

Impact of pharmacist intervention in minimizing inappropriate use of Proton Pump Inhibitors in the elderly

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Problem: What is all the fuss about PPI use?

How to unlock the problem?

Your team may have the key - and a pharmacist may be holding it!

Factors leading to PPI overuse

- Very effective for reducing stomach acid
- Relatively benign when used as recommended
- Usual maximum course of therapy is 4 to 8 weeks
- Marketing and OTC status has made it readily available
- Commonly used for almost any type of gastric acid ailment
- Actual GERD prevalence in the U.S. ranges from 18% - 27.8%
- Often continued after hospitalization regardless of need

Despite FDA alerts/concerns of PPI long-term use

- Increased risk of fractures – hip, wrist, spine (problematic in the elderly due to an already increased risk for falls)
- Increased risk of *Clostridium difficile*-associated diarrhea (problematic in the elderly due to an already diminished immune system)
- Increased risk of hypomagnesemia → cramps, arrhythmias (problematic in the elderly due to an already limited intake and absorption)
- On 4/30/14, Public Citizen filed a lawsuit against the FDA demanding that the long term side effects of PPIs be upgraded to a black box warning – the issue will not go away

And CMS requires evaluation of appropriate PPI use

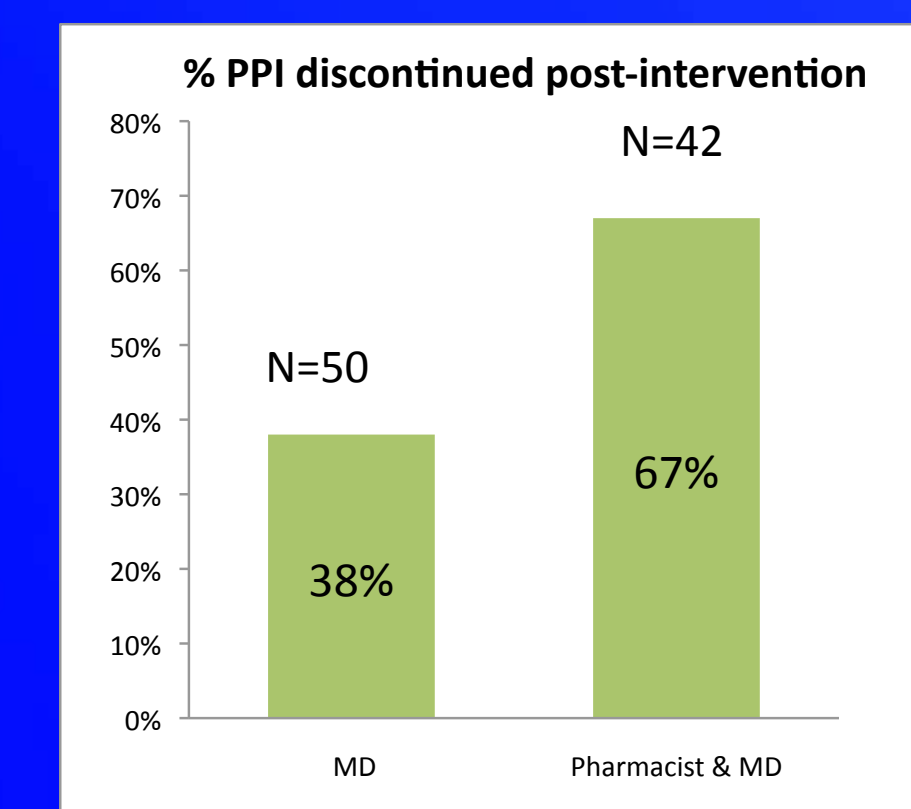
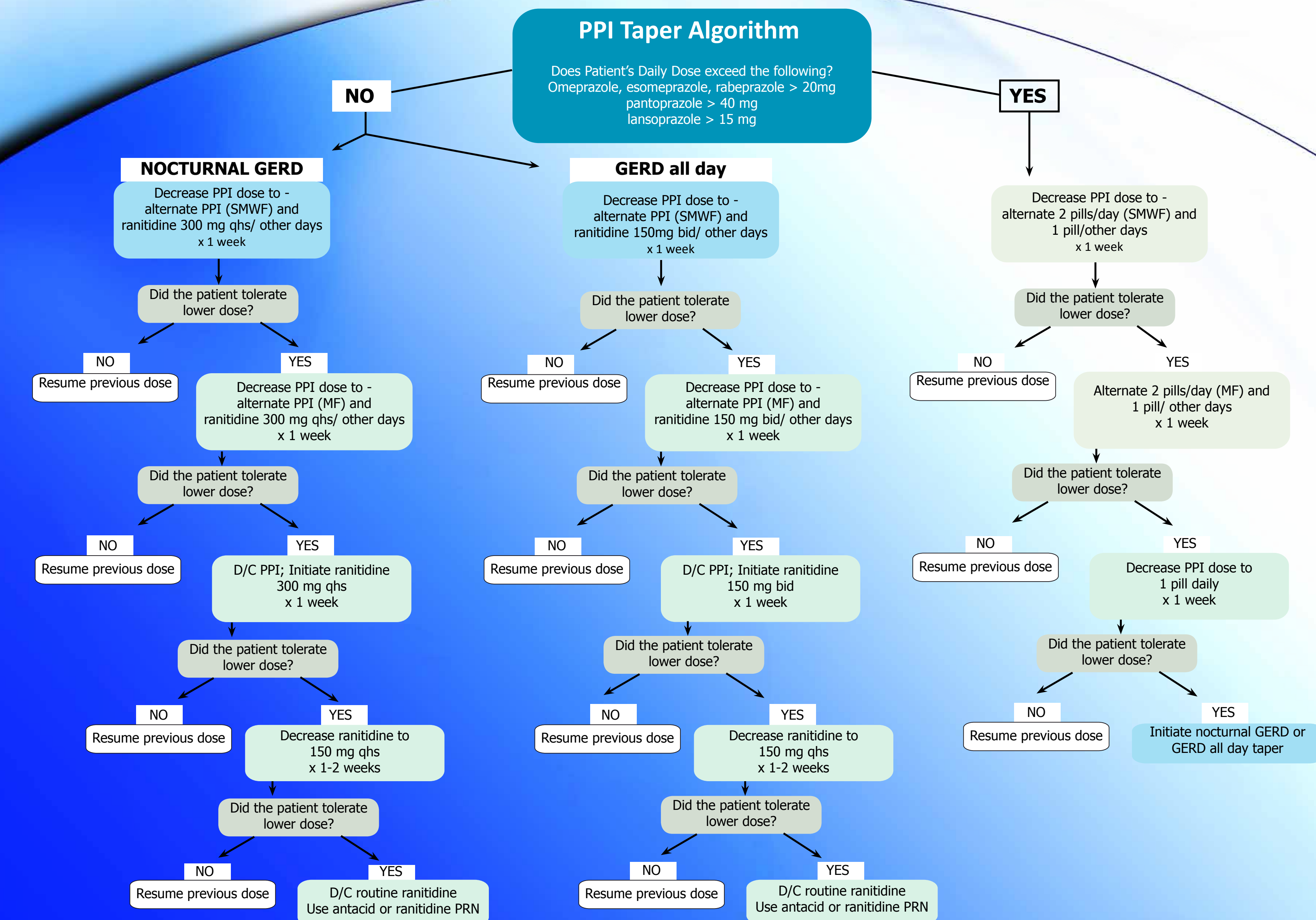
- CMS included PPIs in F-tag 329, Unnecessary Drugs
- CMS expects PPI prescribing to meet one of the FDA approved indications and dosing options
- CMS expects justifying documentation if used for more than 12 weeks
- F-tag 329 citations are among the most prevalent assessed
- CMS also warned about adverse reactions and risks with long-term use of PPIs

Stomach acid is a necessary bodily function!

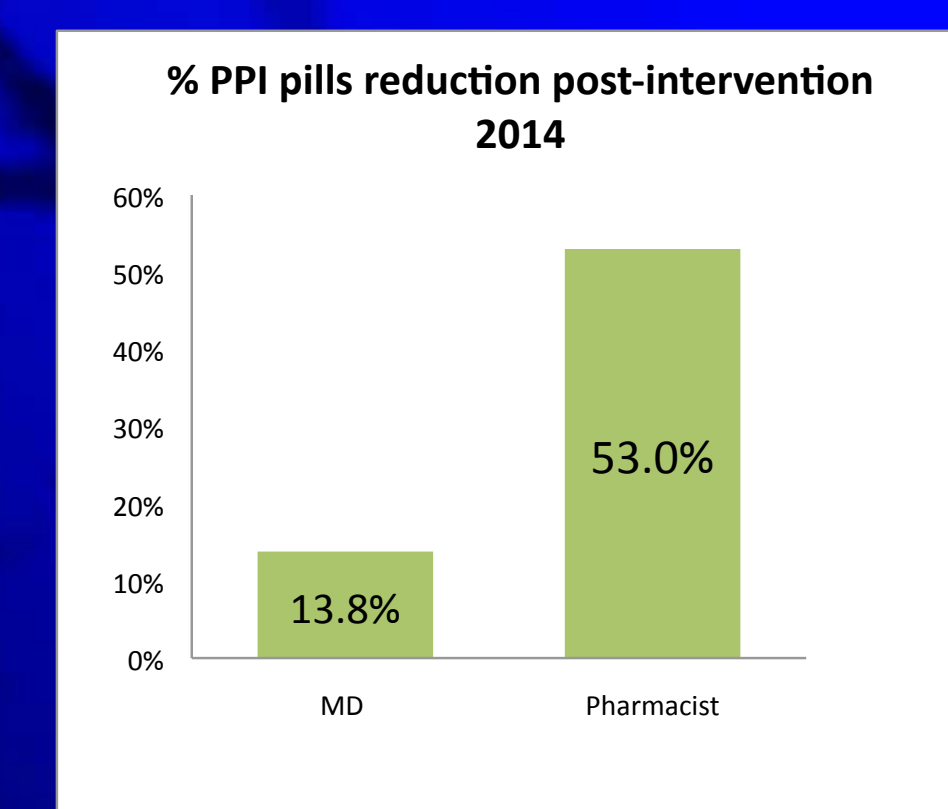
- High acidity poses as a barrier to infections
- Lack of acid is associated with gastric polyps
The effects of PPI therapy on the gastric mucosa, hypergastrinemia, parietal cell protrusion, ECL-cell hyperplasia, progression of *H. pylori* gastritis and the development of atrophy may predispose to the formation of gastric polyps
- Acidic environment of stomach is needed for proper digestion
- Paradoxically, sufficient stomach acid helps prevent GERD!
Proper digestion of food allows appropriate stomach emptying leading to a decrease risk of gastritis and GERD

Objectives: How do we unlock the problem

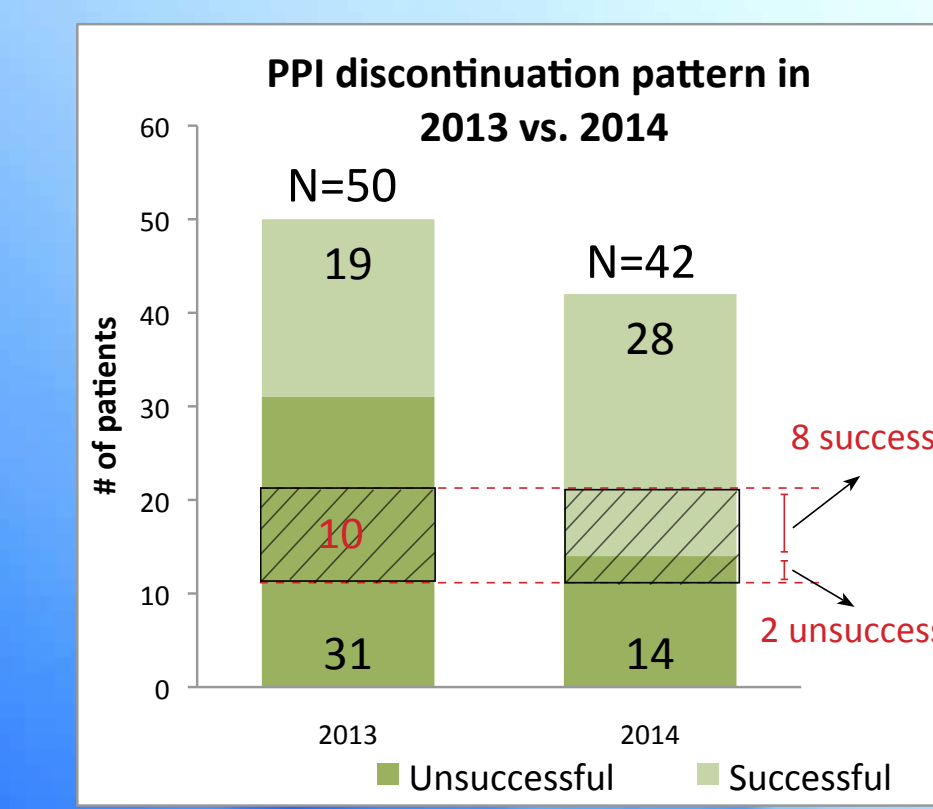
- Identify unnecessary use of PPI and discontinue PPI treatment if possible
- Determine whether an approach such as tapering off of PPI therapy is more successful than discontinuing abruptly in those who have been on long-term PPI therapy (> 1 year)



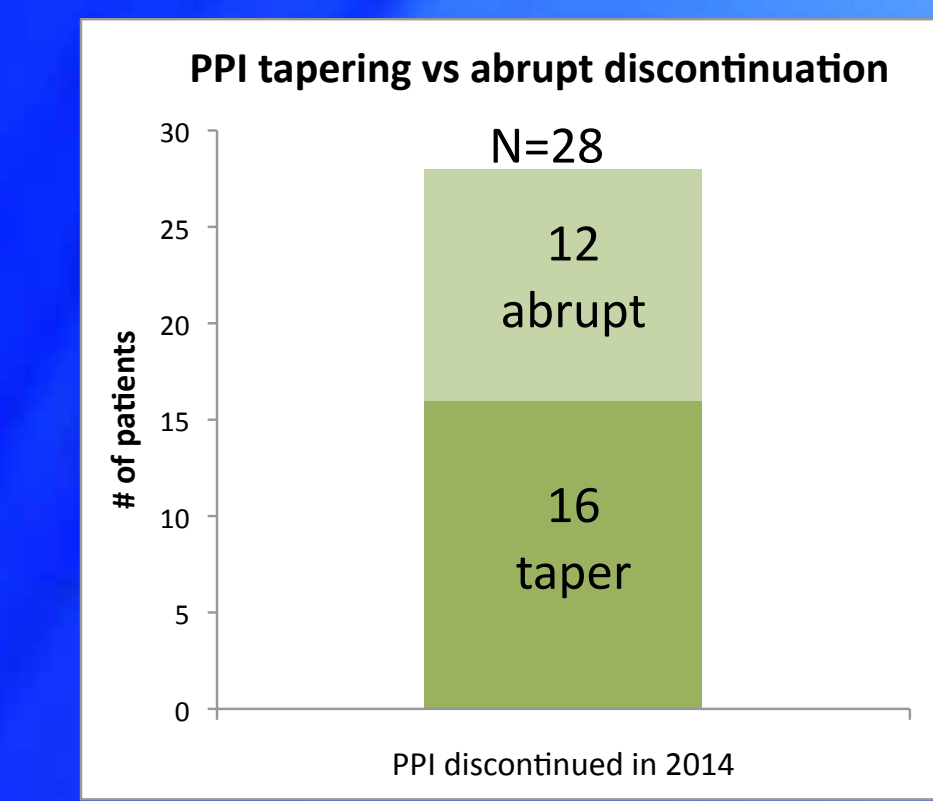
Baseline data from 2013 showed that in the normal course of events, PPI use in the facility was discontinued in 19 of 50 residents (a rate of 38%). During the first four months of 2014, with the addition of pharmacist intervention, PPI use was discontinued in 28 of 42 residents (a rate of 67%), a statistically significant difference ($p < 0.05$).



In 2014, some residents in the pharmacy intervention group were able to decrease their PPI dosage. Looking at the results in another way, the number of PPI pills taken by the residents was reduced 53% with pharmacist intervention versus 13.8% without pharmacist intervention, also statistically significant ($p < 0.05$).



Of 31 residents who were still on PPIs in 2013 going into 2014, 22 were discontinued with pharmacist intervention in 2014 (71%). Among those 31 that continued into 2014, 10 residents had failed abrupt PPI discontinuation in 2013 and of those 10, 8 were successfully tapered off in 2014 with pharmacist intervention. Some subjects who discontinued PPIs were transitioned to H2RA and/or pancrelipase to prevent or treat breakthrough symptoms.



There was no significant difference in number of PPI discontinuations comparing tapering vs abrupt. However, many of the abrupt discontinuations were successful because residents were already not taking the PPI. But as mentioned in the previous graph, 80% of residents that did not tolerate an abrupt discontinuation did so when tapered off.

Three main reasons for PPI misuse

- 1) The problem is easily overlooked
 The key is **pharmacist drug regimen reviews**
 Prioritization and limited time are often the reason that PPI misuse is overlooked. Through the drug regimen review, the pharmacist can bring attention to this, but that alone is not enough.
- 2) Adverse effects of long-term PPI use are insidious
 The key is **pharmacist education on PPI potential harm**
 Adverse effects from PPI misuse are those that the elderly may associate with old age so the connection is not obvious. Getting the message out on the long-term side effects to patients is lacking so education is imperative—something a pharmacist is trained to do.
- 3) Patients feel the PPI is needed or the burning will return
 The key is **pharmacist monitoring of PPI taper progress**
 Patients may complain of pill burden but continue to take a PPI, because it removes the burning sensation. Abrupt withdrawal may lead to an acid rebound effect, so a gradual reduction may be required. A pharmacist can play key role in monitoring the progress of a controlled, gradual tapering off of PPIs. In cases where abrupt discontinuation failed, tapering was proven to be 80% effective in our study.

Alternative treatments in place of PPIs

1. H₂RA (Histamine₂ Receptor Antagonist)
 PPIs irreversibly inhibit proton pumps to stop the production of acid, which contributes to its long-term adverse effects. H₂RAs only temporarily block gastric acid secretion and do not affect pepsin secretion making this class of drug a safer choice.
2. Antacids
 Antacids provide quick, temporary relief from “burning” by directly neutralizing the acid in the stomach.
2. Other supplementary aids
 Lack of sufficient amount of digestive enzymes can be the cause of improper digestion. When food stays undigested, stomach emptying is delayed & more acid is produced, increasing chance of burning & GERD.

Benefits

- 1) Minimizing of potential negative health effects from PPIs
- 2) Cost savings from discontinuance of unnecessary medications and avoidance of associated health problems
- 3) Greater compliance with CMS F-tag 329
- 4) Likely improved digestive process for the resident
- 5) Enhanced utilization of resources, namely the pharmacist

Acknowledgements/References

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