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COVID-19 Webinar Series

September 12, 2022

1



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2

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Heather D'Adamo, MD, CMD

Janice Hoffman-Simen, Pharm.D., EdD, APh, BCGP, FASCP

Ashkan Javaheri, MD

Albert Lam, MD

Dominic Lim, MPH

Karl Steinberg, MD, CMD, HMDC

Michael Wasserman, MD, CMD



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3



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5



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CALTCM COVID-19 Webinar Series November 7



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6



Webinar Faculty

Jessica de Jarnette, MS, MD

Medical Officer

COVID-19 Response, Clinical Team

Science Branch

California Department of Public Health
(CDPH)



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7



Webinar Faculty

Jay Luxenberg, MD

Retired Geriatrician

CALTCM, Wave Editor-in-Chief

San Francisco, CA



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Webinar Faculty

Christopher Wang, PharmD

General Manager

Omnicare of Northern California



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Webinar Moderator

Michael Wasserman, MD, CMD

Geriatrician

CALTCM, Immediate Past-President and
Chair, Policy & Professional Services

Committee

Newbury Park, CA



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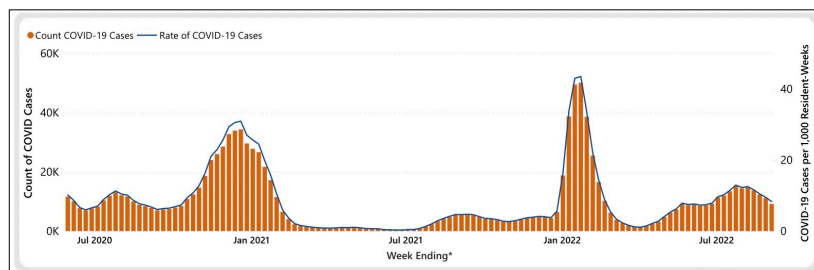
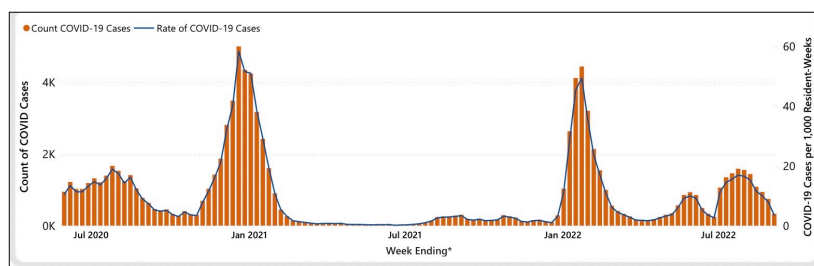
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COVID-19 Treatment Updates for Nursing Homes

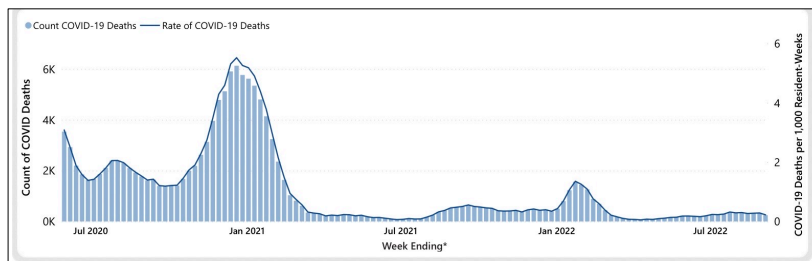
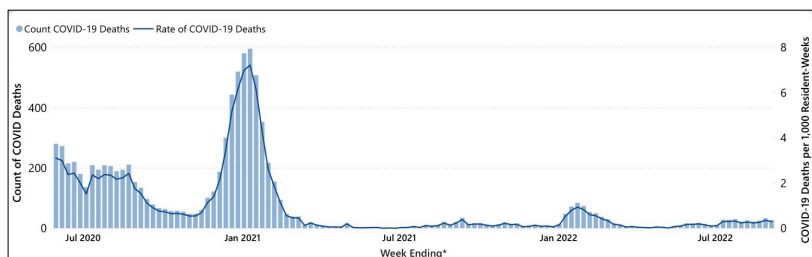
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National/ CA NH Resident Covid Cases



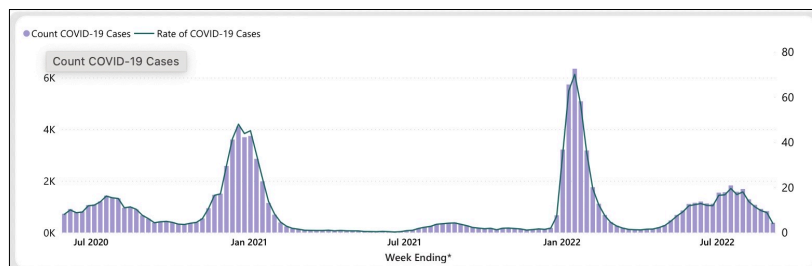
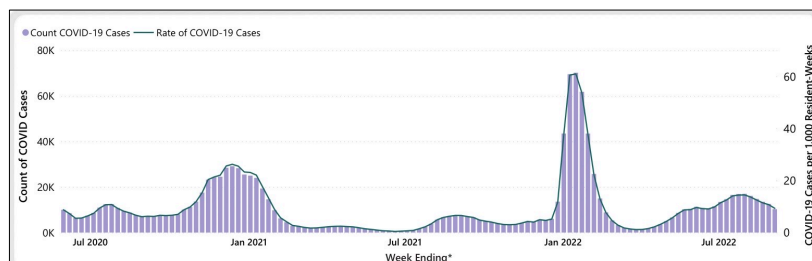
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National/ CA NH Resident Covid Deaths



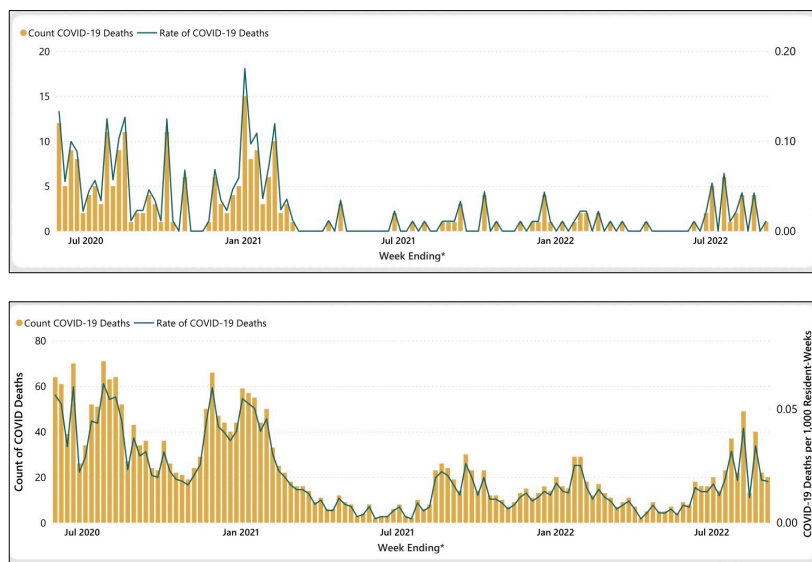
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National/ CA NH Staff Cases



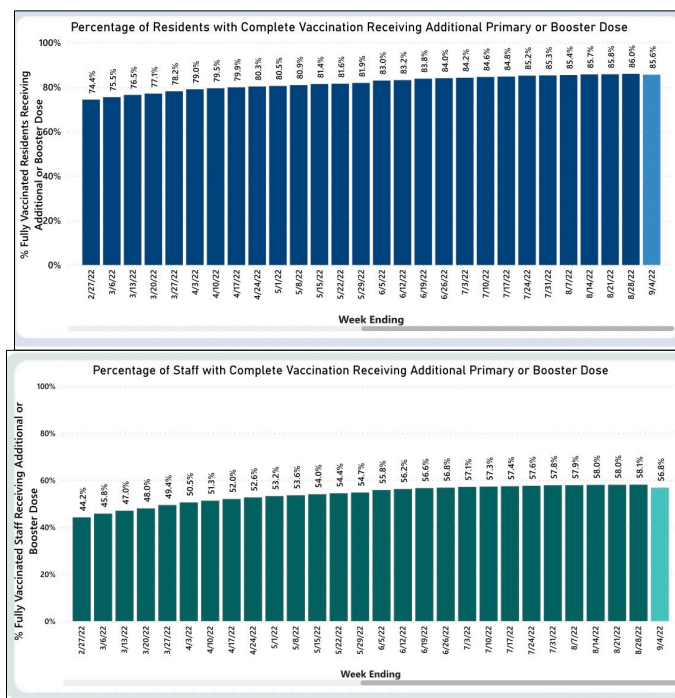
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National/ CA NH Staff COVID Deaths



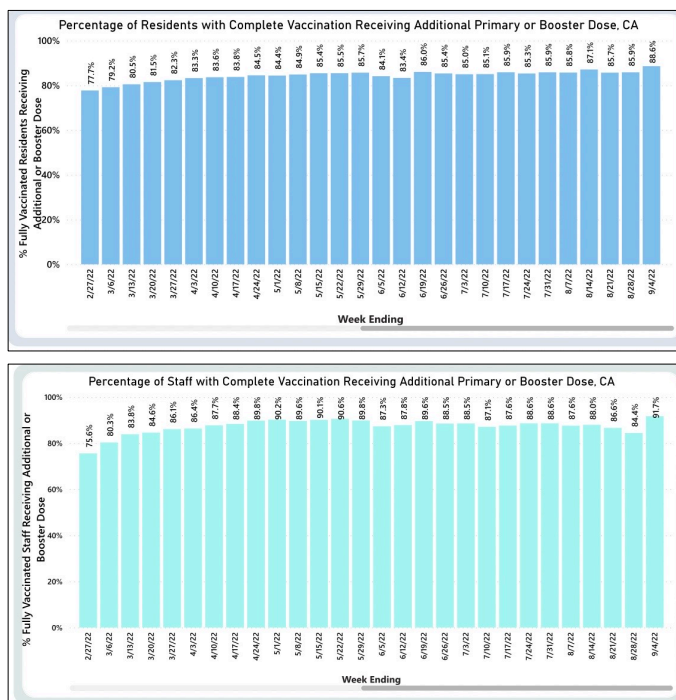
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Percentage of National Staff and Residents w/ Vax/Boost



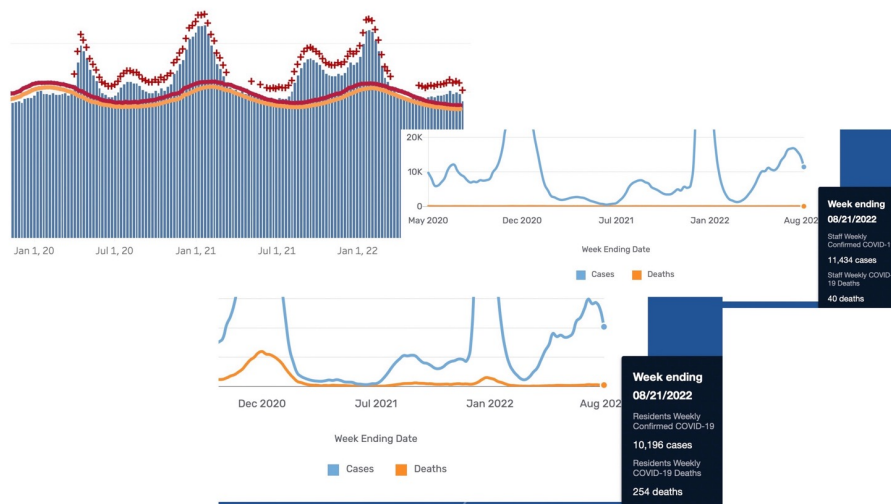
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Percentages of CA Staff and Residents w/ Vax/Boost

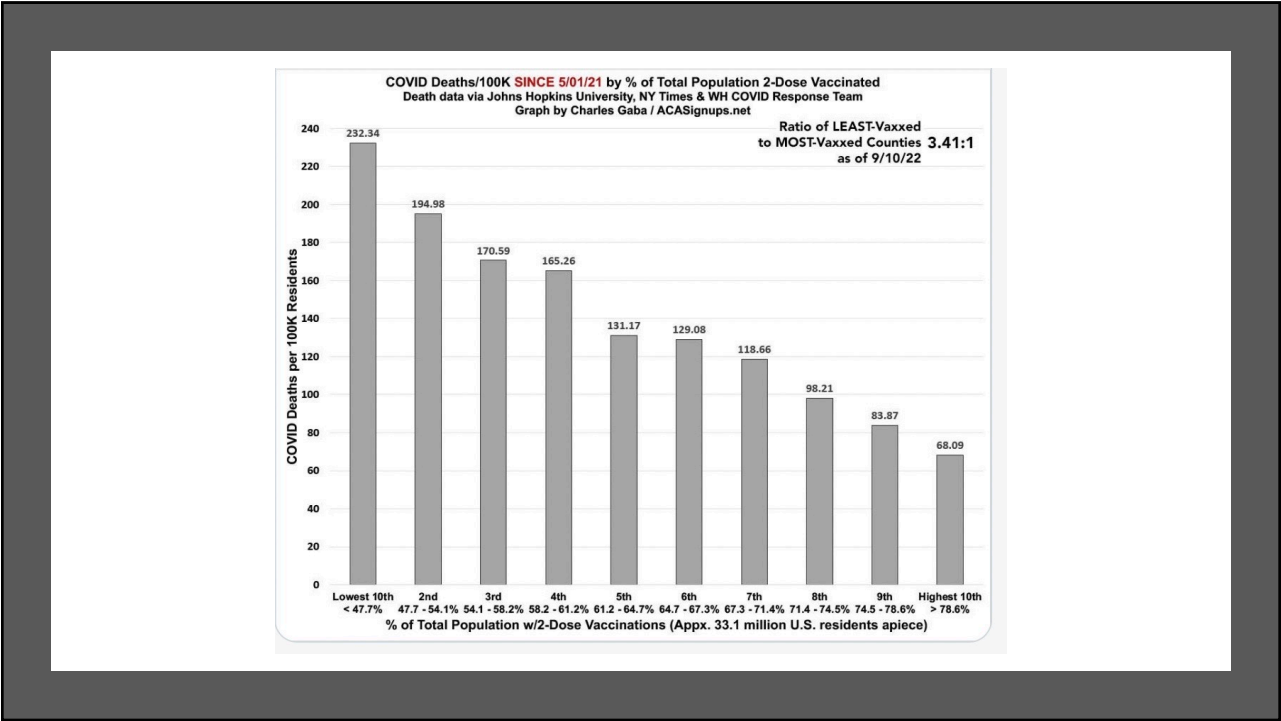


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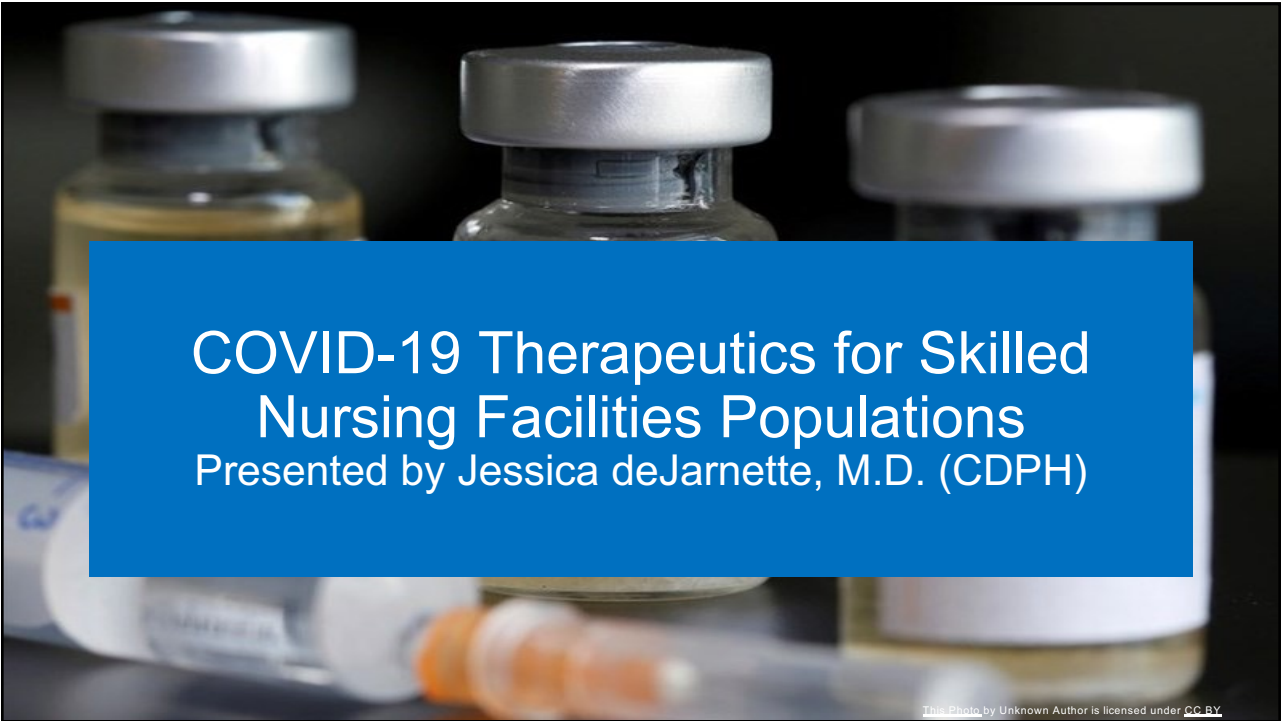
NATIONAL EXCESS DEATH AND NURSING HOME STAFF AND RESIDENT DEATH DATA



18



19



20

COVID-19 Therapeutics for Skilled Nursing Facilities Populations

Presented by Jessica deJarnette, M.D. (CDPH)



September 12, 2022

1

1

Agenda

- Current COVID mortality and TX data in LTC populations
- Benefits of Paxlovid and other COVID TX use in LTC population
 - Epidemiologic data and preventable deaths
 - Clinical trial data
- Preparing for COVID TX use in fall and winter surges
- Best practices

2

2

Benefits of COVID TX in LTC Population

Epidemiological Data and Preventable Deaths

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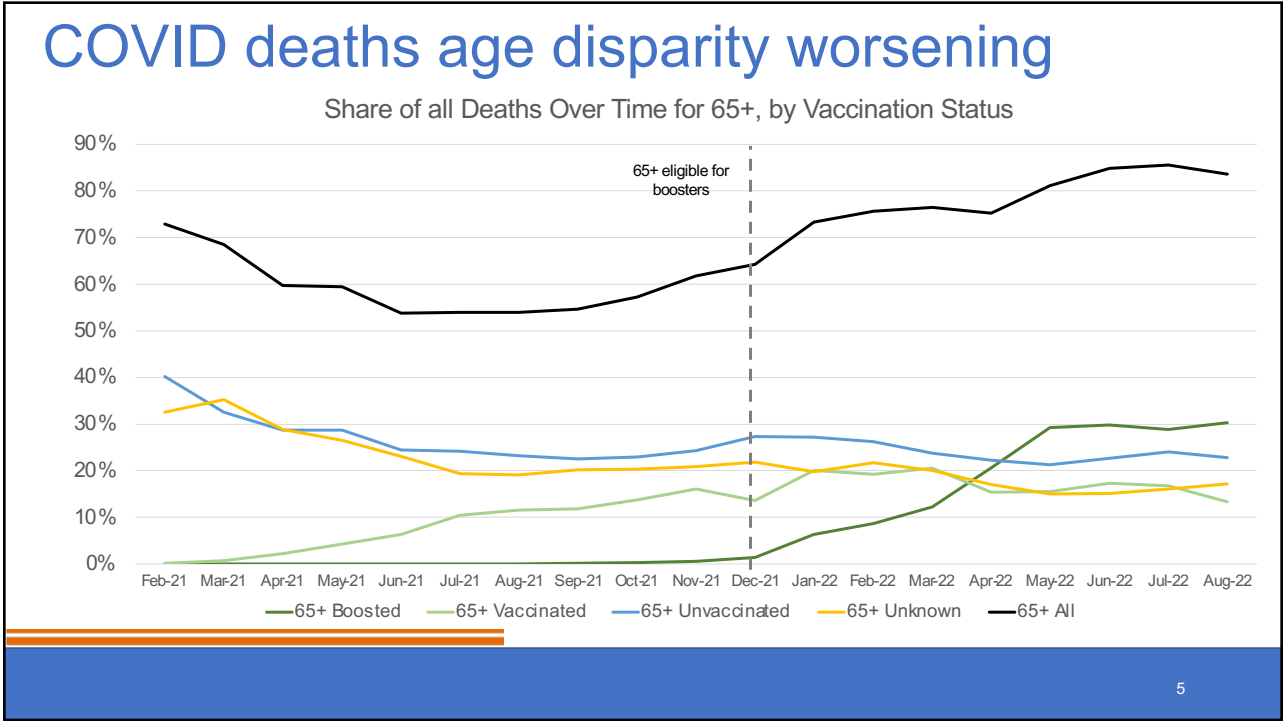
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COVID deaths disproportionately affect 65+

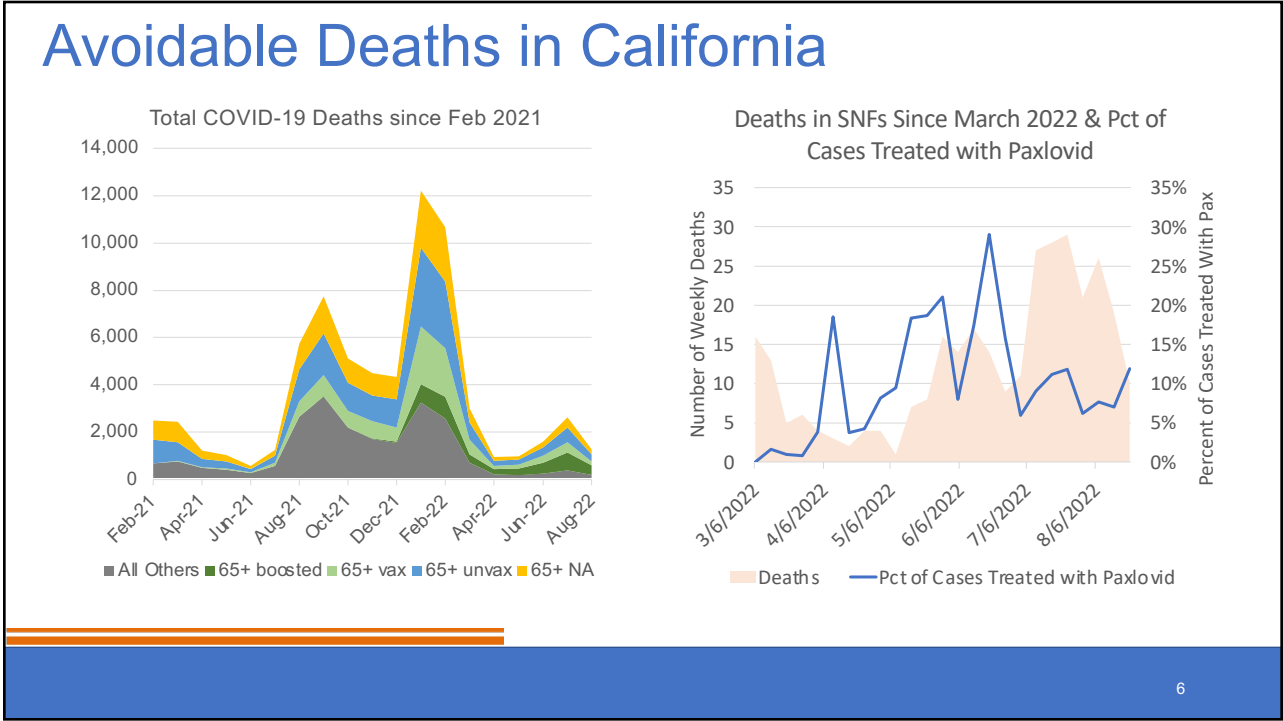
- 65+ only accounts for 10% of entire CA population
- Share of deaths > share of cases for 65+, even for vaccinated and boosted
- Data is for February 2021 and after, which is after 65+ became eligible for vaccinations in CA

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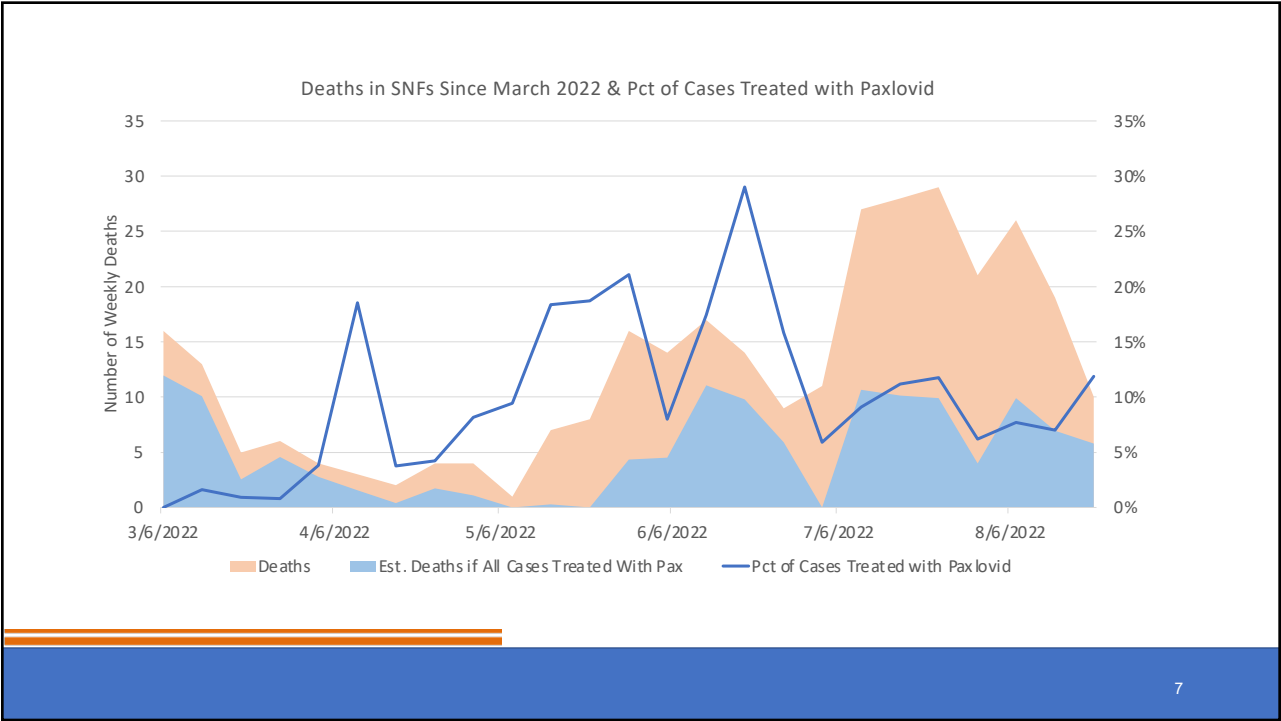
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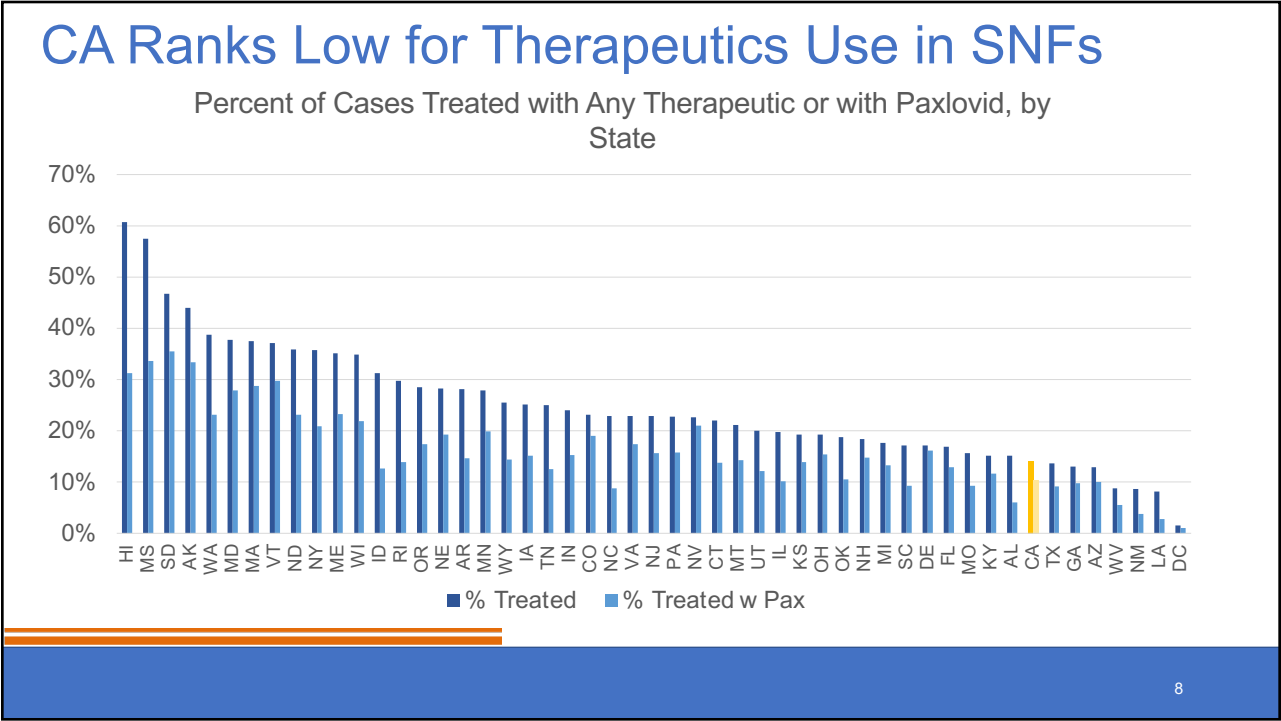
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Benefits of COVID TX in LTC Population

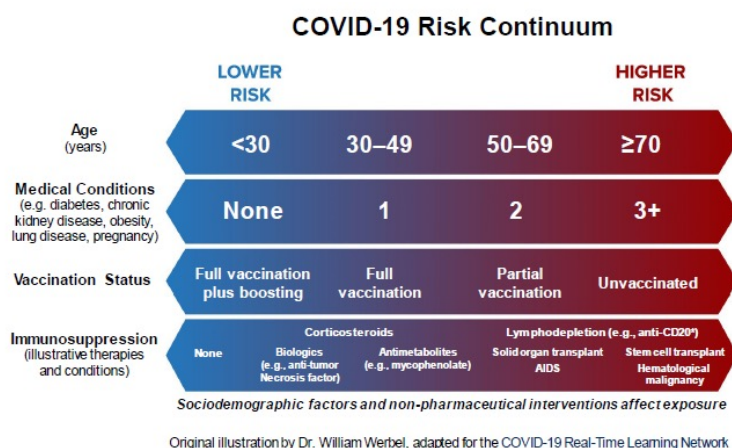
Clinical Trial Data

11

9

LTC Residents and Severe Risk for COVID-19

- Paxlovid and other COVID Tx are recommended for people with "risk of progressing to severe COVID-19"
- LTC facility residents, by definition, almost always fall in severe risk category
- Risk factors include older age, medical conditions, or being immunosuppressed
- Note that even when vaccinated and/or boosted, LTC residents are generally on higher end of risk continuum for other risk categories



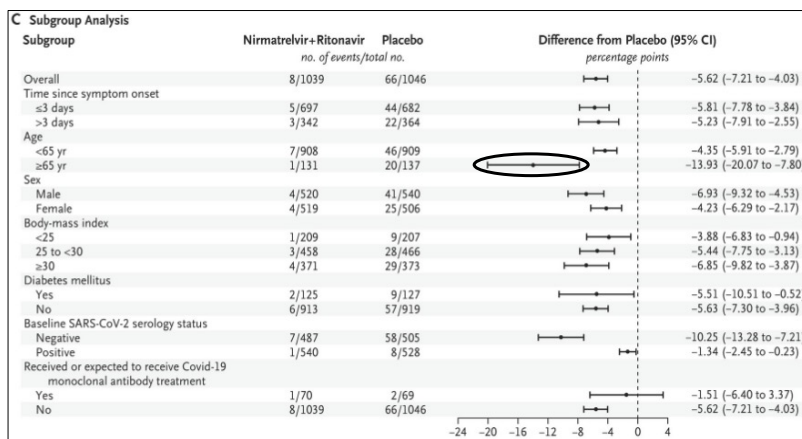
[IDSA Immunocompromised Populations](#)
[CDC Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals](#)

10

10

Paxlovid has stronger benefits for older age groups

- [Original NEJM Paxlovid clinical trial](#): Reduction in hospitalization/death strongest in ≥ 65
- Difference in proportion of patients w/ death or hospitalization from drug vs. placebo was -13.93 (95% CI -20.07 to -7.80)
- Small number of serious adverse events related to drug (1 in 1,109)

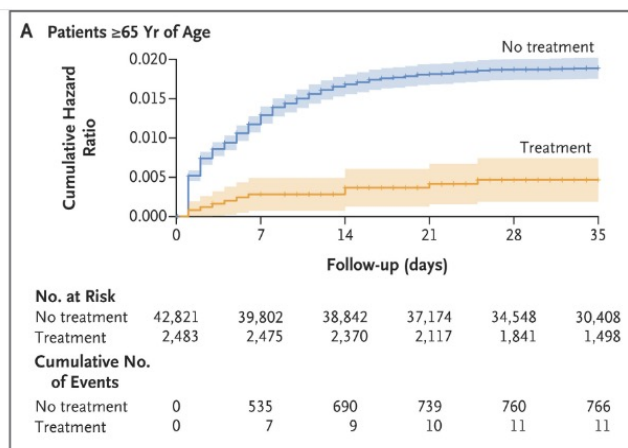


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Paxlovid has stronger benefits for older age groups

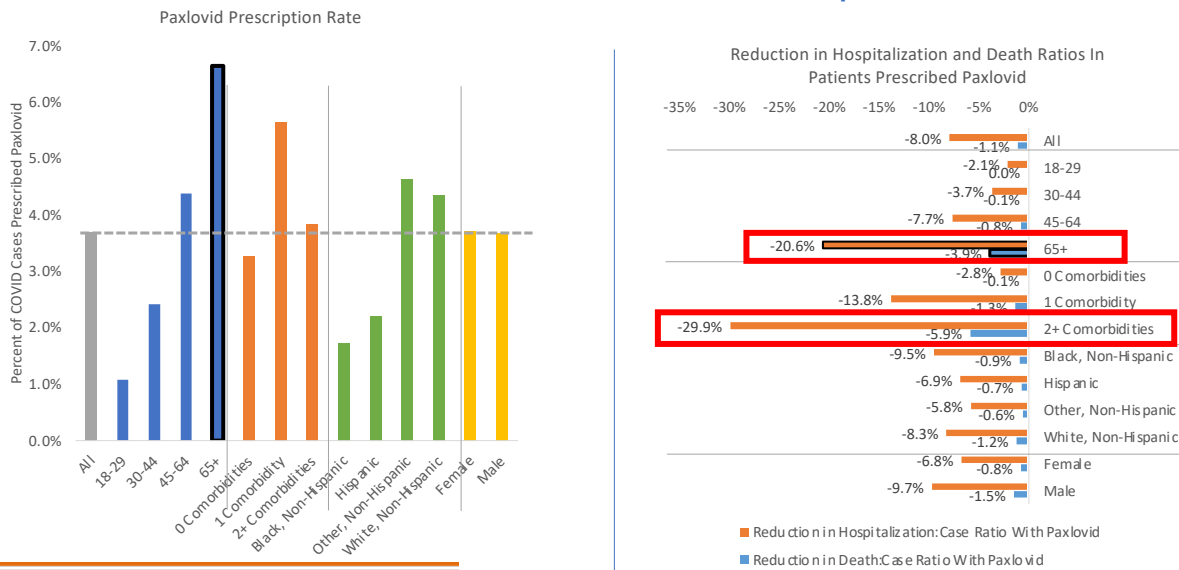
- Large Israel studies in June and August: Age one of the strongest predictors of benefit
- Highly immune populations
- Mean age of treated populations 67-68



14

12

Nationwide EPIC Data: Paxlovid Rx and Hospitalizations/Deaths



Game Changer: Paxlovid Reduces Hospitalizations and Saves Lives

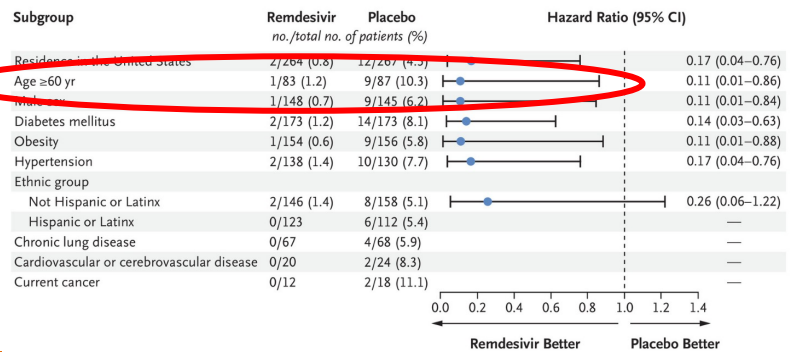
Dual Team Study
Team A: Steve Allen, MD • Keith Johnson • Joey Haddock
Team B: Jeff Trinkl, MD • Soumil Narani • Brendan Joyce

15

13

Remdesivir

- NEJM RCT, Outpatient Remdesivir. 87% reduction in risk of hospitalization and death in all age groups.
- Benefit similar in >60



<https://www.nejm.org/doi/full/10.1056/NEJMoa2116846>

16

14

Remdesivir in the very elderly

- Daily IV infusion x 3 d (some of these studies look at 5 days)
- [Safe](#) and [effective](#) in >80 year olds
 - Remdesivir-induced liver dysfunction was the most frequent adverse event, which occurred in 29 (36.3%) patients. There were no significant differences between younger and older patients in the incidence of remdesivir-induced liver dysfunction, renal dysfunction, and fatigue.
- [Feasible](#) in SNF setting
 - 124-bed SNF with outbreak late 2020
 - 34 patients were treated
 - Average age >80
 - 17-fold reduction in risk of death

17

15

Molnupiravir

- Oral, 5 days, twice daily
- Can be used in patients with renal/hepatic impairment, or with significant DDI's with Paxlovid
- Real world [study](#) in Hong Kong, Lancet, 8/24/22
 - 1646 patients >65 hospitalized without O2 requirement treated with Molnupiravir
 - 43% risk reduction in disease progression

18

16

Paxlovid Rebound Study #1

- 483 high-risk patients treated with Nirmatrelvir/Ritonavir for COVID-19
- Patients treated with Paxlovid at Mayo Clinic February-April 2022
- Two patients (0.4%) required hospitalization by day 30. Four patients (0.8%) experienced rebound of symptoms, which were generally mild, at median of 9 days after treatment, and all resolved without additional COVID-19-directed therapy.

Paxlovid Rebound Study #2

- 13,644 patients age ≥ 18 years who contracted COVID-19 between 1/1/2022-6/8/2022 and were treated with Paxlovid (n =11,270) or with Molnupiravir (n =2,374) within 5 days of their COVID-19 infection.
- **The 7-day and 30-day COVID-19 rebound rates after Paxlovid treatment were 3.53% and 5.40% for COVID-19 infection, 2.31% and 5.87% for COVID-19 symptoms, and 0.44% and 0.77% for hospitalizations.**
- The 7-day and 30-day COVID-19 rebound rates after Molnupiravir treatment were 5.86% and 8.59% for COVID-19 infection, 3.75% and 8.21% for COVID-19 symptoms, and 0.84% and 1.39% for hospitalizations.

17

17

Bottom Line: All LTC Residents Should Be Considered for C19 Treatment

Evidence

- Clinical trial results
- High COVID-19 hospitalization and death rates in >65
- Safe and effective medications



Takeaway

- We have several interventions that can decrease mortality risk
- Treatments have increasing benefit in older age
- Treatments are well-tolerated



Recommendation

- All SNF residents evaluated for COVID-19 treatment within 48 hours of diagnosis
- Ready availability of approved agents: eg Paxlovid, Remdesivir, Molnupiravir

- Detailed [side by side comparison](#) of outpatient agents
- [NIH Treatment guidelines](#)

21

18

Preparing for Fall and Winter Surges

Exploring Next Steps

22

19

Steps SNFs Can Take Now to Prep for TX Use in Winter Surge

- Perform renal and hepatic function tests and DDI analyses on all patients to check for Paxlovid eligibility
- Create notes in each resident's chart for which therapeutic they should receive if sick with COVID
- Confirm supply of Paxlovid with LTC pharmacy supplier or in-house pharmacy
- Review pharmaceutical dispensing regulations to investigate possibility of dispensing Paxlovid in-house if no in-house pharmacy (i.e., often doctors can dispense, refer to CDPH's T2T Playbook for more information)

[Test to Treat Playbook](#)

23

20

Steps Non-Medical LTCFs Can Take Now to Prep for TX Use in Winter Surge

- Identify pathway to get medications for residents if they get sick with COVID
 - Is Telehealth an option? Are there infusion centers nearby?
 - Make sure patients have up to date renal and hepatic function labs
 - Which nearby pharmacies stock Paxlovid and other therapeutics?
 - Can be found at [HHS's Therapeutics Locator](#)

[Therapeutics Locator](#)

24

21

Other Best Practices

For Medical and Non-Medical Facilities

22

22

Recognizing COVID-19 in Elderly or Nonverbal Patients

- Check patients for possible signs often to be aware of changes
- Possible early signs of COVID include:
 - Behavior changes like being more unsettled, expressing new delusions, wandering more than normal, eating/drinking less than usual, appearing sleepy
 - Physical symptoms like headache, warmer than usual or chills, hoarse voice/sore throat, shortness of breathing, eye infections, runny nose, new/changed cough, nausea or vomiting, unexplained diarrhea
- Non-standard COVID symptoms common in older adults:
 - Delirium, falls, fatigue, lethargy, low blood pressure, painful swallowing, fainting, diarrhea, abdominal pain

Signs of shortness of breath in nonverbal patients:

Lethargy or unusual tiredness

Panting or loud breathing

Sucking in (retraction) at base of throat or ribs while inhaling

Belly breathing - seeing the stomach extended more than usual on inhale

Stomach muscles tensing while trying to push air out

Longer time to exhale than inhale

Tripod stance (leaning over with hands on knees)

Bluish nail beds or lips

Change of mental status/confusion

23

23

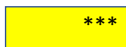
Paxlovid Prescribing Details

27

24

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

Interaction Codes:



Coadministration of this drug with Paxlovid should be avoided, dose should be adjusted or held, or special monitoring is necessary, refer to Healthcare fact sheet for more information



Coadministration of this drug with Paxlovid is contraindicated, refer to Healthcare fact sheet for more information

PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

Drug	Drug Class	Interaction Code
buspirone	Sedative/hypnotic	***
carbamazepine	Anticonvulsant	XXX
cariprazine	Neuropsychiatric agent	***
ceritinib	Anticancer drug	***
ciclesonide	Systemic corticosteroid	***
cilostazol	Cardiovascular agent	***
clarithromycin	Anti-infective	***
clonazepam	Anticonvulsant	***
clorazepate	Sedative/hypnotic	***
clopidogrel	Cardiovascular agent	***
clozapine	Antipsychotic	***
colchicine	Anti-gout	XXX
cyclosporine	Immunosuppressant	***
dabigatran	Anticoagulants	***
darifenacin	Muscarinic receptor antagonist	***
dasabuvir	Hepatitis C direct acting antiviral	***

Drug-Drug Interactions

- Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir (Paxlovid) and Concomitant Medications
- Prescribers can reference drug-drug interaction tools
 - DDI Checkers can help guide clinical decision-making: [Liverpool DDI Checker](#)
 - Other resources include [NIH website](#), [Ontario COVID-19 Science Advisory Table](#) with recommendations on specific DDIs, FDA EUA [fact sheet](#) and [checklist](#)

Paxlovid vs. Renal Paxlovid



- Renal Paxlovid has half the amount of Nirmatrelvir (150 mg vs. 300 mg) component, ritonavir is the same (100 mg)
- For use in **moderate renal impairment** (eGFR ≥ 30 to < 60 ml/min)
- Paxlovid not recommended in severe renal impairment (eGFR < 30)

Paxlovid in Hepatic Impairment

Mild and moderate

- No dosage adjustment of PAXLOVID is needed for patients with either mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment.

Clinical and Lab Criteria	Points*		
	1	2	3
Encephalopathy	None	Mild to moderate (grade 1 or 2)	Severe (grade 3 or 4)
Ascites	None	Mild to moderate (diuretic responsive)	Severe (diuretic refractory)
Bilirubin (mg/dL)	< 2	2-3	> 3
Albumin (g/dL)	> 3.5	2.8-3.5	< 2.8
Prothrombin time			
Seconds prolonged	< 4	4-6	> 6
International normalized ratio	< 1.7	1.7-2.3	> 2.3
Child-Turcotte-Pugh Class obtained by adding score for each parameter (total points) Class A = 5 to 6 points (least severe liver disease) Class B = 7 to 9 points (moderately severe liver disease) Class C = 10 to 15 points (most severe liver disease)			

Severe

- No pharmacokinetic or safety data are available regarding the use of PF-07321332 or ritonavir in trial participants with severe hepatic impairment (Child-Pugh Class C), therefore, PAXLOVID is contraindicated in patients with severe hepatic impairment.

Summary

Main Takeaways

32

29

Summary

- Epidemiological data for CA indicates that Paxlovid and other COVID Tx could be used more widely, especially in older and LTCF populations
- Clinical trial data shows that Paxlovid has a clear benefit for older adults
 - Data is still in early stages, but appears to indicate benefit gets stronger as patients get older
- It is important to weigh risks and benefits of DDIs, renal/hepatic function, side effects and symptom rebound with C19 therapeutics but should not be a barrier to considering patients for treatment, even in vaccinated/boosted persons
- LTCFs can take steps NOW to prepare for this winter's surge
- Most impactful step is identifying which COVID therapeutic is right for each patient and putting that information in their chart

33

30

Thank you!

