older
Desoxyn	methamphetamine	6 and older
Dexedrine	dextroamphetamine	3 and older
Dextrostat	dextroamphetamine	3 and older
Focalin	dexmethylphenidate	6 and older
Focalin XR	dexmethylphenidate (extended release)	6 and older
Intuniv	guanfacine	6 and older
Metadate ER	methylphenidate (extended release)	6 and older
Metadate CD	methylphenidate (extended release)	6 and older
Methylin	methylphenidate (oral solution and chewable tablets)	6 and older
Ritalin	methylphenidate	6 and older
Ritalin SR	methylphenidate (extended release)	6 and older
Ritalin LA	methylphenidate (long-acting)	6 and older
Strattera	atomoxetine	6 and older
Vyvanse	lisdexamfetamine dimesylate	6 and older

Medications Organized by Generic Name

Generic Name	Trade Name	FDA Approved Age
Combination Antipsychotic and Antidepressant Medication		
fluoxetine & olanzapine	Symbyax (Prozac & Zyprexa)	18 and older
Antipsychotic Medications		
aripiprazole	Abilify	10 and older for bipolar disorder, manic, or mixed episodes; 13 to 17 for schizophrenia and bipolar
chlorpromazine	Thorazine	18 and older
clozapine	Clozaril	18 and older
fluphenazine (generic only)	fluphenazine	18 and older
haloperidol	Haldol	3 and older
iloperidone	Fanapt	18 and older
loxapine	Loxitane	18 and older
molindone	Moban	18 and older
olanzapine	Zyprexa	18 and older; ages 13 to 17 as second line treatment for manic or mixed episodes of bipolar disorder and schizophrenia
paliperidone	Invega	18 and older
perphenazine (generic only)	perphenazine	18 and older
pimozide (for Tourette's syndrome)	Orap	12 and older
quetiapine	Seroquel	13 and older for schizophrenia; 18 and older for bipolar; 10 to 17 for treatment of manic and mixed episodes of bipolar disorder
risperidone	Risperdal	13 and older for schizophrenia; 10 and older for bipolar mania and mixed episodes; 5 to 16 for irritability associated with autism
thioridazine (generic only)	thioridazine	2 and older
thiothixene	Navane	18 and older
trifluoperazine	Stelazine	18 and older
ziprasidone	Geodon	18 and older

Generic Name	Trade Name	FDA Approved Age
Antidepressant Medications (also used for anxiety disorders)		
amitriptyline (tricyclic)	Elavil	18 and older
amoxapine	Asendin	18 and older
bupropion	Wellbutrin	18 and older
citalopram (SSRI)	Celexa	18 and older
clomipramine (tricyclic)	Anafranil	10 and older (for OCD only)
desipramine (tricyclic)	Norpramin	18 and older
desvenlafaxine (SNRI)	Pristiq	18 and older
doxepin (tricyclic)	Sinequan	12 and older
duloxetine (SNRI)	Cymbalta	18 and older
escitalopram (SSRI)	Lexapro	18 and older; 12 to 17 (for major depressive disorder)
fluoxetine (SSRI)	Prozac	8 and older
fluoxetine (SSRI)	Sarafem	18 and older for premenstrual dysphoric disorder (PMDD)
fluvoxamine (SSRI)	Luvox	8 and older (for OCD only)
imipramine (tricyclic)	Tofranil	6 and older (for bedwetting)
imipramine pamoate (tricyclic)	Tofranil-PM	18 and older
isocarboxazid (MAOI)	Marplan	18 and older
maprotiline (tricyclic)	Ludiomil	18 and older
mirtazapine	Remeron	18 and older
nortriptyline (tricyclic)	Aventyl, Pamelor	18 and older
paroxetine (SSRI)	Paxil	18 and older
paroxetine mesylate (SSRI)	Pexeva	18 and older
phenelzine (MAOI)	Nardil	18 and older
protriptyline (tricyclic)	Vivactil	18 and older
selegiline	Emsam	18 and older
sertraline (SSRI)	Zoloft	6 and older (for OCD only)
tranylcypromine (MAOI)	Parnate	18 and older
trazodone	Desyrel	18 and older
trimipramine (tricyclic)	Surmontil	18 and older
venlafaxine (SNRI)	Effexor	18 and older

Generic Name	Trade Name	FDA Approved Age
Mood Stabilizing and Anticonvulsant Medications		
carbamazepine	Tegretol	any age (for seizures)
divalproex sodium (valproic acid)	Depakote	2 and older (for seizures)
gabapentin	Neurontin	18 and older
lamotrigine	Lamictal	18 and older
lithium carbonate	Eskalith, Lithobid	12 and older
lithium citrate (generic only)	lithium citrate	12 and older
oxcarbazepine	Trileptal	4 and older
topiramate	Topamax	18 and older
Anti-anxiety Medications (All of these anti-anxiety medications are benzodiazepines, except buspirone.)		
alprazolam	Xanax	18 and older
buspirone	BuSpar	18 and older
chlordiazepoxide	Librium	18 and older
clonazepam	Klonopin	18 and older
clorazepate	Tranxene	18 and older
diazepam	Valium	18 and older
lorazepam	Ativan	18 and older
oxazepam (generic only)	oxazepam	18 and older

Generic Name	Trade Name	FDA Approved Age
ADHD Medications (All of these ADHD medications are stimulants, except atomoxetine and guanfacine.)		
amphetamine	Adderall	3 and older
amphetamine (extended release)	Adderall XR	6 and older
atomoxetine	Strattera	6 and older
dexmethylphenidate	Focalin	6 and older
dexmethylphenidate (extended release)	Focalin XR	6 and older
dextroamphetamine	Dexedrine, Dextrostat	3 and older
guanfacine	Intuniv	6 and older
lisdexamfetamine dimesylate	Vyvanse	6 and older
methamphetamine	Desoxyn	6 and older
methylphenidate	Ritalin	6 and older
methylphenidate (extended release)	Metadate CD, Metadate ER, Ritalin SR	6 and older
methylphenidate (long-acting)	Ritalin LA, Concerta	6 and older
methylphenidate patch	Daytrana	6 and older
methylphenidate (oral solution and chewable tablets)	Methylin	6 and older

Citations

1. Lieberman JA, Stroup TS, McEvoy JP, Swartz MS, Rosenheck RA, Perkins DO, Keefe RS, Davis SM, Davis CE, Lebowitz BD, Severe J, Hsiao JK; Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE). Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. *New England Journal of Medicine*. 2005 Sep 22;353(12):1209-1223.

2. Rush JA, Trivedi MH, Wisniewski SR, Stewart JW, Nierenberg AA, Thase ME, Ritz L, Biggs MM, Warden D, Luther JF, Shores-Wilson K, Niederehe G, Fava M. Bupropion-SR, sertraline, or venlafaxine-XR after failure of SSRIs for depression. *New England Journal of Medicine*. 2006 Mar 23; 354(12):1231-1242.

3. Trivedi MH, Fava M, Wisniewski SR, Thase ME, Quitkin F, Warden D, Ritz L, Nierenberg AA, Lebowitz BD, Biggs MM, Luther JF, Shores-Wilson K, Rush JA. Medication augmentation after the failure of SSRIs for depression. *New England Journal of Medicine*. 2006 Mar 23; 354(12): 1243-1252.

4. Hypericum Depression Trial Study Group. Effect of Hypericum perforatum (St. John's wort) in major depressive disorder: a randomized controlled trial. *Journal of the American Medical Association*. 2002; 287(14): 1807-1814.

5. Bridge JA, Iyengar S, Salary CB, Barbe RP, Birmaher B, Pincus HA, Ren L, Brent DA. Clinical response and risk for reported suicidal ideation and suicide attempts in pediatric antidepressant treatment, a meta-analysis of randomized controlled trials. *Journal of the American Medical Association*. 2007; 297(15): 1683-1696.

6. Bowden CL, Calabrese JR, McElroy SL, Gyulai L, Wassef A, Petty F, Pope HG, Jr., Chou JC, Keck PE, Jr., Rhodes LJ, Swann AC, Hirschfeld RM, Wozniak PJ, Group DMS. A randomized, placebo-controlled 12-month trial of divalproex and lithium in treatment of outpatients with bipolar I disorder. *Archives of General Psychiatry*. 2000 May; 57(5):481-489.

7. Rothschild AJ, Bates KS, Boehringer KL, Syed A. Olanzapine response in psychotic depression. *Journal of Clinical Psychiatry*. 1999 Feb; 60(2):116-118.

8. Suppes T, Webb A, Paul B, Carmody T, Kraemer H, Rush AJ. Clinical outcome in a randomized 1-year trial of clozapine versus treatment as usual for patients with treatment-resistant illness and a history of mania. *American Journal of Psychiatry*. 1999 Aug;156(8): 1164-1169.

9. Thase ME, Sachs GS. Bipolar depression: pharmacotherapy and related therapeutic strategies. *Biological Psychiatry*. 2000 Sep 15;48(6):558-572.

10. Sachs G, Nierenberg AA, Calabrese JR, Marangell LB, Wisniewski SR, Gyulai L, Friedman ES, Bowden CL, Fossey MD, Ostacher MJ, Ketter TA, Patel J, Hauser P, Rapport D, Martinez JM, Allen MH, Miklowitz DJ, Otto MW, Dennehy EB, Thase ME. Effectiveness of adjunctive antidepressant treatment for bipolar depression: a double-blind placebo-controlled study. *New England Journal of Medicine*. Epub 28 Mar 2007; 356(17): 1771-1773.

11. Vainionpaa LK, Rattya J, Knip M, Tapanainen JS, Pakarinen AJ, Lanning P, Tekay A, Myllyla VV, Isojarvi JI. Valproate-induced hyperandrogenism during pubertal maturation in girls with epilepsy. *Annals of Neurology*. 1999 Apr;45(4):444-450.

12. Joffe H, Cohen LS, Suppes T, McLaughlin WL, Lavori P, Adams JM, Hwang CH, Hall JE, Sachs GS. Valproate is associated with new-onset oligoamenorrhea with hyperandrogenism in women with bipolar disorder. *Biological Psychiatry*. 2006 Jun 1;59(11):1078-1086.

13. Joffe H, Cohen LS, Suppes T, Hwang CH, Molay F, Adams JM, Sachs GS, Hall JE. Longitudinal follow-up of reproductive and metabolic features of valproate-associated polycystic ovarian syndrome features: A preliminary report. *Biological Psychiatry*. 2006 Dec 15;60(12):1378-1381.

14. Wilens TC, Faraone, SV, Biederman J, Gunawardene S. Does stimulant therapy of attention-deficit/hyperactivity disorder beget later substance abuse? A meta-analytic review of the literature. *Pediatrics*. 2003; 111(1):179-185.

15. Swanson J, Greenhill L, Wigal T, Kollins S, Stehli A, Davies M, Chuang S, Vitiello B, Skroballa A, Posner K, Abikoff H, Oatis M, McCracken J, McGough J, Riddle M, Ghouman J, Cunningham C, Wigal S. Stimulant-related reductions in growth rates in the PATS. *Journal of the Academy of Child and Adolescent Psychiatry*. 2006 Nov; 45(11): 1304-1313.

16. Greenhill L, Kollins S, Abikoff H, McCracken J, Riddle M, Swanson J, McGough J, Wigal S, Wigal T, Vitiello B, Skroballa A, Posner K, Ghuman J, Cunningham C, Davies M, Chuang S, Cooper T. Efficacy and safety of immediate-release methylphenidate treatment for preschoolers with attention-deficit/hyperactivity disorder. *Journal of the Academy of Child and Adolescent Psychiatry*. 2006 Nov; 45(11):1284-1293.

17. Wigal T, Greenhill L, Chuang S, McGough J, Vitiello B, Skrobala A, Swanson J, Wigal S, Abikoff H, Kollins S, McCracken J, Riddle M, Posner K, Ghuman J, Davies M, Thorp B, Stehli A. Safety and tolerability of methylphenidate in preschool children with attention-deficit/hyperactivity disorder. *Journal of the Academy of Child and Adolescent Psychiatry*. 2006 Nov; 45(11): 1294-1303.

18. Alwan S, Reefhuis J, Rasmussen S, Olney R, Friedman J for the National Birth Defects Prevention Study. Use of selective serotonin-reuptake inhibitors in pregnancy and the risk of birth defects. *New England Journal of Medicine*. 2007 Jun 28; 356(26):2684-2692.

19. Louik C, Lin An, Werler M, Hernandez S, Mitchell A. First-trimester use of selective serotonin-reuptake inhibitors and the risk of birth defects. *New England Journal of Medicine*. 2007 Jun 28; 356(26):2675-2683.

20. Austin M. To treat or not to treat: maternal depression, SSRI use in pregnancy and adverse neonatal effects. *Psychological Medicine*. 2006 Jul 25; 1-8.

21. Cohen L, Altshuler L, Harlow B, Nonacs R, Newport DJ, Viguera A, Suri R, Burt V, Hendrick AM, Loughead A, Vitonis AF, Stowe Z. Relapse of major depression during pregnancy in women who maintain or discontinue antidepressant treatment. *Journal of the American Medical Association*. 2006 Feb 1; 295(5): 499-507.

22. U.S. Food and Drug Administration (FDA). FDA Medwatch drug alert on Effexor and SSRIs, 2004 Jun 3. Available at www.fda.gov/medwatch/safety/2004/safety04.htm#effexor.

23. Jain AE, Lacy T. Psychotropic drugs in pregnancy and lactation. *Journal of Psychiatric Practice*. 2005 May; 11(3): 177-191.

24. Ward RK, Zamorski MA. Benefits and risks of psychiatric medications during pregnancy. *American Family Physician*. 15 Aug. 2002; 66(4): 629-636.

For More Information on Medications:

Visit the National Library of Medicine's MedlinePlus
http://www.nlm.nih.gov/medlineplus

En Español
http://medlineplus.gov/spanish

For information on Clinical Trials
http://www.nimh.nih.gov/trials/index.shtml

National Library of Medicine Clinical Trials Database
http://www.clinicaltrials.gov

Information from NIMH is available in multiple formats. You can browse online, download documents in PDF, and order paper brochures through the mail. If you would like to have NIMH publications, you can order them online at http://www.nimh.nih.gov. If you do not have Internet access and wish to have information that supplements this publication, please contact the NIMH Information Resource Center at the numbers listed below.

National Institute of Mental Health
Science Writing, Press & Dissemination Branch
6001 Executive Boulevard
Room 8184, MSC 9663
Bethesda, MD 20892-9663
Phone: 301-443-4513 or
1-866-615-NIMH (6464) toll-free
TTY: 301-443-8431 or
866-415-8051 toll-free
FAX: 301-443-4279
E-mail: **nimhinfo@nih.gov**
Website: **http://www.nimh.nih.gov**

Reprints

NIMH publications are in the public domain and may be reproduced or copied without the permission from the National Institute of Mental Health. NIMH encourages you to reproduce them and use them in your efforts to improve public health. Citation of the National Institute of Mental Health as a source is appreciated. However, using government materials inappropriately can raise legal or ethical concerns, so we ask you to use these guidelines:

- NIMH does not endorse or recommend any commercial products, processes, or services, and publications may not be used for advertising or endorsement purposes.
- NIMH does not provide specific medical advice or treatment recommendations or referrals; these materials may not be used in a manner that has the appearance of such information.
- NIMH requests that non-Federal organizations not alter publications in a way that will jeopardize the integrity and "brand" when using publications.
- Addition of non-Federal Government logos and Web site links may not have the appearance of NIMH endorsement of any specific commercial products or services or medical treatments or services.
- Images used in publications are of models and are used for illustrative purposes only. Use of some images is restricted.

If you have questions regarding these guidelines and use of NIMH publications, please contact the NIMH Information Resource Center at 1-866-615-6464 or e-mail **nimhinfo@nih.gov**.

NIMH
National Institute
of Mental Health

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
NIH Publication No. 12–3929
Revised 2010
Reprinted 2012

THE UNIVERSITY OF IOWA

IOWA GERIATRIC EDUCATION CENTER

INFO-CONNECT

Family Involvement in Care

For Persons with Dementia in Long-Term Care Facilities

The Facts . . .

⇒ 50 to 70 percent of persons living in nursing homes have dementia.

⇒ Although family members seek assistance for care of their relatives, they maintain an interest in quality of caregiving.

⇒ Long-term care staff as well as families report many difficulties sharing the caregiving role.

Family Involvement in Care Intervention

The Family Involvement in Care (FIC) intervention refers to a strategy that partners family caregiver(s) and long-term care facility staff to provide the best possible care for a person with dementia.

One key to the FIC intervention is for both parties to continually negotiate and clarify their expectations to establish mutually satisfactory roles and relationships.

Another key is for staff to help family members choose the type and frequency of activities in which they want to participate.

Benefits of FIC Intervention

Benefits can be seen from the FIC intervention for family and staff, as well as for persons with dementia.

For Family and Staff

- Improved staff attitudes about families
- Decreased family caregiver guilt and burden
- Improved communication between family and staff

For Persons with Dementia

- Improved quality of interaction with families
- Increased therapeutic and diversional activities
- Increased preservation of individual identity

Risk Factors in Care Relationships

Both the person with dementia and the family caregiver(s) are at risk for unsatisfactory relationships and care. Families may experience conflict with staff over competing priorities. Without family involvement in care, long-term care facility staff may unintentionally neglect aspects of caregiving that are important to both the family and the resident.

Situations that put the person with dementia or their families at risk include:

- Family caregiver's assumption of a new role once staff becomes the primary caregiver
- Change in the type of care services or resources available
- Change from care in a familiar environment to care in an unfamiliar institution
- Change in care providers
- Deteriorating mental or physical capacity of the person with dementia
- Deteriorating physical or mental capacity of the family caregiver(s)
- Traditional expectations of staff that families are visitors and, therefore, minimally involved in caregiving
- Institutional barriers (e.g. lack of staffing, policy, procedures, or environmental structures)
- Resident and family's negative feelings about the new care environment

Information to Share

For families and staff to form successful family involvement in care partnerships, the following information should be shared about the person with dementia, the family caregivers, and the formal care provider.

Person with Dementia

- Date of admission to new care situation
- Cognitive function status
- Usual behaviors and activities
- Basic and instrumental activities of daily living
- Medical and nursing diagnoses
- Plan of care

Family Caregivers

- Date of admission to new care situation
- Reason for change in care situation
- Filial relationship of family member to person with dementia
- Primary caregiver at home
- Employment status
- Degree of family support
- Other social support
- Other family roles/obligations
- Feelings about new care situation
- Frequency of caregiving
- Care provided
- Ability to provide care (physical/emotional)
- Problems encountered in providing care
- Expectations for continuing participation in caregiving
- Expected frequency of contact
- Major concerns about new care situation

Formal Care Provider

- Type of setting
- Plan of care for person with dementia
- Philosophy of care of persons with dementia
- Policies regarding visitation
- Policies regarding family participation in caregiving
- Presence of family support group
- Attitudes about family participation in caregiving
- Expectations of staff for family participation in caregiving
- Staff knowledge about dementia and care of persons with dementia

For Additional Information about the FIC Intervention

Maas, M. *et. al*. (1994, November/December). "The caring partnership: Staff and families of persons institutionalized with Alzheimer's disease." *The American Journal of Alzheimer's Care and Related Disorders & Research*, 21-30.

Kelley, L., Specht, J., & Maas, M. (1999). "Research-Based protocol: Family involvement in care for persons with dementia." In M. Titler (Series Ed.) *Series on Evidence-Based Practice for Older Adults.* Iowa City, IA: The University of Iowa College of Nursing Gerontological Nursing Interventions Research Center, Research Dissemination Core.

Specht, J., Kelley, L., *et al*. (2000). "Who's the boss? Family/staff partnership in care of persons with dementia." *Nursing Administration Quarterly, 24*(3), 64-77.

Kelley, L., Specht, J., & Maas, M. (2000, February). "Family involvement in care for individuals with dementia protocol." *Journal of Gerontological Nursing*, 13-21.

A Service of:

Iowa Geriatric Research Center

University of Iowa

2153 Westlawn

Iowa City, IA 52242

(319) 353-5756

Grant funded by the Department of Health Resources and Services Administration (HRSA)

Visit us at:

http://www.medicine.uiowa.edu/igec

Content provided by:

Janet Specht, PhD, RN
Associate Professor, College of Nursing
University of Iowa

Meridean Maas, PhD, RN, FAAN
Professor and Chair, Adult and Gerontology Area
Director of Doctoral Studies
College of Nursing
University of Iowa

Lisa Skemp Kelley, MA, RN
Doctoral Candidate, College of Nursing
University of Iowa

(Work funded by grant NR01 NR01689-03A2
M. Maas, PhD, RN, FAAN Principal Investigator;
E. Swanson, PhD., RN Co-Principal Investigator; and
D. Reed, PhD, Project Director.)

Editorial review by:

Margo Schilling, MD
Assistant Professor of Clinical Medicine
Division of General Internal Medicine
University of Iowa

Implementing the *FIC* Intervention

The FIC intervention is accomplished by establishing and implementing a Partnership Agreement which consists of four key phases:

- Orientation of family and staff;
- Education of all care providers;
- Negotiation and formation of the Partnership Agreement; and
- Ongoing evaluation and renegotiation of the Partnership Agreement.

Orientation

The purpose of the orientation phase is to establish a foundation of the FIC intervention. There are three important steps in this phase:

- A formal care provider who will act as nurse care manager (NCM) is identified.
- The NCM visits with family to identify primary family caregiver(s).
- The family caregiver(s) is taken on a tour of the care environment, reviewing philosophies and policies and discussing expectations and concerns.

Education

The purpose of the education phase is to educate family and staff regarding general principles of caregiving as well as the more specific principles associated with caring for someone with dementia. The following are suggested components of this education:

- Communication and visitation strategies
- Role adjustments required for family members and staff
- Therapeutic approaches to facilitate quality of care in a new care situation
- Negotiation and partnership information
- Negotiation skills for formation, maintenance and termination of partnership
- Role playing to practice negotiation and partnership agreement

Negotiation and Formation

Family members and staff review, discuss, agree upon, and document the goals and approaches for care of the person with dementia.

The negotiated Partnership Agreement specifically documents the plan for both family member and staff care provider involvement, as well as the frequency and anticipated length of time for each of the activities.

Ongoing Evaluation and Renegotiation

The care setting influences the frequency of evaluation and renegotiation. For example, in the nursing home setting, this is achieved by discussions between the NCM and the family member at least each week. If the family member does not initiate this weekly contact, the NCM contacts the family by phone.

A quarterly care conference is an ideal time to formally evaluate family, resident, and staff satisfaction with the FIC intervention. Although the length of time for these conferences is often brief, frequent communications provide a critical time for the NCM to solicit feedback and suggestions from family and staff.

EXAMPLES OF PARTNERSHIP ACTIVITIES

⇒ Family member constructs a photo life story book or room bulletin board.

- Photo life story book can be used during visits.
- Family member shares life story book with new staff.
- Staff uses life story book to reminisce with the resident on days when the family does not visit.

⇒ Family member supplies staff with information about the person's life experiences, personality, and accomplishments.

- Family member prepares a tape for all staff to listen to.
- Family member participates in resident care conferences.

⇒ Family member assists in physical care (e.g. bathing, exercise, and grooming).

- Wife assists with bathing on Monday and Thursday evenings.
- Daughter feeds father lunch on Monday, Wednesday and Fridays.
- Son trims mother's fingernails every other week.
- Daughter-in-law monitors physical care by observing cleanliness of resident and reporting any problems to a designated person.

FAMILY AND STAFF PARTNERSHIP ACTIVITIES AGREEMENT

Staff and family have agreed that they are partners in planning, providing, and evaluating care for

_____ (Resident)

Family member(s) will do the following activities (Please include frequency and amount of time for each activity):

_____

_____

_____

_____

Staff will do the following activities (Please include frequency and amount of time for each activity):

_____

_____

_____

_____

Comments and Explanations:

Family Member(s) Signature(s)

_____

_____

Facility Staff Signatures

_____

_____

ANTIDEPRESSANT MEDICATIONS

MEDICATION INFORMATION

Depression is commonly treated with antidepressant medications. Antidepressants work to balance some of the natural chemicals in our brains. These chemicals are called neurotransmitters, and they affect our mood and emotional responses. Antidepressants work on neurotransmitters such as serotonin, norepinephrine, and dopamine.

The most popular types of antidepressants are called selective serotonin reuptake inhibitors (SSRIs). These include:

- Fluoxetine (Prozac)
- Citalopram (Celexa)
- Sertraline (Zoloft)
- Paroxetine (Paxil)
- Escitalopram (Lexapro)

Other types of antidepressants are serotonin and norepinephrine reuptake inhibitors (SNRIs). SNRIs are similar to SSRIs and include venlafaxine (Effexor) and duloxetine (Cymbalta). Another antidepressant that is commonly used is bupropion (Wellbutrin). Bupropion, which works on the neurotransmitter dopamine, is unique in that it does not fit into any specific drug type.

SSRIs and SNRIs are popular because they do not cause as many side effects as older classes of antidepressants. Older antidepressant medications include tricyclics, tetracyclics, and monoamine oxidase inhibitors (MAOIs). For some people, tricyclics, tetracyclics, or MAOIs may be the best medications.

HOW SHOULD ANTIDEPRESSANTS BE TAKEN

People taking antidepressants need to follow their doctors' directions. The medication should be taken in the right dose for the right amount of time. It can take three or four weeks until the medicine takes effect. Some people take the medications for a short time, and some people take them for much longer periods. People with long-term or severe depression may need to take medication for a long time.

Once a person is taking antidepressants, it is important not to stop taking them without the help of a doctor. Sometimes people taking antidepressants feel better and stop taking the medication too soon, and the depression may return. When it is time to stop the medication, the doctor will help the person slowly and safely decrease the dose. It's important to give the body time to adjust to the change. People don't get addicted, or "hooked," on the medications, but stopping them abruptly can cause withdrawal symptoms.

Source of Information: http://www.nimh.nih.gov/health/publications/mental-health-medications/nimh-mental-health-medications.pdf

IF YOU HAVE ANY QUESTIONS REGARDING YTHIS INFORMATION OR THE RESIDENT'S PLAN OF CARE, PLEASE CONTACT: **MIRA JENSEN, MSN RN NP**

ENSIGN FACILITY SERVICES
(949) 487- 9500

WHAT ARE THE SIDE EFFECTS?

Antidepressants may cause mild side effects that usually do not last long. **Any unusual reactions or side effects should be reported to a doctor immediately.**

The most common side effects associated with SSRIs and SNRIs include:

- Headache, which usually goes away within a few days
- Nausea (feeling sick to your stomach), which usually goes away within a few days
- Sleeplessness or drowsiness, which may happen during the first few weeks but then goes away Sometimes the medication dose needs to be reduced or the time of day it is taken needs to be adjusted to help lessen these side effects
- Agitation (feeling jittery)
- Sexual problems, which can affect both men and women and may include reduced sex drive, and problems having and enjoying sex

Tricyclic antidepressants can cause side effects, including:

- Dry mouth
- Constipation
- Bladder problems. It may be hard to empty the bladder, or the urine stream may not be as strong as usual. Older men with enlarged prostate conditions may be more affected.
- Sexual problems, which can affect both men and women and may include reduced sex drive, and problems having and enjoying sex
- Blurred vision, which usually goes away quickly
- Drowsiness Usually, antidepressants that make you drowsy are taken at bedtime

People taking MAOIs need to be careful about the foods they eat and the medicines they take. Foods and medicines that contain high levels of a chemical called tyramine are dangerous for people taking MAOIs. Tyramine is found in some cheeses, wines, and pickles. The chemical is also in some medications, including decongestants and over-the-counter cold medicine.

Mixing MAOIs and tyramine can cause a sharp increase in blood pressure, which can lead to stroke. People taking MAOIs should ask their doctors for a complete list of foods, medicines, and other substances to avoid. An MAOI skin patch has recently been developed and may help reduce some of these risks. A doctor can help a person figure out if a patch or a pill will work for him or her.

FDA Warning on Antidepressants

Antidepressants are safe and popular, but some studies have suggested that they may have unintentional effects, especially in young people. In 2004, the FDA looked at published and unpublished data on trials of antidepressants that involved nearly 4,400 children and adolescents. They found that 4 percent of those taking antidepressants thought about or tried suicide (although no suicides occurred), compared to 2 percent of those receiving placebos (sugar pill).

In 2005, the FDA decided to adopt a "black box" warning label—the most serious type of warning—on all antidepressant medications. The warning says there is an increased risk of suicidal thinking or attempts in children and adolescents taking antidepressants. In 2007, the FDA proposed that makers of all antidepressant medications extend the warning to include young adults up through age 24.

The warning also says that patients of all ages taking antidepressants should be watched closely, especially during the first few weeks of treatment Possible side effects to look for are depression that gets worse, suicidal thinking or behavior, or any unusual changes in behavior such as trouble sleeping, agitation, or withdrawal from normal social situations Families and caregivers should report any changes to the doctor The latest information from the FDA can be found at http://www fda gov.

ANTIPSYCHOTIC MEDICATIONS

MEDICATION INFORMATION

WHAT ARE THE SIDE EFFECTS?

Some people have side effects when they start taking these medications. Most side effects go away after a few days and often can be managed successfully. People who are taking antipsychotics should not drive until they adjust to their new medication. Side effects of many antipsychotics include:

- Drowsiness
- Dizziness when changing positions
- Blurred vision
- Rapid heartbeat
- Sensitivity to the sun
- Skin rashes
- Menstrual problems for women

Atypical antipsychotic medications can cause major weight gain and changes in a person's metabolism. This may increase a person's risk of getting diabetes and high cholesterol. A person's weight, glucose levels, and lipid levels should be monitored regularly by a doctor while taking an atypical antipsychotic medication.

Typical antipsychotic medications can cause side effects related to physical movement, such as:

- Rigidity
- Persistent muscle spasms
- Tremors
- Restlessness

Note: The FDA issued a Public Health Advisory for atypical antipsychotic medications The FDA determined that death rates are higher for elderly people with dementia when taking this medication A review of data has found a risk with conventional antipsychotics as well Antipsychotic medications are not FDA-approved for the treatment of behavioral disorders in patients with dementia.

Long-term use of typical antipsychotic medications may lead to a condition called **tardive dyskinesia** (TD).

TD causes muscle movements a person can't control. The movements commonly happen around the mouth. TD can range from mild to severe, and in some people the problem cannot be cured. Sometimes people with TD recover partially or fully after they stop taking the medication.

Every year, an estimated 5 percent of people taking typical antipsychotics get TD. The condition happens to fewer people who take the new, atypical antipsychotics, but some people may still get TD. People who think that they might have TD should check with their doctor before stopping their medication.

Antipsychotic medications have been available since the mid- 1950's. The older types are called conventional or "typical" antipsychotics. Some of the more commonly used typical medications include:

- **Chlorpromazine (Thorazine)**
- **Haloperidol (Haldol)**
- **Perphenazine (Etrafon, Trilafon)**
- **Fluphenazine (Prolixin)**

In the 1990's, new antipsychotic medications were developed. These new medications are called second generation, or "atypical" antipsychotics. Examples include:

- **Aripiprazole (Abilify)**
- **Asenapine Maleate (Saphris)**
- **Clozapine (Clozaril)**
- **Iloperidone (Fanapt)**
- **Lurasidone (Latuda)**
- **Olanzapine (Zyprexa)**
- **Olanzapine/Fluoxetine (Symbyax)**
- **Paliperidone (Invega)**
- **Quetiapine (Seroquel)**
- **Risperidone (Risperdal)**
- **Ziprasidone (Geodon)**

HOW ARE ANTIPSYCHOTICS TAKEN AND HOW DO PEOPLE RESPOND TO THEM?

Antipsychotics are usually pills that people swallow, or liquid they can drink. Some antipsychotics are shots that are given once or twice a month.

Symptoms of schizophrenia, such as feeling agitated and having hallucinations, usually go away within days. Symptoms like delusions usually go away within a few weeks. After about six weeks, many people will see a lot of improvement.

However, people respond in different ways to antipsychotic medications, and no one can tell beforehand how a person will respond. Sometimes a person needs to try several medications before finding the right one. Doctors and patients can work together to find the best medication or medication combination, and dose.

Some people may have a relapse—their symptoms come back or get worse. Usually, relapses happen when people stop taking their medication, or when they only take it sometimes. Some people stop taking the medication because they feel better or they may feel they don't need it anymore. **But no one should stop taking an antipsychotic medication without talking to his or her doctor.** When a doctor says it is okay to stop taking a medication, it should be gradually tapered off, never stopped suddenly.

Source of Information:

http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm094303.htm

http://www.nimh.nih.gov/health/publications/mental-health-medications/nimh-mental-health-medications.pdf

If you have any questions regarding this information or the resident's plan of care, please contact:

Mira Jensen, MSN RN NP
Director of Clinical Services
Ensign Facility Services
(949) 487- 9500
mjensen@ensigngroup.net

FAST FACTS: What You Need to Know About Antipsychotic Drugs for Persons Living with Dementia

The AHCA/NCAL Quality Initiative

What is an antipsychotic drug?

An antipsychotic (an-tie-sy-COT-ick) drug is a medicine that works in the brain, which may help to block certain chemicals that can cause symptoms of psychosis, such as hallucinations or delusions.

- Hallucinations are when a person sees or hears things that are not there.
- Delusions are when a person believes something that isn't true, even after being told.

Some people with some mental illnesses like schizophrenia and bipolar disorder often have these symptoms.

What are common antipsychotics?

- Haldol
- Quetiapine (Seroquel)
- Olanzapine (Zyprexa)
- Aripiprazole (Abilify)
- Risperidone (Risperdal)

Why are these drugs used in people with Dementia?

These drugs can help for some people with dementia who do have psychosis. However, most of the time these drugs are used when a person acts in way that is challenging or disturbing to others, such as

- hitting, yelling, screaming
- refusing care, walking around
- crying, banging, throwing things

Some people think that these drugs may help with these behaviors however; studies show that many of these behaviors in people with dementia are normal reactions to something they find scary, upsetting or uncomfortable. Or, their actions may also be telling us that they need something such as:

- food because they are hungry,
- water or juice to drink because they are thirsty,
- to take a nap because they are tired,
- to go to the bathroom, or
- something to do because they are bored.

In these cases, drugs will not help.

Do these drugs work in people with dementia?

For people with dementia who have hallucinations or delusions, these drugs can help. However, most people with dementia don't have hallucinations or delusions. For many people, these drugs slow them down, making them drowsy or groggy. These drugs don't get to the heart of the reason for the person's actions. Scientific studies show that for only a small number of people with dementia these drugs will help a little bit. Overall, most people do not get better. Of those who get better, it is those with psychosis and hallucination.

What can these drugs NOT do?

These drugs do not help:

- Stop yelling or repeating questions over and over;
- Calm being restless, fidgety or uneasy,
- Stop memory problems;
- Persons do more for themselves;
- Persons interact better with others; or
- Stop inappropriate things being said.

Why am I hearing so much about them?

Recent scientific studies from both universities and government agencies have found:

1. That these drugs are often used too much in people with dementia
2. That these drugs do not work as well as people first believed in people with dementia.

What are the risks?

People with dementia who are given these drugs are more likely to:

- be unsteady when they walk
- fall
- break their bones
- have incontinence ("pee in their pants")
- have a stroke
- die sooner

Because of these dangers, the US Food and Drug Administration (FDA) requires a warning on the label of all antipsychotic drugs. Such "black box" warnings are only required for drugs with serious risks. The warning includes the following:

Warning: Increased Mortality in Elderly Patients with Dementia-Related Psychosis. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. [Name of Antipsychotic] is not approved for the treatment of patients with dementia-related psychosis

Is it safe to stop these drugs?

Studies in nursing homes show that it is very safe to try stopping these drugs in people who:

- are taking a low dose;
- did not have any actions recently; or
- did not have hallucinations before starting the drugs.

In studies of people already on an antipsychotic drug that was then replaced with a fake pill, doctors and nurses could not tell the difference between who stopped the drug and who took the drug. This shows that stopping these drugs is safe.

Many experts suggest trying a lower dose or stopping these drugs because

- in nursing homes, staff watch to see if there is a reason to keep using these drugs;
- many of the actions these drugs are used for are about unmet needs and cannot be fixed by drugs; and
- about one out of three people will still act in challenging ways, whether the drug is continued or not.

Why do people with dementia behave in ways that can be challenging?

They may have a need they cannot express or be in a situation they don't understand. For example, when it's time to get undressed for bed or a bath, some people with dementia may hit or try to stop their care giver. This can be because they don't understand why someone is taking off their clothes. A person with dementia can't always tell us how they feel. They may get upset when they need to go to the bathroom. They may get angry when they are tired or hungry. Skilled care givers do their best to predict the needs of people with dementia. Sometimes, they can take steps to meet those needs and keep the person from getting upset. Skilled care givers look at what is going on physically, emotionally, and environmentally that might be causing the person to react.

- Are they cold, hungry, tired, thirsty, or in pain?
- Are they bored; scared, stressed out, upset by too much noise or another person's actions?
- Are they missing their family or friends?
- Do they find a task they are trying to do, like dressing or bathing, too hard?

These kinds of things can all upset a person. However, drugs do not help with these kinds of needs.

What should I do?

If your loved one is already taking these drugs, ask:

- What type of drug is my loved one on?
- What caused the drug to be prescribed?
- How has the care team tried to help solve the problem without drugs?
- What is the plan to decrease or stop the drug?

If your loved one is not currently on an antipsychotic, BEFORE any are prescribed, ask:

- What is causing the drug to be prescribed?
- What has the care team tried to respond to my loved one's challenging behaviors?
- How will they track the behaviors once the drug is started?
- What is the plan to decrease or stop the drug?

How can I help?

Staff will never know all that you know! You can help by providing answers to questions such as:

- How does your family member express themself when they are scared, angry, anxious, and hungry?
- What, in the past, has comforted them?
- What is their typical daily routine?
- Are there any behaviors that you have found more difficult to respond to than others?
- What have you tried to prevent them?
- Stay involved in your loved ones care and attend care plan meetings.

THE UNIVERSITY OF IOWA

IOWA GERIATRIC EDUCATION CENTER

INFO-CONNECT

Oral Hygiene Care for Nursing Home Residents with Dementia

The Facts . . .

- Oral hygiene care is very difficult for many residents with dementia.
- Residents with dementia are frequently admitted with complex dental needs.
- These residents have the highest risk of developing severe dental decay and other dental problems.
- Residents' problem behaviors could be the result of dental pain.
- These residents often cannot communicate their dental pain or problems to others.
- More residents are keeping their natural teeth and fewer have complete dentures.

Why Good Oral Health is Important

Poor oral health and dental pain significantly affect residents in a variety of ways, including:

- Appearance and social interactions
- Ability to eat
- Diet type and nutrition
- Weight changes
- Speech and swallowing
- Hydration
- Behavior
- General health

Oral Health Problems

Residents with dementia tend to have the highest dental needs of all residents including:

- Reduced function of salivary glands resulting in dry mouth
- High levels of dental plaque on teeth and dentures
- High levels of bleeding gums
- High levels of dental decay on tooth crowns and roots
- High levels of decayed tooth roots
- Decreased use of dentures
- High levels of gum, cheek, and tongue lesions, especially related to dentures
- Problems with swallowing and control of muscles of the mouth and tongue

Bleeding gums

The main aim of good oral hygiene care is to remove as much plaque as possible, in order to control oral diseases.

Dental plaque contains bacteria that cause the two main oral diseases: tooth decay (caries) and gum (periodontal) disease.

When plaque grows around teeth and dentures, it inflames the gums (gingivitis), which will often bleed, causing pain and discomfort. This also makes the resident's breath smell bad. The bleeding will worsen unless the plaque is regularly removed.

If plaque is not controlled, it will lead to mouth pain, eating problems, behavioral problems, and many medical complications, including the risk of aspiration pneumonia.

If residents have bleeding gums:

- Use a very soft toothbrush to gently brush the teeth and gums.
- The bleeding will stop over the next few days as the plaque is removed.
- A dentist can prescribe an antimicrobial mouth rinse called chlorhexidine gluconate to help reduce the bleeding.

- This special mouth rinse can also be brushed on the teeth or sprayed on using a small spray bottle.

Dry mouth and medications

- Saliva is the key to maintaining a healthy mouth.
- Many medications taken by residents with dementia have a side effect of drying the mouth.
- When the quantity and quality of saliva is reduced, oral diseases can develop very quickly.
- A dry mouth can be very painful and is also at high risk for developing bacterial and viral infections.
- Saliva substitutes can make a resident's mouth more comfortable.

Saliva substitutes do not increase the amount of saliva produced. They usually come as a gel or spray, and are used to replace the missing saliva. These substitutes can be used as often as needed.

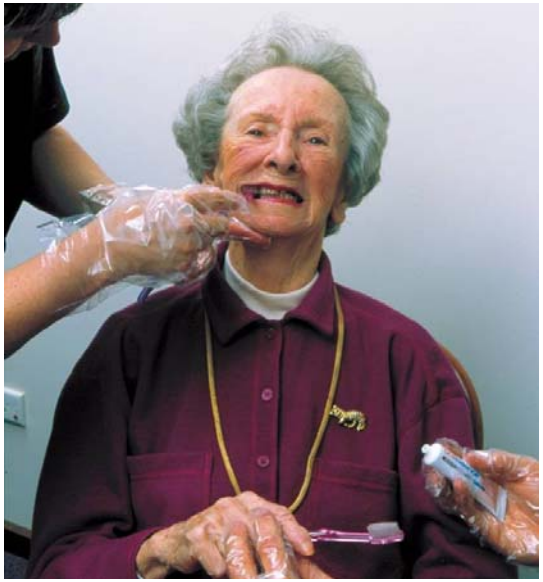
Strategies

Be prepared when providing oral hygiene care:

- Decide where, when, and how you will brush the resident's teeth.
- Have the toothbrush, toothpaste, and any other equipment ready.
- Consider whether you will need help from other CNAs.
- Wash your hands and put on gloves.
- Position the resident in comfortable seating in the bathroom or wherever is best for the resident and for you.

Make good use of verbal and nonverbal communication:

- Always approach the resident from the front, then move slowly and calmly to the side as necessary.
- Identify yourself to the resident, speaking slowly and clearly.
- Maintain eye contact and sit or stand at the same level as the resident.
- Move slowly and calmly alongside the resident if he or she moves.
- Provide cues about what you are going to do.
- Smile and use gentle touch; minimize sensory stimulation in the environment.
- Be patient and reassuring; try to enlist the resident's participation.
- Always explain what you are doing, and assume the resident can understand more than he or she is able to express.



- **Bridging** involves engaging the resident's senses, especially sight and touch, to help them understand the task you are trying to do for them.
  - ⇒ Place a toothbrush or denture in the resident's hands (**note**: use an old denture, in case the resident drops or throws it; a dentist can provide your facility with some spare dentures).
  - ⇒ Many residents will then start to brush their own teeth after holding a toothbrush for a few minutes.
  - ⇒ However, never give a toothbrush to a very aggressive resident who is likely to throw it or use it inappropriately.
- **Distraction** involves placing a familiar item such as a towel, cushion, or activity board in the resident's hands during oral hygiene care.
  - ⇒ This item will help to distract the resident's attention from the task.
  - ⇒ Familiar music is another good way to distract and relax the resident during oral hygiene care.
- **Chaining** means that the caregiver begins the oral hygiene task and the resident then helps to finish it.
- **Hand-over-hand** is a technique that can help to improve sensory awareness of the task.
  - ⇒ The caregiver places his or her hand over the resident's and then starts to brush the resident's teeth or remove or replace a denture.
- **Rescuing** is often used to help with completing hygiene tasks for residents with dementia.
  - ⇒ If attempts at oral hygiene care are not going well, walk away and have another caregiver complete the task.
  - ⇒ This technique works well with some uncooperative residents.
- If a resident verbally refuses oral hygiene care, the caregiver can:
  - ⇒ Review what strategies were used and improve their use or try different strategies next time.
  - ⇒ Try again later at a different time or place.
  - ⇒ Ask a nurse or other caregiver for help.
  - ⇒ Ask relatives if they had any special strategies for providing the resident's oral hygiene care.

Oral Health Assessment Tool for Dental Screening

Nursing facility staff can screen residents' oral health when they are admitted and throughout their stay. The OHAT[1] can be used to:

- Monitor dental problems
- Evaluate oral hygiene care interventions
- Act as a trigger to call in a dentist when required
- Assist with residents' oral hygiene care needs
- Assist with triaging and prioritizing residents' dental care needs

[1]Blanco VL, Chalmers JM. Oral hygiene care for dependent older adults—evidence based protocol. Gerontological Nursing Interventions Center. Research Dissemination Core. Iowa City, IA:The University of Iowa, 2001.

A Service of the:

Iowa Geriatric Education Center
University of Iowa
2153 Westlawn
Iowa City, IA 52242
(319) 353-5756
http://www.healthcare.uiowa.edu/igec

Funded by
The Department of Health Resources and Services Administration (HRSA)

Content provided by:

Jane Chalmers, BDSc, MS, PhD
Associate Professor, College of Dentistry
University of Iowa

Erin Lacey Spector, DDS
Assistant Professor, College of Dentistry
University of Iowa

Info-Connect

Iowa Geriatric Education Center
2153 Westlawn
Iowa City, IA 52242

Non-Profit Org
U.S. POSTAGE
PAID
Permit No. 45
Iowa City, IA

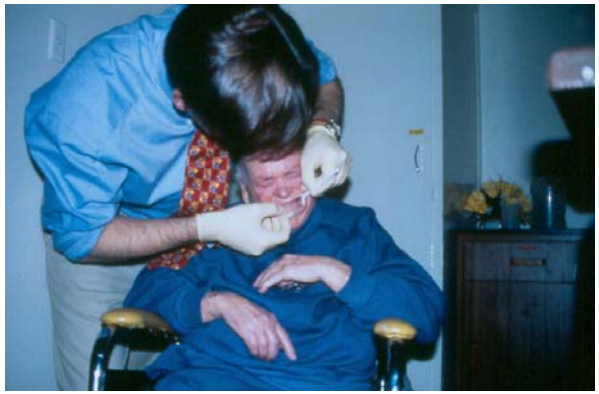
Assessing level of oral hygiene care abilities

- Think of all the small steps involved in brushing the teeth or cleaning dentures.
- Ask the resident to brush his or her teeth or clean dentures.
- Observe which oral hygiene care steps the resident is able to do and which require assistance.
- Encourage the resident to perform the steps he or she can do and assist with the steps the resident is unable to perform.
- This process is called “Task Breakdown” and promotes dignity and independence.

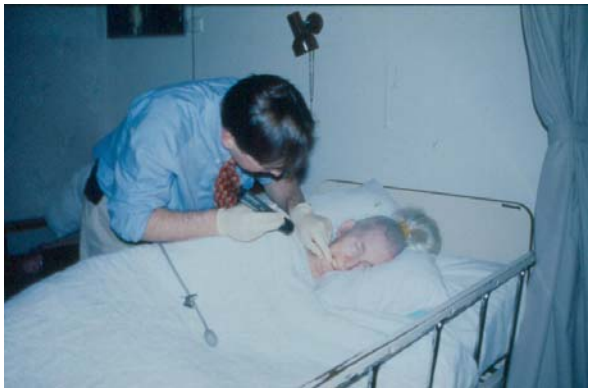
Caregivers should note in detail the resident’s level of oral hygiene care abilities in the comprehensive care plan to help communicate this information to other staff.

Most residents can be categorized as one of the following:

- Resident is independent and does not need assistance.
- Resident needs reminding and prompting.
- Resident needs some assistance.
- Resident needs full assistance.



Residents with dementia can require a great deal of assistance with their oral hygiene care. Behavior problems during oral hygiene care and other activities related to the mouth, such as shaving and eating, make such care difficult.



Oral Hygiene Care Plan (OHCP)

(Chalmers, 2004)

<table>
<tr><td colspan="4">Resident: _____ Completed by: _____ Date: _____/_____/_____</td></tr>
<tr><td colspan="4">Dentist: public or private (please circle) Name:_____ Phone: _____</td></tr>
<tr><td colspan="3">List all dental appointments:_____</td><td>Date for next OHCP review: _____/_____/_____</td></tr>
<tr><td>Dentures:</td><td>Upper</td><td>Full / Partial / Not worn / No denture</td><td>Attempt denture cleaning: ☐ daily ☐ when possible</td></tr>
<tr><td>(please circle)</td><td>Lower</td><td>Full / Partial / Not worn / No denture
Named / Not named Does/Does not wear at night</td><td>Best time and person (staff/relative) to clean dentures:
_____</td></tr>
<tr><td>Natural teeth:</td><td>Upper</td><td>Yes / No/ Roots present</td><td>Attempt teeth cleaning: ☐ daily ☐ when possible</td></tr>
<tr><td>(please circle)</td><td>Lower</td><td>Yes / No / Roots present</td><td>Best time and person (staff/relative) to clean teeth:
_____</td></tr>
<tr><td>Interventions for oral hygiene care:

(check all that apply and circle frequency needed)</td><td colspan="2">____ is independent and no assistance needed
____ needs reminding / prompting / task breakdown
____ needs supervision / checking of oral hygiene
____ needs full assistance from staff
____ use bridging / chaining / distraction techniques
____ use electric / suction toothbrush
____ use toothbrush: normal / backward bent / 2 toothbrushes
____ use chlorhexidine: spray bottle/gel daily/weekly
____ use fluoride: gel / mouthrinse in spray bottle daily/weekly
____ use regular 1000ppm toothpaste
____ use extra-strength 5000ppm toothpaste: daily/weekly
____ scrub denture/s with soap and water: morning/night
____ soak denture/s at night in: water/denture tablet
____ use saliva substitute for dry mouth
____ other _____
____ other _____</td><td>Regular problems with oral hygiene care:

(check all that apply)</td><td>____ forgets to do oral hygiene care
____ refuses oral hygiene care
____ won’t open mouth
____ no compliance with directions
____ is aggressive / kicks / hits
____ bites toothbrush and /or staff
____ can’t swallow properly
____ can’t rinse and spit
____ constantly grinding / chewing
____ head faces downwards
____ won’t take dentures out at night
____ other _____
____ other _____</td></tr>
</table>

Oral Health Assessment Tool (OHAT) for Dental Screening

modified from Kayser-Jones et al. by Chalmers (2004)

Resident: _____ **Completed by:** _____ **Date:** _____/_____/_____

***Scores—Circle individual words and give a score in each category**

Category	0 = healthy	1 = changes*	2 = unhealthy*	Category scores
Lips	smooth, pink, moist	dry, chapped, or red at corners	swelling or lump, white/red/ulcerated patch; bleeding/ulcerated at corners	
Tongue	normal, moist, roughness, pink	patchy, fissured, red, coated	patch that is red &/or white, ulcerated, swollen	
Gums and tissues	pink, moist, smooth, no bleeding	dry, shiny, rough, red, swollen, one ulcer/sore spot under dentures	swollen, bleeding, ulcers, white/red patches, generalised redness under dentures	
Saliva	moist tissues, watery and free flowing saliva	dry, sticky tissues, little saliva present, resident thinks they have a dry mouth	tissues parched and red, very little/no saliva present, saliva is thick, resident thinks they have a dry mouth	
Natural teeth Yes/No	no decayed or broken teeth/roots	1-3 decayed or broken teeth/roots or very worn down teeth	4 + decayed or broken teeth/roots, or very worn down teeth, or less than 4 teeth	
Dentures Yes/No	no broken areas or teeth, dentures regularly worn, and labeled with name of resident	1 broken area/tooth or dentures only worn for 1-2 hours daily, or dentures not named, or loose	more than 1 broken area/tooth, denture missing or not worn, loose and needs denture adhesive, or not named	
Oral cleanliness	clean and no food particles or tartar in mouth or dentures	food particles/tartar/plaque in 1-2 areas of the mouth or on small area of dentures or halitosis (bad breath)	food particles/tartar/plaque in most areas of the mouth or on most of dentures or severe halitosis (bad breath)	
Dental pain	no behavioral, verbal, or physical signs of dental pain	are verbal &/or behavioral signs of pain such as pulling at face, chewing lips, not eating, aggression	are physical pain signs (swelling of cheek or gum, broken teeth, ulcers), as well as verbal &/or behavioral signs (pulling at face, not eating, aggression)	

☐ **Arrange for resident to have a dental examination by a dentist** ☐ **Resident and/or family/guardian refuses dental treatment**

☐ **Complete Oral Hygiene Care Plan and start oral hygiene care interventions for resident**

☐ **Review this resident's oral health again on: Date: _____/_____/_____**

TOTAL: _____

SCORE: 16

***if 1 or 2 scored for any category, please arrange for a dentist to examine the resident**

THE UNIVERSITY OF IOWA

IOWA GERIATRIC EDUCATION CENTER

INFO-CONNECT

Managing Bathing Challenges in Nursing Home Residents with Dementia

The Facts . . .

- *Over 80 percent of nursing home residents with dementia display interfering-with-care behavioral symptoms.*
- *Problems during bathing are common, and disruptive, agitated, and resistive behaviors affect 41 percent to 73 percent of residents.*
- *Behavioral and environmental interventions promote comfort and reduce the risk of agitation.*

Bathing is a Challenge for Staff

Time constraints, strict routines, and poor understanding of bathing or of behaviors create challenges for the staff.

- Time constraints make bathing a task to be done and finished, as opposed to a potentially therapeutic experience for the resident.
- Certified nurse aides, who provide most personal cares, may not understand or have training in the therapeutic values of bathing.
- Bathing is viewed as a depersonalized task that must be done as part of the institutional routine, whether the resident likes it or not.
- The caregiver neglects a person-centered approach: bathing is 'done to' the resident.
- Caregivers may not understand that behaviors such as withdrawal, resistance, or combativeness are a protective response to what the resident perceives as a threat.

Physically and verbally aggressive behaviors have negative effects on staff.

- Job-related distress, lowered moral
- Frustration with caregiving
- Job dissatisfaction, burn-out and turnover
- Staff avoidance of residents

Bathing is a Challenge for the Resident with Dementia

The resident with dementia is often confronted with unpleasant stimuli during bathing.

- Removal of clothing and nudity cause fear and embarrassment.
- Bathing rooms are often impersonal and uncomfortable (e.g., cold, noisy, institutional).
- Bathing routines, such as showering or use of lifts, are unfamiliar and frightening.
- Multiple caregivers helping may over stimulate the resident.
- Pain during movement and other discomforts (e.g., water in eyes) contribute to problems.

Stress during bathing may result in a variety of behavioral symptoms.

- Verbal complaining or explicit refusal
- Perseveration or verbal agitation
- Withdrawal or attempts to leave the tub or bathing room
- Increased confusion and fear
- Catastrophic behaviors, including agitation and combativeness

Assess the Resident Before Bathing

Know the bathing history.

- How does this person usually bathe (e.g., shower, tub, sponge bath)?
- When does the person usually bathe (e.g., morning before dressing, evening before bedtime, Saturday night before Sunday church)?
- How often does the person bathe (e.g., daily, weekly)?

- Are there other personal preferences or habits that make bathing more enjoyable (e.g., soaps, scents, cleansing routines)?
- When is the person alert and least stressed, and likely to be most cooperative?
- What factors seem to provoke fear (e.g., water in face, stepping into tub)?

Consider current abilities and needs.

- What tasks can the person do?
- How much and what type of assistance is needed?
- What type of equipment is most appropriate?

Consider adjustments to routines or approaches.

- Wash hair on another day (e.g., at beauty or barber shop).
- Use non-rinse soap or shampoo.
- Pat dry instead of rubbing.
- Schedule pain medication prior to bathing.

Make the bathing environment friendly.

- Check for comfortable room and water temperature.
- Reduce or eliminate noise (e.g., running water, loud talking, echo from tiles).
- Provide decorations or home-like touches (attractive shower curtain, drapes, beach towels on wall to buffer noise).
- Adapt facilities to meet residents' needs (e.g., replace tub with lift tub that has easy access panel door; use shower chair with padded seat and foot rests).

Educate Staff to Enhance Comfort and Cooperation

Shift the focus from the task to the person.

- Emphasize flexibility vs. following a set routine.
- Train staff to appreciate therapeutic values of bathing.
- Promote 'team' approaches that reduce fear of reprimand for not completing tasks.
- Individualize care: View the resident as a 'whole person'.
- Empathize with the person's experience of bathing.

Individualize Bathing Approaches for Residents with Dementia

Following are two examples of how to promote person-centered bathing care.

1. The Three **F's** of bathing[1]

   ⇒ What **Function** does bathing serve (e.g., reduce body odors, remove urine from skin)?

   ⇒ What **Form** of bathing best meets current needs (e.g., towel bath vs. shower or tub)?

   ⇒ How **Frequently** does this person need to be bathed to meet individual needs?

---

[1] Hoeffer, B. et al. (1997). Reducing aggressive behavior during bathing cognitively impaired nursing home residents. *Journal of Gerontological Nursing*, *23* (5), 16-23.

Info-Connect
Iowa Geriatric Education Center
2153 Westlawn
Iowa City, IA 52242

2. The **PRIDE** approach to individualized care[2]

⇒ **P**rivacy

⇒ **R**eassurance

⇒ **I**nformation

⇒ **D**istraction

⇒ **E**valuation

Maintain Privacy and dignity at all times.

- Undress the person in the bathing room.
- Close the door and pull privacy curtains.
- Keep body parts covered unless being washed (e.g., bathing blankets, towels to cover).

Provide Reassurance to promote comfort and feeling safe (e.g., I'll help keep you steady).

- Talk to resident, checking for comfort and unmet needs (e.g., How does that feel?).
- Ask how the person is feeling and doing.
- Offer encouragement and support (e.g., "You are doing great!" "You smell so good.").
- Encourage the resident involvement and provide only needed assistance (e.g., Gently guide their hands with yours)
- Use a calm, personal, unhurried approach.
- Have one consistent caregiver provide baths.
- If two caregivers are needed, have one provide reassurance and support while the other washes (e.g., called 'good guy/ bad guy'[3] or 'buddy system'[4]).

Offer Information about what is being done and why.

- Assume the person has the ability to understand
- Offer a reason for bathing (e.g., "Let's get you cleaned up for your company.").
- Explain step-by-step what you are doing
- Break bath chores into steps and use simple verbal cues to promote function
- Gently guide those who are unable to respond to verbal cues (e.g., touch then put pressure behind knees while asking person to sit)
- Promote control by letting the resident perform self-cares
- Offer choices (e.g., "Do you want to unbutton your shirt or should I?").

Distractions often reduce anxiety and promote cooperation.

- Soft, familiar recorded music may reduce agitation.
- Try singing a favorite song with the resident.
- Reminisce about the resident's family, history, or favorite activities.
- Use aromatherapy, such as bath oils, offering choices of scents (e.g., rose or lavender).
- Keep the resident's hand busy holding a washcloth, sponge, or other soft item.

Evaluate progress toward outcome goals of comfort, safety, cleanliness.

- Adjust times and routines to accommodate the person.
- Use team approaches, with nurse aides, to problem-solve difficult bathing situations.
- Implement 'buddy system' and other alternative methods of dignity.[3,4]
- Record specific recommendations and instructions in care plans to promote continuity and quality care.
- Slow down and reevaluate if resistance or signs of discomfort appear.
- Remember: No one suffers if the bath isn't given today; try another time if resistance occurs.

---

[2] Mickus, M.A., et al. (2002). Developing effective bathing strategies for reducing problematic behavior for resident with dementia: The PRIDE approach. *Journal of Mental Health and Aging*, 8(1), 37-43

[3] Sloan, P.D., et al. (1995). Bathing persons with dementia. *The Geronotologist, 3*(5), 672-678.

[4] Martin, L.S., et al. (1991). Using a towel bath to give tender care in dementia: A case example. *Perspectives, 23*(1), 8-11.

INFO-CONNECT brochures provide ,practical information for practitioners on key topics. The following brochures are available. You may access them at: http://www.healthcare.uiowa.edu/igec.

Title	Description
Hospice Approach to End-of-Life Dementia Care	Reviews the characteristic problems of advanced dementia care as well as the hospice barriers and goals for advanced dementia.
Pain Assessment in Nursing Home Residents with Dementia	Describes the pain assessment and consequences of untreated pain, and provides assessment tools for use with cognitively impaired elders.
Pain Management in Nursing Home Residents with Dementia	Reviews the principles of pain management and provides information on non-opioid and opioid medications, and adjuvant medications.
Infections in Long-Term Care Facilities	Discusses infections in long-term care facilities, including bacterial pneumonia, urinary tract infections, skin and soft tissue infections, and different prevention strategies.
Understanding and Managing Aggression	Provides common risk factors for aggressive behaviors and discusses assessment strategies, behavioral intervention, medication management, and common care challenges.
The 3D's: Delirium, Depression, Dementia	Describes symptoms, courses of action, and medications associated with delirium, depression and dementia.
Fall Prevention	Reviews the extrinsic and intrinsic risk factors for falls, as well as strategies for the development of a fall intervention program.
Pressure Ulcers: Prevention & Treatment	Describes five strategies that can be used to prevent pressure ulcers and five strategies for treating ulcers.
Need-Driven Behavior 4-Part Series	
Need-Driven Dementia-Compromised Behavior (NDB)	Reviews Need-Driven Dementia-Compromised Behavior, together with assessment and management strategies.
Disruptive Vocalizations	Reviews disruptive vocalizations including what they are, who they affect, various types of DV, potential triggers and medical management.
Sleep Disturbances	Describes sleep disturbances, including background information, circadian rhythm disturbance, assessment, and suitable treatment approaches.
Great Escapes: The Wandering Dilemma	Describes the behavior of wandering and elopment including an overview, patterns, goals of interventions, risk factors, assessment, strategies for intervention, behavior management, and medication management.

A Service of the:

Iowa Geriatric Education Center
University of Iowa
2153 Westlawn
Iowa City, IA 52242
(319) 353-5756
http://www.healthcare.uiowa.edu/igec

Funded by
The Department of Health Resources and Services Administration (HRSA)

Content provided by:

Marianne Smith, PhD, ARNP, BC
Assistant Professor
University of Iowa College of Nursing

Editorial review by:

Margo Schilling, MD
Associate Professor of Clinical Medicine
Division of General Internal Medicine
University of Iowa

THE UNIVERSITY OF IOWA | IOWA GERIATRIC EDUCATION CENTER

INFO-CONNECT

Pain Assessment in Nursing Home Residents with Dementia

The Facts . . .

⇒ *45 to 85 percent of residents in long-term care facilities report chronic pain.*

⇒ *Pain symptoms in advanced dementia may mimic "agitation."*

⇒ *Pain is as common in those with dementia as in those who do not have dementia.*

⇒ *When one cannot communicate pain verbally, he or she will act it out.*

Under-treatment of Pain

A particular problem for those with advanced dementia because:

- Cognitively impaired nursing home residents are both prescribed and given less analgesic medication than cognitively intact residents.
- Cognitive impairment interferes with the resident's ability to perceive, recall, describe, and report pain to providers.
- Caregivers may lack tools necessary to detect pain among residents who are unable to verbally describe pain.
- Caregivers may doubt the validity of pain reports in cognitively impaired residents.
- Caregivers may not realize that residents with dementia are just as likely to have pain as other older adults.

Consequences of Untreated Pain

- Worsening of physical, functional, and mental health conditions.
- Increased depression, fatigue, anxiety, and sleep disturbances.
- Worsening of cognitive function.
- Increased risk of malnutrition.
- Decreased socialization and involvement in activities.
- Increased mobility impairment, gait disturbances, and falling.
- Increased risk of behavioral symptoms among those with dementia.

Common Myths about Pain

- If residents don't complain of pain, they must not have any.
- 'Nothing can be done' to relieve pain.
- Pain is a 'natural consequence' of growing older.
- Treatment of pain leads to addiction.
- Older people just need to 'learn to live' with their pain.

Assessing Pain in Advanced Dementia

- Pain assessment relies on **OBSERVING** the person's behavior.
- Research suggests that **KNOWING** the person is key to identifying pain.
- Residents who cannot clearly communicate their discomfort are at high risk for under-treatment of pain.
- All 'traditional' pain assessment scales rely on both verbal and cognitive skills, which make them ineffective in advanced dementia:
  - Responding to 'simple' questions like, "Are you having pain?" may not be possible.
  - Being able to 'point where it hurts' requires problem-solving skills no longer available.
  - Rating the 'intensity' of pain on a scale using numbers or words is beyond the person's ability.

- Like other feelings, sensations, and needs, pain emerges in ***behavior*** such as:

Facial grimacing	**Moaning**
Agitation	**Combativeness**
Pulling away if touched	**Restless body movements**
Changes in mobility or gait	**Changes in respiration**
Withdrawal	**Exiting behavior**
Sleep disturbance	**Decreased appetite**
Tense muscles	**Anger**
Disruptive vocalization	**Rubbing or holding body parts**

Pain Assessment Tools in Advanced Dementia

The following four assessment tools were tested with cognitively impaired elders:

1. **Pain Assessment in Advanced Dementia:** Five domains are rated from 0-2 resulting in a 10 point scale. Shown later in the pamphlet, this tool is used extensively in the Veteran's Administration and is found to be a brief, easy to use, and sensitive measure of pain in persons with advanced dementia. *Source*: Warden, V., Hurley, A. C., & Volicer, L. (2003). Development and psychometric evaluation of the Pain Assessment in Advanced Dementia (PAINAD) scale. *Journal of the American Medical Directors Association*, *4*(1); 9-15.

2. **Proxy Pain Questionnaire:** Three questions are answered by a nursing assistant who knows the resident well; shown to be better than MDS in identifying pain. *Source*: Fisher, S. E., Burgio, L. D., Thorn, B. E., Allen-Burge, R. A., Gerstle, J., Roth, D. L., et al. (2002). Pain assessment and management in cognitively impaired nursing home residents: Association of certified nursing assistant pain report, minimum data set pain report, and analgesic medication use. *Journal of the American Geriatrics Society*, *50*(1); 152-156.

3. **Assessment for Discomfort in Dementia:** Provides step-wise instruction for assessment and interventions for persons with dementia; not a pain scale in the traditional sense but a useful protocol. *Source*: Kovach, C. R., Weissman, D. E., Griffie, J., Matson, S., & Muchka, S. (1999). Assessment and treatment of discomfort for people with late-stage dementia. *Journal of Pain & Symptom Management*, *18*(6); 412-419.

4. **Checklist of Nonverbal Pain Indicators:** Six pain behaviors are rated as present or absent; cannot easily determine if pain increases or decreases due to limited score (0-6). *Source*: Felt, K. S. (2000). The checklist of nonverbal pain indicators (CNPI). *Pain Management Nursing*, *1*(1); 13-21.

A Service of the:

Iowa Geriatric Education Center
University of Iowa
2153 Westlawn
Iowa City, IA 52242
(319) 353-5756
http://www.healthcare.uiowa.edu/igec

Funded by
The Department of Health Resources and Services Administration (HRSA)

Content provided by:
Marianne Smith, PhD, ARNP, BC
Assistant Professor
University of Iowa College of Nursing

Editorial review by:
Margo Schilling, MD
Associate Professor of Clinical Medicine
Division of General Internal Medicine
University of Iowa

Permission provided by:
Victoria Warden, RN
Nursing Research Health Scientist
Geriatric Research Education Clinical Center
Edith Nourse Rogers Memorial Veterans Medical Center

Pain Assessment in Advanced Dementia (PAINAD)

PAINAD has been tested with older adults who have advanced dementia and is able to detect changes in pain,

	0	1	2	Score
Breathing	Normal	• Occasional labored breathing • Short period of hyperventilation	• Noisy labored breathing • Long period of hyperventilation • Cheyne-Stokes respirations	
Negative Vocalization	None	• Occasional moan/groan • Low level speech with a negative or disapproving quality	• Repeated, troubled calling out • Loud moaning or groaning • Crying	
Facial Expression	Smiling or Inexpressive	• Sad • Frightened • Frown	• Facial Grimacing	
Body Language	Relaxed	• Tense • Distressed • Pacing • Fidgeting	• Rigid • Fists clenched • Knees pulled up • Pulling/pushing away • Striking out	
Consolability	No need to console	• Distracted or reassured by voice or touch	• Unable to console, distract, or reassure	
				TOTAL

PAINAD Scoring: 1 - 3 = Mild; 4 - 6 = Moderate; 7 - 10 = Severe

* Some institutions have developed policies in which a PAINAD score of four or greater must be addressed in the nursing care plan.

Breathing

Normal: Effortless, quiet, or rhythmic respirations.
Occasional Labored: Episodic bursts of harsh, difficult, or wearing respirations.
Short Period of Hyperventilation: Intervals of rapid, deep breaths lasting a short period of time.
Noisy Labored Breathing: Negative sounding respirations on inspiration or expiration. May be loud, gurgling, wheezing, and appear strenuous or wearing.
Long Period of Hyperventilation: An excessive rate and depth of respirations lasting a considerable time.
Cheyne-Stokes Respirations: Rhythmic waxing and waning of breathing from very deep to shallow respirations with periods of apnea (cessation of breathing).

Negative Vocalization

None: Speech/vocalization with neutral/pleasant quality.
Occasional Moan or Groan: Moaning is characterized by mournful sounds, wails, laments, or groaning, by louder than usual inarticulate involuntary sounds, often abruptly beginning and ending.
Low Level Speech: Muttering, mumbling, whining, grumbling, or swearing in a low volume with a complaining, sarcastic, or caustic tone.
Repeated Troubled Calling Out: Phrases or words used over and over in a tone that suggests anxiety, uneasiness, or distress.

Facial Expression

Smiling or Inexpressive: Upturned corners of the mouth, brightening of the eyes, a look of pleasure or contentment. Inexpressive refers to neutral, at ease, relaxed, or blank.
Sad: Unhappy, lonesome, sorrowful, or dejected.
Frightened: Look of fear, alarm, or heightened anxiety. Eyes wide open.
Frown: Downward turn of the corners of the mouth; increased facial wrinkling on forehead and around mouth.
Facial Grimacing: Distorted, distressed look. Brow and mouth are more wrinkled. Eyes may be squeezed shut.

Body Language

Relaxed: Calm, restful, mellow appearance.
Tense: Strained, apprehensive, or worried appearance. Jaw may be clenched (exclude any contractures).
Distressed Pacing: Unsettled activity; fearful, worried, or disturbed element present. Rate may be faster/slower.
Fidgeting: Restless movement. Squirming, wriggling, repetitive touching, tugging, or rubbing body parts.
Rigid: Stiffening of the body. Arms and/or legs are tight and inflexible. Trunk may appear straight and unyielding (exclude any contractures).
Fists Clenched: Tightly closed hands that may be opened and closed repeatedly or held tightly shut.
Knees Pulled Up: Flexing legs and drawing knees up toward chest. Overall troubled appearance (exclude contractures).
Pulling/Pushing Away: Resistiveness upon approach or care. Trying to escape by yanking, wrenching, or shoving away.
Striking Out: Hitting, kicking, grabbing, punching, biting, or other form of personal assault.

Consolability

No Need to Console: A sense of well-being. Person appears content.
Distracted or Reassured by Voice or Touch: Disruption of behavior when the person is spoken to or touched. Behavior stops during the period of interaction with no indication that the person is at all distressed.
Unable to Console, Distract, or Reassure: Inability to sooth the person or stop a behavior with words or actions.

PAIN IN ADVANCED DEMENTIA

KEY PRINCIPLES	COMMENTS / RECOMMENDATIONS
Symptoms of pain in dementia may easily emerge as agitation or other behavioral symptoms.	1. Ask the caregiver who knows the resident best: "Could this behavior be a symptom of pain?" 2. Assess pain using one or more pain scales that DO NOT rely on the person's verbal report. ✓ The Proxy Pain Questionnaire (PPQ) asks 3 questions of nurse assistants who know the resident well. ✓ Pain Assessment in Advanced Dementia (PAINAD) rates five factors from 0 to 2 resulting a 10 point scale.
Document the behavior carefully, ruling out common causes of pain before resorting to psychotropic medication.	1. Use the Antecedent-Behavior-Consequence model to document the behavior. ✓ **Antecedents**: What triggers the behavior? Does it occur in relationship to personal cares? Does movement seem to set it off? ✓ **Behavior**: What? When? Where? How long? How intense is the behavior? ✓ **Consequences**: What reactions occur after the behavior occurs? What comfort measures are offered? 2. Conduct a thorough pain assessment as you consider possible "antecedents." 3. What medical diagnoses does the person have that might cause pain? Degenerative joint disease? Chronic back pain syndrome? Osteoporosis? History of fractures? Immobility? Neuropathic conditions? Restless leg syndrome? Post-stroke syndrome? Peripheral vascular disease? Pressure ulcers? 4. Does the person have any new injuries or acute illnesses that might contribute to discomfort or pain? 5. Any signs of injury on physical exam? Any infections (e.g., respiratory, bladder, oral, other)?
Treat pain like you would in a person who is able to report pain verbally.	1. A three-step ladder is recommended: Start with nonopioids ➞ Proceed to opioid therapies ➞ Use adjunctive nonopioid medications to augment opioid medication. 2. Reassessment of pain using a standardized method is highly recommended. ✓ Documentation is key to using different and more potent medications. ✓ Do not rely on informal verbal reports alone (e.g., "Is the pain better?"). ✓ Use of different/more potent medication relies on nursing documentation of the person's behavioral symptoms. 3. The minimum data set (MDS) pain assessment tends to rely on verbal report and is NOT as effective as other measures, such as the Proxy Pain Questionnaire, in advanced dementia.

THE UNIVERSITY OF IOWA | IOWA GERIATRIC EDUCATION CENTER

INFO-CONNECT

Pain Management in Nursing Home Residents with Dementia

The Facts . . .

- *45 to 80 percent of residents in long-term care facilities report chronic pain.*
- *40 to 60 percent of long-term care residents don't use the 'as-needed' medications prescribed for them.*
- *Untreated pain has serious, varied, and widespread consequences for older adults.*
- *Effective use of behavioral and medication therapies relies on accurate and ongoing assessment of pain.*[1]

Assessing Pain in Advanced Dementia[1]

- Pain assessment relies on OBSERVING the person's behavior.
- Research suggests that KNOWING the person is key to identifying pain.
- Residents who cannot clearly communicate their discomfort are at high risk for under-treatment of pain.
- All 'traditional' pain assessment scales rely on both verbal and cognitive skills, which make them ineffective in advanced dementia:
  - Responding to 'simple' questions like, "Are you having pain?" may not be possible.
  - Being able to 'point where it hurts' requires problem-solving skills no longer available.
  - Rating the 'intensity' of pain on a scale using numbers or words is beyond the person's ability.

Principles of Pain Management

- Identify and treat multi-dimensional factors that contribute to pain.
  - Depression, anxiety, fatigue, poor eating habits, and nutritional deficits
- Help the resident be comfortable and functional by focusing on overall health and well being.
  - Treatment should decrease pain and improve function, mood, and sleep.

[1] See "INFO-CONNECT: Pain Assessment in Nursing Home Residents with Advanced Dementia," Iowa Geriatric Education Center, for more information on assessment methods.

- Use non-pharmacological interventions in combination with analgesic medication.
  - Using non-pharmacological and analgesic interventions in combination may reduce the level of medication needed.
  - Below is a table of non-pharmacological interventions that may be recommended for those with advanced dementia.

NON-PHARMACOLOGICAL INTERVENTIONS	
Comfort Measures:	**Distraction/Redirection:**
Positioning	Art therapy
Verbal reassurance	Music therapy
Gentle touch	Pet therapy
Massage	Humor/laughter
Support/Counseling:	Relaxation techniques
Spiritual support	Activities/recreation
Support groups	Life review/reminiscence
Talking with friends	**Cognitive Techniques:**
Social support	Psychotherapy
Stress control	Biofeedback
Supportive Physical Methods	Guided imagery/meditation
Balance and fall protection	Hypnosis
Heat/cold applications	**Alternative Therapies:**
Hydrotherapy	Physical therapy
Bracing/splinting	Ultrasound
Joint protection	Chiropractic
Stretching exercises	Acupuncture
Movement and range of motion	Transcutaneous Electrical Nervous Stimulation (TENS)

- The World Health Organization (WHO) suggests using a three-step ladder for pharmacological management of pain.
  1. Start with nonopioids
  2. Proceed to opioid therapies
  3. Use adjunctive nonopioid medications to augment opioid medication

- Follow basic principles to ensure safe and effective analgesic use.
  - Use the least invasive route of administration.
  - Use short-acting drugs for episodic pain and around-the-clock administration for continuous pain.
  - Use long-acting or sustained release formulas for continuous pain only.
  - Adjust doses carefully following the motto: “Start low and go (titrate) slow”.
  - Use both short-acting and long-acting opioids for chronic pain.
  - Consider alternatives for neuropathic pain.
  - Topical analgesics may be helpful with arthritic pain.
- Recognize that older adults, as a group, are more sensitive to analgesics and individual side effects may vary considerably. Anticipate, monitor, and treat the side effects prophylactically.
  - Anticipate mild cognitive impairment and sedation until tolerance develops.
  - Start a bowel protocol.
- Avoid certain analgesic drugs altogether when treating residents.
  - Meperidine
  - Methadone
  - Propoxyphene

CARES Model[2]

This conceptual model helps health care facilities with incorporating national pain standards and guidelines into practice.

Commitment - identify facility commitment toward excellent pain management

Assessment - develop pain assessment criteria and documentation for specific patient populations

Responsibility - assign responsibility within the facility to ensure that standards are continually reviewed and maintained

Education - develop ongoing health professional competency guidelines, educational programs, and an organized system for patient and family education

Standards - develop patient care standards defining expected outcomes of care

[2] Weissman DE. (1995). Educating home health professionals in cancer pain management. *Home Health Care Consultant*, *2*,10-18. Used with permission.

For more information about the CARES model, please contact Sandra Muchka, RN, OCN, by phone at (414) 805-6828 or email at smuchka@mcw.edu

Info-Connect

Iowa Geriatric Education Center
2153 Westlawn
Iowa City, IA 52242

Non-Profit Org
U.S. POSTAGE
PAID
Permit No. 45
Iowa City, IA

NON-OPIOID MEDICATIONS[3]

Drug	Dose	Max Dose/24	Medication-related Adverse Effects	Comments
Acetaminophen (Tylenol®)	325-1000 mg every 4-6 hrs	4000 mg	Hepatoxicity above maximum dose.	Avoid exceeding maximum dose. Potent analgesic but no anti-inflammatory effect. No GI or anti-platelet side effects. Potentiates nonsteroidal anti-inflammatory drugs and opiates. Those consuming more than 2 ounces of alcohol per day should not exceed 2000 mg Anetaminophen per day due to increased risk of liver toxicity.
Nonselective Non-steroidal anti-inflammatory Ibuprofen, Naproxen, others COX-2 selective inhibitor Celecoxib (Celebrex®)	Individualize dosage 100-200 mg QD or BID	 200mg	Serious gastrointestinal toxicity can occur. May cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.	May be considered rarely, with extreme caution when other therapies fail Use requires ongoing assessment of adverse events/risks/benefits Contraindicated in individuals with active peptic ulcer disease, chronic kidney disease or heart failure. Relatively contraindicated in individuals with hypertension, *H. pylori*, history of peptic ulcer or concomitant use of corticosteroids or SSRIs Use a proton pump inhibitor for gastrointestinal protection with nonselective NSAIDs Use a proton pump inhibitor for gastrointestinal protection in individuals on celecoxib and aspirin

Adapted from:
[3] American Geriatrics Society (AGS) Panel on Chronic Pain in Older Adults. *Journal of the American Geriatrics Society.* 2002;50(suppl):*5205*-24. Used with permission.

OPIOID MEDICATIONS[4]

Drug	Dose	Max Dose/24	Medication-related Adverse Effects	Comments
Tramadol (Ultram®)	25 mg every 4-6 hrs	300 mg	Side effects include dizziness/ vertigo, nausea, constipation.	Central analgesic with weak opioid activity used for moderate to severe pain in osteoarthritis and other chronic pain syndromes. Bowel regimen mandatory.
Hydrocodone (Vicoden®, Lortab®)	5-10 mg every 3-4 hrs	NA	Acetaminophen, nonsteroidal anti-inflammatory drug combinations limit dose; toxicity similar to morphine. Constipation.	Do not exceed recommended maximum dose of acetaminophen. Begin a bowel program early.
Morphine, Immediate release (IR) (Roxanol®)	2.5-30 mg every 4-6 hrs.	NA	Intermediate half-life. Older adults more sensitive to side effects. Constipation.	Continuous use for continuous pain; intermittent use for episodic pain. Titrate does with short acting then convert to sustained release. Gold standard for pain relief. Tolerance develops for all side effects except constipation. Bowel regimen mandatory.
Morphine, Sustained release (MS Contin®, Oramorph SR®)	15-30 mg every 12 hrs. If previously on IR divide 24 hr used and ad-minister q12 hrs	NA	Rarely requires more frequent dosing. Constipation.	Escalate dose slowly due to drug accumulation; immediate release opioid often needed for break-through pain. Switch from IR to sustained release at same dose. Dosing interval can be adjusted if pain is not controlled. Do not crush pills. Bowel regimen mandatory.
Oxycodone, immediate release (IR) (Percodan®, Percocet®, Tylox®)	5-10 mg every 4-6 hrs	NA	Oxycodone is available as a single agent. Acetaminophen-nonsteroidal anti-inflammatory drug combinations limit dose; toxicity similar to morphine. Constipation.	Do not exceed recommended maximum dose of acetaminophen or aspirin. Begin bowel program early.
Oxycodone, Sustained release (OxyContin®)	10-20 mg every 12hrs. If previously on IR divide 24 hr use and administer q12 hrs	NA	Same as sustained-release morphine. Constipation.	Immediate-release opioid often needed for break-through pain. Bowel regimen mandatory.
Hydromorphone (Dilaudid®)	2 mg oral every 3-4 hrs	NA	Half-life may be shorter then morphine (3 hrs); toxicity similar. Constipation.	Similar to morphine; start low and titrate to comfort; give continuously (every 3-4 hrs) for continuous chronic pain. Bowel regimen mandatory.
Fentanyl, transdermal (Duragesic®)	NA>25 mcg/h not recommended for opioid naïve patients	NA	Effective activity may exceed 72 hrs in older patient (designed for 3-day duration). Constipation.	Titrate slowly using immediate-release analgesics for break-through pain; peak effects of first does may take 18-24 hrs. Caution: Fever increases dose absorption rate. Expensive, use selectively. Bowel regimen mandatory.

Adapted from:
[4] American Geriatrics Society (AGS) Panel on Chronic Pain in Older Adults. *Journal of the American Geriatrics Society*. 2002;50(suppl):*5205*-24. Used with permission.

ADJUVANT MEDICATIONS[5]

Drug	Starting Dose	Max Dose/24	Indication	Medication-related Adverse Effects	Comments
Corticosteroids					
Prednisone	2.5-5.0 mg daily	NA	Inflammatory disease	Increased risk of hyperglycemia, osteopenia, and Cushing's.	Avoid high dose for long-term use.
Tricyclic Antidepressants					
Desipramine Nortriptyline	10 mg at bedtime	25-100 mg	Neuropathic pain, sleep distrubance	Increased sensitivity to side effects, especially anticholinergic effects.	Monitor carefully for anticholinergic effects, Desipramine may be as effective as amitriptyline with fewer side effects; start at lowest dose possible; titrate bedtime dose 10 mg q 3-5 days.
Anticonvulsants					
Carbamazepine (Tegretol®)	100 mg	2500 mg	Lancinating pain (e.g., trigeminal neuralgia)	Can cause somnolence, ataxia, dizziness, leukopenia, thromocytopenia, and rarely aplastic anemia.	Start at 100 mg daily; increase slowly; check liver function tests, complete blood count (CBC), renal function at baseline; CBC at 2 and 8 wks.
Gabapentin (Neurontin®)	100 mg	3600 mg	Neuropathic pain	May prove to have less serious side-effects than carbamazepine.	Neuropathic doses not established; monitor for idiosyncratic side effects (e.g., ankle swelling, ataxia).
Topical Agents					
Capsaicin (Zostrix® cream, lotion) Capsaicin (Zostrix-HP®)	0.025% topically every 6 hrs 0.075% topically every 6 hrs	NA	Apply to the site of pain.	Initial burning sensation.	Useful for neuropathic pain. Solarcaine® may help reduce initial burning sensation. Patients should be warned about the transient burning sensation that follows application and need for regular use to maintain effectiveness. Skipping doses results in reaccumulation of substance P and return of pain. As with 0.025% creams and lotions. Several weeks may be needed to be effective. Clinical trials are lacking.
Counter irritants containing menthol (Ben-Gay®, Icy Hot®)	Topically	NA	Apply to the site of pain.	May cause local irritation, especially in patients with sensitive skin.	May be effective in self-management of osteoarthritis.
Lidocaine Patch 5% (Lidoderm®)	Up to three patches to intact skin in painful area	Apply once for 12 hours within a 24 hr period	Localized neuropathic pain	Application site reactions	Little systemic absorption
Diclofenac 1% Gel (Voltaren® Gel)	4 gm to affected lower extremity joint or 2 gm to affected upper extremity joint QID	32 grams	Pain of osteoarthritis of knees and hands	Application site reactions Carries same warning as oral nonselective non-steroidal anti-inflammatory drugs	Should be used with the same caution as orally administered NSAIDS

Adapted from:
[5] American Geriatric Society (AGS) Panel on Chronic Pain in Older Adults. *Journal of the American Geriatric Society*. 2002;50(suppl):*5205*-24. Used with permission.

[3,4,5] A number of guidelines relating to the assessment and treatment of pain among older adults are now available. Additions and changes to the preceding three tables were made by Michael Kelly, PharmD, MS.

Editorial review by:
Margo Schilling, MD
Associate Professor of Clinical Medicine
Division of General Internal Medicine
University of Iowa

Content provided by:
Marianne Smith, PhD, ARNP, BC
Assistant Professor
University of Iowa College of Nursing

Michael Kelly, PharmD, MS
Associate Professor (Clinical)
College of Pharmacy
and Department of Family Medicine
Roy J. and Lucille A. Carver College of Medicine

Funded by
The Department of Health Resources and Services Administration (HRSA)

A Service of the:
Iowa Geriatric Education Center
University of Iowa
2153 Westlawn
Iowa City, IA 52242
(319) 353-5756
http://www.healthcare.uiowa.edu/igec

THE UNIVERSITY OF IOWA

IOWA GERIATRIC EDUCATION CENTER

INFO-CONNECT

Understanding and Managing Aggression

The Facts . . .

⇒ Although behavioral symptoms are common among physically and mentally frail older adults, these symptoms are often misunderstood and mismanaged.

⇒ Accurate assessment of underlying social, psychological, personal, and medical needs is essential to effective management.

⇒ Both behavioral and pharmaceutical interventions are often required to comfort and reassure behaviorally impaired elders.

Personal Care as a Trigger of Aggression

⇒ Most instances of physical aggression occur while personal care is being given to cognitively impaired individuals.

⇒ Aggression commonly occurs as a reaction to the perception of a threat, **NOT** as an offensive or assaultive attempt to injure the caregiver.

⇒ Aggression during personal care is frequently related to the following situations:

- Touch or invasion of personal space
- Fear of unwanted intimacy
- Frustration related to declining abilities
- Discomfort, pain, or fear of pain
- Loss of personal control or choice
- Lack of attention to personal needs or preferences
- Unfamiliar routine or procedure

⇒ Aggressive behaviors may be reduced or eliminated by adjusting care routines.

Understanding the experience from the patient's perspective is critically important when looking for ways to comfort and soothe.

Common Risk Factors Associated with Aggressive Behaviors

⇒ **Cognitive Impairment Due to Dementia**

- Frustration created by progressive loss of function
- Inability to express feelings, needs, and sensations
- Decreased inhibitions, late-day fatigue, pain, or overstimulation leading to disproportionate responses to minimal events (e.g., sundowning, catastrophic reactions)

⇒ **Other Psychiatric Illnesses**

- Delirium
- Depression
- Bipolar disorder
- Schizophrenia, paranoid disorder, and other disorders causing psychotic symptoms

⇒ **Sensory Impairment**

- Impaired hearing and/or vision
- Communication losses
- Misinterpretation of real-life events

⇒ **Inappropriate Sensory Stimulation**

- Excessive stimulation (e.g., noise, confusion, or too many people) can overwhelm and frustrate (e.g., dining room).
- Misinterpreted stimuli (e.g., radio, television, mirrors, or public address systems) may threaten or frustrate.

⇒ **Lifetime Use of Aggression as a Coping Mechanism**

⇒ **Unmet Psychological Needs**

- Isolation or loneliness (possibly precipitating illusions or delusions)
- Invasion of privacy or personal space
- Changes to long-standing patterns of behavior

⇒ **Sleep Disturbance**

- Reduced hours of sleep
- Poor quality of sleep

⇒ **Health Status**

- Pain and discomfort
- Hunger and thirst
- Constipation, urinary tract infection, and other gastrointestinal problems
- Acute hypoxia (lack of oxygen to the brain)
- Fatigue
- Infectious processes
- Electrolyte disturbances
- Endocrine, cardiovascular, neurological, and renal disorders

⇒ **Medications**

- Side effects (e.g., akathisia with psychotropics)
- Toxicity (e.g., levodopa, coricosteroids, anticholinergics, or barbiturates)
- Withdrawal (e.g., central nervous system depressants)
- Paradoxical reactions (e.g., sedative and hypnotic medications, which may lead to agitated delirium)

⇒ **Neurological Disorders**

- Region-specific central nervous system damage
- Neurotransmitter changes (e.g. serotonin metabolism has been linked to impulsive behavior)
- Deterioration in circadian circuitry (e.g., end-of-day agitation)

Assessment is Key

⇒ **Remember**, assessment is an ongoing process.

⇒ The following factors may interact to trigger aggressive behaviors:

- Mental health
- Physical health
- Medication side effects
- Social and family
- Life history
- Long-standing personality

⇒ To determine the underlying cause(s) of aggressive behavior, perform a comprehensive assessment of the following:

- Current symptoms (including onset, duration, intensity, and changes)
- Medical history and physical exam
- Psychiatric history and mental status exam
- Current and previous medications
- Laboratory tests: CBC; urinalysis; T3, T4, TSH; B12 and folate; Chem screen including Na, Cl, K, BUN, Ca, glucose, creatinine
- Electrocardiogram
- CT scan and MRI

⇒ Identify, assess, and treat medical problems that complicate course of behavioral problems.

⇒ Rule in (or rule out) other conditions that interact with or trigger behavioral symptoms.

⇒ Appreciate how the following experiences affect a patient's perspective:

- Loss of power and control
- Unwanted dependency
- Loss of former meaning and purpose in life

A Service of the:

Iowa Geriatric Education Center
University of Iowa
2153 Westlawn
Iowa City, IA 52242
(319) 353-5756
http://www.healthcare.uiowa.edu/igec

Funded by
The Department of Health Resources and Services Administration (HRSA)

Content provided by:

Marianne Smith, PhD, ARNP, BC
Assistant Professor
University of Iowa College of Nursing
Source: Smith, M. & Buckwalter, K. (1999). *Choice & Challenge: Caring for Aggressive Older Adults Across Levels of Care.* Washington DC: APNA.
Used with permission.

Editorial review by:

Margo Schilling, MD
Associate Professor of Clinical Medicine
Division of General Internal Medicine
University of Iowa

The A-B-C Model

The A-B-C Model refers to a three-step method of approaching behavior symptoms.

⇒ Identify the target **B**EHAVIOR to be changed.

- Describe the behavior completely, precisely, and accurately using measurable terms.
- Identify the behavior's frequency, duration, intensity, and correlation with other behaviors.
- Consider for whom the behavior is a problem (i.e., the person, family, staff, or other residents).

⇒ Investigate possible **A**NTECEDENT conditions, or triggers, to the target behavior, which may include the following:

- **INTERNAL** antecedents: sensations, feelings, and experiences such as pain, hunger, fear, or perceived invasion of personal space
- **EXTERNAL** antecedents: factors in the physical or social environment such as noise, too many people, confusing surroundings, or demands to function beyond his or her ability

⇒ Examine and describe possible **C**ONSEQUENCES, or reactions and responses, to the target behavior.

Make a Plan . . .

⇒ Set an achievable, realistic **B**EHAVIORAL goal.

⇒ Change the **A**NTECEDENT conditions to reduce likelihood of behavioral reoccurrence.

⇒ Change the **C**ONSEQUENCES for the targeted behavior.

⇒ Evaluate if any or all of the plan worked.

10 Principles of Behavioral Intervention

1) Know the person "behind the disease" and individualize care.
2) Understand that no two people or situations (even with the same person) are the same.
3) Focus on the person, not the task.
4) Pause to assess the person and the situation.
5) Break tasks into steps, allowing the person to do what he or she can do individually.
6) Respond to the patient's emotions; don't argue logically.

Taking more time during personal care may actually save time by avoiding emotional or physical conflict.

---

7) Use the patient's agenda.
8) Slow down; follow the patient's lead.
9) Redirect the patient with a positive approach.
10) If things are not going well, leave and try again later.

Medication Management

⇒ **Always,** try non-pharmacological therapies unless there is a:

- Danger
- High level of patient distress
- Specific indication (like depression or psychotic symptoms) for which medication is an effective solution

⇒ Target one or more specific symptoms.

⇒ Establish a specific therapeutic goal, which may be to:

- Resolve delusions
- Decrease frequency of hitting
- Reduce disruptive vocalization

⇒ Develop outcome criteria in advance to facilitate decision making.

⇒ Select medication on the basis of the drug's side effect profile in relationship to the patient's symptoms.

⇒ Start at the lowest dose possible and slowly titrate upwards.

⇒ Carefully monitor symptom improvement while watching for problematic side effects.

⇒ Apply principles of medication management outlined in practice guidelines and algorithms for specific disease states.

COMMON CARE CHALLENGES:	Bathing	Toileting	Mealtime	Disruptive Vocalization
Common Antecedents/ Sources of Stress:	• Room temperature (e.g., cold, drafty) • Water temperature (e.g., too hot, too cold) • Unfamiliar facilities or routine (e.g., sterile, not home-like) • Embarrassment or emotional discomfort • Physical discomfort or pain with movement • Misperception or fear	• Lack of privacy or comfort • Misperception (e.g., thinks trash can is the toilet) • Way-finding problems (e.g., unable to see or find toilet) • Language loss (e.g. unable to communicate needs) • Functional deficits (e.g., unable to disrobe or get to the toilet in time) • Unaware of "social rules" • Urinary tract infections • Medications (e.g., diuretics and medication side effects)	• Incontinence/need to void • Pain (e.g., mouth, gums, ill-fitting dentures, mobility) • Overstimulation (e.g., noise, confusion, crowding) • Competing demands for attention (e.g., medications, food, or conversation) • Eating utensils are not understandable • Food or eating style is unfamiliar • Overwhelmed by choices or demands	• Sensory overstimulation or understimulation • Immobility • Pain or discomfort • Fatigue • Vocal tics • Psychotic symptoms (e.g., hallucinations or delusions) • Psychological distress (e.g., boredom, loneliness, anxiety, or fear) • Caregiver behaviors (e.g., indifferent or impersonal)
Behavioral Interventions:	• Collect a "bathing history" • Base bathing method and time of day on history • Use past memories to encourage cooperation • Provide a reason to bathe • Use one person to assist rather than several • Cover all body parts not being washed • Provide a washcloth to cover face and eyes • Wash hair last or wash in a beauty salon or barber shop • Distract person with familiar conversation • Use familiar terms or words • Offer choices, encouragement and feedback • Bathe in room using bed, towel, or sponge bath as an alternative	• Clear pathways to toilet • Provide cues to find toilet (e.g., pictures or signs) • Use color contrast (e.g., a white toilet with a bright-colored wall) • Develop a personalized routine using patient's long-standing habits • Monitor behavior • Use easy-to-remove clothing • Cue or assist as needed • Monitor intake after 6 pm to avoid accidents • Eliminate caffeine • Monitor medication type, interactions, and side effects • Monitor intake/output to assure adequate intake and hydration • Minimize 'fuss' if accidents occur	• Develop calm, quiet, home-like routines • Dine with small groups or in own room • Use tablecloths, flowers, candles, and lowered lighting (all are associated with less mealtime aggression) • Provide space so each has his or her own territory • Tolerate "messy" behavior • Cue or assist as needed • Simplify food presentation • Provide appropriate utensils (e.g., use color contrast and one plate/utensil rather than several) • Redesign routines to avoid overstimulation and confusion • Adopt flexible, adaptable mealtime policies (e.g., open kitchen, cafeteria style, or restaurant style)	• Offer adequate pain medication • Avoid large group activities, noise, and commotion • Create home-like setting • Offer environmental sounds (e.g., tapes of waterfalls, rain, or wind) • Use aroma or pet therapy to soothe or distract • Maximize sensory function • Treat underlying physical problems • Ambulate or escort outdoors • Use one-to-one activities, reassurance, and reminiscence to distract • Reassure through touch, conversation, music, or a taped voice of loved one • Schedule naps and monitor routines

THE UNIVERSITY OF IOWA

IOWA GERIATRIC EDUCATION CENTER

INFO-CONNECT

The 3D's:

DELIRIUM
DEPRESSION
DEMENTIA

The Facts…

⇒ Psychiatric illness has been reported to affect more than 90% of residents of Nursing Homes (NH).

⇒ The number of Nursing Home residents is expected to triple by the year 2020.

⇒ Psychiatric illnesses are often undetected.

⇒ The most common chronic psychiatric illness in all nursing homes is dementia; the most common acute psychiatric illness is delirium.

DELIRIUM *disturbance of awareness*

- Causes abrupt changes in behavior or mental status
- Most frequently caused by underlying infection, medication toxicity or other medical illness

DEPRESSION *disturbance of mood*

Symptoms necessary for diagnosis of major depressive disorder are a depressed (sad) mood/loss of interest for at least two weeks, and at least **5** of the following:

- Tearful or sad feelings
- Weight change, (usually decreased)
- Trouble sleeping
- Psychomotor agitation or retardation
- Fatigue or loss of energy
- Feelings of worthlessness or guilt
- Loss of ability to concentrate
- Indecisiveness

DEMENTIA *disturbance of memory*

The most common type of dementia is Alzheimer's Disease, but cerebrovascular disease (strokes) may also contribute to dementia.

Symptoms for diagnosis of dementia must include:

- **Impaired memory** - an inability to learn new information or recall learned information.

With one additional problem in thinking such as:

- **Aphasia**—language impairment affecting the production or comprehension of speech.
- **Apraxia**—loss of ability to carry out movements such as writing, gait, and complex tasks.
- **Agnosia**—loss of ability to recognize objects or persons.
- **"Executive function" Loss**—loss of ability to plan ahead, foresee consequences, etc.

DELIRIUM

To recognize delirium, look for:

- reduced awareness of the environment
- inability to focus, sustain, or shift attention
- disorientation
- perceptual problems (hallucinations)
- fluctuating course
- abrupt onset

Did you know:

- The most common cause of delirium in the nursing home is urinary tract infection.
- Other common causes of delirium are respiratory infections, electrolyte imbalance, congestive heart failure, and medication interactions.
- Approximately 40% of delirious patients present as apathetic and quiet.
- Persons with dementia and depression are vulnerable to delirium.

First Course of Action:

- Identify source of underlying physical problem through a physical exam,laboratory or other assessment.
- Treat underlying problem immediately.
- Look for possibility of overmedication.

Medical Treatment:

First course of medical action is to reduce or stop a potential offending medication. If symptoms of agitation are problematic, consider a low dose antipsychotic drug such as haloperidol or risperidone to maintain safety until delirium resolves. Avoid physical restraints if possible.

DEPRESSION

Symptoms of depression may be hard to distinguish from symptoms of dementia, but feelings of worthlessness, guilt, sleeplessness and weight loss are indicators of depression. A history of depression in young adulthood is a risk factor for late life depression.

Individuals are at higher risk of depression if they have:

- Cerebrovascular disease—History of stroke
- Parkinson's disease
- Losses/grieving
- Loss of independence
- Social isolation
- Impending dementia
- Multiple medical problems
- Chronic Pain

First Course of Action:

- Work with the environment: Provide social support, minimize isolation, involve in community and family, encourage physical activity.
- Examine potential overuse of benzodiazepines (lorazepam, alprazolam) and other sedatives, or over-the-counter agents that may be contributing to loss of function.
- Investigate possible underlying dementia.
- Consider referral for supportive counseling through clergy, psychologist or therapist.

Intervene with Medications when:

- the environment has been optimized, and medical problems have been ruled out.
- there is severe distress and tearfulness.
- severe symptoms such as substantial weight loss, suicidality/death wish, ongoing sleeplessness, or depressive symptoms are present.

Medical Treatment:

For Major Depressive Disorder, Selective Serotonin Reuptake Inhibitors (SSRIs) are often the first line of treatment. For example: citalopram, sertraline, paroxetine, and fluoxetine.

Some alternative medications include venlafaxine, buproprion and mirtazapine.

Did you know:

Pseudodementia is an older term used to describe cognitive impairment that resolves with successful treatment of depression. Unfortunately, even patients with complete recovery appear to be at high risk for irreversible dementia.

Approximately 20% of persons over 65 suffer from depression.
Treatments for depression are available, safe and effective.

A Service of the:

Iowa Geriatric Education Center

2153 Westlawn
Iowa City, IA 52242
319-353-5756

VISIT US AT:

http://www.medicine.uiowa.edu/igec

Content provided by:
Susan K. Schultz MD
Associate Professor of Psychiatry
University of Iowa

Editorial Review by
Margo Schilling, MD
Assistant Professor of Clinical Medicine
Division of General Internal Medicine
University of Iowa

DEMENTIA

Behavioral signs **in early dementia** include apathy (loss of interest), social withdrawal, and anticipatory anxiousness.

Behavioral signs **in advancing dementia** include suspicious beliefs—such as belongings are being stolen, a spouse is being unfaithful, food is being poisoned or caregivers are imposters.

Common symptoms of visual misperceptions are:

- Somatic delusions (conviction of having cancer or other fatal illness)
- Perceiving people in the room
- Wandering (aimless pacing, entering other's rooms)
- Agitation (physical threats, verbal outbursts)
- Night-time confusion—also called 'Sundowning'
- Uncooperativeness and resistance with bathing/feeding

First Course of Action:

To best manage and minimize problems that may lead to agitation, aggression, hostility and falls:

- Maintain adequate lighting and avoid clutter and loud stimuli.
- Use 'guides' to help orient the resident (e.g. signs that identify their rooms).
- Provide reassurance that the individual is in a safe place.
- Recognize delusions are symptoms of dementia; do not confront or try to 'teach' the individual that their beliefs are incorrect.
- Use reassurance instead of confrontation.
- Recognize that hostility is a common symptom often related to misperceptions; avoid "taking it personally".

When Caring for Persons with Dementia:

- Keep decision-making at a level that fits the person's ability to reason.
- Enhance verbal requests or instructions with physical guidance and demonstration.
- Use distraction techniques instead of verbal explanations when the person is upset.
- Avoid contests of wills.
- Develop a predictable daily routine, including pleasant activities and exercise.
- Keep explanations short—be willing to repeat.
- Focus on use of over-learned skills such as shoe tying and hair brushing that may be retained and brought out by demonstration long after the words for these tasks are forgotten.
- Avoid unfamiliar activities, situations and

For Agitation, Intervene With Medications After You:

- Evaluate for a possible delirium, pain, or undiagnosed medical condition.
- Consider the possibility of medication interaction or adverse medication effect.
- Identify the source of agitation (e.g. medical problems: dehydration, infection; or an inability to express needs, articulate pain, dental problems, etc.)

Medical Treatment:

For agitation with anxiety and restlessness, low-dose, trazodone in divided doses may be beneficial.

For acute treatment of delusions and agitation, low-dose haloperidol or risperidone may be helpful.

For patients with Parkinsonism, olanzapine may be better tolerated.

Notes for Families:

- Too much stimuli during family visits can increase distress. Sometimes brief, small group visits on-site are the best. Trips outside the nursing home can become frightening and distressful as dementia progresses.
- Often when an individual is losing the ability to identify family members it can increase distress to keep checking "You remember me, don't you?"
- Minimize discomfort / unfamiliarity by providing reassuring statements that re-orient the individual without being challenging. (i.e."Isn't your granddaughter, Sally, wonderful. It's so nice she's visiting today.")
- When suspicious beliefs arise, they often involve family members stealing or mismanaging the individual's resources. Recognize these beliefs as symptoms of dementia; do not react with defensive/hurt behaviors.

For additional information about Alzheimer's and other related dementias check the following websites:

Alzheimers.com
http://www.alzheimers.com

Elderweb
http://www.elderweb.com/body/alzheim.htm

Alzwell—Caregiver Page
http://www.alzwell.com

Medication Chart for Depression & Dementia

For Depression			
Medication	**Brand Name**	**Recommended Dosage**	**Comments**
buproprion	Wellbutrin	75 – 100 mg po bid	Stimulant-like qualities may increase energy. May also infrequently cause anxiety, insomnia and psychosis.
citalopram	Celexa	10 – 20 mg po q am	Well tolerated first-line treatment. May interact with protein-bound drugs or those metabolized by hepatic cytochrome p450 2D6 isoenzyme, similar to all SSRIs below.
fluoxetine	Prozac	10 – 20 mg po q am	Longest half-life of SSRIs. May increase likelihood of insomnia. May have liver enzyme inhibition as noted above with Celexa.
mirtazapine	Remeron	7.5 – 30 mg po q hs	May be beneficial for depression with insomnia due to sleep-enhancing properties.
nortriptyline	Pamelor	50 – 150 mg po q hs	Improves sleep and appetite but anticholinergic side effects may include urinary retention, dry mouth, constipation and orthostatic hypotension. Imipramine and amitriptyline are not recommended due to greater anticholinergic effects.
paroxetine	Paxil	10 – 20 mg po q am	Well tolerated first-line treatment. May interact with protein-bound drugs or those metabolized by hepatic cytochrome p450 2D6 isoenzyme.
sertraline	Zoloft	25 – 100 mg po q am	Well tolerated first-line treatment. As with all SSRIs, may interact with protein-bound drugs or those metabolized by hepatic cytochrome p450 2D6 isoenzyme.
trazodone	Desyrel	25 – 200 mg q day	Beneficial for sleep, side effects may include sedation, and occasionally hypotension. Divided doses in daytime may help with agitation.
For Dementia			
busipirone	Buspar	5 – 30 mg TID	Non-sedating drug often perceived as less rapidly effective than benzodiazepines. May be beneficial for agitation with anxiety.
divalproex sodium	Depakote	125 - 500 mg po TID	May stabilize agitated behaviors, but sedation and gastrointestinal side effects may occur. Serum drug levels may be followed.
haloperidol	Haldol	0.5 – 2.0 mg per day	May cause more parkinsonian side effects such as muscle rigidity, tremors, drooling. Low dosages minimize these effects.
lorazepam	Ativan	0.5 – 1 mg bid	Useful for psychomotor agitation and anxiety. May cause sedation and gait instability. Lack of active metabolites is a benefit for use in elderly.
olanzapine	Zyprexa	2.5 – 7.5 mg per day	Does not have parkinsonian side effects, but may cause sedation, other anticholinergic effects.
risperidone	Risperdal	0.25 – 2.0 mg po q hs or bid	May cause more parkinsonian side effects such as muscle rigidity, tremors, drooling. Low dosages minimize side effects.

THE UNIVERSITY OF IOWA

IOWA GERIATRIC EDUCATION CENTER

INFO-CONNECT

Need-Driven Dementia-Compromised Behavior (*NDB*)

The Facts . . .

⇒ *Disruptive, agitated, and aggressive behaviors often result from one or more unmet needs — physical, psychological, emotional or social.*

⇒ *Loss of ability to express needs in language causes the person to "communicate" through behavior.*

⇒ *NDB Model emphasizes the interaction between stable individual characteristics and fluctuating environmental factors that may cause stress or discomfort.*

⇒ *Assessment is the key to accurate interventions and quality of care.*

The NDB Model

Need-Driven Dementia-Compromised Behaviors (NDB) Model presents a different way of thinking about "problem" behaviors.

- Developed by a group of nurse researchers[1] who sought to better understand and manage "problem" behaviors in dementia.
- Arose out of the desire to "re-frame" caregivers' thinking and provide an alternative view.
- Provides a framework to understand behaviors that have been called
  - ⇒ Difficult
  - ⇒ Disturbing
  - ⇒ Disruptive
  - ⇒ Problematic

Essential Features

- Problem behaviors are the result of interaction between:
  - ⇒ Relatively stable INDIVIDUAL CHARACTERISTICS
  - ⇒ Ever-changing ENVIRONMENTAL TRIGGERS
- Problem behaviors are an "expression" of one or more "unmet needs" — physical, psychological, emotional, or social.
- Persons with dementia are unable to form thoughts or express needs in language.
- Unmet need emerges in behavior symptom(s).
- Comfort and quality of care depend on accurate assessment and intervention.

NDB Behaviors

NDBs take many forms, including the following:

- Wandering, elopement
- Disruptive vocalizations
- Agitation and aggression
- Sleep disturbance
- Resistance to personal cares

[1]Algase, D., Beck, C., Kolanowski, A., Whall, A. Berent, S., Rickards, K., & Beattie, E. (1996). Need-driven dementia-compromised behavior: An alternative view of disruptive behavior. *American Journal of Alzheimer's Disease, 11(6),* 10-19.

Management Strategies

- Are highly individualized.
- Arise out of assessment data.
- Rely on thoughtful review and assessment of
  - ⇒ INDIVIDUAL CHARACTERISTICS that are fairly stable and longstanding:
    - ✓ Health conditions
    - ✓ Level of disability due to dementia
    - ✓ Personal history and experiences
    - ✓ Long-standing personality traits and coping patterns
  - ⇒ ENVIRONMENTAL TRIGGERS that tend to fluctuate and vary:
    - ✓ Personal environment
    - ✓ Social environment
    - ✓ Physical environment

Assessment is Key

Comprehensive and ongoing assessment is vital.

- Describe the behavior: WHO? WHAT? WHEN? WHERE? HOW LONG? HOW OFTEN?
- Ask: Who is this a problem for?
  - ⇒ The patient?
  - ⇒ Others around him/her?
- Listen carefully for the message the person is attempting to convey.
- Observe for possible "hidden meanings" in actions, words.
- Involve family who may understand meanings of words or phrases.
- Look for patterns and document habits.
- Attend to nonverbal cues and messages.
- Rule in, rule out medical and/or physical problems.
- Seek to understand the person's internal reality.
- Re-frame the problem: Think of the person as DISTRESSED VS. DISTRESSING.
- Brainstorm with staff and family regarding possible causes and interventions that work even *part* of the time.
- Reevaluate frequently.
  - ⇒ As person's status changes due to dementia, so will the response to interventions. Keep trying!

Assessing NDB

1. OVERSTIMULATION

- Noise?
- Confusion?
- Number of people?
- Level of activity?
- Competing demands for attention?
- Lighting, visual illusions, level of stimulation?
- Need for privacy?
- Hurried approach of caregiver?
- Confused by directions or requests?
- Dislikes being "done to" in personal cares?

2. UNDERSTIMULATION

- Hearing?
- Vision?
- Touch?
- Smell?
- Taste?
- Prosthesis in place?
- Prosthesis working?
- Alone in room?
- Visitors, social contacts?

3. PAIN/DISCOMFORT

- New, reoccurring health conditions?
- Joint pain, stiffness (e.g., arthritis, medication side effects, immobility)?
- Skin, mucous membrane integrity?
- Infections (e.g., UTI, respiratory)?
- Ingrown toenails?
- Incontinence?
- Constipation, gas, gastric upset?
- Comfortable clothing, shoes?
- Room temperature?
- Hunger, thirst?
- Dentures fit?

4. IMMOBILITY

- Level of movement?
- Ability to ambulate?
- Gait stability?
- Bedfast?
- Positioning challenges?
- Bedfast?
- Positioning challenges?
- "Fit" of wheelchair?
- Use of assistive devices?
- Physical barriers to movement?
- Use of restraints?

5. PSYCHOSIS

- Level of distress to person?
  - ✓ Simple delusion due to "time confusion"
  - ✓ Troubling, fear-provoking experience?
- Misleading stimuli causing illusions?
  - ✓ Reflections?
  - ✓ Pictures?
  - ✓ Televisions?
  - ✓ Radio, other noise?
  - ✓ Public address system?
  - ✓ Clutter?
  - ✓ Voices?
- "Orienting" physical features?
  - ✓ Calendars?
  - ✓ Clocks?
  - ✓ Family photos?
  - ✓ Signs, labels?
  - ✓ Understandable physical features?

6. DEPRESSION

- Observable signs?
  - ✓ Facial grimacing?
  - ✓ Sad expression?
  - ✓ Crying?
  - ✓ Anxious, worrisome appearance?
  - ✓ Words/phrases sound sad, helpless, fearful?
  - ✓ Appetite disturbed?
  - ✓ Weight loss?
  - ✓ Sleep disturbed?
  - ✓ Energy level reduced?
  - ✓ Attention span reduced?
  - ✓ Psychomotor activity disturbed?
  - ✓ Unwilling to conduct ADLs when has ability?
  - ✓ Withdraws to room, bed?
  - ✓ Resists socialization?
- MDS score?
- Real-life stress, loss, grief reaction?
- Past history of depression?
- Past "nervous" problem?
- History of vascular problems?

7. FATIGUE

- Daily routines consistent with past routines?
  - ✓ Hour of rising?
  - ✓ Rest, napping?
  - ✓ Level of activity?
  - ✓ Type of activity?
  - ✓ Bedtime?
- Appropriate level of stimulation?
  - ✓ Too much?
  - ✓ Wrong type?

8. PHYSICAL DESIGN

- Institutional vs. homelike
- Signs & symbols to promote wayfinding?
  - ✓ Picture of toilet
  - ✓ Stop sign near doors
  - ✓ Orienting objects near doors (e.g., memory box)
- Personal items to comfort, orient?
- Familiar pictures on walls?
- Furniture inviting?
- Adequate color contrast? Use of bright, primary colors?
- Adequate level of light? Use of natural light?
- Opportunities to sit, visit?
- Inviting smells, views?
- Disguised exits?
- Outdoor opportunities?
  - ✓ Courtyards
  - ✓ Fenced areas
  - ✓ Things to safely do outside

NDB: Part 1 of a 4-Part Series

Part 2: Disruptive Vocalizations
Part 3: Sleep Disturbance
Part 4: Wandering and Elopement

Content provided by:

Marianne Smith, PhD, ARNP, BC
Assistant Professor
University of Iowa College of Nursing

The University of Iowa | Iowa Geriatric Education Center

INFO-CONNECT

Disruptive Vocalizations

The Facts . . .

⇒ *Disruptive vocalization (DV) is a common problem among cognitively impaired older adults.*

⇒ *DV is common in long-term care settings, affecting as many as 10 to 30% of nursing home residents.*

⇒ *Adverse effects of DV can be huge - frustration for staff, irritability among other residents, retaliation toward the vocalizer, and stress for everyone involved.*

⇒ *Assessment of DV as a Need-Driven Dementia-Compromised Behavior (NDB) is the key to effective intervention.*

What is DV?

The term Disruptive Vocalization (DV) is used to describe verbal utterances that are:

- Excessively loud and/or repetitive in nature.
- Socially inappropriate due to the intensity, frequency, duration and/or setting in which they occur.
- Both distressed sounding and distressing to hear.
- The result of some form of brain injury, often severe dementia.
- Often indicative of unmet physical, psychological or social needs *or* a reaction to physical or environmental stress.

Also known as:

- Problematic vocalization
- Verbally agitated behavior
- Vocally disruptive behavior
- Aggressive vocalization
- Noisy behavior

Who exhibits this behavior?

The frequency, duration and intensity of the DV vary substantially:

- THE MAJORITY OF PERSONS WITH DV:
  - ⇒ Are vocally active for short, discrete periods of time, often in response to clearly identifiable stimuli.
  - ⇒ Exhibit behavior that is manageable.
- A SMALL MINORITY OF RESIDENTS WITH DV:
  - ⇒ Engage in DV without obvious provocation for many hours a day.
  - ⇒ Are called *Severe Disruptive Vocalizers*.

The greatest management problems are not the rare DVs of the many,

but the frequent DVs of the few.

Both types of behavior deserve assessment and intervention.

Why focus on DV?

Some believe DV is the most frequent, persistent and annoying of all dementia-related behaviors.

The adverse impact of DV can be huge, leading to:

- Frustration and distraction for staff;
- Anxiety and agitation for other residents;
- Retaliation toward or isolation of the person who vocalizes; and
- Increased stress for everyone involved.

In short, DV deserves our attention!

Types of DV:

- Includes a wide range of verbal expressions, ranging from the fluent use of words to repetition of nonsensical sounds.
- Can be roughly grouped into verbalization that is considered AGGRESSIVE or AGITATED as outlined below.

Verbally Aggressive Behaviors

The following are characteristics of verbally aggressive behaviors:

- Tend to be situation-specific.
- Duration is often time-limited.
- Behavior is a reaction to perceived threat like personal cares (e.g., being bathed).

Examples of these behaviors include:

⇒ Making threats of bodily harm
⇒ Cursing or swearing
⇒ Use of profanity or obscenities
⇒ Accusatory language
⇒ Threats
⇒ Sexual comments
⇒ Harassment
⇒ Racial insults
⇒ Name calling

Verbally Agitated Behaviors

The following are characteristics of verbally agitated behaviors:

- Tend to be generalized.
- Duration is longer-lasting (i.e., hours vs. minutes).
- Underlying causes are often difficult to detect.

Examples of these behaviors include:

⇒ Moaning
⇒ Yelling
⇒ Screaming
⇒ Nonsensical sounds or noises
⇒ Calling out
⇒ Repetitive questions
⇒ Grunting
⇒ Grumbling or negative comments
⇒ Constant talking

It is important to note that this division is arbitrary. Problems associated with DV are highly individualized.

Triggers to DV

Common antecedents or "triggers" to DV include:

- Overstimulation
- Understimulation, sensory deprivation
- Immobility, restricted movement
- Pain, discomfort
- Fatigue
- Psychotic symptoms
- Depression
- Psychological distress
- Caregiver behaviors
  - ⇒ Ignoring the person or behavior
  - ⇒ Telling the person to be quiet
  - ⇒ Asking the person why he/she is yelling

Medication Management

- Use medications only as an adjunct to behavioral interventions.
- Select medications with the lowest adverse side effect profile.
- Use standing doses, not prn, since effects are cumulative.
- Start at the lowest dose possible and titrate upwards.
- Change one medicine at a time to evaluate effectiveness.

Severe DV

Remember – severe DV occurs in the minority!

- Persist for hours each day in spite of "best interventions."
- Often do not respond to behavioral/medication interventions, or do not respond consistently.
- Same interventions that help for some will make others worse.
- Highly individualized approaches required.
- Prognosis per one large study: Good News and Bad News after 6 months:
  - ⇒ 66% vocalized fewer hours.
  - ⇒ 45% considered improved by nursing staff.
  - ⇒ 25% died.
- Believed to be part of terminal phase of disease, suggesting use of hospice approach.
- **The bottom line?** *Most severe DV problems require patience, but will probably resolve themselves.*

Managing Severe DV

- Provide staff education — frame as dementia-related behavior.
- Create one or more sound-proof bedrooms or quiet rooms.
- Provide ear plugs for staff who must provide care.
- Place near hearing impaired residents.

Info-Connect
Iowa Geriatric Education Center
2153 Westlawn
Iowa City, IA 52242

Non-Profit Org
U.S. POSTAGE
PAID
Permit No. 45
Iowa City IA

DV Interventions & Management Strategies

UNDERSTIMULATION

- Involve in social, leisure activities.
- Place near activities, traffic (e.g., nurses station).
- Increase environmental sounds (e.g., hair dryers, loud audiotapes via earphones or in room).
- Increase light, especially natural light.
- Place in vibrating or rocking chair.
- Use aromatherapy.
- Use pet therapy.
- Offer dolls, stuffed animals, or soft blankets.
- Maximize sensory function.

OVERSTIMULATION

- Decrease noise and commotion.
- Remove to quiet area.
- Use calm, quiet approach.
- Speak slowly and clearly.
- Avoid large group activities or congregate dining.
- Create home-like settings and routines.
- Adapt personal care routines to reduce fear and agitation.
  - ⇒ Provide privacy.
  - ⇒ Use one versus many caregivers.
  - ⇒ Tell person what you are doing and why.
  - ⇒ Slow down.
  - ⇒ Offer explanations.
  - ⇒ Use gentle touch and stay in visual field.

DEPRESSION

- Reduce or eliminate sources of stress and factors causing fear (e.g., room, roommate change).
- Offer talking options to discuss fear, anxiety, or grief.
  - ⇒ Day-to-day staff
  - ⇒ Family support, phone calls
  - ⇒ Chaplain services
  - ⇒ Therapist, counselor
- Slow down and listen to concerns.
- Remember fears are real to persons.
- Provide specific reassurance (e.g., methods to promote safety and comfort).
- Offer one-to-one activities to distract or redirect attention.
- Reminisce regarding strengths and positive experiences.
- Encourage involvement and socialization.
- Use antidepressant medications (see chart).

PSYCHOSIS

- Maximize sensory input.
  - ⇒ Increase lighting.
  - ⇒ Put on glasses.
  - ⇒ Use hearing aide.
- Reduce or eliminate illusions.
- Simplify the environment.
- Use validation principles to reassure.
- Redirect or distract to an alternative activity.
- Increase appropriate auditory or visual stimuli (e.g., music, old movie, or video of family).
- Speak slowly and clearly.
- Provide specific reassurance (e.g., “You are safe with me.”).
- Reminisce or review life history.
- Avoid confrontation or *you-are-wrong* messages.
- Use low-dose, high potency antipsychotics (see chart).

PAIN/DISCOMFORT

- Treat underlying diseases.
- Schedule toileting.
- Institute bowel protocols.
- Offer snacks and fluids.
- Employ exercise or range of motion activities.
- Reposition, stand, or change chairs.
- Schedule pain medications versus prn use.
- Titrate pain medications upward using alternative categories of pain relief (see chart).
- Assess and reassess pain level.
- Document nonverbal pain behaviors to justify medication increases or adjustments.

FATIGUE

- Regulate or control length of activities.
- Monitor number and type of appointments or visits.
- Adjust level of stimulation (see *Overstimulation).*
- Alternate high stimulus activities with low stimulus activities.
- Schedule quiet times.
  - ⇒ Rest in recliner
  - ⇒ Time out in room
  - ⇒ Naps of short duration

IMMOBILITY

- Ambulate or wheel person regularly.
- Escort outdoors.
- Offer choices for positioning.
- Reposition and turn often.
- Use alternative seating like recliners.
- Position in place person enjoys.
- Reduce or eliminate restraints.

GENERAL INTERVENTIONS

- Use massage and comforting touch.
- Provide specific reassurance (e.g., “You are safe with me.”).
- Avoid generalities (e.g., “It’s okay.” or “You’re fine.”).
- Provide a hot water bottle.
- Provide stuffed toys, soft objects, or dolls to hold.
- Make and play audiotapes of loved one’s voice.
- Use rocking chairs or beds.
- Make and play videotapes of loved ones at home, reminiscing or talking to resident.
- Play audiotapes of familiar sounds.
  - ✓ Heartbeat
  - ✓ Nature sounds, like ocean waves, wind or waterfall
- Play music.
  - ✓ Preferably personal cassette with headphones
  - ✓ Relaxing, classical tunes (e.g., Pachelbel’s Canon in D)
  - ✓ Favorite tunes from the past (e.g., hymn, western, big band)
- Engage in spiritual activities if indicated from past history.
- Use “white noise.”
  - ✓ Fan noise
  - ✓ Hairdryer blowing
  - ✓ Other loud, continuous noise that “drowns out” other sounds
- Use sound amplifier to provide direct feedback to person regarding volume of his/her voice.

DV: Medication Management

Antidepressants

Prescribed for vocalizers who exhibit symptoms of depression or mood disturbance.

- Persons with sudden unexplained vocalization or crying are good candidates.
- Low serotonin associated with impulsivity.
- Provides rationale for using medications with serotonergic properties like SSRIs.
- Many options:
  - ⇒ Citalopram
  - ⇒ Trazodone used because of sedating qualities
  - ⇒ Antidepressants used successfully to treat depression in past

Antianxiety

Prescribed for vocalizers with anxious appearance or features.

- Benzodiazepines should be used with caution due to potential negative side effects.
  - ⇒ Sedation with associated fall risk
  - ⇒ Disinhibition, making behavior worse
  - ⇒ Rebound anxiety on discontinuation after prolonged use
- Valuable in managing short-term anxiety (e.g., appointments, procedures).
- Low doses of short-taking medications preferred:
  - ⇒ Lorazepam
  - ⇒ Alprazolam
- Buspar may also be used.

Antipsychotics

Prescribed for vocalizers exhibiting psychotic symptoms, including hallucinations (unreal sensory experiences) or delusions (false, fixed beliefs).

- Medications with the fewest anticholinergic side effects are preferred.
- Literature review suggests use of:
  - ⇒ Risperidone as first line
  - ⇒ Haloperidol, olanzapine as second line
  - ⇒ Quetiapine or traditional low potency antipsychotics as third line
  - ⇒ Thiothixene also recommended by some
- Monitor extrapyramidal side effects (e.g., stiffness causing more discomfort).

Anti convulsants

Prescribed for severe DV, persons who are resistant to other therapies and who exhibit other agitated behaviors such as physical aggression.

- Used as mood stabilizers:
  - ⇒ Divalproate
  - ⇒ Carbamazepine
  - ⇒ Gabapentin
  - ⇒ Topiramate

Psychostimulants

Prescribed occasionally for persons who fail to respond to traditional antidepressants.

- ⇒ Methylphenidate
- ⇒ Dextroamphetamine

Other Options

- Acetylcholinesterase inhibitors
  - ⇒ Have been found to reduce cognitive and behavioral symptoms in dementia and theoretically should reduce DV.
  - ⇒ e.g., donepezil, galantamine, rivastigmine
- Electroconvulsive Therapy (ECT)
  - ⇒ Reported to eliminate DV in patients resistant to other medications, but use still quite controversial

A Service of the:

Iowa Geriatric Education Center
University of Iowa
2153 Westlawn
Iowa City, IA 52242
(319) 353-5756
http://www.healthcare.uiowa.edu/igec

Funded by
The Department of Health Resources and Services Administration (HRSA)

Content provided by:

Marianne Smith, PhD, ARNP, BC
Assistant Professor
University of Iowa College of Nursing

Julie Filips, MD
Geriatric Psychiatry Fellow
Department of Psychiatry
University of Iowa

Editorial review by:

Margo Schilling, MD
Associate Professor of Clinical Medicine
Division of General Internal Medicine
University of Iowa

THE UNIVERSITY OF IOWA

IOWA GERIATRIC EDUCATION CENTER

INFO-CONNECT

Sleep Disturbances

The Facts . . .

⇒ *Sleep pattern changes are part of normal aging, affecting both quantity and quality of sleep.*

⇒ *Persons with mental disorders, particularly dementia and depression, are more "at risk" for being awake at night.*

⇒ *Sleep disturbance in dementia is best understood by assessing it using the NDB model.*

⇒ *Sleep hygiene, which emphasizes personal habits and daily routines, is the "backbone" of managing both "normal" disturbances and those caused by mental disorder.*

Background Information:

The 3 W's of Sleep Disturbances

Sleep disturbance is a common and upsetting problem for adults of all ages. Although medication may be used as a short-term intervention, "sleep hygiene" — which calls for changes in daily routines and habits — is the foundation of longer-term solutions.

To understand and manage sleep disturbance, consider the "3 W's" as outlined below.

WHAT are sleep disturbances?

Sleep disturbances are various forms of insomnia. This refers to an inability to:

- Get to sleep
- Stay asleep
- Return to sleep after awakening
- Remain asleep early in the morning

WHY focus on sleep disturbances?

Insomnia is an important quality-of-life issue.

- It is a common problem in people of ALL ages!
- 1/3 of all adults report sleep problems.
- 1/2 of these individuals consider the problem serious.

WHO is "at risk"?

There are a number of groups who are especially at risk.

1. Advancing age alone increases the risk of sleep disturbance. Older adults report:
   - More hours in bed
   - Fewer hours asleep
   - Reduced quality of sleep
   - Associated with "normal" aging
2. Geriatric factors further increase risk:
   - Normal aging changes affecting sleep
   - Medical problems or other health conditions:
     - ⇒ Sleep apnea
     - ⇒ Restless legs
   - Medication side effects
   - Psychiatric conditions, like depression
   - Poor sleep hygiene
   - Environmental factors
3. Losses resulting from dementia further complicate risks. Sleep-wake disturbances:
   - Are a common problem due to circadian rhythm changes.
   - Are associated with more severe cognitive impairment.
   - Co-exist frequently with disruptive vocalizations (e.g., aggressive, disruptive, and agitated vocal behaviors).
   - Result in nighttime wandering, the second most common reason for placement.

Circadian Rhythm Disturbance

The circadian rhythm refers to the internal biological clock. It is important to consider this because it affects many levels of function.

Rhythm disruption in Alzheimer's disease is suggested by:

- Disrupted body temperature rhythms
- Disturbed circadian pattern of locomotor function
- End-of-day patterns in disruptive vocalization
- End-of-day patterns of overall agitation (e.g., sundowning)
- Seasonal variations in sundowning

Remember, brain changes disturb the person's natural daily rhythms and often contribute to sleep problems.

Thus, staff may need to adjust their expectations and better accommodate nighttime wakefulness.

Understanding the effect of circadian rhythm disturbance on residents is essential!

Assessment —
The Basis for All Interventions

Sleep disturbance in older adults is rarely caused by a single factor. Investigate and reverse all possible causes.

- ***Consider behavior as a Need-Driven Dementia-Compromised Behavior (NDB).***
  - ⇒ Review assessment parameters.
  - ⇒ Consider life-long patterns and habits.
  - ⇒ Place in context: Who is sleep disturbance a problem for?
- ***Rule out physical and medical causes.*** *STOP* ***and Ask . . .***
  - ⇒ Medical problem?
  - ⇒ Pain, need to void?
  - ⇒ Medication side effect?
  - ⇒ Psychiatric illness?
  - ⇒ Sleep apnea?
  - ⇒ Restless legs?
  - ⇒ Don't assume behavior is dementia-specific.
- ***Review NDB assessment parameters.***
  - ⇒ ***Overstimulation***
  - ⇒ ***Pain and discomfort***
  - ⇒ ***Depression***
  - ⇒ ***Psychosis***

4 Principles of Sleep Management

1. *Don't assume problem is "dementia-specific."*
2. *Identify and treat underlying or contributing causes of sleep disturbance.*
3. *Apply sleep hygiene principles.*
4. *Use medication on "as needed," intermittent basis only.*

Apply Suitable Treatment Approaches

Effective sleep management relies on individualized care practices that address the unique characteristics of the RESIDENT, the STAFF who provide care, AND the FACILITY ENVIRONMENT in which care is delivered.

Interactions between these three must be considered when addressing sleep disturbances.

- ***Identify and treat all concurrent problems first.***
- ***Then use behavioral interventions.***
  - ⇒ Keep a sleep diary, log.
  - ⇒ Apply principles of sleep hygiene.
- ***Medications are the last choice.***
  - ⇒ Consider risks and benefits.
  - ⇒ Use only "as needed."
- ***Individualize care and routines.***
  - ⇒ View the person a whole.
  - ⇒ Know person's history and personal preferences.
  - ⇒ Accommodate nighttime wakefulness.
  - ⇒ ASK: Who has the problem? (e.g., STAFF? FAMILY? PATIENT?)
  - ⇒ Do caregivers need to adjust their expectations? (e.g., All residents should sleep at night.)
- ***Create systems in which person can be up safely.***
  - ⇒ Nursing facilities
    - ❖ Allow to be up until tired again.
    - ❖ Encourage sitting in facility public area.
    - ❖ Suggest sitting in recliner to induce sleep.
  - ⇒ At home
    - ❖ Modify home to increase nighttime safety.
    - ❖ Use respite or trade care with family members.

Info-Connect

Iowa Geriatric Education Center
2153 Westlawn
Iowa City, IA 52242

Non-Profit Org
U.S. POSTAGE
PAID
Permit No. 45
Iowa City, IA

Interventions —
Principles of Sleep Hygiene

Sleep hygiene involves changes to certain daily routines and habits of residents. The regular utilization of good sleep hygiene strategies is necessary to manage residents' sleep disturbances.

- ***Apply patterns of living that contribute to sound sleep:***
  - ⇒ Eating, sleeping, resting, exercising
  - ⇒ Person-centered, individualized
  - ⇒ Affected by retirement, illness, institutional "routines"
  - ⇒ Goals:
    - ❖ Reestablish "habits."
    - ❖ Develop and maintain a routine.
- ***Rise and retire at the same time each day:***
  - ⇒ Keep up routine on weekends or days off.
  - ⇒ Consistency in habits is important.
- ***Exercise regularly – but not late in the day.***
- ***Get out in the sun, especially in late afternoon.***
- ***Eat meals on a regular schedule:***
  - ⇒ Avoid heavy meals close to bedtime.
  - ⇒ Light snacks are okay if hunger is an issue.
- ***Avoid daytime sleeping:***
  - ⇒ Naps should be no longer than 30 minutes.
  - ⇒ Rest in a recliner or on the couch.
  - ⇒ Use your bedroom for nighttime sleep.
  - ⇒ Don't lounge in bed (e.g., avoid reading, watching TV).
- ***Avoid caffeine, nicotine and alcohol.***
- ***Reduce night-time voiding urges:***
  - ⇒ Limit fluid intake after supper.
  - ⇒ Toilet before going to bed.
  - ⇒ Take diuretics early in the day if possible.
- ***Treat pain appropriately.***
- ***Regulate environmental factors:***
  - ⇒ Temperature too hot or cold?
  - ⇒ Noise?
    - ❖ Reduce or eliminate adverse stimuli (e.g., call systems, excessive noise at night, roommate snoring).
    - ❖ Consider nature sounds or soft music to calm and soothe.
    - ❖ Try white noise to mask sounds.
  - ⇒ Lighting?
    - ❖ Evaluate distractions (e.g., moonlight through window or hall light in eyes).
    - ❖ Balance safety with darkness.
  - ⇒ Personal comfort?
    - ❖ Bed clothing or blankets soft and comfortable?
    - ❖ Too hard? Too soft? "Just right"?

Medication Management

Medications should be used only as the final method of managing sleep disturbances, after careful consideration of the risks.

Nevertheless, the following medications can be effectively used on an "as-needed" basis.

- ***Barbiturates***
  - ⇒ Rarely used today, especially with elderly
  - ⇒ High abuse and dependence potential
- ***Chloral Hydrate***
  - ⇒ Old and effective hypnotic
  - ⇒ Gastric irritant
  - ⇒ Potential negative effects on CNS
  - ⇒ Potential for hangover
  - ⇒ Effective for select patients
- ***Benzodiazepines***
  - ⇒ Have antianxiety, muscle relaxant, anticonvulsant, and hypnotic properties
  - ⇒ Some have more hypnotic properties, others more anxiolytic
    - ❖ Higher hypnotic properties – *only* use for sleep
    - ❖ Higher anxiolytic properties – use for anxiety and sleep
  - ⇒ May be long-or short-acting
    - ❖ Long-acting, e.g., Flurazepam (Dalmane)
      - ✓ Increased risk of "hangover," daytime sedation
      - ✓ Associated increased risk of falling
    - ❖ Short-acting, e.g., Lorazepam (Ativan)
      - ✓ Less hangover
      - ✓ Greater risk of "rebound insomnia" when discontinued
    - ❖ Short-acting agents always preferred
  - ⇒ Associated Risks
    - ❖ Rebound insomnia possible when discontinued (e.g., patient has more difficulty sleeping)
    - ❖ Potential increased confusion in dementia
    - ❖ Tolerance, dependence potential with prolonged use (e.g., continuous use in excess of 4 weeks)
- ***Selective Benzodiazepines***
  - ⇒ Newest hypnotics (e.g., zolpidem (Ambien), zaleplon (Sonata)
  - ⇒ May have advantages over others
  - ⇒ Fewer cognitive and psychomotor side effects
  - ⇒ Fewer withdrawal effects
- ***Antidepressants***
  - ⇒ Commonly used with dementia
  - ⇒ Assume underlying depression that contributes to sleep disturbance
  - ⇒ Questionable effectiveness in non-depressed patients
  - ⇒ Antidepressants with sedating qualities are selected, given at bedtime
  - ⇒ Trazodone (Desyrel) good choice for many; sertraline (Zoloft); mirtazapine (Remeron) also used

- ***Antipsychotics***
  - ⇒ May be used in dementia
  - ⇒ Goal: Reduce anxious, fearful, agitated, psychotic behaviors that interfere with sleep
  - ⇒ Low dose often effective
  - ⇒ Common agents: risperidone (Risperdal); haloperidol (Haldol)
  - ⇒ Give at bedtime to exploit sedating side effects
- ***Antihistimines***
  - ⇒ Diphenhydramine (Benadryl) commonly used as sleep aid
  - ⇒ Included in many OTC sleep medicines (e.g., Nytol, Sominex; Anacin PM, Exedrin PM, Tylenol PM)
  - ⇒ Many risks for older adults
  - ⇒ Increased confusion, impaired cognition, morning sedation
- ***Melatonin***
  - ⇒ Natural element that increases sleep
  - ⇒ Value disputed in the literature
  - ⇒ No adverse effects
  - ⇒ What do we have to lose?

Geriatric Hypnotic Doses

MEDICATION	HALF LIFE	DOSE (mg)
Lorazepam	10-20	0.5 – 2
Oxazepam	3-21	10-15
Temazepam	10-20	15
Zolpidem	1.5-4	5
Zaleplon	1-2	5

- Diazepam, flurazepam and chlordiazepoxide are not recommended for older adults.

Table based on:
"Choice of Hypnotics in the Elderly," Virtual Hospital.

Sleep Disturbances:
Part 3 of a 4-Part Series

*The **N**eed-Driven **D**ementia-Compromised **B**ehaviors, or NDB, model of care can be easily applied to a variety of difficult-to-manage behaviors in dementia.*

This edition of Info-Connect is the third in a four-part series focusing on various NDBs:

Part 1: Need-Driven Dementia-Compromised Behaviors (NDB)

Part 2: Disruptive Vocalizations

*Look for the final Info-Connect in this series: **Wandering & Elopement**.*

Alternative Interventions

The following alternative interventions can also be used to promote sleep:

- Bright light therapy
  - ⇒ Apply light
    - ❖ Evening if early bedtime, early awakening
    - ❖ Morning if late bedtime, late awakening
  - ⇒ Value disputed in literature
  - ⇒ Sleep hours increase with light therapy
  - ⇒ Issue: Clinical vs. "statistical" significance?
- Relaxation principles
  - ⇒ Structured relaxation programs not practical in dementia
  - ⇒ Principles may be applied:
    - ❖ Low stimulus, relaxing activities
    - ❖ Back rub, facial or shoulder massage, warm bath, other "comfort" measures
    - ❖ Music therapy
    - ❖ Aromatherapy

A Service of the:

Iowa Geriatric Education Center
University of Iowa
2153 Westlawn
Iowa City, IA 52242
(319) 353-5756
http://www.healthcare.uiowa.edu/igec

Funded by
The Department of Health Resources and Services Administration (HRSA)

Content provided by:

Marianne Smith, PhD, ARNP, BC
Assistant Professor
University of Iowa College of Nursing

Judith H. W. Crossett, MD, PhD
Director of Geriatric Psychiatry
Department of Psychiatry
University of Iowa

Editorial review by:

Margo Schilling, MD
Associate Professor of Clinical Medicine
Division of General Internal Medicine
University of Iowa

THE UNIVERSITY OF IOWA

IOWA GERIATRIC EDUCATION CENTER

INFO-CONNECT

Great Escapes: The Wandering Dilemma

The Facts . . .

⇒ *Wandering is defined as ambulating behavior of a person with dementia who walks away from, or walks into, an area "without permission."*

⇒ *Elopement occurs when wandering extends outside the environmental "limits" of the person's home or facility.*

⇒ *Wandering is a common problem for persons with dementia — 36% of community dwellers wander; 65% of nursing home residents wander.*

Overview

Wandering regularly precedes elopement, and often is the only way to predict who is at risk.

Before creating an intervention program, the following general facts should be understood.

- **It causes substantial stress for caregivers.**
  - ⇒ Often leads to institutionalization
  - ⇒ Causes significant stress for nursing home staff
- **It is the source of many negative outcomes.**
  - ⇒ Restraint use and associated immobility
  - ⇒ Retaliation by other residents for "trespassing"
  - ⇒ Increased risk of falling and fractures
  - ⇒ Danger of exposure to elements
  - ⇒ Risk of getting lost or injured, or even death

Wandering Varies Considerably

Wandering behaviors vary from person to person, and from time to time. Take a minute to assess the following:

- What is the volume of ambulation?
  - ⇒ Paces for hours
  - ⇒ Is unable to sit down
- What is the quality or pattern of ambulation?
  - ⇒ Is unable to focus on eating
  - ⇒ Walks off during meals
- Does ambulation reveal spatial disorientation?
  - ⇒ Is unable to find what they are seeking
- Does ambulation transgress environmental limits?
  - ⇒ Wanders in and out of other residents' rooms
  - ⇒ Wants to leave
  - ⇒ Packs things up
  - ⇒ Stands at outer door
  - ⇒ Attempts to get outside
  - ⇒ Elopes

Four Common Patterns

1. *Direct Travel*
   - Movement from one location to another without diversion
2. *Random Travel*
   - Roundabout or haphazard movement to many locations within an area without interruption (the most common type)
3. *Pacing*
   - Repetitive back-and-forth movement within a limited area
4. *Lapping*
   - Repetitive travel characterized by circling large areas

Goals of Interventions

The multiple simultaneous goals of elopement intervention programs are to change:

- Wandering behaviors
  - ⇒ Improve way-finding
  - ⇒ Improve travel efficiency
- Physical environment
  - ⇒ Disguise exits
  - ⇒ Alter physical properties
- Social environment
  - ⇒ Activities
  - ⇒ Distractions
- Facility policies
  - ⇒ Staff training
  - ⇒ Drills
  - ⇒ Management of incidents

It is crucial to balance a person's rights and autonomy with his/her safety and the protection of other individuals.

Benefits of Wandering

It is important to realize that some forms of wandering might be beneficial. Some benefits that may result from these behaviors include:

- Preserves independence via autonomous activity.
- Supports self-determination and provides a sense of control.
- Provides exercise, increased circulation, and muscle toning.
- Prevents consequences of immobility.
  - ⇒ Deconditioning, muscle weakness, stiffness
  - ⇒ Stasis, orthostatic hypotension
  - ⇒ Urinary tract infection, pneumonia, decubitis ulcers

Risk Factors

The following risk factors are associated with wandering:

1. *Cognitive and neurological loss*

- Greater disease severity and duration
- Younger age at onset (AD)
- Lower scores on global cognitive performance
- Circadian rhythm disturbance, particularly sleep disturbance
- Poorer discrete cognitive skills, including greater impairment in:
  - ⇒ Memory, both short- and long-term
  - ⇒ Language
  - ⇒ Concentration or attention
  - ⇒ Visual-spatial/construction tasks
  - ⇒ Orientation
  - ⇒ Judgment
  - ⇒ Conceptualization
  - ⇒ Initiation and perseveration
- Impaired higher order cognitive and planning abilities observed in way-finding study, including:
  - ⇒ Reduced ability to form an overall plan to reach a goal
  - ⇒ Inability to detect relevant from irrelevant information, reducing ability to problem-solve
  - ⇒ Impulsive responses to stimuli, drawing them off track
  - ⇒ Inability to stop a search once the desired destination was found (e.g., a form of perseveration)

2. *Personal Factors*

- Reasonably good general health
  - ⇒ Better appetite
  - ⇒ Fewer medications
  - ⇒ Fewer medical conditions
- Pre-morbid patterns
  - ⇒ Motor behavior used as a means to cope with stress
  - ⇒ Walking part of daily habit
  - ⇒ Pre-morbid lifestyle or work involved outdoor activity
- Pre-morbid personality
  - ⇒ Active
  - ⇒ Sociable characteristics
- Personal comfort and experience
  - ⇒ Discomfort
  - ⇒ Boredom
  - ⇒ Stress or tension
  - ⇒ Lack of control
  - ⇒ Lack of exercise
  - ⇒ Nocturnal delirium
  - ⇒ Medical problems
    - ❖ Pneumonia
    - ❖ Constipation
    - ❖ CHF
  - ⇒ Language deficits
    - ❖ Cannot understand
    - ❖ Cannot make self understood
  - ⇒ Mood disturbance
    - ❖ Fear
    - ❖ Anxiety
    - ❖ Depression

3. *Environmental Factors*

- Unfamiliar environment
  - ⇒ Inability to way find
  - ⇒ Anxiety and fear
- Cues to leave (e.g., coat or keys by door)
- Cues to investigate or walk
  - ⇒ Long corridors
  - ⇒ Doors at end of corridor

Assessment

The following strategies can be used to assess wandering behaviors:

- Consider wandering and elopement as Need-Driven Dementia-Compromised Behaviors (NDB), caused by interaction between:
  - ⇒ Stable individual characteristics
  - ⇒ Ever-changing environmental triggers
- Describe behavior specifically: Who, what, when, where, how, how much, how long?
- ASK: Who has the "problem"? The person with dementia? The caretaker?
- Assess person's history and habits.
  - ⇒ What is his/her usual routine?
  - ⇒ Is this an extension of a normal activity pattern?
  - ⇒ What was his/her usual sleep-wake habit?
  - ⇒ What was his/her pre-dementia lifestyle?
- ASK: What are possible unmet needs? What environmental triggers exist?
  - ⇒ "SEARCHING?" – quest to find something familiar? (e.g., childhood home, food, bathroom, place to hide something?)
  - ⇒ "ESCAPING?" – flight from threat? (e.g., disturbing television, perceived harm?)
  - ⇒ "WITH PURPOSE?" – attempt to fulfill previous lifestyle responsibility? (e.g., child care, going to office, doing chores?)
  - ⇒ "AIMLESS MEANDERING?" – result of having nothing else to do? (e.g., bored, no meaningful activities, walking to entertain self?)

Interventions

The following interventions can be used to reduce wandering behaviors.

Environmental Adaptations

- Create "safe" wandering areas.
  - ⇒ Create halls and rooms that are free of hazards.
  - ⇒ Provide wandering "lounge" where persons can be safe and supervised.
  - ⇒ Divert persons away from kitchens, storage areas and outdoor exits.
- Camouflage existing exits.
  - ⇒ Use cloth panels across width of door to conceal door knob.
  - ⇒ Place full-length mirror in front of door.
  - ⇒ Paint (or wallpaper) door trim, wall, and door in same vs. contrasting color.
  - ⇒ Paint door knob to match color of door.
  - ⇒ Place mini-blinds or curtains over window of door to reduce outside view.
  - ⇒ Place drape or curtain over door to conceal from view.
  - ⇒ Use bright orange mesh netting across open doorway to "detour" persons.
- Place grid patterns at exits.
  - ⇒ Patterns create 3-dimensional appearance on 2-dimensional surface:
    - 8 horizontal stripes beginning 3 feet from door.
    - 8-stripe horizontal and vertical pattern in front of door.
- Provide cues with signs.
  - ⇒ Mark important destinations clearly, using both symbols and words.
  - ⇒ Use stop signs on exit doors.
  - ⇒ Place "Off Limits" signs by fence.
- Create "stopping places."
  - ⇒ Inviting spots to sit, converse, or rest
  - ⇒ Small, homelike settings to enhance socialization
  - ⇒ Simulated natures scenes indoors: bench, plants, aromas

Interventions

Environmental Adaptations (cont'd)

- Use working dog to protect exits.
  - ⇒ Should be trained to watch or guard exit from wanderers.
  - ⇒ Can guide residents back to living areas if an attempt is made to leave.
- Implement security systems and/or devices.
  - ⇒ Are commonly used but few studies to document effectiveness
  - ⇒ Allow limited wandering: motion detectors with remote chimes, night-lights, Dutch doors, surveillance cameras, door and window locks, alarms
  - ⇒ Reduce falling: pull-tab alarm, pressure-sensitive floor mat with alarm, monitor or surveillance camera, pressure-release chair or bed-mat with alarm, distance-monitoring device with alarm
  - ⇒ Use personal electronic devices: alarms set by individual "bracelet" on wanderer
  - ⇒ Tracking devices: post-elopement management
  - ⇒ May be frightening, stressful, and offensive (e.g., alarms)
  - ⇒ Thus, important to search out alternatives
    - Card-reading devices to silence alarms quickly
    - Key pad at entrance with sign instructing visitors to use code
    - Improved visual surveillance
- Use music to facilitate way finding.
  - ⇒ Play familiar tunes to introduce bedtime or mealtime.
  - ⇒ Cue arrival near bathroom or dining room with music.
- Develop secure (locked) units.
  - ⇒ Increased mobility and range of motion due to "freedom to wander"
  - ⇒ Allow more frequent nighttime wandering
  - ⇒ Distraction, alternative activities more common
  - ⇒ Restraints uncommon
- Create secure outdoor areas.
  - ⇒ Courtyards, gardens, parks, patios, or fenced areas
  - ⇒ Easy access with visibility from inside
  - ⇒ Walking paths, outdoor activities
  - ⇒ Adequate outdoor lighting
  - ⇒ Seating options (e.g., benches) to reduce pacing

Behavior Management

- Ignore the behavior if not a threat or hazard.
- Provide reality orientation when appropriate and not upsetting.
- Offer comfort measures.
  - ⇒ Food, fluids, warmth
  - ⇒ Pain management
  - ⇒ Relief from overstimulation and/or understimulation
  - ⇒ Other unmet personal needs
- Accommodate habits or traits.
  - ⇒ Trade rooms to change travel patterns.
  - ⇒ Move to interior of facility to reduce exit access.
  - ⇒ Place in highly supervised/monitored area.
  - ⇒ Position to facilitate way finding (e.g., in sight of bathroom).
  - ⇒ Reduce distractions in travel path to important locations.
- Reduce unsafe or excess wandering.
  - ⇒ Clarify intended destination; escort or direct to promote way finding.
  - ⇒ Provide rest periods.
  - ⇒ Distract to another repetitive activity like rocking or folding clothes.
  - ⇒ Distract from going "home" or "to work" via "validation" techniques or fantasy therapy.
    - "Bus is late", "tire flat"
    - "No transportation until tomorrow"
    - Telephone call to distract or inform of change in plan

Activity Principle: "Engage them or Chase Them"

- Structure activities to reduce stress or anxiety.
  - ⇒ Develop or maintain routines to balance activity with rest.
  - ⇒ Encourage "quiet time" with soft music.
  - ⇒ Create special activities like "Men's Club" to redirect or calm.
- Create diversion through normal, social, and recreational activities.
  - ⇒ Provide one-to-one or group activities to reduce boredom or increase socialization.
    - ❖ Modified craft or model work
    - ❖ 3-dimensional interactive wall art
    - ❖ Simulated cooking, baking, cleaning
    - ❖ Simplified recreational games
  - ⇒ Engage in normal activities (e.g., household chores, gardening).
  - ⇒ Offer person-centered work activities (e.g., mechanical, business, agricultural).
  - ⇒ Use ADLs as "activity" (e.g., grooming).
- Offer walking as a scheduled activity, indoors and/or outside.
  - ⇒ Volunteer-led, on-going programs
  - ⇒ Groups of 8-10 walkers
  - ⇒ Incorporate music, reminiscence to promote socialization while walking

Medication Management: Treat Possible Causes of Wandering

- Antipsychotics: Psychotic symptoms like hallucinations or delusions
- Antianxiety: Anxious, fearful, restless symptoms
- Antidepressants: Depression, anxiety, sadness, tearfulness
- Others reported in literature: Antiandrogens, sedatives (nighttime wandering), propranolol, acetylcholinesterase inhibitors (e.g., donepezil), fasudil hydrochloride

Early Intervention Program

- Increase safety while maintaining dignity.
  - ⇒ Sew labels, including name of person and name to contact, into outerwear in place of commercial labels.
  - ⇒ Purchase customized jewelry with engraved name of person to call if lost.
  - ⇒ Maintain recent photographs.
  - ⇒ Register person with *Alzheimer's Association Safe Return Program*.
- Develop and implement facility policies to guide actions.
  - ⇒ Establish written screening criteria to identify persons at risk for elopement.
    - ❖ Prior history of elopement at home or in facility
    - ❖ Degree of cognitive impairment, other neurological deficits
    - ❖ Long-standing patterns, lifestyle
  - ⇒ Outline use of surveillance equipment, alarms, or other electronic devices.
    - ❖ Stairwells, exits, individual electronic elopement devices
    - ❖ Methods to assure timely response, on-going use
  - ⇒ Develop an "Immediate Action Plan" that responds to elopement, including:
    - ❖ How lost resident will be identified
    - ❖ How search will be conducted
    - ❖ How each staff member is involved, including clear roles, responsibilities
    - ❖ When police will be involved
    - ❖ When family are notified, by whom
    - ❖ When or if *Safe Return* is used
  - ⇒ Develop and implement staff training programs to assure prompt, effective responses.
    - ❖ Dementia: causes, losses, behavioral symptoms
    - ❖ Pacing, wandering: types, possible consequences, management strategies
    - ❖ Facility-specific elopement management strategies and plan
  - ⇒ Use "elopement drills" like fire drills.
    - ❖ Have staff member "exit" as if wandering resident.
    - ❖ Initiate search.
    - ❖ Note methods used and time/place found.
    - ❖ Encourage staff involvement and problem-solving.
    - ❖ Maintain records for quality assurance.
- Develop personalized care plans.
  - ⇒ Address special needs of person's wandering or elopement risk.
    - ❖ Specific patterns
    - ❖ Documentation of frequency, duration
    - ❖ Range of potential interventions
    - ❖ Documentation of resident's responses
  - ⇒ Include family in discussion or plans.
    - ❖ Incorporate life history or possible triggers.
    - ❖ Identify strategies to distract or reassure.
- Involve ALL staff, especially "front-line" caregivers (i.e., nursing assistants).

Wandering & Elopement:

Part 4 of a 4-Part Series

Part 1: Need-Driven Dementia-Compromised Behavior (NDB)

Part 2: Disruptive Vocalizations

Part 3: Sleep Disturbances

Content provided by:

Marianne Smith, PhD, ARNP, BC
Assistant Professor
University of Iowa College of Nursing

Susan Schultz, M.D.
Geriatric Psychiatrist
Department of Psychiatry
University of Iowa

Antipsychotic Use in Dementia

Ryan Carnahan, PharmD, MS, BCPP; Jeffrey Reist, BS, PharmD, BCPS; Michael Kelly, BS, PharmD, MS; Susan Schultz, MD

Overview

This resource page provides the rationale and evidence for the "IA-ADAPT: Improving Antipsychotic Appropriateness in Dementia Patients" pocket guides and other resources as they relate to antipsychotic use. The bulk of this evidence comes from a systematic review of evidence for off-label use of antipsychotics, commissioned by the Agency for Healthcare Research and Quality (AHRQ). As of this writing, the last update was released on September 27th, 2011 [Maglione et al. 2011]. We encourage users to view the summary guides and full report on the AHRQ website for further details. http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=786

Other key sources of evidence for our pocket guides include Centers for Medicare and Medicaid Services (CMS) guidelines addressing use of antipsychotics in nursing homes [Centers for Medicare and Medicaid Services 2011], and other reviews and individual research studies.

This overview will summarize key points regarding antipsychotic use, as well as other commonly studied medication treatment options. The overview will at times discuss "conventional" (or "typical") antipsychotics. Conventional antipsychotics are mostly older agents, and generally pose a higher risk of movement side effects compared to the newer atypical antipsychotics. Atypical antipsychotics are occasionally referred to as "second generation" antipsychotics.

Before Considering an Antipsychotic

Antipsychotics should not be considered a first-line treatment for problem behaviors, or even psychosis, in people with dementia. They should only be considered when non-drug behavioral management strategies have been unsuccessful, and the behavior or target symptoms causes danger or severe distress to the person with dementia or others. This is because antipsychotics pose a serious risk of side effects, including an increased risk of death when compared to placebo [Jeste et al. 2008]. It is also important to thoroughly explore the possible causes of the problem behavior or psychosis, and address these causes before considering an antipsychotic. An exception may be short-term use in acutely dangerous emergency situations, where the antipsychotic may be used first for the immediate safety of the person or others and a full evaluation of the underlying source of the problem can then be conducted after the acute situation has resolved. Addressing possible causes of behaviors may include treating a medical condition; discontinuing medications; and altering the environment, routines, activities, caregiver approaches, or other factors that might be contributing to the problem. For further information on assessment and non-drug management strategies, please see *Algorithm for Treating Behavioral and Psychological Symptoms of Dementia: Assessment and Non-Drug Management*.

Appropriate and Inappropriate Treatment Targets for Antipsychotics

CMS guidelines for long-term care facilities list appropriate and inappropriate treatment targets [Centers for Medicare and Medicaid Services 2011]. To be considered an appropriate treatment target, a symptom must present a danger to the person with dementia or others, or cause the person with dementia to experience one of the following:

- Inconsolable or persistent distress
- A significant decline in function
- Substantial difficulty receiving needed care

Appropriate treatment targets include:

- Aggressive behavior
    - Includes particularly physically aggressive or violent behavior that cannot be managed using non-drug strategies (excluding restraints, since restraints have their own serious risks).
- Hallucinations
    - Most often includes seeing or hearing things that are not real. For example, hearing voices or seeing people who aren't there.
    - Antipsychotics should only be used if the hallucinations are distressing to the patient, or causing danger, a significant decline in function, or substantial difficulty providing needed care.
- Delusions
    - False beliefs that a person has in spite of evidence they aren't true. For example, a person may think his/her spouse is having an affair without any reason for believing it, or think family members are imposters.
    - It's important to recognize that, as dementia progresses, patients cannot discern what is real from what is not real. It generally is not helpful to argue with them about false beliefs, or to remind them of distressing things they've forgotten (e.g., the death of a spouse). This may worsen behaviors and agitation.
    - As with hallucinations, delusions should only be treated with an antipsychotic if they're distressing to the patient, or causing danger, a significant decline in function, or substantial difficulty providing needed care.

Inappropriate treatment targets include:

- Wandering
- Unsociability
- Poor self-care
- Restlessness
- Nervousness
- Fidgeting
- Mild anxiety

- Impaired memory
- Uncooperativeness without aggressive behavior
- Inattention or indifference to surroundings
- Verbal expressions or behaviors that do not represent a danger to the patient or others

Antipsychotics are not recommended for these symptoms because any benefits generally do not justify the risks. For most of these symptoms, antipsychotics would provide no benefit. It is also not considered appropriate to use an antipsychotic to induce sedation for the ease of caregiving, except perhaps in extreme cases where symptoms prevent medically necessary care and pose a risk to the person or others as a result.

Antipsychotic Selection

If an antipsychotic is considered necessary for a person with dementia, effectiveness and side effects should be considered when selecting a specific drug for a specific patient. The patient's comorbidities may help determine which side effects are most important to avoid. This will be discussed further under the side effects section.

Cost may also be a factor. Currently available generic medications with some evidence for efficacy in dementia include haloperidol, olanzapine, and risperidone. Olanzapine was not available in a generic form when our mini-lectures were filmed, so this is not noted in the lecture on antipsychotic selection.

Antipsychotic Efficacy/Effectiveness in Dementia

Atypical Antipsychotics: The AHRQ-funded evidence review addressing the off-label use of atypical antipsychotics summarized the strength of evidence for using atypical antipsychotics to treat agitation or psychosis in dementia. Readers should keep in mind that "agitation" is not an appropriate target symptom for antipsychotics, but rather refers to a cluster of symptoms that may include aggressive behavior or other appropriate treatment targets. The evidence review describes the results of randomized controlled trials of four atypical antipsychotics studied in people with dementia: aripiprazole (Abilify®), olanzapine (Zyprexa®), quetiapine (Seroquel®), and risperidone (Risperdal®). As of the time of this writing, there is no strong randomized controlled trial evidence supporting the efficacy of other atypical antipsychotics for this purpose. Table 1 summarizes the evidence on efficacy of atypical antipsychotics in dementia.

Table 1: Summary of Evidence for Efficacy of Atypical Antipsychotics in Dementia

	Aripiprazole (Abilify®)	Olanzapine (Zyprexa®)	Quetiapine (Seroquel®)	Risperidone (Risperdal®)
Dementia overall	**+ +**	**+**	**+**	**+ +**
Dementia psychosis	**+**	**+ / -**	**+ / -**	**+ +**
Dementia agitation	**+**	**+ +**	**+ / -**	**+ +**

+ + = moderate or high evidence of efficacy

+ = low or very low evidence of efficacy

+/ - = mixed results

As can be seen from Table 1, risperidone has the strongest and most consistent evidence suggesting that it is effective for agitation and psychosis in dementia. Aripiprazole is also rated as having strong evidence overall, based on global ratings of severity, though the evidence is rated low or very low for psychosis and agitation. "Dementia overall" should not be mistaken as an indication that these drugs improve cognition or other aspects of dementia beyond the appropriate treatment targets for antipsychotics. These categories reflect different types of measurement scales used in the studies. Olanzapine is rated as having moderate or high evidence of efficacy for agitation in dementia, but as having mixed results for psychosis. This relates to clinical trial results suggesting that olanzapine may worsen psychosis in some patients.

We do not recommend quetiapine as a first-line antipsychotic in dementia based on available evidence. Of four randomized controlled trials of quetiapine for agitation or psychosis in dementia, none have found that quetiapine is more effective than placebo on the main analysis of the primary outcome measure. A secondary analysis of one study suggested that 200 mg/day might be more effective than placebo, but this exceeds the CMS allowable maximum dose for chronic treatment in long-term care facilities (150 mg/day). Overall, the evidence in dementia studies, which mostly included people with Alzheimer's disease, suggests that it has minimal or no effectiveness. It is sedating, however, which may lead to the false appearance of efficacy due to somnolence.

Some studies also suggested that quetiapine worsens cognition in dementia [Ballard et al. 2005, Schneider et al. 2006]. This is not surprising since its active metabolite, norquetiapine, has anticholinergic properties [Seroquel XR® Package Insert 2011]. Anticholinergic medications are known to worsen cognition in dementia, and may be a risk factor for psychosis [Cancelli et al. 2009]. However, all the atypical antipsychotics summarized here showed some capacity to impair cognition and cause confusion in people with dementia, whether or not they are anticholinergic. Olanzapine appears to pose the greatest risk of this side effect [Schneider et al. 2006]. It is also highly anticholinergic, whereas risperidone and aripiprazole have negligible anticholinergic effects [Chew et al. 2008].

Conventional Antipsychotics: Unfortunately, conventional antipsychotics as a class have not been the subject of such a recent and thorough review on use in dementia as the atypical antipsychotics. In general, they also have not been studied in as large of clinical trials in dementia as the atypical antipsychotics, since they have been off-patent for many years. However, the Cochrane Collaboration has published systematic reviews on specific conventional antipsychotics in dementia, haloperidol and thioridazine [Lonergan et al. 2002, Kirchner et al. 2001].

The review on haloperidol suggested that it is effective for treatment of aggression in dementia at doses of 1.2-3.5 mg/day. It concluded that no strong evidence has been found of any significant general improvement of manifestations of agitation other than aggression [Lonergan et al. 2002]. It is notable that haloperidol has a higher risk of movement side effects (e.g., parkinsonism) than the atypical antipsychotics. In clinical trials in dementia, dropouts due to movement side effects were twice as common with haloperidol compared to placebo. Dropouts due to sedation were also twice as common with haloperidol [Lonergan et al. 2002]. Some patients may tolerate the drug, however, particularly at lower doses.

The review on thioridazine stated that there is "no evidence to support the use of thioridazine for dementia." It also notes that it is quite sedating, and has marked anticholinergic properties which may worsen cognition in people with dementia. The review generally recommends against using thioridazine in dementia [Kirchner et al. 2001].

In contrast to these reviews, older meta-analyses had difficulty identifying significant differences among conventional antipsychotics that have been studied for neuropsychiatric symptoms in dementia, despite finding some evidence for efficacy overall. A systematic review published in 2005, which reviewed these meta-analyses and other data, concluded that there is no clear evidence that conventional antipsychotics are effective for treating neuropsychiatric symptoms when defined broadly. This review affirmed the finding of the Cochrane review that haloperidol may have efficacy for reducing aggression [Sink et al. 2005]. It is notable that many low-potency antipsychotics (e.g., chlorpromazine) have potent anticholinergic properties, and can also cause substantial orthostatic hypotension.

Antipsychotic Side Effects Comparison

Antipsychotics are often referred to as 'conventional' or 'atypical' with atypical antipsychotics generally causing fewer extrapyramidal movement side effects compared to conventional antipsychotics. However, the broad categories of atypical versus conventional actually contain very diverse drugs within them. Haloperidol is the only conventional antipsychotic that is discussed in our pocket guides, because it is the only one for which efficacy in dementia is supported by a strong systematic review. Haloperidol does have a higher risk of extrapyramidal movement side effects compared to the atypical antipsychotics. This is reflected in Table 2, which can be found in our pocket guides. The most common extrapyramidal movement side effects include:

- Parkinsonism
    - Symptoms resembling Parkinson's disease, including tremor, tight muscles, cogwheel rigidity, shortened and unsteady gait, swallowing difficulties, and others. This is generally thought to be the most common extrapyramidal movement side effect in older people.
- Akathisia
    - Feeling of internal restlessness that leads to an irresistible urge to move or pace. Difficulty sitting still. This may look like agitation to an observer. This side effect is less frequent in older adults and restlessness more commonly occurs as a consequence of the dementia itself.
- Dystonia
    - Abrupt tensing or contraction of a muscle group that will not relax. Often this occurs in the muscles of the neck or trunk. The person is stuck in a position and can't move the muscles. This requires rapid treatment with anticholinergic drugs for resolution. Occasionally if an acute dystonic reaction does not resolve with anticholinergic medication (e.g., benztropine) , then a benzodiazepine may be necessary for resolution. An acute reaction may require parenteral treatment to achieve the necessary rapid response.
- Tardive dyskinesia
    - Side effect of longer-term use, often characterized by twitching of muscles in the face or trunk. This may be irreversible.

In addition to movement side effects, it is important to consider the risk of mortality with various drugs. All antipsychotics appear to increase mortality in people with dementia. The absolute risk has been estimated as 3.5% in people receiving antipsychotics compared to 2.3% with placebo. The relative risk is about 1.6-1.7. The number needed to harm is 83, meaning that for every 83 people approximately one additional death will occur in antipsychotic-treated patients. The number needed to treat has been estimated to range from 5-14 depending on the drug, meaning that 5-14 people have to be treated in order for one to respond to the antipsychotic. This means that for every 9-25 people helped by an antipsychotic, one death is associated with the antipsychotic treatment [Jeste et al. 2008].

Randomized controlled trials provide insufficient evidence to compare antipsychotics on the risk of mortality. All antipsychotics seem to increase risk of death [Jeste et al. 2008]. However, a growing body of evidence from observational studies examining both community-based and long-term care cohorts suggests that the risk may be higher with conventional antipsychotics. A large study of Medicaid beneficiaries residing in nursing homes using data from 45 states on over 80,000 patients found that about 30% of patients receiving conventional antipsychotics died within 180 days of initiation, compared to about 20% of those receiving atypical antipsychotics. The investigators used multiple contemporary approaches to adjust for patient characteristics and consistently found an elevated risk with conventional antipsychotics. These studies raise concern that conventional antipsychotics such as haloperidol may pose a higher risk of mortality compared to atypical antipsychotics [Huybrechts et al. 2011].

In addition to the increased risk of mortality, antipsychotics appear to increase the risk of stroke in people with dementia. In 2006, a pooled analysis of randomized controlled trials of atypical antipsychotics found that cerebrovascular events occurred in 1.9% of those receiving atypical antipsychotics compared to 0.9% receiving placebo [Schneider et al. 2006b]. The rate was not elevated with quetiapine, though the available data was insufficient to rule out risk. Observational studies have found comparable risk among people receiving conventional or atypical antipsychotics [Jeste et al. 2008].

Table 2 compares the antipsychotics on the risk of a number of other important side effects. We chose to use boxes and colors to compare risk of each side effect among antipsychotics instead of using specific numbers to illustrate side effect risk. This is because different sources provide different information, and it is difficult to decide which specific number to use as a rate. The evidence used to create this table comes from the AHRQ systematic review on off-label use of antipsychotics [Maglione et al. 2011], the CATIE-AD trial that compared antipsychotics in dementia [Schneider et al. 2006], two Cochrane systematic reviews [Lonergan et al. 2002, Ballard et al. 2006], and a review of the cardiovascular risks of atypical antipsychotics [Drici and Priori 2007]. The number of boxes reflecting risk should be interpreted as a qualitative and subjective summary of the various adverse event rates found from different sources, and not a reflection of absolute rates.

The table can be used to select a medication based on patient comorbidities. For example, olanzapine is probably a poor choice for a person with obesity, diabetes, or hyperlipidemia, since it may induce metabolic side effects on its own as well as exacerbate preexisting conditions. In a person who is sensitive to extrapyramidal movement side effects, haloperidol usually isn't the best choice. Quetiapine causes the most sedation, but has a very low risk of movement side effects. It might be an option for people at high risk of movement side effects, except that the vast majority of evidence suggests that it is ineffective.

Urinary symptoms related to antipsychotics were identified as a safety signal in the AHRQ systematic review [Maglione et al. 2011]. The comparison of drugs in this regard was difficult. The highest rate of urinary symptoms was reported in people receiving aripiprazole compared to what was reported with other drugs. Thus, it was assigned an extra box suggesting higher risk. However, the rate was also higher in the placebo groups in studies of aripiprazole, to the extent that the odds ratio for urinary symptoms with aripiprazole versus placebo was non-significant (OR 1.37, 95% CI 0.92-2.09). Thus, the higher rate may have actually reflected better reporting of urinary symptoms in these studies or differences in patient populations treated. The odds ratio for urinary symptoms was actually numerically highest with olanzapine despite a much lower reported rate of urinary symptoms (OR 9.51, 95% CI 1.47-401.07), next highest for quetiapine (OR 2.37, 95% CI 1.16-5.15), and next highest for risperidone (1.55, 95% CI 1.13-2.13). The numbers needed to harm were 16 for quetiapine, 21 for risperidone, and 36 for olanzapine. Ultimately, it is difficult to fully differentiate the risk of this side effect with these drugs given the variability in the rates among placebo groups in these trials.

Table 2: Antipsychotic Side Effects Comparison

Drug *Brand Name* (daily dose range)	Aripiprazole *Abilify* (2-10 mg)	Haloperidol *Haldol* (0.25-2 mg)	Olanzapine *Zyprexa* (2.5-7.5 mg)	Quetiapine *Seroquel* (12.5-150 mg)	Risperidone *Risperdal* (0.25-2 mg)
Movement Side Effects[1]	■■	■■■	■■	■	■■
Central Nervous System					
Sedation	■■	■■	■■■	■■■■	■■
Confusion, delirium, cognitive worsening	■	0	■■	■	■
Worsening psychotic symptoms	0	0	■	0	0
Cardiovascular/Metabolic					
Orthostatic hypotension	■?	■■	■	■?	■?
Edema	■?	0	■	0	■■
Weight gain/glucose ↑	0	■?	■■■	■	■■
Triglyceride ↑	0	0	■■■■	■■■	0
Urinary incontinence, UTI	■■■	■■	■■	■■	■■

■= more boxes indicates greater risk. Colors are darker with increasing risk.

■? = evidence poor in dementia, but evidence in other conditions indicates some risk

0 = no clear evidence that the drug causes this side effect in a clinically important way, or very rarely

[1] Movement side effects = parkinsonism, akathisia (restlessness), dystonia, tardive dyskinesia

Antipsychotic Dosing and Dosage Forms

Doses: CMS provides specific recommendations for antipsychotic doses that are acceptable for chronic use in long-term care facilities. These provide reasonable guidance for the dosage ranges that might be considered acceptable in patients with dementia. Occasionally, higher doses are used for acute treatment. Generally, starting with a very low dose is recommended to reduce the chance of side effects, and to ensure that the lowest necessary dose is used. The dose ranges considered acceptable by CMS for use in long-term care facilities are listed in Table 3.

Timing: Antipsychotics are usually given once daily at night prior to bedtime. This may help reduce sedation-related adverse effects. In patients with sundowning, or behaviors and psychotic symptoms that arise late in the day, they are sometimes given in the evening prior to the usual time of onset of symptoms. It is important to monitor for sedation-related adverse effects, especially when the drug is given some hours before bedtime.

Dosage Forms: Table 3 also describes various dosage forms that are available other than standard tablets. It should be noted that rapidly disintegrating tablets are absorbed at the same rate as standard tablets, according to pharmacokinetic studies of these drugs [Currier and Medori 2006]. They may offer advantages for patients with difficulty swallowing. Regular-release tablets may also be crushed and mixed with food such as applesauce in patients with swallowing difficulty.

Short-acting intramuscular injection preparations of antipsychotics can be used for emergency situations, but are generally not used if the patient will take oral medication. The table does not discuss the availability of long-acting injectable formulations. Haloperidol, olanzapine, and risperidone are available as long-acting injections, but would rarely if ever be recommended for someone with dementia.

We also recommend against the use of topical antipsychotic preparations that are sometimes compounded by pharmacies. We are unaware of any evidence to guide proper dosing, and it is unclear whether they are absorbed consistently or at all. As an example, a recent study of a topical gel containing haloperidol, lorazepam, and diphenhydramine found that no haloperidol or lorazepam was detectable in the blood stream up to 4 hours after application. Diphenhydramine absorption was minimal and erratic [Smith et al. 2011]. Uncertainties about absorption raise concerns about effectiveness, patient safety, and prescriber liability if an adverse event was to occur. While some patients may improve when given topical antipsychotic formulations, one has to ask whether it is because they are being given attention and touch when the formulation is applied, or whether it's really because of the antipsychotic contained in the topical formulation.

Table 3: Antipsychotic Dosing and Dosage Forms

	Starting Dose (mg/day)	**Maximum Dose for Maintenance*** (mg/day)	**Special Dosage Forms****
Aripiprazole	2-5	10	ODT, L , IM
Haloperidol	0.25	2	L , IM
Olanzapine	2.5-5	7.5	ODT, L , IM
Quetiapine	12.5-25	150	XR
Risperidone	0.25-0.5	2	ODT, L

*per CMS regulations for long-term care facilities. Doses for acute treatment sometimes exceed maintenance doses [CMS 2011].

**ODT = orally dissolving tablet, L = liquid, IM = short-acting intramuscular, XR = extended release.

Guidance for Special Populations: frontotemporal dementia, Parkinson's disease, Lewy body dementia, renal impairment, hepatic impairment

Frontotemporal Dementia (FTD)

FTD differs from other dementias in its pathophysiology and response to treatment. The frontal and temporal lobes of the brain that are primarily damaged are responsible for maintaining social appropriateness of behaviors, among other things. This damage can lead to socially inappropriate behavior, changes in personality, a lack of empathy for others, poor financial judgment, impulsiveness, and apathy. Language deficits are common, particularly problems with expression, naming difficulties, and difficulty remembering the meaning of words. Early in the disease memory is usually intact, though it worsens later. This is in contrast to Alzheimer's disease, in which social appropriateness is usually

maintained in the early stages of disease but memory problems are a major feature. Other symptoms of FTD can include overeating, including unusual compulsive dietary patterns. Parkinsonism can occur in certain types of FTD. Early symptoms of FTD are commonly misdiagnosed as primary psychiatric disorders [McKhann et al. 2001]. Though it makes up a relatively small proportion of dementias overall, FTD is about as common as Alzheimer's disease in people 45-64 years of age, occurring at a rate of about 15 per 100,000 people. Alzheimer's and other dementias are predominant among older age groups [Cardarelli et al. 2010].

Medications for Behavioral Symptoms in FTD

Clinical trials of various medications have been conducted for FTD, though medications have not been studied to the extent that they have in other more common types of dementia. Unfortunately, the results of most clinical trials have not been very promising to-date. Therefore, prescribing in clinical practice often comes down to trial and error, or N of 1 trials [Huey et al. 2006]. Small trials have been conducted suggesting possible benefits from certain medications, however, which provide some guidance when sorting through treatment options.

Antidepressants: Antidepressants that affect serotonin have been studied for behavioral symptoms in FTD, based in part on observations of damage to the serotonin system in FTD. Despite these observations, a number of studies were not able to show reductions in cerebrospinal fluid serotonin metabolites in FTD, though some studies found non-significant trends in that direction [Huey et al. 2006]. At least three small controlled studies of antidepressants have been conducted [Deakin et al. 2003, Moretti et al. 2002, Lebert et al. 2004].

Paroxetine (Paxil®) was studied at a dose of 40 mg/day in a 6-week randomized placebo-controlled trial for FTD patients. In contrast to open label studies suggesting a benefit of SSRIs on behavior, this study showed no benefit of paroxetine for behavioral symptoms. The trends in rating scales actually suggested that paroxetine might have worsened behavioral symptoms. Cognition was worsened significantly in the paroxetine group compared to placebo, possibly reflecting the anticholinergic properties of this drug [Huey et al. 2006, Deakin et al. 2003].

Paroxetine was studied at a dose of 20 mg/day in another 14-month randomized trial, compared to piracetam. The study included 8 patients per group. No differences were seen in cognition, with both groups worsening from baseline. However, neuropsychiatric symptoms improved in the paroxetine group, and were significantly less than with piracetam. Transitory nausea occurred in 3 of 8 patients who received paroxetine and resolved within 10 days. No other adverse effects were noted, other than worsening of agitation and aggressiveness in half of the piracetam-treated patients. It is difficult to determine whether both paroxetine and piracetam worsened cognition during this study, or if this was a result of disease progression and not the drug. Thus, this study is slightly more supportive of paroxetine use in FTD, particularly at this lower dose, but leaves unanswered questions about its safety [Moretti et al. 2002].

Trazodone, an antidepressant with mixed and unique pharmacology, was studied in 26 FTD patients in a double-blind placebo-controlled crossover study at doses up to 300 mg/day. In contrast to others, this study showed a significant decrease in neuropsychiatric symptoms with the drug, and no changes in cognition. Despite some efficacy, about half of patients had a treatment-emergent adverse event. These included fatigue, dizziness, hypotension, and cold extremities. It is difficult to discern whether the benefits observed in this study were due to anything other than sedation. However, this study suggests trazodone may be a reasonable option to help manage behaviors in FTD given the limitations of evidence on other treatments [Huey et al. 2006, Lebert et al. 2004].

Cholinesterase Inhibitors: Evidence on cholinesterase inhibitor use in FTD suggests little if any benefit, and potential harm in some subjects. The lack of benefit is consistent with observations that the cholinergic neural system remains relatively intact in FTD [Huey et al. 2006].

Only one randomized controlled trial of a cholinesterase inhibitor in FTD has been published to date. Galantamine (Razadyne®) was studied in a group of 36 FTD patients with either predominant behavioral manifestations or primary progressive aphasia. In this study, all patients received galantamine for 18 weeks. They were then randomized to either continued galantamine or placebo for 8 more weeks. No differences were identified in behavior or language for the group as a whole, suggesting that galantamine is not of benefit for behavioral symptoms. A subgroup of patients with primary progressive aphasia showed better global severity scores, but this was not statistically significant after adjusting for multiple comparisons. They also showed stable language scores in contrast to a decline in the placebo group. Overall, this study does not support the use of galantamine in FTD [Kertesz et al. 2007].

While not a randomized or placebo-controlled study, another open label trial examined donepezil (Aricept®) in 12 subjects for 6 months, using 12 FTD patients who did not receive donepezil as controls. The donepezil group had worse FTD Inventory scores after 6 months of treatment, despite similar scores between groups at baseline, suggesting a harmful effect of the drug. No changes in cognition or other measures were seen. Caregivers of 4 patients who received donepezil reported increased disinhibited or compulsive acts, which led to discontinuation of the drug. These problems returned to baseline levels after 4 weeks off of the drug. When these 4 patients were not included in the analysis, no differences between groups was seen. Overall, this study does not support the use of donepezil, and suggests that some patients may be vulnerable to behavioral worsening when they receive donepezil [Mendez et al. 2007].

Antipsychotics or Stimulants: Dopamine deficits have been found in FTD. This has led some to believe that stimulants may be helpful since they increase dopamine neurotransmission and improve executive function in some conditions (e.g., attention deficit hyperactivity disorder). A small amount of evidence supports this theory. Antipsychotics, in contrast, generally block dopamine, so they could conceivably worsen this condition. They are often used clinically to manage FTD behaviors despite a general lack of evidence to support their use. It is notable that some patients with FTD appear to be extra sensitive to extrapyramidal movement side effects of antipsychotics, possibly due to these dopamine deficits [Huey et al. 2006].

No randomized placebo-controlled studies of antipsychotics or stimulants in FTD were identified, though one cross-over study comparing a stimulant to an antipsychotic has been conducted [Huey et al. 2008]. Dextroamphetamine 20 mg/day and quetiapine 150 mg/day were compared in 8 patients with the behavioral variant of FTD in a double-blind cross-over trial, in which the order of drug was randomized. Each drug was given for 3 weeks, with a 1-week washout period between treatments. The study showed improvement in neuropsychiatric symptoms with dextroamphetamine compared to baseline, though there were no significant differences between quetiapine and baseline or quetiapine and dextroamphetamine. Though this study is small and thus preliminary, it suggests there could be some benefit to the use of stimulants. The long-term effect of these treatments in FTD remains unknown [Huey et al. 2008].

Parkinson's Disease and Lewy Body Dementia

Parkinson's disease dementia (PDD) and Lewy body dementia (LBD) share many similarities. Some have argued that the distinction is arbitrary since they are ultimately slightly different manifestations of the same underlying pathologic processes, possibly distinguished by the areas of the brain that are impacted first or to the greatest extent. Both commonly involve cognitive deficits, psychiatric manifestations, and movement disorders. PDD is diagnosed if motor symptoms occurred greater than 12 months prior to the onset of dementia. LBD is diagnosed if dementia symptoms occur before the onset of motor symptoms or within 12 months of the onset of motor symptoms [McKeith 2007].

LBD is characterized by visual hallucinations, fluctuations in attention and cognition, and parkinsonism. While one might expect hallucinations to respond to antipsychotics, these drugs are often harmful to patients with LBD. They can worsen attention and cognition, and lead to life-threatening neuroleptic malignant syndrome (NMS). NMS usually presents with rigidity and fever and autonomic fluctuations, among other symptoms. People with PDD are also more vulnerable to neuroleptic malignant syndrome. In general, people with PDD and LBD may have substantially slowed motor activity and slow cognition, but comparatively their memory may be more intact than other patients with dementia. For this reason, behavioral approaches that permit more time to complete tasks and conduct ADLs may be helpful in avoiding agitation and the need for antipsychotics.

People with PDD or LBD are also extremely sensitive to the extrapyramidal movement side effects of antipsychotics. Many treatments for the movement manifestations of these disorders work by increasing dopamine or stimulating dopamine receptors (e.g., dopamine agonists). Antipsychotics block dopamine, counteracting the effects of dopamine agonists, and thus worsen movement symptoms in people who already have a movement disorder at baseline. Thus, if antipsychotics are used it is best to choose one with a very low risk of movement side effects and use a very low dose. It is unclear that these drugs are effective in PDD and LBD, and even those with the lowest risk of movement side effects can cause severe reactions in these patients. The evidence is discussed further in the subsequent sections on specific drug classes.

Prior to considering an antipsychotic, it is important to consider that Parkinson's disease treatments such as dopamine agonists frequently worsen psychosis. It is often advisable to decrease the dose of antiparkinsonian medications to see if the psychotic symptoms resolve or become manageable prior to considering an antipsychotic [Weintraub and Hurtig 2007].

Medications for psychosis and related symptoms in PDD and LBD

The number of well-controlled studies of medications to treat neuropsychiatric symptoms in PDD and LBD is limited. However, those studies that have been conducted provide useful information. Medications that have been studied include cholinesterase inhibitors, memantine, and atypical antipsychotics. Evidence suggests that cholinesterase inhibitors, specifically rivastigmine, might lessen hallucinations and improve attention in some patients. Memantine appears to benefit global disease severity, but its effect on neuropsychiatric symptoms is unclear. Antipsychotics pose significant risks, and the few studies that have been conducted do not support their use in PDD and LBD.

Cholinesterase Inhibitors: Cholinesterase inhibitors have been studied to treat neuropsychiatric symptoms in PDD and LBD. Several small randomized placebo-controlled trials of donepezil in PDD showed no benefit on psychiatric symptoms. However, these studies included only people with minimal psychiatric symptoms at baseline [Weintraub and Hurtig 2007]. One large placebo-controlled 24-week study of rivastigmine in 541 patients with PDD was more positive. The rivastigmine group was less likely to report hallucinations as an adverse event [Emre et al. 2004, Weintraub and Hurtig 2007]. A follow-up analysis suggested that rivastigmine provided the greatest benefit for patients with hallucinations at baseline [Burn et al. 2006, Weintraub and Hurtig 2007]. This evidence complements case reports and observations of clinicians suggesting that cholinesterase inhibitors may reduce psychosis in PDD [Weintraub and Hurtig 2007]. Side effects of rivastigmine included nausea, vomiting, tremor, anorexia and dizziness. Movement symptoms overall did not differ between groups [Emre et al. 2004, Weintraub and Hurtig 2007].

Another randomized controlled 24-week trial compared donepezil to placebo in 550 patients with PDD [Dubois et al. 2009, Ballard et al. 2011]. The donepezil group performed better than the placebo group on one cognitive test but not another. The overall clinician-rated severity scores favored donepezil, but measures of activities of daily living and neuropsychiatric symptoms showed no difference from placebo. The benefit of donepezil is unclear from these data. It is notable that syncope and carotid sinus hypersensitivity leading to falls has been observed with donepezil [McLaren et al. 2003]. This may be a particular concern in PDD and LBD, since autonomic dysfunction is common. It is unclear whether cholinesterase inhibitors differ in their likelihood of inducing autonomic dysfunction [Ballard et al. 2011]. One randomized placebo-controlled trial evaluated rivastigmine in 120 patients with LBD [McKeith et al. 2000]. A composite neuropsychiatric symptom scale showed greater improvements with rivastigmine compared to placebo, though subscale scores for psychotic symptoms were not reported. Hallucinations at baseline did predict improvements in attention with rivastigmine treatment, however [McKeith et al. 2004]. Side effects included nausea, vomiting, anorexia, and somnolence. No difference in movement symptoms between groups was observed [McKeith et al. 2000, Weintraub and Hurtig 2007].

Overall the strongest data support the use of cholinesterase inhibitors in PDD or LBD, particularly those patients with hallucinations. The best evidence is for rivastigmine. The most common side effects are gastrointestinal, but cardiovascular effects leading to falls are also a concern.

Memantine: Memantine appears to have some benefit in PDD and LBD, and is well-tolerated. However, it is unclear whether it provides benefit for neuropsychiatric symptoms.

Memantine has been studied in 3 randomized placebo-controlled trials in people with PDD or LBD, ranging in size from 25 to 195 participants [Ballard et al. 2011]. All 3 studies allowed people with either a PDD or LBD diagnosis to participate. The smallest study showed that memantine was well-tolerated, and there was a trend towards better global outcomes with memantine [Leroi et al. 2009]. The 2 larger trials, both 24 weeks in duration, showed global improvements with memantine. In one, the memantine group showed improvement in neuropsychiatric symptoms but not cognition. In the other, the memantine group showed improvement in cognition but not neuropsychiatric symptoms. The studies also differed in whether people with PDD or LBD improved to a greater extent [Ballard et al. 2011]. Given the similarities in the pathophysiology and symptoms of these disorders, any observed difference in people classified as one or the other may be irrelevant. A secondary analysis of one study suggested that sleep improved in the memantine group, which has been suggested as a possible explanation for the global improvement observed with the drug [Ballard et al. 2011].

Overall, these studies suggest that memantine may benefit people with PDD or LBD, but they are inconclusive regarding any benefit for neuropsychiatric symptoms. Side effect rates were similar with memantine and placebo in all studies, suggesting that it is well-tolerated [Ballard et al. 2011].

Antipsychotics: The risks of antipsychotics in people with PDD or LBD cannot be overemphasized. Exacerbation of movement symptoms is a likely result of antipsychotic use, and in the worst cases severe reactions such as neuroleptic malignant syndrome (NMS) may be deadly. Cognitive problems may also result from antipsychotic use.

Quetiapine and clozapine have the lowest risk of extrapyramidal movement side effects. This is very likely because they rapidly dissociate from dopamine receptors [Seeman and Tallerico 1999]. They have thus been recommended as the antipsychotics of choice for psychosis in Parkinson's disease, and are sometimes used at very low doses to treat psychosis in this disorder [Weintraub and Hurtig 2007]. However, only one placebo-controlled study in PDD has evaluated an antipsychotic in PDD or LBD. Low-dose quetiapine was tested in patients with PDD, LBD, or Alzheimer's disease with parkinsonism and no benefit was seen [Kurlan et al. 2007, Weintraub and Hurtig 2007]. Other studies in people with Parkinson's disease and psychosis related to dopaminergic drugs have supported the efficacy of low-dose clozapine, but its impact when dementia is present is unclear [Weintraub and Hurtig 2007]. In addition, even clozapine has caused NMS in some patients with PDD or LBD [Ballard et al. 2011]. Clozapine is highly anticholinergic, and quetiapine has a highly anticholinergic active metabolite [Seroquel XR prescribing information, Young et al. 1998]. Thus, there may be a risk of cognitive

worsening in PDD and LBD since anticholinergics can impair cognition [Cancelli et al. 2009]. Use of clozapine is also complicated by the need for frequent blood draws to monitor for drops in white blood cell counts.

Overall, evidence suggests that antipsychotics should usually be avoided in PDD and LBD because of their substantial risks and questionable efficacy. Lowering the dose of dopamine agonists or other movement symptom treatments is recommended as a first option to treat psychosis. If an antipsychotic is deemed necessary for an extreme case, very low dose quetiapine or clozapine are probably better options than other antipsychotics because of the lower risk of movement side effects with these drugs. However, extreme caution and careful monitoring for adverse effects is needed.

Renal Impairment

Product labeling recommends caution and slow titration if risperidone is given to people with renal impairment. This is largely because it has an active metabolite that is eliminated by the kidneys (9-OH-risperidone, also marketed as paliperidone or Invega®). Product labels of other antipsychotics described in the pocket guides do not recommend dose changes in renal impairment.

In dementia, antipsychotics should be started at low doses and titrated slowly regardless of whether renal function is impaired. However, it is important to recognize that it will take longer to reach maximum steady state levels of risperidone and its active metabolite when renal function is impaired.

Hepatic Impairment

Product labeling recommends caution, slow titration, and possibly lower doses of olanzapine, quetiapine, and risperidone when used in people with hepatic impairment. All five antipsychotics highlighted in our tools are metabolized by the liver, so it is wise to use caution with all of them and generally titrate doses more slowly in people with severe liver problems.

Monitoring for Antipsychotic Response

The most important tip for monitoring for response is to be as specific and objective as possible when documenting problem behaviors or psychotic symptoms. A number of behavioral monitoring tools are available for this purpose. “Agitation” is not a good description of a behavior, for example, while "hitting," "kicking," or "biting" is more specific. The circumstances surrounding behaviors are also important to describe in documentation, since these may provide clues on what is triggering the behavior. With objective documentation, it’s possible to create charts to describe changes in behaviors over time. If behaviors lessened in severity and frequency after starting an antipsychotic, the drug may have been effective.

It is also important to keep in mind that behaviors change over time with or without drug treatment. If behaviors have been manageable for a while, it is very reasonable to reduce the dose or discontinue the antipsychotic to see if it’s actually necessary. While nursing home guidelines require documentation of dose reductions or reasons for not reducing the dose every six months, some experts recommend using

time-limited trials of antipsychotics and reducing the dose or discontinuing after only one or two months of treatment to determine if the drug is necessary. Studies of antipsychotic discontinuation in dementia have shown that many people do not get worse when the antipsychotic is removed, and some actually get better [Thapa et al. 1994, Ballard et al. 2008, Ballard et al. 2011]. Long-term follow-up of one antipsychotic discontinuation trial showed a higher risk of death in people who continued their antipsychotic (mostly risperidone and haloperidol) compared to those randomized to placebo [Ballard et al. 2008, Ballard et al. 2011]. In addition, there were no differences in symptoms between groups after randomization to antipsychotic discontinuation, suggesting that most were not benefiting from continued antipsychotic use. However, there was some suggestion that those with higher levels of neuropsychiatric symptoms at baseline may have benefited from continued treatment [Ballard et al. 2008].

Monitoring for Antipsychotic Adverse Effects

Antipsychotics can cause a multitude of adverse effects. Some of the most catastrophic adverse effects of antipsychotics include falls leading to fracture, stroke, arrhythmias, neuroleptic malignant syndrome, and death. Other adverse effects include extrapyramidal movement side effects, sedation, confusion or worsened cognition, worsening psychotic symptoms, orthostatic hypotension, edema, weight gain, hyperglycemia or diabetes, triglyceride increases, and urinary problems such as urinary tract infection, incontinence, or urinary retention.

Monitoring for many of these adverse effects should occur through carefully observing the patient. Any significant change in health status or new symptom should prompt a more thorough evaluation.

Adverse effects such as orthostatic hypotension, other changes in blood pressure, weight gain, and changes in blood sugar or lipids can be monitored objectively. The recommendations on the pocket guides for glucose and lipid monitoring are based on an expert consensus panel's recommendations for people receiving atypical antipsychotics [American Diabetes Association et al. 2004]. They were not developed specifically for people with dementia who receive these drugs, so providers should use their judgment on whether exceptions should be made. Often people with dementia suffer from weight loss, so weight gain is not always an undesirable effect [Smith and Greenwood 2008]. Hunger induced by some antipsychotics could conceivably result in agitation in some patients, however [Balt et al. 2011]. Other objective monitoring recommendations are based on the time of onset of the adverse effect, as-needed assessments, and standard assessment schedules for nursing home residents.

Some adverse effects can be evaluated using rating scales. For example, the Abnormal Involuntary Movement Scale is the most commonly used scale to assess tardive dyskinesia, a late onset movement side effect that can be permanent. It should be administered at baseline and every six months in people receiving antipsychotics, and also if any new abnormal movements are noted.

Antipsychotics can prolong the QTc interval in a dose-dependent manner, which may contribute to arrhythmias and sudden death. While a baseline electrocardiogram (ECG) is often recommended for people receiving antipsychotics, it is not always done since it is impractical for some settings and

patients. Providers should especially consider monitoring ECGs in people with known cardiovascular disease, a history or family history of syncope, electrolyte disturbances, or who are receiving other drugs that prolong the QT interval [Gupta et al. 2007, Vieweg et al. 2009]. A list of drugs that prolong the QT interval can be found at http://www.azcert.org/medical-pros/drug-lists/bycategory.cfm.

Recommendations for monitoring for antipsychotic side effects can be found in Tables 4 and 5, excerpted from the pocket guides. Note that the Table 4 is meant for clinicians. Table 5 is meant for direct care providers with less training on health conditions and medication side effects. It provides more details of specific observations that should prompt them to contact a clinician or prescriber to further evaluate a sign or symptom.

Table 4: Monitoring for Antipsychotic Side Effects: Clinician Table

Other possible adverse effects include: falls, constipation, urinary tract infection, urinary incontinence or retention, stroke, arrhythmias, and neuroleptic malignant syndrome.

Side Effect	Monitoring
Movement Side Effects	Observation for tremor, gait changes, difficulty swallowing, signs of parkinsonism, restlessness (akathisia), unusual movements (tardive dyskinesia).
	Abnormal Involuntary Movement Scale (AIMS) at baseline, every 6 months, or if movement side effects are suspected.
Central Nervous System	
Sedation	Observation, sedation scale if needed.
Confusion, delirium, or other cognitive worsening	Observation for mental status or behavior changes.
	Delirium screening tool, e.g., CAM (Confusion Assessment Method) if delirium is suspected.
Psychotic symptoms	Observation for worsening symptoms.
Cardiovascular / Metabolic	
Orthostatic hypotension	Observation for signs of dizziness or falls.
	Orthostatic blood pressure (if feasible). Monthly, or if signs of dizziness occur. More frequent on initiation or after dose increase.
Edema	Observation for swelling of extremities.
Weight gain	Monthly weight. Consider weekly for 1 month if overweight. Watch for increased appetite.
Hyperglycemia / Diabetes	Blood glucose at baseline, 3 & 6 months, then q6 months. Also PRN symptoms or mental status change. Monitor symptoms: increased thirst, urination, hunger, weakness.
Triglyceride ↑	Fasting blood lipid panel at baseline, 3 & 6 months, then q6 months. Especially if patient has cardiovascular risk factors: e.g., obesity, diabetes, hyperlipidemia.

Table 5: Monitoring for Antipsychotic Side Effects: Direct Care Provider Table

Side Effect	Report to RN or prescriber if these problems occur
Movement Side Effects	Tremors, tight muscles, changes in walking or falls, abnormal movements like face or eye twitching, drooling.
Central Nervous System	
Sedation	Sleepiness, slow to respond, hard to wake up.
Confusion, delirium, or other cognitive worsening	Worsening mental status compared to normal. Seems more confused; sedated or agitated; worsened communication abilities; problems paying attention; slower movements or speech. These may be a sign of a serious medical illness or a drug side effect.
Worsening psychotic symptoms (delusions or hallucinations)	Hallucinations: seeing, hearing, smelling, tasting, or feeling things that aren't there. Delusions: false fixed beliefs that a person holds in spite of evidence they aren't true. Antipsychotics usually lessen these symptoms, but sometimes make them worse.
Cardiovascular / Metabolic	
Rapid drop in blood pressure on standing	Signs of dizziness or falls. Check an orthostatic blood pressure by checking the blood pressure when lying down and then again shortly after standing. Drugs sometimes cause an unwanted drop in blood pressure.
Swelling	Swelling is most common in the legs and ankles, but can occur in other places.
Weight gain	Big increases in appetite. Hungry even after eating. Unwanted increases in weight.
High blood sugar	Confusion, increased thirst, frequent urination, unusual tiredness, blurred vision. Blood sugar can be checked to see if this might be the cause of these symptoms.
Urinary Symptoms	Changes in frequency—increased, or decreased with urinary retention. Worsened incontinence. Pain on urination. May be infection or drug-related problem.
Constipation	Fewer bowel movements. Hard stools. Poor appetite. Gut pain or distention.

Other Options for Drug Therapy to Manage Problem Behaviors or Psychosis

Many drug therapies have been studied for the treatment of problem behaviors and psychosis in dementia. Few have been shown to be effective when studied in randomized controlled trials, the study design that provides the strongest evidence. This section summarizes evidence for several treatment options that have been historically used in clinical practice. It is notable that most are not recommended given currently available data, while evidence is mixed on others such as antidepressants. A pain control algorithm even in the absence of an identified source of pain was also effective in a recent trial. This evidence applies mostly to Alzheimer's disease, and in some cases to mixed or vascular dementia. Evidence on treatment of frontotemporal dementia, Parkinson's disease dementia, and Lewy body dementia is discussed under the Guidance for Special Populations section on page 9 of this review.

Pain Control

Uncontrolled pain can contribute to behavioral and psychiatric symptoms in people with dementia [Tosato et al. 2011]. People with dementia can have difficulty communicating about their pain, so agitation may sometimes reflect uncontrolled pain. A recent cluster randomized trial using a stepwise pain medication protocol and staff training to improve management of pain found that this reduced agitation in nursing home residents with dementia. It is important to note that these patients were not selected because they were known to be in pain, but rather because they had shown symptoms of agitation for at least a week. The treatment steps and percent of the intervention group receiving them included: step 1—acetaminophen (68%), step 2—oral morphine (2%), step 3—buprenorphine transdermal patch (23%), and step 4—pregabalin (7%). This intervention was effective in reducing agitation in the 8-week trial. Agitation worsened in the 4 weeks after the intervention was discontinued, providing further support that the intervention was effective. Activities of daily living measures and cognition were similar between groups [Husebo et al. 2011].

While factors such as staff training need to be considered when interpreting these results, they support the effectiveness of pain management for reducing agitation. The majority of patients in the intervention group received only acetaminophen, a relatively safe medication at appropriate doses. Therefore, acetaminophen may be considered a first-line treatment for agitation without a known cause. Other pain medications should also be considered if the patient shows signs and symptoms consistent with poorly controlled pain.

Anticonvulsants

Valproate (Depakote®) and carbamazepine (Tegretol®) have been studied to treat agitated behaviors in dementia in randomized controlled trials. Valproate has consistently been found to be ineffective [Lonergan and Luxenberg 2009]. In the most recent and largest study to date, it was found to be ineffective and harmful [Tariot et al. 2011]. The group receiving valproate showed a more rapid cognitive decline than those receiving placebo. The hippocampus, an area of the brain related to memory, also reduced in volume to a greater extent in the valproate group compared to placebo [Fleisher et al. 2011]. Thus, it is possible that valproate accelerates brain damage in dementia. Other noteworthy side effects of valproate include movement disorders (e.g., tremor and gait disturbances),

sedation, diarrhea, and weakness [Tariot et al. 2011]. Given the available evidence, we recommend against the use of valproate.

The little evidence regarding the effectiveness of carbamazepine for agitation or aggression in dementia has been mixed [Sink et al. 2005, Konovalov et al. 2008]. Many clinicians do not use it because of side effects. Drug interactions are also problematic. Early side effects of carbamazepine include ataxia, cognitive impairment, sedation, and nausea. Many of these side effects decrease after time on the drug, but tolerability remains a concern, especially since studies in older people with dementia have not characterized long-term safety and tolerability. In addition, carbamazepine is a strong inducer of cytochrome P450 enzymes 2C19 and 3A4, which are important to the metabolism of many drugs. Use of carbamazepine requires careful attention to these drug interactions and their effect on other drug therapies received by the patient. It is difficult to recommend carbamazepine as a first-line medication given the limited evidence and concerns about adverse effects, though it might be a reasonable option to try for some patients with close monitoring for adverse effects and drug interactions.

Antidepressants

Antidepressants have been studied for both agitation and depression in people with dementia. The bulk of the evidence suggests that they are not very effective, if at all, for treating depression in people with dementia [Bains et al. 2002]. Limited and inconsistent evidence suggests certain antidepressants may reduce agitation and psychosis in people with dementia [Seitz et al. 2011].

Depression: Recent randomized controlled trials have evaluated sertraline (Zoloft®), a selective serotonin reuptake inhibitor (SSRI), for depression in dementia. The largest found no benefit [Rosenberg et al. 2010]. Some believe that an earlier trial showed small positive effects because the inclusion criteria were stricter and captured more severe depression. A key difference was that the earlier trial required a one-week placebo run-in period to confirm that depression was persistent (i.e., both groups get placebo and people who respond are excluded thereafter so that only more persistent depression is included) [Lyketsos et al. 2003]. Mood often fluctuates in dementia, so a person may look depressed at one time point but shift to a better mood with time and positive interactions. Another proposed explanation was that caregivers were provided training and support in the more recent trial in which sertraline was no more effective than placebo. Both the sertraline and placebo groups showed improvement, suggesting that caregiver training and support may be more important than the medication in improving depressive symptoms for people with dementia [Lyketsos 2010]. Despite the mixed evidence, it may be reasonable to consider an SSRI for more severe and persistent cases of depression in people with dementia. However, the possibility needs to be considered that the presence of dementia limits the effectiveness of these treatments, even though they are often effective in people without dementia and may be modestly effective even in the context of dementia.

More common side effects of SSRIs include headache and gastrointestinal disturbances such as diarrhea or nausea. Hyponatremia (low sodium levels) due to syndrome of inappropriate antidiuretic hormone secretion is another side effect to be aware of in older people. This can lead to confusion or delirium,

irritability, fatigue, headache, gastrointestinal symptoms, and other symptoms. SSRIs may also increase the risk of falls, bleeding (e.g., GI bleeds), parkinsonism, and akathisia (restlessness), among other less common side effects [Murphy et al. 2008, Spigset 1999, Jacob and Spinler 2006].

Agitation and Psychosis: Some randomized controlled trials suggest certain antidepressants may produce slight reductions in agitation and psychotic symptoms compared to placebo, but the evidence is mixed and most studies were relatively small. Therefore additional research is recommended by the authors of a systematic review on the topic [Seitz et al. 2011].

SSRIs: Studies of sertraline (Zoloft®) and citalopram (Celexa®), another SSRI, showed slight reductions in agitation and psychotic symptoms with these drugs compared to placebo. Combined analysis of all studies of SSRIs versus placebo also showed some benefit, though this finding was mostly due to one large study. Not all studies showed advantages of SSRIs over placebo. Citalopram had similar efficacy to risperidone, an atypical antipsychotic, in one study, with fewer adverse events. Three studies that compared SSRIs to conventional antipsychotics (haloperidol—2 studies, perphenazine—1 study) did not show statistically significant differences between the SSRIs and antipsychotics, even when the studies were combined and analyzed in a meta-analysis. It is likely that the small sample sizes in these studies may have kept them from identifying differences in safety and efficacy. Overall, there is some evidence that citalopram or sertraline might reduce agitation or psychosis in some patients. Given the side effects of antipsychotics, it would not be unreasonable to consider citalopram or sertraline as a treatment option despite the mixed evidence [Seitz et al. 2011].

Trazodone: Trazodone has also been studied in people with dementia and agitation or psychosis in randomized controlled trials. It is sometimes used for its sedative properties, which some think may be helpful in calming an agitated person. Occasionally prescribers use small doses (e.g., 25 mg) multiple times a day for the sedative effects. As far as evidence, one study compared trazodone to placebo and found no differences in efficacy or tolerability. Two studies compared trazodone to haloperidol, and also found no statistically significant differences in efficacy or tolerability. It is notable that all of these studies were small, which limits their ability to identify differences between treatments. Overall, the evidence on trazodone for treatment of agitation or psychosis is inconclusive, so it is difficult to make a strong recommendation for or against its use. Possible side effects to consider include orthostatic hypotension, falls, and over-sedation, among others [Seitz et al. 2011].

Benzodiazepines

Benzodiazepines are generally not recommended for use in dementia. Case reports and other evidence suggest their use can worsen confusion and increase risk of falls. Cases of paradoxically increased agitation have also been observed in dementia, which may be due to disinhibition related to intoxication by these drugs. Generally, benzodiazepines worsen cognition and should be avoided. Expert consensus recommendations reinforce this position. The occasional use of benzodiazepines for acute anxiety may be acceptable, but they should not be used long-term [Sink et al. 2005]. In particular, long-acting benzodiazepines such as clonazepam and diazepam have a greater likelihood of inducing adverse events

such as falls in the elderly than short-acting benzodiazepines. The duration of action is essentially equivalent to the duration of risk with benzodiazepines, and long-acting benzodiazepines may accumulate over time and cause excessive sedation.

Cholinesterase Inhibitors

Most studies of cholinesterase inhibitors for dementia have not been designed to address their effects on neuropsychiatric symptoms, such as problem behaviors and psychosis. Small benefits have been seen in some trials and a meta-analysis comparing the effect of these drugs and placebo on neuropsychiatric symptoms. The differences were small and not likely to be clinically significant. In addition, studies that have examined these drugs specifically for patients with neuropsychiatric symptoms have shown no benefit. Therefore, these drugs are not recommended specifically to treat problem behaviors or psychosis in dementia [Sink et al. 2005]. Lewy body dementia or Parkinson's disease dementia are exceptions, since cholinesterase inhibitors appear to reduce fluctuations in consciousness and hallucinations in some patients [Ballard et al. 2011, Ballard et al. 2009].

Memantine

Similar to cholinesterase inhibitors, most studies of memantine did not use the drug specifically to target problem behaviors or psychosis. Two studies in people with moderate to severe Alzheimer's disease that examined neuropsychiatric symptoms as secondary outcomes had differing results. One found no difference between memantine and placebo. The other showed a slight worsening of symptoms in the placebo group and no significant change in the memantine group, but this difference was small and of questionable clinical significance. Thus, there does not appear to be an important benefit of memantine on these symptoms. Based on these data, the decision to use or not use memantine should probably not be driven by the presence of problem behaviors or psychosis [Sink et al. 2005].

References

American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, North American Association for the Study of Obesity. Consensus development conference on antipsychotic drugs and obesity and diabetes. *Diabetes Care*. 2004;27(2):596-601.

Ballard C, Hanney ML, Theodoulou M, et al. The dementia antipsychotic withdrawal trial (DART-AD): long-term follow-up of a randomized placebo-controlled trial. *Lancet Neurol*. 2009;8:151-7.

Ballard C, Kahn Z, Corbett A. Treatment of dementia with Lewy bodies and Parkinson's disease dementia. *Drugs Aging*. 2011;28(10):769-77.

Ballard C, Lana MM, Theodoulou M, et al. A randomized, blinded, placebo-controlled trial in dementia patients continuing or stopping neuroleptics (the DART-AD trial). *PLoS Med*. 2008;5(4):e76. doi:10.1371/journal.pmed.0050076.

Ballard C, Margallo-Lana M, Juszczak E, et al. Quetiapine and rivastigmine and cognitive decline in Alzheimer's disease: randomized double blind placebo controlled trial. *BMJ*. 2005;330(7496):874-8.

Ballard CG, Waite J, Birks J. Atypical antipsychotics for aggression and psychosis in Alzheimer's disease. *Cochrane Database of Systematic Reviews*. 2006, Issue 1. Art. No.: CD003476. doi:10.1002/14651858.CD003476.pub2

Balt SL, Galloway GP, Baggot MJ, Schwartz Z, Mendelson J. Mechanisms and genetics of antipsychotic-associated weight gain. *Clin Pharmacol Ther*. 2011;90(1):179-183.

Burn D, Emre M, McKeith I, De Deyn PP, Aarsland D, Hsu C, Lane R. Effects of rivastigmine in patients with and without visual hallucinations in dementia associated with Parkinson's disease. *Mov Disord*. 2006;21:1899-1907.

Cancelli I, Beltrame M, D'Anna L, Gigli GL, Valente M. Drugs with anticholinergic properties: a potential risk factor for psychosis onset in Alzheimer's disease? *Expert Opin Drug Saf*. 2009;8(5):549-57.

Cardarelli R, Kertesz A, Knebl JA. Frontotemporal dementia: a review for primary care physicians. *Am Fam Physician*. 2010;82(11):1372-7.

Centers for Medicare and Medicaid Services (CMS). State Operations Manual: Appendix PP: Guidance to Surveyors for Long-Term Care Facilities. Revision 70: 01-07-11. Accessed 11/23/11 at: http://www.cms.gov/manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

Chew ML, Mulsant BH, Pollock BG, et al. Anticholinergic activity of 107 medications commonly used by older adults. *J Am Geriatr Soc*. 2008;56:1333-41.

Currier GW, Medori R. Orally versus intramuscularly administered antipsychotic drugs in psychiatric emergencies. *J Psychiatric Pract*. 2006;12:30-40.

Deakin JB, Rahman S, Nestor PJ, Hodges JR, Sahakian BJ. Paroxetine does not improve symptoms and impairs cognition in frontotemporal dementia: a double-blind randomized controlled trial. *Psychopharmacology*. 2003;10:10.

Drici MD, Priori S. Cardiovascular risks of atypical antipsychotic drug treatment. *Pharmacoepidemiol Drug Saf*. 2007;16(8):882-90.

Dubois B. A randomized controlled trial of donepezil for the treatment of Parkinson's disease dementia [abstract]. Presented at International Conference on Alzheimer's Disease (ICAD); 2009 Jul 11-16; Vienna.

Emre M, Aarsland D, Albanese A, Byrne EJ, Deuschl G, De Deyn PP, Durif F, Kulisevsky J, van Laar T, Lees A, Poewe W, Robillard A, Rosa MM, Wolters E, Quarg P, Tekin S, Lane R. Rivastigmine for dementia associated with Parkinson's disease. *N Engl J Med*. 2004;351:2509-18.

Fleisher AS, Truran D, Mai JT, et al. Chronic divalproex sodium use and brain atrophy in Alzheimer disease. *Neurology*. 2011;77(13):1263-71.

Gupta A, Lawrence AT, Krishnan K, Kavinsky CJ, Trohman RG. Current concepts in the mechanisms and management of drug-induced QT prolongation and torsade de pointes. *Am Heart J*. 2007;153:891-9.

Huey ED, Garcia C, Wasserman EM, Tierney MC, Grafman J. Stimulant treatment of frontotemporal dementia in 8 patients. *J Clin Psychiatry*. 2008;69(12):1981-2.

Huey ED, Putnam KT, Grafman J. A systematic review of neurotransmitter deficits and treatments in frontotemporal dementia. *Neurology*. 2006;66:17-22.

Husebo BS, Ballard C, Sandvik R, Nilsen OB, Aarsland D. Efficacy of treating pain to reduce behavioural disturbances in residents of nursing homes with dementia: cluster randomized clinical trial. *BMJ*. 2011;343:d4065; published online early. doi: 10.1136/bmj.d4065.

Huybrechts KF, Brookhart MA, Rothman KJ, et al. Comparison of different approaches to confounding adjustment in a study of the association of antipsychotic medication with mortality in older nursing home patients. *Am J Epidemiol*. 2011;174(9):1089-99.

Jacob S, Spinler SA. Hyponatremia associated with selective serotonin-reuptake inhibitors in older adults. *Ann Pharmacother*. 2006;40(9):1618-22.

Jeste DV, Blazer D, Casey D, et al. ACNP white paper: update on use of antipsychotic drugs in elderly persons with dementia. *Neuropsychopharmacology*. 2008;33:957-70.

Kertesz A, Morlog D, Light M, et al. Galantamine in frontotemporal dementia and primary progressive aphasia. *Dement Geriatr Cogn Disord*. 2008;25:178-85.

Kirchner V, Kelly CA, Harvey RJ. Thioridazine for dementia. *Cochrane Database of Systematic Reviews*. 2001, Issue 4. Art. No.: CD000464. doi: 10.1002/14651858.CD000464

Konovalov S, Muralee S, Tampi RR. Anticonvulsants for the treatment of behavioral and psychological symptoms of dementia: a literature review. *Int Psychogeriatr*. 2008;20(2):293-308.

Kurlan R, Cummings J, Raman R, Thal L, Alzheimer's Disease Cooperative Study Group. Quetiapine for agitation or psychosis in patients with dementia and parkinsonism. *Neurology*. 2007;68(17):1356-63.

Lebert F, Stekke W, Hasenbroekx C, Pasquier F. Frontotemporal dementia: a randomized, controlled trial with trazodone. *Dement Geriatr Cogn Disord*. 2004;17:355-9.

Leroi I, Overshott R, Byrne J, Daniel E, Burns A. Randomized controlled trial of memantine in dementia associated with Parkinson's disease. *Mov Disord*. 2009;24(8):1217-21.

Lonergan E, Luxenberg J. Valproate preparations for agitation in dementia. *Cochrane Database of Systematic Reviews*. 2009, Issue 3. Art. No.: CD003945. doi: 10.1002/14651858.CD003945.pub3

Lonergan E, Luxenberg J, Colford JM, Birks J. Haloperidol for agitation in dementia. *Cochrane Database of Systematic Reviews*. 2002, Issue 2. Art. No.: CD002852. doi: 10.1002/14651858.CD002852

Lyketsos CG. The interface between depression and dementia: where are we with this important frontier? *Am J Geriatr Psychiatry*. 2010;18(2):95.

Lyketsos CG, DelCampo L, Steinberg M, et al. Treating depression in Alzheimer disease: efficacy and safety of sertraline therapy, and benefits of depression reduction: the DIADS. *Arch Gen Psychiatry*. 2003;60:737-46.

Maglione M, Ruelaz Maher A, Hu J, Wang Z, Shanman R, Shekelle PG, Roth B, Hilton L, Suttorp MJ, Ewing BA, Motala A, Perry T. Off-Label Use of Atypical Antipsychotics: An Update. Comparative Effectiveness Review No. 43. (Prepared by the Southern California Evidence-based Practice Center under Contract No. HHSA290-2007-10062-1.) Rockville, MD: Agency for Healthcare Research and Quality. September 2011. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

McKeith I. Dementia with Lewy bodies and Parkinson's disease with dementia: where two worlds collide. *Pract Neurol*. 2007;7:374-382.

McKeith I, Del Ser T, Spano P, et al. Efficacy of rivastigmine in dementia with Lewy bodies: a randomized, double-blind, placebo-controlled international study. *Lancet*. 2000;356:2031-6.

McKeith IG, Wesnes KA, Perry E, Ferrara R. Hallucinations predict attentional improvements with rivastigmine in dementia with Lewy bodies. *Dement Geriatr Cogn Disord*. 2004;18:94-100.

McKhann GM, Albert MS, Grossman M, Miller B, Dickson D, Trojanowski JQ. Clinical and pathological diagnosis of frontotemporal dementia: report of the work group on frontotemporal dementia and Pick's disease. *Arch Neurol*. 2001;58:1803-9.

McLaren AT, Allen J, Murray A, et al. Cardiovascular effects of donepezil in patients with dementia. *Dement Geriatr Cogn Disord*. 2003;15:183-8.

Mendez MF, Shapira J, McMurtray A, Licht E. Preliminary findings: behavioral worsening on donepezil in patients with frontotemporal dementia. *Am J Geriatr Psychiatry*. 2007;15(1):84-7.

Moretti R, Torre P, Antonello RM, Cazzato G, Bava A. Frontotemporal dementia: paroxetine as a possible treatment of behavior symptoms. *Eur Neurol*. 2003;49:13-9.

Murphy TK, Segarra A, Storch EA, Goodman WK. SSRI adverse events: how to monitor and manage. *Int Rev Psychiatry*. 2008;20(2):203-8.

Rosenberg PB, Drye LT, Martin BK, et al. Sertraline for the treatment of depression in Alzheimer disease. *Am J Geriatr Psychiatry*. 2010;18(2):136-45.

Schneider LS, Tariot PN, Dagerman KS, et al. Effectiveness of atypical antipsychotic drugs in patients with Alzheimer's disease. *N Engl J Med*. 2006;355(15):1525-38.

Schneider LS, Dagerman K, Insel PS (2006b). Efficacy and adverse effect of atypical antipsychotics for dementia: meta-analysis of randomized, placebo-controlled trials. *Am J Geriatr Psychiatry*. 2006;14(3):191-210.

Seeman P, Tallerico T. Rapid release of antipsychotic drugs from dopamine D_2 receptors: an explanation for low receptor occupancy and early clinical relapse upon withdrawal of clozapine or quetiapine. *Am J Psychiatry*. 1999;156:876-84.

Seitz DP, Adunuri N, Gill SS, Gruneir A, Herrmann N, Rochon P. Antidepressants for agitation and psychosis in dementia. *Cochrane Database of Systematic Reviews*. 2011, Issue 2. Art. No.: CD008191. doi: 10.1002/14651858.CD008191.pub2

Seroquel XR (quetiapine fumarate extended-release tablets) Full Prescribing Information [package insert]. Wilmington, DE: AstraZeneca, 2011.

Sink KM, Holden KF, Yaffe K. Pharmacological treatment of neuropsychiatric symptoms of dementia: a review of the evidence. *J Am Med Assoc*. 2005;293(5):596-608.

Smith KL, Greenwood CE. Weight loss and nutritional considerations in Alzheimer disease. *J Nutr Elder*. 2008;27(3-4):381-403.

Smith TJ, Ritter JK, Coyne PJ, Parker GL, Dodson P, Fletcher DS. Testing the cutaneous absorption of lorazepam, diphenhydramine, and haloperidol gel (ABH gel) used for cancer-related nausea. *J Clin Oncol*. 2011;29:(suppl;abstr 9021).

Spigset O. Adverse reactions of selective serotonin reuptake inhibitors: reports from a spontaneous reporting system. *Drug Saf*. 1999;20(3):277-87.

Tariot PN, Schneider LS, Cummings J, et al. Chronic divalproex sodium to attenuate agitation and clinical progression of Alzheimer disease. *Arch Gen Psychiatry*. 2011;68(8):853-61.

Thapa PB, Meador KG, Gideon P, Fought RL, Ray WL. Effects of antipsychotic withdrawal in elderly nursing home residents. *J Am Geriatr Soc*. 1994;42:280-6.

Tosato M, Lukas A, van der Roest HG, et al. Association of pain with behavioral and psychiatric symptoms among nursing home residents with cognitive impairment: results from the SHELTER study. *Pain*. 2011; published online early. doi: 10.1016/j.pain.2011.10.007.

Vieweg WV, Wood MA, Fernandez A, Beatty-Brooks M, Hasnain M, Pandurangi AK. Proarrhythmic risk with antipsychotic and antidepressant drugs: implications in the elderly. *Drugs Aging*. 2009;26(12):997-1012.

Weintraub D, Hurtig HI. Presentation and management of psychosis in Parkinson's disease and dementia with Lewy bodies. *Am J Psychiatry*. 2007;164:1491-8.

Young CR, Bowers MB Jr., Mazure CM. Management of the adverse effects of clozapine. *Schizophrenia Bulletin*. 1998;24(3):381-90.

Delirium Assessment and Management

Ryan Carnahan, PharmD, MS, BCPP; Michelle Weckmann, MD, MS; Susan Schultz, MD

Overview

This review describes the rationale and evidence for the "IA-ADAPT: Improving Antipsychotic Appropriateness in Dementia Patients" pocket guide on delirium assessment and management.

Delirium, also known as "acute confusion," is common in older adults with acute medical illnesses. People with dementia have a much greater risk of delirium because of their pre-existing cognitive impairment and sensitivity to stressors such as medical illnesses and medication side effects. About two-thirds of delirium cases occur in people with dementia [Inouye 2006]. Estimates of the prevalence of delirium in hospitalized older adults with dementia have ranged from 22% to 89% [Fick et al. 2002]. The rates of delirium in people with dementia are not as well characterized in other settings of care (e.g., home or nursing home) but can be assumed to be substantial when acute medical illness is present. One study of delirium in nursing home residents found that approximately 22% had delirium during a one-month observation period. Lower baseline cognitive scores were, as expected, associated with a higher risk of delirium [Culp et al. 2004].

Delirium is a state of acute cognitive impairment caused by a medical problem. In contrast to dementia, its onset is rapid (hours to days), severity often fluctuates throughout the day, and it is reversible. Particularly among persons with concurrent dementia, it is possible to have persistent symptoms of delirium for long period of time, even weeks to months, so in some cases the exact time of onset may be difficult to determine. Changes in the sleep-wake cycle are also common, such that a person may be quiet and subdued or asleep during the day and awake or agitated at night. Though delirium is primarily characterized by acute cognitive deficits, behavioral and psychiatric manifestations are common. Delirium may present as hypoactive, where the person appears over-sedated or subdued and is difficult to arouse. This is often overlooked or mistaken for depression. It may also present as hyperactive or agitated, or as some mix of hypoactive and hyperactive characteristics. Delirium is important to consider as a possible cause of problem behaviors and psychosis in people with dementia, given the high prevalence of delirium in people with dementia [Fick et al. 2002, Fong et al. 2009].

The current standard criteria for diagnosing delirium in the United States as of the time of this writing come from the Diagnostic and Statistical Manual of Mental Disorders, 4th edition, text revision (DSM-IV-TR). These are:

1. Disturbance of consciousness (i.e., reduced clarity of awareness of the environment) with reduced ability to focus, sustain, or shift attention.
2. A change in cognition (such as memory deficit, disorientation, language disturbance) or the development of a perceptual disturbance that is not better accounted for by a pre-existing, established, or evolving dementia.
3. The disturbance develops over a short period of time (usually hours to days) and tends to fluctuate during the course of the day.

4. There is evidence from the history, physical examination, or laboratory findings that the disturbance is caused by the direct physiological consequences of a general medical condition.

Screening for Delirium

Delirium screening tests can be used by people without specific expertise in diagnosing delirium to help identify patients who may be suffering from delirium. These screening tests are not intended to diagnose delirium but rather to identify patients who might have delirium. Since delirium is often undetected, the regular use of screening tests in high-risk patients is recommended to help overcome under-diagnosis [Adamis et al. 2010]. As you might expect, some screening tests are too sensitive and identify patients as possibly being delirious who do not have delirium and some are not sensitive enough and miss identifying patients who actually have delirium. In general, patients with hypoactive delirium are more commonly missed with the screening tools that we currently have. The best screening tools include some sort of basic cognitive testing.

Our pocket guide provides a delirium screening tool adapted from several sources. The basic criteria match those of the short version of the Confusion Assessment Method (CAM) [Inouye 2003], which is included in the Minimum Data Set, version 3.0. The specific assessments for inattention and disorganized thinking are drawn from the Confusion Assessment Method for the ICU (CAM-ICU) [Ely et al. 2001]. These were selected for their ease of administration. More information can be found at the following website: www.icudelirium.org. There is some evidence that the CAM-ICU may not be particularly sensitive in detecting delirium in general medical patients [Neufeld et al. 2011]. Therefore, if a person passes the tests but still seems more confused than usual, further evaluation may be necessary to rule out delirium.

A first step in screening for delirium may be to ask a simple question to a caregiver who knows the person well, “Does this person seem more confused today than usual?” If not, then it may not be necessary to screen for delirium. If yes, then the person may have delirium and further evaluations should be performed. This question has been referred to as the Single Question in Delirium, or SQiD. It performed quite well in identifying or ruling out delirium in patients with cancer when compared to other screening tests and a psychiatrist interview [Sands et al. 2010].

The second step to screening for delirium is to conduct a brief cognitive assessment. We have recommended some simple tasks that evaluate sustained attention, since sustained attention often remains relatively intact in mild to moderate Alzheimer’s dementia but is impaired in delirium. In other types of dementia such as vascular dementia, attention impairments may be more common in earlier stages [McGuinness et al. 2010]. Attention may also suffer in later stages of Alzheimer’s disease in the absence of delirium, making changes more difficult to assess. Thus, these tests are far from perfect in determining whether deficits are due to delirium or dementia. They are most useful if providers are aware of the person’s usual capacity to perform these tasks and can determine whether their ability has changed. When the tests are performed, it is also useful to observe the person’s level of consciousness and communication patterns to help determine if these have changed from the person’s normal state.

One simple assessment of attention may involve asking the patient to name the months of the year and/or days of the week backwards, which may help detect inattention in patients with mild dementia. For people with moderate dementia, we have recommended asking them to count from 20 to 1 backwards. This is an easier task that many people with moderate dementia should be able to complete if they are not delirious. In severe dementia the assessment may need to be even simpler, such as determining whether the person is aware of the examiner or able to follow simple commands that they are usually able to follow.

Screening Tool

If it is determined that a more thorough screening exam for delirium should be conducted, the CAM-based screening tool on the pocket guide can be used. There are four basic domains assessed, which relate to the DSM-IV-TR criteria for delirium. The screen is considered positive for probable delirium if both of the first two criteria and at least one of the last two criteria are met. In other words, there has to be evidence of an acute onset and inattention, and either disorganized thinking or an altered level of consciousness.

1. Acute Onset:
    - Is there evidence of an acute change in mental status from the person's baseline?
        - This differentiates delirium from dementia. If the person's mental status changed quickly (i.e., they're more confused than usual), then the answer is yes.
2. Inattention
    - Does the person have difficulty focusing attention (i.e., easily distracted or can't follow what's being said)?
        - This could be evaluated using the previously discussed sustained attention tests, or by observation. The evaluator can also do the attention screening examination described in the pocket guide.
3. Disorganized Thinking
    - Is the person's thinking disorganized or incoherent, as evidenced by rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject?
        - Questions and commands to evaluate this domain are provided in the pocket guide. Each question counts for one point. The command counts for one point. Any combined score equal to or less than 4 is positive for disorganized thinking.
        - Disorganized thinking may be present in dementia with or without delirium, adding to the challenge of differentiating the disorders. It may be best to consider a change from the person's recent normal ability.
4. Altered Level of Consciousness
    - Is the patient anything other than alert, calm, and cooperative (at the current time)?
        - Delirium can be either hyperactive or hypoactive. So agitated or hyper-vigilant states may indicate delirium. A sedated or difficult to arouse state may also indicate delirium. Hypoactive delirium is more common in elderly patients.

- Psychomotor retardation, or sluggishness, slower than normal movement or responses, or staring into space, can also count as a 'yes' on this domain.

Ultimately, delirium can be challenging to assess in people with dementia, since they have cognitive problems even when they are not delirious. When uncertain, a good rule of thumb is to go ahead and perform a medical evaluation for possible causes of any acute change in mental status. Delirium symptoms may indicate problems ranging from mild infections to drug side effects to medical emergencies. Delirium is often caused by more than one medical problem, so it's important to be thorough when evaluating possible causes.

Assessing Causes of Delirium

Delirium can be caused by just about any acute or uncontrolled medical condition or stressor, including infections, pain, sleep deprivation, dehydration, metabolic or electrolyte disturbances, constipation, and many others. Medications are also common contributors to delirium, especially psychoactive medications. People with dementia are at a high risk since their cognition is already impaired. People with sensory impairment such as visual or hearing impairment are also at a higher risk, so it is important to ensure that glasses and hearing aids are available and working if needed, and that ear wax is not causing hearing impairment [Inouye 2006, Gleason 2003, Fong et al. 2009, Fick et al. 2002].

Evaluation for Medical Conditions

The evaluation for medical conditions that may be causing delirium is perhaps unique only in that it needs to consider a large number of possible causes, since delirium is a non-specific symptom. As with any evaluation, it starts with a general review of systems and evaluation of the current status of any known medical conditions. Physical evaluation may initially focus on more common conditions such as pain, constipation, skin ulcers, or pneumonia, but should also rule out severe conditions such as myocardial infarction or stroke that would require immediate treatment. Reviewing current vitals can also give clues as to the cause of delirium. Elevated temperature and heart rate can indicate infection, while an elevated heart rate and low blood pressure may indicate sepsis. Laboratory evaluations such as a urinalysis, electrolytes, serum creatinine/blood urea nitrogen, blood glucose, and a complete blood count with differential are useful for evaluating infections or metabolic/electrolyte disturbances, which are common causes of delirium [Inouye 2006, Gleason 2003, Fong et al. 2009, Fick et al. 2002].

In addition to examining medical conditions, it is important to evaluate the need for any restraining devices that might limit normal movement. Catheters, IV lines, and restraints should be removed if they aren't necessary, or if the person is at risk of harming themselves by pulling out lines while confused. There is some evidence suggesting that restraints may worsen agitation and increase the risk of further cognitive worsening, so it is best to avoid them if possible [Flaherty and Little 2011].

DELIRIUM(S) is one mnemonic for remembering a number of common causes of delirium, further described in Table 1. Other mnemonics and more information on delirium can be found at the excellent website, www.icudelirium.org, from Vanderbilt University. The information is focused on delirium in the intensive care unit, but much is applicable to other settings.

Table 1. DELIRIUM(S): Mnemonic for Common Causes of Delirium

D	Drugs, Drugs, Drugs
E	Eyes, ears—poor hearing and vision are risk factors
L	Low oxygen states—myocardial infarction, acute respiratory distress syndrome, pulmonary embolism, congestive heart failure, chronic obstructive pulmonary disease
I	Infection, immobilization
R	Retention (of urine or stool), restraints
I	Ictal—seizures can cause delirium
U	Underhydration, undernutrition
M	Metabolic abnormalities
(S)	Subdural, sleep deprivation

Evaluating Medications

Determining the role of medications in delirium can be challenging. People with dementia are at a higher risk of drug-induced cognitive impairment. This has been illustrated by studies that have administered drugs such as anticholinergics to people with dementia and normal controls and examined their effect on cognition and other symptoms [Carnahan et al. 2004]. Medications may play a role in causing delirium in several ways.

1. Medications can directly impair cognition and be a primary cause of delirium. New drugs should especially be examined as possible causes. A new drug may also impair the metabolism of a medication that a patient has been taking for a while and increase its adverse impact on cognition.
2. Medications can impair cognition and lower the threshold at which other medical conditions or stressors will cause delirium. All medications should be carefully examined to determine if they might be contributing to cognitive impairment, even if they aren't a primary cause of the delirium. Delirium is often due to multiple causes, and medications may be contributing or predisposing factors.
3. Medications may induce electrolyte disturbances, metabolic disturbances, or other medical conditions that can lead to delirium.
4. Withdrawal from medications may cause delirium. Withdrawal from sedatives such as benzodiazepines or alcohol should be considered as a possible cause depending on the patient and circumstances.

Our pocket guide on drugs that can contribute to delirium or problem behaviors focuses on drugs that can have a direct adverse impact on cognition or psychiatric symptoms. It focuses on those medications for which substantial evidence suggests they can cause these problems. The list includes most psychoactive medications, including those that treat psychiatric disorders, anticonvulsants, and pain medications. It also includes steroids and certain cardiac medications (digoxin and antiarrhythmics) [Gray et al. 1999, Karlsson 1999].

The presence of a drug on this list does not necessarily mean that it should never be given to a patient with dementia, but rather that these drugs should be used with caution. If delirium does occur, the risk-benefit balance of their use should be considered. If discontinuation or dose reduction does not put the patient at risk of other problems, it is often a good choice. This is not always possible, however, particularly for opiates in people with pain or other drugs necessary for the treatment of serious medical conditions.

Case reports and other evidence suggest that a number of antibiotics, antivirals, and antifungals may cause cognitive or behavioral side effects [Gray et al. 2009]. The impact of these medications can be difficult to determine since they are often given to people with infections, and infections can cause delirium. However, the evidence is strong enough to consider them as potential causes.

Anticholinergic medications may be particularly harmful for people with dementia. The cholinergic system is damaged in Alzheimer's disease and some other types of dementia. Challenge studies have shown that people with Alzheimer's disease are extremely sensitive to the cognitive deficits induced by anticholinergics. These drugs also appear to worsen psychotic and behavioral problems in some patients. Cholinesterase inhibitors are used to help maintain cognition in dementia, and work by reducing the breakdown of acetylcholine. Anticholinergics are likely to lessen or reverse any cognitive benefits of cholinesterase inhibitors since they block the effects of acetylcholine. Thus, anticholinergic medications are generally not recommended for use in people with dementia. The Beers criteria, an expert consensus statement on potentially inappropriate medications in older adults, support avoiding anticholinergics in people with dementia [Carnahan et al. 2004].

Anticholinergic medications include those used specifically for their anticholinergic effects (e.g., bladder and gastrointestinal antispasmodics, motion sickness medications, movement disorder medications). They also include medications with anticholinergic side effects for which the anticholinergic effect is not considered central to the therapeutic effect (e.g., antihistamines, tricyclic antidepressants, certain antipsychotics). Our pocket guide focuses on those medications that are known to have strong anticholinergic effects, or those that have been associated with delirium.

The pocket guide is not a comprehensive list of all medications that can cause cognitive impairment. It focuses on the worst or more common offenders, and serves as a starting point of a thorough medication review. Other medications to be aware of with potential to cause cognitive impairment include chemotherapy agents, cytokines, immunosuppressants, metoclopramide, and antihypertensives [Gray et al. 2009, Karlsson 1999, Dyrud 2004]. Since it is nearly impossible to list all medications that have been associated with cognitive or behavioral side effects, it is important to review potential side effects of any medication a delirious person is receiving and not rely solely on the pocket guide to identify such drugs.

Just because a drug can cause cognitive impairment does not mean that it is the cause for a given individual. However, it is usually best to err on the side of caution and discontinue any non-essential medication that may be causing harm to a delirious patient. To further explore the relationship between the drug and cognition, one might consider the relationship in time to the delirium (e.g., was the drug

started recently), whether cognition improves when the drug is discontinued or the dose is lowered, whether cognition worsens when it is added back or the dose is increased, and whether blood levels of drugs for which they are measured are in the toxic range.

Delirium Management

First and foremost, the main treatment for delirium is to identify and treat the underlying medical problems that are causing it. Managing symptoms of delirium is also important, but the only real treatment is to treat the underlying cause. Once the medical problem is brought under control, it may still take time for delirium to resolve [Inouye et al. 2006, Gleason 2003, Fong et al. 2009]. Since so many medical problems can cause delirium it is impossible to review their management here. Thus, this section focuses on symptom management strategies.

Non-Drug Management

Non-drug management strategies for delirium focus on optimizing function and orientation, maintaining a clear and calm environment, ensuring adequate nutrition and hydration, normalizing the sleep-wake cycle, and ensuring safety. Some strategies for each of these are listed below [Inouye 2006, Gleason 2003].

Optimizing function and orientation:

- Re-orient and reassure the person frequently.
- Re-introduce yourself regularly. Use consistent staff.
- Communicate slowly and clearly. Use simple, step by step instructions when providing care. Avoid jargon.
- Use an interpreter if necessary.
- Involve family in low-stimulating visits.
- Make sure glasses, hearing aids, and dentures are available. Remove ear wax if necessary.
- Maintain mobility and self-care ability to the extent feasible.

Maintain a calm and clear environment:

- Clock, calendar/date, and schedule clearly visible.
- Reduce excessive noise and alarms.
- Simplify the care area. Remove unnecessary objects, except familiar objects that may promote comfort.
- Consider a private room.
- Consider playing the patient's preferred music during the day.
- Lights on during the day.
- Maintain comfortable room temperature.
- Don't correct harmless misbeliefs. For example, if a patient talks about visiting with a friend earlier in the day (who did not visit), agree and ask how the visit went.

Ensure adequate nutrition and hydration:

- Monitor food intake. Offer easy to eat foods during times of wakefulness and clarity.
- Keep beverage of choice available and within reach. Avoid excessive caffeine as this may contribute to dehydration.

Normalize sleep-wake cycle:

- Keep lights on during normal waking hours. Open shades/curtains if a window is available to allow natural light exposure.
- Discourage naps.
- Allow uninterrupted sleep at night.

Maintain safety:

- Use sitters.
- Use non-drug strategies for agitation (e.g., music, massage, relaxation techniques).
- Avoid restraints. Remove unnecessary lines and catheters.

Medications to Manage Delirium Symptoms

Antipsychotics

Antipsychotics are the mainstay of treatment to manage distressing hallucinations, delusions, or agitation that can occur in delirium. It is not necessary to treat all delirious patients with antipsychotics, but the drugs may be helpful for those with distressing psychotic or agitated symptoms. Some providers support use of antipsychotics in hypoactive delirium, in which the patient appears sedated rather than agitated, but this is controversial and may expose the patient to the risks of antipsychotics unnecessarily [Fong et al. 2009].

Haloperidol has been used extensively to manage symptoms of delirium, and is often a good choice unless the patient is at high risk of extrapyramidal side effects. Other antipsychotics can also be used [Fong et al. 2009]. We recommend caution with those that are more sedating or have significant anticholinergic effects, such as olanzapine or quetiapine, as it is possible that these could worsen delirium in some patients [Lim et al. 2006, Sim et al. 2000, Huang and Wei 2010]. However, there is little evidence from clinical trials suggesting one antipsychotic is safer or more effective than another for delirium management [Fong et al. 2009].

Antipsychotics should be started at low doses, such as those recommended in the pocket guides, and titrated to effect. The dose should be minimized in elderly patients to avoid side effects. The total dose required to provide symptom control can be used as a guide for scheduled dosing, if deemed necessary, which can be titrated down and discontinued as the delirium resolves. It is not necessary to continue antipsychotic treatment after the delirium has resolved, though some clinicians recommend continuing or tapering the antipsychotic for 5-7 days after symptom resolution to prevent rebound delirium. Response to and need for antipsychotic treatment should be evaluated at least every 24 hours during a delirium episode [Gleason 2003].

Benzodiazepines and Other Sedative-Hypnotics

Benzodiazepines are not usually recommended to manage delirium. They may worsen confusion and prolong delirium since they impair cognition and can cause over-sedation. The same applies to other sedative hypnotics and sleep medications, most of which can impair cognition. Non-drug strategies are preferred to promote sleep [Fong et al. 2009]. If non-drug strategies are ineffective low dose melatonin might be tried, e.g., 2.5-10 mg. Evidence for this strategy is limited and inconclusive, but some observations suggest it may be effective and safe for some patients with delirium and circadian rhythm disturbances [de Jonghe 2010].

If the delirium is due to alcohol or sedative-hypnotic withdrawal, then a benzodiazepine is the drug of choice. Other drugs such as antipsychotics or anticonvulsants are also sometimes used, but usually as adjuncts to benzodiazepines. Signs of alcohol or sedative-hypnotic withdrawal include increased blood pressure, increased heart rate, increased temperature, nausea, vomiting, sweating, tremor, anxiety, insomnia, and agitation. Seizures, hallucinations, or illusions may also occur [Bayard et al. 2004]. A full review of alcohol or sedative hypnotic withdrawal is outside of the scope of this website, so readers should refer to other resources if they need more information.

Cholinesterase Inhibitors

Cholinesterase inhibitors are not recommended as first-line treatments for delirium. While benefits have been reported in some cases, such as in anticholinergic overdose or Lewy body dementia, the evidence is too weak to support their regular use for delirium. Randomized controlled trials conducted to date have not supported the efficacy of cholinesterase inhibitors in delirium [Grover et al. 2011]. One randomized controlled trial testing the addition of rivastigmine to haloperidol for delirium in the intensive care unit found an increased risk of mortality with rivastigmine compared to placebo (22% vs. 8%) [van Eijk et al. 2010].

Further study is necessary before cholinesterase inhibitors can be considered safe or effective for the treatment of delirium. On the other hand, there is little reason to recommend discontinuation of a cholinesterase inhibitor that a delirious patient was already receiving for dementia, unless side effects are a concern.

Summary

Delirium is a state of acute cognitive impairment caused by a medical condition, and people with dementia are at high risk. Delirium should be considered as a possible cause of new psychiatric or behavioral disturbances in a person with dementia. The treatment for delirium is to manage the underlying medical condition that caused it. Medications should be reviewed in delirious patients to ensure that they are not causing or contributing to the delirium. Non-drug strategies can be used to manage many cases of delirium. If drug therapy is necessary, antipsychotics are usually the drugs of choice.

References:

Adamis D, Sharma N, Whelan PJP, Macdonald AJD. Delirium scales: a review of current evidence. *Aging & Mental Health*. 2010;14(5):543-55.

Bayard M, Mcintyre J, Hill KR, Woodside J Jr. Alcohol withdrawal syndrome. *Am Fam Phys*. 2004;69(6):1443-50.

Carnahan RM, Lund BC, Perry PJ, Chrischilles EA. The concurrent use of anticholinergics and cholinesterase inhibitors: rare event or common practice? *J Am Geriatr Soc*. 2004;52(12):2082-7.

Culp KR, Wakefield B, Dyck MJ, Cacchione PZ, DeCrane S, Decker S. Bioelectrical impedance analysis and other hydration parameters as risk factors for delirium in rural nursing home residents. *J Gerontol A Biol Sci Med Sci*. 2004;59A(8):813-7.

de Jonghe A, Korevaar JC, van Munster BC, de Rooij SE. Effectiveness of melatonin treatment on circadian rhythm disturbances in dementia. Are there implications for delirium? A systematic review. *Int J Geriatr Psychiatr*. 2010;25(12):1201-8.

Dyrud JE Jr. Posttransplantation delirium: a review. *Curr Opin Organ Transplant*. 2004;9(4):428-31.

Ely EW, Margolin R, Francis J, et al. Evaluation of delirium in critically ill patients: validation of the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU). *Crit Care Med*. 2001;29(7):1370-9.

Fick DM, Agostini JV, Inouye SK. Delirium superimposed on dementia: a systematic review. *J Am Geriatr Soc*. 2002;50(10):1723-32.

Flaherty JH, Little MO. Matching the environment to patients with delirium: lessons learned from the delirium room, a restraint-free environment for older hospitalized adults with delirium. *J Am Geriatr Soc*. 2011;59:S295-S300.

Fong TG, Tulebaev SR, Inouye SK. Delirium in elderly adults: diagnosis, prevention, and treatment. *Nat Rev Neurol*. 2009;5(4):210-20.

Gleason OC. Delirium. *Am Fam Physician*. 2003;67(5):1027-34.

Gray SL, Lai KV, Larson EB. Drug-induced cognition disorders in the elderly: incidence, prevention, and management. *Drug Saf*. 1999;21(2):101-22.

Grover S, Mattoo SK, Gupta N. Usefulness of atypical antipsychotics and choline esterase inhibitors in delirium: a review. *Pharmacopsychiatry*. 2011;44:43-54.

Huang C, Wi I. Unexpected interaction between quetiapine and valproate in patients with bipolar disorder. *Gen Hosp Psychiatry*. 2010;32:446.e1-446.e2.

Inouye SK. The Confusion Assessment Method (CAM): Training Manual and Coding Guide. 2003; New Haven: Yale University School of Medicine. Accessed 12/9/11 at: http://www.hospitalelderlifeprogram.org/pdf/TheConfusionAssessmentMethod.pdf

Inouye SK. Delirium in older persons. *N Engl J Med*. 2006;354:1157-65.

Karlsson I. Drugs that induce delirium. *Dement Geriatr Cogn Disord*. 1999;10:412-15.

Lim CJ, Trevino C, Tampi RR. Can olanzapine cause delirium in the elderly? *Ann Pharmacother*. 2006;40:135-8.

McGuinness B, Barret SL, Craig D, Lawson J, Passmore AP. Attention deficits in Alzheimer's disease and vascular dementia. *J Neurol Neurosurg Psychiatry*. 2010;81:157-9.

Neufeld KJ, Hayat MJ, Coughlin JM, et al. Evaluation of two intensive care delirium screening tools for non-critically ill hospitalized patients. *Psychosomatics*. 2011;52(2):133-40.

Sands MB, Dantoc BP, Hartshorn A, Ryan CJ, Lugic S. Single Question in Delirium (SQiD): testing its efficacy against psychiatrist interview, the Confusion Assessment Method and the Memorial Delirium Assessment Scale. *Palliat Med*. 2010;24(6):561-5.

Sim FH, Brunet DG, Conacher GN. Quetiapine associated with acute mental status changes. *Can J Psychiatry*. 2000;45(3):299.

van Eijk MMJ, Roes KCB, Honing MLH, et al. Effect of rivastigmine as an adjunct to usual care with haloperidol on duration of delirium and mortality in critically ill patients: a multicenter, double-blind, placebo-controlled trial. *Lancet*. 2010;376(9755):1829-37.

TOOLKIT

Clinical Considerations of Antipsychotic Management

Table of Contents

ABOUT THE CLINICAL CONSIDERATIONS OF ANTIPSYCHOTIC MANAGEMENT TOOLKIT

The Clinical Considerations of Antipsychotic Management Toolkit is a clinically-focused resource containing steps and objectives, expectations at each step, and offers or identifies tools and resources that will help you meet performance expectations and outcomes. It identifies the steps that need to be taken in order to clinically manage individuals who are taking antipsychotic medications, in attempting gradual dose-reduction, and to lower the off-label use of medications.

The model used for the toolkit framework is the Nursing Process, also referred to as the Care Delivery Process, with the addition of two steps. The Nursing Process steps include: recognition/assessment, diagnosis/clinical judgment, outcomes planning, implementation, and evaluation. The additional steps include: leadership and staff training. This model was chosen because it is one that nurses are familiar with, it is comprehensive and ongoing, and incorporates input from various disciplines. The model is a universally acknowledged method used to identify and address complex issues. It is consistent with standard problem-solving and quality improvement.

In keeping with recommended quality improvement approaches, the Leadership and Staff Training sections were added to the toolkit. Nursing center leaders/supervisors need to be invested and lead this quality improvement effort with input from all staff, residents, families and practitioners. This section of the framework details the support leadership must provide to ensure quality improvement success.

The Staff Training section was added to support the need for staff education in order to meet the center's quality expectations to safely lower antipsychotics.

This toolkit is designed to assist centers in moving toward a more appropriate decision-making process for antipsychotic medication use. However, it does not provide a comprehensive package of all aspects of care.

THE CLINICAL CONSIDERATIONS OF ANTIPSYCHOTIC MANAGEMENT FRAMEWORK

To access the tools or resources, click on the tool/resource name appearing in each section of the framework.

STEPS / OBJECTIVES	EXPECTATIONS	TOOLS / RESOURCES
Leadership Set facility direction & goal to better manage antipsychotic drug use and individuals with dementia Ensure staff and others understand what needs to be done and how to accomplish the goal Provide staff education needed to achieve results (see Section of Staff Education)	• Know your facility's antipsychotic prevalence rates (short & long-stay) by using CMS Quality Measures (QM) when available, AHCA and/or facility data • Set a facility antipsychotic quality measurement goal – focus on outcomes • Make sure all supervisors, staff and physicians are aware of and understand the goal • Make sure employees know their performance expectations • Hold employees accountable for following care process steps • Make regular employee rounds to address questions about the goal • Ensure all staff are trained on how to identify unmet needs and nurses are trained on recognizing common antipsychotics • Recognize departments and staff doing well in implementing process and using tools	**Nursing Process Approach for Antipsychotic Drug – Gradual Dose Reduction** **Antipsychotic Prescription Log** **Sample Facility Policy for Use of Antipsychotic Medications** **Sample Antipsychotic Physician Memo** **LTC Trend Tracker: www.ltctrendtracker.com**
Recognition/Assessment Timely identification of antipsychotic drug use and behavior, mood, cognition and function changes	• Be able to recognize antipsychotic drugs commonly used in the LTC setting and the issues surrounding the use of these drugs • Observe resident behaviors • Describe behavior/symptom details like onset, intensity, duration, severity to self and/or others • Identify change in level of consciousness (e.g. alert, drowsy, stuporous, comatose) • Determine the necessity to control or limit behavior • Assess mood, thinking, function, and behavior within 24 hours of admission if an individual is taking an antipsychotic or identified as having a behavior problem • For individuals taking antipsychotics, identify where and why treatment started and how effective/problematic the treatment has been	**INTERACT Care Path for Mental Status Change: www.INTERACT2.net** **Other Resources** **Individual's medical record, progress notes, hospital discharge summary, MAR, Stop and Watch Reports, and latest MDS assessment**

STEPS / OBJECTIVES	EXPECTATIONS	TOOLS / RESOURCES
Diagnosis/Clinical Judgment Use existing medical information and assessment data to form an opinion about probable cause(s) of behavior/symptom Evaluate the current medical regimen as the potential source of behavior/symptom	• Review assessment and observation data • Evaluate psychiatric reports • Contact family and/or others who may provide insight about behavior or add to medical history • Systematically determine if the behavior/symptom(s) are likely related to: o medical condition o use of an antipsychotic drug o the current medication regimen o psychosocial/unmet need o environmental cause	Approach to Considering Causes of Behavior Algorithm Guidance to Using the Behavioral Approach Algorithm **INTERACT Change in Condition Cards:** www.INTERACT2.net
Outcomes Planning Collect pertinent information as the basis for having identified a specific cause or causes of the problematic behavior/symptom	• Contact your consultant pharmacist to identify/verify high risk medications most likely related to behavior/symptom • If antipsychotic drug use is likely part of the problem, consider discussing possible gradual dose reduction or drug discontinuance with the physician	Antipsychotic Medication Tapering Checklist
Implementation Organize and prepare assessment findings and information to be discussed with the physician Identify specific goals for managing the behavior/symptom After consultation with the physician, document the basis for having identified the problem/symptom(s) and basis for the cause of behavior/symptom	• Collaborate with practitioners to identify possible urgent situations such as delirium or psychosis • Discuss your finding with the practitioner and work together to form a care plan and next steps • Discuss and document why causes were not sought or efforts to identify them were not fruitful • Implement/update care plan to address causes of behavior/system(s) • If indicated, develop a plan to taper or discontinue antipsychotic treatment • As much as possible, the plan should include non-pharmacological and behavior management strategies • Adapt or adjust the environment to minimize related causes • Include family in the plan development and approval of plan • Document in the medical record the basis for interventions	Antipsychotic SBAR What Is CHAT? **Relevant CHATs** Agitation CHAT Altered Mental Status CHAT Dizziness/Unsteadiness CHAT Fall CHAT

STEPS / OBJECTIVES	EXPECTATIONS	TOOLS / RESOURCES
Evaluation Monitor responses to interventions for each individual and adjust them accordingly Identify and address complications related to interventions Monitor facility frequency of antipsychotic drug use and the effectiveness of strategies	• Monitor for care plan effectiveness • Review each resident's medication regimen for high risk medications and the appropriateness of continued use of any antipsychotic or other psychopharmacological medications • Form a Behavior Management Team to identify unmet needs and monitor and document the effectiveness of interventions	**Antipsychotic Medication QA Review Tool** **Assessment of Resident Receiving Psychotropic Medication**
Staff Education Ensure that staff have the knowledge and skills needed to appropriately provide care to individuals with behavior/symptom(s)	• Instruct clinical staff on how to recognize and identify antipsychotic drugs commonly used in the LTC setting • Instruct clinical staff on how to apply a systematic approach to collecting, analyzing, documenting, and reporting medical information and clinical findings for potential cause for behavior/symptom • Educate all staff in identifying unmet needs	**Antipsychotic Drugs Common Terms and Definitions** **Case Study 1: Behavior Issues in a Resident Who is Already Receiving Psychopharmacological Medications** **AHCA's Suggested Tools for Reducing Off Label Use of Antipsychotics: How These Tools Can Improve Regulatory Compliance** **University of Iowa – Improving Antipsychotic Appropriateness in Dementia Patients** https://www.healthcare.uiowa.edu/igec/IAADAPT

USING THE NURSING PROCESS APPROACH TO CONSIDER GRADUAL DOSE REDUCTION (GDR)

Tapering For Off-Label Use of Antipsychotic Medications

The best approach to considering GDR is person-centered. Before contacting the individual's physician to discuss potential dose reduction, it is important for the nurse to follow the nursing process and gather observations and pertinent information. The nursing process uses clinical judgment to strike a balance between personal interpretation and research evidence. The process fosters the use of critical thinking to categorize clients issue and course of action. Below, the nursing process is applied to the nurse's role when considering the potential for GDR for off-label use of antipsychotic medication.

Nurse/Interdisciplinary Team Assessment

- Conduct an assessment and identify conditions possibly related to drug side-effect(s).
- Review most recent MDS assessment for mood, function, behavior, evidence of delirium and facility-based behavior tracking record. Compare to findings of the just completed assessment. Review most recent scoring tool (e.g., AIMS) and compare to prior score.
- Review medical record taking note of:
    - Psychiatric conditions, psychiatric hospitalizations, abnormal clinical and lab findings, and related physician, pharmacist, and psychologist notes.
    - Any GDR attempts during past 6 – 12 months and the outcome
- For individuals staying in the facility for longer periods of time:
    - Check the pharmacist's recommendations recorded on the monthly medication regimen review for information related to drug doses, duration and continued need.
- Review the CNA Stop and Watch reports for changes in behavior, cognition, mood, ADL performance, and daily routine. (Stop and Watch is an INTERACT II tool).

Diagnosis/Clinical Judgment

- Identify symptoms that may be related to antipsychotic medication side-effects.
    - e.g. orthostatic hypotension, increase weight gain, increase glucose level, urinary retention, constipation, sedation, akathisia (restlessness, pacing, inability to sit still, anxiety, sleep disturbance), dystonia/torticollis - stiffness of neck, pseudoparkinsonism (drooling, tremors, rigidity, bradykinesia - slowness of movement, cogwheel rigidity - jerk responses of body muscles when force is applied while bending a limb), tardive dyskinesia (lip smacking/chewing, abnormal tongue movement, involuntary movement of arms/legs), dry mouth, blurred vision, worsening confusion/delirium, edema, blood abnormalities (increased triglycerides)
    - Evaluate if symptoms are old or new
- Is the individual at optimal ADL function and quality of life?
- Will GDR/tapering possibly improve the individual's symptoms and functioning?

Outcomes/Planning

- Gather clinical information and diagnoses.
    - Include all medications currently taken by the individual, including:
        - Dosages and times of administration
        - Which of these medications may be contributing to issues and concerns?
- Gather information about drug considered for GDR
    - Current dose, time(s) of drug administration, and method of administration (tablets, capsules, liquid, injectable, IV).
    - How long has the individual been taking this drug?
    - Is the current drug dose at the lowest available dose? If so, does the dose provide the individual optimal quality of life and ADL functioning?
- Identify the non-pharmacological approaches used to help address challenging behavioral responses. Did these approaches work?
- Note assessment findings in the medical record.

Implementation

- Complete the SBAR designed for nurse consideration of antipsychotic medication GDR.
- If the individual is over-sedated:
    - Hold the drug until the physician is contacted.
    - A lower dose or a different medication may be used if behaviors or symptoms requiring antipsychotic treatment emerge.
- Attempt non-pharmaceutical approaches to help address challenging behavioral responses (examples include: music therapy, exercise).
- When possible, inform the individual and his/her family and care staff about the plan for GDR to gain their understanding and support.
- Call the physician to discuss possible medication discontinuance or tapering.

Evaluation

- Assess the individual's response to medication discontinuance or tapering.
- After one month, determine if the individual is at optimal ADL functioning and has an improved quality of life.
    - Repeat any clinical tests and labs ordered by the physician, and evaluate for improvement.
    - Evaluate the effectiveness of non-pharmaceutical approaches to challenging behavioral responses that have been employed, document and change if needed.
- Continue to evaluate and note medication reduction responses in the medical record. Notify the physician about further tapering or drug maintenance as necessary.

RECOMMENDED PHYSICIAN GUIDELINES FOR GDR

- Periodically review the progress of any resident receiving antipsychotic medications, including the frequency, duration, and intensity of any symptoms
- Review the resident's overall condition and symptoms, to identify anything else that may be impairing behavior or mood stability
- At any time, if it is uncertain whether a psychopharmacological medication (including antipsychotic medications) is making a difference, consider initiating a trial reduction (e.g., lower dose, lesser frequency of administration) to see the effects
- If behavior is worse or at least not stable within 72 hours of initiating a psychopharmacological medication (including antipsychotic medications), review the working diagnosis and treatment to see whether a change in treatment may be indicated.
- For an antipsychotic medication prescribed for an acute episode (for example: during a recent hospital stay), consider a trial dose reduction if the medication's effectiveness or the need for continued treatment is uncertain.
- If the drug is currently at the lowest dose, consider a different approach to dose reduction (e.g., fewer doses per day, treatment every other day).
- It is generally prudent to reduce doses gradually (over several days to several weeks), to be able to observe for effects of medication reduction and to allow the brain to adjust to changes in chemical balances.
- For individuals taking an antipsychotic drug for one year, attempt dose reduction in two separate quarters with at least one month apart unless the individual is at optimal functioning.
- After longer than one year of drug therapy, attempt drug reduction once per year. If GDR is unsuccessful after two or more attempts, further reduction may be "clinically contraindicated." Documentation is needed in the individual's record why additional dose reduction will cause impairment, psychiatric instability, or exacerbate the underlying psychiatric disorder.

RESOURCES

American Medical Directors Association. Delirium and Acute Problematic Behavior, Clinical Practice Guideline, 2008

American Nurses Association. The Nursing Process. http://nursingworld.org/EspeciallyForYou/What-is-Nursing/Tools-You-Need/Thenursingprocess.html

The Long Term Care Survey, F-TAG 329. AHCA October 2010 Edition, pp. 441-555

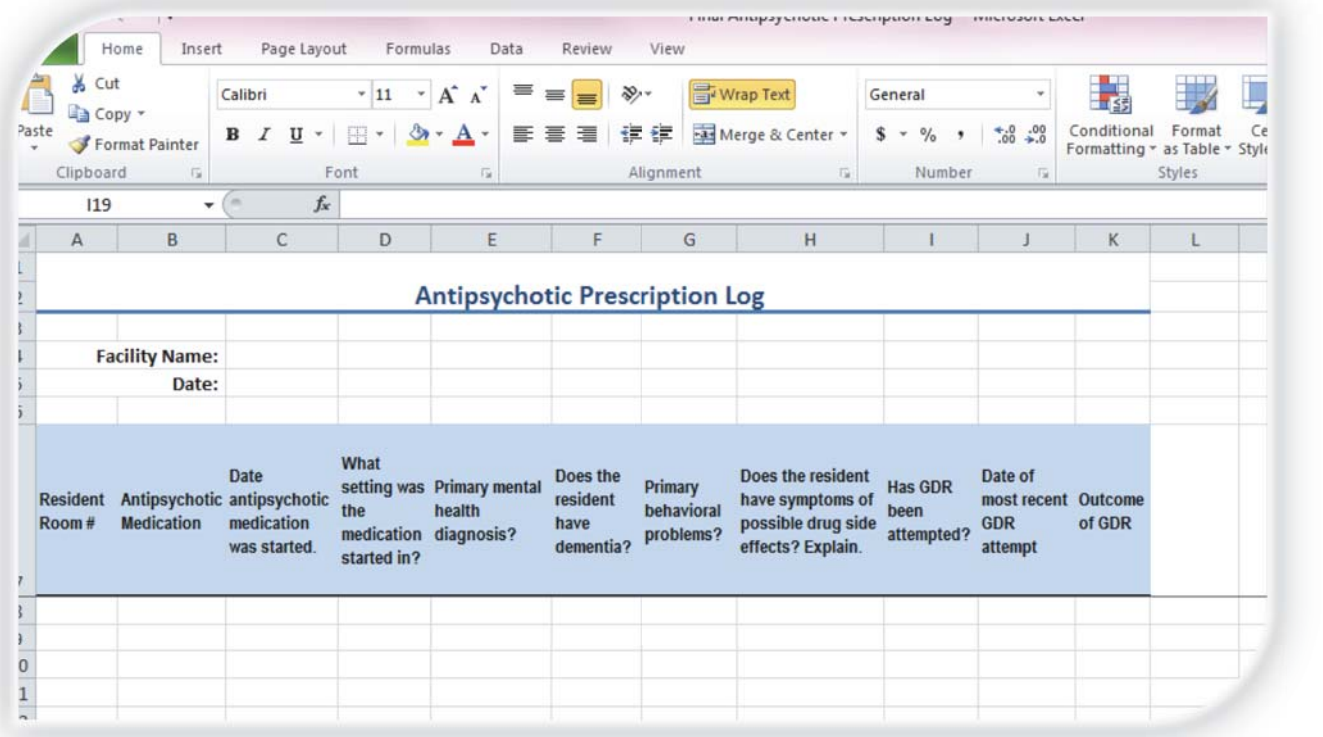
Power, AG. Dementia Beyond Drugs: Changing The Culture of Care. Health professions press, February 2010, pp. 237-238

Psychopharmacological Drugs Gradual Dose Reduction Schedule. Skilled Care Pharmacy 2009 - http://www.skilledcare.com/Userfiles/Care-Letters/GRADUAL-DOSE-REDUCTION-SCHEDULE.pdf

Ryan Carnahan, Phar.D., M.S., BCPP, Assistant Professor (Clinical), The University of Iowa College of Public Health, Recommendations offer to Dr. Gifford, February 27, 2012

ANTIPSYCHOTIC PRESCRIPTION LOG

Download this Excel tool to help keep tack for antipsychotic medication use in your organization.



SAMPLE FACILITY POLICY FOR USE OF ANTIPSYCHOTIC MEDICATIONS

(Facility Name)_____ recognizes that antipsychotics benefit only some residents and can be associated with side effects and risks. Therefore, when antipsychotic medications are used in our facility, the facility will identify target behaviors and implement a care plan with both non-pharmacological and pharmacological interventions. Potential adverse drug reactions and side effects will also be evaluated along with a plan for periodic attempts at dose reduction, where indicated or unless clinically contraindicated.

SAMPLE FACILITY MEMO TO PHYSICIANS ON ANTIPSYCHOTIC MEDICATION USE

Date:

To: Facility Physicians
From: Facility Administrator / DON

Dear Doctors:

On May 30, 2012 Centers for Medicare and Medicaid (CMS) announced the Partnership to Improve Dementia Care, an initiative to ensure appropriate care and use of antipsychotic medications for nursing home patients. This partnership consists of federal and state entities, nursing homes and other providers, advocacy groups, and caregivers. The initiative was spurred by research showing that one quarter of Medicare beneficiaries in nursing homes are prescribed antipsychotic medications and that the use of these drugs may be beneficial but may also be associated with increased risk of death.

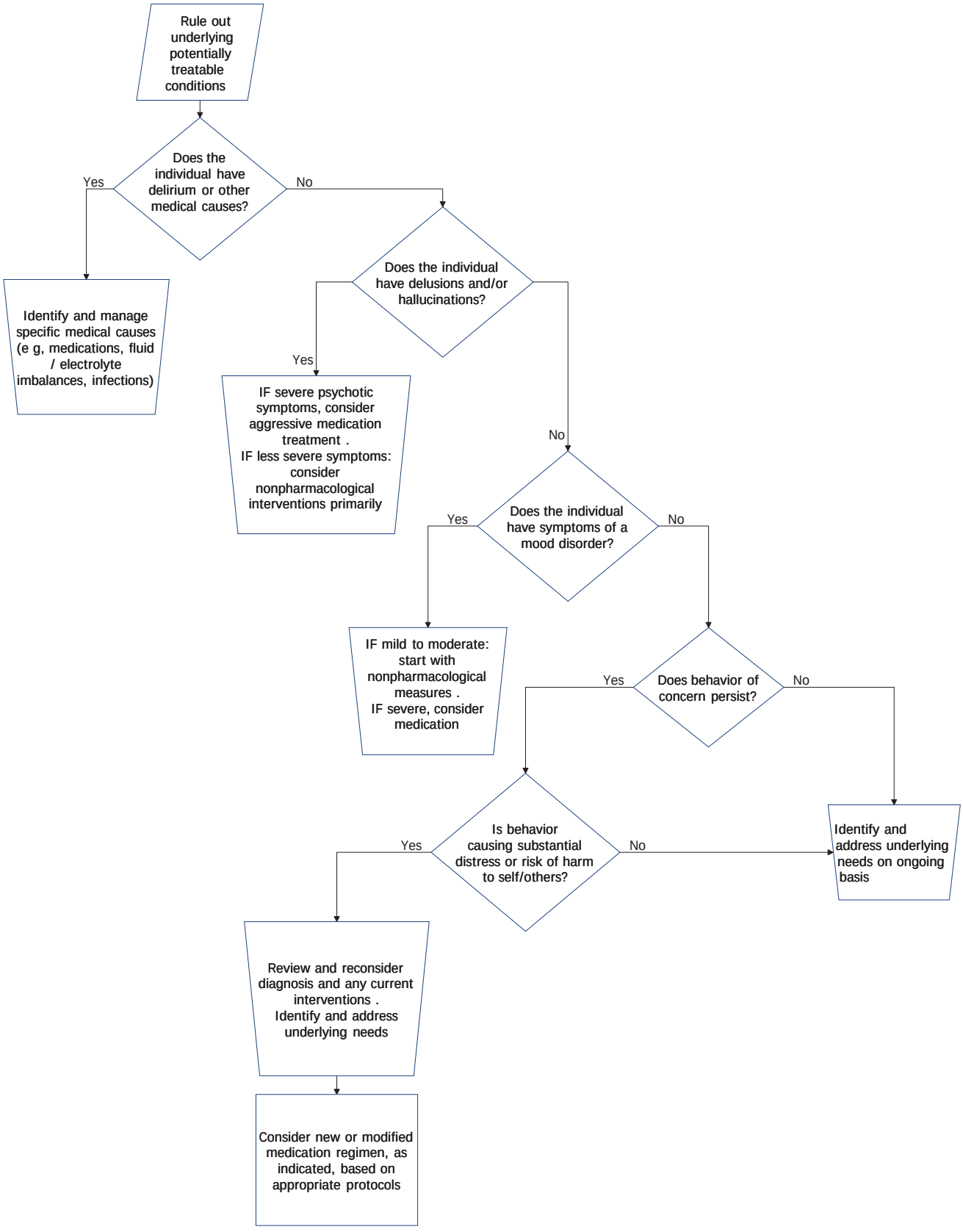
According to federal guidance, antipsychotics should not be used if the only indication for drug use is one or more of the following issues: wandering, poor self care, restlessness, impaired memory, anxiety, depression (without psychotic features), insomnia, unsociability, indifference to surroundings, fidgeting, nervousness, uncooperativeness, or agitated behaviors that do not represent a danger to the resident or others. CMS requires attempted gradual dose reductions of the antipsychotic and the use of behavioral interventions (unless clinically contraindicated).

In keeping with the Partnership to Improve Dementia Care, _____ Nursing Center is focusing on dementia care and reducing the use of antipsychotic medications, when possible, to address disruptive behaviors. We would like you to be aware of our effort and to support our clinical staff in managing behavioral issues with the limited use of antipsychotics and to consider gradual dose reductions or eliminate medication use for individuals without a history of psychiatric illness or current psychiatric symptoms.

We appreciate your support in helping us provide the best possible care to the individuals we serve. If you have any questions or need further information, please contact _____ (DON) at _____ (phone number).

We cannot achieve success without you!

Approach to Considering Causes of Behavior



GUIDANCE TO USING THE CONSIDERING CAUSES OF BEHAVIOR ALGORITHM

How to Use the Algorithm

This algorithm, entitled, "Approach to Consider Causes of Behavior," is intended to provide a framework for thinking about medical and psychiatric conditions that cause or contribute to behavior, especially when:

- The situation is not simple (that is, something other than a straightforward intervention that readily corrects an identifiable cause).
- The causes are unclear.
- Interventions have been based mostly on conjecture.
- Behavior details or patterns are markedly different than baseline or anticipated.
- Behavior is accompanied by other symptoms, abnormalities or changes in condition, such as falling, loss of appetite, unstable vital signs, breathing difficulty, and change in level of consciousness.
- The individual is getting worse despite interventions, or initial or previous interventions are not working or not working as well as anticipated.

How to Do Cause identification

The algorithm focuses on cause identification. Cause identification is always preceded by recognition, description (organizing a story of what is happening) and assessment (gathering details). Effective cause identification (including, for doctors, diagnosis) depends heavily on the clarity and pertinence of information gathered by the nurse during assessment and the organization and completeness of the "story" of the situation.

The cause identification steps include:

- **Observe** and describe the situation in detail (what happened, in what sequence, who was involved, when, how often, how severe, etc.) and give the sequence of events before, during, and after the behavior occurred.
- **Gather** more details about the individual (past history, medications, environment, specific findings such as presence of hallucinations or paranoia, etc.).
- **Organize** the information.
- **Plan** by identifying appropriate interventions, based as much as possible on the thinking about likely causes.
- **Review** the information with a practitioner and discuss what the information leads to about possible or likely underlying causes.

When to Use the Algorithm

The algorithm is designed for nurses and practitioners. It can be used at a safety meeting/huddle or any interdisciplinary team meeting about the resident where the underlying causes of behavior are discussed.

For more direction on how to identify the causes of behavior, go to the Case Study 1: Antipsychotic Drug issues.

ANTIPSYCHOTIC MEDICATION TAPERING CHECKLIST

Tapering More Likely to Succeed If	Potential Problems If
☐ There is a clear and detailed picture of the individual's cognition, mood, and behavior, including accurate diagnoses and identification of underlying causes	☐ The picture of the individual's cognition, mood, and behavior are muddled, with vague descriptions, questionable or unconfirmed diagnoses, and unclear identification of underlying causes
☐ The individual does not have delirium or acute psychosis	☐ The individual has delirium or acute psychosis
☐ The individual was not recently ill or hospitalized with significant medical illness that has affected mood, behavior, cognition, or function	☐ The individual was recently ill or hospitalized with significant medical illness that has affected mood, behavior, cognition, or function
☐ Individual's behavior and mood have been stable for an extended period (weeks to months)	☐ Individual's behavior and mood have been unstable in recent weeks or only stable for several weeks
☐ The reason why an antipsychotic was started is clear, based on reliable information	☐ The reason why an antipsychotic was started is unclear and/or speculative
☐ The individual is not taking any other medications that can cause psychosis and/or adversely affect behavior or mood	☐ The individual is taking other medications (in any category, not just psychopharmacological medications) that can cause psychosis and/or adversely affect behavior or mood
☐ There are specific goals related to target symptoms and a pertinent approach to documenting, monitoring, and reporting those target symptoms	☐ There are no specific goals, or only vague ones, related to target symptoms and a pertinent approach to documenting, monitoring, and reporting those target symptoms
☐ A practitioner is available and willing to help staff reassess the individual's status during the period of medication tapering	☐ A practitioner is unavailable, unable, or unwilling to help staff reassess the individual's status during the period of medication tapering
☐ The individual (where feasible) and family (or other substitute decision maker) are involved in the plan for tapering medication and monitoring results	☐ The individual (where feasible) and family (or other substitute decision maker) are not involved in the plan for tapering medication and monitoring results
☐ Effective non-pharmacological interventions have been instituted	☐ Non-pharmacological interventions have not been successful in preventing or controlling symptoms
☐ Previous attempts at tapering psychopharmacological medications were successful, and symptoms have not recurred to any significant extent	☐ Previous attempts at tapering psychopharmacological medications were unsuccessful, and/or medications have had to be restarted previously or added, due to recurrence of significant symptoms

Using of the checklist:
1. Check off the applicable boxes for each of the 10 rows above.
2. Count the number of boxes checked in each column.
3. Tapering of an antipsychotic medication is more likely to succeed if substantially more items in the left-hand column are checked compared to the right-had column.
4. To the extent possible, address the issues checked off in the right-hand column before or while attempting to taper an antipsychotic medication, in order to make successful tapering more likely.

SBAR

Patient Name:

Physician/NP/PA Communication and Progress Note Date of Birth:

To Discuss Possible Drug Reduction for an Individual Medical record #:

Already Receiving an Antipsychotic Drug for Off-Label Use

Before Calling the MD/NP/PA:

__ Evaluate the patient and complete the SBAR form
__ Check VS: BP, pulse, respiratory rate, neurological check, lung sound, temperature, pain level
__ Review chart for:

- psychiatric conditions and/or hospitalizations
- recent physician or psychologist progress notes
- pharmacist medication regimen review notes
- abnormal clinical and laboratory findings
- notes on possible drug side-effects

__ Be prepared to report on dosing changes, changes in target symptoms and potential side effects
__ Have relevant information available when reporting (medication list including doses, method and time(s) of administration)
__ Be prepared to have a list of all medications, including PRNs, and the individual's medical record

Situation

The drug and behavior (if problematic) I am calling about is _____
Date drug started ___/___/___
Date of last dose adjustment and dosage change made ___/___/___
Individual's symptoms has gotten worse/better/stayed the same since the drug started _____
Have any potential side effects been noticed? __No __Yes (If yes describe)

_____
_____

Things that make the symptoms worse

_____
_____

Things that make the symptoms better (non-pharmacological approach)

_____
_____

Other things that have occurred related to this symptom and treatment

_____
_____

Background

Primary diagnosis and/or reason person is at the nursing home

_____
_____

Pertinent mental health history

_____
_____

Behavioral concerns identified by family

_____

Vital signs BP_____/_____ HR_____ RR _____ Temp_____
Individual is on a scheduled pain management program ___Yes ___No
If yes, what medication interventions is the individual receiving?

_____

Conditions (check all those that apply)

- ☐ orthostatic hypotension
- ☐ weight gain
- ☐ increase glucose level
- ☐ urinary retention
- ☐ constipation
- ☐ sedation
- ☐ restlessness
- ☐ pacing
- ☐ drooling
- ☐ tremors
- ☐ rigidity
- ☐ slowness of movement
- ☐ jerk body responses
- ☐
- ☐ lip smacking/ chewing/abnormal tongue movement
- ☐ involuntary movement of extremities
- ☐ worsening confusion/delirium
- ☐ fall

Other _____

Medication changes or new orders in the last two weeks _____
Recent Labs _____
Allergies _____
Any other data _____

Assessment (RN) or Appearance (LPN)

(For RNs): The individual's symptoms appear (better/worse/same) _____
I think the symptoms may be related to _____
Do you believe the individual has achieved a therapeutic dose? ___ No ___Yes If yes: Do you believe dose reduction may be needed? _____
(For LPNs): The individual's symptom(s) appear (better/worse/same) _____

Request

I suggest or request (check all that applies):

- ☐ Other (start/change non-pharmacological approach)
- ☐ Change in/stop current med order(s)
- ☐ Provider visit (MD/NP/PA)
- ☐ Continued monitoring
- ☐ Lab work

Staff name _____ **RN/LPN** _____
Reported to: Name _____ (MD/NP/PA)
Date___/___/___ **Time**____AM/PM
If to MD/NP/PA, communicated via: _____
Phone (____) ____ - _____ In-person ____

Progress Note (complete and place SBAR/progress note in medical record)

_____
_____
_____
_____

__ Family or health care proxy notified
Return call/new orders from MD/NP/PA Date___/___/___ Time___/___AM/PM

Signature_____ RN/LPN Date___/___/___ Time___/___AM

WHAT IS CHAT?

CHAT stands for **C**ommunicating **H**ealth **A**ssessments by **T**elephone. It is a quality improvement program to enhance telephone communication between the nurse and the physician.

The quality improvement program was developed by Heather Whitson, MD, S. Nicole Hastings, MD, Deborah Lakan, RNC, MSN, Richard Sloane, MPH, Heidi White, MS and Eleanor McConnell, RN, PhD from the Department of Medicine and the Center for the Study of Aging and Human Development and School of Nursing at Duke University, Durham, NC. The program was studied and conducted at Extended Care and Rehabilitation Center, Durham Veterans Affairs Medical Center. Funding support was provided by the AMDA Foundation and the John A. Hartford Foundation.

The purpose of the study program was to improve the communication of health assessment by telephone and determine whether satisfaction of on-site nurses improved after the **CHAT** intervention.

CHATs are point-of-care decision support tools adapted from the 2004 American Medical Director's Association (AMDA) protocols. They represent 16 common clinical problems found in long term care settings. The common conditions include:

- Abdominal Pain
- Agitation
- Confusion
- Altered Mental Status
- Bloor pressure
- Low Blood Pressure
- Chest pain
- Constipation
- Diarrhea
- Dizziness/Unsteadiness
- Dyspnea/Shortness of Breath
- Fall
- Fever
- Hyperglycemia
- Hypoglycemia
- Musculoskeletal Complaint
- Nausea or Vomiting
- Urinary Complaints or Positive urinalysis

Each **CHAT** is designed to identify pertinent information that needs to be assessed and communicated for the specific clinical issue. The tools focus on the questions needing to be answered and the examinations needing to be conducted before calling the physician.

Patient Name: _____
Date of Birth: _____
Medicaid Record Number: _____

CHAT: AGITATION/CONFUSION/ALTERED MENTAL STATUS

History
How long ago did the symptoms start? Tell the story: _____
_____
_____
_____

Other symptoms or events in the last 24 hours:

- ☐ Fall
- ☐ Constipation
- ☐ Medication changes
- ☐ Cough
- ☐ Fever
- ☐ Pain
- ☐ Urinary symptoms

Exam
Current vital sign _____
Oxygen saturation _____
Finger stick (blood glucose), if diabetic _____

Other pertinent information may include neurological assessment, signs of injury, dehydration or infection.
_____
_____
_____
_____

Staff Name: _____ RN/LPN
_____

Reported to:
Name: _____(MD/NP/PA) Date: _____ Time: _____ am __ pm__
If to MD/NP/PA, communicated via: _____ Phone _____ In person
_____

(This CHAT has been modified by AHCA. The original CHAT is a product of Duke University)

Patient Name: _____
Date of Birth: _____
Medicaid Record Number: _____

CHAT Progress Note

Progress Note (complete and place CHAT/progress note in medical record)

__ Family or health care proxy notified
Return call/new orders from MD/NP/PA Date___/___/___
Time___/___AM/PM

Signature_____RN/LPN Date___/___/___
Time___/___AM/PM

(This CHAT has been modified by AHCA. The original CHAT is a product of Duke University)

Patient Name: _____
Date of Birth: _____
Medicaid Record Number: _____

CHAT: DIZZINESS/UNSTEADINESS

History

How long ago did this symptom start? Tell the story: _____
_____
_____
_____

Has the patient had these symptoms on other occasions? Tell the story: _____
_____
_____
_____

Any changes to the medication list or doses in the last week? _____
If yes, what medication changed? _____

Any PRN medication doses given in the last 24 hours?
If yes, what medication? _____

Exam

Blood pressure and pulse (sitting and standing): _____ and _____
Finger stick (blood sugar), if diabetic: _____

Other pertinent information may include a neurologic exam and assessment of mental status.
_____
_____
_____
_____

Staff Name: _____

Reported to:
Name: _____(MD/NP/PA) Date: _____Time: _____ am __pm __

If to MD/NP/PA, communicated via: _____ Phone _____ In person _____

(This CHAT has been modified by AHCA. The original CHAT is a product of Duke University.)

Patient Name: _____
Date of Birth: _____
Medicaid Record Number: _____

CHAT Progress Note

Progress Note (complete and place CHAT/progress note in medical record)

__ Family or health care proxy notified
Return call/new orders from MD/NP/PA Date___/___/___
Time___/___AM/PM

Signature_____RN/LPN Date___/___/___
Time___/___AM/PM

(This CHAT has been modified by AHCA. The original CHAT is a product of Duke University)

Patient Name: _____
Date of Birth: _____
Medicaid Record Number: _____

CHAT: FALL

History
Is the patient having new pain anywhere since the fall? Tell the story: _____
_____
_____
_____

Did the patient hit his/her head? Tell the story: _____
_____
_____
_____

Any loss of consciousness before or after the fall? Tell the story: _____
_____
_____
_____

Exam
Can the patient ambulate as well as he/she could before the fall? _____

Any obvious injuries (lacerations,deformities)? _____

Blood pressure and pulse (sitting and standing) _____

Other pertinent information may include joint assessment for range of motion, assessment of mental status (level of consciousness, orientation, speech), blood glucose if patient is diabetic.

_____
_____
_____
_____

Staff Name: _____(RN/LPN) _____

Reported to:
Name: _____(MD/NP/PA) Date: _____ Time: _____am __ pm __

If to MD/NP/PA, communicated via: _____ Phone _____ In person

(This CHAT has been modified by AHCA. The original CHAT is a product of Duke University.

Patient Name: _____
Date of Birth: _____
Medicaid Record Number: _____

CHAT Progress Note

Progress Note (complete and place CHAT/progress note in medical record)

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

__ Family or health care proxy notified
Return call/new orders from MD/NP/PA Date___/___/___
Time___/___AM/PM

Signature_____RN/LPN Date___/___/___
Time___/___AM/PM

(This CHAT has been modified by AHCA. The original CHAT is a product of Duke University)

Developed by
Heather Whitson, MD; Susan N. Hastings, MD; Eleanor McConnell, RN, PhD (GRECC)

ECRC Steering Committee:
Cheryl Barker, RN; Alison Bingman, GNP; Nicole Davis, GNP; Linda Fish, RN; Lily Foster, RN; Mary Francis, RN; Ruth Frank, RN; Lorraine Galkowski, RN; Linda Heeg-Krause, RN, Carol Paniccia, RN; Jennifer Shaffer, RN; Mary Tatum, RN; and Janette Warsaw, RN

Designed by
Lesa Hall, Medical Illustrator

Reference:
AMDA – Protocols for Physician Notification 2004

Funding Support:
AMDA Foundation and the John A. Hartford Foundation

EVALUATION

ANTIPSYCHOTIC MEDICATIONS QA REVIEW TOOL

The Antipsychotic Medications QA Review Tool is intended to be used by centers to help evaluate prescribing and gradual dose reduction decision making practices The tool is structured to follow nursing process and should be used to evaluate adherence to process with regard to treatment and care plan decisions involving medication use, reduction or discontinuation. Evaluate question responses to determine practice improvement areas.

	YES	NO	N/A
RECOGNITION			
1. Is there documentation of the details of any potentially problematic behavioral responses?			
2. Is there a clearly documented rationale for why a behavioral response is considered problematic?			
3. Is there documentation of a careful review of the medication regimen, including review for medications that impact behavior, mood, and cognition?			
CAUSE IDENTIFICATION			
4. Is there documented effort to review underlying medical and nonmedical causes of problematic behavioral responses, beyond attributing them to dementia or sundowning?			
5. Did you ask the resident and/or the family directly about a possible cause/trigger of their behavior?			
6. Are direct caregivers consulted about possible cause/trigger of behavior?			
MANAGEMENT			
7. Are there specific goals and objectives for responding to a resident's behavioral expressions?			
8. Is there a documented rationale for choosing and implementing specific interventions, including non-pharmacological approaches?			
9. Is there a documented rationale for initiating or continuing to use any medications in any category that can affect mood, cognition, level of consciousness, or behavior?			
10. Is the resident and family involved in the decision to stop or continue medication and other care plan decisions?			
MONITORING			
11. Is there evidence of ongoing monitoring/documentation of an individual's responses to interventions and related adjustment of interventions?			
12. Is there evidence of ongoing monitoring/documentation for complications of any interventions and for addressing the causes of such complications?			
13. Is there a documented rationale, included in the care plan, for initiating, continuing, or modifying any interventions, including antipsychotics?			

ASSESSMENT OF RESIDENT RECEIVING PSYCHOTROPIC MEDICATION

The goal of this assessment is to review residents who are receiving psychopharmacological medications. The tool can be used to guide discussion in reviewing resident behavior during Risk or Care Management and/or Standards of Care Committee meeting where appropriate interdisciplinary members are in attendance, for example, Pharmacy Consultant, Medical Director, Behavioral Health Specialists, etc.

Use this tool for all residents admitted on psychotropic drugs and periodically after the medication has been started and/or severity of symptoms noted.

Resident Name: _____

Date of Admission: _____ Date of initial medication assessment: _____

Previous living arrangements prior to admission (check appropriate selection):

Home ___ AL ___ SNF ___ Other _____

BIMs Score * _____ Date _____ or MMSE Score*_____Date _____

List psychotropic drugs including antipsychotics, anxiolytics, sedative/hypnotics, antidepressants, and other drugs used to treat psychiatric/behavioral disorders or symptoms

Drug Name/Dose	Directions	Diagnosis/Indication	Start Date (If known)	Effective/Side Effects

Behaviors that prompted initiation of above medications; if not known, describe behaviors observed since admission: _____

_____

Discussion at meeting is focused on effectiveness and relevance of continuing the medication. Also consider potential benefits of tapering and/or a trial off of psychotropic drugs, especially of antipsychotics and hypnotics. The following questions may prompt discussion.

- Have non-drug interventions been attempted in the past? If so, what have been the results and what interventions have been used?
- Has pain been assessed and managed?
- What are the possible needs the resident may be trying to communicate behaviorally?
- Are behaviors causing negative outcomes/ disturbing for the resident?
- Could behaviors be addressed by staff intervention instead of medication?

- Could behaviors be addressed by staff intervention instead of medication?
- Can these interventions be implemented routinely? If not, what are the barriers?
- Have medical causes been addressed? (i.e. metabolic and endocrine disorders, infections. etc.)
- Is staff response contributing to or increasing behaviors?
- Are families concerned about behaviors typically found in AD?
- Are family interactions with resident contributing to or increasing behaviors?
- Previous successes or failures with medications?
- Is the resident experiencing side effects from the medications? Are there other medications that might be contributing to behaviors?

Would a tapering or trial off antipsychotic or hypnotic meds be appropriate at this time?

If so, why? If not, why not? _____

_____

Note: If a tapering or trial off is implemented, monitor carefully using behavior monitoring sheets.

Summary of discussion: _____

_____

_____

Recommendation(s) and Action Plan: _____

_____

_____

Identify team members completing this assessment: _____, _____,

_____, _____, _____, _____.

Date of follow up assessment: _____

Summary of behaviors since changes implemented: _____

_____

_____

Further recommendation(s) and Action Plan: _____

_____

_____

Identify team members completing this assessment: _____, _____,

_____, _____, _____, _____.

* MMSE – Mini Mental State Exam BIMs – Brief Interview of Mental Status

ANTIPSYCHOTIC DRUGS – COMMON TERMS & DEFINITIONS

Atypical Antipsychotic (Second Generation) – Is a newer class of antipsychotic medication approved by the U.S. Food and Drug Administration (FDA) primarily for the treatment of schizophrenia and bipolar disorder.

There are currently 9 FDA-approved atypical antipsychotic drugs including:

1. Aripiprazole (Abilify) – Schizophrenia, Bipolar, and as added therapy for major depressive disorder
2. Asenapine (Saphris) – Schizophrenia and bipolar disorder
3. Clozapine (Clozaril) – Schizophrenia (restricted distribution)
4. Iloperidone (Fanapt) – Schizophrenia
5. Olanzapine (Zyprexa) – Schizophrenia, Bipolar, and as added therapy for treatment-resistant major depressive disorder
6. Paliperidone (Invega)– Schizophrenia and schizoaffective disorder
7. Quetiapine (Seroquel) – Schizophrenia, Bipolar, and as added therapy for major depressive disorder (Seroquel-XR)
8. Risperidone (Risperdal) – Schizophrenia and Bipolar
9. Ziprasidone (Geodon) – Schizophrenia and Bipolar

Behavioral Interventions are individualized non-pharmacological approaches (including direct care and activities) that are provided as part of a supportive physical and psychosocial environment, and are directed toward preventing, relieving, and/or accommodating a resident's distressed behavior.

Black Box Warning refers to the FDA warning to communicate the risks associated with increased mortality in elderly patients with dementia-related psychosis treated with antipsychotic drugs.

WARNING

Increased Mortality in Elderly Patients with Dementia-Related Psychosis — Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. [this drug] is not approved for the treatment of patients with dementia-related psychosis.

Environmental Causes of Behavior are situations or factors external to the individual that may cause or contribute to exacerbations of behavior and psychiatric symptoms; for example, level/type of stimulation, noise, confusion, lighting, caregiver approach, institutional routines/expectations, and lack of cues.

Extrapyramidal symptoms (EPS) are neurological side effects of medications (including, but not limited to, antipsychotic medications) that result from an imbalance of the extrapyramidal nervous system. EPS includes various syndromes such as:

- Akathisia, which refers to a distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing or rocking.

- Pseudoparkinsonism is a syndrome of Parkinson-like symptoms including tremors, shuffling gait, slowness of movement, expressionless face, drooling, postural unsteadiness and rigidity of muscles in the limbs, neck and trunk.

- Dystonia, which refers to an acute, painful, spastic contraction of muscle groups (commonly the neck, eyes and trunk) that often occurs soon after initiating treatment and is more common in younger individuals.

Gradual Dose Reduction (GDR) is the stepwise tapering of a dose of medication to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

Off-Label use of Antipsychotic Antipsychotic drug used for indications other than those that are approved by the FDA.

Psychiatric Causes of Behavior are commonly recognized disorders (e.g., depression, delirium, psychosis, personality disorders) that appear to cause or contribute to behavior and related symptoms.

Psychoactive Medication (or Psychotropic Medication) is a chemical substance that crosses the blood-brain barrier and acts primarily upon the central nervous system where it affects brain function, resulting in changes in perception, mood, consciousness, cognition and behavior.

Typical Antipsychotic (First Generation Antipsychotics, Neuroleptics, or Major Tranquillizers) refers to the original group of medications that were first used successfully to treat primary psychotic disorders such as schizophrenia. Common First Generation drugs include Compazine, Haldol, Loxitane, Mellaril, Moban, Navane, Orap, Prolixin, Stelazine, Thorazine, and Trilafon.

Unmet Physical Needs are basic human physical conditions or needs that have yet to be satisfied, for example; pain, illness, hunger, sleep disturbance, constipation, elimination needs. {NOTE: Medication is not a physical need; it is a treatment for physical or other needs.}

Unmet Psychological Needs are imbalances related to basic human emotions, for example; loneliness, boredom, apprehension, worry, fear, lack of socialization, loss of intimacy.

CASE STUDY 1: BEHAVIOR ISSUES IN A RESIDENT WHO IS ALREADY RECEIVING PSYCHOPHARMACOLOGICAL MEDICATIONS

The Story - Part 1

The Patient: Mr. Donald Lee, born in February 1925, admitted to the facility in September 2011.

Problem Statement: Donald is an 87-year-old male with advanced dementia who has been a resident in the facility for 5 months. Until recent weeks, he had been relatively stable. In the past few weeks, His behavior issues have become more frequent, problematic and unpredictable. He had become increasingly restless and combative over several weeks. Sleep was very poor with continuing restlessness throughout the night. He has had a colostomy for several years. Recently, he had begun pulling on and dislodging his colostomy. He has become increasingly combative and restless, with a shorter than usual attention span. Repeated efforts to redirect his behavior failed. He talks incessantly and despite being asked repeatedly about personal needs, his responses were not relevant. He has a very short attention span. Staff was unable to keep him engaged in any activities.

"The Story" – Background:

- Donald was admitted to the facility immediately after hospitalization due to a fall down steps at home that caused a subdural hematoma.
- Admission diagnoses included cerebellar mass, subdural hematoma, dementia, dysphagia, atrial fibrillation, peripheral vascular disease, hypertension, COPD, hypothyroidism, polymyalgia rheumatica, glaucoma, history of resected rectal carcinoma with colostomy and depression.
- Donald had lived at home with his wife, who comes and visits him daily. He has a daughter who is very involved in his care.
- During his working days, Donald was a Marine. He has been retired for many years. He was a smoker and has significant chronic obstructive pulmonary disease (COPD) and heart disease.

Medications and Outcomes:

- On admission to the facility, his key medications included Sertraline 25 mg hs for mood disorder, Levothyroxine 0.050 mg qd for hypothyroidism, Namenda 10 mg qd for dementia, Prednisone 10 mg qd for COPD, Digoxin 0.125 mg qd for atrial fibrillation, and Tramadol 25 mg q8h PRN for pain.
- Namenda was subsequently increased some time after admission to b.i.d. Olanzapine 2.5 mg qd PRN was added for severe agitation. Melatonin 2 mg hs was added to help with sleep.
- On 4/1/12, Olanzapine 2.5 mg qd PRN was discontinued. There was no improvement noted.
- On 4/2/12, Sertraline was changed to every other day. No improvement was noted.
- On 4/19/12, Melatonin was increased from 2 to 3 mg hs. No improvement in his sleep was noted.
- On 4/23/12, Risperdal 0.25 mg was ordered for 3 days. A psychiatric consultation was requested.
- On 4/30/12, the psychiatrist recommended discontinuing Melatonin and Zoloft and starting Risperdal 0.25 mg qhs for possible dementia with mania. No improvement was noted.
- On 5/1/12, a Digoxin level was within the therapeutic range. Donald was restless and up much of the night.
- On 5/2/12, Trazodone 25 mg qhs was ordered with no improvement in sleep noted.
- On 5/7/12, staff noted an acute change in mental status and found Donald difficult to arouse.

Teaching: Part 1

Communicating with the Attending Physician about the Resident's Change in Condition

Have nurses review the background information for Donald Lee and then instruct them to respond to the questions below.[1]

1. What information is least relevant to have in preparation for the call?
    a. Resident history of advanced dementia
    b. He has a history of COPD
    c. Increasing incidents of restlessness and problem behavior
    d. Recent history of dislodging his colostomy

2. When using the SBAR communication technique, the nurse's initial statement to the physician should be?
    a. I'm sorry to bother you about the resident
    b. One of your residents seems to have a problem
    c. Resident has a history of dislodging his colostomy
    d. I'm concerned about Mr. Lee, he has an acute change in mental status and is difficult to arouse

3. In this situation, what patient data should be reported first?
    a. Details of the current mental status change
    b. Admission diagnoses
    c. Outcomes of medication changes
    d. Psychiatric consultation recommendations

4. Before discussing subsequent treatment or testing with the physician, the nurse should be prepared to
    a. Discuss potential causes of the acute change in mental status
    b. Review the resident's story in chronological order
    c. Review the current medication regimen
    d. All of the above

Answers

1. B – The resident's COPD history is not immediately relevant to this situation. A list of diagnoses is not nearly as helpful as a clear and concise description of current mental status, including behavior, mood, and cognition.
2. D – The first part of the SBAR is to clearly and concisely describe the situation. Giving the resident's name, a clear and meaningful statement of the clinical problem and the nurse's concern, alerts the physician to the problem.
3. A – Since the change in mental status is the primary current issue, this information should be presented first and will then set the foundation for offering and evaluating additional pertinent information.
4. D – The nurse's communication with the physician, regardless of clinical problem, should always give enough information so that the practitioner can begin to think about possible causes of the symptom or problem, in order to identify, to the extent possible, parameters for monitoring and the need for possible diagnostic testing, follow-up, and changes in treatment. It is important to

[1] Questions adapted from NURSE.com, Nursing Spectrum (DC/Maryland/Virginia), Clinical Vignette, June 18, 2012, page 31.

give the practitioner time to think through the situation in order to do more than just guess about what is going on or what to do next.

Continuing Case of Donald Lee

- On 5/7/12, Donald was transferred to the hospital Emergency Room. Lab and diagnostic tests that were done in the hospital were unremarkable. The resident was returned to the facility without hospitalization.
- On 5/8/12, Trazodone was discontinued and Namenda was reduced from b.i.d. to daily.
- On 5/9/12, Risperdal was discontinued.

The Story – Part 2

How to Apply Critical Thinking/Reasoning to Determine Problem Cause:

Every discipline can contribute to cause identification, by following an appropriate process. When done by a health care practitioner, cause identification is referred to as "diagnosis." Nurses and those of other disciplines can help practitioners by providing enough of the right information to allow thoughtful diagnostic decision making. Every discipline, including nursing, can potentially apply the same thoughtful approaches to improve other cause identification activities.

Once the nurses/interdisciplinary team have completed the "Communicating with the Physician about the Resident's Change in Condition" questions section, and have identified and discussed the correct answers, have the group focus on their **Critical Thinking/Reasoning** in trying to understand the cause of the resident's issues. Critical Thinking/Reasoning can be accomplished by asking basic questions about the resident to distinguish between potential causes of the problem.

Clinical Thinking/Reasoning Question for Donald Lee

1. Could Mr. Lee have a medical cause of his behavior?
   - Could he be hypothyroid? He was taking a relatively low dose of thyroid replacement. His TSH on 9/19/11 was WNL (3.06). A repeat TSH on 3/23/12 was also WNL. Probability of hypothyroidism as a cause: **very low**.
   - Could he have an infection or heart failure? Chest X-ray 9/30/11 had shown small bilateral infiltrates and an L pleural effusion. In early 2/12, he had been hospitalized with pneumonia. However, there was no current clinical evidence of infections and lab tests were negative. Breathing and vital signs were unchanged. Probability of infectious or cardiac cause: **unlikely**.
   - Could Donald have delirium? The resident had a shortened attention span, frequent fluctuation in behavior and level of consciousness, increased level of involuntary motor activity (restlessness), and altered sleep cycle. All of these findings are consistent with delirium. Possibility of delirium: **high**.
   - Could Donald have some other contributing medical problem? He was not anemic. Despite his COPD, he was not hypoxic enough to account for these symptoms. Also, behavior issues fluctuated regardless of oxygen levels. Possibility of hypoxia: **unlikely**.

2. Could Mr. Lee have a medication cause for his behavior?
   - Could he have digoxin toxicity? Digoxin toxicity can cause various psychiatric symptoms. However, the serum digoxin level was in the middle of the therapeutic range. Probability of Digoxin toxicity: **very low**.
   - Could he have other medication-related adverse consequences? Prednisone can cause psychosis and other behavioral and mood changes. However, his dose was about equal to what the body produces

normally, and the dose had remained constant for years. Probability of prednisone-related cause: **very low**.

- Could he have side effects from his psychopharmacological medications? Sertraline had been continued under the presumption that the resident had a diagnosis of depression. However, it was not clear why or when this was started. There was no clear evidence that he had a mood disorder. Any psychopharmacological medications, including antidepressants and antipsychotic medications, can potentially exacerbate behavior and psychiatric symptoms. In this case, they were not helping improve the symptoms. His behavior was getting worse. Possibility of adverse effects from existing medication regimen: **likely**.

3. Could Mr. Lee have a psychiatric basis for his behavior?
   - Could Donald have psychosis? He could have psychosis, although the condition was fluctuating more than it was escalating steadily. Hallucinations, delusions, and paranoia were noticeably absent. Antipsychotic medications did not result in symptom improvement. Possibility of psychosis: **low**.
   - Could he have a mood disorder? He was already receiving an antidepressant, despite lack of evidence for a mood disorder. His symptoms represented more than simple anxiety. Possibility of mood disorder: **unlikely**.
   - Could he have a personality disorder? There was no evidence of a personality disorder during his earlier years, and the symptoms were not compatible with that. Possibility of personality disorder: **unlikely**.
   - Could he have simple dementia-related symptoms? The determination of dementia-related symptoms is reached by first ruling out other possible causes. In this case, other likely causes were identified. Possibility that this was simply related to dementia: **unlikely**.

4. Could Mr. Lee have a psychosocial or environmental cause for his behavior?
   - Could Mr. Lee have unmet personal needs causing his behavior? Between staff and family, his needs had been addressed consistently since admission. His worsening behavior was ongoing regardless of his personal needs being met. When asked about personal needs and comfort, Mr. Lee's responses were not coherent or relevant. Possibility of unmet personal needs: **unlikely**.
   - Could he have environmental causes? His environment had not changed since admission. Throughout his stay, multiple psychosocial interventions were implemented without success. Symptoms persisted and were not correlated with the presence or absence of such interventions. Nothing was working. Effort to redirect behavior failed. Possibility of environmental factors: **unlikely**.
   - Was he indicating that he did not want the colostomy by trying to remove it? From the time of admission until his recent episodes started, he had never expressed or shown discomfort with the colostomy previously. It had never caused him any complications. The pulling on the colostomy was not an isolated activity, but was associated with increasing restlessness and uncontrolled motor activity. He seemed unaware about what he had done. Possibility of behavior relating to not wanting his colostomy: **unlikely**.

Outcome of Critical Thinking/Reasoning

Based on the above critical thinking questions, the answers indicating **Yes/Likely** help narrow down the thinking about likely causes of the behavior. These outcomes include:

- Primary: He has delirium and side effects from psychopharmacological medications
- Secondary: He has a baseline of chronic, dementia-related behavior

The reporting nurse gives the practitioner enough information to engage in a meaningful conversation about these potential causes. Before and after the specific incident that is reported, the entire staff works with the

practitioner to identify next steps (medication changes, monitoring, etc.) to test these hypotheses about causes.

The Subsequent Story of Donald Lee

After stopping his Sertraline and Trazodone and reducing the Namenda dose, there was a remarkable and rapid improvement. Donald became calmer, stopped pulling on his colostomy, slept much better at night, was easily directable, sat out in the hallway with his family, attended some activities, and was generally pleasant and responsive. He has remained stable for several months. However, he was just as confused and disoriented as before.

Teaching: Section 2

How to Apply Critical Thinking/Reasoning to Determine Problem Cause:

- When teaching a group of caregivers, consider using a **Learning-Circle*** approach. Ask clinicians to frame a question (**Could the resident have …)** and repeat the exercise until all possible questions are identified. Keep a list of the questions.
- Once all the questions are put forth, consolidate them by eliminating redundancies. It will be helpful to categorize question based on possible **Medical Causes, Medication Causes, Psychiatric Causes,** and **Psychosocial/Environmental Causes**.
- Discuss the answers to the questions and ask clinicians to identify and help staff understand the reasoning behind answers to the various possibilities, including Yes/Likely, Unlikely/No, and Probability High, Probability Low
- From the critical thinking exercise, have clinicians develop the key clinical assumption(s) and develop a SBAR in preparation for reporting to the physician on this case.
- Have clinicians use this approach in reporting to the physician in other cases (not just behavior or psychiatric issues).

***Learning Circle Resources**
http://www.pioneernetwork.net/Data/Documents/LearningCircleKeane.PDF

http://www.iearn.org/circles/lcguide/ A teachers' guide to cross-classroom collaboration on projects integrated with curriculum.

AHCA'S SUGGESTED TOOLS FOR REDUCING OFF-LABEL USE OF ANTIPSYCHOTICS:

How These Tools Can Improve Regulatory Compliance

AHCA suggests a number of tools that can be used in a facility to assist in the reduction of off-label use of antipsychotics. To help achieve compliance with some regulatory requirements that relate to the off-label use and reduction of antipsychotics, the ideal is to use all of these tools or tools with similar components. By using them effectively, a facility may not only reduce the off-label use of antipsychotics but may also receive improved regulatory compliance related to their use.

"Clinical Guideline: Managing Behaviors Expressed by Residents with Dementia" directs the nurse to assess and evaluate a resident using the SBAR algorithm. The review must include, at a minimum, seven specified areas. Communication with professionals as well as with the patient and the patient's family are important elements of this Guideline.

The SBAR is a communication tool that assists a nurse effectively convey to a physician the assessment process that has been used to reach certain conclusions and recommendations. This tool may be used when a patient has experienced a significant change and when the nurse would like to discuss a different approach for the care or a patient.

Antipsychotic Medication Tapering Checklist provides a systematic way to determine the likely success of tapering an antipsychotic. When completed and added to a patient's medical record, this provides strong support for the decisions made related to each patient and implementing a tapering regimen.

Both the Antipsychotic Medications QA Review Tool and the Assessment of Psychotropic Medications will provide necessary information and guide discussion and decision-making related to the use of psychotropic medications for individual patients. This can be done within or independent of the QA&A process.

Taken in total, these tools will assist a facility to be in compliance with the following F-Tags:

F157 – Notification of Changes
F154, F155 – Notice of Rights and Services
F272, F273, F274, F275, F276, F278 – All related to assessments, reassessments, or coordination of assessments
F279 – Comprehensive Assessments
F281 – Professional Standards of Care
F309 – Pain Management
F329 – Unnecessary Medications
F281 – Professional Standards
F428 – Medication Regimen Review
F520 – Quality Assessment and Assurance

Dedicated/Consistent Caregivers Tip Sheet

WHAT IS IT:

Dedicated/consistent assignment means the same CNAs and nurses care for the same residents every day, as an on-going assignment, whenever these staff are working. **Rotating assignment** means rotating caregivers from one group of residents to the next after a period of time, whether daily, weekly, monthly, or even after 3 months. Best practice is dedicated assignment for housekeeping, dietary services, activities, social services as well as CNAs and nurses.

WHY DO IT:

The research is now conclusive that dedicated/consistent assignment of CNAs and nurses improves clinical, workforce, and organizational outcomes. The results from 13 research studies show that dedicated assignments lead to enhanced relationships; improved staff attendance; improved staff, resident, and family satisfaction; lower staff turnover; improved accuracy and timeliness of screening and assessments; improved clinical outcomes; and improved quality of life.

Dedicated assignments transform caregiving from "tasks" to relationship-based care. Residents know who is taking care of them and feel secure in the consistency of the relationship. They trust that "their CNA" knows just how to take care of them. Families share that trust and feel they are in a "partnership" with "their caregiver."

Dedicated assignments are the foundation for high quality individualized care and good teamwork because staff know residents so well that they can anticipate their needs and preferences. Dedicated CNAs have a finely-tuned awareness of residents' needs and any changes in their condition. They can catch problems at the earliest warning signs and know how to respond.

Dedicated assignments provide stability – for residents and for staff. With consistent assignments, CNAs know how to plan their work day. Staff then are able to get into a good regular rhythm in their own work that gives them a good regular rhythm with co-workers. CNAs work better as a team when they work with the same co-workers regularly. And the trust between nurses and CNAs is stronger when they work together regularly and when nurses know how well CNAs know their resident, so that if they come with a concern, it is based on that deep knowing.

HOW CONSISTENT ARE YOU NOW? LOOK AT YOUR DATA!

- **Number of Different CNAs Who Care For A Resident:** Here's an easy way to evaluate the extent to which you currently have consistent assignments. For a sample of residents, look at the CNA documentation for a month. Count how many different CNAs have signed off on care. Compare that with how many CNAs would be involved in a resident's care if you were at 100% consistency. That number would probably be somewhere between 8 – 12 CNAs, depending on scheduling.

Prepared by B&F Consulting for the Pioneer Network's National Learning Collaborative
Funded by The Retirement Research Foundation

- **Number of Times CNAs are Moved From Their Consistent Assignment:** For a sample of CNAs, count how many times they are moved from their consistent assignment to cover in another area due to another employee's absence.

HOW TO DO IT:

➢ **Make it Fair and Sensible:**

The success of dedicated assignments depends on the effectiveness of the implementation process. It needs to be put in place through a process that ensures fairness of workload, compatibility of assignments, and supervisory practices that foster teamwork, conflict resolution, and problem solving, particularly in regard to care for residents who staff find challenging. It needs to be accompanied by regular team meetings where information about residents is shared among staff so that anyone can be a back-up in caring for a resident.

Assignments must be fair for staff and a good match for residents and for staff, playing to staff's strengths. For fairness and compatibility, staff members need to be involved in determining assignments, and supervisors need to facilitate adjustments when assignments do not work. Consider involving residents in choosing their caregivers. For residents that all staff find challenging to care for, consider a paired assignment.

➢ **Steps in the Process**

1. **Meet:** Hold a meeting with staff who will be working consistently together.
2. **Scale:** Ask team to make a rating scale for the level of difficulty for each resident.

Resident	Physical	Non-Physical	Total

3. **Rate:** Have the team discuss and rate each resident by that scale.
4. **Select:** Have staff select assignments, making sure that all assignments have a fair mix of residents by degree of difficulty, and are well-matched based on which staff have best relationships with residents. Defer to any resident preferences.
5. **Pair-Up:** Double up for residents staff find physically or emotionally taxing.
6. **Be Fair:** Use a team process to monitor workload and make adjustments as needed, and as residents move out, come in, or have changes in condition.
7. **Trouble-Shoot:** Regularly talk through any situations that staff find challenging, so staff have assistance from co-workers and other clinicians to develop effective strategies to resolve these challenges.
8. **Have Back-Up:** Make consistent assignments of back-ups for when the first line dedicated staff person has time off. Give a solid orientation to any staff serving as back-up, and assure a good introduction is made between the back up and the resident if they don't know one another.

Prepared by B&F Consulting for the Pioneer Network's National Learning Collaborative
Funded by The Retirement Research Foundation

SYSTEMS TO SECURE DEDICATED ASSIGNMENTS

Your scheduling and hiring practices have an impact on consistency of assignments.

- **Scheduling for Dedicated Assignments by Providing Dedicated Back-ups: A 4 on 2 off schedule:**

Your scheduling has a significant impact on your ability to make the math work to support consistent assignments. David Farrell, with SnF Management in California, uses a 4 days on, 2 days off schedule for CNAs, in which 3 CNAs cover two resident assignments with the third CNA having a split assignment. Here's how it looks:

CNA	M	T	W	TH	F	SAT	SUN	M	T	W	TH	F	SAT	SUN
Mary	1	1	1	1	Off	Off	1	1	1	1	Off	Off	1	1
Jane	2	2	Off	Off	2	2	2	2	Off	Off	2	2	2	2
Beth	Off	Off	2	2	1	1	Off	Off	2	2	1	2	Off	Off

- Mary has resident assignment 1, Jane has resident assignment 2, and Beth has two days with assignment 1 and two days with assignment 2.

David suggests you invite staff to trial this approach for 3 months. They'll likely love it and not want to go back because it provides consistency in care and among co-workers. Staff have fewer weekends off than in a traditional alternate weekend schedule but they get real rest. Everyone works weekends, rather than having a separate, disconnected, weekend staff. The stability and consistency work for staff and for residents.

- **Support Dedicated Assignments with Other Organizational Practices:**

Consistent assignment works best when it is surrounded by tremendous support from the rest of the organization. Dedicated assignment depends on:

- Leadership to trouble-shoot problems and foster teamwork within/across shifts.
- Collaboration to problem-solve difficulties and maximize opportunities. Together with clinical and operations staff, consistently assigned CNAs and nurses, can identify effective interventions and work together to implement them.

- **Maintain Consistency When There Are Staff Absences:**

- This is the time to walk the talk. If one group of assignments is affected by an absence, do not compound it by taking another CNA away from her assignment to fill the gap. This will create two groups of residents without their dedicated caregiver. Instead, have an "All Hands on Deck" approach where department heads and nurse managers help out at the busiest times. Ask food service and housekeeping staff to pitch in at meal times. Your actions show your dedication to consistent assignments.
- Develop a pool of consistent back-ups who know the residents they will care for.

Prepared by B&F Consulting for the Pioneer Network's National Learning Collaborative
Funded by The Retirement Research Foundation

- Have a longer huddle at the beginning of the shift to help any CNA who is serving as a substitute be made familiar with the residents they are caring for.
- Make staff assignments by resident group so that the same CNAs always back each other up. Encourage them to work together to work out schedule substitutions for each other so that residents still have consistency.

➢ **Hiring for Dedicated Assignments:**

Connie McDonald at Glenridge Living Community in Augusta, Maine, suggests reversing hiring and scheduling from staff-centered to resident-centered. Here's how:

- Each 8 hour shift x 7 days = 56 hours
- 56 hours are shared by 2 CNAs, one at 32 hours and one at 24 hours; they alternate weekends
- Note that 32 hours is full-time with benefits at this home
- Hire into 32 hr or 24 hr positions by assignment
- CNAs who share a group of residents can switch days if they need to.
- Have CNAs who want to pick up extra hours become the back-up pool for any co-workers working on the same neighborhood/household/unit

Resident Assignments	32 hrs Days	24 hrs Days	32 hrs PMs	24 hrs PMs	32 hrs. nights	24 hrs. nights
Group One	CNA 1	CNA 2	CNA 3	CNA 4	CNA 5	CNA 6
Group Two	CNA 7	CNA 8	CNA 9	CNA 10	CNA 11	CNA 12
Group Three	CNA 13	CNA 14	CNA 15	CNA 16	CNA 17	CNA 18

➢ **Involve Dedicated CNAs in Care Conferences**

- Have the care conference in a location easy for CNAs to get to
- When residents are in their ARD period, let CNAs know. (One home in Webinar One describes using a different color for the CNA assignment sheet when residents are in their ARD and including additional documentation areas that mirror the MDS on mood and Functional Status)
- When a CNA's resident is having a care conference, let the CNA know at the shift huddle.
- Have CNAs routinely share about their residents at shift huddles so that they are used to doing so.
- Provide guidance to CNAs on what kinds of information are useful to share.
- Have members of the interdisciplinary team use non-technical language.
- When CNAs bring up issues about how residents are doing, discuss and explain.
- Follow-up, closing the loop so that CNAs know that the information they share is used and so they know what they are seeing.

For more information on how to calculate and improve your current consistency go to the Advancing Excellence website - **www.nhqualitycampaign.org**. See resource section, Goal 2 for consistent assignments.

Prepared by B&F Consulting for the Pioneer Network's National Learning Collaborative
Funded by The Retirement Research Foundation

Shift Huddles Tip Sheet

What It Is:
A **Huddle** is a quick meeting to share and discuss important information. **Start of Shift and End of Shift Huddles** provide a way to share information about each resident as everyone starts work and to recap any information at the end of the shift that needs to be shared with the next shift. They can be done in a stand-up meeting or as room to room walking rounds with the charge nurse and CNAs together checking on each resident. It helps to have other disciplines join in to share their information and to hear information that can help them contribute to the team caring for residents.

Why Do It:
A shift huddle reinforces teamwork and allows everyone to hear about every resident so staff can provide help to residents not on their assignment. Communication of essential information cannot be left to chance. When it is shared in a group, everyone hears EXACTLY the same information and can share what they know. The group can problem-solve any issues on the spot.

Who Participates:
Shift Huddle is a gathering of the nurses and CNAs working together by unit and shift. It is good to include housekeeping, social work, activities, and therapy or to huddle again quickly later in the shift when these others can participate.

When To Do It:
Shift huddle should occur at the beginning and at the end of the shift. If there is a paid shift overlap, it can be done with staff from both shifts. Huddles can also occur at other times as needed, such as before staff go on break, when a new resident arrives, when an issue arises that needs the team to come together, or when other departments can participate in a short discussion.

How Long:
Start and end of shift huddles should take no more than 15 minutes. In-the-moment huddles can often complete business in less than 5 minutes but may take longer.

How To Do It:
This needs to be a positive mutual exchange of information needed to care for each resident on the hall. Standing Agenda Items may include:

- **Resident by resident report by exception**, focused on *risks and opportunities, including quality of life and quality of care*, using MDS areas of functional status, mood, and customary routines as a guide. INTERACT^{II} *Stop and Watch* is an excellent tool to focus the end of shift exchange.
- Anyone due for their **MDS** (in their **A**ssessment **R**eference **D**ate - ARD)
- **Changes in Census – people coming in or leaving**

Prepared by B&F Consulting for the Pioneer Network's National Learning Collaborative
Funded by The Retirement Research Foundation

- **Information about new residents**, including social history, family information, medical needs, customary routines and special needs
- **Reportable Events, Incidents, Accidents** for any resident
- **Complaints and Compliments** for any resident
- **Follow-up on any issues** raised for which the loop needs to be closed
- Any **clinical area** that is being worked on (e.g., pressure ulcers)
- **News from any department** requiring staff knowledge or coordination
- Introduction of and check-in with **new employees**

Keys to Success:
Be on time, this is a short meeting. It needs to start and end on time. **Everyone** needs to be there on time and be prepared to share.

Process:
This is an exchange among CNAs and with the charge nurse and other staff. At the end of the shift, **CNAs share information** for each resident on their assignment. At the start of shift, nurses give information provided by CNAs and nursing from the previous shift's end of shift report. Other staff may add relevant information about that resident.

Report is **by exception**, focused on risks and opportunities in **quality of care and quality of life**. For example if someone is at risk for pressure ulcers, discussion will include how well they ate and drank, and any positioning issues. If someone has been depressed, the discussion will include their interactions and participation in activities. If a resident does not seem to be oneself that day, this is noted and discussed. See **INTERACT**[II] ***Stop and Watch*** for good examples of issues to note.

Critical Thinking:
To be successful shift huddles have to be valuable to the participants. These are not rote reports. They are opportunities for critical thinking and problem-solving together to ensure the best care for each resident.

Provide Support:
It is optimal to have the support of nursing management answering lights and meeting residents' needs while CNAs and the charge nurse are rounding or having stand-up so that they can have uninterrupted time.

Huddles should be supportive, not negative. Provide mentoring to those nurses who need help on how to facilitate positive team building huddles.

For a short video How-to on Shift Huddles go to
www.BandFConsultingInc.com/WhatYouDoMatters

Prepared by B&F Consulting for the Pioneer Network's National Learning Collaborative
Funded by The Retirement Research Foundation

American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults

The American Geriatrics Society 2012 Beers Criteria Update Expert Panel

Potentially inappropriate medications (PIMs) continue to be prescribed and used as first-line treatment for the most vulnerable of older adults, despite evidence of poor outcomes from the use of PIMs in older adults. PIMs now form an integral part of policy and practice and are incorporated into several quality measures. The specific aim of this project was to update the previous Beers Criteria using a comprehensive, systematic review and grading of the evidence on drug-related problems and adverse drug events (ADEs) in older adults. This was accomplished through the support of The American Geriatrics Society (AGS) and the work of an interdisciplinary panel of 11 experts in geriatric care and pharmacotherapy who applied a modified Delphi method to the systematic review and grading to reach consensus on the updated 2012 AGS Beers Criteria. Fifty-three medications or medication classes encompass the final updated Criteria, which are divided into three categories: potentially inappropriate medications and classes to avoid in older adults, potentially inappropriate medications and classes to avoid in older adults with certain diseases and syndromes that the drugs listed can exacerbate, and finally medications to be used with caution in older adults. This update has much strength, including the use of an evidence-based approach using the Institute of Medicine standards and the development of a partnership to regularly update the Criteria. Thoughtful application of the Criteria will allow for (a) closer monitoring of drug use, (b) application of real-time e-prescribing and interventions to decrease ADEs in older adults, and (c) better patient outcomes. **J Am Geriatr Soc 2012.**

Key words: Beers list; medications; Beers Criteria; drugs; older adults

Medication-related problems are common, costly, and often preventable in older adults and lead to poor outcomes. Estimates from past studies in ambulatory and long-term care settings found that 27% of adverse drug events (ADEs) in primary care and 42% of ADEs in long-term care were preventable, with most problems occurring at the ordering and monitoring stages of care.[1,2] In a study of the 2000/2001 Medical Expenditure Panel Survey, the total estimated healthcare expenditures related to the use of potentially inappropriate medications (PIMs) was $7.2 billion.[3]

Avoiding the use of inappropriate and high-risk drugs is an important, simple, and effective strategy in reducing medication-related problems and ADEs in older adults. Methods to address medication-related problems include implicit and explicit criteria. Explicit criteria can identify high-risk drugs using a list of PIMs that have been identified through expert panel review as having an unfavorable balance of risks and benefits by themselves and considering alternative treatments available. A list of PIMs was developed and published by Beers and colleagues for nursing home residents in 1991 and subsequently expanded and revised in 1997 and 2003 to include all settings of geriatric care.[4–6] Implicit criteria may include factors such as therapeutic duplication and drug–drug interactions. PIMs determined by explicit criteria (Beers Criteria) have also recently been found to identify other aspects of inappropriate medication use identified by implicit criteria.[7]

As summarized in two reviews, a number of investigators in rigorously designed observational studies have shown a strong link between the medications listed in the Beers Criteria and poor patient outcomes (e.g., ADEs, hospitalization, mortality).[7–14] Moreover, research has shown that a number of PIMs have limited effectiveness in older adults and are associated with serious problems such as delirium, gastrointestinal bleeding, falls, and fracture.[8,12] In addition to identifying drugs for which safer pharmacological alternatives are available, in many instances a safer nonpharmacological therapy could be substituted for the use of these medications, highlighting that a "less-is-more approach" is often the best way to improve health outcomes in older adults.[15]

Since the early 1990s, the prevalence of PIM usage has been examined in more than 500 studies, including a number of long-term care, outpatient, acute care, and community settings. Despite this preponderance of information, many PIMs continue to be prescribed and used as first-

From The American Geriatrics Society, New York, New York.

Address correspondence to Christine M. Campanelli, The American Geriatrics Society, 40 Fulton Street, 18th Floor, New York, NY 10038. E-mail: ccampanelli@americangeriatrics.org

DOI: 10.1111/j.1532-5415.2012.03923.x

0002-8614/12/$15.00

line treatment for the most vulnerable of older adults.[16,17] These studies illustrate that more work is needed to address the use of PIMs in older adults, and there remains an important role in policy, research, and practice for an explicit list of medications to avoid in older adults. Because an increasing number of interventions have been successful in decreasing the use of these drugs and improving clinical outcomes,[18,19] PIMs now form an integral part of policy and practice in the Centers for Medicare and Medicaid Services (CMS) regulations and are used in Medicare Part D. They are also used as a quality measure in the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS). Several stakeholders, including CMS, NCQA, and the Pharmacy Quality Alliance (PQA) have identified the Beers Criteria as an important quality measure. In addition, a few studies have begun to identify nonpharmacological alternatives to inappropriate medications[20] and are incorporating Beers Criteria PIMs into electronic health records as an aid to real-time e-prescribing.[19]

An update of the Beers Criteria should include a clear approach to reviewing and grading the evidence for the drugs to avoid. In addition, the criteria need to be regularly updated as new drugs come to the market, as new evidence emerges related to the use of these medications, and as new methods to assess the evidence develop. Being able to update these criteria quickly and transparently is crucial to their continued use as decision-making tools, because regular updates will improve their relevancy, dissemination, and usefulness in clinical practice.

The 2012 update of the Beers Criteria heralds a new partnership with the American Geriatrics Society (AGS). This partnership allows for regular, transparent, systematic updates and support for the wider input and dissemination of the criteria by expert clinicians for their use in research, policy, and practice. To keep this tool relevant, the updated 2012 AGS Beers Criteria must be current with other methods for determining best-practice guidelines. A rigorous systematic review was performed to update and expand the criteria. As in the past, this update will categorize PIMs into two broad groups: medications to avoid in older adults regardless of diseases or conditions and medications considered potentially inappropriate when used in older adults with certain diseases or syndromes. A third group, medications that should be used with caution, has been added. Medications in this group were initially considered for inclusion as PIMs. In these cases, the consensus view of the panel (described below) was that there were a sufficient number of plausible reasons why use of the drug in certain individuals would be appropriate but that the potential for misuse or harm is substantial and thus merits an extra level of caution in prescribing. In some cases, these medications were new to the market, and evidence was still emerging.

OBJECTIVES

The specific aim is to:

Update the previous Beers Criteria using a comprehensive, systematic review and grading of the evidence on drug-related problems and ADEs in older adults.

The strategies to achieve this aim are to:

1. Incorporate new evidence on currently listed PIMs and evidence from new medications or conditions not addressed in the previous (2003) update.
2. Grade the strength and quality of each PIM statement based on level of evidence and strength of recommended grading.
3. Convene an interdisciplinary panel of 11 experts in geriatric care and pharmacotherapy who will apply a modified Delphi method to the systematic review and grading to reach consensus on the updated 2012 AGS Beers Criteria.
4. Incorporate needed exceptions into the criteria as deemed clinically appropriate by the panel. These evidence-based exceptions will be designed to make the criteria more individualized to clinical care and more relevant across settings of care.

INTENT OF CRITERIA

The 2012 AGS Beers Criteria are intended for use in all ambulatory and institutional settings of care for populations aged 65 and older in the United States. The primary target audience is the practicing clinician. Researchers, pharmacy benefit managers, regulators, and policy-makers also use the criteria widely. The intentions of the criteria include improving the selection of prescription drugs by clinicians and patients, evaluating patterns of drug use within populations, educating clinicians and patients on proper drug usage, and evaluating health-outcome, quality of care, cost, and utilization data.

The goal of the 2012 AGS Beers Criteria is to improve care of older adults by reducing their exposure to PIMs. This is accomplished by their use as an educational tool and a quality measure—two uses that are not always in agreement. These criteria are not meant to be applied in a punitive manner. Prescribing decisions are not always clear cut, and clinicians must consider multiple factors. Quality measures must be clearly defined, easily applied, and measured with limited information. The panel considered both roles during deliberations. The panel's review of evidence at times identified subgroups of individuals who should be exempt from the criteria or for whom only a specific criterion applies. Such a criterion may not be easily applied as a quality measure. These applications were balanced with the needs and complexities of the individual. The panel felt that a criterion could not be expanded to include all adults aged 65 and older when only individuals with specific characteristics may benefit or be at greater risk of harm.

METHODS

For this new update, the AGS employed a well-tested framework that has long been used for development of clinical practice guidelines.[6,21–23] Specifically, the framework involved the appointment of an 11-member interdisciplinary expert panel with relevant clinical expertise and experience and an understanding of how the criteria have been previously used. To ensure that potential conflicts of interest are disclosed and addressed appropriately, panelists disclosed potential conflicts of interest with the panel at the beginning. Each panelist's potential conflict of inter-

ests are provided toward the end of this article. This framework also involved a development process that included a systematic literature review and evaluation of the evidence base by the expert panel. Finally, the Institute of Medicine's 2011 report on developing practice guidelines,[23] which included a period for public comments, guided the framework. These three framework principles are described in greater detail below.

Literature Search

The literature from December 1, 2001 (the end of the previous panel's search) to March 30, 2011, was searched to identify published systematic reviews and meta-analyses that were relevant to the project. Search terms included adverse drug reactions, adverse drug events, medication problems, polypharmacy, inappropriate drug use, suboptimal drug therapy, drug monitoring, pharmacokinetics, drug interactions, and medication errors. Terms were searched alone and in combination. Search limits included human subjects, English language, and aged 65 and older. Data sources for the initial search included Medline, the Cochrane Library (Cochrane Database of Systematic Reviews), International Pharmaceutical abstracts, and references lists of selected articles that the panel co-chairs identified.

The initial search identified 25,549 citations, of which 6,505 were selected for preliminary review. The panel co-chairs reviewed 2,267 citations, of which 844 were excluded for not meeting the study purpose or not containing primary data. An additional search was conducted with the additional terms drug–drug and drug–disease interactions, pharmacoepidemiology, drug safety, geriatrics, and elderly prescribing. An additional search for randomized clinical trials and postmarketing and observational studies published between 2009 and 2011 was conducted using terms related to major drug classes and conditions, delimited by more-general topics (e.g., adverse drug reactions, Beers Criteria, suboptimal prescribing, and interventions). Previous searches were used to develop additional terms to be included in subsequent searches, such as a list of authors whose work was relevant to the goals of the project. When evidence was sparse on older medications, searches were conducted on drug class and individual medication names and included older search dates for these drugs. The co-chairs continually reviewed the updated search results for articles that might be relevant to the project. Panelists were also asked to forward pertinent citations that might be useful for revising the previous Beers Criteria or supporting additions to them.

At the time of the panel's face-to-face meeting, the co-chairs had selected 2,169 unduplicated citations for the full panel review. This total included 446 systematic reviews or meta-analyses, 629 randomized controlled trials, and 1,094 observational studies. Additional articles were found in a manual search of the reference lists of identified articles and the panelist's files, book chapter, and recent review articles, with 258 citations selected for the final evidence tables to support the list of drugs to avoid.

Panel Selection

After consultation with the AGS, the co-chairs identified prospective panel members with recognized expertise in geriatric medicine, nursing, pharmacy practice, research, and quality measures. Other factors that influenced selection were the desire to have interdisciplinary representation, a range of medical specialties, and representation from different practice settings (e.g., long-term care, ambulatory care, geriatric mental health, palliative care and hospice). In addition to the 11-member panel, representatives from CMS, NCQA, and PQA were invited to serve as ex-officio members.

Each expert panel member completed a disclosure form that was shared with the entire panel before the process began. Potential conflicts of interest were resolved by the panel co-chairs and were available during the open comment period. Panel members who disclosed affiliations or financial interests with commercial entities are listed under the disclosures section of this article.

Table 1. Designations of Quality and Strength of Evidence

Designation	Description
Quality of evidence	
High	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes ($\geq$2 consistent, higher-quality randomized controlled trials or multiple, consistent observational studies with no significant methodological flaws showing large effects)
Moderate	Evidence is sufficient to determine effects on health outcomes, but the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes ($\geq$1 higher-quality trial with $>$ 100 participants; $\geq$2 higher-quality trials with some inconsistency; $\geq$2 consistent, lower-quality trials; or multiple, consistent observational studies with no significant methodological flaws showing at least moderate effects) limits the strength of the evidence
Low	Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality studies, important flaws in study design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes
Strength of recommendation	
Strong	Benefits clearly outweigh risks and burden OR risks and burden clearly outweigh benefits
Weak	Benefits finely balanced with risks and burden
Insufficient	Insufficient evidence to determine net benefits or risks

Table 2. 2012 American Geriatrics Society Beers Criteria for Potentially Inappropriate Medication Use in Older Adults

Organ System or Therapeutic Category or Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
Anticholinergics (excludes TCAs)				
First-generation antihistamines (as single agent or as part of combination products) Brompheniramine Carbinoxamine Chlorpheniramine Clemastine Cyproheptadine Dexbrompheniramine Dexchlorpheniramine Diphenhydramine (oral) Doxylamine Hydroxyzine Promethazine Triprolidine	Highly anticholinergic; clearance reduced with advanced age, and tolerance develops when used as hypnotic; greater risk of confusion, dry mouth, constipation, and other anticholinergic effects and toxicity. Use of diphenhydramine in special situations such as acute treatment of severe allergic reaction may be appropriate	Avoid	Hydroxyzine and promethazine: high; All others: moderate	Strong
Antiparkinson agents Benztropine (oral) Trihexyphenidyl	Not recommended for prevention of extrapyramidal symptoms with antipsychotics; more-effective agents available for treatment of Parkinson disease	Avoid	Moderate	Strong
Antispasmodics Belladonna alkaloids Clidinium-chlordiazepoxide Dicyclomine Hyoscyamine Propantheline Scopolamine	Highly anticholinergic, uncertain effectiveness	Avoid except in short-term palliative care to decrease oral secretions	Moderate	Strong
Antithrombotics				
Dipyridamole, oral short acting* (does not apply to extended-release combination with aspirin)	May cause orthostatic hypotension; more-effective alternatives available; intravenous form acceptable for use in cardiac stress testing	Avoid	Moderate	Strong
Ticlopidine*	Safer effective alternatives available	Avoid	Moderate	Strong
Anti-infective				
Nitrofurantoin	Potential for pulmonary toxicity; safer alternatives available; lack of efficacy in patients with CrCl < 60 mL/min due to inadequate drug concentration in the urine	Avoid for long-term suppression; avoid in patients with CrCl < 60 mL/min	Moderate	Strong
Cardiovascular				
$Alpha_1$ blockers Doxazosin Prazosin Terazosin	High risk of orthostatic hypotension; not recommended as routine treatment for hypertension; alternative agents have superior risk/benefit profile	Avoid use as an antihypertensive	Moderate	Strong
Alpha agonists, central Clonidine Guanabenz* Guanfacine* Methyldopa* Reserpine (> 0.1 mg/d)*	High risk of adverse CNS effects; may cause bradycardia and orthostatic hypotension; not recommended as routine treatment for hypertension	Avoid clonidine as a first-line antihypertensive. Avoid others as listed	Low	Strong

(Continued)

Table 2. (Contd.)

Organ System or Therapeutic Category or Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
Antiarrhythmic drugs (Class Ia, Ic, III) Amiodarone Dofetilide Dronedarone Flecainide Ibutilide Procainamide Propafenone Quinidine Sotalol	Data suggest that rate control yields better balance of benefits and harms than rhythm control for most older adults. Amiodarone is associated with multiple toxicities, including thyroid disease, pulmonary disorders, and QT- interval prolongation	Avoid antiarrhythmic drugs as first-line treatment of atrial fibrillation	High	Strong
Disopyramide*	Disopyramide is a potent negative inotrope and therefore may induce heart failure in older adults; strongly anticholinergic; other antiarrhythmic drugs preferred	Avoid	Low	Strong
Dronedarone	Worse outcomes have been reported in patients taking dronedarone who have permanent atrial fibrillation or heart failure. In general, rate control is preferred over rhythm control for atrial fibrillation	Avoid in patients with permanent atrial fibrillation or heart failure	Moderate	Strong
Digoxin > 0.125 mg/d	In heart failure, higher dosages associated with no additional benefit and may increase risk of toxicity; slow renal clearance may lead to risk of toxic effects	Avoid	Moderate	Strong
Nifedipine, immediate release*	Potential for hypotension; risk of precipitating myocardial ischemia	Avoid	High	Strong
Spironolactone > 25 mg/d	In heart failure, the risk of hyperkalemia is higher in older adults especially if taking > 25 mg/d or taking concomitant NSAID, angiotensin converting-enzyme inhibitor, angiotensin receptor blocker, or potassium supplement	Avoid in patients with heart failure or with a CrCl < 30 mL/min	Moderate	Strong
Central nervous system				
Tertiary TCAs, alone or in combination: Amitriptyline Chlordiazepoxide-amitriptyline Clomipramine Doxepin > 6 mg/d Imipramine Perphenazine-amitriptyline Trimipramine	Highly anticholinergic, sedating, and cause orthostatic hypotension; safety profile of low-dose doxepin ($\leq$6 mg/d) is comparable with that of placebo	Avoid	High	Strong
Antipsychotics, first (conventional) and second (atypical) generation (see Table 8 for full list)	Increased risk of cerebrovascular accident (stroke) and mortality in persons with dementia	Avoid use for behavioral problems of dementia unless nonpharmacological options have failed and patient is threat to self or others	Moderate	Strong
Thioridazine Mesoridazine	Highly anticholinergic and risk of QT-interval prolongation	Avoid	Moderate	Strong

(Continued)

Table 2. (Contd.)

Organ System or Therapeutic Category or Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
Barbiturates Amobarbital* Butabarbital* Butalbital Mephobarbital* Pentobarbital* Phenobarbital Secobarbital*	High rate of physical dependence; tolerance to sleep benefits; risk of overdose at low dosages	Avoid	High	Strong
Benzodiazepines *Short and intermediate acting:* Alprazolam Estazolam Lorazepam Oxazepam Temazepam Triazolam *Long acting:* Clorazepate Chlordiazepoxide Chlordiazepoxide-amitriptyline Clidinium-chlordiazepoxide Clonazepam Diazepam Flurazepam Quazepam	Older adults have increased sensitivity to benzodiazepines and slower metabolism of long-acting agents. In general, all benzodiazepines increase risk of cognitive impairment, delirium, falls, fractures, and motor vehicle accidents in older adults May be appropriate for seizure disorders, rapid eye movement sleep disorders, benzodiazepine withdrawal, ethanol withdrawal, severe generalized anxiety disorder, periprocedural anesthesia, end-of-life care	Avoid benzodiazepines (any type) for treatment of insomnia, agitation, or delirium	High	Strong
Chloral hydrate*	Tolerance occurs within 10 days, and risks outweigh benefits in light of overdose with doses only 3 times the recommended dose	Avoid	Low	Strong
Meprobamate	High rate of physical dependence; very sedating	Avoid	Moderate	Strong
Nonbenzodiazepine hypnotics Eszopiclone Zolpidem Zaleplon	Benzodiazepine-receptor agonists that have adverse events similar to those of benzodiazepines in older adults (e.g., delirium, falls, fractures); minimal improvement in sleep latency and duration	Avoid chronic use (> 90 days)	Moderate	Strong
Ergot mesylates* Isoxsuprine*	Lack of efficacy	Avoid	High	Strong
Endocrine				
Androgens Methyltestosterone* Testosterone	Potential for cardiac problems and contraindicated in men with prostate cancer	Avoid unless indicated for moderate to severe hypogonadism	Moderate	Weak
Desiccated thyroid	Concerns about cardiac effects; safer alternatives available	Avoid	Low	Strong
Estrogens with or without progestins	Evidence of carcinogenic potential (breast and endometrium); lack of cardioprotective effect and cognitive protection in older women Evidence that vaginal estrogens for treatment of vaginal dryness is safe and effective in women with breast cancer, especially at dosages of estradiol < 25 μg twice weekly	Avoid oral and topical patch. Topical vaginal cream: acceptable to use low-dose intravaginal estrogen for the management of dyspareunia, lower urinary tract infections, and other vaginal symptoms	Oral and patch: high Topical: moderate	Oral and patch: strong Topical: weak
Growth hormone	Effect on body composition is small and associated with edema, arthralgia, carpal tunnel syndrome, gynecomastia, impaired fasting glucose	Avoid, except as hormone replacement after pituitary gland removal	High	Strong

(Continued)

Table 2. (Contd.)

Organ System or Therapeutic Category or Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
Insulin, sliding scale	Higher risk of hypoglycemia without improvement in hyperglycemia management regardless of care setting	Avoid	Moderate	Strong
Megestrol	Minimal effect on weight; increases risk of thrombotic events and possibly death in older adults	Avoid	Moderate	Strong
Sulfonylureas, long duration Chlorpropamide Glyburide	Chlorpropamide: prolonged half-life in older adults; can cause prolonged hypoglycemia; causes syndrome of inappropriate antidiuretic hormone secretion. Glyburide: greater risk of severe prolonged hypoglycemia in older adults	Avoid	High	Strong
Gastrointestinal				
Metoclopramide	Can cause extrapyramidal effects including tardive dyskinesia; risk may be even greater in frail older adults	Avoid, unless for gastroparesis	Moderate	Strong
Mineral oil, oral	Potential for aspiration and adverse effects; safer alternatives available	Avoid	Moderate	Strong
Trimethobenzamide	One of the least effective antiemetic drugs; can cause extrapyramidal adverse effects	Avoid	Moderate	Strong
Pain				
Meperidine	Not an effective oral analgesic in dosages commonly used; may cause neurotoxicity; safer alternatives available	Avoid	High	Strong
Non–COX-selective NSAIDs, oral Aspirin > 325 mg/d Diclofenac Diflunisal Etodolac Fenoprofen Ibuprofen Ketoprofen Meclofenamate Mefenamic acid Meloxicam Nabumetone Naproxen Oxaprozin Piroxicam Sulindac Tolmetin	Increases risk of GI bleeding and peptic ulcer disease in high-risk groups, including those aged > 75 or taking oral or parenteral corticosteroids, anticoagulants, or antiplatelet agents. Use of proton pump inhibitor or misoprostol reduces but does not eliminate risk. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occur in approximately 1% of patients treated for 3–6 months and in approximately 2–4% of patients treated for 1 year. These trends continue with longer duration of use	Avoid chronic use unless other alternatives are not effective and patient can take gastroprotective agent (proton pump inhibitor or misoprostol)	Moderate	Strong
Indomethacin Ketorolac, includes parenteral	Increases risk of GI bleeding and peptic ulcer disease in high-risk groups. (See above Non-COX selective NSAIDs.) Of all the NSAIDs, indomethacin has most adverse effects	Avoid	Indomethacin: moderate Ketorolac: high	Strong

(Continued)

Table 2. (Contd.)

Organ System or Therapeutic Category or Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
Pentazocine*	Opioid analgesic that causes CNS adverse effects, including confusion and hallucinations, more commonly than other narcotic drugs; is also a mixed agonist and antagonist; safer alternatives available	Avoid	Low	Strong
Skeletal muscle relaxants Carisoprodol Chlorzoxazone Cyclobenzaprine Metaxalone Methocarbamol Orphenadrine	Most muscle relaxants are poorly tolerated by older adults because of anticholinergic adverse effects, sedation, risk of fracture; effectiveness at dosages tolerated by older adults is questionable	Avoid	Moderate	Strong

The primary target audience is the practicing clinician. The intentions of the criteria are to improve the selection of prescription drugs by clinicians and patients; evaluate patterns of drug use within populations; educate clinicians and patients on proper drug usage; and evaluate health-outcome, quality of care, cost, and utilization data.

* Infrequently used drugs.

CNS = central nervous system; COX = cyclooxygenase; CrCl = creatinine clearance; GI = gastrointestinal; NSAID = nonsteroidal anti-inflammatory drug; TCA = tricyclic antidepressant.

Correction made after online publication February 29, 2012: Table 2 has been updated.

Development Process

The co-chairs and AGS staff edited the survey used in the previous Beers Criteria development process, excluding products no longer marketed. The resulting survey had three parts: medications currently listed as potentially inappropriate for older adults independent of diseases or conditions, medications currently listed as potentially inappropriate when used in older adults with certain diseases or conditions, and new submissions from the panel. Each panelist was asked to complete the survey using a 5-point Likert scale ranging from strongly agree to strongly disagree (or no opinion). Ratings were tallied and returned to the panel along with each panelist's original ratings. Two conference calls allowed for review of survey ratings, discussion, and consensus building.

The panel convened for a 2-day in-person meeting on August 2 and 3, 2011, to review the second draft of the survey and the results of the literature search. Panel discussions were used to define terms and to address questions of consistency, the inclusion of infrequently used drugs, the best strategies for evaluating the evidence, and the consolidation or expansion of individual criterion. The panel then split into four groups, with each assigned a specific set of criteria for evaluation. Groups were assigned as closely as possible according to specific area of clinical expertise (e.g., cardiovascular, central nervous system). Groups reviewed the literature search, selected citations relevant to their assigned criteria, and determined which citations should be included in an evidence table. During this process, panelists were provided copies of abstracts and full-text articles. The groups then presented their findings to the full panel for comment and consensus. After the meeting, each group met in a conference call to resolve any questions or to include additional supporting literature.

An independent researcher prepared evidence tables, which were distributed to the four criteria-specific groups. Each panelist independently rated the quality of evidence and strength of recommendation for each criterion using the American College of Physicians' Guideline Grading System[24] (Table 1), which is based on the Grades of Recommendation Assessment, Development, and Evaluation (GRADE) scheme developed previously.[25] AGS staff compiled the panelist ratings for each group and returned them to that group, which then reached consensus in conference call. Additional literature was obtained and included as needed. When group consensus could not be reached, the full panel reviewed the ratings and worked through any differences until they reached consensus. For some criteria, the panel provided a "strong" recommendation even though the quality of evidence was low or moderate. In such cases, the strength of recommendation was based on potential severity of harm and the availability of treatment alternatives.

RESULTS

Fifty-three medications or medication classes encompass the final updated 2012 AGS Beers Criteria, which are divided into three categories (Tables 2–4). Tables were constructed and organized according to major therapeutic classes and organ systems.

Table 2 shows the 34 potentially inappropriate medications and classes to avoid in older adults. Notable new additions include megestrol, glyburide, and sliding-scale insulin.

Table 3 summarizes potentially inappropriate medications and classes to avoid in older adults with certain diseases and syndromes that the drugs listed can exacerbate. Notable new inclusions are thiazolidinediones or glitazones with heart failure, acetylcholinesterase inhibitors with history of syncope, and selective serotonin reuptake inhibitors with falls and fractures.

Table 3. 2012 American Geriatrics Society Beers Criteria for Potentially Inappropriate Medication Use in Older Adults Due to Drug–Disease or Drug–Syndrome Interactions That May Exacerbate the Disease or Syndrome

Disease or Syndrome	Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
Cardiovascular					
Heart failure	NSAIDs and COX-2 inhibitors Nondihydropyridine CCBs (avoid only for systolic heart failure) Diltiazem Verapamil Pioglitazone, rosiglitazone Cilostazol Dronedarone	Potential to promote fluid retention and exacerbate heart failure	Avoid	NSAIDs: moderate CCBs: moderate Thiazolidinediones (glitazones): high Cilostazol: low Dronedarone: moderate	Strong
Syncope	AChEIs Peripheral alpha blockers Doxazosin Prazosin Terazosin Tertiary TCAs Chlorpromazine, thioridazine, and olanzapine	Increases risk of orthostatic hypotension or bradycardia	Avoid	Alpha blockers: high TCAs, AChEIs, and antipsychotics: moderate	AChEIs and TCAs: strong Alpha blockers and antipsychotics: weak
Central nervous system					
Chronic seizures or epilepsy	Bupropion Chlorpromazine Clozapine Maprotiline Olanzapine Thioridazine Thiothixene Tramadol	Lowers seizure threshold; may be acceptable in patients with well-controlled seizures in whom alternative agents have not been effective	Avoid	Moderate	Strong
Delirium	All TCAs Anticholinergics (see Table 9 for full list) Benzodiazepines Chlorpromazine Corticosteroids H_2-receptor antagonist Meperidine Sedative hypnotics Thioridazine	Avoid in older adults with or at high risk of delirium because of inducing or worsening delirium in older adults; if discontinuing drugs used chronically, taper to avoid withdrawal symptoms	Avoid	Moderate	Strong
Dementia and cognitive impairment	Anticholinergics (see Table 9 for full list) Benzodiazepines H_2-receptor antagonists Zolpidem Antipsychotics, chronic and as-needed use	Avoid because of adverse CNS effects. Avoid antipsychotics for behavioral problems of dementia unless nonpharmacological options have failed, and patient is a threat to themselves or others. Antipsychotics are associated with an increased risk of cerebrovascular accident (stroke) and mortality in persons with dementia	Avoid	High	Strong
History of falls or fractures	Anticonvulsants Antipsychotics Benzodiazepines Nonbenzodiazepine hypnotics Eszopiclone Zaleplon Zolpidem TCAs and selective serotonin reuptake inhibitors	Ability to produce ataxia, impaired psychomotor function, syncope, and additional falls; shorter-acting benzodiazepines are not safer than long-acting ones	Avoid unless safer alternatives are not available; avoid anticonvulsants except for seizure disorders	High	Strong

(Continued)

Table 3. (Contd.)

Disease or Syndrome	Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
Insomnia	Oral decongestants Pseudoephedrine Phenylephrine Stimulants Amphetamine Methylphenidate Pemoline Theobromines Theophylline Caffeine	CNS stimulant effects	Avoid	Moderate	Strong
Parkinson's disease	All antipsychotics (see Table 8 for full list, except for quetiapine and clozapine) Antiemetics Metoclopramide Prochlorperazine Promethazine	Dopamine receptor antagonists with potential to worsen parkinsonian symptoms. Quetiapine and clozapine appear to be less likely to precipitate worsening of Parkinson's disease	Avoid	Moderate	Strong
Gastrointestinal					
Chronic constipation	Oral antimuscarinics for urinary incontinence Darifenacin Fesoterodine Oxybutynin (oral) Solifenacin Tolterodine Trospium Nondihydropyridine CCB Diltiazem Verapamil First-generation antihistamines as single agent or part of combination products Brompheniramine (various) Carbinoxamine Chlorpheniramine Clemastine (various) Cyproheptadine Dexbrompheniramine Dexchlorpheniramine (various) Diphenhydramine Doxylamine Hydroxyzine Promethazine Triprolidine Anticholinergics and antispasmodics (see Table 9 for full list of drugs with strong anticholinergic properties) Antipsychotics Belladonna alkaloids Clidinium-chlordiazepoxide Dicyclomine Hyoscyamine Propantheline Scopolamine Tertiary TCAs (amitriptyline, clomipramine, doxepin, imipramine, and trimipramine)	Can worsen constipation; agents for urinary incontinence: antimuscarinics overall differ in incidence of constipation; response variable; consider alternative agent if constipation develops	Avoid unless no other alternatives	For urinary incontinence: high All others: Moderate to low	Weak

(Continued)

Table 3. (Contd.)

Disease or Syndrome	Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
History of gastric or duodenal ulcers	Aspirin (>325 mg/d) Non–COX-2 selective NSAIDs	May exacerbate existing ulcers or cause new or additional ulcers	Avoid unless other alternatives are not effective and patient can take gastroprotective agent (proton pump inhibitor or misoprostol)	Moderate	Strong
Kidney and urinary tract					
Chronic kidney disease Stages IV and V	NSAIDs Triamterene (alone or in combination)	May increase risk of kidney injury	Avoid	NSAIDs: moderate Triamterene: low	NSAIDs: strong Triamterene: weak
Urinary incontinence (all types) in women	Estrogen oral and transdermal (excludes intravaginal estrogen)	Aggravation of incontinence	Avoid in women	High	Strong
Lower urinary tract symptoms, benign prostatic hyperplasia	Inhaled anticholinergic agents Strongly anticholinergic drugs, except antimuscarinics for urinary incontinence (see Table 9 for complete list)	May decrease urinary flow and cause urinary retention	Avoid in men	Moderate	Inhaled agents: strong All others: weak
Stress or mixed urinary incontinence	Alpha blockers Doxazosin Prazosin Terazosin	Aggravation of incontinence	Avoid in women	Moderate	Strong

The primary target audience is the practicing clinician. The intentions of the criteria are to improve the selection of prescription drugs by clinicians and patients; evaluate patterns of drug use within populations; educate clinicians and patients on proper drug usage; and evaluate health-outcome, quality of care, cost, and utilization data.

CCB = calcium channel blocker; AChEI = acetylcholinesterase inhibitor; CNS = central nervous system; COX = cyclooxygenase; NSAID = nonsteroidal anti-inflammatory drug; TCA = tricyclic antidepressant.

Table 4 lists medications to be used with caution in older adults. Fourteen medications and classes were categorized. Two of these involve recently marketed antithrombotics for which early evidence suggests caution for use in adults aged 75 and older.

Table 5 is a summary of medications that were moved to another category or modified since the last update, and Tables 6 and 7 summarize medications that were removed or added since the last update. Nineteen medications and medication classes were dropped from the 2003 to the 2012 update of the criteria based on consensus of the panel and evidence or a rationale to justify their exclusion from the list. In several cases, medications were removed because they had been taken off the U.S. market since the 2003 update (e.g., propoxyphene) or because of insufficient or new evidence that was evaluated by the panel (e.g., ethacrynic acid). Table 8 includes a list of the antipsychotics included in the statements. Table 9 is the list of anticholinergic medications to be avoided in older adults compiled from drugs rated as having strong anticholinergic properties in the Anticholinergic Risk Scale,[26] Anticholinergic Drug Scale,[27] and Anticholinergic Burden Scale.[28]

DISCUSSION

The 2012 AGS Beers Criteria is an important and improved update of previously established criteria widely used by healthcare providers, educators, and policy-makers and as a quality measure. Previously, as many as 40% of older adults received one or more medications on this list, depending on the care setting.[29–31] The new criteria are based upon methods for determining best-practice guidelines that included a rigorous systematic literature review, the use of an expert consensus panel, and grading of the strength of evidence and recommendations.

The updated criteria should be viewed as a guideline for identifying medications for which the risks of their use in older adults outweigh the benefits. The medications that have a high risk of toxicity and adverse effects in older adults and limited effectiveness, and all medications in Table 2 (Independent of Diagnosis or Condition) should be avoided in favor of an alternative safer medication or a nondrug approach. The drug–disease or –syndrome interactions summarized in Table 3 are particularly important in the care of older adults because they often take multiple medications for multiple comorbidities. Their occurrence may have greater consequences in older adults because of age-related decline in physiological reserve. Recent studies in which drug–disease interactions have been shown to be important risk factors for ADEs highlight their importance.[32]

This list is not meant to supersede clinical judgment or an individual patient's values and needs. Prescribing and managing disease conditions should be individualized and involve shared decision-making. The historical lack of

Table 4. 2012 American Geriatrics Society Beers Criteria for Potentially Inappropriate Medications to Be Used with Caution in Older Adults

Drug	Rationale	Recommendation	Quality of Evidence	Strength of Recommendation
Aspirin for primary prevention of cardiac events	Lack of evidence of benefit versus risk in individuals aged ≥ 80	Use with caution in adults aged ≥ 80	Low	Weak
Dabigatran	Greater risk of bleeding than with warfarin in adults aged ≥ 75; lack of evidence for efficacy and safety in individuals with CrCl < 30 mL/min	Use with caution in adults aged ≥ 75 or if CrCl < 30 mL/min	Moderate	Weak
Prasugrel	Greater risk of bleeding in older adults; risk may be offset by benefit in highest-risk older adults (e.g., with prior myocardial infarction or diabetes mellitus)	Use with caution in adults aged ≥ 75	Moderate	Weak
Antipsychotics Carbamazepine Carboplatin Cisplatin Mirtazapine Serotonin–norepinephrine reuptake inhibitor Selective serotonin reuptake inhibitor Tricyclic antidepressants Vincristine	May exacerbate or cause syndrome of inappropriate antidiuretic hormone secretion or hyponatremia; need to monitor sodium level closely when starting or changing dosages in older adults due to increased risk	Use with caution	Moderate	Strong
Vasodilators	May exacerbate episodes of syncope in individuals with history of syncope	Use with caution	Moderate	Weak

The primary target audience is the practicing clinician. The intentions of the criteria are to improve the selection of prescription drugs by clinicians and patients; evaluate patterns of drug use within populations; educate clinicians and patients on proper drug usage; and evaluate health-outcome, quality of care, cost, and utilization data.
CrCl = creatinine clearance.

Table 5. Medications Moved to Another Category or Modified Since 2003 Beers Criteria

Independent of Diagnoses or Condition	Considering Diagnoses
Amphetamines (excluding methylphenidate hydrochloride and anorexics)	Fluoxetine, citalopram, fluvoxamine, paroxetine, and sertraline with syndrome of inappropriate antidiuretic hormone secretion
All barbiturates (except phenobarbital) except when used to control seizures	Olanzapine with obesity
Naproxen, oxaprozin, and piroxicam	Vasodilators with syncope
Nitrofurantoin	
Non-cyclooxygenase selective nonsteroidal anti-inflammatory drugs (excludes topical)	
Oral short-acting dipyridamole; does not apply to the extended-release combination with aspirin	
Oxybutynin	
Reserpine in doses >0.25 mg	

inclusion of many older adults in drug trials[33–35] and the related lack of alternatives in some individual instances further complicate medication use in older adults. There may be cases in which the healthcare provider determines that a drug on the list is the only reasonable alternative (e.g., end-of-life or palliative care). The panel has attempted to evaluate the literature and best-practice guidelines to cover as many of these instances as possible, but not all possible clinical situations can be anticipated in such a broad undertaking. In these cases, the list can be used clinically not only for prescribing medications, but also for monitoring their effects in older adults. If a provider is not able to find an alternative and chooses to continue to use a drug on this list in an individual patient, designation of the medication as potentially inappropriate can serve as a reminder for close monitoring so that ADEs can be incorporated into the electronic health record and prevented or detected early. These criteria also underscore the importance of using a team approach to prescribing, of the use of nonpharmacological approaches, and of having economic and organizational incentives for this type of model.

Table 6. Medications Removed Since 2003 Beers Criteria

Independent of Diagnoses	Considering Diagnoses
Cimetidine (H_2 antihistamines added as a class; see Table 7)	Antispasmodics and muscle relaxants; CNS stimulants: dextroamphetamine, methylphenidate, methamphetamine, pemoline, with cognitive impairment
Cyclandelate	CNS stimulants: dextroamphetamine, methylphenidate, methamphetamine, pemoline, and fluoxetine with anorexia and malnutrition
Daily fluoxetine	Clopidogrel with blood clotting disorders or receiving anticoagulant therapy
Ferrous sulfate >325 mg/d	Guanethidine with depression
Guanadrel	High-sodium content drugs with heart failure
Guanethidine	Monoamine oxidase inhibitors with insomnia
Halazepam	Oxybutynin and tolterodine with bladder outlet obstruction
Long-term use of stimulant laxatives: bisacodyl, cascara sagrada, and neoloid except in the presence of opiate analgesic use	Pseudoephedrine and diet pills with hypertension
Mesoridazine	Tacrine with Parkinson's disease
Propoxyphene and combination products	
Tripelennamine	

CNS = central nervous system.

These criteria have some limitations. First, even though older adults are the largest consumers of medication, they are often underrepresented in drug trials.[33,35] Thus, using an evidence-based approach may underestimate some drug-related problems or lead to a weaker evidence grading. As stated previously, the intent of the updated 2012 AGS Beers Criteria, as an educational tool and quality measure, is to improve the care of older adults by reducing their exposure to PIMs. Second, it does not address other types of potential PIMs that are not unique to aging (e.g., dosing of primarily renally cleared medications, drug–drug interactions, therapeutic duplication). Third, it does not comprehensively address the needs of individuals receiving palliative and hospice care, in whom symptom control is often more important than avoiding the use of PIMs. Finally, the search strategies used might have missed some studies published in languages other than English and studies available in unpublished technical reports, white papers, or other "gray literature" sources.

Regardless, this update has many strengths, including the use of an evidence-based approach using the Institute of Medicine standards and the development of a partnership to regularly update the criteria. Thoughtful application of the criteria will allow for closer monitoring of drug use, application of real-time e-prescribing and interventions to decrease ADEs in older adults, and better patient outcomes. Regular updates will allow for the evidence for medications on the list to be assessed routinely, making it more relevant and sensitive to patient outcomes, with the goal of evaluating and managing drug use in older adults while considering the dynamic complexities of the healthcare system.

PANEL MEMBERS AND AFFILIATIONS

The following individuals were members of the AGS Panel to update the 2012 AGS Beers Criteria: Donna Fick, PhD, RN, FGSA, FAAN, School of Nursing and College of Medicine, Department of Psychiatry, Pennsylvania State University, University Park, PA (co-chair); Todd Semla, PharmD, MS, BCPS, FCCP, AGSF, U.S. Department of Veterans Affairs National Pharmacy Benefits Management Services and Northwestern University, Chicago, IL (co-chair); Judith Beizer, PharmD, CGP, FASCP, St. Johns University, New York, NY; Nicole Brandt, PharmD, BCPP, CGP, University of Maryland, Baltimore, MD; Robert Dombrowski, PharmD, Centers for Medicare and Medicaid Services, Baltimore, MD (nonvoting member); Catherine E. DuBeau, MD, University of Massachusetts Medical School, Worcester, MA; Nina Flanagan, CRNP, CS-BC, Binghamton University, Dunmore, PA; Joseph Hanlon, PharmD, MS, BCPS, FASHP, FASCP, FGSA, AGSF, Department of Medicine (Geriatric Medicine) School of Medicine, University of Pittsburgh and Geriatric Education and Research and Clinical Center, Veterans Administration Health System, Pittsburgh, PA; Peter Hollmann, MD, AGSF, Blue Cross Blue Shield of Rhode Island, Cranston, RI; Sunny Linnebur, PharmD, FCCP, BCPS, CGP, Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado, Aurora, CO; David Nau, PhD, RPh, CPHQ, Pharmacy Quality Alliance, Inc, Baltimore, MD (nonvoting member); Bob Rehm, National Committee for Quality Assurance, Washington, DC (nonvoting member); Satinderpal Sandhu, MD, MetroHealth Medical Center and Case Western Reserve University School of Medicine, Cleveland, OH; Michael Steinman, MD, University of California at San Francisco and San Francisco Veterans Affairs Medical Center, San Francisco, CA.

ACKNOWLEDGMENTS

The decisions and content of the 2012 AGS Beers Criteria are those of the AGS and the panelists and are not necessarily those of the U.S. Department of Veterans Affairs.

Sue Radcliff, Independent Researcher, Denver, Colorado, provided research services. Susan E. Aiello, DVM, ELS, provided editorial services. Christine Campanelli and Elvy Ickowicz, MPH, provided additional research and

Table 7. Medications Added Since 2003 Beers Criteria

Independent of Diagnoses	Considering Diagnoses	
Medication	Corresponding Diagnosis or Syndrome	
Aspirin for primary prevention of cardiac events	Acetylcholinesterase inhibitors	Syncope
Antiarrhythmic drugs, Class 1a, 1c, III	Anticonvulsants	History of falls or fractures
Belladonna alkaloids	H_1 and H_2 antihistamines	Delirium
Benztropine (oral)	Aspirin >325 mg	History of gastric or duodenal ulcers
Brompheniramine	Brompheniramine	Chronic constipation
Carbinoxamine	Caffeine	Insomnia
Chloral hydrate	Carbamazepine	SIADH or hyponatremia
Clemastine	Carbinoxamine	Chronic constipation
Clomipramine	Carboplatin	SIADH or hyponatremia
Clonazepam	Clemastine (various)	Chronic constipation
Dabigatran	Clozapine	Chronic seizures or epilepsy
Desiccated thyroid	Cisplatin	SIADH or hyponatremia
Dexbrompheniramine	Cyclooxygenase-2 inhibitors	Heart failure
Doxylamine	Darifenacin	Chronic constipation
Dronedarone	Desipramine	Falls and fractures
Estazolam	Dexbrompheniramine	Chronic constipation
Eszopiclone	Dexchlorpheniramine	Chronic constipation
First- and second-generation antipsychotics	Doxylamine	Chronic constipation
Flurazepam	Estrogen, transdermal	Urinary incontinence (all types) in women
Glyburide	Eszopiclone	History of falls or fractures
Growth hormone	Fesoterodine	Chronic constipation
Guanabenz	Inhaled anticholinergics	Lower urinary tract symptoms and benign prostatic hyperplasia
Guanfacine	Maprotiline	Chronic seizures or epilepsy
Insulin, sliding scale	Mirtazapine	SIADH or hyponatremia
Megestrol	Nondihydropyridine calcium channel blockers	Heart failure
Metoclopramide	Nortriptyline	Falls and fractures
Oral doxepin >6 mg/d	Pioglitazone	Heart failure
Phenobarbital	Prochlorperazine	Parkinson disease
Prasugrel	Rosiglitazone	Heart failure
Prazosin	Scopolamine	Chronic constipation
Scopolamine	Serotonin-norepinephrine reuptake inhibitors	SIADH or hyponatremia
Spironolactone	Solifenacin	Chronic constipation
Testosterone	Thiothixene	Chronic seizures or epilepsy
Trihexyphenidyl	Thioridazine	Syncope
Trimipramine	Triamterene	Chronic kidney disease Stages IV and V
Triprolidine	Triprolidine	Chronic constipation
Zaleplon	Trospium	Chronic constipation
Zolpidem	Vincristine	SIADH or hyponatremia
	Zaleplon	History of falls or fractures
	Zolpidem	Dementia and cognitive impairment

SIADH = syndrome of inappropriate antidiuretic hormone secretion.

Table 8. First- and Second-Generation Antipsychotics

First-Generation (Conventional) Agents	Second-Generation (Atypical) Agents
Chlorpromazine	Aripiprazole
Fluphenazine	Asenapine
Haloperidol	Clozapine
Loxapine	Iloperidone
Molindone	Lurasidone
Perphenazine	Olanzapine
Pimozide	Paliperidone
Promazine	Quetiapine
Thioridazine	Risperidone
Thiothixene	Ziprasidone
Trifluoperazine	
Triflupromazine	

administrative support. The development of this paper was supported in part by an unrestricted grant from the John A. Hartford Foundation.

The following organizations with special interest and expertise in the appropriate use of medications in older adults provided peer review of a preliminary draft of this guideline: American Academy of Family Physicians; American Academy of Nurse Practitioners; American Academy of Nursing; American College of Clinical Pharmacy; American College of Obstetrics and Gynecology; American College of Physicians; American College of Surgeons; American Medical Association; American Medical Directors Association; American Society of Anesthesiologists; American Society of Consultant Pharmacists; Centers for Medicare and Medicaid Services; Gerontological Advanced Practice Nurses Association; Gerontological Society of

Table 9. Drugs with Strong Anticholinergic Properties

Antihistamines	Antiparkinson agents	Skeletal Muscle Relaxants
Brompheniramine	Benztropine	Carisoprodol
Carbinoxamine	Trihexyphenidyl	Cyclobenzaprine
Chlorpheniramine		Orphenadrine
Clemastine		Tizanidine
Cyproheptadine		
Dimenhydrinate		
Diphenhydramine		
Hydroxyzine		
Loratadine		
Meclizine		
Antidepressants	Antipsychotics	
Amitriptyline	Chlorpromazine	
Amoxapine	Clozapine	
Clomipramine	Fluphenazine	
Desipramine	Loxapine	
Doxepin	Olanzapine	
Imipramine	Perphenazine	
Nortriptyline	Pimozide	
Paroxetine	Prochlorperazine	
Protriptyline	Promethazine	
Trimipramine	Thioridazine	
	Thiothixene	
	Trifluoperazine	
Antimuscarinics (urinary incontinence)	Antispasmodics	
Darifenacin	Atropine products	
Fesoterodine	Belladonna alkaloids	
Flavoxate	Dicyclomine	
Oxybutynin	Homatropine	
Solifenacin	Hyoscyamine products	
Tolterodine	Propantheline	
Trospium	Scopolamine	

America; National Academies of Practice, Academy of Pharmacy; National Committee for Quality Assurance; Pharmacy Quality Alliance; Society for General Internal Medicine; Society of Hospital Medicine.

Conflict of Interest: Drs. Dombrowski, Flanagan, Hanlon, Hollmann, Rehm, Sandhu, and Steinman indicated no conflicts of interest. Dr. Beizer is an author and editor for LexiComp, Inc. She is on the Pharmacy and Therapeutics Committee for Part D at Medco Health Solutions. Dr. Brandt is on the Pharmacy and Therapeutics Committees at Omnicare and receives grants from Talyst (research grant), Econometrics (research grant), Health Resources and Services Administration (educational grant), and the State of Maryland Office of Health Care Quality (educational grant). Dr. Dubeau serves as a consultant for Pfizer, Inc. (urinary incontinence) and the New England Research Institute (nocturia). Dr. Fick is partially supported by the National Institute of Health (NIH) for National Institute of Nursing Research grants R01 NR011042 and R01NR012242. Dr. Hanlon is supported in part by National Institute on Aging grants and contracts (R01AG027017, P30AG024827, T32 AG021885, K07AG033174, R01AG034056), a National Institute of Nursing Research grant (R01 NR010135), and Agency for Healthcare Research and Quality grants (R01 HS017695, R01HS018721). Dr. Linnebur receives an honorarium for serving as a member of the Pharmacy and Therapeutics Committee for Colorado Access (a health plan serving indigent children and adults and Medicare members). Dr. Nau works for the PQA, which has received demonstration project grants from Pfizer, Inc., Merck & Co, Inc, sanofi-aventis, and GlaxoSmithKline. He also has held shares with CardinalHealth in the past 12 months. Dr. Semla receives honoraria from the AGS for his contribution as an author of Geriatrics at Your Fingertips and for serving as a Section Editor for the *Journal of the American Geriatrics Society*. He is a past President and Chair of the AGS Board of Directors. His spouse is an employee of Abbott Laboratories. He serves on the Omnicare Pharmacy and Therapeutics Committee. He is an author and editor for LexiComp, Inc.

Author Contributions: All panel members contributed to the concept, design, and preparation of the manuscript.

Sponsor's Role: AGS staff participated in the final technical preparation and submission of the manuscript.

REFERENCES

1. Gurwitz JH, Field TS, Harrold LR et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. JAMA 2003;289:1107–1116.
2. Gurwitz JH, Field TS, Judge J et al. The incidence of adverse drug events in two large academic long-term care facilities. Am J Med 2005;118:251–258.
3. Fu AZ, Jiang JZ, Reeves JH et al. Potentially inappropriate medication use and healthcare expenditures in the US community-dwelling elderly. Med Care 2007;45:472–476.
4. Beers MH, Ouslander JG, Rollingher I et al. Explicit criteria for determining inappropriate medication use in nursing home residents. Arch Intern Med 1991;151:1825–1832.
5. Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly. An update. Arch Intern Med 1997;157:1531–1536.
6. Fick DM, Cooper JW, Wade WE et al. Updating the Beers Criteria for potentially inappropriate medication use in older adults: Results of a US consensus panel of experts. Arch Intern Med 2003;163:2716–2724.
7. Lund BC, Steinman MA, Chrischilles EA et al. Beers Criteria as a proxy for inappropriate prescribing of other medications among older adults. Ann Pharmacother 2011;45:1363–1370.
8. Stockl KM, Le L, Zhang S et al. Clinical and economic outcomes associated with potentially inappropriate prescribing in the elderly. Am J Manag Care 2010;16:e1–e10.
9. Dimitrow MS, Airaksinen MS, Kivela SL et al. Comparison of prescribing criteria to evaluate the appropriateness of drug treatment in individuals aged 65 and older: A systematic review. J Am Geriatr Soc 2011;59:1521–1530.
10. Jano E, Aparasu RR. Healthcare outcomes associated with Beers' Criteria: A systematic review. Ann Pharmacother 2007;41:438–447.
11. Chang CM, Liu PY, Yang YH et al. Use of the Beers Criteria to predict adverse drug reactions among first-visit elderly outpatients. Pharmacotherapy 2005;25:831–838.
12. Chrischilles EA, VanGilder R, Wright K et al. Inappropriate medication use as a risk factor for self-reported adverse drug effects in older adults. J Am Geriatr Soc 2009;57:1000–1006.
13. Dedhiya SD, Hancock E, Craig BA et al. Incident use and outcomes associated with potentially inappropriate medication use in older adults. Am J Geriatr Pharmacother 2010;8:562–570.
14. Passarelli MC, Jacob-Filho W, Figueras A. Adverse drug reactions in an elderly hospitalised population: Inappropriate prescription is a leading cause. Drugs Aging 2005;22:767–777.
15. Garfinkel D, Mangin D. Feasibility study of a systematic approach for discontinuation of multiple medications in older adults: Addressing polypharmacy. Arch Intern Med 2010;170:1648–1654.
16. Fick D, Semla T. Improving medication use in gerontological nursing: Now is the time for interdisciplinary collaboration and translation. J Gerontol Nurs 2011;37:3–4.
17. Morandi A, Vasilevskis EE, Pandharipande PP et al. Inappropriate medications in elderly ICU survivors: Where to intervene? Arch Intern Med 2011;171:1032–1034.

18. Agostini JV, Zhang Y, Inouye SK. Use of a computer-based reminder to improve sedative-hypnotic prescribing in older hospitalized patients. J Am Geriatr Soc 2007;55:43–48.
19. Hume AL, Quilliam BJ, Goldman R et al. Alternatives to potentially inappropriate medications for use in e-prescribing software: Triggers and treatment algorithms. BMJ Qual Saf 2011;20:875–884.
20. McCurry SM, Pike KC, Vitiello MV et al. Increasing walking and bright light exposure to improve sleep in community-dwelling persons with Alzheimer's disease: Results of a randomized, controlled trial. J Am Geriatr Soc 2011;59:1393–1402.
21. American Geriatrics Society Panel on Pharmacological Management of Persistent Pain in Older Persons. Pharmacological management of persistent pain in older persons. J Am Geriatr Soc 2009;57:1331–1346.
22. Panel on Prevention of Falls in Older Persons, American Geriatrics Society, British Geriatrics Society. Summary of the updated American Geriatrics Society/British Geriatrics Society clinical practice guideline for prevention of falls in older persons. J Am Geriatr Soc 2011;59:148–157.
23. Graham R, Mancher M, Wolman DM et al. Institute of Medicine: Clinical Practice Guidelines We Can Trust. Washington, DC: National Academies Press, 2011.
24. Qaseem A, Snow V, Owens DK et al. The development of clinical practice guidelines and guidance statements of the American College of Physicians: Summary of methods. Ann Intern Med 2010;153:194–199.
25. Atkins D, Best D, Briss PA et al., for the GRADE Working Group. Grading quality of evidence and strength of recommendations. BMJ 2004;328:1490–1498.
26. Rudolph JL, Salow MJ, Angelini MC et al. The Anticholinergic Risk Scale and anticholinergic adverse effects in older persons. Arch Intern Med 2008;168:508–513.
27. Carnahan RM, Lund BC, Perry PJ et al. The Anticholinergic Drug Scale as a measure of drug-related anticholinergic burden: Associations with serum anticholinergic activity. J Clin Pharmacol 2006;46:1481–1486.
28. Boustani M, Campbell N, Munger S et al. Impact of anticholinergics on the aging brain: A review and practical appllication. Aging Health 2008;4:311–320.
29. Curtis LH, Ostbye T, Sendersky V et al. Inappropriate prescribing for elderly Americans in a large outpatient population. Arch Intern Med 2004;164:1621–1625.
30. Fick DM, Mion LC, Beers MH et al. Health outcomes associated with potentially inappropriate medication use in older adults. Res Nurs Health 2008;31:42–51.
31. Laroche ML, Charmes JP, Nouaille Y et al. Is inappropriate medication use a major cause of adverse drug reactions in the elderly? Br J Clin Pharmacol 2007;63:177–186.
32. Hanlon JT, Sloane RJ, Pieper CF et al. Association of adverse drug reactions with drug-drug and drug-disease interactions in frail older outpatients. Age Ageing 2011;40:274–277.
33. Applegate WB, Curb JD. Designing and executing randomized clinical trials involving elderly persons. J Am Geriatr Soc 1990;38:943–950.
34. Cherubini A, Del Signore S, Ouslander J et al. Fighting against age discrimination in clinical trials. J Am Geriatr Soc 2010;58:1791–1796.
35. Hutchins LF, Unger JM, Crowley JJ et al. Underrepresentation of patients 65 years of age or older in cancer-treatment trials. N Engl J Med 1999;341:2061–2067.

Managing a Crisis

Caring for a person with dementia and problem behaviors can be challenging and stressful. The purpose of this document is to help caregivers learn to manage difficult situations, especially when the person with dementia is upset, angry, or scared.

1. First, tune in to your own ATTITUDES and FEELINGS about what is going on.

   -- Getting angry won't help and will probably make things worse.

   Remember: Being caught off guard puts you at risk for "fueling the fire" (e.g. the first time it happens you "fight back" vs. assess and problem-solve through the crisis).

   Likewise, if you are angry or resentful about past experiences with the person, you probably won't be effective.

   -- Try to remain calm, cool, and collected.

   -- Use positive self-talk to get yourself under control. For example, remind yourself:

   "This person is uncomfortable and needs my help."

   "I can handle this. I don't need to get upset too."

   "They're not really angry with me. They're just upset and I'm in the way."

   -- Avoid words or actions that might threaten the person even more.

   -- If you can't get your own feelings under control, leave the area immediately, alerting other staff if needed.

2. Keep track of what you are doing with your body and what that might mean to the person.

   -- Don't surprise them; move slowly and steadily.

   -- Keep your hands out where they can see them, palms up and open, which is non-threatening.

   -- Respect their "personal space;" the more threatened they are, the more distance you should give them.

   -- Don't stand squarely in front of them (which is very confronting and threatening); turn slightly to one side.

   -- Be careful to not stare, glare, or otherwise challenge the person with eye contact.

   -- Don't turn your back on the person.

   -- Always leave yourself an escape route.

   -- Avoid standing over the person (if they are sitting or reclining), which can be very threatening.

3. Think about WHAT you say and HOW you say it.

   -- Speak in short, simple phrases.

   -- Use a normal tone of voice and talk at a normal rate.

   -- Communicate concern and caring.

   -- Avoid sarcasm, insulting remarks, and even humor (which can easily be misinterpreted).

4. Use DIRECTIONS or EXPLANATIONS that are APPROPRIATE for the person and the situation. For example:

   -- "I'm sorry if I upset you. That wasn't what I meant to do."

   -- "Your behavior worries (frightens, upsets) me."

   -- "How can I help you be more comfortable?"

   -- "Mr. Smith, let's go to your room (a quiet place, etc.)."

   -- "It's all right now. You are safe with me. I won't let anything bad happen to you."

5. Listen carefully to what they are saying and try to respond to the message they are trying to communicate.

   -- Check for meaning, "You're saying that ..."

   -- Avoid giving advice.

   -- Respond to the content of their message (the actual meaning), not the way it's being said.

      * Try to understand what they are upset about.

      * Respond to that unmet need or feeling.

   -- Don't assume that they have heard or understood you.

      * Our focus becomes very narrow when we're anxious.

6. Try to calm or soothe them, remembering that the first priority is to protect yourself and others.

   -- Leave the room or area if they continue to threaten you.

   -- Get assistance, even if you aren't sure if you really need it.

   -- Use physical control only as the last resort! Try everything else first!

Current Process Analysis

- A process is a series of activities or steps that is meant to achieve a particular result.
- When defining a process, think about staff roles in the process, the tools or materials staff use, and the flow of activities.
- Everything is a process, whether it is admitting a patient, serving meals, assessing pain, or managing a nursing unit. The ultimate goal of defining a process is identifying problems in the current process.

Have the team identify and define every step in the current process that the facility has chosen to improve.

Tips:

- Take time to "brainstorm" and listen to every team member.
- Make sure the process is understood and documented.
- Make each step in the process very specific.
- Use one Post-it® note, index card, or piece of paper for each step in the process.
- Lay out each step, move steps, and add/remove steps until the team agrees on a final process.
- If the problem is that a process does not exist (e.g., there is no current process for handoffs between shifts), then identify the related processes (e.g., the process for transitioning patients between units).
- If a process is different for different shifts, identify each individual process.

Example—
Process for reporting an incident:

Step	Define
1	An incident is witnessed.
2	Respond and assess.
3	Intervene as appropriate.
4	Notify essential personnel (physician, security, supervisor, etc.).
5	Complete an incident report.
6	Forward the report to the party responsible for risk management.

Write the steps of your defined process on the next page or attach an additional sheet.

This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. Publication No. CA-10SOW-7.2-050812-06

Team discussion—evaluate your current process as you define it.

What policies and procedures do we have in place for this process?

What forms do we use?

How does our physical environment support or hinder this process?

What staff is involved in this process?

What part of this process does not work?

Do we duplicate any work unnecessarily?

Are there any delays in the process? Why?

Continue asking questions that are important in learning more about this process.

When you discover a problem in your current process, continue to perform a root cause analysis to determine the root cause(s) of the problem.

This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. Publication No. CA-10SOW-7.2-050812-06

Transforming the lives of nursing home residents through continuous attention to quality of care and quality of life

QAPI at a Glance:

A Step by Step Guide to Implementing Quality Assurance and Performance Improvement (QAPI) in Your Nursing Home

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

UNIVERSITY OF MINNESOTA

StratisHealth

Table of Contents

Disclaimer: Use of this guide or its tools is not mandated by CMS for regulatory compliance.

Introduction: Why This Guide?

As you use this guide, please take note of the following:

- The term "Caregiver" refers to individuals who provide care in nursing homes.
- The tool icon:  indicates that there is a QAPI tool associated with that concept in Appendix A of this guide. Click the tool icon to access the corresponding QAPI tool.
- Words underlined in **bold blue** are defined in Appendix B. Click the underlined word icon to be automatically linked to the definitions listed in Appendix B.

Effective Quality Assurance and Performance Improvement (QAPI) is critical to our national goals to improve care for individuals and improve health for populations, while reducing per capita costs in our healthcare delivery system. We have the opportunity to accomplish these goals in each local nursing home with the aid of QAPI tools and the establishment of an effective QAPI foundation. Nursing homes are in the best position to assess, evaluate, and improve their care and services because each home has first-hand knowledge of their own organizational systems, culture, and history. Effective QAPI leverages this knowledge to maximize the return on investments made in care improvement. This *QAPI at a Glance* guide is a resource for nursing homes striving to embed QAPI principles into their day to day work of providing quality care and services.

Nursing homes in the United States will soon be required to develop QAPI plans. QAPI will take many nursing homes into a new realm in quality—a systematic, comprehensive, data-driven, proactive approach to performance management and improvement. This guide provides detailed information about the "nuts and bolts" of QAPI. We hope that *QAPI at a Glance* conveys a true sense of QAPI's exciting possibilities. Once launched, an effective QAPI plan creates a self-sustaining approach to improving safety and quality while involving all nursing home caregivers in practical and creative problem solving. Your QAPI results are generated from your own experiences, priority-setting, and team spirit.

The Affordable Care Act of 2010 requires nursing homes to have an acceptable QAPI plan within a year of the promulgation of a QAPI regulation. However, a more basic reason to build care systems based on a QAPI philosophy is to ensure a systematic, comprehensive, data-driven approach to care. When nursing home leaders promote such an approach, the results may prevent adverse events, promote safety and quality, and reduce risks to residents and caregivers. This effort is not only about meeting minimum standards—it is about continually aiming higher. Many nursing homes are already demonstrating leadership in developing and implementing effective QAPI plans.

We encourage nursing home leaders to use *QAPI at a Glance* as a reference as they examine their own activities in the context of the goals and expectations for QAPI and sustainable improvement. You can also visit the QAPI website at http://go.cms.gov/Nhqapi, which we will update regularly as new materials and resources become available.

WHAT IS QAPI?

QAPI is the merger of two complementary approaches to quality management, Quality Assurance **(QA)** and Performance Improvement **(PI)**. Both involve using information, but differ in key ways:

- QA is a process of meeting quality standards and assuring that care reaches an acceptable level. Nursing homes typically set QA thresholds to comply with regulations. They may also create standards that go beyond regulations. QA is a reactive, retrospective effort to examine why a facility failed to meet certain standards. QA activities do improve quality, but efforts frequently end once the standard is met.
- PI (also called Quality Improvement - QI) is a pro-active and continuous study of processes with the intent to prevent or decrease the likelihood of problems by identifying areas of opportunity and testing new approaches to fix underlying causes of persistent/systemic problems. PI in nursing homes aims to improve processes involved in health care delivery and resident quality of life. PI can make good quality even better.

The chart below was adapted from the Health Resources and Services Administration (HRSA)[1] and shows some key differences between QA and PI efforts.

	QUALITY ASSURANCE	PERFORMANCE IMPROVEMENT
Motivation	Measuring compliance with standards	Continuously improving processes to meet standards
Means	Inspection	Prevention
Attitude	Required, reactive	Chosen, proactive
Focus	Outliers: *"bad apples"* Individuals	Processes or Systems
Scope	Medical provider	Resident care
Responsibility	Few	All

QA + PI = QAPI

QA and PI combine to form QAPI, a comprehensive approach to ensuring high quality care.

QAPI is a data-driven, proactive approach to improving the quality of life, care, and services in nursing homes. The activities of QAPI involve members at all levels of the organization to: identify opportunities for improvement; address gaps in systems or processes; develop and implement an improvement or corrective plan; and continuously monitor effectiveness of interventions.

[1] U.S. Department of Health and Human Services, Health Resources and Services Administration. Quality Improvement adapted from http://www.hrsa.gov/healthit/toolbox/HealthITAdoptiontoolbox/QualityImprovement/whatarediffbtwqinqa.html

WHY QAPI IS IMPORTANT

Once QAPI is launched and sustained, many people report that it is a rewarding and even an enjoyable way of working. The rewards of QAPI include:

- Competencies that equip you to solve quality problems and prevent their recurrence;
- Competencies that allow you to seize opportunities to achieve new goals;
- Fulfillment for caregivers, as they become active partners in performance improvement; and
- Above all, better care and better quality of life for your residents.

Being new at QAPI is like being a new driver…

A new driver must coordinate so many actions and pay attention to so many cues that driving feels awkward, confusing, and almost impossible at first. Yet when it suddenly comes together, it becomes automatic and ushers in new horizons for that driver. In the same way, once you get some QAPI experience, it will come together, seem automatic, and will take you to new places in your quality management.

In the following pages, we discuss QAPI and its inter-related components (QA and PI), and emphasize how it can readily fit into your nursing home. Launching QAPI is not necessarily easy or quick, but it has a compelling logic and it is feasible for all nursing homes, beginning wherever your nursing home is right now.

QAPI Builds on QA&A

QAPI is not entirely new. It uses the existing QA&A, or Quality Assessment and Assurance regulation and guidance as a foundation. Maybe you recognize some of the statements below as things you are already doing:

- You create systems to provide care and achieve compliance with nursing home regulations.
- You track, investigate, and try to prevent recurrence of adverse events.
- You compare the quality of your home to that of other homes in your state or company.
- You receive and investigate complaints.
- You seek feedback from residents and front-line caregivers.
- You set targets for quality.
- You strive to achieve improvement in specific goals related to pressure ulcers, falls, restraints, or permanent caregiver assignment; or other areas; (for example by joining the Advancing Excellence Campaign).
- You are committed to balancing a safe environment with resident choice.
- You strive for deficiency-free surveys.
- You assess residents' strengths and needs to design, implement, and modify person-centered, measurable and interdisciplinary care plans.

You are already partly there. All of this is part of QAPI.

QAPI Features

> *"Not all change is improvement, but all improvement is change."*
>
> *Donald Berwick, MD*
> *Former CMS Administrator*

QAPI includes components that may be new for many nursing homes. It emphasizes improvements that can not only elevate the care and experience of all residents, but also improve the work environment for caregivers. With QAPI, your organization will use a systems approach to actively pursue quality, not just respond to external requirements. Look at the following list of QAPI features. How many are you already using?

- Using data to not only identify your quality problems, but to also identify other opportunities for improvement, and then setting priorities for action
- Building on residents' own goals for health, quality of life, and daily activities
- Bringing meaningful resident and family voices into setting goals and evaluating progress
- Incorporating caregivers broadly in a shared QAPI mission
- Developing Performance Improvement Project **(PIP)** teams with specific "charters"
- Performing a **Root Cause Analysis** to get to the heart of the reason for a problem
- Undertaking systemic change to eliminate problems at the source
- Developing a feedback and monitoring system to sustain continuous improvement

Illustrating QAPI in Action

The scenario below illustrates how a QAA committee might develop a plan of correction in response to deficiencies identified during an annual survey. The example shows how facilities often react to regulatory non-compliance with a "band-aid" approach. The activities described are representative of the types of plans of corrections that are often submitted to Survey Agencies and accepted. It addresses the immediate problem, and then takes steps assumed to prevent recurrence of the problem.

Scenario 1

The Issue: Your nursing home, Whistling Pines, received deficiencies during their annual survey because residents had unexplained weight loss, and weights and food intake were not accurately and consistently documented.

What Whistling Pines did: The QA Committee developed a Plan of Correction, which contained the following components: Re-weighing all residents, and updating the weight records for the affected residents; in-servicing the Nursing Department on obtaining and documenting weights and intake. They stated they would conduct 3 monthly audits of weight and intake records, with results reported to the QA committee.

This plan of correction was accepted by the State Survey Agency.

The next case study shows a facility with effective QAPI systems in place to identify issues proactively, before trends become serious problems. A nursing home chooses a limited number of PIP projects in "high-risk, high volume, problem-prone" areas.

Scenario 2

The Issue: During the monthly QAPI meeting at Whistling Pines, staff discovered a trend of unexplained weight loss among several residents over the last two months. During the discussion, a representative from dining services noted that there had been an increase in the amount of food left on plates, as well as an increase in the amount of supplements being ordered. Although other issues and opportunities for improvement were identified at the meeting, the QAPI Steering Committee decided to launch a Performance Improvement Project (PIP) on the weight loss trend because unexplained weight loss posed a high-risk problem for residents.

What Whistling Pines did: The QAPI Steering Committee chartered a PIP team composed of a certified nursing assistant (CNA), charge nurse, social worker, dietary worker, registered dietitian, and a nurse practitioner. The team studied the issue, and then performed a root cause analysis (RCA) to help direct a plan of action. The RCA revealed several underlying factors, which included:

- No process existed for identifying and addressing risks for weight loss such as dental condition, diagnosis, or use of appetite suppressing medications;
- No system existed to ensure resident preferences are honored;
- Staff lacked an understanding of how to document food intake percentages; and
- Residents reported the food was not appetizing.

Based on the identified underlying causes, the PIP team recommended the following interventions:

- Development of a protocol for identifying residents at risk for weight loss to be done on admission and with each care plan. This protocol included a review of medications (appetite suppressants), new diagnoses, and resident assessments, including dental issues;
- Development of standing orders for residents identified as "at risk" for weight loss. These would include bi-weekly weights, referral to attending physician and dietitian for assessment, and documentation of meal percentages;
- Development of a new program for CNAs to be "Food Plan Leads" for at risk residents. The program would include identification of food preferences and accurate documentation of meals - laminated badge cards with pictures of meal percentages were distributed to all CNAs; and
- Revision of the menu to focus on favorite foods, adding finger foods and increasing choices outside of mealtimes.

The interventions were implemented in one area of the building that was home to 25 residents. The PIP team collected data from dietary (food wasted and supplement use), CNAs (observation of resident satisfaction and meal percentages), residents (satisfaction surveys), and weights.

After 3 months, they found that 5 residents gained weight, 15 remained stable, and 5 lost weight, but the weight loss was not unexpected and consistent with their clinical condition. Food costs did not increase and supplement costs decreased by 12%.

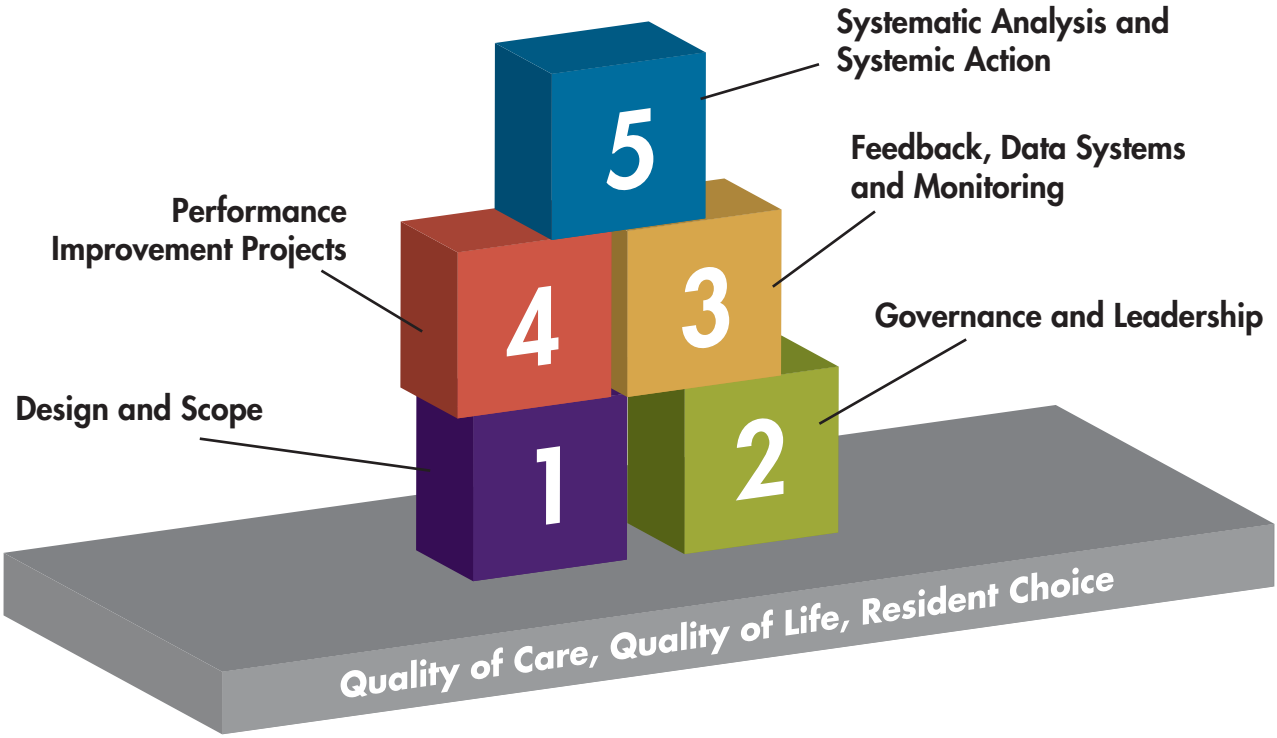
Whistling Pines decided to adopt and expand the changes to other areas of the facility. They received no deficiencies in the areas of nutrition on their annual survey. Using QAPI allowed them to identify and correct developing issues before they escalated to larger problems.

Many of the QAPI action steps discussed in this guide are found in the second scenario. Here are some of the key highlights:

- The facility had a structured Steering Committee for directing the QAPI activities (Step 1).
- The facility established performance measures and was conducting routine monitoring (Step 6).
- The facility used data to identify gaps or opportunities for improvement (Step 8).
- The QAPI Steering Committee used prioritization to decide when to conduct PIPs (Step 9).
- The QAPI Steering Committee created an interdisciplinary team, and as seen in this example, each discipline in the team brought a unique perspective that contributed to a balanced and comprehensive analysis (Step 2).
- The QAPI Steering Committee gave each team member real responsibility to study the issue, analyze the data, and recommend corrective actions (Step 2).
- The PIP team explored the issue, and designed interventions using a Plan-Do-Study-Act (PDSA) model (Steps 9 and 10).
- The PIP team's investigation revealed several underlying systemic issues and made recommendations that addressed those systems, rather than focusing on individual behavior (Step 12).

Five Elements for Framing QAPI in Nursing Homes

CMS has identified five strategic elements that are basic building blocks to effective QAPI. These provide a framework for QAPI development.



The 5 elements are your strategic framework for developing, implementing, and sustaining QAPI. In doing so, keep the following in mind:

- Your QAPI plan should address all five elements.
- The elements are all closely related. You are likely to be working on them all at once—they may all need attention at the same time because they will all apply to the improvement initiatives you choose.
- Your plan is based on your own center's programs and services, the needs of your particular residents, and your assessment of your current quality challenges and opportunities.

THE FIVE ELEMENTS ARE:

Element 1: Design and Scope

A QAPI program must be ongoing and comprehensive, dealing with the full range of services offered by the facility, including the full range of departments. When fully implemented, the QAPI program should address all systems of care and management practices, and should always include clinical care, quality of life, and resident choice. It aims for safety and high quality with all clinical interventions while emphasizing autonomy and choice in daily life for residents (or resident's agents). It utilizes the best available evidence to define and measure goals. Nursing homes will have in place a written QAPI plan adhering to these principles.

Element 2: Governance and Leadership

The governing body and/or administration of the nursing home develops a culture that involves leadership seeking input from facility staff, residents, and their families and/or representatives. The governing body assures adequate resources exist to conduct QAPI efforts. This includes designating one or more persons to be accountable for QAPI; developing leadership and facility-wide training on QAPI; and ensuring staff time, equipment, and technical training as needed. The Governing Body should foster a culture where QAPI is a priority by ensuring policies are developed to sustain QAPI despite changes in personnel and turnover. Their responsibilities include, setting expectations around safety, quality, rights, choice, and respect by balancing safety with resident-centered rights and choice. The governing body ensures staff accountability, while creating an atmosphere where staff are comfortable identifying and reporting quality problems as well as opportunities for improvement.

Element 3: Feedback, Data Systems and Monitoring

The facility puts in place systems to monitor care and services, drawing data from multiple sources. Feedback systems actively incorporate input from staff, residents, families, and others as appropriate. This element includes using Performance Indicators to monitor a wide range of care processes and outcomes, and reviewing findings against benchmarks and/or targets the facility has established for performance. It also includes tracking, investigating, and monitoring Adverse Events that must be investigated every time they occur, and action plans implemented to prevent recurrences.

Element 4: Performance Improvement Projects (PIPs)

A Performance Improvement Project (PIP) is a concentrated effort on a particular problem in one area of the facility or facility wide; it involves gathering information systematically to clarify issues or problems, and intervening for improvements. The facility conducts PIPs to examine and improve care or services in areas that the facility identifies as needing attention. Areas that need attention will vary depending on the type of facility and the unique scope of services they provide.

Element 5: Systematic Analysis and Systemic Action

The facility uses a systematic approach to determine when in-depth analysis is needed to fully understand the problem, its causes, and implications of a change. The facility uses a thorough and highly organized/ structured approach to determine whether and how identified problems may be caused or exacerbated by the way care and services are organized or delivered. Additionally, facilities will be expected to develop policies and procedures and demonstrate proficiency in the use of Root Cause Analysis. Systemic Actions look comprehensively across all involved systems to prevent future events and promote sustained improvement. This element includes a focus on continual learning and continuous improvement.

Action Steps to QAPI

The next few sections detail action steps that may help you on your road to implementing QAPI. They do not need to be achieved sequentially, but each step builds on other QAPI principles.

The most important aspect of QAPI is effective implementation. Learning and understanding the principles is just the first step.

STEP 1: Leadership Responsibility and Accountability

Creating a culture to support QAPI efforts begins with leadership. Support from the top is essential, and that support should foster the active participation of every caregiver. The administrator and senior leaders must create an environment that promotes QAPI and involves all caregivers.

Executive leadership sets the tone and provides resources. Their challenge is to help leadership flourish in each home.

Put a Personal Face on Quality Issues

Leadership should:

- give residents, family and staff the opportunity to meet board members and executive leaders to generate support for QAPI.
- tour the organization regularly, meeting with residents and caregivers where they live and work.
- choose the person or persons who will be the QAPI lead in conjunction with top management—QAPI needs champions.

Here are some ways leadership can take action:

- Develop a steering committee, a team that will provide QAPI leadership:
  - The steering committee has overall responsibility to develop and modify the plan, review information, and set priorities for PIPs. The steering committee charters teams to work on particular problems. It reviews results and determines the next steps. The steering committee must learn and use systems thinking—a nursing home has many competing interests and needs. Top leadership such as the Administrator and the Director of Nursing must be part of this structure.
  - It is also important to have a medical director who is actively engaged in QAPI. It is possible to adapt your Quality Assurance committee to become your "Steering committee" to oversee QAPI. For this to work, the QA Committee may need to meet more often, include more people, and establish permanent and time-limited workgroups that report to it.
- Provide resources for QAPI—including equipment and training:
  - Caregivers may need time to attend team meetings during working hours, requiring others to cover their clinical duties for a period of time.
  - Equipment might include anything from additional computers, to low-cost supplies like posters to create story boards, or multiple copies of resource books or CDs.
  - Leadership may want to consider sending one or more team members to a specialized training.

- Establish a climate of open communication and respect. Leadership may wish to consider:
  - Having an open-door policy to communicate with staff and caregivers.
  - Emphasizing communication across shifts and between department heads.
  - Creating an environment where caregivers feel free to bring quality concerns forward without fear of punishment.
  - Understand your home's current culture and how it will promote performance improvement:
  - Create the expectation that everyone in your nursing home is working on improving care and services.
  - Establish an environment where caregivers, residents, and families feel free to speak up to identify areas that need improvement.
  - Expect and build effective teamwork among departments and caregivers.

STEP 2: Develop a Deliberate Approach to Teamwork

Teamwork is a core component of QAPI and too often it is taken for granted. You will hear and read that you should discuss a situation with "your team," or that the opinion of "everyone on the team" is valued. The word "teamwork" may have different meanings. Many people work together without being a designated or formal "team."

Characteristics of an effective team include the following:

- Having a clear purpose
- Having defined roles for each team member to play
- Having commitment to active engagement from each member

The roles of team workers may grow out of their original discipline (e.g., nurse, social worker, physical therapist) or their defined job responsibilities.

QAPI relies on teamwork in several ways:

- Task-oriented teams may be specially formed to look into a particular problem and their work may be limited and focused.
- PIP teams are formed for longer-term work on an issue.
- When chartering a PIP, careful consideration must be given to the purpose of the PIP and type of members needed to achieve that purpose. Here are some examples:
  - A PIP team with the goal of helping residents go outside more often decided that grounds personnel needed to be on that team so that procedures for snow removal, sun protection, and outdoor seating could be considered.
  - Another PIP team working at simplifying medication regimens included a pharmacist, even though the time needed to be added to the consultant contract.
  - After a PIP team began working on the problem of anxiety among residents, the members realized that many of the affected residents reported reassurance from the pastor and asked the QA committee to add him to the team that was planning the approach.
  - A PIP team working on reducing falls asked that the housekeeping department be involved as it considered root causes of falls and realized that equipment in the corridors and clutter in the bathrooms contributed.

Note: Generally, each team should be composed of interdisciplinary members. For example, a concern with medication administration should include nursing and pharmacy team members. However, even other disciplines or family members may bring a different perspective to understanding this issue and should be considered for this type of team.

- Family members and residents may be team members, though for confidentiality reasons, they may not review certain data or information that identifies individuals.
- PIP teams need to plan for sufficient communication—including face-to-face meetings to get to know each other and plan the work. The team should also plan for the way each team member will review information that emerges from the PIP.
- Leadership needs to convey that being on a PIP team is an important part of the job—not something to put aside if other things come up. They must also support this idea through action and resources to enable staff to complete daily assignments, provide clinical care and also participate on QAPI teams.

STEP 3: Take your QAPI "Pulse" with a Self-Assessment

In order to establish QAPI in your organization, it is helpful to conduct a self-assessment in your organization. As you continue implementing the action steps outlined in this guide, you should periodically evaluate QAPI in your organization – see how far you've come.

To get you started, we've developed a self-assessment tool to take your QAPI "pulse." It will assist you in evaluating the extent to which components of QAPI are in place within your organization and identifying areas requiring further development. It will help you determine how you really know whether QAPI is taking hold.

You may use the self-assessment tool as you begin work on QAPI and then for annual or semiannual evaluation of your organization's progress. You should complete the tool with input from the entire QAPI team and organizational leadership. This is meant to be an honest reflection of your progress with QAPI. The results of this assessment will direct you to areas you need to work on in order to establish QAPI in your organization.

Click here to go to the QAPI Self-Assessment Tool in Appendix A

STEP 4: Identify Your Organization's Guiding Principles

It is important to lay a foundation that will help you think about what principles will guide your decision making and help you set priorities.

Nursing homes are complex organizations, with numerous departments performing different functions that interact with and depend on each other. Establishing a purpose and guiding principles will unify the facility by tying the work being done to a fundamental purpose or philosophy. These principles will help guide your facility in determining programmatic priorities.

Use the Guide for Developing Purpose, Guiding Principles, and Scope for QAPI to establish the principles that will give your organization direction. The team completing this assignment should include senior leadership. Taking time to articulate the purpose, develop guiding principles, and define the scope will help you to understand how QAPI will be used and integrated into your organization. This information will also help your organization to develop a written QAPI plan.

Click here to go to the Guide for Developing Purpose, Guiding Principles, and Scope for QAPI in Appendix A

STEP 5: Develop Your QAPI Plan

Your plan will assist you in achieving what you have identified as the purpose, guiding principles and scope for QAPI. This is a living document that you may revisit as your facility evolves.

A written QAPI plan guides the nursing home's quality efforts and serves as the main document to support implementation of QAPI. The plan describes guiding principles that will be used in QAPI as well as the scope QAPI will have based on the unique characteristics and services of the nursing home. The QAPI plan should be something that is actually used and not viewed as a task that must be completed. You should continually review and refine your QAPI plan.

- Tailor the plan to fit your nursing home including all units, programs, and resident groups (for example, your sub-acute care unit, your dementia care unit, or your palliative care program). Think also of the range of residents. Do you have some younger residents? You may need to consciously develop a distinct plan to create quality of life for those residents.
- Some large organizations or corporations may choose to develop a general plan for all nursing homes in the group—in fact many multi-home organizations already have a corporate quality plan. Flexibility must be built in because individual nursing homes must have a plan that works for them. Leaders at the facility level need flexibility to develop plans for the priorities that fit their needs.

You may use the Guide for Developing a QAPI Plan to help you create a comprehensive plan that addresses the full range and scope of care and services provided by your organization.

Click here to go to the Guide for Developing a QAPI Plan in Appendix A 

STEP 6: Conduct a QAPI Awareness Campaign

COMMUNICATE WITH ALL CAREGIVERS

- Let everyone know about your QAPI plan—often and in multiple ways.
- Plan ongoing caregiver education beyond single exposures—the goal is widespread awareness of QAPI initiatives.
- Train through dialogue, examples, and exercises. Transform the material in this guide into smaller pieces and easily understood ideas. Use your home's own experiences with certain caregivers or residents as part of the learning materials.
- Convey the message that QAPI is about systems of care, management practices, and business practices—systems should support quality and/or acceptable business practices, or they must change. Use examples to get the message across, and ask caregivers to think of examples of their own.
- Be sure consultants, contractors, and collaborating agencies are also aware of your QAPI approach. Maybe you have several hospice organizations coming in and out of your home. You may work with a podiatrist who visits regularly. They each have a role in your system.
- Convey the message that any and every caregiver is expected to raise quality concerns, that it is safe to do so, and that everyone is encouraged to think about systems.

- Discuss the hard questions—what is meant by a culture of safety here in our nursing home? How does the nursing home try to balance issues of safety and resident choice/autonomy? These types of questions often do not have easy answers but QAPI opens up these types of issues for discussion and deeper thinking.

Try this:

An exercise where groups that cross disciplines and roles brainstorm the various ways their work influences the work of others. For example, activities personnel may find that their events are cut short because no one is available to help residents to and from activity areas. Also seek examples where resident choice did not prevail. For instance, evening caregivers may say residents cannot be up and out of their rooms after 9:30 pm because no one will be able to help them to bed after 10:00 pm. Brainstorm how to solve problems like these, even if jobs and routines would change.

If systems don't exist, they may need to be developed. If systems impede quality, they must be changed.

COMMUNICATE WITH RESIDENTS AND FAMILIES

- Make sure all residents and families know that their views are sought, valued, and considered in facility decision-making and process improvements by announcing and discussing QAPI in resident and family councils and other venues.
- Ask residents and family members to tell you about their quality concerns. Many facilities today are using some type of customer-satisfaction survey—results should be used to identify opportunities for improvement that will proactively have an impact on all residents and their families.
- Try to view concerns through residents' eyes. For example, getting back to a resident in 10 minutes may seem responsive, but may feel like an eternity to the resident. How would that feel to a resident waiting an answer to a call light or for help to the bathroom?
- Consider including QAPI information in routine communications to families.

Family and resident complaints are often underused, and yet they are a valuable way of identifying more general problems.

STEP 7: Develop a Strategy for Collecting and Using QAPI Data

Your team will decide what data to monitor routinely. Areas to consider may include:

- Clinical care areas, e.g., pressure ulcers, falls, infections
- Medications, e.g., those that require close monitoring, antipsychotics, narcotics
- Complaints from residents and families
- Hospitalizations and other service use
- Resident satisfaction
- Caregiver satisfaction
- Care plans, including ensuring implementation and evaluation of measurable interventions
- State survey results and deficiencies
- Results from MDS resident assessments
- Business and administrative processes—for example, financial information, caregiver turnover, caregiver competencies, and staffing patterns, such as permanent caregiver assignment. Data related to caregivers who call out sick or are unable to report to work on short notice, caregiver injuries, and compensation claims may also be useful.

This data will require systematic organization and interpretation in order to achieve meaningful reporting and action. Otherwise, it would only be a collection of unrelated, diverse data and may not be useful.

Compare this to an individual resident's health—you must connect many pieces of information to reach a diagnosis. You also need to connect many pieces of information to learn your nursing home's quality baseline, goals, and capabilities.

- Your team should set targets for performance in the areas you are monitoring. A target is a goal, usually stated as a percentage. Your goal may be to reduce restraints to zero; if so, even one instance will be too many. In other cases, you may have both short and longer-term goals. For example, your immediate goal may be reducing unplanned rehospitalizations by 15 percent, and then subsequently by an additional 10 percent. Think of your facility or organization as an athlete who keeps beating his or her own record.
- Identifying benchmarks for performance is an essential component of using data effectively with QAPI. A benchmark is a standard of comparison. You may wish to look at your performance compared to nursing homes in your state and nationally using Nursing Home Compare (www.medicare.gov/nhcompare); some states also have state report cards. You may compare your nursing home to other facilities in your corporation, if applicable. But generally, because every facility is unique, the most important benchmarks are often based on your own performance. For example, seeking to improve hand-washing compliance to 90 percent in 3 months based on a finding of 66 percent in the prior quarter. After achieving 90 percent for some period of time, the benchmark can be raised higher as part of ongoing, continuous improvement.
- It may be helpful to monitor what happens when residents leave the nursing home or come back, including discharges to the hospital or home. You may examine discharge rates from your post-acute care area, preventable hospitalizations (i.e., hospitalizations that can be avoided through good clinical care), and what happens after the resident returns from the hospital.

- You'll want to develop a plan for the data you collect. Determine who reviews certain data, and how often. Collecting information is not helpful unless it is actually used. Be purposeful about who should review certain data, and how often—and about the next steps in interpreting the information.

STEP 8: Identify Your Gaps and Opportunities

This step involves reviewing your sources of information to determine if gaps or patterns exist in your systems of care that could result in quality problems. Or, are there opportunities to make improvements?

Potential areas to consider when reviewing your data:

- MDS data for problem patterns.
- Nursing Home Compare (provides quality information about every certified nursing home in the country).
- State survey results and plans of correction.
- Resident care plans for documented progress towards specified goals.
- Trends in complaints.
- Resident and family satisfaction for trends.
- Patterns of caregiver turnover or absences.
- Patterns of ER and/or hospital use.

During this step, you may decide to spend more time discussing the quality themes you have identified with residents and caregivers. They may pick up patterns you have not yet identified, and they may have ideas about what is at the root of the problem. Consider hosting a series of small group meetings with your caregivers, and arrange to meet with your Resident Council. You may wish to provide refreshments and have an informal discussion.

This step should lead to the next steps involving PIPs. Such projects are expected to be chosen to deal with "high risk, high volume, problem-prone areas" related to quality of care or quality of life. Take time to notice the things you are doing well—that's important too, and deserves recognition.

But while you are celebrating accomplishments, you can also begin to set priorities for improvement around issues that the team identifies.

STEP 9: Prioritize Quality Opportunities and Charter PIPs

Prioritizing opportunities for improvement is a key step in the process of translating data into action.

As you continue to implement QAPI, you and your team will:

- Prioritize opportunities for more intensive improvement work. Problems versus opportunities are a matter of perspective and often require discussion.
- Choose problems or issues that you consider important (consider if the issue is high risk, high frequency, and/or problem prone). Remember that problems affecting psychosocial well-being and the ability of residents to exercise choice should also be considered as they may lead to resident suffering.
- Consider which problems will become the focus for a PIP.

- All identified problems need attention—and usually from more than one person, but they do not all require PIPs.
- Begin some PIPs with problems you think you can solve relatively easily. A quick win is worthwhile.

Charter PIP teams:

We use the word "charter" on purpose. A PIP is more than a casual effort - it entails a specific written mission to look into a problem area. The PIP team should include people in a position to explore the problem (usually direct caregivers, such as nursing assistants, are needed). If the problem being addressed involves, for example, dietary choices, then someone from the dietary department should also be on the PIP team.

Chartering implies that the team has been entrusted with a mission, and that it reports back to the Steering Committee at intervals. Being part of a formally chartered PIP team must be interpreted as an important assignment that team members and their supervisors must take seriously. The development of a charter adds strength, importance, and formality to the PIP process. The team typically has a leader—either chosen in the charter or by the team itself. Soon after it begins its work, the PIP should develop a proposed time line, and indicate the budget that is needed.

Use the Goal Setting Worksheet to help your PIP team establish appropriate goals for organizational quality measures, informal improvement initiatives, and PIPs.

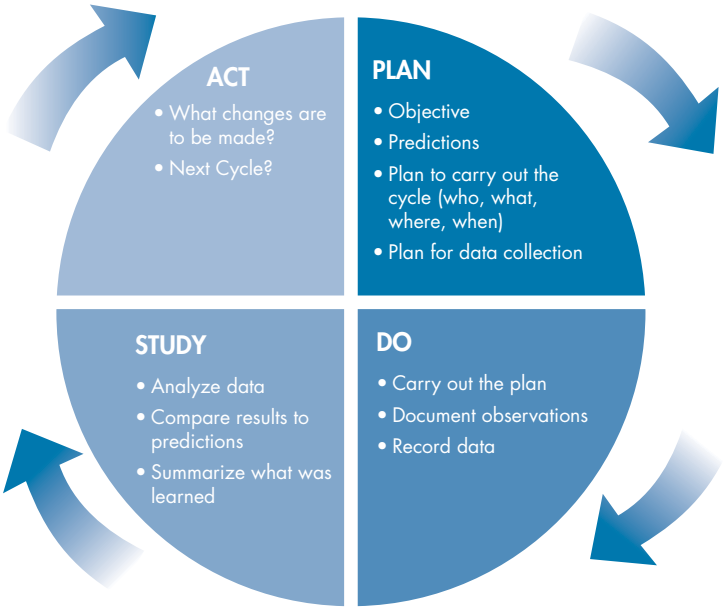
Click here to go to the Goal Setting Worksheet in Appendix A

STEP 10: Plan, Conduct and Document PIPs

Careful planning of PIPs includes identifying areas to work on through your comprehensive data review which are meaningful and important to your residents. It is important to focus your PIPs by defining the scope, so they do not become overwhelming.

You and your team may:

- consider each PIP a learning process.
- determine what information you need for the PIP.
- determine a timeline and communicate it to the Steering Committee.
- identify and request any needed supplies or equipment.
- select or create measurement tools as needed;
- prepare and present results.
- use a problem solving model like PDSA (Plan-Do-Study-Act).
- report results to the Steering Committee.



PDSA MODEL

PLAN-DO-STUDY-ACT (PDSA) CYCLE

During a PIP you will try out some changes and then see whether or not they made a difference in the area you were trying to improve. In the PLAN stage, the team learns more about the problem, plans for how improvement would be measured, and plans for any changes that might be implemented. In the DO stage, the plan is carried out, including the measures that are selected. In the STUDY phase, the team summarizes what was learned. In the ACT phase, the team and leadership determine what should be done next. The change can be adapted (and re-studied), adopted (perhaps expanded to other areas), or abandoned. That decision determines the next steps in the cycle.

STEP 11: Getting to the "Root" of the Problem

A major challenge in process improvement is getting to the heart of the problem or opportunity.

There is danger in starting with a solution without thoroughly exploring the problem. Multiple factors may have contributed, and/or the problem may be a symptom of a larger issue. What seems like a simple issue may involve a number of departments.

Root Cause Analysis (RCA) is a term used to describe a systematic process for identifying contributing causal factors that underlie variations in performance. This structured method of analysis is designed to get to the underlying cause of a problem –which then leads to identification of effective interventions that can be implemented in order to make improvements.

RCA helps teams understand that the most immediate or seemingly obvious reason for the problem or an event may not be the real reason that an event occurred. The RCA process leads to digging deeper and deeper—looking for the reasons behind the reasons. This process will generally lead to the identification of more than one root cause. The root cause(s) and any contributing factors can then be sorted into categories to facilitate the identification of various actions that can be taken to make improvements.

RCA focuses primarily on systems and processes, not individual performance.

The RCA process takes practice, but can be a valuable tool for performance improvement. In order to get familiar with RCA you and your team may consider:

- studying case examples of RCA.
- applying RCA to an adverse event and discussing this technique with the team.
- building RCA examples into training opportunities.

STEP 12: Take Systemic Action

Identifying root causes is only the first step in improving performance. Next you will want to implement changes or corrective actions that will result in improvement or reduce the chance of the event recurring. This is often the most challenging step in the process. Common solutions such as providing more training/education or asking clinicians to "be more careful" do not change the process or system. These proposed solutions are based on two assumptions: lack of knowledge contributed to the event, and if a person is educated or trained, the mistake won't happen again.

Choosing actions that are tightly linked to the root causes and that lead to a system or process change are considered to have a higher likelihood of being effective. Actions that simply support the current process are considered "weaker" and should not be selected as the sole intervention. The goal is to make changes that will result in lasting improvement. Avoiding quick fixes and weak actions is vital to achieving that goal.

To be effective, interventions or corrective actions should target the elimination of root causes, offer long term solutions to the problem, and have a greater positive than negative impact on other processes. In addition, interventions must be achievable, objective, and measurable.

Pilot Test:

Think about testing or "piloting" changes in one area of your facility before launching throughout. Some changes have unintended consequences.

The Department of Veterans Affairs National Center for Patient Safety's Hierarchy of Actions[2] classifies corrective actions as:

Weak: Actions that depend on staff to remember their training or what is written in the policy. Weak actions enhance or enforce existing processes.

Examples of weak actions:

- double checks
- warnings/labels
- new policies/procedures/memoranda
- training/education
- additional study

Intermediate: Actions are somewhat dependent on staff remembering to do the right thing, but they provide tools to help staff to remember or to promote clear communication. Intermediate actions modify existing processes.

Examples of intermediate actions:

- decrease workload
- software enhancements/modifications
- eliminate/reduce distraction
- checklists/cognitive aids/triggers/prompts
- eliminate look alike and sound alike
- read back
- enhanced documentation/communication
- build in redundancy

[2]U.S. Department of Veterans Affairs. National Center for Patient Safety Root Cause Analysis Tools. Retrieved from http://www.patientsafety.gov/CogAids/RCA/index.html#page+page-1.

Strong: Actions that do not depend on staff to remember to do the right thing. The action may not totally eliminate the vulnerability but provides strong controls. Strong actions change or re-design the process. They help detect and warn so there is an opportunity to correct before the error reaches the patient. They may involve hard stops which won't allow the process to continue unless something is corrected or gives the chance to intervene to prevent significant harm.

Examples of strong actions:

- physical changes: grab bars, non slip strips on tubs/showers
- forcing functions or constraints: design of gas lines so that only oxygen can be connected to oxygen lines; electronic medical records – cannot continue charting unless all fields are filled in
- simplifying: unit dose

Prevent future problems by developing and testing strong actions.

QAPI Principles Summarized

- All of QAPI may not be new to your facility. You already have a Quality Assessment and Assurance program—consider beginning by evaluating or re-evaluating that program and then conducting a self evaluation using the QAPI Self Assessment Tool.
- QAPI leadership starts at the top with executive management and the Board of Directors, Owners, or Trustees, and includes top management in each home.
- Three important principles of QAPI are Systems, Systems, and Systems. Start using systems thinking as you assess your own QAPI efforts, and develop a QAPI plan moving forward. Think of your entire center or community as you plan for monitoring, as you conduct PIPs, and particularly as you think about the way problems might be caused and how care is organized.
- Involve the people directly working in a process in order to improve that process. These are the people who really know what happens at any point in the process. It is crucial to focus on organization-wide inclusion, not for the sake of inclusion, but to truly understand what is going on in any given process.
- Communication about QAPI should be continuous throughout the whole organization. QAPI principles and ongoing training should be built into a facility-wide educational effort that involves all caregivers, residents, and families.
- Residents' perspectives need to be considered in setting QAPI priorities. Solicit residents' viewpoints and talk to residents and families about quality as they experience it.
- Two important components of your QAPI plan will be setting priorities and chartering PIP teams. Everyone should have an opportunity to participate in these activities.
- Create a record of QAPI activities. Consider using past experience as a resource as you move ahead. Keeping an ongoing record of QAPI achievements may help to sustain the improvements regardless of crises or changes in leadership. Build it into your plan.
- Celebrate and reward successes.

How to Learn More

Our QAPI website: http://go.cms.gov/Nhqapi

An excellent resource on QAPI in Nursing Homes is CMS' QAPI website. It contains a number of tools and resources including:

- Learning modules complete with videos, QAPI Process Tools and how to use them, case study examples, best practices information, sections to help engage consumers, and much more
- Downloadable QAPI process tools with instructions for their use
- Best practice examples organized by topic
- QAPI tools for specific topics and purposes with links to many related resources
- Special resources for you in your particular practice role in the "Communities of Practice" section
- News Briefs on QAPI implementation

QAPI Tools and Related Resources

QAPI PROCESS TOOLS

These are tools that help make QAPI processes work. They may include:

- checklists
- templates
- flow charts
- reporting forms or outlines
- worksheets

QAPI process tools are important to:

- organize multiple tasks.
- enhance communication within and across teams.
- help generate ideas and reach decisions.
- keep information organized and accessible.
- track successes and challenges using data.

QAPI is largely about well-functioning and tightly coordinated systems that can identify, solve, and prevent problems effectively. Using QAPI can improve diverse aspects of care and services as well as resident, family, caregiver, and staff experience and satisfaction. **TOOLS CAN HELP.**

QAPI TOPIC TOOLS

QAPI Topic Tools are used to study and improve particular topic areas. Many tools are available to assess care processes and outcomes and to allow you to follow progress in areas you want to track and/or improve. Topic tools can take many forms, ranging from simple to complex, and they use multiple sources of information.

- Checklists or audits completed by caregivers and practitioners. Checklists can be used to review records of various kinds to determine that all steps have been taken. For example, an admission or fall prevention checklist.
- Rating forms completed by caregivers. For example,residents' mood states are rated when residents cannot respond to direct questions.
- Structured observation (e.g., observations of interactions among residents and caregivers or of physical environments). Observations are objective and made at specific times and places; later they may be summarized into a score.
- Direct interviews with residents and family. Such tools, sometimes called resident self-report tools, may be related to single areas of functioning.
- Protocols to guide caregivers' behavior to improve quality in a particular area. Such protocols may include procedures and forms meant to shape caregiver behavior around pressure ulcer prevention, respecting residents' rights, etc. This comprehensive set of tools could be considered a QAPI process toolkit as well.

Nursing homes may wish to select established tools that have been tested and use them consistently.

QAPI RESOURCES FOR PROVIDERS

Each state is served by a Quality Improvement Organization that offers resources and tools for nursing homes. To find your Quality Improvement Organization, visit http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1144767874793

RESOURCES AND TOOLS AVAILABLE THROUGH QIOS

Oklahoma Foundation for Medical Quality
Provides tools and resources for nursing homes.
http://www.ofmq.com/nhtoolsandresources Improvement basics for nursing homes, Change management, and Facilitating group agreement.

Stratis Health
The following recorded webinars cover some basic principles of QI and can be used for caregiver education: http://www.stratishealth.org/events/recorded.html

WEBSITES ON SELECTED QUALITY TOPICS

Advancing Excellence in America's Nursing Homes
Supported by CMS, the Commonwealth Fund, and others, The Advancing Excellence Campaign provides tools and resources to improve nursing home care in clinical and organizational areas.
http://www.nhqualitycampaign.org/

Agency for Healthcare Research and Quality
The Department of Defense and the Agency for Healthcare Research and Quality developed the Team STEPPS program to optimize performance among teams of healthcare professionals and improve collaboration and communication. The Long-Term Care version addresses issues specific to nursing homes: http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/ltc/index.html.

Department of Veterans Affairs
National Center for Patient Safety supports and leads the patient safety activities for all VA medical centers and has developed tools including Root Cause Analysis investigations: http://www.patientsafety.gov/CogAids/RCA/.

Getting Better All the Time: Working Together for Continuous Improvement
The Isabella Geriatric Center and Cobble Hill Health Center have developed a web manual on quality improvement approaches as a guide for nursing home caregivers. This is a particularly practical and lively resource that explains and illustrates performance monitoring and improvement approaches in ways that are understandable to most nursing home caregivers. *Getting Better All the Time* was written by Ann Wyatt, a social worker and nursing home administrator; it aims to present a model of quality improvement that integrates quality of care and quality life.
http://www.susanwehrymd.com/files/gettingbetterall-the-time.pdf

Interact II
An example of a more extensive set of tools, INTERACT II is a system of tools to improve how nursing home caregivers communicate around change in resident condition. This comprehensive set of tools could be considered a QAPI process toolkit as well. www.interact2.net

Institute for Health Care Improvement (IHI)
IHI uses the Model for Improvement as the framework to guide improvement work. The Model for Improvement, developed by Associates in Process Improvement, is a simple, yet powerful tool for accelerating improvement. Learn about the fundamentals of the Model for Improvement and testing changes on a small scale using Plan-Do-Study-Act (PDSA) cycles.
http://www.ihi.org/knowledge/Pages/HowtoImprove/default.aspx

WEBSITES ON PERSON-CENTERED CARE

Implementing Change in Long-Term Care: A Practical Guide to Transformation
This resource was prepared by Barbara Bowers and others with a grant from the Commonwealth Fund to the Pioneer Network. Although it deals with implementing culture change (not QAPI), it is a good resource on the change process.
http://www.pioneernetwork.net/Data/Documents/Implementation_Manual_ChangeInLongTermCare%5B1%5D.pdf

Picker Institute Publications
These include a *Long-Term Care Improvement Guide*, commissioned in 2010 and a *Patient-Centered Care Improvement Guide*, commissioned in 2008, both by Susan Frampton and others. The website also carries information on current books related to person centered care that Picker Institute recommends.
http://pickerinstitute.org/publications-and-resources/

Appendix A: QAPI Tools

Disclaimer: Use of these tools is not mandated by CMS for regulatory compliance nor does their completion ensure regulatory compliance.

QAPI Self-Assessment Tool

Directions: Use this tool as you begin work on QAPI and then for annual or semiannual evaluation of your organization's progress with QAPI. This tool should be completed with input from the entire QAPI team and organizational leadership. This is meant to be an honest reflection of your progress with QAPI. The results of this assessment will direct you to areas you need to work on in order to establish QAPI in your organization. You may find it helpful to add notes under each item as to why you rated yourself a certain way.

Date of Review:_____ Next review scheduled for:_____

Rate how closely each statement fits your organization	Not started	Just starting	On our way	Almost there	Doing great
Our organization has developed principles guiding how QAPI will be incorporated into our culture and built into how we do our work. For example, we can say that QAPI is a method for approaching decision making and problem solving rather than considered as a separate program. Notes:					
Our organization has identified how all service lines and departments will utilize and be engaged in QAPI to plan and do their work. For example, we can say that all service lines and departments use data to make decisions and drive improvements, and use measurement to determine if improvement efforts were successful. Notes:					
Our organization has developed a written QAPI plan that contains the steps that the organization takes to identify, implement and sustain continuous improvements in all departments; and is revised on an ongoing basis. For example, a written plan that is done purely for compliance and not referenced would not meet the intent of a QAPI plan. Notes:					
Our board of directors and trustees (if applicable) are engaged in and supportive of the performance improvement work being done in our organization. For example, it would be evident from meeting minutes of the board or other leadership meetings that they are informed of what is being learned from the data, and they provide input on what initiatives should be considered. Other examples would be having leadership (board or executive leadership) representation on performance improvement projects or teams, and providing resources to support QAPI. Notes:					

Rate how closely each statement fits your organization	Not started	Just starting	On our way	Almost there	Doing great
QAPI is considered a priority in our organization. For example, there is a process for covering caregivers who are asked to spend time on improvement teams. Notes:					
QAPI is an integral component of new caregiver orientation and training. For example, new caregivers understand and can describe their role in identifying opportunities for improvement. Another example is that new caregivers expect that they will be active participants on improvement teams. Notes:					
Training is available to all caregivers on performance improvement strategies and tools. Notes:					
When conducting performance improvement projects, we make a small change and measure the effect of that change before implementing more broadly. An example of a small change is pilot testing and measuring with one nurse, one resident, on one day, or one unit, and then expanding the testing based on the results. Notes:					
When addressing performance improvement opportunities, our organization focuses on making changes to systems and processes rather than focusing on addressing individual behaviors. For example, we avoid assuming that education or training of an individual is the problem, instead, we focus on what was going on at the time that allowed a problem to occur and look for opportunities to change the process in order to minimize the chance of the problem recurring. Notes:					
Our organization has established a culture in which caregivers are held accountable for their performance, but not punished for errors and do not fear retaliation for reporting quality concerns. For example, we have a process in place to distinguish between unintentional errors and intentional reckless behavior and only the latter is addressed through disciplinary actions. Notes:					

Rate how closely each statement fits your organization	Not started	Just starting	On our way	Almost there	Doing great
Leadership can clearly describe, to someone unfamiliar with the organization, our approach to QAPI and give accurate and up-to-date examples of how the facility is using QAPI to improve quality and safety of resident care. For example, the administrator can clearly describe the current performance improvement initiatives, or projects, and how the work is guided by caregivers involved in the topic as well as input from residents and families. Notes:					
Our organization has identified all of our sources of data and information relevant to our organization to use for QAPI. This includes data that reflects measures of clinical care; input from caregivers, residents, families, and stakeholders, and other data that reflects the services provided by our organization. For example, we have listed all available measures, indicators or sources of data and carefully selected those that are relevant to our organization that we will use for decision making. Likewise, we have excluded measures that are not currently relevant and that we are not actively using in our decision making process. Notes:					
For the relevant sources of data we identify, our organization sets targets or goals for desired performance, as well as thresholds for minimum performance. For example, our goal for resident ratings for recommending our facility to family and friends is 100% and our threshold is 85% (meaning we will revise the strategy we are using to reach our goal if we fall below this level). Notes:					
We have a system to effectively collect, analyze, and display our data to identify opportunities for our organization to make improvements. This includes comparing the results of the data to benchmarks or to our internal performance targets or goals. For example, performance improvement projects or initiatives are selected based on facility performance as compared to national benchmarks, identified best practice, or applicable clinical guidelines. Notes:					
Our organization has, or supports the development of, employees who have skill in analyzing and interpreting data to assess our performance and support our improvement initiatives. For example, our organization provides opportunities for training and education on data collection and measurement methodology to caregivers involved in QAPI. Notes:					

Rate how closely each statement fits your organization	Not started	Just starting	On our way	Almost there	Doing great
From our identified opportunities for improvement, we have a systematic and objective way to prioritize the opportunities in order to determine what we will work on. This process takes into consideration input from multiple disciplines, residents and families. This process identifies problems that pose a high risk to residents or caregivers, is frequent in nature, or otherwise impact the safety and quality of life of the residents. Notes:					
When a performance improvement opportunity is identified as a priority, we have a process in place to charter a project. This charter describes the scope and objectives of the project so the team working on it has a clear understanding of what they are being asked to accomplish. Notes:					
For our Performance Improvement Projects, we have a process in place for documenting what we have done, including highlights, progress, and lessons learned. For example, we have project documentation templates that are consistently used and filed electronically in a standardized fashion for future reference. Notes:					
For every Performance Improvement Project, we use measurement to determine if changes to systems and process have been effective. We utilize both process measures and outcome measures to assess impact on resident care and quality of life. For example, if making a change, we measure whether the change has actually occurred and also whether it has had the desired impact on the residents. Notes:					
Our organization uses a structured process for identifying underlying causes of problems, such as Root Cause Analysis. Notes:					

Rate how closely each statement fits your organization	Not started	Just starting	On our way	Almost there	Doing great
When using Root Cause Analysis to investigate an event or problem, our organization identifies system and process breakdowns and avoids focus on individual performance. For example, if an error occurs, we focus on the process and look for what allowed the error to occur in order to prevent the same situation from happening with another caregiver and another resident. Notes:					
When systems and process breakdowns have been identified, we consistently link corrective actions with the system and process breakdown, rather than having our default action focus on training education, or asking caregivers to be more careful, or remember a step. We look for ways to assure that change can be sustained. For example, if a policy or procedure was not followed due to distraction or lack of caregivers, the corrective action focuses on eliminating distraction or making changes to staffing levels. Notes:					
When corrective actions have been identified, our organization puts both process and outcome measures in place in order to determine if the change is happening as expected and that the change has resulted in the desired impact to resident care. For example, when making a change to care practices around fall prevention there is a measure looking at whether the change is being carried out and a measure looking at the impact on fall rate. Notes:					
When an intervention has been put in place and determined to be successful, our organization measures whether the change has been sustained. For example, if a change is made to the process of medication administration, there is a plan to measure both whether the change is in place, and having the desired impact (this is commonly done at 6 or 12 months). Notes:					

Guide for Developing Purpose, Guiding Principles, and Scope for QAPI

Directions: Use this tool to establish the purpose, guiding principles and scope for QAPI in your organization. The team completing this worksheet should include senior leadership. Taking time to articulate the purpose, develop guiding principles, and define the scope will help you to understand how QAPI will be used and integrated into your organization. This information will also help your organization to develop a written QAPI plan. Use these step-by-step instructions to create a separate document that may be used as a preamble to your QAPI plan.

STEP 1. LOCATE OR DEVELOP YOUR ORGANIZATION'S VISION STATEMENT

A **vision statement** is sometimes called a picture of your organization in the future; it is your inspiration and the framework for your strategic planning. Consider involving staff in the development of your vision statement. Post it for everyone to view.

For example, the vision of the Good Samaritan Society is to create an environment where people are loved, valued and at peace.

STEP 2. LOCATE OR DEVELOP YOUR ORGANIZATION'S MISSION STATEMENT

A **mission statement** describes the purpose of your organization. The mission statement should guide the actions of the organization, spell out its overall goal, provide a path, and guide decision-making. It provides the framework or context within which the company's strategies are formulated. As above, get caregivers involved in establishing your organizations mission.

For example, Meadowlark Hills is each resident's home. We are committed to enhancing quality of life by nurturing individuality and independence. We are growing a value-driven community while leading the way in honoring inherent senior rights and building strong and meaningful relationships with all whose lives we touch.

STEP 3. DEVELOP A PURPOSE STATEMENT FOR QAPI

A **purpose statement** describes how QAPI will support the overall vision and mission of the organization. If your organization does not have a vision or mission statement, the purpose statement can still be written and would state what your organization intends to accomplish through QAPI.

For example, the purpose of QAPI in our organization is to take a proactive approach to continually improving the way we care for and engage with our residents, caregivers and other partners so that we may realize our vision to [reference aspects of vision statement here]. To do this, all employees will participate in ongoing QAPI efforts which support our mission by [reference aspects of mission statement here].

STEP 4. ESTABLISH GUIDING PRINCIPLES

Guiding Principles describe the organization's beliefs and philosophy pertaining to quality assurance and performance improvement. The principles should guide what the organization does, why it does it and how.

For example:

- Guiding Principle #1: QAPI has a prominent role in our management and Board functions, on par with monitoring reimbursement and maximizing revenue.
- Guiding Principle #2: Our organization uses quality assurance and performance improvement to make decisions and guide our day-to-day operations.
- Guiding Principle #3: The outcome of QAPI in our organization is the quality of care and the quality of life of our residents.
- Guiding Principle #4: In our organization, QAPI includes all employees, all departments and all services provided.
- Guiding Principle #5: QAPI focuses on systems and processes, rather than individuals. The emphasis is on identifying system gaps rather than on blaming individuals.
- Guiding Principle #6: Our organization makes decisions based on data, which includes the input and experience of caregivers, residents, health care practitioners, families, and other stakeholders.
- Guiding Principle #7: Our organization sets goals for performance and measures progress toward those goals.
- Guiding Principle #8: Our organization supports performance improvement by encouraging our employees to support each other as well as be accountable for their own professional performance and practice.
- Guiding Principle #9: Our organization has a culture that encourages, rather than punishes, employees who identify errors or system breakdowns.

Add any additional Guiding Principles that may be important to your nursing home. Review the five QAPI elements to ensure you identify and capture guiding principles for your organization.

STEP 5. DEFINE THE SCOPE OF QAPI IN YOUR ORGANIZATION

The **Scope** outlines what types of care and services are provided by the organization that impact clinical care, quality of life, resident choice, and care transitions. Be sure to incorporate the care and services delivered by all departments.

For example:

Post-acute care
Dementia care and services
Dietary
Dining

Once the list of care and service area has been identified, you can determine how each will use QAPI to assess, monitor and improve performance on an ongoing basis.

STEP 6. ASSEMBLE DOCUMENT

Once you've completed steps 1-5, assemble the vision and mission statements, guiding principles, and scope of QAPI into a separate document that may be used as a preamble to your QAPI plan. This document will help you articulate the goals and objectives of your organization; QAPI will help you get there. Consider posting for all to see.

The next step is to develop a written QAPI plan that will meet your purpose, guiding principles and comprehensive scope described above. See *"Guide for Developing a QAPI Plan."*

Guide for Developing a QAPI Plan

DIRECTIONS:

The QAPI plan will guide your organization's performance improvement efforts. Prior to developing your plan, complete the *Guide to Develop Purpose, Guiding Principles, and Scope for QAPI.* Your QAPI plan is intended to assist you in achieving what you have identified as the purpose, guiding principles and scope for QAPI, therefore this information is needed before you begin working on your plan. This is a living document that you will continue to refine and revisit. Use these step-by-step instructions to create your QAPI plan. This plan should reflect input from caregivers representing all roles and disciplines within your organization.

I. QAPI Goals

Based on the *Guide to Develop Purpose, Guiding Principles, and Scope for QAPI*, indicate the QAPI goals that your plan will strive to meet. Goals should be specific, measurable, actionable, relevant, and have a time line for completion. (See *Goal Setting Worksheet*).

II. Scope

a. Describe how QAPI is integrated into all care and service areas of your organization.

b. Describe how the QAPI plan will address:

   i. Clinical care

   ii. Quality of life

   iii. Resident choice (i.e., individualized goals for care)

c. Describe how QAPI will aim for safety and high quality with all clinical interventions while emphasizing autonomy and choice in daily life for residents (or resident's agents).

d. Describe how QAPI will utilize the best available evidence (e.g., data, national benchmarks, published best practices, clinical guidelines) to define and measure goals.

III. Guidelines for Governance and Leadership

a. Describe how QAPI is integrated into the responsibilities and accountabilities of top-level management and the Board of Directors (if applicable).

b. Describe how QAPI will be adequately resourced.

   i. Designate one or more persons to be accountable for QAPI leadership and for coordination.

   ii. Indicate the plan for developing leadership and facility-wide training on QAPI.

   iii. Describe the plan to provide caregivers time, equipment, and technical training as needed for QAPI.

   iv. Indicate how you will determine if resources are adequate for QAPI.

   v. Describe how your caregivers will become and remain proficient with process improvement tools and techniques. How will you assess their level of proficiency?

c. QAPI Leadership

i. While everyone in the organization is involved in QAPI, you will likely have a small group of individuals who will provide the backbone or structure for QAPI in your organization. Who will be part of this group? Many of these individuals may be on your current QAA committee.

ii. Describe how this group of people will work together, communicate, and coordinate QAPI activities. This could include but is not limited to:

- Establishing a format and frequency for meetings
- Establishing a method for communication between meetings
- Establishing a designated way to document and track plans and discussions addressing QAPI.

iii. Describe how the QAPI activities will be reported to the governing body; i.e., Board of Directors, owner.

IV. Feedback, Data Systems, and Monitoring

a. Describe the overall system that will be put in place to monitor care and services, drawing data from multiple sources.

b. Identify the sources of data that you will monitor through QAPI

i. Input from caregivers, residents, families, and others

ii. Adverse events

iii. Performance indicators

iv. Survey findings

v. Complaints

c. Describe the process for collecting the above information.

d. Describe the process for analyzing the above information, including how findings will be reviewed against benchmarks and/or targets established by the facility.

e. Describe the process to communicate the above information. What types of reports will be used? One way to accomplish this is to use a dashboard or dashboards for individual performance improvement projects.

f. Identify who will receive this information (i.e., executive leadership, QAPI leadership, resident/family council, and a center's caregivers), in what format, and how frequently information will be disseminated.

V. Guidelines for Performance Improvement Projects (PIPs)

a. Describe the overall plan for conducting PIPs to improve care or services.

i. Indicate how potential topics for PIPs will be identified.

ii. Describe criteria for prioritizing and selecting PIPs: areas important and meaningful for the specific type and scope of services unique to the facility, requires a concentrated effort on a particular problem in one area of the facility or facility wide.

iii. Indicate how and when PIP charters will be developed.

iv. Describe the process for reporting the results of PIPs. Identify who will receive this information (i.e., quality committee, resident/family council, and a center's caregivers), in what format, and how frequently information will be disseminated.

b. Describe how to designate PIP teams and establish and describe a process for assembling teams to work on specific PIPs.

c. Define the required characteristics for any PIP team. This may include that the team be interdisciplinary (i.e., representing each of the job roles affected by the project), that it include resident representation (as appropriate), and that a qualified team leader is selected (i.e., ability to coordinate, organize and direct all activities of the project team). Describe how PIP teams should document and report their work.

d. Describe your process for documenting PIPs, including highlights, progress, and lessons learned. For example, what project documentation templates will you use consistently and file electronically in a standardized fashion for future reference.

VI. Systematic Analysis and Systemic Action

a. Any change that is made has the potential to have broader impact than intended. If you are trying to make a change to a specific system or process, it is important to recognize any "unintended" consequences of your actions. Describe how your organization will identify these consequences which may be either positive or negative.

b. Describe the process you will use to ensure you are getting at the underlying causes of issues, rather than applying quick fixes that address symptoms only.

c. Describe how you will monitor to ensure that interventions or actions are implemented and effective in making and sustaining improvements.

VII. Communications

Outline the audiences for QAPI communications and the frequency and format of these communications.

VIII. Evaluation

a. Describe the process for assessing QAPI in your organization on an ongoing basis. (See *QAPI Self-Assessment Tool*.)

b. Describe the purpose of this evaluation – to help your organization to expand your skills in QAPI and increase the impact of QAPI in your organization.

IX. Establishment of Plan

a. Date your plan.

b. Determine when you will revisit the plan (i.e., at least annually).

c. Determine how you will track revisions or updates to the plan.

Goal Setting Worksheet

Directions: Goal setting is important for any measurement related to performance improvement. This worksheet is intended to help QAPI teams establish appropriate goals for individual measures and also for performance improvement projects. Goals should be clearly stated and describe what the organization or team intends to accomplish. Use this worksheet to establish a goal by following the SMART formula outlined below. Note that setting a goal does **not** involve describing what steps will be taken to achieve the goal.

Describe the business problem to be solved:

Use the SMART formula to develop a goal:

SPECIFIC

Describe the goal in terms of 3 'W' questions:

What do we want to accomplish?
Who will be involved/affected?
Where will it take place?

MEASURABLE

Describe how you will know if the goal is reached:

What is the measure you will use?
What is the current data figure (i.e., count, percent, rate) for that measure?
What do you want to increase/decrease that number to?

ATTAINABLE

Defend the rationale for setting the goal measure above:

Did you base the measure or figure you want to attain on a particular best practice/average score/ benchmark?
Is the goal measure set too low that it is not challenging enough?
Does the goal measure require a stretch without being too unreasonable?

RELEVANT

Briefly describe how the goal will address the business problem stated above.

TIME-BOUND

Define the timeline for achieving the goal:

What is the target date for achieving this goal?

Write a goal statement, based on the SMART elements above. The goal should be descriptive, yet concise enough that it can be easily communicated and remembered.

[*Example:* Increase the number of long-term residents with a vaccination against both influenza and pneumococcal disease documented in their medical record from 61 percent to 90 percent by December 31, 2011.]

Tip: It's a good idea to post the written goal somewhere visible and regularly communicate the goal during meetings in order to stay focused and remind caregivers that everyone is working toward the same aim.

Appendix B: QAPI Definitions

Performance Improvement (PI)

PI (also called Quality Improvement - QI) is a pro-active and continuous study of processes with the intent to prevent or decrease the likelihood of problems by identifying areas of opportunity and testing new approaches to fix underlying causes of persistent/systemic problems. PI in nursing homes aims to improve processes involved in health care delivery and resident quality of life. PI can make good quality even better.

Performance Improvement Project (PIP)

A PIP project typically is a concentrated effort on a particular problem in one area of the facility or facility wide; it involves gathering information systematically to clarify issues or problems, and intervening for improvements. PIPs are selected in areas important and meaningful for the specific type and scope of services unique to each facility.

Quality Assurance and Performance Improvement (QAPI)

QAPI is a data-driven, proactive approach to improving the quality of life, care, and services in nursing homes. The activities of QAPI involve members at all levels of the organization to: identify opportunities for improvement; address gaps in systems or processes; develop and implement an improvement or corrective plan; and continuously monitor effectiveness of interventions.

Quality Assurance (QA)

QA is a process of meeting quality standards and assuring that care reaches an acceptable level. Nursing homes typically set QA thresholds to comply with regulations. They may also create standards that go beyond regulations. QA is a reactive, retrospective effort to examine why a facility failed to meet certain standards. QA activities do improve quality, but efforts frequently end once the standard is met.

Root Cause Analysis (RCA)

Root cause analysis is a term to describe a systematic process to get to the underlying cause of a problem.

Systems Thinking

Systems thinking is a perspective that considers how things influence one another as a whole, rather than individual elements, or static "snapshots."

Scenario 1

The Issue:
Your nursing home, Green Acres, received deficiencies in F309 and F329 during the annual survey because its residents reflected pattern-use of antipsychotic medications as a first-step treatment intervention for traditional dementia "behavior" symptoms. Green Acres failed to identify non-pharmacologic, person-centered care approaches prior to using antipsychotic medications to properly care for the affected residents.

What Green Acres Did:
The facility's Quality Assurance (QA) Committee developed a Plan of Correction (POC), which contained the following components:

- Implementing an antipsychotic medication gradual-dose reduction (GDR) plan for the affected residents.
- Conducting a chart audit of all residents with dementia to ensure no other residents are affected by the deficient practice.
- In-servicing the Nursing Department (licensed nurses) on appropriate vs. inappropriate requests to attending physicians for antipsychotic medications.
- Conducting three monthly audits of medication administration records (MARs) of residents with dementia to ensure compliance.
- Reporting audit results to the QA Committee.

The director of nursing (DON) or designee will monitor the above areas for compliance. The POC was accepted by the State Survey Agency.

Scenario 2

The Issue:
During the monthly Quality Assurance & Performance Improvement (QAPI) meeting at Green Acres, staff members discovered an increased trend of long-stay residents on antipsychotic medications over the last three months, as documented in the **CASPER MDS 3.0 Reports**. During the discussion, a licensed vocational nurse (LVN) in charge of the facility's nursing department noted that there had been a spike in antipsychotic medication use in the Memory (i.e., dementia) Care Unit (MCU). In response, the QAPI Committee decided to launch a **Performance Improvement Project (PIP)** on the increased use of antipsychotic medications because this trend posed a high-risk, quality-of-life problem for residents. Furthermore, the QAPI Committee set a Specific, Measureable, Attainable, Relevant, Time-bound (**SMART) Goal** for antipsychotic medication reduction for the unit.

What Green Acres Did:
The QAPI Committee chartered a PIP Team composed of a certified nursing assistant (CNA), the LVN charge nurse, social worker, activity director, and nurse practitioner—all associated with the MCU. The team studied the issue by performing **a Root Cause Analysis (RCA)** to generate a **Plan of Action**. The RCA revealed several underlying factors, including:

- Traditional activities designed for alert-and-oriented-nursing home residents were being performed on the MCU.
- There was a high number of resident falls on the unit.
- Staff members on the unit reported an increase of resident "behaviors," including poor safety awareness, agitation, crying or yelling out loud, and "hallucinations."
- No system existed to ensure resident preferences were honored.
- Staff members did not understand how to provide validation-orientation for nursing home residents with dementia.

Based on the identified underlying causes, the PIP Team recommended these interventions:

- Have the MCU staff members visit a local best-practice nursing home specializing in dementia care. They will learn to complete bio sketches on new residents during advanced-care planning meetings with immediate family members to tailor person-centered care activities, referencing the residents' daily routines.
- Help staff members learn to view resident "behaviors" as "needs-driven expressions." This understanding will help staff members realize that the "behaviors" are ways residents with dementia communicate unmet physical or psychosocial needs.
- Have staff members on the MCU create "life stations" based on the bio sketches of the collective resident population, reflecting typical life situations. One life station can be designed as a "laundry room," while another can be a "maintenance shop." The life stations compliment the validation-orientation training of the facility's direct-care staff members.
- Have the nursing home administrator and DON enlist the help of the facility's medical director to educate its practitioners on the Food and Drug Administration's black-box warnings regarding antipsychotic medication use for persons with dementia, as well as the above person-centered care approaches recently implemented at Green Acres.
- Review all physician order requests for antipsychotic medications by the DON prior to presenting to the attending physician.
- Have all physician orders, new admission charts, incident reports, and 24-hour reports reviewed daily by the Interdisciplinary Team following the director's stand-up meeting.

The interventions were implemented in the MCU that was home to 25 residents. The PIP Team collected data from the CASPER MDS 3.0 Reports, the MARs, 24-hour reports, and daily CNA meetings.

After three months, the MCU staff members found that eight residents were able to discontinue use of their prescribed antipsychotic medication(s) through gradual-dose reduction. In addition, five residents who were scheduled to receive antipsychotic medications due to exhibited "behaviors" ultimately did not receive them because of the changes in resident policies.

Green Acres decided to adopt and expand the changes to other areas of the facility **using PDSA: Plan-Do-Study-Act cycles**. The facility received no deficiencies in F309 and F329 on its annual survey. Using QAPI allowed staff members at Green Acres the opportunity to identify and correct developing issues before they escalated to larger problems.

This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. Publication No. CA-10SOW-7.2-080713-02

Quality Assurance & Performance Improvement (QAPI): An Antipsychotic Medication Reduction Story

Joe Bestic, NHA, BA
Director, Nursing Home
Health Services Advisory Group of California, Inc.
(HSAG of California)

1

Objectives

- Understand the differences between Quality Assurance (QA) and Performance Improvement (PI).
- Review a QAPI example of antipsychotic medication reduction.
- Learn the key elements to include in a QAPI Performance Improvement Project (PIP).

2

The Big Picture—the Basics

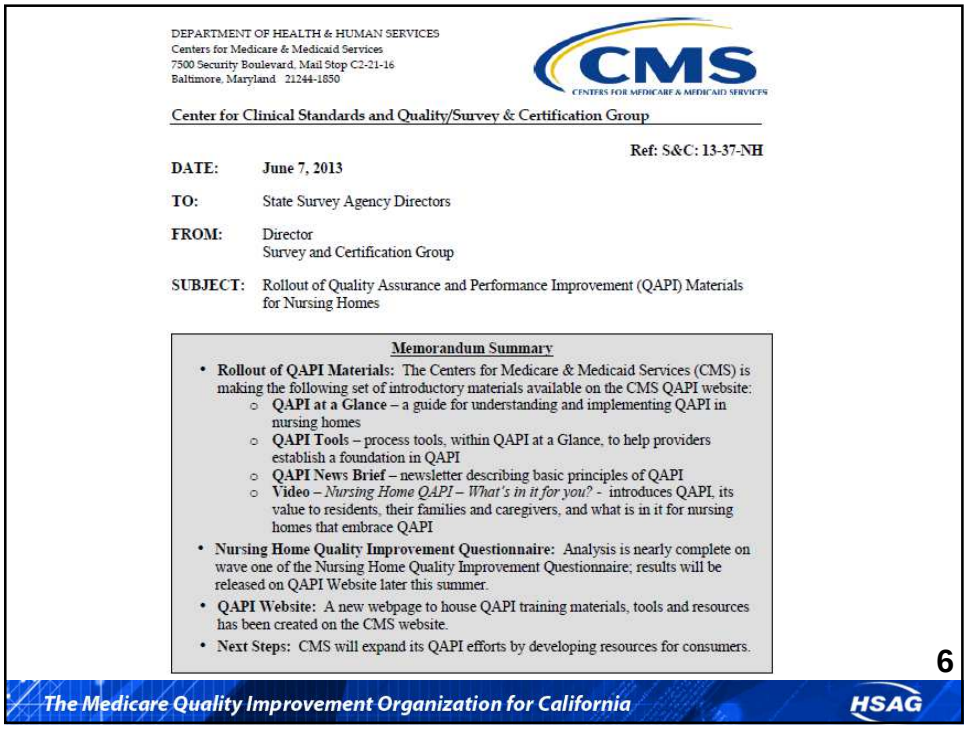
- QA is focused on regulatory standards and is reactive to requirements.
- PI is applying quality improvement methods to daily work and is continuous. It is proactive, and a facility must choose to make improvements.
- The ability to think, make decisions, and take action at the system level is a prerequisite for QAPI success.

4

Background

- The QAPI program in nursing homes (NHs) was required by the Affordable Care Act, enacted March 2010.
- Legislation requires the Centers for Medicare & Medicaid Services (CMS) to establish QAPI program standards and provide technical assistance to NHs.
  - It is an opportunity for CMS to develop and test QAPI technical assistance tools and resources before rule promulgation.

5



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-37-NH

DATE: June 7, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

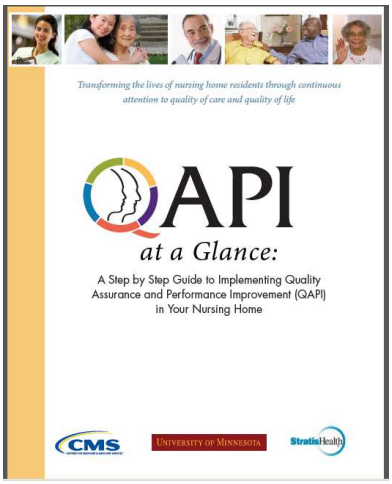
SUBJECT: Rollout of Quality Assurance and Performance Improvement (QAPI) Materials for Nursing Homes

Memorandum Summary

- **Rollout of QAPI Materials:** The Centers for Medicare & Medicaid Services (CMS) is making the following set of introductory materials available on the CMS QAPI website:
  - **QAPI at a Glance** – a guide for understanding and implementing QAPI in nursing homes
  - **QAPI Tools** – process tools, within QAPI at a Glance, to help providers establish a foundation in QAPI
  - **QAPI News Brief** – newsletter describing basic principles of QAPI
  - **Video** – *Nursing Home QAPI – What's in it for you?* - introduces QAPI, its value to residents, their families and caregivers, and what is in it for nursing homes that embrace QAPI
- **Nursing Home Quality Improvement Questionnaire:** Analysis is nearly complete on wave one of the Nursing Home Quality Improvement Questionnaire; results will be released on QAPI Website later this summer.
- **QAPI Website:** A new webpage to house QAPI training materials, tools and resources has been created on the CMS website.
- **Next Steps:** CMS will expand its QAPI efforts by developing resources for consumers.

6

QAPI at a Glance



http://go.cms.gov/Nhqapi

7

The Medicare Quality Improvement Organization for California HSAG

An Antipsychotic Medication Reduction Story

8

The Medicare Quality Improvement Organization for California HSAG

PIP

Includes:

- Data review (MDS 3.0 CASPER Reports)
- Specific, Measureable, Attainable, Relevant, Time-bound (SMART) Goals
- Root Cause Analysis (RCA)
- Plan of Action
- Plan-Do-Study-Act (PDSA) Cycles

9

CASPER Report
MDS 3.0 Facility Quality Measure Report

Page 1 of 1

Facility ID: [redacted]
CCN: [redacted]
Facility Name: [redacted]
City/State: [redacted]
Data was calculated on: 11/22/2011

Report Period: 05/01/11 - 10/31/11
Comparison Group: 03/01/11 - 08/31/11
Run Date: 12/16/11
Report Version Number: 1.00

Note: Dashes represent a value that could not be computed
Note: S = short stay, L = long stay

Measure Description	CMS ID	Data	Num	Denom	Facility Observed Percent	Facility Adjusted Percent	Comparison Group State Average	Comparison Group National Average	Comparison Group National Percentile
SR Mod/Severe Pain (S)	N001.01		41	235	17.4%	17.4%	19.8%	21.4%	49
SR Mod/Severe Pain (L)	N014.01		23	155	14.8%	12.4%	8.9%	10.7%	74
Hi-risk Pres Ulcer (L)	N015.01		6	141	4.3%	4.3%	7.5%	7.1%	33
New/worse Pres Ulcer (S)	N002.01		0	354	0.0%	0.0%	1.5%	1.6%	0
Phys restraints (L)	N027.01		6	234	2.6%	2.6%	3.0%	1.9%	**80 ***
Falls (L)	N032.01		104	234	44.4%	44.4%	30.3%	44.3%	46
Falls w/Maj Injury (L)	N013.01		2	234	0.9%	0.9%	1.6%	3.4%	19
Antipsych Med (S)	N011.01		5	80	6.3%	6.3%	2.7%	3.2%	**88 ***
Antipsych Med (L)	N031.02		46	130	35.4%	35.4%	20.0%	23.0%	**90 ***
Antianxiety/Hypnotic (L)	N033.01		3	53	5.7%	5.7%	11.7%	12.1%	30
Behav Sx affect Others (L)	N034.01		69	171	40.4%	40.4%	21.4%	25.5%	**83 ***
Depress Sx (L)	N030.01		0	196	0.0%	0.0%	2.5%	7.2%	0
UTI (L)	N024.01		7	230	3.0%	3.0%	6.7%	7.5%	28
Cath Insert/Left Bladder (L)	N026.01		8	207	3.9%	3.9%	4.7%	4.5%	57
Lo-Risk Lose B/B Con (L)	N025.01		33	101	32.7%	32.7%	44.0%	42.8%	29
Excess Wt Loss (L)	N029.01		8	226	3.5%	3.5%	6.7%	8.0%	17
Incr ADL Help (L)	N028.01		14	190	7.4%	7.4%	12.8%	16.3%	14

10

Goal Setting Worksheet

QAPI

Directions: Goal setting is important for any measurement related to performance improvement. This worksheet is intended to help QAPI teams establish appropriate goals for individual measures and also for performance improvement projects. Goals should be clearly stated and describe what the organization or team intends to accomplish. Use this worksheet to establish a goal by following the SMART formula outlined below. Note that setting a goal does **not** involve describing what steps will be taken to achieve the goal.

Describe the business problem to be solved:

Green Acres has a 35.4 percent long-stay antipsychotic quality-measure rate, compared to the state (CA) average of 20.0 percent. This is a problem due to antipsychotic medications producing significant side effects in the nursing home dementia population, affecting quality of care and life.

Use the SMART formula to develop a goal:

SPECIFIC

Describe the goal in terms of 3 'W' questions:

What do we want to accomplish? Decrease antipsychotic medication rates at Green Acres.
Who will be involved/affected? Memory Care Unit (MCU) nursing staff, social worker, activity director, nurse practitioner.
Where will it take place? Memory Care Unit.

11

The Medicare Quality Improvement Organization for California HSAG

SMART Goal Example *(cont'd)*

MEASURABLE

Describe how you will know if the goal is reached:

What is the measure you will use? Facility long-stay antipsychotic quality-measure rate.
What is the current data figure (i.e., count, percent, rate) for that measure? 35.4 percent long-stay antipsychotic quality-measure rate.
What do you want to increase/decrease that number to? 25.0 percent long-stay antipsychotic quality-measure rate.

12

The Medicare Quality Improvement Organization for California HSAG

SMART Goal Example *(cont'd)*

ATTAINABLE

Defend the rationale for setting the goal measure above:

Did you base the measure or figure you want to attain on a particular best practice/average score/ benchmark? Yes, based on the long-stay antipsychotic quality-measure state (CA) average of 20.0 percent.
Is the goal measure set too low that it is not challenging enough? No, goal is reasonable.
Does the goal measure require a stretch without being too unreasonable? Yes, goal is reasonable.

13

The Medicare Quality Improvement Organization for California HSAG

SMART Goal Example *(cont'd)*

RELEVANT

Briefly describe how the goal will address the business problem stated above. Decreasing antipsychotic rates will improve resident care and quality of life.

TIME-BOUND

Define the timeline for achieving the goal:

What is the target date for achieving this goal? December 31, 2013.

14

The Medicare Quality Improvement Organization for California HSAG

SMART Goal Example *(cont'd)*

Decrease the long-stay antipsychotic quality-measure rate at Green Acres, with a concentration on the Memory Care Unit (MCU), from the baseline rate (Q3−4 2012) of 35.4 percent to the (Q3−4 2013) remeasurement rate of 25.0 percent, based on the MDS 3.0 CASPER Reports.

15

RCA

16

5 Whys Method

The problem: Green Acres has a 35.4 percent long-stay antipsychotic quality-measure rate, compared to the state (CA) average of 20.0 percent.

Why does this occur?

1. High number of resident falls on the Memory Care Unit. → **Why is that?**
2. Increase of resident "behaviors," including poor safety awareness, agitation, crying/yelling out and "hallucinations." → **Why is that?**
3. Traditional activities designed for alert and oriented nursing home residents are being performed on the Memory Care Unit. → **Why is that?**
4. Staff lacked an understanding of how to provide validation orientation for nursing home residents with dementia. → **Why is that?**
5. No system existed to ensure resident preferences are honored.

17

The Medicare Quality Improvement Organization for California HSAG

Plan of Action

Task	Responsible Party	Goal Date	Completed Date
Visit a local best-practice nursing home specializing in dementia care.	MCU Director	8/6/13	8/6/13
Implement bio sketches during advanced-care-plan meetings.	MCU Director	8/15/13	8/16/13
Train MCU staff members on "needs-driven expressions."	MCU Director	9/30/13	In progress.
Create "life stations" on MCU.	Activities Director	10/15/13	In progress.

18

The Medicare Quality Improvement Organization for California HSAG

Plan of Action *(cont'd)*

Task	Responsible Party	Goal Date	Completed Date
Medical Director will educate all practitioners of the facility on FDA black-box warnings regarding antipsychotic medication use.	Medical Director, Director of Nursing (DON), MCU Director	8/30/13	8/23/13
All physician order requests for antipsychotic medications are reviewed by the DON prior to presenting to the attending physician.	DON MCU Director	8/6/13	8/6/13
All physician orders, new admission charts, incident reports and 24-hour reports are reviewed by the Interdisciplinary Team (IDT) daily.	DON IDT Members	8/6/13	8/6/13

19

The Medicare Quality Improvement Organization for California HSAG

PDSA Model for Improvement

What are we trying to accomplish?

How will we know that change is an improvement?

What change can we make that will result in an improvement?

20

The Medicare Quality Improvement Organization for California HSAG

PDSA

- Plan:
  - SMART Goal setting, RCA, create a Plan of Action.
- Do:
  - Implement Plan of Action items.
- Study:
  - Measure results via MDS CASPER 3.0 Reports, medication administration records (MARs), 24-hour reports, incident reports.
- Act:
  - Spread the results through peer-to-peer sharing.

21

The Medicare Quality Improvement Organization for California HSAG

QAPI Rollout Materials

- QAPI at a Glance
- CMS QAPI Web site: http://go.cms.gov/Nhqapi
- Survey and Certification Memo 13-37: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

22

The Medicare Quality Improvement Organization for California HSAG

References

- QAPI at a Glance: A Step-by-Step Guide to Implementing QAPI in Your Nursing Home. CMS, University of Minnesota, & Stratis Health. June 7, 2013.
- CMS National Nursing Home Quality Care Collaborative Learning Series: Session One. February 26, 2013.
- Lyon, Debra. CMS QAPI Rollout for Nursing Homes. Advancing Excellence Webinar. June 13, 2013.
- The CMS QAPI Guide: What You Need to Know A Companion to QAPI at a Glance. Ohio Medicare Quality Improvement Organization. 2013.

23

Join With Us

All providers, stakeholders, and Medicare beneficiaries with the will to improve health care are invited to be part of these improvement initiatives.

24

Contact Information

Joe Bestic, NHA, BA
HSAG of California Director, Nursing Home

- jbestic@hsag.com
- Phone: 818.409.9229
- Fax: 818.409.0835

25

The Medicare Quality Improvement Organization for California HSAG

Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES

HSAG HEALTH SERVICES ADVISORY GROUP

We convene providers, practitioners, and patients to build and share knowledge, spread best practices, and achieve rapid, wide-scale improvements in patient care; increases in population health; and decreases in health care costs for all Americans.

www.hsag.com

This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. **Publication No. CA-10SOW-7.2-080713-01**

26

The Medicare Quality Improvement Organization for California HSAG

Root Cause Analysis: 5 Whys Method

How to Use the 5 Whys

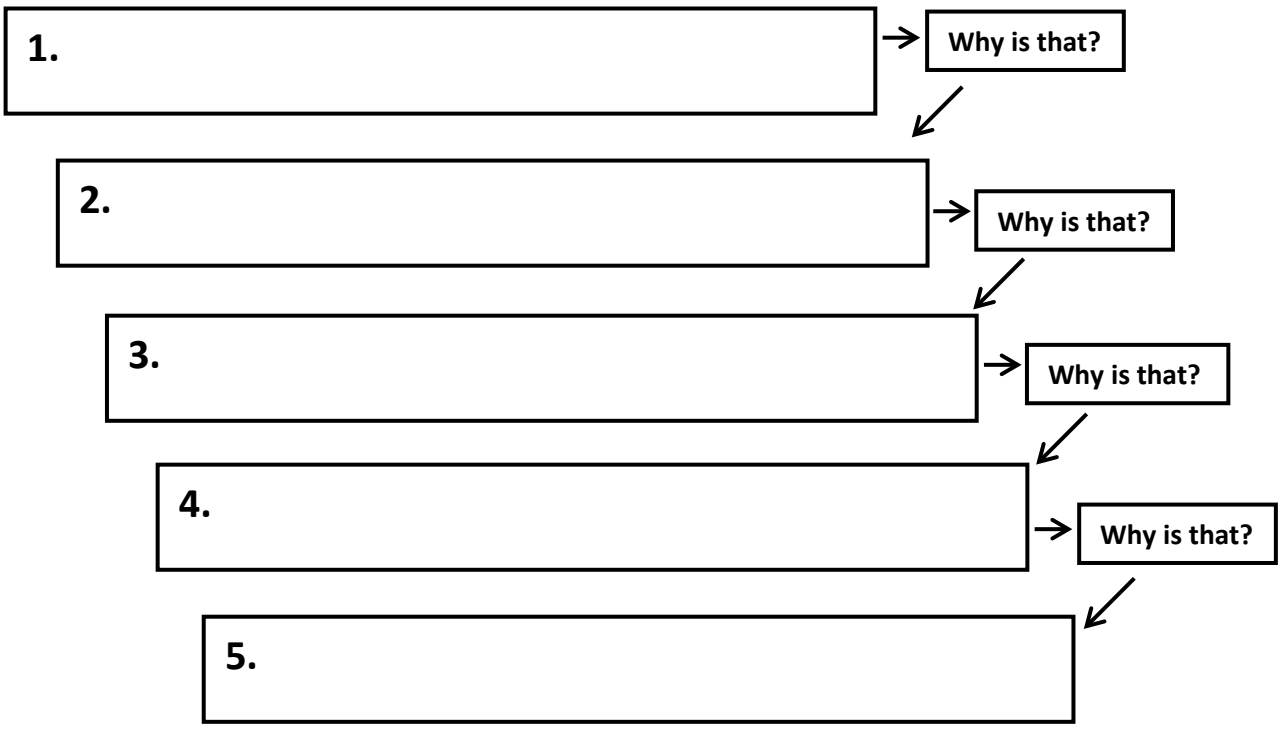
Root cause analysis (RCA) allows you and your team to discover the source of the problem, which you will be able to identify in your facility's processes and systems. By getting to the root causes of a problem, your team will be able to prevent the problem from happening again. The 5 Whys is an RCA method.

5 Whys Steps:

1. Define the problem.
2. Asked your team, "Why does the problem occur?"
3. Continue the process until you get to root of the problem. This may take less than 5 Whys, or it may take more than 5 Whys.
4. The deeper you can drill down on the problem, the more likely your team will be able get to root causes of the problem.
5. After completion of the 5 Whys, develop an action plan and conduct plan-do-study-act (PDSA) cycles of improvement.

The Problem: _____

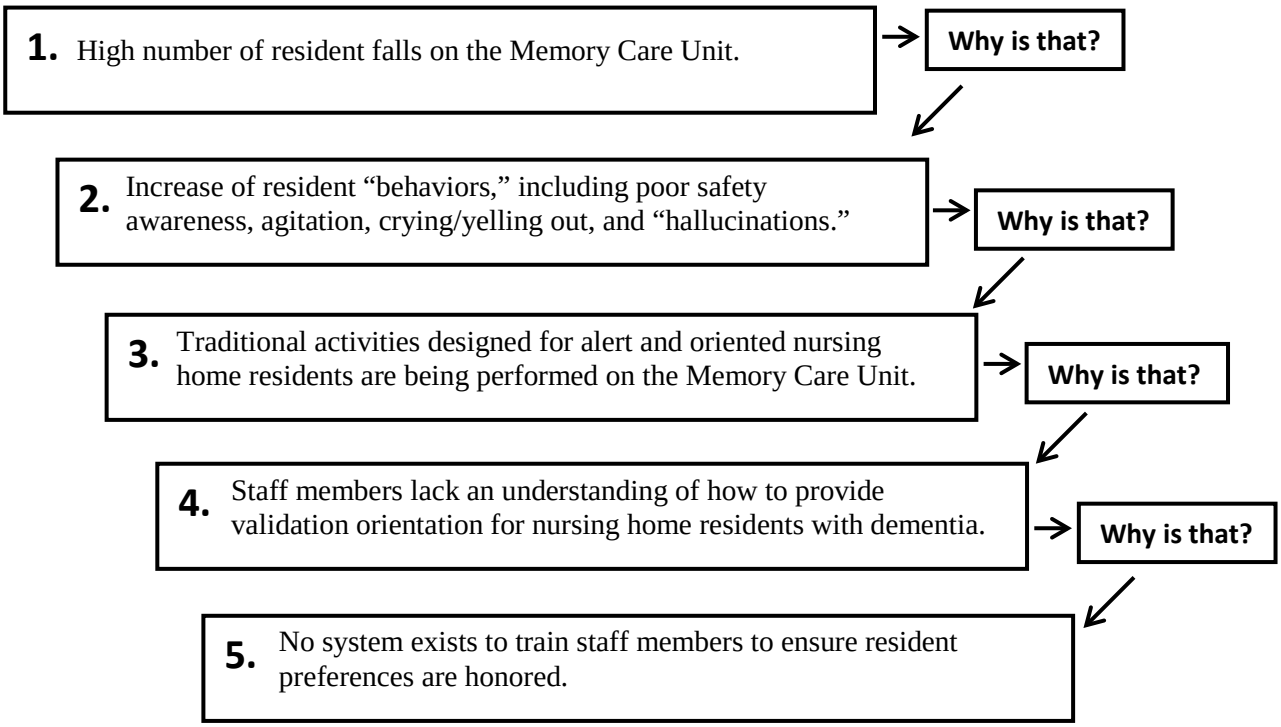
Why does this occur?



5 Whys Example

The problem: Green Acres has a long-stay antipsychotic quality-measure rate of 35.4 percent, compared to the state of California's average of 20.0 percent.

Why does this occur?



This material was prepared by Health Services Advisory Group of California, Inc., the Medicare Quality Improvement Organization for California, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy.
Publication No. CA-10SOW-7.2-100413-01

Partnership to Improve Dementia Care in Nursing Homes Suggestions for Provider Checklist

% of residents in facility on atypical antipsychotics: __ Quality Measure State Percentile Rank – antipsychotics: __

	YES	NO
Staff in all departments, are trained in person-centered care and how to respond effectively to behaviors (access sample training programs on Advancing Excellence website; Hand in Hand).		
In addition to medical and psychiatric history, recent changes in behavior or cognition and other standard clinical evaluations, at admission information is obtained from the resident, family, and/or caregivers on the resident's preferences, routines, pre-dementia personality, social patterns, responses to stress and effective interventions.		
The information obtained on during the admission process is conveyed to direct caregivers.		
This admission information is integrated into the care plan and may be revised over time as the resident's condition and needs change.		
Interviews with staff demonstrate that they have implemented and are following the care plan, continue to seek input from family members or care givers for unresolved issues, and communicate with practitioners regarding change in condition or new or persistent symptoms.		
If a resident is placed on an antipsychotic medication, there is documentation in the record that the resident or appropriate legal representative was involved in the decision.		
Facility has consistent staff assignments (same Certified Nursing Assistant to same resident 5 days/week).		
Certified Nursing Assistant to Resident Ratio 1st shift/2nd shift/3rd shift		
Senior leadership (Nursing Home Administrator, Director of Nursing, Medical Director) attend care plan meetings periodically for residents with unresolved behavioral or psychological symptoms of dementia.		
Interdisciplinary team seeks input at care plan meetings from the Medical Director, Consultant Pharmacist and Certified Nursing Assistants for residents with behavioral or psychological symptoms.		
Providers conduct outreach and education to the resident's family and strongly encourage their participation in care plan meetings (offering to flex the schedule or use conference calls when the family cannot physically be in attendance).		
Nursing Home Administrators and Directors of Nursing review quality measures (e.g., monthly) and use the Quality Measures report to identify residents who may need alternative interventions and oversee their implementation.		
Each month, Nursing Home Administrators and Directors of Nursing review Quality Measures report, along with the Pharmacy Consultant report, to identify residents appropriate for possible reduction/elimination of antipsychotics. The review of aggregate data should be combined with real-time, case-based information and input from practitioners.		
Nursing Home Administrators and Directors of Nursing review Pharmacy Consultant's report quarterly with Consultant Pharmacist and Medical Director to track and trend data.		
Direct caregivers (Certified Nursing Assistants), together with the family and care plan team, is involved in the process of developing and implementing effective, person-specific interventions to address behavioral symptoms.		
If any resident is admitted on an antipsychotic or is started on an antipsychotic after admission, the Consultant Pharmacist, along with the practitioner, reviews that resident's care plan, including all medications, within 24-48 hours.		
A documented process is in place and is utilized when initiating an antipsychotic prescription (e.g., standard order set, decision support algorithm, routine monitoring recommendations, etc.).		

"Yes" answers require supporting documentation and visual confirmation by quality improvement personnel.

Checklist

Review of Care and Services for a Resident with Dementia

(for use with the Interpretive Guidance at F309)

Assessment and Underlying Cause Identification

- ✓ Did staff describe behavior (onset, duration, intensity, possible precipitating events or environmental triggers, etc.) and related factors (appearance, alertness, etc.) in the medical record with enough specific detail of the actual situation to permit underlying cause identification to the extent possible?
- ✓ If the behaviors represent a sudden change or worsening from baseline, did staff contact the attending physician/practitioner immediately for a medical evaluation, as appropriate?
- ✓ If medical causes are ruled out, did staff attempt to establish other root causes of the behavior using individualized knowledge about the person and when possible, information from the resident, family, previous caregivers and/or direct care staff?
- ✓ As part of the comprehensive assessment did facility staff evaluate:
    - The resident's usual and current cognitive patterns, mood and behavior, and whether these present a risk to the resident or others?
    - How the resident typically communicates a need such as pain, discomfort, hunger, thirst or frustration?
    - Prior life patterns and preferences customary responses to triggers such as stress, anxiety or fatigue, as provided by family, caregivers, and others who are familiar with the resident before or after admission?
- ✓ Did staff, in collaboration with the practitioner, identify risk and causal/contributing factors for behaviors, such as:
    - Presence of co-existing medical or psychiatric conditions, or decline in cognitive function?
    - Adverse consequences related to the resident's current medications?

1. ***If the condition or risks were present at the time of the required comprehensive assessment, did the facility comprehensively assess the physical, mental and psychosocial needs of the resident with dementia to identify the risks and/or to determine underlying causes (to the extent possible) of the resident's behavioral and/or mental psychosocial symptoms, and needed adaptations, and the impact upon the resident's function, mood and cognition?***
   If No, cite F272

Care Planning

- ✓ Was the resident and/or family/representative involved (to the extent possible) in discussions about the potential use of any interventions, and was this documented in the medical record?
- ✓ Does the care plan reflect an individualized team approach with measureable goals, timetables and specific interventions for the management of behavioral and psychological symptoms?
- ✓ Does the care plan include:
    - Involvement of the resident/representative to the extent possible?
    - A description of and how to prevent targeted behaviors?
    - Why behaviors should be prevented or otherwise addressed (e.g., severely distressing to resident)?
    - Monitoring of the effectiveness of any/all interventions?
- ✓ If the resident or family/representative refused a recommended treatment or approach, was counseling on consequences and alternative approaches to address behavioral symptoms provided?

Note: If the resident lacks decisional capacity and lacks effective family/representative support, contact the facility social worker to determine what type of social services or referrals have been attempted to assist the resident.

2. ***Did the facility develop a plan of care with measurable goals and interventions to address the care and treatment for a resident with dementia related to the behavioral and/or mental/psychosocial symptoms, in accordance with the assessment, resident's wishes and current standards of practice? If No, cite F279***

Implementation of the Care Plan

Did staff:

Identify, document and communicate specific targeted behaviors and expressions of distress as well as desired outcomes?

- ✓ Implement individualized, person-centered interventions by qualified persons and document the results?
- ✓ Communicate and consistently implement the care plan, over time and across various shifts?
- ✓ If there is a sudden change in the resident's condition and medical causes of behavior or other symptoms (e.g., delirium or infection) are suspected, is the physician contacted immediately and treatment initiated?
- ✓ Is there a sufficient number of staff to consistently implement the care plan? (*Surveyors should focus on observations of staff interactions with residents who have dementia to determine whether staff consistently applies basic dementia care principles in the care of those individuals*).

3. ***Did the facility provide or arrange services to be provided by qualified persons in accordance with the resident's written plan of care? If No, cite F282***

Note: If during the survey a concern is identified that an antipsychotic medication is given by staff for purposes of discipline or convenience and not required to treat the resident's medical symptoms, review F222 – §483.13(a).

Care Plan Revision/Monitoring and Follow up

- ✓ Does staff, in collaboration with the practitioner, adjust the interventions based on the impact on behavior or other symptoms as well as any adverse consequences related to treatment?
- ✓ When concerns related to the effectiveness or adverse consequences of a resident's treatment regimen are identified:
    - Does staff modify the care plan and, if appropriate, notify the physician and does the physician respond and initiate a change to the resident's care as necessary?

4. ***Did the facility reassess the effectiveness of the interventions and review and revise the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident with dementia? If No, cite F280***

    - If the physician does not respond to the notification, does staff contact the medical director for further review? If the medical director was contacted, does he/she respond and intervene as needed?

5. ***Did the facility provide the necessary care and services for a resident with dementia to support his or her highest practicable level of physical, mental and psychosocial well-being in accordance with the comprehensive assessment and plan of care? If No, cite F309***

Quality Assessment and Assurance

Note: Please refer to F520 Quality Assessment and Assurance for guidance regarding the information that may be obtained from the QAA committee.

- ✓ Do resident care policies and procedures clearly outline a systematic process for the care of residents with dementia?
- ✓ Does the QAA Committee monitor for consistent implementation of the policies and procedures for the care of residents with dementia?
- ✓ Has the QAA committee corrected any identified quality deficiencies related to the care of residents with dementia?
- ✓ Has the QAA committee provided monitoring and oversight for the care and services for a resident with dementia?

ADMISSION SAMPLE RECORD REVIEW

Facility Name: _____ Facility ID: _____ Date: _____

Surveyor Name: _____

Resident Name: _____ Resident ID: _____ Admit Date: _____ Resident Room: _____

For each resident use the admission date identified on the Stage 1 screen or in the Admission Sample report to complete this review.

***Exclusions**	
If the ASE-Q has MDS data for the resident, the terminal prognosis question will be inapplicable (will have a check mark) in the ASE-Q, and the surveyor does not need to answer this question.	
1) Did the resident have an explicit terminal prognosis?	☐ No ☐ Yes
2) Was the resident's length of stay at this facility at least 15 days?	☐ No ☐ Yes
B Death QP059	
If the resident has an explicit terminal prognosis, skip to Hospitalization.	
1) Did the resident die within 30 days of the nursing home admission?	☐ No ☐ Yes
C Hospitalization QP058	
1) Was the resident hospitalized (admission greater than 24 hours), for other than a planned elective surgery, within 30 days of the NH admission?	☐ No ☐ Yes

ADMISSION SAMPLE RECORD REVIEW

D Pressure Ulcer QP109

Review the admission skin assessment, and all subsequent skin assessments, treatment records, nursing progress notes, and MDS. The MDS should be the last source type reviewed.

1) Did the resident develop a pressure ulcer in the first 30 days following admission to the nursing home?	☐ No ☐ Yes ☐ Unknown
2) Was the resident admitted with one or more pressure ulcers?	☐ No **(skip to Weight Loss)** ☐ Yes
3) Was there an increase in the stage of the ulcer(s)?	☐ No ☐ Yes

If a skin ulcer is repaired with a flap graft, it should be coded as a surgical wound and not as a skin ulcer. If the graft fails, continue to code it as a surgical wound until healed.

Stage 1 − Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have a visible blanching; in dark skin tones only it may appear with persistent blue or purple hues.

Stage 2 − Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister.

Stage 3 − Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon, or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

Stage 4 − Full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.

Unstageable − Pressure ulcer is known but not stageable due to non-removable dressing/device or due to the coverage of the wound bed by slough or eschar.

Suspected Deep Tissue Injury (sDTI) − Suspected deep tissue injury in evolution. Localized area of discolored (darker than surrounding tissue) intact skin or blood-filled blister related to damage of underlying soft tissue from pressure and/or shear. Area of discoloration may be preceded by tissue that is painful, firm, mushy, boggy, warmer, or cooler as compared to adjacent tissue.

ADMISSION SAMPLE RECORD REVIEW

E Weight Loss QP105

Do not complete this section if the resident has an explicit terminal prognosis or a length of stay of less than 15 days.

1) Is the resident on a planned weight loss program?

☐ No
☐ Yes **(review is complete)**

2) Height and Weights:

Height: _____ (inches) If the ASE-Q has MDS data for the resident, the Height field will be gray (inapplicable), and the surveyor does not need to enter the resident's height.

Date and weight closest to admission date:	____/____/____	**Weight:_____ lbs.**	☐ Unavailable **(review is complete)**
Date and weight closest to day 15 after admission:	____/____/____	**Weight:_____ lbs.**	☐ Unavailable
Date and weight closest to day 30 after admission:	____/____/____	**Weight:_____ lbs.**	☐ Unavailable
Date and weight closest to day 60 after admission:	____/____/____	**Weight:_____ lbs.**	☐ Unavailable

Note: The ASE-Q calculates the requested dates and percentage weight loss. Weight loss QCLIs are included in ASE-Q QCLI Results.

RESIDENT INTERVIEW & RESIDENT OBSERVATION

Facility Name: _____ Facility ID: _____ Date: _____

Surveyor Name: _____

Resident Name: _____ Resident ID: _____ Admit Date: _____ Resident Room: _____

Resident Interview

Ask screening questions similar to the following:

1. Are you from around here, the area, etc?
2. Tell me a little about yourself.
3. How long have you been here?
4. What is the food like here?

Proceed with the interview questions below if you are comfortable that the resident is interviewable.

A Cognitive Status

1) Is the resident able to be interviewed?

- ☐ Not Interviewable
- ☐ Interviewable
- ☐ Resident refused interview
- ☐ Resident is unavailable for an interview

If the resident is interviewable, proceed to the Resident Interview section on the following page. If the resident is not interviewable, refuses, or is unavailable (after repeated attempts to interview) proceed to the Resident Observation section on the following page (the resident is excluded from the resident interview).

Notes:

RESIDENT INTERVIEW & RESIDENT OBSERVATION

Resident Interview

B Choices QP234

1) Do you choose when to get up in the morning? If No: What time do you get up? What time would you like to get up in the morning?	☐ No ☐ Yes ☐ N/A, the resident is independent with ADLs
2) Do you choose when to go to bed at night? If No: What time do you go to bed? What time would you like to go to bed?	☐ No ☐ Yes ☐ N/A, the resident is independent with ADLs
3) Do you choose how many times a week you take a bath or shower? If No: How many times a week do you get a bath or shower? How many times a week would you like to bathe?	☐ No ☐ Yes ☐ N/A, the resident is independent with ADLs
4) Do you choose whether you take a shower, tub, or bed bath? If No: What type of bathing are you receiving? What would you like to receive?	☐ No ☐ Yes ☐ N/A, the resident is independent with ADLs
5) Can you have visitors anytime during the day or night? If No: What are the visiting restrictions?	☐ No ☐ Yes

Comments:

C Dignity QP212

1) Do staff treat you with respect and dignity? If No, Tell me some examples about when staff did not treat you with respect and dignity. The focus of this question is how well staff interacts with the resident.	☐ No ☐ Yes

Resident Observation

A Cleanliness/Grooming/Oral QP075 (excluding A1E)

1) **Based on general observations, did you see any of the following?** (Mark all that apply)
- ☐ A: Unpleasant body odor (other than signs of incontinence)
- ☐ B: Skin unclean (i.e., food on face and hands)
- ☐ C: Eyes are matted
- ☐ D: Mouth contains debris, or teeth/dentures not brushed, or mouth odor, or dentures not in place
- ☐ E: Teeth broken/loose, or inflamed/bleeding gums, or problems with dentures QP216
- ☐ F: Hair is uncombed and not clean
- ☐ G: Facial hair not removed or unshaven
- ☐ H: Fingernails are unclean and untrimmed
- ☐ I: Clothing and/or linens are soiled (other than signs of incontinence)
- ☐ J: Glasses are dirty or broken
- ☐ K: None of the above

B Incontinence QP260

1) Are there signs of incontinence, such as odor and/or wetness?	☐ No ☐ Yes

C Dressing QP074

1) **Based on general observations, did you see any of the following?** (Mark all that apply)
- ☐ A: Clothing in poor repair, improper fit, or worn inappropriately
- ☐ B: Inappropriate foot coverings (i.e., shoes without non-skid soles)
- ☐ C: None of the above

Comments:

RESIDENT INTERVIEW & RESIDENT OBSERVATION

Resident Interview

D Activities QP208

1) Do you participate in the activity programs here? If "No", ask why he/she doesn't participate.	☐ No ☐ Yes ☐ Does not wish to participate **(Skip to 4)**
2) Do the activities meet your interests?	☐ No ☐ Yes
3) Are the activities provided as often as you would like, including on weekends and evenings?	☐ No ☐ Yes
4) Does staff provide items so you can do activities on your own, like books or cards?	☐ No ☐ Yes ☐ N/A, family provides

Comments:

E Building and Environment

1) Is the building clean?	☐ No QP201 ☐ Yes
2) Do you have any problems with the temperature, lighting, noise or anything else in the building that affects your comfort? (Mark all that apply)	☐ Temperature QP272 ☐ Lighting QP273 ☐ Noise QP274 ☐ Other identified issues QP275 ☐ None of the above

Comments:

F Participation in Care Plan QP210

1) Have you been involved in decisions about your daily care?	☐ No ☐ Yes

Resident Observation

D Activities QP096

(Complete for residents who are not interviewable due to cognitive screening. Do not complete for residents who are interviewable, have refused to be interviewed, or are unavailable.)

1) Did you observe the resident in activities during the two days of Stage 1? (This is not limited to group activities or scheduled activities.)	☐ No **(skip to E)** ☐ Yes
2) Is the resident actively participating in the activities or does staff encourage the resident to participate?	☐ No ☐ Yes

Comments

E Contractures QP077 QP076

1) Does the resident have a contracture? (Defined as a condition of fixed high resistance to passive stretch of a muscle.) ***If unable to determine ask staff member.***	☐ No **(skip to F)** ☐ Yes
2) Does the resident have splint devices in place? (Answer "No" if device not present or is incorrectly applied.)	☐ No ☐ Yes

Comments:

RESIDENT INTERVIEW & RESIDENT OBSERVATION

Resident Interview

G Abuse QP253

1)	Has staff, a resident or anyone else here abused you – this includes verbal, physical or sexual abuse? If "Yes," ask who the abuser was, what happened, when it occurred, where it happened, and how often.	☐ No **(skip to 3)** ☐ Yes
2)	Did you tell staff? If "Yes," ask who the resident told. If "No," report immediately to the administrator. If you have concerns with how the facility handles the investigation after you report it, consider initiating abuse.	☐ No ☐ Yes
3)	Have you seen any resident here being abused? If "Yes," ask who the abuser was, what happened, when it occurred, where it happened, and how often.	☐ No **(skip to H)** ☐ Yes
4)	Did you tell staff? If "Yes," ask who the resident told. If "No," report immediately to the administrator. If you have concerns with how the facility handles the investigation after you report it, consider initiating abuse.	☐ No ☐ Yes

H Interaction with Others QP246

1)	Have there been any concerns or problems with a roommate or any other resident?	☐ No **(skip to I)** ☐ Yes
2)	Has the staff addressed the concern(s) to your satisfaction?	☐ No ☐ Yes

Resident Observation

F Abuse QP205

1)	Is the resident being treated by staff, other residents, or anyone else at the facility in a way that may indicate physical, sexual, mental, or emotional abuse?	☐ No ☐ Yes

G Skin Problems/Conditions (other than pressure ulcers) QP261

1) **Were any of the following observed?** (Mark all that apply)
- ☐ A: Abrasions and/or lacerations
- ☐ B: Bruises
- ☐ C: Skin Tears
- ☐ D: Burns
- ☐ E: None of the above

H Potential Restraints QP092 QP089

1)	Does the resident have a potential restraint in place (physical device or equipment that may potentially restrict a resident's movement and/or access to her/his body)?	☐ No **(skip to I)** ☐ Yes

2) **Which potential restraints are being used?** (Mark all that apply)
- ☐ A: Potential limb restraint
- ☐ B: Potential trunk restraint
- ☐ C: Chair potentially prevents rising
- ☐ D: Bed side rails
- ☐ E: Other (e.g., mittens), please describe_____

3)	Is the device correctly applied? (Such as potential trunk and limb restraints. See Section L below for bed side rails.)	☐ No ☐ Yes

Comments:

RESIDENT INTERVIEW & RESIDENT OBSERVATION

Resident Interview

I Personal Property QP194

1) Were you encouraged by staff to bring in any personal items? If No: Do you wish to have items brought in?	☐ No ☐ Yes ☐ N/A, the resident is a short-stay resident
2) Have you had any missing personal items? If Yes: What is still missing and how long has it been missing?	☐ No ☐ Yes
3) Did you tell staff about the missing item(s)? If Yes: Who did you tell about the missing item? If the answer is "Yes," then ask question 4.	☐ No ☐ Yes
4) Has staff told you they are looking for your missing item(s)? If No, do you know who or which department is supposed to be looking for your missing item?	☐ No ☐ Yes
Comments:	

J Pain QP255

1) Do you have any discomfort now or have you been having discomfort such as pain, heaviness, burning, or hurting with no relief?	☐ No ☐ Yes
Comments:	

Resident Observation

I Pain QP129

1) **Were any of the following observed?** (Mark all that apply)
- ☐ A: Vocalization of pain: constant muttering, moaning, groaning
- ☐ B: Breathing: strenuous, labored, negative noise on inhalation or expiration
- ☐ C: Pained facial expressions: clenched jaw, troubled or distorted face, crying
- ☐ D: Body language: clenched fists, wringing hands, strained and inflexible position, rocking
- ☐ E: Movement: restless, guarding, altered gait, forceful touching or rubbing body parts
- ☐ F: None of the above

Comments:

J Hydration QP182

1) Does the resident demonstrate physical signs of dehydration (i.e., dry, cracked lips and/or dry mouth; exhibits signs of thirst, etc.)?	☐ No ☐ Yes

Comments:

RESIDENT INTERVIEW & RESIDENT OBSERVATION

Resident Interview

K Food Quality QP249

1) Does the food taste good and look appetizing?	☐ No ☐ Yes
2) Is the food served at the proper temperature?	☐ No ☐ Yes

L Hydration QP258

1) Do you receive the fluids you want between meals?	☐ No ☐ Yes ☐ N/A, does not take fluids orally

Comments:

M Sufficient Staff QP232

1) Do you feel there is enough staff available to make sure you get the care and assistance you need without having to wait a long time?	☐ No ☐ Yes

Resident Observation

K Positioning QP233

1) **Were any of the following observed?** (Mark all that apply)
- ☐ A: Sagging mattress while lying in bed
- ☐ B: Bed sheets tucked tightly over toes holding the feet in plantar flexion
- ☐ C: Legs and/or feet hanging off the end of a too-short mattress
- ☐ D: No padding between bony prominences (residents not able to position themselves)
- ☐ E: Wheelchair too big or too small (i.e., seat too long/short, seat too high/low)
- ☐ F: Uncomfortable geri-chair positioning, hyperflexion of the neck, sliding down in the chair, no-support for the legs
- ☐ G: Dangling legs and feet (that do not comfortably reach floor and/or without needed foot pedals in place)
- ☐ H: Leaning to the side without support to maintain an upright position
- ☐ I: Lack of needed head or torso support
- ☐ J: Lack of arm/shoulder support
- ☐ K: Resident observed in the same position for long periods of time when in the wheelchair or in bed (Resident is not repositioned in chair at least every hour and in bed at least every two hours)
- ☐ L: None of the above

Comments:

L Potential Accident Hazards/Bed Side Rails QP218

1) If the bed side rails are in the up position, do the bed side rails fit the bed properly to prevent the resident from being caught between the side rails and mattress?	☐ No ☐ Yes ☐ N/A, side rails are not observed in the up position

Comments:

RESIDENT INTERVIEW & RESIDENT OBSERVATION

Resident Interview	
N Oral Health QP254 QP256	
1) Do you have mouth/facial pain with no relief?	☐ No ☐ Yes
2) Do you have any chewing or eating problems (could be due to: no teeth, missing teeth, oral lesions, broken or loose teeth)?	☐ No ☐ Yes
3) Do you have tooth problems, gum problems, mouth sores, or denture problems?	☐ No ☐ Yes
4) Does staff help you as necessary to clean your teeth?	☐ No ☐ Yes ☐ N/A, do not need assistance **(Skip to O)**
5) How often are your teeth/dentures/mouth cleaned (routine oral hygiene)?	☐ Daily ☐ Weekly ☐ Monthly ☐ Never
O Privacy QP204	
1) Does staff provide you privacy when they work with you, changing your clothes, providing treatment?	☐ No ☐ Yes
2) Do you have privacy when on the telephone?	☐ No ☐ Yes ☐ N/A, do not use telephone
3) If you would have a visitor, do you have a private place to meet?	☐ No ☐ Yes
Comments:	

Resident Observation
M Resident's Room
1) **Were any of the following observed?** (Mark all that apply) ☐ A: Odor in resident's room QP221 ☐ B: Walls, floors, ceilings, drapes, or furniture are not clean or are in disrepair QP222 ☐ C: Environment does not accommodate individual needs and preferences QP147 ☐ D: Lighting levels are inadequate or uncomfortable QP223 ☐ E: Room temperatures are uncomfortable or unsafe QP224 ☐ F: Sound levels are uncomfortable QP225 ☐ G: Bedrooms are not equipped to assure full privacy (i.e., curtains, moveable screens, private rooms, etc.) QP151 ☐ H: Clean bed/bath linens are not available or are in poor condition QP152 ☐ I: Evidence of insects or rodents in bedrooms or bathrooms QP226 ☐ J: None of the above
Comments:
2) **Were any of the following observed?** (Mark all that apply) ☐ A: Electric cords, extension cords, or outlets are in disrepair or used in an unsafe manner QP228 ☐ B: Bed and linens are visibly soiled with stool or urine QP260 ☐ C: Resident care equipment is unclean, in disrepair or stored in an improper or unsanitary manner QP140 ☐ D: Ambulation, transfer or therapy equipment are unclean or in unsatisfactory condition QP229 ☐ E: Safety equipment in bedroom or bathroom is inadequate (i.e. grab bars, slip surface) QP230 ☐ F: Call system in room or bathroom is not functioning. QP231 ☐ G: Call light not within reach for residents capable of using it QP267 ☐ H: Accessible chemicals or other hazards in bedroom or bathroom QP268 ☐ I: Unsafe hot water in room QP269 ☐ J: Hot water is too cool QP270 ☐ K: Room not homelike QP271 ☐ L: None of the above
Comments:

RESIDENT INTERVIEW & RESIDENT OBSERVATION

Resident Interview

P Exercise of Rights QP250

1) Have you been moved to a different room or had a roommate change in the last nine months?	☐ No **(Skip to Q)** ☐ Yes
2) Were you given notice before a room change or a change in roommate?	☐ No ☐ Yes

Q Personal Funds QP199

1) Do you have a personal funds account with the facility?	☐ No **(Skip #2 & 3)** ☐ Yes ☐ Do Not Know **(Skip #2 & 3)**
2) Does the facility let you know how much money you have in your account?	☐ No ☐ Yes ☐ Do Not Know
3) Can you get your money when you need it, including on weekends?	☐ No ☐ Yes ☐ Do Not Know

Resident Observation

N Dignity QP266

1) Based on general observation, did you see any of the following? (Mark all that apply)

- ☐ A: Staff dressed resident in institutional fashion such as a hospital type gown during the day
- ☐ B: Clothes labeled with the resident's name visible
- ☐ C: Staff failed to knock and/or request permission to enter the room or wait to receive permission to enter
- ☐ D: Staff failed to explain the service or care they are going to provide
- ☐ E: Staff failed to include the resident in conversations while providing care or services
- ☐ F: Staff used a label for the resident (e.g., "feeder" or "honey")
- ☐ G: Staff posted confidential clinical or personal care instructions in areas that can be seen by others
- ☐ H: Staff failed to treat the resident respectfully when providing care to the resident's roommate;
- ☐ I: Staff failed to treat the resident with respect and dignity during care and services, such as:
  - Making disapproving comments as "What do you want now?"
  - Mimicking or making fun of the resident
  - Displaying disapproving behavior (rolling their eyes, or sighing)
- ☐ J: Staff failed to provide visual privacy of the resident's body while transporting him/her through common areas, or uncovered in their rooms but visible to others
- ☐ K: Staff failed to cover a urinary catheter bag or any other type of body fluid collection device
- ☐ L: Staff failed to respond to the resident's call for assistance in a timely manner
- ☐ M: Any other identified dignity concerns (document concerns)
- ☐ N: None of the above

O Sedation

1) Is the resident excessively sedated?	☐ No ☐ Yes

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STAFF INTERVIEW

Facility Name: _____ Facility ID: _____ Date: _____ Time: _____

Surveyor Name: _____ Staff Name: _____

Resident:	**Resident:**	**Resident:**	**Resident:**	**Resident:**	**Resident:**	**Resident:**	**Resident:**	**Resident:**	**Resident:**
A Catheter Use QP079									
1) Is there use of an indwelling foley catheter?									
☐ No **(Skip to B)** ☐ Yes	☐ No **(Skip to B)** ☐ Yes	☐ No **(Skip to B)** ☐ Yes	☐ No **(Skip to B)** ☐ Yes	☐ No **(Skip to B)** ☐ Yes	☐ No **(Skip to B)** ☐ Yes	☐ No **(Skip to B)** ☐ Yes	☐ No **(Skip to B)** ☐ Yes	☐ No **(Skip to B)** ☐ Yes	☐ No **(Skip to B)** ☐ Yes
2) What is the reason for the resident's catheter? **(The diagnosis of neurogenic bladder must be verified in the medical record) (Mark all that apply)**									
☐A:Obstruction	☐A:Obstruction	☐A:Obstruction	☐A:Obstruction	☐A:Obstruction	☐A:Obstruction	☐A:Obstruction	☐A:Obstruction	☐A:Obstruction	☐A:Obstruction
☐B: Neurogenic / atonic bladder	☐B: Neurogenic / atonic bladder	☐B: Neurogenic / atonic bladder	☐B: Neurogenic / atonic bladder	☐B: Neurogenic / atonic bladder	☐B: Neurogenic / atonic bladder	☐B: Neurogenic / atonic bladder	☐B: Neurogenic / atonic bladder	☐B: Neurogenic / atonic bladder	☐B: Neurogenic / atonic bladder
☐C: Stage III or IV perineal / sacral pressure ulcer	☐C: Stage III or IV perineal / sacral pressure ulcer	☐C: Stage III or IV perineal / sacral pressure ulcer	☐C: Stage III or IV perineal / sacral pressure ulcer	☐C: Stage III or IV perineal / sacral pressure ulcer	☐C: Stage III or IV perineal / sacral pressure ulcer	☐C: Stage III or IV perineal / sacral pressure ulcer	☐C: Stage III or IV perineal / sacral pressure ulcer	☐C: Stage III or IV perineal / sacral pressure ulcer	☐C: Stage III or IV perineal / sacral pressure ulcer
☐D: Terminal illness	☐D: Terminal illness	☐D: Terminal illness	☐D: Terminal illness	☐D: Terminal illness	☐D: Terminal illness	☐D: Terminal illness	☐D: Terminal illness	☐D: Terminal illness	☐D: Terminal illness
☐ E: Mobility impairment	☐ E: Mobility impairment	☐ E: Mobility impairment	☐ E: Mobility impairment	☐ E: Mobility impairment	☐ E: Mobility impairment	☐ E: Mobility impairment	☐ E: Mobility impairment	☐ E: Mobility impairment	☐ E: Mobility impairment
☐F: Coma	☐F: Coma	☐F: Coma	☐F: Coma	☐F: Coma	☐F: Coma	☐F: Coma	☐F: Coma	☐F: Coma	☐F: Coma
☐G: Resident request	☐G: Resident request	☐G: Resident request	☐G: Resident request	☐G: Resident request	☐G: Resident request	☐G: Resident request	☐G: Resident request	☐G: Resident request	☐G: Resident request
☐H: Incontinence	☐H: Incontinence	☐H: Incontinence	☐H: Incontinence	☐H: Incontinence	☐H: Incontinence	☐H: Incontinence	☐H: Incontinence	☐H: Incontinence	☐H: Incontinence
☐I: Unknown	☐I: Unknown	☐I: Unknown	☐I: Unknown	☐I: Unknown	☐I: Unknown	☐I: Unknown	☐I: Unknown	☐I: Unknown	☐I: Unknown
☐J: Other, describe _____ _____	☐J: Other, describe _____ _____	☐J: Other, describe _____ _____	☐J: Other, describe _____ _____	☐J: Other, describe _____ _____	☐J: Other, describe _____ _____	☐J: Other, describe _____ _____	☐J: Other, describe _____ _____	☐J: Other, describe _____ _____	☐J: Other, describe _____ _____

STAFF INTERVIEW

Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:

B Nutrition QP082

1) Is this resident receiving a nutritional supplement, defined as a prescribed high protein, high calorie, nutritional supplement between or with meals? **(There must be documentation in the medical record.)**

Following discussion with staff about whether a resident receives a supplement, request documentation of a recording and monitoring system to support a 'Yes' answer. This documentation may include a checkbox or checklist that the supplement was given, a percentage of supplement consumed or the amount consumed. Any of these methods are acceptable. The following sources may provide supporting documentation:

- Medication Administration Record
- Treatment Record
- Snack/Supplement List
- Meal documentation with supplements listed separately
- Other source(s) as indicated by facility staff

☐ No ☐ Yes ☐ N/A, resident receives tube feedings/ NPO	☐ No ☐ Yes ☐ N/A, resident receives tube feedings/ NPO	☐ No ☐ Yes ☐ N/A, resident receives tube feedings/ NPO	☐ No ☐ Yes ☐ N/A, resident receives tube feedings/ NPO	☐ No ☐ Yes ☐ N/A, resident receives tube feedings/ NPO	☐ No ☐ Yes ☐ N/A, resident receives tube feedings/ NPO	☐ No ☐ Yes ☐ N/A, resident receives tube feedings/ NPO	☐ No ☐ Yes ☐ N/A, resident receives tube feedings/ NPO	☐ No ☐ Yes ☐ N/A, resident receives tube feedings/ NPO	☐ No ☐ Yes ☐ N/A, resident receives tube feedings/ NPO

STAFF INTERVIEW

Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:

C Skin Care/Pressure Ulcers QP049 QP050

1) Does the resident currently have one or more pressure ulcers? If yes, describe the most advanced stage for each pressure ulcer when they were at their deepest visible anatomical level.

☐ No pressure ulcers	☐ No pressure ulcers	☐ No pressure ulcers	☐ No pressure ulcers	☐ No pressure ulcers	☐ No pressure ulcers	☐ No pressure ulcers	☐ No pressure ulcers	☐ No pressure ulcers	☐ No pressure ulcers
☐ Stage 1	☐ Stage 1	☐ Stage 1	☐ Stage 1	☐ Stage 1	☐ Stage 1	☐ Stage 1	☐ Stage 1	☐ Stage 1	☐ Stage 1
☐ Stage 2	☐ Stage 2	☐ Stage 2	☐ Stage 2	☐ Stage 2	☐ Stage 2	☐ Stage 2	☐ Stage 2	☐ Stage 2	☐ Stage 2
☐ Stage 3	☐ Stage 3	☐ Stage 3	☐ Stage 3	☐ Stage 3	☐ Stage 3	☐ Stage 3	☐ Stage 3	☐ Stage 3	☐ Stage 3
☐ Stage 4	☐ Stage 4	☐ Stage 4	☐ Stage 4	☐ Stage 4	☐ Stage 4	☐ Stage 4	☐ Stage 4	☐ Stage 4	☐ Stage 4
☐ Unstageable (eschar/slough)	☐ Unstageable (eschar/slough)	☐ Unstageable (eschar/slough)	☐ Unstageable (eschar/slough)	☐ Unstageable (eschar/slough)	☐ Unstageable (eschar/slough)	☐ Unstageable (eschar/slough)	☐ Unstageable (eschar/slough)	☐ Unstageable (eschar/slough)	☐ Unstageable (eschar/slough)
☐ Suspected Deep Tissue Injury	☐ Suspected Deep Tissue Injury	☐ Suspected Deep Tissue Injury	☐ Suspected Deep Tissue Injury	☐ Suspected Deep Tissue Injury	☐ Suspected Deep Tissue Injury	☐ Suspected Deep Tissue Injury	☐ Suspected Deep Tissue Injury	☐ Suspected Deep Tissue Injury	☐ Suspected Deep Tissue Injury

Staff should answer the question based on the most advanced stage of each existing ulcer. Staff should not "reverse" stage. To describe a healing wound, it is more accurate not to reclassify it at a lower stage, but rather to use the historically deepest stage and prefix this with the term "healing." A Stage 4 pressure ulcer that is almost healed is designated a "healing Stage 4" and not "downstaged" to a Stage 3, 2, or 1. If a skin ulcer is repaired with a flap graft, it should be coded as a surgical wound and not as a skin ulcer. If the graft fails, continue to code it as a surgical wound until healed.

Stage 1 − Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have a visible blanching; in dark skin tones only it may appear with persistent blue or purple hues.

Stage 2 − Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister.

Stage 3 − Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon, or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

Stage 4 − Full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.

Unstageable − Pressure ulcer is known but not stageable due to non-removable dressing/device or due to the coverage of the wound bed by slough or eschar.

Suspected Deep Tissue Injury (sDTI) − Suspected deep tissue injury in evolution. Localized area of discolored (darker than surrounding tissue) intact skin or blood-filled blister related to damage of underlying soft tissue from pressure and/or shear. Area of discoloration may be preceded by tissue that is painful, firm, mushy, boggy, warmer, or cooler as compared to adjacent tissue.

STAFF INTERVIEW

Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:	Resident:
D Side Rails QP093									
1) Are side rails (includes half or quarter rails) used for this resident?									
☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes
2) Is the resident physically capable of getting out of bed on his or her own?									
☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes	☐ No **(Skip to E)** ☐ Yes
3) When the rails are raised, do they prevent the resident from voluntarily getting out of bed?									
☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes
E Contractures QP264									
1) Does the resident have a contracture? (Defined as a condition of fixed high resistance to passive stretch of a muscle.)									
☐ No **(Skip to F)** ☐ Yes	☐ No **(Skip to F)** ☐ Yes	☐ No **(Skip to F)** ☐ Yes	☐ No **(Skip to F)** ☐ Yes	☐ No **(Skip to F)** ☐ Yes	☐ No **(Skip to F)** ☐ Yes	☐ No **(Skip to F)** ☐ Yes	☐ No **(Skip to F)** ☐ Yes	☐ No **(Skip to F)** ☐ Yes	☐ No **(Skip to F)** ☐ Yes
2) Does the resident receive range of motion services or have a splint device in place?									
☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes
F Falls & Fractures QP265									
1) Has the resident had a fall and/or sustained a fracture within the last 30 days?									
☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

CENSUS SAMPLE RECORD REVIEW

Facility Name: _____ Facility ID: _____ Date: _____

Surveyor Name: _____

Resident Name: _____ Resident ID: _____ Admit Date: _____ Resident Room: _____

A MDS Items

If the ASE-Q has MDS data for the resident, do not answer this question (the MDS Item will have a check mark [inapplicable]). If the ASE-Q does not have MDS data for the resident, obtain the information from the MDS in the chart or other data sources as instructed for each item.

1) Prognosis (MDS – J1400): Does the resident have a condition or chronic disease that may result in a life expectancy of less than 6 months? (If the MDS is not completed, reference other data sources such as the physician orders and/or progress notes. Terminal illness means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.)	☐ No ☐ Yes ☐ Information not available

B Pressure Ulcers QP262 QP263

1) Does the resident currently have one or more pressure ulcers? If yes, indicate the stage of the most advanced pressure ulcer.

☐ No pressure ulcer.
☐ **Stage 1** − Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have a visible blanching; in dark skin tones only it may appear with persistent blue or purple hues.
☐ **Stage 2** − Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister.
☐ **Stage 3** − Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon, or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.
☐ **Stage 4** − Full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.
☐ **Unstageable (eschar/slough)** − Pressure ulcer is known but not stageable due to non-removable dressing/device or due to the coverage of the wound bed by slough or eschar.
☐ **Suspected Deep Tissue Injury (sDTI)** − Suspected deep tissue injury in evolution. Localized area of discolored (darker than surrounding tissue) intact skin or blood-filled blister related to damage of underlying soft tissue from pressure and/or shear. Area of discoloration may be preceded by tissue that is painful, firm, mushy, boggy, warmer, or cooler as compared to adjacent tissue.

CENSUS SAMPLE RECORD REVIEW

C Unnecessary Medications

1) Is this resident currently receiving any of the following medications at least one time in the last 30 days? (Mark all that apply)

- ☐ A: Antipsychotic
- ☐ B: Antianxiety
- ☐ C: Antidepressant
- ☐ D: Hypnotic
- ☐ E: Mood Stabilizer
- ☐ F: Anticoagulant − Warfarin, Heparin, Low Molecular Weight Heparin (e.g., Fragmin), Direct thrombin inhibitors (e.g., Pradaxa)
- ☐ G: Antibiotic
- ☐ H: Diuretic
- ☐ I: Insulin
- ☐ J: None of the above

Code medications according to a drug's pharmacological classification, not how it is used.

CENSUS SAMPLE RECORD REVIEW

D Weight Loss QP081 QP084

Do not complete this section if the resident has an explicit terminal prognosis.

1) Is the resident on a planned weight loss program?	☐ No ☐ Yes **(review is complete)**

1) Height and Weights:

Height: _____ (inches) If the ASE-Q has MDS data for the resident, the Height field will be gray (inapplicable), and the surveyor does not need to enter the resident's height.

Date and weight closest to today's date: ____/____/____ **Weight:_____ lbs.** ☐ Unavailable **(review is complete)**

Date and weight closest to 30 days prior to today's date: ____/____/____ **Weight:_____ lbs.** ☐ Unavailable

Date and weight closest to 90 days prior to today's date: ____/____/____ **Weight:_____ lbs.** ☐ Unavailable

Date and weight closest to 180 days prior to today's date: ____/____/____ **Weight:_____ lbs.** ☐ Unavailable

Note: The ASE-Q calculates the requested dates and percentage weight loss. Weight loss QCLIs are included in ASE-Q QCLI Results.

Unnecessary Meds/Med Regimen Review CE Pathway

Use for a sampled resident who has potentially unnecessary medications and has experienced a potential adverse outcome to determine whether facility practices are in place to identify, evaluate, and intervene for potential or actual unnecessary medications.

****If the resident has a diagnosis of dementia and is receiving any psychopharmacological medications (including but not limited to antipsychotic medications) the surveyor should refer to the checklist "Care for a Resident with Dementia" as a guide to determine the facility's compliance at F309.****

Review the following to guide your observations and interviews:

1. Review all of the meds currently ordered and or discontinued by the prescriber going back to the most recent signed recapitulation. (*Refer to the guidance at F329 of the SOM Appendix PP. Utilize Tables I and II*). Determine if the facility:

☐ **Documents an acceptable clinical indication for use**

- The following are not appropriate reasons to use antipsychotics
  - Wandering, restlessness or mild anxiety
  - Poor self-care or inattention or indifference to surroundings
  - Impaired memory
  - Insomnia
  - Sadness or crying alone that is not related to depression or other psychiatric disorders
  - Fidgeting or nervousness
  - Uncooperativeness (e.g., refusal/difficulty receiving care)

☐ **Demonstrates monitoring for each medication as appropriate**

- The following high risk meds should be monitored
  - ***Narcotics***- assess pain, implement bowel program
  - ***Anticoagulant***- bleeding/bruising, PT/INRs, interaction with other medications
  - ***Diuretics***- edema, K+ level, signs of electrolyte imbalance
  - Track appropriate behaviors for all ***psychoactive medications***
    - Hypnotics, causes for insomnia, hours of sleep
    - Antidepressants, duplicative therapies, effectiveness

☐ **Demonstrates appropriate dosing of each medication**

- Is there documentation of a rationale for any med that exceeds the manufacturer's recommendations, clinical practice guidelines, evidence based guidelines or standards of practice?

☐ **Documents clinical rationale for continued use of the medication(s) as appropriate**

- Including a clinical explanation for the concomitant use of two or more meds in the same pharmacological class
- Potential incompatibilities between meds

☐ **Demonstrates a system that monitors and addresses the presence of or potential for adverse consequences as appropriate**

- Ensure the physician provided a clear clinical rationale for continuing a med that may be causing an adverse consequence, including risks and benefits.

☐ **Demonstrates a system for and documents considerations for GDR as appropriate**

- For a resident who is receiving an antipsychotic, a GDR is required, unless clinically contraindicated.
  - An attempt must be made with the first year in which a resident is admitted or after the facility has initiated an antipsychotic. The facility must make the attempts in two separate quarters with at least one month between the attempts and then annually thereafter unless clinically contraindicated.

Review the following to guide your observations and interviews (continued)

2. Did the pharmacist conduct a MRR (medication regimen review),
    - Did the pharmacist identify and report any med irregularities?
    - Did the MD and DON act on the reported irregularities?
3. Allergies,
4. The most recent comprehensive MDS/CAAS (focus on areas pertinent to the meds ordered such as adverse consequences and behaviors, etc.), and
5. Care plan for high risk meds and individualized interventions, including non-pharmacological interventions.

Observation

Make observations as appropriate, over various shifts to corroborate the information obtained during the record review. You may also find it important to make further observations for information obtained from staff interviews. Potential pertinent observations are listed below. If further guidance is needed, surveyors should refer to the regulation and IG as they conduct the investigation.

- ☐ Are care planned interventions implemented for meds that pose a high risk for adverse consequences?
- ☐ Are non-pharmacological interventions being used?
- ☐ Observe for med effectiveness such as;
    - Analgesics – is pain relieved?
    - Psychoactive – is identified behavior/mood addressed?
- ☐ How does staff respond and interact with the resident?
- ☐ Does staff address the resident request for a med appropriately?
- ☐ Does the resident show mood or behavior concerns?
    - Does staff appropriately interact when the resident shows mood or behavior concerns (e.g., redirected, invited to an activity)?
- ☐ Observe for side effects and/or adverse consequences that may be related to the resident's current medication regimen.
    - Anorexia/unplanned weight changes, edema;
    - Behavioral changes or unusual behavior patterns;
    - Mental status changes or decline in physical functioning;
    - Sedation (excessive), changes in alertness;
    - Insomnia or sleep disturbances;
    - Rash, pruritus;
    - Bleeding or bruising, spontaneous or unexplained;
    - Respiratory changes;
    - Bowel dysfunction, urinary retention, incontinence;
    - Dehydration or swallowing difficulty;
    - Fall, dizziness, or headaches; and
    - Muscle/nonspecific pain or unexplained abnormal movement.

Interview

*As part of the investigation, surveyors should attempt to initially interview **the most appropriate direct care staff member first.** Your interview question should be specific to the investigation at hand and based on findings from the record review and observations. Consider interviewing the CNA, DON, MD, CNP, PA, social services, and/or pharmacist as needed to complete the investigation. Only ask the probes that are pertinent to your investigation. If further guidance is needed, surveyors should refer to the regulation, IG, and investigative protocol as they conduct the investigation.*

Resident and/or representative:

- ☐ Has staff talked to you about which meds you are on and why you need to take them?
- ☐ Did staff discuss with you any goals for your meds?
- ☐ Were you provided any information on the risk and benefits of meds?
- ☐ Did staff discuss with you other alternatives (when appropriate) to taking some of the meds? Do you think that the med has helped (e.g., pain control, improvements in function, decrease in edema, mood)?
- ☐ Have you had any side effects from the med (ask about specific meds)?
- ☐ Do you have any allergies to any medications?

Staff, as appropriate:

- ☐ What, when, and to whom do you report changes (e.g., behavior or pain)?
- ☐ How are you made aware of the resident's daily care needs?
- ☐ What non-pharmacological approaches are used?
- ☐ What is the clinical indication for the high risk med?
- ☐ What is the facility monitoring for each high risk med?
  - ○ What monitoring tools or systems are used?
  - ○ How did the IDT team determine what should be monitored?
  - ○ For antipsychotic or antianxiety meds, how did you determine what behavior to monitor?
  - ○ How do you assure MD orders for med monitoring are implemented (e.g., hgA1C, PT/INR monitoring)?
  - ○ How do you communicate relevant information regarding med monitoring for this resident to other team members?
- ☐ How do you assess whether each med is effective?
- ☐ Why does the resident have two meds in the same med class?
- ☐ How does the IDT team determine what dose and duration is clinically indicated?
  - ○ If the amount of any med exceeds the manufacturer's recommendations, clinical practice guidelines, evidence-based guidelines or standards of practice, what is the rationale?
- ☐ How do you monitor for potentially clinical significant adverse consequences?
- ☐ Has the resident had a change in medical regimen, diet, weight loss, dehydration, or acute illness? If so, what was done to assess the possible consequences/complications for these changes due to possible meds?
- ☐ Has the resident had an adverse reaction? If so, what and how was the adverse reaction addressed?
- ☐ How does the facility evaluate whether meds should be continued, reduced, discontinued, or otherwise modified? And how often?
- ☐ How does the facility ensure a review of meds for required GDRs?
  - ○ If the resident is on an antipsychotic: When did you attempt to reduce the med in the last year and what were the results?
  - ○ If the MD denied a GDR: Did the MD provide a risk-benefit statement describing the contra-indications for a GDR?
- ☐ How do you monitor staff to ensure they are implementing care planned interventions?
- ☐ What was the rationale for the MD's decisions in managing the resident's meds and/or med-related issues or concerns?
- ☐ How did you involve the resident in decisions regarding meds?
- ☐ If problems were identified with the Medication Regimen Review (MRR):
  - ○ How is the MRR conducted and how often?
  - ○ Under what circumstances is the MRR conducted more often than monthly?
  - ○ How are medication-related issues communicated to other staff, MD, residents/families?
  - ○ How is the MRR process conducted for short-stay residents?
- ☐ Has there been a change in the resident's overall function and mood that potentially may indicate unnecessary meds or adverse reactions?

Pharmacist and physician, as appropriate:

- ☐ Pharmacist interview
  - ○ Do you perform a monthly med review (or more frequently if needed)?
  - ○ What are you reviewing (e.g., adequate indication, dose, continued need, and adverse consequences)?
  - ○ Did you identify and report to the DON and attending MD any irregularities with this resident's med regimen?
  - ○ If the pharmacist didn't identify your issue, ask the following:
    - ▪ What do you think of this issue?
    - ▪ Is this something you should've identified during the monthly review?
  - ○ How is the MRR process conducted for short stay residents?

- ☐ Physician interview
  - o Were you notified of med-related concerns?
    - ▪ If the MD wasn't notified, ask for his/her assessment of the med-related concern?
  - o If the MD was notified about a med issue and the MD declined to address the issue: Why?
  - o If a med is being used inappropriately (e.g., Seroquel for dementia): What is the rationale behind why the med is being used?

Record Review

You may need to return to the record to corroborate information from the observations and interviews. Potential pertinent items in the record are listed below. If further guidance is needed, surveyors should refer to the regulation, IG, and investigative protocol as they conduct the investigation.

- ☐ Underlying cause (medical, environmental, or psychosocial stressors) of the conditions or symptoms requiring the med?
- ☐ If a med was discontinued, was there evidence of tapering, if applicable (e.g., antipsychotic meds)?
- ☐ If the resident had a change in condition such as dietary needs, dehydration or acute illness, was the medication regimen reviewed? Did the pharmacist complete a MRR?
- ☐ Has the care plan been revised to reflect any changes?
- ☐ Ensure the MAR is accurate and followed according to standards of practice.
- ☐ Review facility policy and procedures for systems of monitoring residents on psychoactive meds?
- ☐ Facility response when monitoring indicates a lack of progress toward the therapeutic goal?

Make compliance decisions below by answering the six Critical Elements.

Note: *Remember if the facility failed to complete a comprehensive assessment resulting in a citation at F272, surveyors should not cite F279 and F280 as the facility could not have developed or revised a plan of care based on a comprehensive assessment they did not complete.*

Critical Element

1. Did the facility comprehensively assess the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes (to the extent possible) of the resident's condition and the impact of use of the medication on the resident's function, mood, and cognition?
   If No, cite F272
   NA, condition/risks were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change MDS OR a comprehensive assessment is not required yet.

2. Did the facility develop a plan of care based on the assessment of the resident's conditions, risks, needs, and behaviors that was consistent with the resident's therapeutic goals and considered the need to monitor for effectiveness based on those therapeutic goals and for the emergence or presence of interventions to address the use of medications and prevent adverse consequences?
   If No, cite F279
   NA, the comprehensive assessment was not completed.

3. Did the facility provide or arrange for services to be provided by qualified persons in accordance with the resident's written plan of care and did the facility implement the care plan adequately and/or correctly
   If No, cite F282
   NA, no provision in the written plan of care for the concern being evaluated.

4. Did the facility reassess the effectiveness of the interventions and review and revise the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident?
   If No, cite F280
   NA, the comprehensive assessment was not completed OR the care plan was not developed OR the care plan did not have to be revised.

5. Did the facility ensure that each resident's medication regimen was free from unnecessary medications? An unnecessary medication is a medication used:
   - In excessive doses (including duplicate therapy); or
   - For excessive duration; or
   - Without adequate monitoring; or
   - Without adequate indication for its use; or
   - In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
   - Any combination of the reasons above.

   If No, cite F329

6. Did the licensed pharmacist:
   - Conduct a review of the drug regimen of the resident at least once a month?
   - Report irregularities if any to the attending physician and the director of nursing?
   - If there were irregularities, were these reports acted upon?

   If No, cite F428
   N/A, the resident was just admitted and monthly drug regimen review is not required yet.

Other Tags and Care Areas to consider: F154, F155, Notification of Change (F157), F222, Abuse (F223, F224, F226), Choices (F155, F242, F246), Social Services (F250), F271, F274, F278, F281, Pain (F309), General Pathway for Diabetic Management (F309), F309 (dementia care), ADLs (F310, F311, F312), Urinary Incontinence (F315), Behavioral and Emotional Status (F319, F 320), Nutrition (F325), Hydration (F327), Sufficient Staffing (F353, F354), F385, F386, F425, Infection Control (F441), F498, F501, F514, QA&A (F520).

Stage 2 Critical Elements for Behavioral and Emotional Status

Facility Name: _____ Facility ID: _____ Date: _____

Surveyor Name: _____

Resident Name: _____ Resident ID: _____

Initial Admission Date: _____ Interviewable: ☐ Yes ☐ No Resident Room: _____

Care Area(s): _____

Use

Use this protocol for a sampled resident exhibiting physically or verbally abusive behaviors; socially inappropriate or disruptive behaviors, including resistance to care; psychosocial adjustment difficulties after admission; symptoms of depression; and/or presence of delirium.

Procedure

☐ Briefly review the assessment, care plan, and orders to identify facility interventions and to guide observations to be made.

☐ Corroborate observations by interview and record review.

Observations (if the resident is still in the facility)

Observe whether staff consistently implement the care plan over time and across various shifts. Staff are expected to assess and provide appropriate care for residents with behavioral, mental status and/or emotional status symptoms from the day of admission. During observations of the interventions, note and/or follow up on deviations from the care plan as well as potential negative outcomes, including but not limited to the following:

☐ The quality of staff–to–resident interactions—staff respond to residents who are exhibiting behavioral and/or mental/psychosocial symptoms in a manner that emphasizes the resident's quality of life while ensuring the safety of others; and

☐ Specific interventions consistently employed from one staff to another and across shifts.

Notes:

Stage 2 Critical Elements for Behavioral and Emotional Status

Resident/Representative Interview	
Interview the resident, family or responsible party to the degree possible to identify: ☐ Resident's/Representative's involvement in the development of the care plan including providing insight into why behavioral or mood reactions might occur, defining the approaches and goals, and if interventions reflect choices and preferences; ☐ Resident's/Representative's awareness of management programs to address behavioral, mental status or mood symptoms and if interventions are provided according to the care plan; and ☐ If interventions are refused, whether counseling on alternatives, consequences, and/or other alternative approaches to address behavioral, mental, and/or emotional symptoms were offered.	**Notes:**

Staff Interviews	
Interview staff on various shifts to determine: ☐ Knowledge of behavioral management or mental/psychosocial interventions that should be carried out, and how this information is communicated between disciplines and to direct care staff; ☐ The process that is in place to review behavior and/or mental/psychosocial symptoms and the roles various disciplines play in the management of behavioral and/or mental/psychosocial symptoms; ☐ If nursing assistants know what, when, and to whom to report indications of behavioral, mental and/or emotional status changes; and ☐ How staff monitor for the implementation of the care plan, effectiveness of interventions, and any changes in symptoms that have occurred over time.	**Notes:**

Stage 2 Critical Elements for Behavioral and Emotional Status

Assessment	
Review the MDS, physician orders, therapy notes, and other progress notes that may have information regarding the assessment of behavior symptoms, assessment of mental and/or psychosocial needs, and resident responsiveness to management programs or interventions. Determine whether the assessment information accurately and comprehensively reflects the status of the resident for: ☐ Time, duration, and severity of behaviors and/or mental/psychosocial symptoms (depression, labile or volatile mood, adjustment reactions, delirium) exhibited; ☐ Causal, risk, and contributing factors for any behavioral and/or mental/psychosocial symptom(s) that the resident is exhibiting, such as decline in cognitive functioning, confusion, or delirium; and ☐ Resident participation in any behavioral management interventions or programs to address mental/psychosocial symptoms (such as symptoms of depression, labile or volatile mood, adjustment reactions). NOTE: If a resident is resisting ADL care, it may be due to a genuine psychological symptom or may be a legitimate defensive reaction to coercive facility practices (such as forcing a resident to endure a shower even while the resident is striking out and protesting). The surveyor should determine whether the facility's practices are the causal factor for the resident's reaction. If so, these constitute deficient practices (Abuse) and not a behavioral symptom. ☐ Determine whether there was a "significant change" in the resident's condition and whether the facility conducted a significant change comprehensive assessment within 14 days. A "significant change" is a decline or improvement in a resident's status that: 1. Will not normally resolve itself without intervention by staff or by implementing standard disease-related clinical interventions, is not "self-limiting;" 2. Impacts more than one area of the resident's health status; and	**Notes:**

Stage 2 Critical Elements for Behavioral and Emotional Status

Assessment	
3. Requires interdisciplinary review and/or revision of the care plan. If there was a "significant change" in the resident's condition and the facility did not conduct a significant change comprehensive assessment within 14 days, initiate **F274, Resident Assessment When Required**. If a comprehensive assessment was not conducted, also cite F272.	
1. If the condition or risks were present at the time of the required comprehensive assessment, did the facility comprehensively assess the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes (to the extent possible) of the resident's behavioral and/or mental/psychosocial symptoms, and needed adaptations, and the impact upon the resident's function, mood, and cognition? ☐ Yes ☐ **No** **F272**	
☐ **NA, condition/risks were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change MDS**	
NOTE: Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the assessment process is more fluid and should be ongoing. *The comprehensive assessment is not required to be completed until 14 days after admission. For newly admitted residents, before the 14–day assessment is complete, the lack of sufficient assessment and care planning to meet the resident's needs should be addressed under **F281, Professional Standards of Quality**.*	

Stage 2 Critical Elements for Behavioral and Emotional Status

Care Planning	
If the comprehensive assessment was not completed (CE#1 = No), mark CE#2 "NA, the comprehensive assessment was not completed". ☐ Determine whether the facility developed a care plan that was consistent with the resident's specific conditions, risks, needs, behaviors, and preferences and current standards of practice, and included measurable objectives and timetables, with specific interventions/services for the management and treatment of behavioral, mental and/or emotional symptoms. ☐ If the care plan refers to a specific facility treatment protocol that contains details of the treatment regimen, the care plan should refer to that protocol and should clarify any deviations from or revisions to the protocol for this resident. The treatment protocol must be available to the caregivers, and staff should be familiar with the protocol requirements. If care plan interventions that address aspects of the behavioral management/treatment plan are integrated within the overall care plan, the interventions do not need to be repeated. ☐ Review the care plan to determine whether the plan is based upon the goals, needs, and strengths specific to the resident and reflects the comprehensive assessment. ☐ Determine whether the plan: ▪ Identifies the degree of staff assistance or involvement needed to manage behavior/mental/emotional symptoms; ▪ States problems with behavioral and/or mental/psychosocial symptoms in behavioral and/or functional terms as they relate specifically to the individual resident; ▪ Identifies specific interventions related to managing the resident's behavioral and/or mental/psychosocial symptoms and related risk or causal factors that reflect the resident's medical/health condition and resident preferences and opinions; ▪ Includes baseline and ongoing measurement of the behavior	**Notes:**

Stage 2 Critical Elements for Behavioral and Emotional Status

Care Planning	
and/or mental/psychosocial symptom(s) and expected response to interventions; and ▪ If the resident refuses or is resistant to the behavior management program or mental/psychosocial intervention, the care plan reflects efforts to find alternative means to address the behavior and/or mental/psychosocial symptoms based on causal and contributing factors determined in the assessment process. ☐ If care plan concerns are noted, interview staff responsible for care planning as to the rationale for the current plan of care. **2. Did the facility develop a plan of care with measurable goals and interventions to address the care and treatment related to the resident's behavioral and/or mental/psychosocial symptoms, in accordance with the assessment, resident's wishes, and current standards of practice?** ☐ Yes ☐ **No** **F279** ☐ **NA, the comprehensive assessment was not completed** *The comprehensive care plan does not need to be completed until 7 days after the comprehensive assessment (the assessment completed with the CAAS). Lack of sufficient care planning to meet the needs of a newly admitted resident should be addressed under* ***F281, Professional Standards of Quality****.*	

Stage 2 Critical Elements for Behavioral and Emotional Status

Care Plan Implementation by Qualified Persons	
Observe care and interview staff over several shifts and determine whether: ☐ Care is being provided by qualified staff, and/or ☐ The care plan is adequately and/or correctly implemented. **3. Did the facility provide or arrange services to be provided by qualified persons in accordance with the resident's written plan of care?** ☐ Yes ☐ **No F282** ☐ **NA, no provision in the written plan of care for the concern being evaluated**	**Notes:**

Stage 2 Critical Elements for Behavioral and Emotional Status

Care Plan Revision

If the comprehensive assessment was not completed (CE#1 = No), OR, if the care plan was not developed (CE#2 = No), mark CE#4 "NA, the comprehensive assessment was not completed OR the care plan was not developed".

☐ Determine whether the staff have been monitoring the resident's response to interventions for prevention and/or treatment and have evaluated and revised the care plan based on the resident's response, outcomes, and needs.

☐ Review the record and interview staff for information and/or evidence that:

- If the resident experienced a decline in behavior or mental/psychosocial status or lack of improvement in behavior mental/psychosocial symptoms, the care plan was revised/updated with more appropriate goals or interventions, based on a determination of causal or contributing/risk factors (e.g., unstable condition, acute health problem or change in condition, change in ability to make decisions, change in cognition, a change in medications, sensory problems, environmental disturbances);
- Staff evaluated outcomes of the plan (the effect of care plan goals and interventions); and
- The resident and/or the responsible person was involved in the review and revision of the plan.

4. Did the facility reassess the effectiveness of the interventions and review and revise the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident?

☐ Yes ☐ **No F280**

☐ **NA, the comprehensive assessment was not completed OR the care plan was not developed**

Notes:

Stage 2 Critical Elements for Behavioral and Emotional Status

Provision of Care and Services	
For the resident who displays mental or psychosocial adjustment difficulties:	
Determine whether staff have: ☐ Recognized and assessed factors affecting the resident's behavioral and/or mental/psychosocial/emotional status; ☐ Defined and implemented pertinent interventions consistent with resident condition, goals, and recognized standards of practice to try to: ▪ Address factors contributing to psychosocial adjustment difficulties or symptoms such as delirium or behavioral and/or emotional symptoms unrelated to adjustment difficulties; ▪ Monitored and evaluated the resident's response to interventions; and ▪ Revised the approaches as appropriate. ☐ Determine whether there was an avoidable onset of problems or decline in behavioral or mental/psychosocial status, or lack of improvement in behavior or mental/psychosocial status.	**Notes:**

Stage 2 Critical Elements for Behavioral and Emotional Status

Provision of Care and Services	
5. Based on observation, interviews, and record review, did the facility provide appropriate treatment and services to correct the assessed problem for a resident who displays mental or psychosocial adjustment difficulty? ☐ Yes ☐ **No** ☐ **NA** **F319** ☐ **NA, the resident does not display mental or psychosocial adjustment difficulty**	**Notes:** `
For the resident whose assessment did not reveal a mental or psychosocial adjustment difficulty:	
6. Based on observation, interviews, and record review did the facility ensure that the resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawal, anger, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern is unavoidable? ☐ Yes ☐ **No** ☐ **NA** **F320** ☐ **NA, the resident's assessment revealed a mental or psychosocial adjustment difficulty**	**Notes:** `

Stage 2 Critical Elements for Behavioral and Emotional Status

Provision of Care and Services	
For the resident who requires care and services to attain or maintain the highest practicable mental or psychosocial well-being:	
7. Based on observation, interviews, and record review did the facility provide the necessary care and services to attain or maintain the highest practical physical, mental, and psychosocial well-being in accordance with the comprehensive assessment and plan of care? ☐ Yes ☐ **No** **F309**	**Notes:** `

Stage 2 Critical Elements for Behavioral and Emotional Status

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
During the investigation of services that address behavioral, mental and/or psychosocial needs, the surveyor may have identified concerns with related outcome, process and/or structure requirements, such as the examples listed below. If an additional concern has been identified, the surveyor should initiate the appropriate care area or F tag and investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance. ☐ **Notification of Changes** — Determine whether staff: ▪ Consulted with the physician regarding significant changes in the resident's condition, including the need to alter treatment significantly or failure of the treatment plan; and ▪ Notified the resident's representative (if possible) of significant changes in the resident's condition. ☐ **Abuse** — Determine whether the facility is engaging in coercive practices to force a resident to endure ADLs or treatments against his/her will. Initiate the Abuse care area for the resident and Abuse Prohibition for the facility if concerns were identified. ☐ **Dignity** — Determine whether staff respond to behavioral and/or emotional symptoms in a manner that promotes a sense of dignity and self–worth. ☐ **Social Services** — Determine whether the facility is providing medically–related social services, including ▪ Maintaining contact with family; ▪ Providing or arranging for provision of needed counseling services; ▪ Supporting preferences, customary routines, concerns, and choices; ▪ Finding options that most meet the psychosocial and emotional	**Notes:**

Stage 2 Critical Elements for Behavioral and Emotional Status

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
needs of the residents; ▪ Providing alternatives to drug therapy or restraints by understanding and communicating to staff why residents act as they do, what they are attempting to communicate, and what needs the staff must meet; ▪ Teaching staff how to understand and support resident's individual needs; and ▪ Promoting actions by staff that maintain or enhance dignity. ☐ **F271, Admission Orders** — Determine whether the facility received physician orders for provision of immediate care before conducting the comprehensive assessment and developing an interdisciplinary care plan. ☐ **F278, Accuracy of Assessments —** Determine whether staff, that are qualified to assess relevant care areas and are knowledgeable about the resident's status, needs, strengths, and areas of decline, conducted an accurate assessment. ☐ **F281, Professional Standards** — Determine whether the services provided or arranged by the facility met professional standards of quality. Professional standards of quality is defined as services that are provided according to accepted standards of clinical practice. ☐ **Unnecessary Medication Review** — Determine whether the facility ensures the resident is free from unnecessary medications and that antipsychotic drugs are used appropriately. An unnecessary medication is any medication when used: ▪ In excessive dose (including duplicate therapy); or ▪ For excessive duration; or ▪ Without adequate monitoring; or	

Stage 2 Critical Elements for Behavioral and Emotional Status

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
▪ Without adequate indications for its use; or ▪ In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or ▪ Any combinations of the reasons above. Antipsychotic medication use based on comprehensive assessment of the resident: ▪ The facility has ensured that residents who have not used antipsychotic medications are not given these medications unless antipsychotic medication therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and ▪ The facility has ensured that residents who use antipsychotic medications receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these medications. ☐ **Sufficient Nursing Staff** — Determine whether the facility had qualified staff in sufficient numbers to provide necessary care and services, based upon the comprehensive assessment and care plan, to manage and/or treat the resident's behavioral, mental and/or emotional symptoms. ☐ **F514, Clinical Records —** Determine whether the clinical records: ▪ Accurately and completely document the resident's status, the care and services provided (e.g., to prevent, to the extent possible, or manage the resident's pain) in accordance with current professional standards and practices and the resident's goals; and ▪ Provide a basis for determining and managing the resident's progress including response to treatment, change in condition, and changes in treatment.	

Stage 2 Critical Elements for Pain Recognition and Management

Facility Name: _____ Facility ID: _____ Date: _____

Surveyor Name: _____

Resident Name: _____ Resident ID: _____

Initial Admission Date: _____ Interviewable: ☐ Yes ☐ No Resident Room: _____

Care Area(s): _____

Use

- Use this protocol to determine whether the facility has provided, and the resident has received care, and services to address and manage the resident's pain in order to support his or her highest practicable level of physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.
- Use this protocol for a resident who has pain symptoms or who has the potential for pain symptoms related to conditions or treatments. This includes a resident:
  - Who states he/she has pain or discomfort,
  - Who displays possible indicators of pain that cannot be readily attributed to another cause;
  - Who has a disease or condition or who receives treatments that cause or can reasonably be anticipated to cause pain;
  - Whose assessment indicates that he/she experiences pain;
  - Who receives or has orders for treatment for pain; and/or
  - Who has elected a hospice benefit for pain management.

Procedure

- Briefly review the care plan and orders to identify any current pain management interventions and to focus observations.
- Corroborate observations by interview and record review.

NOTE: Determine who is involved in the pain management process (for example, the staff and practitioner, and/or another entity such as a licensed/certified hospice).

Stage 2 Critical Elements for Pain Recognition and Management

Observations	
Observe to determine: ☐ If the resident exhibits signs or symptoms of pain, verbalizes the presence of pain, or requests interventions for pain, or whether the pain appears to affect the resident's function or ability to participate in routine care or activities; ☐ If there is evidence of pain, whether staff have assessed the situation, identified, and implemented interventions to try to prevent or address the pain, and have evaluated the status of the resident's pain after interventions; ☐ If care and services are being provided that reasonably could be anticipated to cause pain, whether staff have identified and addressed these issues, to the extent possible; ☐ Staff response, if there is a report from the resident, family, or staff that the resident is experiencing pain; ☐ If there are pain management interventions for the resident, whether the staff implements them. Follow up on: ▪ Deviations from the care plan; ▪ Whether pain management interventions have a documented rationale and if it is consistent with current standards of practice; ▪ Potential adverse consequence(s) associated with treatment for pain (e.g., medications); and ▪ How staff responded if the interventions implemented did not reduce the pain consistent with the goals for pain management.	**Notes:**

Stage 2 Critical Elements for Pain Recognition and Management

Interviews	
Resident/Representative Interview	
Interview the resident or representative to the degree possible to identify: ☐ The resident's/representative's involvement in the development of the care plan, defining the approaches and goals, and if the interventions reflect choices and preferences, and how they are involved in developing and revising pain management strategies; revisions to the care plan if the interventions do not work. ☐ If the resident is presently or periodically experiencing pain, determine: ▪ Characteristics of the pain, including the intensity, type (e.g., burning, stabbing, tingling, aching), patterns of pain (e.g., constant or intermittent), location, radiation of pain, and frequency, timing and duration of pain; ▪ Factors that may precipitate or alleviate the pain; ▪ How the resident typically has expressed pain and responded to various interventions in the past; ▪ Who the resident and/or representative has told about the pain/discomfort, and how the staff responded; ▪ What treatment options (pharmacological and/or non-pharmacological) were discussed and attempted; ▪ How effective the interventions have been; and ▪ If interventions have been refused, whether there was a discussion of the potential impact on the resident, and whether alternatives or other approaches were offered.	**Notes:**

Stage 2 Critical Elements for Pain Recognition and Management

Staff Interviews	
Nurse Aide(s) Interview	
Interview staff who provide direct care on various shifts to determine: ☐ If they are aware of a resident's pain complaints or of signs and symptoms that could indicate the presence of pain; ☐ To whom they report the resident's complaints and signs or symptoms; and ☐ If they are aware of and implement interventions for pain/discomfort management for the resident consistent with the resident's plan of care (for example, allowing a period of time for a pain medication to take effect before bathing and/or dressing).	**Notes:**

Stage 2 Critical Elements for Pain Recognition and Management

Assessment	
Review information such as orders, medication administration records, multidisciplinary progress notes, the RAI/MDS, and any specific assessments regarding pain that may have been completed. Determine whether the information accurately and comprehensively reflects the resident's condition, such as: ☐ Identifies the pain indicators and the characteristics, causes, and contributing factors related to pain; ☐ Identifies a history of pain and related interventions, including the effectiveness and any adverse consequences of such interventions; ☐ Identifies the impact of pain on the resident's function and quality of life; and ☐ Identifies the resident's response to interventions, including efficacy and adverse consequences and any modification of interventions as indicated. ☐ Determine whether there was a "significant change" in the resident's condition and whether the facility conducted a significant change comprehensive assessment within 14 days. A "significant change" is a decline or improvement in a resident's status that: 1. Will not normally resolve itself without intervention by staff or by implementing standard disease-related clinical interventions, is not "self-limiting" 2. Impacts more than one area of the resident's health status; and 3. Requires interdisciplinary review and/or revision of the care plan. If there was a "significant change" in the resident's condition and the facility did not conduct a significant change comprehensive assessment within 14 days, initiate **F274, Resident Assessment When Required**. If a comprehensive assessment was not conducted, also cite F272.	**Notes:**

Stage 2 Critical Elements for Pain Recognition and Management

Assessment	
1. Did the facility comprehensively assess the resident's physical, mental, and psychosocial needs to identify characteristics and/or to determine underlying causes (to the extent possible) of the resident's pain and the impact of the pain upon the resident's function, mood, and cognition? ☐ Yes ☐ **No** **F272** ☐ **NA, condition/risks were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change MDS** *NOTE: Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the assessment process is more fluid and should be ongoing.* *The comprehensive assessment is not required to be completed until 14 days after admission. For newly admitted residents, before the 14–day assessment is complete, the lack of sufficient assessment and care planning to meet the resident's needs should be addressed under* ***F281, Professional Standards of Quality****.*	

Stage 2 Critical Elements for Pain Recognition and Management

Care Planning	
If the comprehensive assessment was not completed (CE#1 = No), mark CE#2 "NA, the comprehensive assessment was not completed". Review the care plan to determine whether pain management interventions include, as appropriate: ☐ Measurable pain management goals, reflecting resident needs and preferences; ☐ Pertinent non-pharmacological and/or pharmacological interventions; ☐ Time frames and approaches for monitoring the status of the resident's pain, including the effectiveness of the interventions; and ☐ Identification of clinically significant medication-related adverse consequences, such as falling, constipation, anorexia, or drowsiness, and a plan to try to minimize those adverse consequences. NOTE: If the care plan refers to a specific facility pain management protocol, determine whether interventions are consistent with that protocol. If a resident's care plan deviates from the protocol, determine through staff interview or record review the reason for the deviation. ☐ If the resident has elected a hospice benefit, all providers must coordinate their care of the resident. This care includes aspects of pain management, such as: ▪ Choice of palliative interventions; ▪ Responsibility for assessing pain and providing interventions; and ▪ Responsibility for monitoring symptoms and adverse consequences of interventions and for modifying interventions as needed.	**Notes:**

Stage 2 Critical Elements for Pain Recognition and Management

Care Planning	
2. Did the facility develop a plan of care with measurable goals and interventions to prevent (to the extent possible) or manage the resident's pain in accordance with the assessment, the resident/representative's input, and current standards of practice? ☐ Yes ☐ **No** **F279** ☐ **NA, the comprehensive assessment was not completed** *The comprehensive care plan does not need to be completed until 7 days after the comprehensive assessment (the assessment completed with the CAAS). Lack of sufficient care planning to meet the needs of a newly admitted resident should be addressed under* ***F281, Professional Standards of Quality****.*	

Stage 2 Critical Elements for Pain Recognition and Management

Care Plan Implementation by Qualified Persons	
Observe care and interview staff over several shifts and determine whether: ☐ Care is being provided by qualified staff, and/or ☐ The care plan is adequately and/or correctly implemented. **3. Did the facility provide or arrange services to be provided by qualified persons in accordance with the resident's written plan of care?** ☐ Yes ☐ **No F282** ☐ **NA, no provision in the written plan of care for the concern being evaluated** *NOTE: If there is a failure to provide necessary care and services, the related care issue should also be cited when there is actual or potential outcome.*	**Notes:**

Stage 2 Critical Elements for Pain Recognition and Management

Care Plan Revision

If the comprehensive assessment was not completed (CE#1 = No), OR, if the care plan was not developed (CE#2 = No), mark CE#4 "NA, the comprehensive assessment was not completed OR the care plan was not developed".

Determine whether the pain has been reassessed and the care plan has been revised as necessary (with input from the resident or representative, to the extent possible). For example:

- The current interventions are not effective,
- The pain has resolved, or
- The resident has experienced a change of condition or status.

4. Did the facility reassess the pain and review and revise the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident?

☐ Yes ☐ **No** **F280**

☐ **NA, the comprehensive assessment was not completed OR the care plan was not developed**

Notes:

Stage 2 Critical Elements for Pain Recognition and Management

INTERVIEWS TO CONDUCT ONLY IF PROBLEMS HAVE BEEN IDENTIFIED

Nurse Interview

Interview a nurse who is knowledgeable about the needs and care of the resident to determine:

- ☐ How and when staff try to identify whether a resident is experiencing pain and/or circumstances in which pain can be anticipated;
- ☐ How the resident is assessed for pain;
- ☐ How the interventions for pain management have been developed and the basis for selecting them;
- ☐ How staff monitor for the emergence or presence of adverse consequences of interventions;
- ☐ If the resident receives routine pain medication (including PRN and adjuvant medications), how, when, and by whom the results of the medications are evaluated (including the dose, frequency of PRN use, schedule of routine medications, and effectiveness);
- ☐ What is done if pain persists or recurs despite treatment, and the basis for decisions to maintain or modify approaches;
- ☐ How staff communicate with the prescriber about the resident's pain status, current measures to manage pain, and the possible need to modify the current pain management interventions; and
- ☐ For a resident who is receiving care under a hospice benefit, how the hospice and the facility coordinate their approaches and communicate about the resident's needs and monitor the outcomes (both effectiveness and adverse consequences).

Notes:

Stage 2 Critical Elements for Pain Recognition and Management

INTERVIEWS TO CONDUCT ONLY IF PROBLEMS HAVE BEEN IDENTIFIED	
Interviews with Other Health Care Professionals	
If the interventions or care provided do not appear to be consistent with current standards of practice and/or the resident's pain appears to persist or recur, interview one or more health care professionals as necessary (e.g., attending physician, medical director, consultant pharmacist, director of nursing, or hospice nurse) who, by virtue of training and knowledge of the resident, should be able to provide information about the evaluation and management of the resident's pain/symptoms. Depending on the issue, ask about: ☐ How chosen interventions were determined to be appropriate; ☐ How they guide and oversee the selection of pain management interventions; ☐ The rationale for not intervening, if pain was identified and no intervention was selected and implemented; ☐ Changes in pain characteristics that may warrant review or revision of interventions; or ☐ When and with whom the professional discussed the effectiveness, ineffectiveness, and possible adverse consequences of pain management interventions. NOTE: If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the treatment regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries. If the attending physician is unavailable, interview the medical director as appropriate.	**Notes:**

Stage 2 Critical Elements for Pain Recognition and Management

Provision of Care and Services	
Determine whether the facility: ☐ Recognized and evaluated the resident who experienced pain to determine (to the extent possible) causes and characteristics of the pain, as well as factors influencing the pain; ☐ Developed and implemented interventions for pain management for a resident experiencing pain, consistent with the resident's goals, risks, and current standards of practice; or has provided a clinically pertinent rationale why they did not do so; ☐ Recognized and provided measures to minimize or prevent pain for situations where pain could be anticipated; ☐ Monitored the effects of interventions and modified the approaches as indicated; and ☐ Communicated with the health care practitioner when a resident was having pain that was not adequately managed or was having a suspected or confirmed adverse consequence related to the treatment. **5. Based on observation, interviews, and record review, did the facility provide care and services necessary to meet the needs of the resident in order to attain or maintain the highest practicable physical, mental and psychosocial well being including the identification, treatment, monitoring, and management of pain to the extent possible in accordance with the comprehensive assessment and plan of care?** ☐ Yes ☐ **No** **F309**	**Notes:**

Stage 2 Critical Elements for Pain Recognition and Management

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
During the investigation of care and services provided to prevent or manage the resident's pain, the surveyor may have identified concerns with related structure, process, and/or outcome requirements. If an additional concern has been identified, the surveyor should initiate the appropriate care area or F tag and investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance or non-compliance with the related or associated requirement. Some examples include, but are not limited to the following; ☐ **F155, Rights Regarding Treatment, Experimental Research and Advance Directives** – For concerns regarding the resident's right to refuse treatment, to participate in experimental research, and to formulate an advanced directive ☐ **Choices (the Right to Refuse Treatment) —** If a resident has refused treatment or services, determine whether the facility has assessed the reason for this resident's refusal, clarified and educated the resident as to the consequences of refusal, offered alternative treatments, and continued to provide all other services. ☐ **Notification of Change** — Determine whether staff: ▪ Notified the physician when pain persisted or recurred despite treatment, or when they suspected or identified adverse consequences related to treatments for pain; and ▪ Notified the resident's representative (if known) of significant changes in the resident's condition in relation to pain management and/or the plan of care. ☐ **Choices (Self-Determination and Participation) —** Determine whether the facility has provided the resident with relevant choices about aspects pain management. ☐ **F246, Accommodation of Needs —** Determine whether the facility has adapted the resident's physical environment (room, bathroom, furniture) to accommodate the resident's individual needs related to	**Notes:**

Stage 2 Critical Elements for Pain Recognition and Management

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
pain management. ☐ **F278, Accuracy of Assessments —** Determine whether staff that are qualified to assess relevant care areas and are knowledgeable about the resident's status, needs, strengths, and areas of decline conducted an accurate assessment. ☐ **F281, Professional Standards of Quality** — Determine whether care was provided in accordance with accepted standards of quality for pain management. ☐ **Unnecessary Medication Review —** Determine whether medications ordered to treat pain are being monitored for effectiveness and for adverse consequences, including whether any symptoms could be related to the medications. ☐ **F385, Physician Supervision —** Determine whether pain management is being supervised by a physician, including participation in the comprehensive assessment process, development of a treatment regimen consistent with current standards of practice, monitoring, and response to notification of change in the resident's medical status related to pain. ☐ **F425, Pharmacy Services —** Determine whether the medications required to manage a resident's pain were available and administered as indicated and ordered at admission and throughout the stay. ☐ **F501, Medical Director —** Determine whether the medical director: ▪ Helped the facility develop and implement policies and procedures related to preventing, identifying, and managing pain, consistent with current standards of practice; and ▪ Interacts with the physician supervising the care of the resident if requested by the facility to intervene on behalf of the resident with pain or one who may have been experiencing adverse consequences related to interventions to treat pain.	

Stage 2 Critical Elements for Pain Recognition and Management

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
☐ **F514, Clinical Records —** Determine whether the clinical records: ▪ Accurately and completely document the resident's status, the care and services provided (e.g., to prevent, to the extent possible, or manage the resident's pain) in accordance with current professional standards and practices and the resident's goals; and ▪ Provide a basis for determining and managing the resident's progress including response to treatment, change in condition, and changes in treatment.	

Stage 2 Critical Elements for the Use of Physical Restraints

Facility Name: _____ Facility ID: _____ Date: _____

Surveyor Name: _____

Resident Name: _____ Resident ID: _____

Initial Admission Date: _____ Interviewable: ☐ Yes ☐ No Resident Room: _____

Care Area(s): _____

Use

Use this protocol for:

☐ A sampled resident who has MDS data that indicates a physical restraint is used; or

☐ Surveyor observation of a device or practice that may be physically restraining the resident.

The goal of using this CE is to determine, for a resident the surveyor has determined to be restrained, whether the restraint is in compliance with the regulations. To be in compliance, the restraint:

☐ Must be necessary to treat a medical symptom;

☐ Must not be used to discipline a resident or for staff convenience in the absence of a medical symptom;

☐ Must not be used because of family request in the absence of a medical symptom; and

☐ Must be the least restrictive device possible, in use for the least amount of time per day possible; and the facility must have an active plan in place to decrease usage or for eventual removal of the restraint.

NOTE: Physical restraint includes all devices and practices used by the facility that restrict freedom of movement or normal access to one's body. This includes side rails as well as facility practices such as tucking in bed sheets so tightly that the resident is unable to leave the bed. Do not rely on facility documentation alone to determine whether the device or practice is a restraint. It is a surveyor's determination whether the device or practice is restraining the resident, despite facility documentation to the contrary. If facility records state that the device (or practice) is not a restraint, but your investigation finds otherwise, the device or practice is a restraint. NOTE: If the device does not meet the definition of a physical restraint, discontinue completion of this CE. Remove the care area and replace the sampled resident with a more appropriate one (note that the device did not meet the definition of a physical restraint in the Reason for Removal window).

Would this care area have triggered without this resident?

- If the care area would have triggered without the resident, replace the one “inappropriate” resident with another who meets the criteria for QP089 – Potential Restraints (based on Resident Observation).
- If the care area would not have triggered without the resident, remove the care area for this one resident and continue with the other two sampled resident investigations.
    - If the remaining sampled residents’ devices prove to not meet the definition of a physical restraint, go through the decision process again, “would this care area have triggered without this resident?”
    - If the remaining sampled residents’ devices lead to noncompliance decisions, the team has the option to expand the sample as in any other care area investigation.

Stage 2 Critical Elements for the Use of Physical Restraints

Procedure
☐ Briefly review the assessment, care plan, and orders to identify facility interventions and to guide observations to be made.
☐ Corroborate observations by interview and record review.

Observations (if the resident is still in the facility)	
Observe whether staff consistently implement the care plan over time and across various shifts. Staff are expected to assess and provide appropriate care from the day of admission. During observations of the interventions, note and/or follow up on deviations from the care plan as well as potential negative outcomes. Determine: ☐ The type of restraint in place; ☐ The resident's reaction to the restraint; ☐ Whether the restraint is applied correctly; ☐ The services that are provided to meet resident needs while the restraint is not in place; and ☐ If the restraint affects position and body alignment, the resident is positioned appropriately. NOTE: A resident may have a device in place that the facility has stated can be removed by the resident. For safety reasons, do not ask the resident to release the device unless there is facility staff supervision.	**Notes:**

Stage 2 Critical Elements for the Use of Physical Restraints

Resident/Representative Interview	
Interview the resident, family, or responsible party to the degree possible to identify: ☐ The resident's/representative's involvement in the development of the care plan, goals, and if interventions reflect choices and preferences; ☐ The resident's/representative's awareness of care plan approaches; and ☐ Whether counseling on alternatives, consequences, and/or other interventions were offered prior to, or in addition to physical restraint use.	**Notes:**

Stage 2 Critical Elements for the Use of Physical Restraints

Staff Interviews	
Interview staff on various shifts to determine: ☐ Knowledge of specific interventions for the resident, including: ▪ The restraint(s) being used (and when use was initiated); ▪ How often and under what circumstances the restraint(s) is used; ▪ When, and for how long, the restraint is released; ▪ The potential risks of using the restraint; ▪ How the resident is monitored when the restraint is in use; and ▪ Interventions that are in place to minimize or eliminate the medical symptom or underlying problems causing the medical symptom. ☐ Knowledge of facility-specific guidelines/protocols; and ☐ Whether the nurse monitors for the implementation of the care plan, and the frequency of review and evaluation of changes in the effectiveness or resident response to the restraint. ▪ What the resident's functional ability is, such as bed mobility and ability to transfer between positions, to and from bed or chair, and to stand and toilet; and ▪ Any changes over the past year such as increased incontinence, decline in ADLs or ROM, increased confusion, agitation, and depression.	**Notes:**

Stage 2 Critical Elements for the Use of Physical Restraints

Assessment	
☐ Review the MDS, assessments, physician orders, therapy and nursing notes and other progress notes that may have assessment information related to use of the restraint. ☐ Determine whether the assessment information accurately and comprehensively reflects the status of the resident for: ▪ Specific medical symptom(s) for which the restraint is used, and a determination if the cause(s) of the medical symptom(s)s can be eliminated or reduced; ▪ Functional ability, including strength and balance (such as bed mobility and ability to transfer between positions, to and from bed or chair, and to stand and toilet); ▪ Risk/benefit—the team's determination that the risks of using the restraint are less than the risks of not using it; ▪ Other interventions to utilize instead of, and prior to, applying the restraint(s); and ▪ Potential complications or side effects of the use of the restraint such as increased incontinence, decline in ADLs or ROM, increased confusion, agitation and depression. ☐ Determine whether there was a "significant change" in the resident's condition and whether the facility conducted a significant change comprehensive assessment within 14 days. A "significant change" is a decline or improvement in a resident's status that: 1. Will not normally resolve itself without intervention by staff or by implementing standard disease-related clinical interventions, is not "self-limiting" 2. Impacts more than one area of the resident's health status; and 3. Requires interdisciplinary review and/or revision of the care plan.	**Notes:**

Stage 2 Critical Elements for the Use of Physical Restraints

Assessment	
If there was a "significant change" in the resident's condition and the facility did not conduct a significant change comprehensive assessment within 14 days, initiate **F274, Resident Assessment When Required**. If a comprehensive assessment was not conducted, also cite F272.	
1. If the condition or risks were present at the time of the required comprehensive assessment, did the facility comprehensively assess the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes (to the extent possible) of the resident's medical symptom that warrants the use of the restraint and the impact upon the resident's function, mood, and cognition? ☐ Yes ☐ **No** **F272**	
☐ **NA, condition/risks were identified after completion of the required comprehensive assessment and did not meet the criteria for a significant change MDS**	
NOTE: Although Federal requirements dictate the completion of RAI assessments according to certain time frames, standards of good clinical practice dictate that the assessment process is more fluid and should be ongoing.	
*The comprehensive assessment is not required to be completed until 14 days after admission. For newly admitted residents, before the 14–day assessment is complete, the lack of sufficient assessment and care planning to meet the resident's needs should be addressed under **F281, Professional Standards of Quality**.*	

Stage 2 Critical Elements for the Use of Physical Restraints

Care Planning	
If the comprehensive assessment was not completed (CE#1 = No), mark CE#2 "NA, the comprehensive assessment was not completed". ☐ Determine whether the facility developed a care plan that was consistent with the resident's specific conditions, risks, needs, behaviors, preferences, current standards of practice, and included measurable objectives and timetables, with specific interventions/services for use of the restraint. ☐ If the care plan refers to a specific facility treatment protocol that contains details of the treatment regimen, the care plan should refer to that protocol and should clarify any deviations from or revisions to the protocol for this resident. The treatment protocol must be available to the care givers and staff should be familiar with the protocol requirements. If care plan interventions that address aspects of the use of the restraint are integrated within the overall care plan, the interventions do not need to be repeated. ☐ Review the care plan to determine whether the plan is based upon the goals, needs, and strengths specific to the resident and reflects the comprehensive assessment. Determine whether the plan includes at least the following: ▪ The type of device to be used and under what circumstances the device is to be used; ▪ How often and under what circumstances the restraint(s) is used; ▪ How the resident is monitored when the restraint is in use; ▪ Measurable goals for the use of the restraint; ▪ Under what circumstances the restraint is released (such as for activities, for repositioning and toileting); ▪ Interventions to minimize potential functional decline due to use of the restraint and to assist the resident in reaching his/her highest level of physical and psychosocial well-being; and	**Notes:**

Stage 2 Critical Elements for the Use of Physical Restraints

Care Planning	
▪ Staff members' responsibilities in caring for the resident while the restraint is in use. ☐ If the resident refuses or resists staff interventions to treat medical symptoms with use of the restraint, determine whether the care plan reflects efforts to seek alternatives to address the needs identified in the assessment. ☐ If care plan concerns are noted, interview staff responsible for care planning as to the rationale for the current plan of care. **2. Did the facility develop a plan of care with measurable goals and interventions to address the appropriate use of the restraint, in accordance with the assessment, resident's wishes, and current standards of practice?** ☐ Yes ☐ **No** **F279** ☐ **NA, the comprehensive assessment was not completed** *The comprehensive care plan does not need to be completed until 7 days after the comprehensive assessment (the assessment completed with the CAAS). Lack of sufficient care planning to meet the needs of a newly admitted resident should be addressed under* ***F281, Professional Standards of Quality****.*	

Stage 2 Critical Elements for the Use of Physical Restraints

Care Plan Implementation by Qualified Persons	
Observe care and interview staff over several shifts and determine whether: ☐ Care is being provided by qualified staff, and/or ☐ The care plan is adequately and/or correctly implemented. **3. Did the facility provide or arrange services to be provided by qualified persons in accordance with the resident's written plan of care?** ☐ Yes ☐ **No** **F282** ☐ **NA, no provision in the written plan of care for the concern being evaluated** *NOTE: If there is a failure to provide necessary care and services, the related care issue should also be cited when there is actual or potential outcome.*	**Notes:**

Stage 2 Critical Elements for the Use of Physical Restraints

Care Plan Revision	
If the comprehensive assessment was not completed (CE#1 = No), OR, if the care plan was not developed (CE#2 = No), mark CE#4 "NA, the comprehensive assessment was not completed OR the care plan was not developed". ☐ Determine whether the staff have been monitoring the resident's response to restraint use, related to the identified medical symptoms and have evaluated and revised the care plan based on the resident's response, outcomes, and needs. Review the record and interview staff for information and/or evidence that: ▪ Staff evaluate the outcomes of the plan (the effect of care plan goals and interventions); ▪ The effects of the use of the restraint are identified and the care plan is revised/updated accordingly with more appropriate goals or interventions, based on a determination of causal or contributing/risk factors (e.g., negative reactions to the restraint such as struggling to take it off, repeatedly asking for help getting it off) functional decline, development or worsening of behavioral symptoms, development or worsening of incontinence, acute health problem, or change in condition; ▪ Staff respond in a manner to find a solution to problems related to restraint use such as the restraint making the resident more agitated, restless, or depressed; and ▪ The resident and/or the responsible person is involved in the review and revision of the plan. ☐ Determine whether the care plan was periodically reviewed and revised as necessary to ensure that the physical device was effectively treating the resident's medical symptoms.	**Notes:**

Stage 2 Critical Elements for the Use of Physical Restraints

Care Plan Revision	
4. Did the facility reassess the effectiveness of the interventions and review and revise the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident? ☐ Yes ☐ **No** **F280** ☐ **NA, the comprehensive assessment was not completed OR the care plan was not developed**	

Provision of Care and Services	
Determine whether staff have: ☐ Recognized and assessed factors affecting the resident's need for a restraint to treat the resident's medical symptoms; ☐ Defined and implemented pertinent interventions consistent with resident conditions, goals, and recognized standards of practice related to restraint use and treatment of medical symptoms; ☐ Provided the least restrictive restraint for the least time possible; ☐ Developed and implemented a plan for reduction in usage or eventual discontinuance of the restraint; ☐ Monitored and evaluated the resident's response to interventions; and ☐ Revised the approaches as appropriate. **5. Was the resident free from the inappropriate use of physical restraints?** ☐ Yes ☐ **No** **F221**	**Notes:**

Stage 2 Critical Elements for the Use of Physical Restraints

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
During the investigation of care and services provided to meet the needs of the resident, the surveyor may have identified concerns with related structure, process and/or outcome requirements, such as the examples listed below. If an additional concern has been identified, the surveyor should initiate the appropriate care area or F tag and investigate the identified concern. Do not cite any related or associated requirements before first conducting an investigation to determine compliance. ☐ **Notification of Change** — Determine whether staff: ▪ Consulted with the physician regarding significant changes in the resident's condition, including the need to alter treatment significantly or failure of the treatment plan; and ▪ Notified the resident's representative (if possible) of significant changes in the resident's condition. ☐ **Choices (Self-Determination and Participation)** — Determine whether the facility has provided the resident with the right to approve, reject, and make choices about the restraint type and restraint reduction plan. ☐ **F246, Accommodation of Needs** — Determine whether the facility has adapted the resident's physical environment as appropriate to make restraint use unnecessary (such as low bed with cushioning on the floor), bed positioning devices such as a trapeze, etc.) ☐ **Activities** — Determine whether the facility provided for an ongoing program of activities in accordance with the comprehensive assessment, reflecting physical, cognitive and/or emotional health needs. ☐ **F278, Accuracy of Assessments —** Determine whether staff that are qualified to assess relevant care areas and are knowledgeable about the resident's status, needs, strengths, and areas of decline conducted an accurate assessment.	**Notes:**

Stage 2 Critical Elements for the Use of Physical Restraints

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
☐ **F281, Professional Standards of Quality** — Conduct observations and interviews throughout stage 2 using the observation and interview probes identified above. Observe care and interview staff over several shifts to ensure consistent application of interventions that reflect current standards of practice such as: ▪ The type of restraint chosen reflects accepted clinical practice standards; and ▪ The strategies for restraint reduction (programs of activities, strength training, gait training, use of pillows/cushions, non-slip seat pads, environmental safety, etc.) reflect accepted clinical practice. ▪ If the interventions defined or care provided appear not to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident's medical symptoms that are being treated with the restraint. If there is a medical question concerning the identification of a medical symptom, contact the physician if he/she is the most appropriate person to interview. If the attending physician is unavailable, interview the medical director, as appropriate. Depending on the issue, ask about: - How it was determined that chosen interventions were appropriate; - Risks identified for which there were no interventions; - Changes in condition that may justify additional or different interventions; - How staff validated the effectiveness of current interventions; - How they maintain safety for the resident when they are out	

Stage 2 Critical Elements for the Use of Physical Restraints

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
of the restraint; and - What is their procedure for assessment and gradual discontinuation of a restraint. ☐ **Accidents** — Determine whether the restraint use has caused or is likely to cause a resident fall or other accident, either due to the resident's response to the restraint or due to misapplication of the restraint by staff. ☐ **Sufficient Nursing Staff** — Determine whether the facility had qualified staff in sufficient numbers to provide necessary care and services, based upon the comprehensive assessment and care plan, to ensure that each resident receives necessary care and services and that a restraint is not being used due to lack of sufficient staff. ☐ **F385, Physician Supervision** — Determine whether the physician has assessed, evaluated, ordered and revised orders, as appropriate, consistent with the medical symptom being treated. ☐ **Rehabilitation** — Determine whether the facility provides or obtains required therapies such as physical or occupational therapy, based on the comprehensive assessment and care plan, to ensure that residents receive rehabilitative services to address problems related to muscle strength, balance, a need for assistive devices, and other services to maintain or increase physical performance. ☐ **F498, Proficiency of Nurse Aides** — Determine whether nurse aides demonstrate competency in the application of the restraint.	

Stage 2 Critical Elements for the Use of Physical Restraints

Concerns with Independent but Associated Structure, Process, and/or Outcome Requirements	
☐ **F501, Medical Director** — Determine whether the medical director: ▪ Assisted the facility in the development and implementation of policies and procedures for the appropriate assessment, application, evaluation, discontinuation of a restraint used to treat a medical symptom, based on current standards; and ▪ Interacts with the physician supervising the care of the resident if requested by the facility to intervene on behalf of the resident. ☐ **F514, Clinical Records -** Determine whether the clinical records: ▪ Accurately and completely document the resident's status, the care and services provided in accordance with current professional standards and practices; and ▪ Provide a basis for determining and managing the resident's progress, including response to treatment, change in condition, and changes in treatment.	

Sufficient Nursing Staff Review

Facility Name: _____ Facility ID: _____ Date: _____

Surveyor Name: _____

This review is completed to determine whether the facility has sufficient nursing staff available to meet the residents' needs and has licensed registered nurses and licensed nursing staff available to provide and monitor the delivery of resident care. This review is only required if it is triggered from Stage 1 family or resident interview. The review may be used if offsite information warrants investigation (e.g. complaints). Additionally, if the team identifies quality of care concerns during any part of the survey, or from facility-provided staffing information, the team coordinator initiates this protocol for completion at the facility level. Additionally, the protocol is required to be completed during an extended survey, if not already done.

Interview/Review	Notes
Licensed Nursing Staff Schedule Review	
☐ Compare the licensed and registered nursing staff observed onsite to the staffing schedule the facility provided immediately following the Entrance Conference. If there are discrepancies between the duty roster and the staff observed onsite, ask the person in charge to explain the discrepancies. ☐ Determine whether the schedule reflects the following required coverage: • 24-hour licensed nurse, • 8-hour registered nurse, 7 days a week, and • Full-time director of nursing.	

Sufficient Nursing Staff Review

Interview/Review	Notes
Registered/Licensed Nursing Staff Interview	
Determine whether registered/licensed nursing staff are available to: ☐ Supervise and monitor the delivery of care by nursing assistants according to residents' care plans; ☐ Assess resident condition changes; ☐ Monitor dining activities to identify concerns or changes in residents' needs; ☐ Respond to nursing assistants' requests for assistance; ☐ Correct inappropriate or unsafe nursing assistants' techniques; and ☐ Identify training needs for the nursing assistants.	
Supervisory Staff Interview for Care Plan/Services Concerns	
If care plans/services were not provided for residents as needed, determine whether the facility: ☐ Assures that there are adequate staff to meet the needs of the residents; ☐ Assures that staff are knowledgeable about the needs of the residents and are capable of delivering the care as planned; ☐ Assures that staff are appropriately deployed to meet the needs of the residents; ☐ Provides orientation for new or temporary staff regarding the resident needs and the interventions to meet those needs; and ☐ Assures that staff is advised of changes in the care plan.	

Sufficient Nursing Staff Review

Interview/Review	Notes
Nursing Assistant and Other Nursing Staff Interviews	
Determine whether staff are knowledgeable about residents' care needs. Examples of care needs about which staff should be knowledgeable: ☐ Provision of fluids and foods for residents who are unable to provide these services for themselves; ☐ Provision of turning, positioning, and skin care for those residents identified to be at risk for pressure ulcers; and ☐ Provision of incontinence care as needed.	
Nursing Assistant Assignment Review	
☐ If necessary, review nursing assistant assignments in relation to the care and/or services the resident requires to meet his/her needs. *Note: Meeting the state-mandated staffing ratio, if any, does not preclude a deficiency of insufficient staff if the facility is not providing needed care and services to residents.*	
Resident, Family, and/or Other Resident Representative Interview	
☐ Inquire about staff response to requests for assistance, and ☐ Inquire about the timeliness of staff when answering call lights. ☐ Determine whether problems are facility wide, cover all shifts, or are limited to certain units or shifts, or days of the week. *Note: This information may have already been gathered by the team. Conduct additional interviews of residents, families, and staff, as necessary.*	

Sufficient Nursing Staff Review

Interview/Review	Notes
Determination of Compliance	
1. Does the facility have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident as determined by resident assessments and individual plans of care? ☐ Yes **No** ☐ **F353**	
2. Does the facility provide services by sufficient numbers of licensed nurses except when waived in accordance with F355, and other nursing personnel, on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans? ☐ Yes **No** ☐ **F353**	
3. Did the facility designate a licensed nurse to serve as a charge nurse on each tour of duty except when waived in accordance with F355? ☐ Yes **No** ☐ **F353**	
4. Does the facility use a registered nurse for at least 8 consecutive hours a day, 7 days a week, except when waived in accordance with F355? ☐ Yes **No** ☐ **F354**	
5. Did the facility designate a registered nurse to serve as the director of nursing on a full time basis, except when waived in accordance with F355? ☐ Yes **No** ☐ **F354**	
6. Did the facility ensure that the director of nursing served as a charge nurse only when the facility had an average daily occupancy of 60 or fewer residents? ☐ Yes **No** ☐ **F354**	

Abuse Prohibition Review

Facility Name: _____ Facility ID: _____ Date: _____

Surveyor Name: _____

The Abuse Prohibition task is completed only if the resident-level Care Area, Abuse, is investigated in Stage 2. If concerns regarding abuse are identified offsite (e.g., complaints) or are identified during any part of the survey, initiate both the Abuse Care Area for the resident(s) and Abuse Prohibition for the facility.

Interview/Review	Notes
Policies and Procedures Review	
☐ Obtain and review the facility's written policies to determine that they include the following key components: ▪ Screening of potential new hires; ▪ Training of employees (both new employees and ongoing training for all employees); ▪ Prevention policies and procedures; ▪ Identification of possible incidents or allegations which need investigation; ▪ Investigation of incidents and allegations; ▪ Protection of residents during investigations; and ▪ Reporting of incidents, investigations, and facility response to the results of their investigations. ☐ Evaluate how each component of the policies and procedures is operationalized. If the answers to the following questions are not obvious from the policies, interview the individual responsible for coordinating the policies and procedures. If this person is interviewed, ask how do they: ▪ Monitor staff providing and/or supervising the delivery of resident care and services to ensure that care/service is provided as needed to make certain that neglect of care does not occur. ▪ Determine which injuries of unknown origin should be investigated as alleged occurrences of abuse. ▪ Ensure that residents, families, and staff feel free to communicate concerns without fear of reprisal.	

Abuse Prohibition Review

Interview/Review	Notes
Facility Handling of Alleged Violations	
☐ Review written evidence of the facility's handling of a minimum of three alleged violations (if any exist) since the previous standard survey or the previous time this review was done by the State. Include all residents who triggered the Abuse Care Area in the review of the facility's handling of alleged violations. (If less than three (3) residents triggered and the facility has additional allegation, select additional residents to fulfill the minimum of three residents.) ☐ Determine whether the facility implemented adequate procedures for: ▪ Reporting: – Reports any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities. – Ensures that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency). – Ensures that results of all investigations are reported to the administrator or his/her designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident. ▪ Investigating: has evidence that all alleged violations are thoroughly investigated. ▪ Protection of the resident during the investigation: prevent further potential abuse while an investigation is in progress, and; ▪ Provision of corrective action: takes appropriate corrective action for verified violations. ☐ Determine whether the facility re-evaluated and revised applicable procedures as necessary.	

Abuse Prohibition Review

Interview/Review	Notes
Resident/Family Interviews	
Interview several residents and families regarding their awareness of to whom and how to report allegations, incidents, and/or complaints, unless this information has already been obtained. **Name of Person Interviewed** **Date/Time Interviewed** **Aware** ☐ **Not Aware** ☐	
Name of Person Interviewed **Date/Time Interviewed** **Aware** ☐ **Not Aware** ☐	
Name of Person Interviewed **Date/Time Interviewed** **Aware** ☐ **Not Aware** ☐	
Name of Person Interviewed **Date/Time Interviewed** **Aware** ☐ **Not Aware** ☐	

Abuse Prohibition Review

Interview/Review	Notes
Direct-care Staff Interviews	
Interview at least five (5) direct care staff, representing all three shifts, including activity staff and nursing assistants, to determine whether each staff member is: ● Trained in, and knowledgeable about, how to appropriately intervene in situations involving residents who have aggressive or catastrophic reactions. ● Knowledgeable regarding what, when, and to whom to report, according to the facility policies.	
1. Name of Staff Interviewed Date/Time Interviewed Discipline Shift	
2. Name of Staff Interviewed Date/Time Interviewed Discipline Shift	
3. Name of Staff Interviewed Date/Time Interviewed Discipline Shift	
4. Name of Staff Interviewed Date/Time Interviewed Discipline Shift	
5. Name of Staff Interviewed Date/Time Interviewed Discipline Shift	

Abuse Prohibition Review

Interview/Review	Notes
Front-line Supervisor Interviews	
Interview at least three (3) front-line supervisors of staff who interact with residents (Nursing, Dietary, Housekeeping, Activities, Social Services). Determine how they monitor: ● Provision of care/services; ● Staff/resident interactions; ● Deployment of staff to meet the residents' needs; and ● Potential for staff burnout, which could lead to resident abuse.	
1. Name of Supervisor Interviewed Date/Time Interviewed Discipline Shift	
2. Name of Supervisor Interviewed Date/Time Interviewed Discipline Shift	
3. Name of Supervisor Interviewed Date/Time Interviewed Discipline Shift	

Abuse Prohibition Review

Interview/Review	Notes
Pre-screening of New Employees	
Obtain a list of all employees hired within the previous four (4) months, and select five (5) employees from this list. Ask the facility to provide written evidence that the facility conducted pre-screening of the five (5) employees based on the regulatory requirements at 42 CFR 483.13(c). Determine whether the facility has NOT employed individuals meeting either of the following criteria: ● Who have been found guilty of abusing, neglecting, or mistreating residents by a court of law, or ● Who have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property.	
1. Name of New Employee **Hire Date** **Written Evidence of Pre-screening** Yes No	
2. Name of New Employee **Hire Date** **Written Evidence of Pre-screening** ☐ Yes ☐ No	
3. Name of New Employee **Hire Date** **Written Evidence of Pre-screening** ☐ Yes ☐ No	
4. Name of New Employee **Hire Date** **Written Evidence of Pre-screening** ☐ Yes ☐ No	
5. Name of New Employee **Hire Date** **Written Evidence of Pre-screening** ☐ Yes ☐ No	

Abuse Prohibition Review

Determination of Compliance	
1. Did the facility follow the requirements for: ● **Employment of individuals** ● **Reporting, and** ● **Investigation of alleged violations?** ☐ Yes ☐ **No** **F225**	
2. Did the facility develop and implement policies and procedures in the areas of screening, training, prevention, identification, investigation, protection, and reporting? ☐ Yes ☐ **No** **F226**	

Caring for People with Dementia and Problem Behaviors: A Step-by-Step Evidence-Based Approach

Go to www.healthcare.uiowa.edu/IGEC for more information and references

This approach begins with evaluation and treatment of common causes of behaviors, then uses non-drug approaches to management. Antipsychotics are reserved for severe cases due to potential side effects, which include death. **Document** all behaviors, symptoms, interventions, and outcomes. Sections are color-coded to help guide you to accompanying resources, which are *italicized* in ***bold***. Blue=Evaluation. Yellow=Non-drug. Pink=Antipsychotics.

1. Evaluation

- Clearly characterize and document behavior or symptom, including frequency, severity, triggers, and consequences.
- Consider environmental factors and triggers. Are they modifiable?
- Perform medical evaluation (delirium, medical conditions, pain, depression, drugs). See ***Common Causes of Problem Behaviors*** *(on other side)*, ***Delirium Assessment and Management***, and ***Drugs that May Cause Delirium or Problem Behaviors***.
  —Address these causes if they are identified.
- Discuss with family any history that may explain or manage the behavior, e.g. patient habits, preferences, activities they enjoy.

2. Manage with non-drug approaches

- Engage in meaningful activities, redirect, clear communication, etc. See ***Non-Drug Management***.

3. Does the behavior pose risks to the resident or others, or is the resident severely distressed?

- If yes, non-drug approaches fail, and medical work-up does not reveal another cause, consider drug therapy targeted at behaviors. See ***Antipsychotic Prescribing Guide.***

4. Monitor drug therapy for effectiveness and side effects. Continue non-drug management.

5. Consider antipsychotic dose reduction or discontinuation if the drug is not effective, side effects occur, or the behaviors have been manageable. See ***Antipsychotic Prescribing Guide.***
Re-assess need for drug therapy periodically, at least twice a year.

6. Use prevention and maintenance approaches to reduce further exacerbations.

- Clear communication, meaningful activities, etc.
- Simplify and create a calm environment
- Manage medical conditions, depression, pain, etc.
- See ***Non-Drug Management***

Evaluation of Problem Behaviors in People with Dementia

Common Causes of Problem Behaviors

Physical:

- Pain
- Hunger
- Constipation, urinary retention
- Fatigue, insomnia, poor sleep

Psychological:

- Anxiety, fear, depression
- Impaired speech, frustration
- Boredom
- Autonomy/privacy

Environmental:

- Caregiver approaches
- Institutional routines, expectations and demands
- Misinterpretation of events/setting
- Over/under-stimulation
- Changes from normal routine

Delirium, secondary to medical issues such as:

- Medication side effects
- Infections
- Metabolic/electrolyte disturbances
- Dehydration

Consider the Following Assessments

Check Vitals:

- Temperature, pulse, blood pressure, respiration, oxygen saturation

Physical Assessment:

- Signs of constipation or urinary retention
- Changes in breath sounds
- Peripheral edema
- Fluid status: orthostatic blood pressure, mucous membranes

Common Sources of Pain:

- Bed sores, other skin lesions, eye pain from corneal abrasion
- Joint pain, other musculoskeletal pain, foot pain (poorly fitting shoes)
- Oral pain related to dentures/mouth ulceration

Sensory:

- Hearing: check hearing aids, ear wax
- Vision: check glasses

Delirium Assessment:

- See ***Delirium Assessment and Management***

Urinalysis, or other urinary symptoms

Blood glucose, CBC with differential, electrolytes if appropriate

Drug side effects:

- See ***Drugs that May Cause Delirium or Problem Behaviors***

Recent changes: environmental, routine, family, drugs, medical

Delirium Assessment and Management

Definition of Delirium
Acute onset of impaired attention, cognition (memory, orientation, language), consciousness, perception, behaviors, and/or emotions that may fluctuate, **have a medical cause**, and are not due to dementia. Often called "acute confusion." Terminal delirium: irreversible and can occur in the days before dying; antipsychotics used more liberally for comfort in these cases.

1. Is the person more confused today than usual? If yes, the person might have delirium and a brief cognitive assessment should be done.

2. Brief Cognitive Assessment: People with the level of dementia indicated can usually perform these attention-based tasks, while those with delirium cannot. Severe dementia is difficult to test. Change in cognitive status is usually determined by observation. Compare vs. recent baseline.

- Mild Dementia: list days of week and months of year backwards.
- Moderate Dementia: count backwards from 20 to 1.

3. Delirium Screening: See the screening tool, derived from the Confusion Assessment Method (CAM), CAM-ICU, and MDS, on the ***other side***.

4. If the screening suggests delirium, assess and treat possible causes:

- Vitals (pulse, blood pressure, temperature, respiratory rate, pulse-oximetry, pain).
- Physical examination to diagnose infections or other acute medical conditions such as constipation, pneumonia, pressure ulcers, MI (heart attack), CVA/TIA (stroke).
- Basic laboratory evaluation (urinalysis, creatinine, sodium, potassium, calcium, glucose, CBC with differential).
- Review medications with particular attention to anticholinergics, benzodiazepines, or new medications (see ***Drugs that May Cause Delirium or Problem Behaviors).*** Discontinue if benefit does not outweigh potential harm.
- Review restraints (foley catheter, IV lines, other tethers) and discontinue if benefit doesn't outweigh potential harm.
- Assess pain—Is pain management adequate and appropriate?

5. Use non-drug management:

- Sleep: Allow continuous sleep at night. Keep noise down. Recognize that an altered sleep-wake cycle is often a symptom of delirium.
- Orientation: Orient to date and place. Clock and calendar in room. Light on from 7 a.m. to 7 p.m. (sunrise to sunset). Always introduce yourself.
- Environment: Keep hearing aids and glasses accessible. Offer beverage of choice frequently for hydration. Encourage low-key family visits.

6. Use antipsychotic short-term for agitation or distressing psychotic symptoms, e.g. hallucinations. See ***Antipsychotic Prescribing Guide***.

- E.g. haloperidol 0.5 mg PO/IM q1 hour PRN agitation or distressing hallucinations. Can double dose if ineffective. Schedule once or twice daily dose based on the total amount needed to achieve treatment goal in 24 hours. When delirium resolves, discontinue the antipsychotic.

Delirium Screening Tool

Suspect delirium if answer is yes on items 1 + 2 + (3 or 4) below.
First perform a Brief Interview of Mental Status, Staff Assessment, or brief cognitive test described on ***other side***.

1) Acute onset [ ] yes [ ] no [ ] uncertain*
Is there evidence of an acute change in mental status from the person's baseline?
*If uncertain, gather more information.

2) Inattention [ ] yes [ ] no [ ] uncertain*
Does the person have difficulty focusing attention (i.e., easily distracted or can't follow what is being said)?
*If uncertain, perform an Attention Screening Examination (ASE):

Directions: Say to the patient, **"I am going to read you a series of 10 letters. Whenever you hear the letter 'A,' indicate by squeezing my hand."** Read letters from the following letter list in a normal tone.

S A V E A H A A R T

Scoring: Errors are counted when patient fails to squeeze on the letter "A" and when the patient squeezes on any letter other than "A." Inattention is present if **3** or more errors are observed.

3) Disorganized thinking [ ] yes [ ] no [ ] uncertain*
Is the person's thinking disorganized or incoherent, as evidenced by rambling or irrelevant conversation, unclear or illogical flow of ideas, unpredictable switching from subject to subject?
*If uncertain, conduct the following question/command assessments:

Questions:
1. **Will a stone float on water?**
2. **Are there fish in the sea?**
3. **Does one pound weigh more than two pounds?**
4. **Can you use a hammer to pound a nail?**

Score: Patient earns 1 point for each correct answer out of 4.

Command:
Say to patient: **"Hold up this many fingers"** (Examiner holds two fingers in front of patient then puts them back down) **"Now do the same thing with the other hand"** (Not repeating the number of fingers).
Score: Patient earns 1 point if does entire command.
Disorganized thinking is present if combined scores are less than 4.

4) Altered Level of Consciousness [ ] yes [ ] no
Is the patient anything other than alert, calm and cooperative (at current time)? This may include **vigilant** (easily startled), **lethargic** (frequently dozed off when asked questions), or **stuperous** (very difficult to arouse and keep aroused), or **comatose** (could not be aroused).

Psychomotor retardation: (sluggishness, staring into space, staying in one position, moving slowly) may also count as a "yes" for this domain.

Drugs that May Cause Delirium or Problem Behaviors

This reference card lists common and especially problematic drugs that may cause delirium or contribute to problem behaviors in people with dementia. This does not always mean the drugs should not be used, and not all such drugs are listed. If a patient develops delirium or has new problem behaviors, a careful review of all medications is recommended.

Be especially mindful of new medications.

Anticonvulsants

All can cause delirium, e.g.
Carbamazepine – *Tegretol*
Gabapentin – *Neurontin*
Levetiracetam – *Keppra*
Valproic acid – *Depakote*

Pain

All opiates can cause delirium if dose is too high or increased too quickly.
Codiene – *Empirin, many others*
Fentanyl – *Duragesic*
Hydrocodone – *Lortab*
Hydromorphone – *Palladone, Dilaudid*
Meperidine – *Demerol*
Morphine – *MS Contin, MS IR*
Oxycodone – *OxyContin*
Tramadol – *Ultram*

Parkinson's/Restless Legs

Most Parkinson's disease medications can cause psychosis.
Amantadine – *Sinemet*
Bromocriptine – *Parlodel*
Levodopa – *Symadine, Symmetrel*
Pramipexole – *Mirapex*
Rasagiline – *Azilect*
Ropinrole – *Requip*
Rotigotine – *Neupro*
Selegiline – *Anipryl*

Steroids

Corticosteroids *e.g.*
-**Prednisone** – *Deltasone, etc.*
Testosterone – *Androgel, etc.*

Psychiatric

All psychiatric medications should be reviewed as possible causes, as effects are unpredictable. Notable offenders include:
Benzodiazepines e.g.
-**Alprazolam** – *Xanax*
-**Clonazepam** – *Klonopin*
-**Lorazepam** – *Ativan*
Stimulants e.g.
-**Methylphenidate** – *Ritalin*
Hypnotics (Sleep Medications) e.g.
-**Eszopiclone** – *Lunesta*
-**Zaleplon** – *Sonata*
-**Zolpidem** – *Ambien*
Tricyclic Antidepressants e.g.
-**Amitriptyline** – *Elavil*
-**Doxepin** – Silenor, *Sinequan*
-**Nortriptyline** – *Pamelor*

Antibiotics/Antivirals

Difficult to distinguish drug effects from effects of infection. Others may contribute as well.
Antiviral
-**Acyclovir** – *Zovirax*
-**Valacyclovir** – *Valtrex*
Fluoroquinolones e.g.
-**Levofloxacin** – *Levaquin*
-**Ciprofloxacin** – *Cipro*
Metronidazole – *Flagyl*
Vancomycin – *Vancocin*

Cardiac Medications

Antiarrhythmics
Digoxin – Digitek, Lanoxin

Drugs that May Cause Delirium or Problem Behaviors

Anticholinergics—all drugs on this side of the card. May impair cognition and cause psychosis. Drugs available over-the-counter marked with *

Tricyclic Antidepressants

Amitriptyline – *Elavil*
Clomipramine – *Anafranil*
Desipramine – *Norpramin*
Doxepin – *Sinequan*
Imipramine – *Tofranil*
Nortriptyline – *Aventyl, Pamelor*

Antihistamines / Allergy / Cough & Cold Medicines

***Azelastine** – *Astepro*
***Brompheniramine** – *Bromax, Bromfed, Lodrane*
Carbinoxamine – *Rondec*
***Chlorpheniramine** – *Chlor-Trimeton*
***Clemastine** – *Tavist*
Cyproheptadine – *Periactin*
***Dexbrompheniramine** –*Drixoral*
Dexchlorpheniramine – *Polaramine*
***Diphenhydramine** – *Benadryl*
Hydroxyzine – *Atarax, Vistaril*
Olopatadine – *Pataday, Patanol*
Promethazine – *Phenergan*
Triprolidine – *Triacin-C*

Motion Sickness / Dizziness / Nausea

***Dimenhydrinate** – *Dramamine*
***Meclizine** – *Antivert, Dramamine less drowsy*
Promethazine – *Phenergan*
***Scopolamine** – Scopace, *Transderm -Scop, Maldemar*
Trimethobenzamide – *Tigan*

Movement Disorders

Benztropine – *Cogentin*
Trihexyphenidyl – *Artane*

Bladder Antispasmodics

Darifenacin – *Enablex*
Flavoxate – *Urispas*
Oxybutynin – *Ditropan*
Solifenacin – *VESIcare*
Tolterodine – *Detrol*
Trospium – *Sanctura*

Insomnia / Sleep

***Diphenhydramine** – *Sominex, Tylenol-PM, others*
***Doxylamine** – *Unisom, Medi-Sleep*

Stomach and GI Tract

Ulcer and Reflux:
***Cimetidine** – *Tagamet*
Glycopyrrolate – *Robinul*
***Ranitidine** – *Zantac*

GI Antispasmodics:
Atropine – *Sal-Tropine, Atreza*
Belladonna Alkaloids – *Donnatal, Bellamine S, Bel-Tabs, B&O supprettes*
Clidinium – *Librax*
Dicyclomine – *Bentyl*
Hyoscyamine – *Levsin, Anaspaz, Cytospaz*
Methscopolamine – *Pamine, Pamine Forte*
Propantheline – *Pro-Banthine*

Anticholinergic Antipsychotics

Chlorpromazine – *Thorazine*
Clozapine – *Clozaril*
Loxapine – *Loxitane*
Olanzapine – *Zyprexa*
Pimozide – *Orap*
Quetiapine – *Seroquel*
Thioridazine – *Mellaril*

Non-Drug Management of Problem Behaviors and Psychosis in Dementia

Step 1: Assess & Treat Contributing Factors

FOCUS on one behavior at a time

- Note how often, how bad, how long, & document specific details
- Ask: What is really going on? What is causing the problem behavior? What is making it worse?

IDENTIFY what leads to or triggers problems

- **Physical***:* pain, infection, hunger/thirst, other needs?
- **Psychological***:* loneliness, boredom, nothing to do?
- **Environment***:* too much/too little going on; lost?
- **Psychiatric***:* depression, anxiety, psychosis?

REDUCE, ELIMINATE things that lead to or trigger the problems

- Treat medical/physical problems
- Offer pain medications for comfort or to help cooperation
- Address emotional needs: reassure, encourage, engage
- Offer enjoyable activities to do alone, 1:1, small group
- Remove or disguise misleading objects
- Redirect away from people or areas that lead to problems
- Try another approach; try again later
- Find out what works for others; get someone to help

DOCUMENT outcomes

- If the behavior is reduced or manageable, go to Step 3
- If the behavior persists, go to Step 2

Step 2: Select & Apply Interventions

CONSIDER retained abilities, preferences, resources

- Cognitive level
- Physical functional level
- Long-standing personality, life history, interests
- Preferred personal routines, daily schedules
- Personal/family/facility resources

DEVELOP a Person-Centered plan

- Adjust caregiver approaches
- Adapt/change the environment
- Select/use best evidence-based interventions tailored to the person's unique needs/interests/abilities

Step 2: Select & Apply Non-pharmacological Interventions, continued

ADJUST your approach to the person

- **Personal approach:** cue, prompt, remind, distract; focus on person's wishes, interests, concerns; use/avoid touch as indicated. Do not try to reason, teach new routines, or ask to "try harder"
- **Daily routines**: simplify tasks and put them in a regular order; offer limited choices; use long-standing patterns & preferences to guide routines & activities
- **Communication style**: simple words and phrases; speak in short sentences, speak clearly; wait for answers; make eye contact; monitor tone of voice and body language
- **Unconditional positive regard**: do not confront, challenge or explain misbeliefs (hallucinations, delusions, illusions); accept belief as real to the person; reassure, comfort, and distract

ADAPT or CHANGE the environment

- **Eliminate things that lead to confusion**: clutter, TV, radio, noise, people talking; reflections in mirrors/dark windows; misunderstood pictures or decor
- **Reduce things that cause stress**: caffeine; extra people; holiday decorations; public TV
- **Adjust stimulation**: if overstimulated—reduce noise, activity, and confusion; if under-stimulated (bored)—increase activity and involvement
- **Help with functioning**: signs, cues, pictures help way-finding; increase lighting to reduce misinterpretation
- **Involve in meaningful activities**: personalized program of 1:1 and small group or large group as needed
- **Change the setting**: secure outdoor areas; decorative objects; objects to touch and hold; homelike features; smaller, divided recreational and dining areas; natural and bright light; spa-like bathing facilities; signs to help way-finding

SELECT and USE evidence-based interventions

- Work with the team to fit the intervention to the person
- Check care plan for additional information
- Contact supervisor with problems/issues

Step 3. Monitor Outcomes & Adjust Course as needed

- Track behavior problems using rating scale(s)
- Assure adequate "dose" (intensity, duration, frequency) of interventions
- Adapt/add interventions as needed to get the best possible outcomes
- Make sure all people working with the person understand and cooperate with the treatment plan and are trained as needed

Dementia Antipsychotic Guide for Care Providers

General Guidelines:

1. **Look for reversible causes** of challenging behaviors or other target symptoms prior to asking for a drug to treat them. Examples include medical problems, drugs, modifiable stressors.
2. **Try non-drug strategies first.** Keep using these strategies even if antipsychotics are used.
3. **Clearly document treatment targets** (symptoms) before and after a strategy or drug is tried. Include frequency, severity, time of day, and environmental or other triggers of symptoms.
4. **Use of an antipsychotic should be well-justified.** The treatment target symptom must present **a danger to the person or others**, or cause the person to have one of the following:
   - inconsolable or persistent distress
   - a major decline in function
   - substantial difficulty receiving needed care

   Appropriate and inappropriate treatment targets from CMS are listed in the boxes below. Generally antipsychotics should not be used for inappropriate treatment targets.
5. **Monitor for effectiveness and side effects.** (see other side)
6. **If the drug doesn't help, it should be stopped.**

Appropriate Antipsychotic Treatment Targets:

- **Aggressive behavior** (especially physical)
- **Hallucinations:** seeing, hearing, smelling, tasting or feeling things that seem real to the person but not others. For example, hearing voices or seeing people who aren't there.
- **Delusions:** false personal beliefs that a person has in spite of evidence they aren't true. For example, thinks husband or wife is having an affair without reason, or family members are imposters. Note: memory problems are sometimes mistaken for delusions, e.g. thinks people are stealing items that were misplaced and forgotten.
- **Other severe distress** as described above in #4 General Guidelines

Inappropriate Antipsychotic Treatment Targets:

- Wandering
- Not being social or friendly
- Poor self-care
- Restlessness
- Nervousness
- Fidgeting
- Mild anxiety
- Impaired memory
- Uncooperativeness without aggressive behavior
- Not caring about what is going on around them
- Speech or behaviors that are not dangerous to the person or others

Dementia Antipsychotic Guide
Monitoring for Response and Side Effects

Monitoring for Response

-Clearly document treatment target symptoms and whether they improve. The drug should be stopped if it does not help. Symptoms may change over time, with or without drug treatment.
-Do not expect an immediate response. Sedation from the drug may explain much of any effect seen in the first few days.
-Do not ask for higher doses too quickly. It may take several days to a week or more to see the full effect, depending on the drug (talk to prescriber for details). **Higher doses cause more side effects.**

Monitoring for Side Effects

Side Effect	Report to RN or prescriber if these problems occur
Movement Side Effects	Tremors, tight muscles, changes in walking or falls, abnormal movements like face or eye twitching, drooling.
Central Nervous System	
Sedation	Sleepiness, slow to respond, hard to wake up.
Confusion, delirium, or other cognitive worsening	Worsening mental status compared to normal. Seems more confused; sedated or agitated; worsened communication abilities; problems paying attention; slower movements or speech. These may be a sign of a serious medical illness or a drug side effect.
Worsening psychotic symptoms (delusions or hallucinations)	Hallucinations: seeing, hearing, smelling, tasting or feeling things that aren't there. Delusions: false fixed beliefs that a person holds in spite of evidence they aren't true. Antipsychotics usually lessen these symptoms, but sometimes make them worse.
Cardiovascular / Metabolic	
Rapid drop in blood pressure on standing	Signs of dizziness or falls. Check an orthostatic blood pressure by checking the blood pressure when lying down then again shortly after standing. Drugs sometimes cause an unwanted drop in blood pressure.
Swelling	Swelling is most common in the legs and ankles, but can occur in other places.
Weight gain	Big increases in appetite. Hungry even after eating. Unwanted increases in weight.
High blood sugar	Confusion, increased thirst, frequent urination, unusual tiredness, blurred vision. Blood sugar can be checked to see if this might be the cause of these symptoms.
Urinary Symptoms	Changes in frequency—increased, or decreased with urinary retention. Worsened incontinence. Pain on urination. May be infection or drug–related problem.
Constipation	Fewer bowel movements. Hard stools. Poor appetite. Gut pain or distention.

Dementia Antipsychotic Prescribing Guide

General Guidelines:

1. **Rule out reversible causes** prior to using a drug.
2. **Try non-drug management strategies first.**
3. **Clearly document treatment targets** (symptoms) before and after a treatment strategy is tried.
4. **Justify use of an antipsychotic.** The treatment target symptom must present **a danger to the person or others**, or cause the patient to experience one of the following:
   - inconsolable or persistent distress
   - a significant decline in function
   - substantial difficulty receiving needed care
5. **See Guidance for Special Populations,** if the patient has frontotemporal dementia, Parkinson's disease, Lewy body dementia, renal impairment, or hepatic impairment.
6. **Consider the impact of side effects on comorbidities** when choosing a drug, and **start with a low dose.**
7. **If the drug doesn't help, stop it** (use appropriate tapering).

Appropriate antipsychotic treatment targets:*

- Aggressive behavior (especially physical)
- Hallucinations (if distressing)
- Delusions (note: memory problems are often mistaken for delusions, e.g. thinks people are stealing lost items)
- Severe distress as described above in #4 General Guidelines

Inappropriate antipsychotic treatment targets:*

- Wandering
- Unsociability
- Poor self-care
- Restlessness
- Nervousness
- Fidgeting
- Mild anxiety
- Impaired memory
- Uncooperativeness without aggressive behavior
- Inattention or indifference to surroundings
- Verbal expressions or behaviors that do not represent a danger to the resident or others

*According to CMS regulations for long-term care facilities

Antipsychotic Efficacy

Evidence supports modest symptom improvements with **aripiprazole**, **haloperidol*, olanzapine, quetiapine, and risperidone**, but not with use of other antipsychotics in dementia. All antipsychotics appear to increase risk of death. The table below summarizes the strength of evidence supporting the efficacy of each **atypical antipsychotic** for different symptom domains.

	Aripiprazole	Olanzapine	Quetiapine	Risperidone
Dementia overall	+ +	+	+	+ +
Dementia psychosis	+	+ / -	+ / -	+ +
Dementia agitation	+	+ +	+ / -	+ +

+ + = moderate or high evidence of efficacy
+ = low or very low evidence of efficacy
+/ - = mixed results

*Haloperidol has shown efficacy for aggression in randomized trials

Adverse Effects Comparison Table

Drug (daily dose range)	Aripiprazole *Abilify* (2-10 mg)	Haloperidol *Haldol* (0.25-2 mg)	Olanzapine *Zyprexa* (2.5-7.5 mg)	Quetiapine *Seroquel* (12.5-150 mg)	Risperidone *Risperdal* (0.25-2 mg)
***Movement Side Effects*[1]**	■■	■■■	■■	■	■■
Central Nervous System					
Sedation	■■	■■	■■■	■■■	■■
Confusion, delirium, cognitive worsening	■	0	■■	■	■
Worsening psychotic symptoms	0	0	■	0	0
Cardiovascular/Metabolic					
Orthostatic hypotension	■?	■■	■	■?	■?
Edema	■?	0	■	0	■■
Weight gain/glucose ↑	0	■?	■■■	■	■■
Triglyceride ↑	0	0	■■■■	■■■	0
Urinary incontinence, UTI	■■■	■■	■■	■■	■■

■ = more boxes indicates greater risk. Colors are darker with increasing risk.
■? = evidence poor in dementia, but evidence in other conditions indicates some risk
0 = no clear evidence that the drug causes this side effect in a clinically important way, or very rarely
[1]Movement side effects = Parkinsonism, akathisia (restlessness), dystonia, tardive dyskinesia

Dementia Antipsychotic Prescribing Guide
Dosing, Special Populations

Dosing

Timing: Usually once daily at night or prior to sundowning. Beware of sedation-related adverse events if given earlier than bedtime.

	Starting Dose (mg/day)	Max Dose for Maintenance* (mg/day)	Special Dosage Forms**
Aripiprazole	2-5	10	ODT, L , IM
Haloperidol	0.25	2	L , IM
Olanzapine	2.5-5	7.5	ODT, L , IM
Quetiapine	12.5-25	150	XR
Risperidone	0.25-0.5	2	ODT, L

*per CMS regulations for long-term care facilities. Doses for acute treatment sometimes exceed maintenance doses.

**ODT = orally dissolving tablet, L = liquid, IM = short-acting intramuscular, XR = extended release.

Dosage forms:

- Regular tablets can be crushed and mixed with food if needed.
- IM antipsychotics used only in emergencies when oral is refused.
- Topical forms, e.g. compounded creams, not recommended. No evidence to guide proper dosing. Absorption is unknown and unpredictable.

Guidance for Special Populations

Frontotemporal dementia: Some evidence for trazodone. Mixed for SSRIs. See Iowa Geriatric Education Center website for details.

Parkinson's disease (PD) and Lewy body dementia (LBD):

-**Movement disorder treatments** (dopamine agonists, carbidopa-levodopa, anticholinergics) can cause **psychosis or delirium**. Prior to antipsychotic use, consider reducing the dose of these drugs to see if the psychosis or behaviors resolve or become manageable.

-People with PD and LBD are **very sensitive to adverse effects**, particularly **movement side effects and neuroleptic malignant syndrome**. If antipsychotics are used, expert guidelines recommend **quetiapine or clozapine** due to lower movement side effect risk.

Renal Impairment: Reduce risperidone dose. Titrate slowly.

Hepatic Impairment: Possibly reduce dose of olanzapine, quetiapine, risperidone. Caution with all.

Dementia Antipsychotic Prescribing Guide
Monitoring for Response and Adverse Effects

Monitoring for Response

-Clearly document treatment target symptoms. If the drug does not help, discontinue the drug. These symptoms may also change over time, with or without drug treatment.

-Do not expect an immediate response. Sedation may explain much of any immediate effect that is seen. Response may take 2-4 weeks.

-Do not increase doses too quickly if the patient doesn't respond right away. At a stable dose, drug blood levels may rise for several days to a week or more before reaching a steady state level.

Increased doses lead to increased side effects.

Monitoring for Adverse Effects

Other possible adverse effects include: falls, constipation, urinary tract infection, urinary incontinence or retention, stroke, arrhythmias, and neuroleptic malignant syndrome.

Side Effect	Monitoring
Movement Side Effects	Observation for tremor, gait changes, difficulty swallowing, signs of parkinsonism, restlessness (akathisia), unusual movements (tardive dyskinesia).
	Abnormal Involuntary Movement Scale (AIMS) at baseline, every 6 months, or if movement side effects are suspected.
Central Nervous System	
Sedation	Observation, sedation scale if needed.
Confusion, delirium, or other cognitive worsening	Observation for mental status or behavior changes.
	Delirium screening tool, e.g. CAM (Confusion Assessment Method) if delirium is suspected.
Psychotic symptoms	Observation for worsening symptoms.
Cardiovascular / Metabolic	
Orthostatic hypotension	Observation for signs of dizziness or falls.
	Orthostatic blood pressure (if feasible). Monthly, or if signs of dizziness occur. More frequent on initiation or after dose increase.
Edema	Observation for swelling of extremities.
Weight gain	Monthly weight. Consider weekly for 1 month if overweight. Watch for increased appetite.
Hyperglycemia / Diabetes	Blood glucose at baseline, 3 & 6 months, then q6 months. Also PRN symptoms or mental status change. Monitor symptoms: increased thirst, urination, hunger, weakness.
Triglyceride ↑	Fasting blood lipid panel at baseline, 3 & 6 months, then q6 months. Especially if patient has cardiovascular risk factors: e.g. obesity, diabetes, hyperlipidemia.

Algorithm for Treating Behavioral and Psychological Symptoms of Dementia (aka Problem Behaviors)

STEP 1: IDENTIFY, ASSESS, AND TREAT CONTRIBUTING FACTORS[a]

- Determine and document frequency, duration, intensity, and characteristics of **each** problem behavior
- Identify, assess, treat or eliminate **ANTECEDENTS** and **TRIGGERS**[b]

Unmet physical needs?
- Pain
- Infection/illness
- Dehydration/nutrition
- Sleep disturbance
- Medication side-effects
- Sensory deficits
- Constipation
- Incontinence/retention

Unmet psychological needs?
- Loneliness
- Boredom
- Apprehension, worry, fear
- Emotional discomfort
- Lack of enjoyable activities
- Lack of socialization
- Loss of intimacy

Environmental causes?
- Level/type of stimulation: noise, confusion, lighting
- Caregiver approaches
- Institutional routines, expectations
- Lack of cues, prompts to function & way-find

Psychiatric causes?
- Depression
- Anxiety
- Delirium
- Psychosis
- Other mental illness

Monitor outcomes to assure full treatment response
- *If problem behavior persists after antecedents are adequately treated*, **use NON-DRUG INTERVENTIONS**

STEP 2: SELECT AND APPLY NON-PHARMACOLOGICAL INTERVENTIONS

- Select interventions based on the TYPE of problem and ASSESSMENT of retained abilities, preferences, and resources
  - ✓ Cognitive level
  - ✓ Physical function level
  - ✓ Long-standing personality, life history, interests/abilities
  - ✓ Preferred personal routines and daily schedule
  - ✓ Personal/family/facility resources
- Train staff to use selected interventions appropriately/following best practice and evidence guidelines
- Tailor intervention to individualized needs, combining approaches and interventions to promote comfort & function
- Monitor outcomes using rating scales to quantify behaviors

Adjust caregiver approaches
- ***Personal approach***: cue, prompt, remind, distract (treats, activities); focus on person's wishes, interests, concerns; use/avoid touch as indicated; avoid trying to reason, teach new routines, or ask to "try harder"
- ***Daily routines***: simplify, sequence tasks; offer limited choices; use long-standing history & preferences to guide
- ***Communication style***: simple words and phrases; speak clearly; wait for answers; make eye contact; monitor tone of voice/other nonverbal messages
- ***Unconditional positive regard***: do not confront, challenge or "explain" misbeliefs (hallucinations, delusions, illusions); accept belief as "real" to the person; reassure, comfort, and distract
- ***Involvement/engagement***: tailor activities to increase involvement/reduce boredom; individualize social and leisure activities

Change the environment
- ***Eliminate misleading stimuli***: clutter, TV, radio, noise, people talking; reflections in mirrors/dark windows; misunderstood pictures/decor
- ***Reduce environmental stress***: caffeine; extra people; holiday decorations; public TV
- ***Adjust stimulation***: reduce noise, activity, confusion if over-stimulated; increase activity/involvement if under-stimulated (bored)
- ***Enhance function***: signs, cues, pictures to promote way-finding; increase lighting to reduce misinterpretation
- ***Involve in meaningful activities***: personalized program of 1:1 and small group vs. large group
- ***Adapt the physical setting***: secure outdoor areas; decorative tactile objects; homelike features; smaller, segmented recreational and dining areas; natural and bright light; spa-like bathing facilities; signage to promote way-finding

Use Evidence-Based Interventions[c]
- ***Agitated/Irritable***: Calm, soothe, distract
  - ✓ Individualized music
  - ✓ Aromatherapy (e.g., lavender oil)
  - ✓ Simple Pleasures (see website)
  - ✓ Pet therapy
  - ✓ Physical exercise/outdoor activities
- ***Resistant to Care***: Identify source of threat; change routines and approaches
- ***Wandering/Restless/Bored***: Engage, distract
  - ✓ "Rest stations" in pacing path
  - ✓ Adapt environment to reduce exit-seeking
  - ✓ Physical exercise/outdoor activities
  - ✓ Simple Pleasures
- ***Disruptive Vocalization***: Distract, engage
  - ✓ Individualized music; Nature sounds
  - ✓ Presence therapy: tapes of family
- ***Apathetic/Withdrawn***: Stimulate, engage
  - ✓ Individualized music
  - ✓ Simple Pleasures
- ***Repetitive Questions/Mannerisms***: Reassure, address underlying issue, distract
  - ✓ Validation therapy/therapeutic lying
  - ✓ Simple Pleasures
- ***Depression/Anxiety***: Reassure, engage
  - ✓ Physical exercise
  - ✓ Pleasant activities
  - ✓ Cognitive stimulation therapy
  - ✓ Wheelchair biking

STEP 3: MONITOR OUTCOMES AND ADJUST COURSE AS NEEDED

- Quantify behavioral symptoms using rating scale(s)
- Assure adequate "dose" (intensity, duration, frequency) of interventions
- Provide/reinforce staff training and development activities to assure full understanding and cooperation in daily care
- Adapt/add interventions as needed to promote optimal outcomes
- Consider antipsychotics for persistent and severe cases that meet criteria for use. See ***Antipsychotic Prescribing Guide***.

Footnotes:

a. Diverse symptoms must be assessed and treated individually to assure optimal outcomes.

b. Causal and contributing factors must be fully assessed and treated before psychotropic medications are used. Ongoing monitoring of these factors is essential to high quality care. Antecedents or triggers are things that happen before a problem behavior. These may be causal or contributing factors.

c. Use of evidence-based interventions requires full understanding of the protocols and appropriate application to assure optimal outcomes.

22 CA ADC § 72528
§ 72528. Informed Consent Requirements.
22 CCR § 72528

Cal. Admin. Code tit. 22, § 72528

Barclays Official California Code of Regulations Currentness
Title 22. Social Security
Division 5. Licensing and Certification of Health Facilities, Home Health Agencies, Clinics, and Referral Agencies
Chapter 3. Skilled Nursing Facilities
Full text of all sections at this level Article 5. Administration (Refs & Annos)

Current selection§ 72528. Informed Consent Requirements.

(a) It is the responsibility of the attending licensed healthcare practitioner acting within the scope of his or her professional licensure to determine what information a reasonable person in the patient's condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure. Information that is commonly appreciated need not be disclosed. The disclosure of the material information and obtaining informed consent shall be the responsibility of the licensed healthcare practitioner who, acting within the scope of his or her professional licensure, performs or orders the procedure or treatment for which informed consent is required.

(b) The information material to a decision concerning the administration of a psychotherapeutic drug or physical restraint, or the prolonged use of a device that may lead to the inability of the patient to regain use of a normal bodily function shall include at least the following

(1) The reason for the treatment and the nature and seriousness of the patient's illness.
(2) The nature of the procedures to be used in the proposed treatment including their probable frequency and duration.
(3) The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment.
(4) The nature, degree, duration and probability of the side effects and significant risks, commonly known by the health professions.
(5) The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment.
(6) That the patient has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

(c) Before initiating the administration of psychotherapeutic drugs, or physical restraints, or the prolonged use of a device that may lead to the inability to regain use of a normal bodily function, facility staff shall verify that the patient's health record contains documentation that the patient has given

informed consent to the proposed treatment or procedure. The facility shall also ensure that all decisions concerning the withdrawal or withholding of life sustaining treatment are documented in the patient's health record.

(d) This section shall not be construed to require obtaining informed consent each time a treatment or procedure is administered unless material circumstances or risks change.

(e) There shall be no violation for initiating treatment without informed consent if there is documentation within the patient's health record that an emergency exists where there is an unanticipated condition in which immediate action is necessary for preservation of life or the prevention of serious bodily harm to the patient or others or to alleviate severe physical pain, and it is impracticable to obtain the required consent, and provided that the action taken is within the customary practice of licensed healthcare practitioners of good standing acting within the scope of their professional licensure in similar circumstances.

(f) Notwithstanding Sections 72527(a)(5) and 72528(b)(4), disclosure of the risks of a proposed treatment or procedure may be withheld if there is documentation of one of the following in the patient's health record:

(1) That the patient or patient's representative specifically requested that he or she not be informed of the risk of the recommended treatment or procedure. This request does not waive the requirement for providing the other material information concerning the treatment or procedure.

(2) That the licensed healthcare practitioner acting within the scope of his or her professional licensure relied upon objective facts, as documented in the health record, that would demonstrate to a reasonable person that the disclosure would have so seriously upset the patient that the patient would not have been able to rationally weigh the risks of refusing to undergo the recommended treatment and that, unless inappropriate, a patient's representative gave informed consent as set forth herein.

(g) A general consent provision in a contract for admission shall only encompass consent for routine nursing care or emergency care. Routine nursing care, as used in this section, means a treatment or procedure that does not require informed consent as specified in Section 72528(b)(1) through (6) or that is determined by the licensed healthcare practitioner acting within the scope of his or her professional licensure not to require the disclosure of information material to the individual patient. Routine nursing care includes, but is not limited to, care that does not require the order of a licensed healthcare practitioner acting within the scope of his or her professional licensure. This section does not preclude the use of informed consent forms for any specific treatment or procedure at the time of admission or at any other time. All consent provisions or forms shall indicate that the patient or incapacitated patient's representative may revoke his or her consent at any time.

(h) If a patient or his or her representative cannot communicate with the licensed healthcare practitioner acting within the scope of his or her professional licensure because of language or communication barriers, the facility shall arrange for an interpreter.

(1) An interpreter shall be someone who is fluent in both English and the language used by the patient and his or her legal representative, or who can communicate with a deaf person, if deafness is the communication barrier.

(2) When interpreters are used, documentation shall be placed in the patient's health record indicating the name of the person who acted as the interpreter and his or her relationship to the patient and to the facility.

Note: Authority cited: Sections 1275, 100275 and 131200, Health and Safety Code. Reference: Sections 1276, 1316.5, 1599.72, 131050, 131051 and 131052, Health and Safety Code; and Cobbs v. Grant (1972) 8 Cal.3d 229.

HISTORY

1. New section filed 5-27-92; operative 5-27-92 (Register 92, No. 22)

2. Amendment of subsections (a), (e) and (f)(2)-(h) and amendment of Note filed 3-3-2010; operative 4-2-2010 (Register 2010, No. 10).

22 CCR § 72528, 22 CA ADC § 72528

This database is current through 8/16/13 Register 2013, No. 33

END OF DOCUMENT

INFORMED CONSENT

The Enforcement Landscape and a Review of the Basics

DPH All Facilities Letter
June 4, 2009

Informed Consent
for Antipsychotic Medication

DPH AFL June 4, 2009 – Informed Consent

- The AFL discusses the provisions of current law regarding informed consent for prescribing antipsychotic medication pursuant to Health & Safety Code 1418.9.
- The H&S Code section referenced above pertains to residents who have the capacity to offer consent.
- If a resident does not have the capacity, then a designated family member may offer consent. A physician makes the determination on whether capacity exists.

DPH AFL June 4, 2009 – Informed Consent

- **If the attending physician of a resident in a SNF prescribes, orders, or increases an order for an antipsychotic medication for the resident, the physician shall do the following:**
  - Obtain informed consent of the resident for purposes of prescribing, ordering, or increasing an order for the medication; and
  - Seek the consent of the resident to notify the resident's interested family member, as designated in the medical record.

DPH All Facilities Letter January 7, 2011

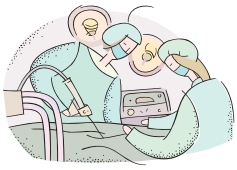
Changes to DPH Interpretation of Section 72528(c)

DPH AFL January 7, 2011 – Informed Consent

- Previously found that unchanged, pre-existing orders for psychotherapeutic drugs/physical restraints or prolonged use of certain devices did not require verification of informed consent in medical records
- DPH now requires verification present in medical records in AFL 11-08

DPH AFL January 7, 2011 – Informed Consent

- **DPH issues comprehensive Q&A in AFL 11-31 (April 12, 2011)**
- **Significant Issues**
  - AFL 11-08 requirement of documenting verification of informed consent
  - No "delegation" of informed consent from M.D. to facility staff permitted
  - Phone informed consent acceptable
  - Facility policies and procedures need to reflect how verification to be obtained



Informed Consent Basics

- Informed consent is not required for the performance of "simple and common" procedures, where the related risks are commonly understood.
- The determination of which procedures are "complex" and, therefore, require informed consent is medical in nature.
- The medical staff at the facility is responsible for identifying those procedures which require informed consent.

Informed Consent Basics

- It is the treating physician's responsibility to obtain informed consent
- How the physician obtains informed consent is within the discretion of the physician, and may include:
  - Verbal discussion
  - Written information (i.e., patient information sheets, informed consent forms)
  - Audiocassette and videocassette

Informed Consent Basics

- Regardless of how the informed consent is obtained, it is recommended that the physician carefully document in the medical record that a discussion was held with the patient (or legal representative) and that informed consent was obtained.
- It is also recommended that the physician place in the medical record a copy of any written information provided to the patient.

Informed Consent Basics

- Note: Physicians may use other health professionals to provide information within their area of expertise (e.g., pharmacists, occupational therapists, etc.). However, the physician is ultimately responsible.

- The facility's role in the informed consent process is limited to verifying that the physician obtained and documented the patient's informed consent prior to initiation of the medical treatment.

Informed Consent Basics

- It is the facility's responsibility to develop policies and procedures and ensure patient's are provided their rights to consent and informed consent.
- Facility policies and procedures must describe how the facility will verify that informed consent was obtained or a treatment or procedure was refused pertaining to key treatments.
- Note: The regulations require that the facility verify that informed consent was obtained prior to initiating the treatment the first time, not each time a treatment is continued or re-applied.

Informed Consent Basics

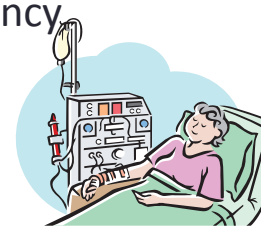
- However, if material circumstances or risks change (as determined by the physician) concerning the treatment, it is necessary to obtain informed consent again.
- If informed consent is not obtained, there must be documentation of an emergency. Documentation of an emergency can be made after treatment is initiated.

Compliance Considerations

- Evaluate informed consent policies and procedures:
  - Are they realistic?
  - Can they be consistently applied?
- Ensure all licensed nursing staff and physicians are able to explain facility informed consent process.

Who May Give Consent

- Determination of who has legal authority to consent is based on:
  - Patient's legal status (e.g., adult, emancipated minor, minor)
  - Patient's physical and mental condition
- If the patient has capacity, then he/she has the right to consent.
- If the patient lacks capacity, then someone else must consent to the treatment on their behalf except in an emergency situation.



Challenges

- Determining whether patient has an advance directive or durable power of attorney for health care
- In cases of incapacity and no advance directive, dealing with:
  - Finding family or friends willing to make health care decisions
  - Dueling family members
  - Delays in getting conservator

Compliance Considerations

- Documentation on admission, during care planning meetings that indicates resident/family is fully informed about care and treatment. (F 156)

- Document periodic communication with resident/family to probe if there are questions and confirm understanding of care approaches, including use of medication.

Use of the Interdisciplinary Team in the SNF Setting

- **<u>Health and Safety Code section 1418.8</u> allows the SNF's interdisciplinary team to authorize medical treatment ordered by physician that requires informed consent if there is no:**
  - Available family member willing to make health care decisions;
  - Conservator of the person, and
  - Other person with legal authority to make health care decisions.

Interdisciplinary Team Process

- Attending physician determines lack of capacity.
- Attending physician determines that there is no person with legal authority to make health care decisions (e.g., power of attorney, guardian, conservator or kin).
- Except in an emergency, facility holds interdisciplinary team review of the medical intervention that includes:
  - **Review of physician's patient assessment;**
  - **Reason for proposed medical intervention;**
  - **Discussion of patient's desires if known (interviews with patient, family members, friends, review of medical records);**
  - **Review of type of medical intervention;**
  - **Probable impact on patient's condition with/without medical intervention;**
  - **Alternative medical intervention considered or utilized and reason for discontinuance or inappropriateness; and**
  - **Evaluation by interdisciplinary team of prescribed medical intervention at least quarterly and upon significant change in patient's medical condition.**

Interdisciplinary Team Process

- **Interdisciplinary team must oversee care using team approach**
  - Participants include attending physician, RN with patient responsibility; and other appropriate staff depending on patient's needs
  - Must include a patient representative when practical (e.g., family member or friend who can't take full responsibility for health care decisions; public guardian or ombudsman)
- All determinations and the reasons must be documented in the medical record.
- Not subject to administrative sanction if the physician or other health care provider believes in good faith that actions consistent with Health and Safety Code 1418.8, desires of patient if known, or the best interests of the patient.

Informed Consent Enforcement Focus CMP Issuance

Consider issuance of a civil money citation for one or more of the following non-compliance(s):

- *Resident/RP indicates (on interview) required material information (as defined in T22 Section 72528 (1-6)) was not received in order to make an informed decision prior to receipt of the antipsychotic medication.*
- *Physician did not obtain informed consent from the resident (the process of informed consent was delegated to licensed nursing staff, ward clerk, etc.).*
- *Facility failed to develop and implement patients' rights policies and procedures, in accordance with state laws and regulations, related to psychotherapeutic informed consent.*

Are You Prepared?
Taking the Necessary Steps

- **Identify on admission if the patient has an advance directive.**
- **Identify if the patient has capacity or lacks capacity to make health care decisions. Make sure it is clearly documented in the medical record and known to facility staff.**
- **Maintain open lines of communication with the patient and family members concerning consent issues.**
- **Address any and all consent issues with the attending physician.**
- **Draft policies and procedures to ensure compliance with laws/regulatory requirements.**
- **Develop all necessary Informed Consent forms and maintain practices consistent with law.**
- **Make sure that compliance with Interdisciplinary Team Meetings held pursuant to Health and Safety Code 1418.8 is well documented in the medical record.**
  - **Consider drafting a form to memorialize the meetings.**
- **Continually educate staff on policies and procedures regarding consent issues.**
- **Create and implement a process for monitoring compliance with consent issues.**
- **Consult legal counsel when necessary.**

Resources

- AHCA Quality Initiative - http://www.ahcancal.org/quality_improvement/qualityinitiative/Pages/default.aspx
- CAHF Quality Initiative - http://www.cahf.org
- CAHF Person Centered Behavior Management Tool Kit - http://www.cahfdownload.com/cahf/nurses/2011BestPractices_PersonCenteredBehaviorMgmt_Toolkit.pdf
- CDPH Surveyor Tool and Antipsychotic Collaborative Report - http://member.cahf.org/Operations/SurveyEnforcement.asp
- Improving Antipsychotic Appropriateness in Dementia Patients (IA-ADAPT website) - https://www.healthcare.uiowa.edu/igec/IAADAPT

THANK YOU!

Questions?

California Association of Health Facilities
2201 K Street. Sacramento, California 95816

CARE CONSIDERATIONS-RESIDENT WITH BEHAVIOR AND PSYCHOTIC SYMPTOMS OF DEMENTIA

TABLE OF CONTENTS

Draft Not For Distribution

USE OF THIS RESOURCE

This evidence-based structure and process guidance is provided as a resource to facilities who are serving residents with challenging behaviors and psychotic symptoms related to dementia. The information in this document is intended as a reference tool only to assist senior leadership to evaluate their resident assessment, care planning, informed consent and facility quality assessment and assurance practices related to non-pharmacological and pharmacological interventions. We recommend that is be used as "quality assurance/performance improvement tool" and hope that it will assist care providers to support those residents who are exhibiting dementia-related behaviors and psychotic symptoms to maintain their highest practicable level of well-being.

DISCLAIMER

THIS CARE CONSIDERATIONS-RESIDENT WITH BEHAVIOR AND PSYCHOTIC SYMPTOMS OF DEMENTIA DOCUMENT FROM THE CALIFORNIA ASSOCIATION OF HEALTH FACILITIES (CAHF) IS EXCLUSIVELY INTENDED TO PROVIDE GUIDANCE. IT DOES NOT CONTAIN OR CONSTITUTE LEGAL ADVICE IN ANY FORM AND DOES NOT MAKE ANY ASSURANCE OR REPRESENTATION THAT THE GUIDANCE CONTAINED HEREIN WILL BE DETERMINED TO CONSTITUTE COMPLIANCE WITH ANY STATE OR FEDERAL LAW OR REGULATION. IN ADDITION, CAHF IS NOT RESPONSIBLE FOR ANY ERRORS OR OMISSIONS CONTAINED IN THE CARE CONSIDERATIONS-RESIDENT WITH BEHAVIOR AND PSYCHOTIC SYMPTOMS OF DEMENTIA DOCUMENT AND ASSUME NO RESPONSIBILITY FOR THE MISUSE OR ERRONEOUS INTERPRETATION OF ITS CONTENTS.

CARE CONSIDERATIONS-RESIDENT WITH BEHAVIOR AND PSYCHOTIC SYMPTOMS OF DEMENTIA

POLICY ELEMENTS	
I. FOUNDATIONAL STRATEGIES	
• Require administrative review of all newly prescribed psychotropic medications	
• Consistent assignments	
• Individualize routines (ADL, meals, activities, sleep/wake)	
• Adequate staffing (nursing, activities, social services)	
• Resident/family involvement in plan of care	
II. RECOGNITION/ASSESSMENT Reference: CFR § 483.20 F Tag 272, CCR Title 22 72311 (a) (1) (A)	
REQUIREMENT: The facility must conduct initially and periodically a comprehensive accurate assessment of residents functional capacity and identify their care needs	
a. ASSESSMENT	
Identify frequency, pattern of occurrence, impact, what makes the behavior better or worse and, if possible, the precipitating factors and consequences of the behavior.	
Utilize:	
• comprehensive assessment information	
• systematic review of medical record	
• Input from facility consultants (e.g. pharmacists, psychiatrist/psychologist)	
• interviews resident, care givers, and families	
• Observation	
Describe:	
• Onset	
• Duration	
• Intensity	
Document findings including discussion of whether or not the behaviors present a danger (including significant impact on functional ability) to self or others	
b. CAUSE IDENTIFICATION/DIAGNOSIS	
Identify triggers for the behavior and psychotic symptoms of dementia (BPSD)	
Unmet physical needs: Interdisciplinary Team (IDT) to evaluate, identify (ID) root causes through evaluation or changes to physical care	
Rule out: • Infection/illness • Electrolyte imbalance • Pain • Hunger • Thirst • Urinary distress • Constipation • Sensory Deficits • Fatigue	**Consider:** • Medical evaluation • Labs • Empirical trial of analgesics • Snacks/meal adjustments • Increased fluids • Medical evaluation • Toileting program • Bowel care

• Sleep disturbance • Medication side effects	• Hearing/vision aids • Lighting • Sleep evaluation/sleep hygiene program • Adequate rest/exercise, mobility/strengthening • Medication review
Unmet environmental needs: IDT to evaluate, ID root causes through adaptation or change to environment	
Rule out: • Noise level • Crowded area • Poor lighting • Restraints • Caregiver approach • Institution routine • Lack of cues for way find	**Consider:** • Eliminate things that agitate or confuse • Adjust stimulation • Add functional cues (signs, pictures, lighting) • Change the setting (homelike, outdoors, spa bath setting) • Change approach (simple words, friendly tone, try later, redirect, don't confront)
Unmet psychological needs: IDT to evaluate, ID root cause(s) and consider appropriate individualized interventions:	
Rule out: Unmet psychological needs • Loneliness • Boredom • Fear/worry • Frustration • Confusion • Grief • Lack of enjoyable activity • Lack of socialization • Sudden situational change (e.g. loss of a spouse)	**Consider interventions geared to:** • Resident's cognitive level, • Physical functional level, • long standing personality, life history, interests • Preferred personal routines

Psychiatric Causes: IDT to consult with medical director and/or attending physician to determine need for follow up	
Rule out: • Depression • Anxiety • Delirium • Psychosis • Other mental illness	**Consider:** • Utilize all data sources to paint a comprehensive clinical picture for MD • Use the SBAR format to summarize info for report to MD • Include information on what interventions have been tried and the effect • Follow up as indicated

III. CARE PLANNING

Reference: CFR § 483.10 (d) (3) F Tag 280, CCR Title 22 72527(a)(3)

REQUIREMENT: A facility must use the results of the assessment to develop the resident's comprehensive plan of care; must correctly and adequately describe the purpose and goals of the care and individualize interventions; and must support the resident or their responsible person's right to participate in the planning of care and treatment.

Based on assessment, develop a person-centered plan of care that is measurable and time limited; identifies desired outcomes; includes systems to monitor and evaluate effectiveness of care

a. NON PHARMACOLOGICAL INTERVENTIONS

Address physical needs through evidenced based approaches to:

- Manage pain
- Support rest
- Maximize nutrition
- Eliminate illness/metabolic imbalance
- Provide exercise to support optimal physical function
- Address sensory deficits
- Mitigate medication side effects

Address psychological needs through individualized approaches based on person's life history, routines and preferences, cognitive and physical functioning level

- Engage in meaningful activity (tactile, manipulative, physical)
- Provide pleasurable experiences including individualized music and comfort foods, massage, aroma therapy
- Simplify daily routine to reflect individual's rhythms
- Facilitate contact with favorite others (family, children, friends, caregivers, pets)
- Provide cues for way finding (pictures, signs, verbal cues)
- Adjust caregiver approach (focus on person not task, redirect, try later, reassure, comfort, accept, don't challenge)
- Communicate effectively (simple words and phrases, wait for answers, make eye contact, wait for response, calm tone)

Address environmental needs through adapting and/or changing the environment, not the person
• Eliminate misleading stimuli (clutter, TV, noise, people)
• Reduce environmental stress (alarms, restraints, caffeine, decorations)
• Adjust the level of stimulation (more if bored, less if agitated)
• Adapt the physical environment to reflect individualized needs (homelike, lighting, smaller areas, low noise, natural light, outdoor time)
Address psychiatric needs through medical evaluation, psychiatric consult
• Employ nonpharmacological approaches as appropriate to do so
• Follow doctor's orders and/or consultant recommendations for additional pharmacological/behavioral interventions
• Comply with requirements for informed consent **(SEE APPENDIX A – Informed Consent Tool Kit)**
IV. MONITORING/FOLLOW UP Reference: CFR § 482.20(d) F Tag 279, CFR § 483.25(I) F Tag 329, CFR § 483.60(c) F Tag 428, CFR §483.75(i) F Tag 501
REQUIREMENT**:** The facility must monitor the effectiveness of the interventions in helping the resident progress toward defined goals; adjust interventions as needed; identify the presence of adverse consequences from interventions; and identify when care objectives have been sufficiently achieved.
a. MONITOR
Care plans are monitored and plans are adjusted as indicated
• The IDT implements interventions consistently
• Target behaviors are identified in the resident plan of care and monitored objectively and quantitatively consistent with the primary indication for use as identified by the physician and IDT.
• In collaboration with the medical director or attending physician, consultant practitioners, and resident the IDT reviews and determine effectiveness of interventions
• If pharmacological interventions are used, appropriate side effects monitoring is in place and the team is aware of and has process for identifying any potential medication side effects.
• Behavioral data are made available to the prescriber in a consolidated manner at least monthly and information is sufficient to determine medication effectiveness as well and presence of any adverse consequences.
• Gradual dose reduction is attempted at least quarterly during two separate quarters initially, and then annually unless contraindicated.
• The pharmacist reviews the resident record monthly.
• If drug irregularities are identified, the information is provided in writing to the attending physician and director of nursing.
• The facility has a process for acting upon any pharmacist-identified drug irregularities.
• The facility utilizes the QAA process to evaluate issues related to informed consent for antipsychotic/psychotherapeutic medication use.

b. REVISE & UPDATE
• In collaboration with the medical director/ attending physician, consultant practitioners, and resident the IDT reviews and determine effectiveness of interventions
• If resident's behaviors do not improve or worsen, evaluate the root cause(s)
• Interventions not implemented consistently? • Staff needs more training and/or accountability? • Wrong interventions? • Inadequate time to evaluate effectiveness?
• Involve family and/or resident
• Adjust approach, change or continue interventions as indicated
• Care plan revised and updated as indicated
V. **QUALITY ASSURANCE PERFORMANCE IMPROVEMENT** Reference: CFR§ 483.75(o) F Tag 520
The facility identifies quality concerns related to care of residents with dementia
QAA Committee monitors and provides oversight for dementia care related areas including:
• Resident Care Policies and Procedures reflect the facility's overall approach to care of residents with dementia
• Staff follow policies and procedures in developing and applying the interventions for the care of residents with dementia
• CNAs receive initial and annual dementia care
• There are sufficient staff to carry out interventions
• Staff collect and analyze data to monitor the non-pharmacological (individualized, person-centered) interventions used to care for residents with dementia
• Committee helps the facility to monitor trends, identify successes, and target areas for future improvement in the non-pharmacological management of behavior and psychotic symptoms in residents with dementia
VI. Resources
Federal Code of Regulations State Operations Manual Appendix PP https://www.cms.gov/Center/Provider-Type/Skilled-Nursing-Facility-Center.html?redirect=/center/snf.asp **California Code of Regulations Title 22** http://ccr.oal.ca.gov/linkedslice/default.asp?SP=CCR-1000&Action=Welcome **California Health and Safety Code** http://www.leginfo.ca.gov/calaw.html **Improving Antipsychotic Appropriateness in Dementia Patients (IA-ADAPT) Website** https://www.healthcare.uiowa.edu/igec/iaadapt/ **Advancing Excellence CMS Partnership To Improve Dementia Care** http://www.nhqualitycampaign.org/star_index.aspx?controls=dementiaCare **National Institute of Mental Health, Health Topics, Mental Health Medications** www.nih.gov

APPENDIX A Informed Consent Tool Kit

INFORMED CONSENT VERIFICATION FOR ANTIPSYCHOTIC/PSYCHOTHERAPEUTIC MEDICATIONS Reference: Title 22, CCR, Section 72527 and 72528, Health and Safety Code (HSC Sections 1418.8 and 1418.9)
The facility shall verify that the physician has obtained informed consent as follows:
• Prior to initiation of antipsychotic or other psychotherapeutic medication;
• Prior to increase in dosage of an antipsychotic medication.
A.PHYSICIAN/ HEALTHCARE PRACTITIONER RESPONSIBILITY Reference: HSC 1418.9, Title 22, CCR, Section 72528, CFR §483.75(i) F Tag 501 **The physician is the sole healthcare practitioner who is authorized to obtain informed consent for antipsychotic medications**. **Informed consent must include material information as specified in state regulation.** NOTE: Other healthcare practitioners, within the scope of their licensure, may obtain informed consent for all other types of psychotherapeutic medications.
The physician will discuss with the resident/ responsible party (RP) information that is material to obtaining informed consent. (See CAHF Exhibits 1A and 1B for examples of the type of written information that the physician may provide.)
Within 48 hours of initiating or increasing the dose of an antipsychotic medication, when the resident consents to notify an interested family member the physician or designee shall make reasonable attempts to make such notification.
B. FACILITY ROLE IN INFORMED CONSENT Reference: HSC 1418.9, Title 22, CCR, Section 72528, CFR §483.75(i) F Tag 501
As specified in state regulation and statute, the facility's role in the informed consent process is limited to verifying that the physician obtained informed consent. The physician and/or licensed healthcare practitioner (as appropriate) within the scope of his/her licensure is deemed to have the technical knowledge to assure adequate disclosure of information, including that pertaining to the risks of treatment, has been given to the resident or RP.
• The facility has written patients' rights policies and procedures related to antipsychotic/psychotherapeutic medication informed consent that include: • How the facility will verify that informed consent was obtained or refused that identifies all ways in which verification may occur and be documented in the resident record. • How the facility, in consultation with the resident's physician will identify who may serve as a resident's representative when an incapacitated patient has no conservator or attorney in fact under a valid Durable Power of Attorney for Health Care. • The medical director has ensured that resident care policies and procedures were implemented.
• Implemented regarding antipsychotic informed consent.
C. DOCUMENTING VERIFICATION OF INFORMED CONSENT Reference: Title 22, CCR, Section 72527 and 72528, CFR §483.75(i) F Tag 501
The resident record must reflect that informed consent has been obtained by the healthcare practitioner **NOTE**: Only a physician may obtain informed consent for antipsychotic medication from the resident/RP. Documentation may include one or more of the following:
• A copy of the informed consent obtained by the healthcare practitioner ordering the medication prior to admission to facility.
• The healthcare practitioner's signature and/or notes in the resident record verifying that

informed consent has been obtained from the resident/RP.
• The signature of the licensed nurse verifying receipt of a verbal and/or written confirmation from the healthcare practitioner that informed consent has been obtained.
• A signed copy of "Verification of Informed Consent for Antipsychotic Medication (see CAHF sample form 1-1)
OR
• For psychotherapeutic medication: a signed copy of "Verification of Informed Consent for Psychotherapeutic Medication (see CAHF sample form 1-2).
• A signed copy of "Resident/RP Consent for Use of Antipsychotic Medication (see CAHF sample form 2-1)
OR
• A signed copy of "Resident/RP Consent for Use of Psychotherapeutic Medication (see CAHF sample form 2-2)
D. FACILITY OBLIGATION TO FULLY INFORM RESIDENT/RP OF HEALTH STATUS Reference: CFR § 483.10(b)(2) and (3) F Tags 153 and 154
The facility is responsible for assuring: • Each resident is fully informed of his or her total health status, including but not limited to his/her medical condition. • The resident is fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being. • At any time, should the resident/RP indicate doubt or confusion about the use of antipsychotic/psychotherapeutic medication, or withdraw consent for same, contact the physician and/or the licensed health care practitioner (as appropriate).
E. EXCEPTIONS TO OBTAINING INFORMED CONSENT Reference: Title 22, CCR, Section 72528
There is documentation within the resident record that any of the following conditions are present:
• An emergency exists where there is an unanticipated condition in which immediate action is necessary for the preservation of life or the prevention of serious bodily hat, to the resident or others or to alleviate severe physical pain, and it is impractical to obtain the required consent and that the action taken is within the customary practice of the licensed healthcare practitioners of good standing acting within the scope of their professional licensure in similar circumstances.
• The resident or RP specifically requested that he/she is not to be informed of the risks of the recommended treatment

- That the licensed healthcare practitioner acting within his/her scope of professional licensure, relied upon objective facts, as documented in the health record, that would demonstrate to a reasonable person that the disclosure would have so seriously upset the resident that the resident would not have been able to rationally weight the risks of refusing to undergo the recommended treatment and that, unless inappropriate, a resident's representative gave informed consent as set forth herein.

F. RESIDENT LACKS CAPACITY AND NO LEGALLY AUTHORIZED DECISION MAKER

Reference: HSC Section, 1418.8

Requirement:

If the attending physician determines the resident lacks capacity and there is no person with legal authority to make those decisions on behalf of the resident, the MD shall inform the facility.

- The resident record contains documentation that there is no person who has legal authority who can or will make health care decisions as determined by the attending physician.

- IDT will review the proposed prescribed medical intervention prior to the administration of the proposed medication.

- The IDT shall include a registered nurse who has responsibility for the resident, other appropriate staff in disciplines as determined by the resident's needs and, where practicable, a patient representative.

The IDT review shall include the following:

- A review of the physician's assessment of the resident's condition.
- The reason for the proposed use of the medical intervention.
- The type of medical intervention to be used in the resident's care including its probable frequency and duration.
- The probable impact on the resident's condition, with and without the use of the medical intervention.
- Reasonable alternative medical interventions considered or utilized and reasons for their discontinuance or inappropriateness.

The IDT shall periodically evaluate the use of the prescribed medical intervention at least quarterly or upon a significant change in the resident's medical condition.

- **EXCEPTION**: In the case of an emergency, a medical intervention may be administered which requires informed consent prior to convening an IDT review. The IDT shall meet within one week of the emergency for evaluation of the medical intervention.

Verification of Informed Consent for Antipsychotic Medication

Resident name: _____

Medication : _____ ***Expected Dosage Range:***_____

Specific medical condition / psychiatric diagnosis:

- ☐ Schizophrenia
- ☐ Schizoaffective Disorder
- ☐ Delusional Disorder
- ☐ Mood Disorders (e.g., Bipolar Disorder, Depression with Psychotic Features, Refractory Depression)
- ☐ Schizophreniform Disorders
- ☐ Psychosis
- ☐ Brief Psychotic Disorder
- ☐ Dementing illnesses w/ associated behavioral symptoms
- ☐ Medical illnesses w/psychotic symptoms and/or related to psychosis/ mania/delirium
- ☐ Tourette's or Huntington's
- ☐ Hiccups or Nausea and Vomiting associated with cancer or chemotherapy
- ☐ Other: _____

Potential/Expected Benefits:

Side Effects / Severity of Risks:

☐ Physician requests the facility send attached information about the medication and a copy of this form to resident and/or resident's surrogate decision-maker. **Date sent** _____ **Signature**_____

Warning for Antipsychotic Medication

The Food and Drug Administration (FDA) issued a Public Health Advisory for atypical antipsychotic medications. The FDA determined that the death rates are higher for elderly people with dementia when taking this medication. A review of the data has found a risk with conventional antipsychotics as well. Antipsychotic medications are not FDA approved for the treatment of behavioral disorders in patients with dementia. Source: National Institute of Mental Health U.S. Department of Health and Human Services ***www.nih.gov***

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

I have discussed with _____, the following:
Circle one: resident and/or the resident's surrogate decision-maker

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ The above-named resident and/or the resident's surrogate decision-maker has given permission for use of the medication.

☐ The above-named resident has given permission to contact a designated family member regarding the use of anti-psychotic medication.

☐ The above-named resident has **not given permission** to contact a designated family member regarding the use of anti-psychotic medication.

_____
Ordering Physician's Signature Date

_____
Licensed Nurse Signature Verifying Evidence of Informed Consent Date

CAHF – Form 1 - 1
Nov. 6, 2012

Resident/Surrogate Decision Maker Informed Consent for Antipsychotic Medication

Resident name: _____

Medication : _____ ***Expected Dosage Range:***_____

Specific medical condition / psychiatric diagnosis:

- ☐ Schizophrenia
- ☐ Schizoaffective Disorder
- ☐ Delusional Disorder
- ☐ Mood Disorders (e.g., Bipolar Disorder, Depression with Psychotic Features, Refractory Depression)
- ☐ Schizophreniform Disorders
- ☐ Psychosis
- ☐ Brief Psychotic Disorder
- ☐ Dementing illnesses w/ associated behavioral symptoms
- ☐ Medical illnesses w/psychotic symptoms and/or related to psychosis/ mania/delirium
- ☐ Tourette's or Huntington's
- ☐ Hiccups or Nausea and Vomiting associated with cancer or chemotherapy
- ☐ Other: _____

Potential/Expected Benefits:

Side Effects / Severity of Risks:

☐ See attached information sheet for additional information about this medication

Warning for Antipsychotic Medication

The Food and Drug Administration (FDA) issued a Public Health Advisory for atypical antipsychotic medications. The FDA determined that the death rates are higher for elderly people with dementia when taking this medication. A review of the data has found a risk with conventional antipsychotics as well. Antipsychotic medications are not FDA approved for the treatment of behavioral disorders in patients with dementia. Source: National Institute of Mental Health U.S. Department of Health and Human Services ***www.nih.gov***

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

The physician has discussed the following:

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ I have given permission for use of the medication.

_____

Resident Signature Date

or

_____

Resident's Surrogate Decision-maker Date

Verification of Informed Consent for Psychoactive Medication

Resident name: _____

Medication : _____	***Expected Dosage Range:***_____
Symptoms to be treated:	
Potential/Expected Benefits:	
Side Effects / Severity of Risks:	
☐ Physician requests the facility send attached information about the medication and a copy of this form to resident and/or resident's surrogate decision-maker. **Date sent** _____ **Signature**_____	

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

I have discussed with _____, the following:
Circle one: resident and/or the resident's surrogate decision-maker

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ The above-named resident and/or the resident's surrogate decision-maker has given permission for use of the medication.

_____
Ordering Physician's Signature Date

_____
Licensed Nurse Signature Verifying Evidence of Informed Consent Date

Resident/Surrogate Decision Maker Informed Consent for Psychoactive Medication

Resident name: _____

Medication : _____	***Expected Dosage Range:***_____
Symptoms to be treated:	
Potential/Expected Benefits:	
Side Effects / Severity of Risks:	
☐ See attached information sheet for additional information about this medication	

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

The physician has discussed the following:

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ I have given permission for use of the medication.

_____

Resident Signature Date

or

_____

Resident's Surrogate Decision-maker Date

Patient Information Sheet

Clozapine
(marketed as Clozaril)

This is a summary of the most important information about Clozaril. For details, talk to your healthcare professional.

What is Clozaril?

Clozaril is a prescription medicine used to treat people with severe forms of schizophrenia that have not responded to or cannot take other treatments. Clozaril is also used to lower the risk of suicidal behavior in people with schizophrenia or schizoaffective disorder. Clozaril is not approved for use in children.

Who Should Not Take Clozaril?

You should not take Clozaril if:

- You are taking other medicines that can cause the same serious bone marrow side effects as Clozaril.
- You can ask your healthcare professional for a complete list of these medications.

What are The Risks?

The following are the risks and potential side effects of Clozaril therapy. However, this list is not complete.

- ***Increased chance of death in elderly persons.*** Elderly patients treated with atypical antipsychotics, such as Clozaril, for dementia had a higher chance for death than patients who did not take the medicine. Clozaril is not approved for dementia.
- ***Agranulocytosis,*** a potentially life-threatening reaction where the body's bone marrow does not produce enough white blood cells. Because of this risk, your healthcare professional must monitor your blood while you are taking Clozaril.
- ***Seizures***. The risk of seizure is increased in people who have a history of seizures or other predisposing factors. Because of this risk you should not engage in any activity where you may suddenly lose consciousness, such as operating complex machinery, driving, swimming, climbing, etc.
- ***Heart problems***. Clozaril can cause a condition called myocarditis, or swelling of the heart muscle. Some of the warning signs of myocarditis are tiredness, shortness of breath, rapid breathing, fever, chest pain, and irregular heart beat. If these happen, call your healthcare professional right away.
- ***Lowering of blood pressure*** when you stand up. This may also lead to fainting. In rare instances, this has been associated with lung and/or heart collapse.

Clozaril and other antipsychotic medications can cause serious problems such as:

- ***A life-threatening nervous system problem called neuroleptic malignant syndrome (NMS).*** NMS can cause a high fever, stiff muscles, sweating, a fast or irregular heart beat, change in blood pressure, and confusion. NMS can affect your kidneys. NMS is a medical emergency. Call your healthcare professional right away if you experience these symptoms.
- ***A movement problem called tardive dyskinesia (TD).*** Call your healthcare professional right away if you get muscle movements that cannot be stopped.
- ***High blood sugar and diabetes.*** Patients with diabetes or who have a higher chance for diabetes should have their blood sugar checked often.
- ***Other serious side effects may*** include fever, blood clots in the lung, increased blood sugar, and liver disease.
- ***The most common side effects*** include drowsiness, increased salivation, rapid heart beat, dizziness, constipation, headache, shaking, and lightheadedness.

What Should I Tell My Healthcare Professional?

Before you start using Clozaril, tell your healthcare professional if you:

- have or had heart or lung problems
- have or had seizures
- have or had blood clots
- have or had diabetes or increased blood sugar
- have or had liver disease
- have or had glaucoma
- have or had stomach problems
- have or had prostate enlargement
- are trying to become pregnant, are already pregnant, or are breast-feeding
- drink alcohol
- smoke

Patient Information Sheet

Clozapine
(marketed as Clozaril)

Are There Any Interactions With Drugs or Foods?

Because certain other medications can interact with Clozaril, review all medications that you are taking with your health care professional, including those that you take without a prescription. You should not take Clozaril if you are taking other medicines that can cause the same serious bone marrow side effects as Clozaril.

Your healthcare professional may have to adjust your dose or watch you more closely if you take the following medications:

- certain medicines used to treat anxiety, called benzodiazepines
- certain medicines used to clear thoughts, called psychotropic drugs
- epinephrine
- phenytoin
- rifampin
- cimetidine
- erythromycin
- carbamazepine
- fluvoxamine
- paroxetine

Avoid drinking alcohol while taking Clozaril.

Is There Anything Else I Need to Know?

- Dizziness, and sometimes fainting, caused by a drop in blood pressure may happen with Clozaril, especially when you first start taking this medicine or when the dose is increased.

- Clozaril may impair judgment, thinking, or motor skills. You should be careful in operating machinery, including automobiles, until you know how Clozaril affects you.

Clozaril FDA Approved 1989
Patient Information Sheet Revised 09/2006

Mental Health Medications: Antipsychotics

Adapted from Mental Health Medications – National Institute of Mental Health
U.S. Department of Health and Human Services

To see more go to:

www.nih.gov

-Click on "Health Topics"
-Click on "Publications"
-Select "Mental Health Medications"

You Have The Right To be Fully Informed About The Benefits and Risks of Antipsychotic Medication

California Informed Consent Requirements

California Code of Regulations, Title 22 § 72528
(a) It is the responsibility of the attending licensed healthcare practitioner acting within the scope of his or her professional licensure to determine what information a reasonable person in the patient's condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure. Information that is commonly appreciated need not be disclosed. The disclosure of the material information and obtaining informed consent shall be the responsibility of the physician. The disclosure of the material information and obtaining informed consent shall be the responsibility of the licensed healthcare practitioner who, acting within the scope of his or her professional licensure, performs or orders the procedure or treatment for which informed consent is required.
(b) The information material to a decision concerning the administration of a psychotherapeutic drug or physical restraint, or the prolonged use of a device that may lead to the inability of the patient to regain use of a normal bodily function shall include at least the following:

(1) The reason for the treatment and the nature and seriousness of the patient's illness.
(2) The nature of the procedures to be used in the proposed treatment including their probable frequency and duration.
(3) The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment.
(4) The nature, degree, duration and probability of the side effects and significant risks, commonly known by the health professions.
(5) The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment.
(6) That the patient has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

Your Company Logo will Appear Here

Mental Health Medications: Antipsychotics Benefits and Risks

Company Phone number
Company FAX number
Website Address
Company Address

Exhibit B

Mental Health Medications: Antipsychotics

Antipsychotic medications are used to treat schizophrenia and schizophrenia-related disorders, psychotic symptoms, hallucinations and delusions (breaks in reality). Some of the "typical" antipsychotics include:

- Chlorpromazine (Thorazine)
- Haloperidol (Haldol)
- Perphenazine
- Fluphenazine

In 2009 new antipsychotic medications were developed. These new medications are called second generation or "atypical" antipsychotics. Some of the "atypical" antipsychotics include:

- Risperidone (Risperdal)
- Olanzapine (Zyprexa)
- Quetiapine (Seroquel)
- Ziprasidone (Geodon)
- Aripiprazole (Abilify)
- Paliperidone (Invega)

NOTE: The FDA issued a Public Health Advisory for atypical antipsychotic medications. The FDA determined that the death rates are higher for elderly people with dementia when taking this medication. A review of the data has found a risk with conventional antipsychotics as well. Antipsychotic medications are not FDA approved for the treatment of behavioral disorders in patients with dementia.

What are the Side Effects?

Side effects may include, but not be limited to:

- Drowsiness
- Dizziness when changing positions
- Blurred vision
- Rapid heartbeat
- Sensitivity to the sun
- Skin rashes
- Major weight gain
- Changes in metabolism
- Rigidity
- Persistent muscle spasms
- Tremors restlessness

Long term use of typical antipsychotic medications may lead to a condition called tardive dyskinesia (TD). TD causes muscle movements a person cannot control the movements commonly happen around the mouth. TD can range from mild to severe, and in some people the problem cannot be cured. Sometimes people with TD recover partially or fully after they stop taking the medication.

Every year, an estimated 5 percent of people taking typical antipsychotics get TD. The condition happens to fewer people who take the new, atypical antipsychotics, but some people may still get TD.

How are Antipsychotics Taken and How do People Respond to Them?

Antipsychotics are usually pills that people swallow or liquid they can drink. Some antipsychotics are shots that are given once or twice a month.

Symptoms of schizophrenia, such as feeling agitated and having hallucinations, usually go away within days. Symptoms like delusions usually go away within a few weeks. After about six weeks, many people will see a lot of improvement.

Add Facility Information Here

California Association of Health Facilities
2201 K Street. Sacramento, California 95816

Informed Consent Tool Kit for-RESIDENTS WITH BEHAVIOR AND PSYCHOTIC SYMPTOMS OF DEMENTIA

TABLE OF CONTENTS

EXHIBITS

DISCLAIMER

This INFORMED CONSENT TOOL KIT FOR RESIDENTS WITH BEHAVIOR AND PSYCHOTIC SYMPTOMS OF DEMENTIA document from the California Association of Health Facilities (CAHF) is exclusively intended to provide guidance. It does not contain or constitute legal advice in any form and does not make any assurance or representation that the guidance contained herein will be determined to constitute compliance with any state or federal law or regulation. In addition, CAHF is not responsible for any errors or omissions contained in the INFORMED CONSENT TOOL KIT FOR RESIDENTS WITH BEHAVIOR AND PSYCHOTIC SYMPTOMS OF DEMENTIA and assumes no responsibility for the misuse or erroneous interpretation of its contents.

Informed Consent Tool Kit

INFORMED CONSENT VERIFICATION FOR ANTIPSYCHOTIC/PSYCHOTHERAPEUTIC MEDICATIONS Reference: Title 22, CCR, Section 72527 and 72528, Health and Safety Code (HSC Sections 1418.8 and 1418.9)
The facility shall verify that the physician has obtained informed consent as follows:
• Prior to initiation of antipsychotic or other psychotherapeutic medication;
• Prior to increase in dosage of an antipsychotic medication.
A.PHYSICIAN/ HEALTHCARE PRACTITIONER RESPONSIBILITY Reference: HSC 1418.9, Title 22, CCR, Section 72528, CFR §483.75(i) F Tag 501 **The physician is the sole healthcare practitioner who is authorized to obtain informed consent for antipsychotic medications**. **Informed consent must include material information as specified in state regulation.** NOTE: Other healthcare practitioners, within the scope of their licensure, may obtain informed consent for all other types of psychotherapeutic medications.
The physician will discuss with the resident/ responsible party (RP) information that is material to obtaining informed consent. (See CAHF Exhibits 1A and 1B for examples of the type of written information that the physician may provide.)
Within 48 hours of initiating or increasing the dose of an antipsychotic medication, when the resident consents to notify an interested family member the physician or designee shall make reasonable attempts to make such notification.
B. FACILITY ROLE IN INFORMED CONSENT Reference: HSC 1418.9, Title 22, CCR, Section 72528, CFR §483.75(i) F Tag 501
As specified in state regulation and statute, the facility's role in the informed consent process is limited to verifying that the physician obtained informed consent. The physician and/or licensed healthcare practitioner (as appropriate) within the scope of his/her licensure is deemed to have the technical knowledge to assure adequate disclosure of information, including that pertaining to the risks of treatment, has been given to the resident or RP.
• The facility has written patients' rights policies and procedures related to antipsychotic/psychotherapeutic medication informed consent that include: • How the facility will verify that informed consent was obtained or refused that identifies all ways in which verification may occur and be documented in the resident record. • How the facility, in consultation with the resident's physician will identify who may serve as a resident's representative when an incapacitated patient has no conservator or attorney in fact under a valid Durable Power of Attorney for Health Care. • The medical director has ensured that resident care policies and procedures were implemented.
• Implemented regarding antipsychotic informed consent.
C. DOCUMENTING VERIFICATION OF INFORMED CONSENT Reference: Title 22, CCR, Section 72527 and 72528, CFR §483.75(i) F Tag 501
The resident record must reflect that informed consent has been obtained by the healthcare practitioner **NOTE**: Only a physician may obtain informed consent for antipsychotic medication from the resident/RP. Documentation may include one or more of the following:
• A copy of the informed consent obtained by the healthcare practitioner ordering the medication prior to admission to facility.
• The healthcare practitioner's signature and/or notes in the resident record verifying that

informed consent has been obtained from the resident/RP.
• The signature of the licensed nurse verifying receipt of a verbal and/or written confirmation from the healthcare practitioner that informed consent has been obtained.
• A signed copy of "Verification of Informed Consent for Antipsychotic Medication (see CAHF sample form 1-1)
OR
• For psychotherapeutic medication: a signed copy of "Verification of Informed Consent for Psychotherapeutic Medication (see CAHF sample form 1-2).
• A signed copy of "Resident/RP Consent for Use of Antipsychotic Medication (see CAHF sample form 2-1)
OR
• A signed copy of "Resident/RP Consent for Use of Psychotherapeutic Medication (see CAHF sample form 2-2)
D. FACILITY OBLIGATION TO FULLY INFORM RESIDENT/RP OF HEALTH STATUS Reference: CFR § 483.10(b)(2) and (3) F Tags 153 and 154
The facility is responsible for assuring: • Each resident is fully informed of his or her total health status, including but not limited to his/her medical condition. • The resident is fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being. • At any time, should the resident/RP indicate doubt or confusion about the use of antipsychotic/psychotherapeutic medication, or withdraw consent for same, contact the physician and/or the licensed health care practitioner (as appropriate).
E. EXCEPTIONS TO OBTAINING INFORMED CONSENT Reference: Title 22, CCR, Section 72528
There is documentation within the resident record that any of the following conditions are present:
• An emergency exists where there is an unanticipated condition in which immediate action is necessary for the preservation of life or the prevention of serious bodily hat, to the resident or others or to alleviate severe physical pain, and it is impractical to obtain the required consent and that the action taken is within the customary practice of the licensed healthcare practitioners of good standing acting within the scope of their professional licensure in similar circumstances.
• The resident or RP specifically requested that he/she is not to be informed of the risks of the recommended treatment

- That the licensed healthcare practitioner acting within his/her scope of professional licensure, relied upon objective facts, as documented in the health record, that would demonstrate to a reasonable person that the disclosure would have so seriously upset the resident that the resident would not have been able to rationally weight the risks of refusing to undergo the recommended treatment and that, unless inappropriate, a resident's representative gave informed consent as set forth herein.

F. RESIDENT LACKS CAPACITY AND NO LEGALLY AUTHORIZED DECISION MAKER

Reference: HSC Section, 1418.8

Requirement:

If the attending physician determines the resident lacks capacity and there is no person with legal authority to make those decisions on behalf of the resident, the MD shall inform the facility.

- The resident record contains documentation that there is no person who has legal authority who can or will make health care decisions as determined by the attending physician.

- IDT will review the proposed prescribed medical intervention prior to the administration of the proposed medication.

- The IDT shall include a registered nurse who has responsibility for the resident, other appropriate staff in disciplines as determined by the resident's needs and, where practicable, a patient representative.

The IDT review shall include the following:

- A review of the physician's assessment of the resident's condition.
- The reason for the proposed use of the medical intervention.
- The type of medical intervention to be used in the resident's care including its probable frequency and duration.
- The probable impact on the resident's condition, with and without the use of the medical intervention.
- Reasonable alternative medical interventions considered or utilized and reasons for their discontinuance or inappropriateness.

The IDT shall periodically evaluate the use of the prescribed medical intervention at least quarterly or upon a significant change in the resident's medical condition.

- **EXCEPTION**: In the case of an emergency, a medical intervention may be administered which requires informed consent prior to convening an IDT review. The IDT shall meet within one week of the emergency for evaluation of the medical intervention.

Verification of Informed Consent for Antipsychotic Medication

Resident name: _____

Medication : _____ *Expected Dosage Range:* _____

Specific medical condition / psychiatric diagnosis:

- ☐ Schizophrenia
- ☐ Schizoaffective Disorder
- ☐ Delusional Disorder
- ☐ Mood Disorders (e.g., Bipolar Disorder, Depression with Psychotic Features, Refractory Depression)
- ☐ Schizophreniform Disorders
- ☐ Psychosis
- ☐ Brief Psychotic Disorder
- ☐ Dementing illnesses w/ associated behavioral symptoms
- ☐ Medical illnesses w/psychotic symptoms and/or related to psychosis/ mania/delirium
- ☐ Tourette's or Huntington's
- ☐ Hiccups or Nausea and Vomiting associated with cancer or chemotherapy
- ☐ Other: _____

Potential/Expected Benefits:

Side Effects / Severity of Risks:

☐ Physician requests the facility send attached information about the medication and a copy of this form to resident and/or resident's surrogate decision-maker. Date sent _____ Signature _____

Warning for Antipsychotic Medication

The Food and Drug Administration (FDA) issued a Public Health Advisory for atypical antipsychotic medications. The FDA determined that the death rates are higher for elderly people with dementia when taking this medication. A review of the data has found a risk with conventional antipsychotics as well. Antipsychotic medications are not FDA approved for the treatment of behavioral disorders in patients with dementia. Source: National Institute of Mental Health U.S. Department of Health and Human Services www.nih.gov

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

I have discussed with _____, the following:
Circle one: resident and/or the resident's surrogate decision-maker

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ The above-named resident and/or the resident's surrogate decision-maker has given permission for use of the medication.

☐ The above-named resident has given permission to contact a designated family member regarding the use of anti-psychotic medication.

☐ The above-named resident has <u>not given permission</u> to contact a designated family member regarding the use of anti-psychotic medication.

_____
Ordering Physician's Signature Date

_____
Licensed Nurse Signature Verifying Evidence of Informed Consent Date

CAHF – Form 1 - 1
Nov. 6, 2012

Resident/Surrogate Decision Maker Informed Consent for Antipsychotic Medication

Resident name: _____

Medication : _____ *Expected Dosage Range:* _____

Specific medical condition / psychiatric diagnosis:

- ☐ Schizophrenia
- ☐ Schizoaffective Disorder
- ☐ Delusional Disorder
- ☐ Mood Disorders (e.g., Bipolar Disorder, Depression with Psychotic Features, Refractory Depression)
- ☐ Schizophreniform Disorders
- ☐ Psychosis
- ☐ Brief Psychotic Disorder
- ☐ Dementing illnesses w/ associated behavioral symptoms
- ☐ Medical illnesses w/psychotic symptoms and/or related to psychosis/ mania/delirium
- ☐ Tourette's or Huntington's
- ☐ Hiccups or Nausea and Vomiting associated with cancer or chemotherapy
- ☐ Other: _____

Potential/Expected Benefits:

Side Effects / Severity of Risks:

☐ See attached information sheet for additional information about this medication

Warning for Antipsychotic Medication

The Food and Drug Administration (FDA) issued a Public Health Advisory for atypical antipsychotic medications. The FDA determined that the death rates are higher for elderly people with dementia when taking this medication. A review of the data has found a risk with conventional antipsychotics as well. Antipsychotic medications are not FDA approved for the treatment of behavioral disorders in patients with dementia. Source: National Institute of Mental Health U.S. Department of Health and Human Services www.nih.gov

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

The physician has discussed the following:

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ I have given permission for use of the medication.

_____

Resident Signature Date

or

_____

Resident's Surrogate Decision-maker Date

Verification of Informed Consent for Psychoactive Medication

Resident name: _____

Medication : _____	*Expected Dosage Range:* _____
Symptoms to be treated:	
Potential/Expected Benefits:	
Side Effects / Severity of Risks:	
☐ Physician requests the facility send attached information about the medication and a copy of this form to resident and/or resident's surrogate decision-maker. Date sent _____ Signature _____	

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

I have discussed with _____, the following:
Circle one: resident and/or the resident's surrogate decision-maker

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ The above-named resident and/or the resident's surrogate decision-maker has given permission for use of the medication.

_____
Ordering Physician's Signature Date

_____
Licensed Nurse Signature Verifying Evidence of Informed Consent Date

Resident/Surrogate Decision Maker Informed Consent for Psychoactive Medication

Resident name: _____

Medication : _____	*Expected Dosage Range:* _____
Symptoms to be treated:	
Potential/Expected Benefits:	
Side Effects / Severity of Risks:	
☐ See attached information sheet for additional information about this medication	

INFORMED CONSENT VERIFICATION (CHECK BOX THAT APPLIES)

The physician has discussed the following:

- The reason for the treatment and the nature and seriousness of the resident's illness
- The nature of the proposed treatment including frequency and duration
- The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment
- The nature, degree, duration, and probability of the side effects and significant risks (e.g., FDA boxed warning), commonly known by the health professions
- The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment
- That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

☐ I have given permission for use of the medication.

_____

Resident Signature Date

or

_____

Resident's Surrogate Decision-maker Date

Patient Information Sheet

Clozapine
(marketed as Clozaril)

This is a summary of the most important information about Clozaril. For details, talk to your healthcare professional.

What is Clozaril?

Clozaril is a prescription medicine used to treat people with severe forms of schizophrenia that have not responded to or cannot take other treatments. Clozaril is also used to lower the risk of suicidal behavior in people with schizophrenia or schizoaffective disorder. Clozaril is not approved for use in children.

Who Should Not Take Clozaril?

You should not take Clozaril if:

- You are taking other medicines that can cause the same serious bone marrow side effects as Clozaril.
- You can ask your healthcare professional for a complete list of these medications.

What are The Risks?

The following are the risks and potential side effects of Clozaril therapy. However, this list is not complete.

- ***Increased chance of death in elderly persons.*** Elderly patients treated with atypical antipsychotics, such as Clozaril, for dementia had a higher chance for death than patients who did not take the medicine. Clozaril is not approved for dementia.
- ***Agranulocytosis,*** a potentially life-threatening reaction where the body's bone marrow does not produce enough white blood cells. Because of this risk, your healthcare professional must monitor your blood while you are taking Clozaril.
- ***Seizures***. The risk of seizure is increased in people who have a history of seizures or other predisposing factors. Because of this risk you should not engage in any activity where you may suddenly lose consciousness, such as operating complex machinery, driving, swimming, climbing, etc.
- ***Heart problems***. Clozaril can cause a condition called myocarditis, or swelling of the heart muscle. Some of the warning signs of myocarditis are tiredness, shortness of breath, rapid breathing, fever, chest pain, and irregular heart beat. If these happen, call your healthcare professional right away.
- ***Lowering of blood pressure*** when you stand up. This may also lead to fainting. In rare instances, this has been associated with lung and/or heart collapse.

Clozaril and other antipsychotic medications can cause serious problems such as:

- ***A life-threatening nervous system problem called neuroleptic malignant syndrome (NMS).*** NMS can cause a high fever, stiff muscles, sweating, a fast or irregular heart beat, change in blood pressure, and confusion. NMS can affect your kidneys. NMS is a medical emergency. Call your healthcare professional right away if you experience these symptoms.
- ***A movement problem called tardive dyskinesia (TD).*** Call your healthcare professional right away if you get muscle movements that cannot be stopped.
- ***High blood sugar and diabetes.*** Patients with diabetes or who have a higher chance for diabetes should have their blood sugar checked often.
- ***Other serious side effects may*** include fever, blood clots in the lung, increased blood sugar, and liver disease.
- ***The most common side effects*** include drowsiness, increased salivation, rapid heart beat, dizziness, constipation, headache, shaking, and lightheadedness.

What Should I Tell My Healthcare Professional?

Before you start using Clozaril, tell your healthcare professional if you:

- have or had heart or lung problems
- have or had seizures
- have or had blood clots
- have or had diabetes or increased blood sugar
- have or had liver disease
- have or had glaucoma
- have or had stomach problems
- have or had prostate enlargement
- are trying to become pregnant, are already pregnant, or are breast-feeding
- drink alcohol
- smoke

Clozapine
(marketed as Clozaril)

Are There Any Interactions With Drugs or Foods?

Because certain other medications can interact with Clozaril, review all medications that you are taking with your health care professional, including those that you take without a prescription. You should not take Clozaril if you are taking other medicines that can cause the same serious bone marrow side effects as Clozaril.

Your healthcare professional may have to adjust your dose or watch you more closely if you take the following medications:

- certain medicines used to treat anxiety, called benzodiazepines
- certain medicines used to clear thoughts, called psychotropic drugs
- epinephrine
- phenytoin
- rifampin
- cimetidine
- erythromycin
- carbamazepine
- fluvoxamine
- paroxetine

Avoid drinking alcohol while taking Clozaril.

Is There Anything Else I Need to Know?

- Dizziness, and sometimes fainting, caused by a drop in blood pressure may happen with Clozaril, especially when you first start taking this medicine or when the dose is increased.

- Clozaril may impair judgment, thinking, or motor skills. You should be careful in operating machinery, including automobiles, until you know how Clozaril affects you.

Clozaril FDA Approved 1989
Patient Information Sheet Revised 09/2006

Mental Health Medications: Antipsychotics

Adapted from Mental Health Medications – National Institute of Mental Health
U.S. Department of Health and Human Services

To see more go to:

www.nih.gov

-Click on "Health Topics"
-Click on "Publications"
-Select "Mental Health Medications"

You Have The Right To be Fully Informed About The Benefits and Risks of Antipsychotic Medication

California Informed Consent Requirements

California Code of Regulations, Title 22 § 72528 (a) It is the responsibility of the attending licensed healthcare practitioner acting within the scope of his or her professional licensure to determine what information a reasonable person in the patient's condition and circumstances would consider material to a decision to accept or refuse a proposed treatment or procedure. Information that is commonly appreciated need not be disclosed. The disclosure of the material information and obtaining informed consent shall be the responsibility of the physician. The disclosure of the material information and obtaining informed consent shall be the responsibility of the licensed healthcare practitioner who, acting within the scope of his or her professional licensure, performs or orders the procedure or treatment for which informed consent is required.

(b) The information material to a decision concerning the administration of a psychotherapeutic drug or physical restraint, or the prolonged use of a device that may lead to the inability of the patient to regain use of a normal bodily function shall include at least the following:

(1) The reason for the treatment and the nature and seriousness of the patient's illness.

(2) The nature of the procedures to be used in the proposed treatment including their probable frequency and duration.

(3) The probable degree and duration (temporary or permanent) of improvement or remission, expected with or without such treatment.

(4) The nature, degree, duration and probability of the side effects and significant risks, commonly known by the health professions.

(5) The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment.

(6) That the patient has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

Your Company Logo will Appear Here

Mental Health Medications: Antipsychotics Benefits and Risks

Company Phone number
Company FAX number
Website Address
Company Address

Exhibit B

Mental Health Medications: Antipsychotics

Antipsychotic medications are used to treat schizophrenia and schizophrenia-related disorders, psychotic symptoms, hallucinations and delusions (breaks in reality). Some of the "typical" antipsychotics include:

- Chlorpromazine (Thorazine)
- Haloperidol (Haldol)
- Perphenazine
- Fluphenazine

In 2009 new antipsychotic medications were developed. These new medications are called second generation or "atypical" antipsychotics. Some of the "atypical" antipsychotics include:

- Risperidone (Risperdal)
- Olanzapine (Zyprexa)
- QueΘapine (Seroquel)
- Ziprasidone (Geodon)
- Aripiprazole (Abilify)
- Paliperidone (Invega)

NOTE: The FDA issued a Public Health Advisory for atypical antipsychotic medications. The FDA determined that the death rates are higher for elderly people with dementia when taking this medication. A review of the data has found a risk with conventional antipsychotics as well. Antipsychotic medications are not FDA approved for the treatment of behavioral disorders in patients with dementia.

What are the Side Effects?
Side effects may include, but not be limited to:

- Drowsiness
- Dizziness when changing posiΘons
- Blurred vision
- Rapid heartbeat
- SensiΘvity to the sun
- Skin rashes
- Major weight gain
- Changes in metabolism
- Rigidity
- Persistent muscle spasms
- Tremors restlessness

Long term use of typical antipsychotic medications may lead to a condition called tardive dyskinesia (TD). TD causes muscle movements a person cannot control the movements commonly happen around the mouth. TD can range from mild to severe, and in some people the problem cannot be cured. Sometimes people with TD recover partially or fully after they stop taking the medication.
Every year, an estimated 5 percent of people taking typical antipsychotics get TD. The condition happens to fewer people who take the new, atypical antipsychotics, but some people may still get TD.

How are Antipsychotics Taken and How do People Respond to Them?

Antipsychotics are usually pills that people swallow or liquid they can drink. Some antipsychotics are shots that are given once or twice a month.

Symptoms of schizophrenia, such as feeling agitated and having hallucinations, usually go away within days. Symptoms like delusions usually go away within a few weeks. After about six weeks, many people will see a lot of improvement.

Add Facility Information Here

Acknowledgements:

The *Improving Dementia Care: Reducing Antipsychotic Medication Use in Nursing Homes Toolkit* was created in collaboration with the California Association of Healthcare Facilities (CAHF) quality improvement subcommittee and Health Services Advisory Group of California, Inc., (HSAG of California). We wish to acknowledge the members of the subcommittee for their involvement and contributions in the creation of this toolkit:

Nancy Beecham, RN

Joseph M. Bestic, NHA, BA

April Diaz, RN

Mira Jensen, RN

Laurie Kjar, CTRS

Jocelyn Montgomery, RN, PHN

Karl Steinberg, MD, CMD

Thank you!

Improving Dementia Care
Reducing Antipsychotic Medications
Helpful Web Sites

American Health Care Association:
http://www.ahcancal.org/

American Health Care Association: Quality Improvement – Antipsychotics:
http://www.ahcancal.org/quality_improvement/qualityinitiative/Pages/Antipsychotics.aspx

Advancing Excellence: Improving Dementia Care in Nursing Homes:
http://www.nhqualitycampaign.org/star_index.aspx?controls=dementiaCare

Barclays Official California Code of Regulations:
http://weblinks.westlaw.com/toc/default.aspx?Abbr=ca%2Dadc&Action=ExpandTree&AP=I70C62EB0D4BC11DE8879F88E8B0DAAAE&ItemKey=I70C62EB0D4BC11DE8879F88E8B0DAAAE&RP=%2Ftoc%2Fdefault%2Ewl&Service=TOC&RS=WEBL13.07&VR=2.0&SPa=CCR-1000&pbc=DA010192&fragment#I70C62EB0D4BC11DE8879F88E8B0DAAAE

CAHF Resources:
http://www.cahf.org/Home/Psychoactives.aspx

CMS Hand in Hand:
http://www.cms-handinhandtoolkit.info/Index.aspx

CMS QIS Forms:
http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/QIS-Survey-Forms.html

CMS: S &C letter 13-35-NH: Dementia F309 and F329:
http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-35.pdf

CMS Surveyor Training Videos:
http://surveyortraining.cms.hhs.gov/index.aspx

FDA Conventional Antipsychotic Web site:
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm107211.htm

Health Services Advisory Group of California:
https://www.hsag.com

Improving Dementia Care
Reducing Antipsychotic Medications
Helpful Web Sites

HSAG of California Resources:
http://www.hsag.com/canursinghomes/default.aspx

Improving Antipsychotic Appropriateness in Dementia Patients (IA-ADAPT) Web site:
https://www.healthcare.uiowa.edu/igec/IAADAPT

Iowa Geriatric Education Center:
http://www.healthcare.uiowa.edu/igec/publications/info-connect/

Music and Memory:
http://musicandmemory.org/

QAPI Web site:
https://go.cms.gov/nhqapi

State Operations Manual-Appendix PP:
http://www.cms.gov/Regulations-and
Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

This program is made possible by a grant from the
Massachusetts Department of Public Health,
Bureau of Health Care Safety and Quality

Statewide Initiative to Safely Reduce the Off-Label Use of Antipsychotics

OASIS Training Materials

Press "Ctrl" on your keyboard while clicking the link to open or copy and paste the link into your internet browser.

Manual: http://www.maseniorcare.org/2012_OASIS_Manual.aspx

Module I

- Welcome to OASIS: http://www.maseniorcare.org/Welcome_to_Oasis.aspx
- Power of Labels Exercise: http://www.maseniorcare.org/Power_of_Labels_Exercise.aspx
- OASIS I Refresher Video: http://youtu.be/NJXaEzYB7bw
- Look at Me Video: http://youtu.be/XBnrWmgfUC8

Module II

- Recovery and Strength Based Person Centered Care: http://www.maseniorcare.org/Recovery_and_Strength_Based_Person_Centered_Care.aspx
- Strength Based Care Exercise: http://www.maseniorcare.org/Strength_Based_Care_Exercise.aspx
- VIPS Framework Quality Assurance Tool: http://www.maseniorcare.org/VIPS_Framework_Quality_Assurance_Tool.aspx
- Module II Refresher Video: http://youtu.be/O2Ikj84VFkg
- Fear Video: http://youtu.be/SqtBxkLCY18
- Suzanne Video- Long Version: http://youtu.be/vJghOYYK_qI
- Suzanne Video- Short Version: http://youtu.be/5LQNn5m_f54

Module III

- All About Behavior: http://www.maseniorcare.org/All_About_Behavior.aspx
- Disruptive Behaviors Form: http://www.maseniorcare.org/Disruptive_Behaviors_Form.aspx
- Emotions Flash Cards – Completed: http://www.maseniorcare.org/Emotions_Flash_Cards_Completed.aspx
- Emotions Flash Cards – Not Completed: http://www.maseniorcare.org/Emotions_Flash_Cards_Not_Completed.aspx
- Module III Refresher Video: http://youtu.be/BKxPcEDryqA
- Getting Dressed Video: http://youtu.be/VECHcoczwUk
- Lost Watch Video: http://youtu.be/ao7Hx-6u26M
- My Chair Video: http://youtu.be/veCH-ia_f0Q
- Taking Meds Video: http://youtu.be/dJmQhmv-TJI

Module IV

- Basic Human Needs Worksheet: http://www.maseniorcare.org/Basic_Human_Needs_Worksheet.aspx
- Interventions: http://www.maseniorcare.org/Interventions.aspx
- Module IV Refresher Video: http://youtu.be/bh5CY8fX4PU
- Leaving Video: http://youtu.be/Qnn0rIcE7N8
- Repetitive Questions Video: http://youtu.be/H-WoeDIJMqY

Miscellaneous

- OASIS Core Competency Test: http://www.maseniorcare.org/OASIS_Core_Competency_Test.aspx
- List of All Video Links: http://www.maseniorcare.org/List_of_All_Video_Links.aspx

Additional Resources

- Physician Engagement:
    - An AHCA Sample Dear Doctor Letter: http://www.maseniorcare.org/AHCA_Sample_Dear_Doctor_Letter.aspx
    - An AMDA Antipsychotics Letter for Medical Directors: http://www.maseniorcare.org/AMDAAntipsychoticsLetter.aspx
    - An OASIS Dear Doctor Letter with the Sample Monthly Follow Up Letter You Can Use: http://www.maseniorcare.org/Sample_monthly_follow_up_letter.aspx
    - Multidisciplinary Guide for Antipsychotic Reduction: http://www.maseniorcare.org/MULTIDISCIPLINARY_MEDICATION_MANAGEMENT_COMMITTEE.aspx

  These are designed for you to use to engage your prescribers.

- Data Tracking:
    - Hard Copy/Paper and Pencil Antipsychotic Tracking Form: http://www.maseniorcare.org/antipsychotic_tracking_form.aspx
    - Excel Spreadsheet Tracking Form: http://www.maseniorcare.org/Excel_Antipsychotic_Prescription_Log.aspx

  You can add/edit/tweak these to fit the needs of your facility

- OASIS Curriculum:
    - The Suzanne Story Background: http://www.maseniorcare.org/suzannes_story_1.aspx

- Engaging Families:
    - The Antipsychotic Fact Sheet: http://www.maseniorcare.org/AntipsychotFctsheetFINAL_508_Compliant_03_18_13.aspx

- Webinars
    - OASIS Webinar Featuring Alice Bonner, PhD, RN from CMS – March 28, 2013 http://www.maseniorcare.org/Webinar_March_28.aspx
    - OASIS Webinar Featuring Clifford P Kibbe, JR from Omnicare – February 7, 2013 http://www.maseniorcare.org/Webinar_February_7.aspx