COVID-19 Therapeutics for Skilled Nursing Facilities Populations

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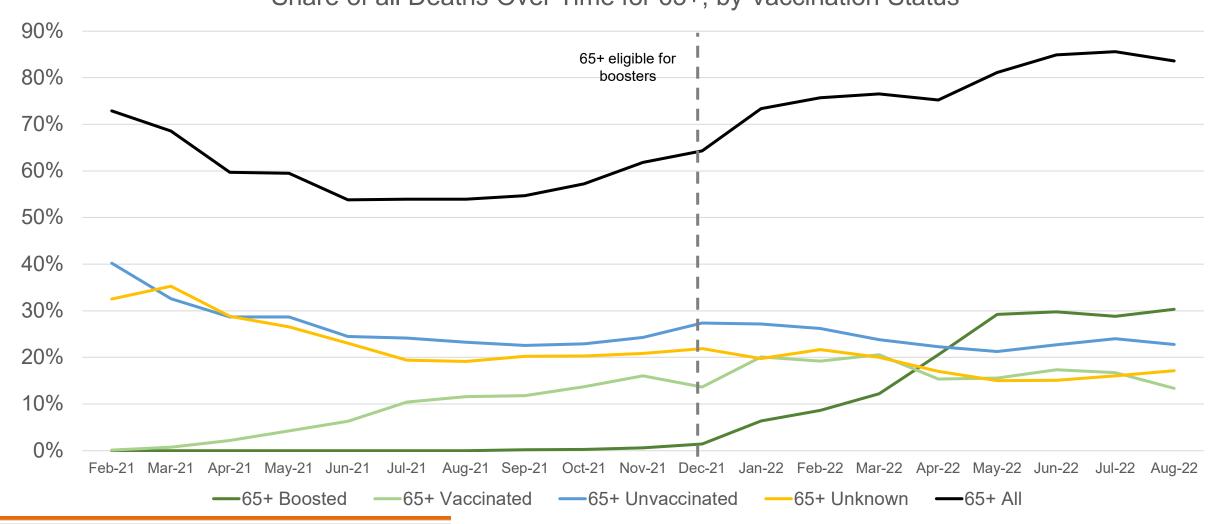
September 14, 2022

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

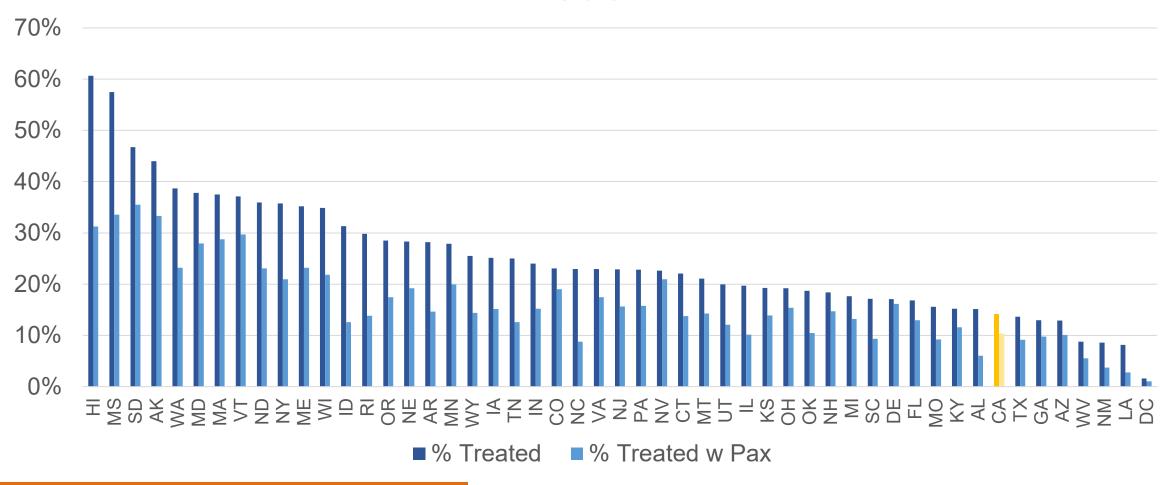
COVID deaths age disparity worsening

Share of all Deaths Over Time for 65+, by Vaccination Status



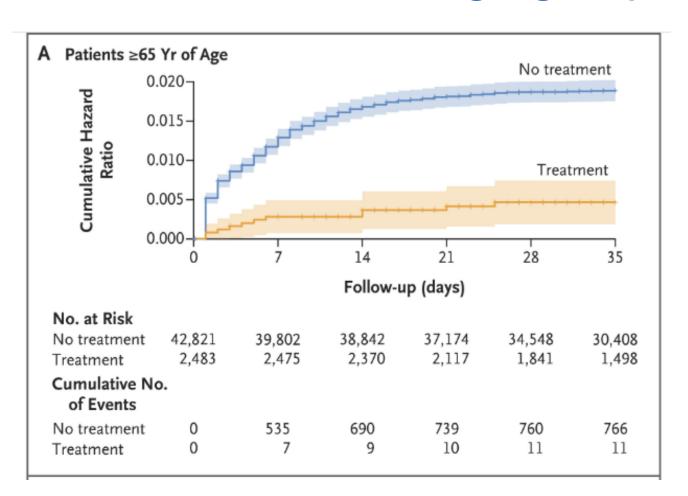
CA Ranks Low for Therapeutics Use in SNFs

Percent of Cases Treated with Any Therapeutic or with Paxlovid, by State



Nimatrelvir safe and MORE effective for older age groups

- Rate of adverse events the same or lower in treated vs untreated arms of initial RCT
- Studies of >100K patients published in <u>June</u> and <u>September</u>: Age one of the strongest predictors of benefit
- Highly immune populations (Israel)
- Mean age of treated populations 67-68
- 45% risk reduction for hospitalization or death



Viral Rebound

- Happens regardless of treatment
- Likely more frequent with treatment
- Rates are low, ~2-6%
- Cases are mild
- Treatment reduces the risk of hospitalization and death by 45-88%

Viral Rebound

Mayo Clinic June 2022

- 483 high-risk patients treated with Nirmatrelvir/Ritonavir for COVID-19 at Mayo Clinic February-April 2022
- 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.

Preprint June 2022

- •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.
- •At 30 days, viral rebound after Paxlovid treatment 5.40%, similar for Molnupiravir
- •>99% of rebound cases are mild, not requiring hospitalization

Viral Rebound

Preprint August 2022 – Rebound in Untreated patients

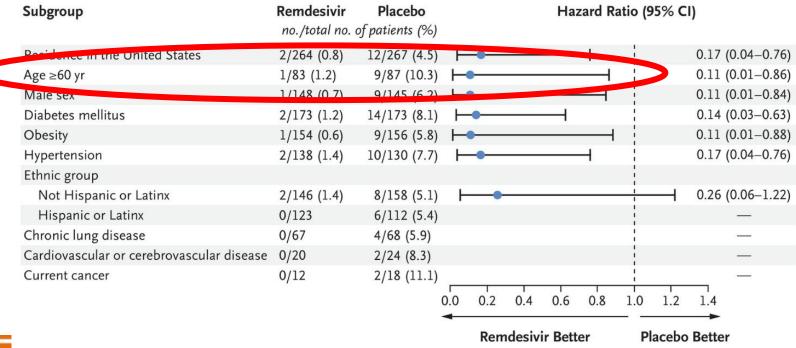
- •568 placebo-treated patients PCR tested through day 28
- •12% had viral rebound, 27% had symptom rebound

Correspondence to NEJM Sept 2022

- •EPIC-HR (Original Paxlovid RCT) participants PCR tested through day 14 after treatment
- •Viral load increase in 2.3% of treated patients and 1.7% of placebo

Remdesivir

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



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.
- <u>Feasible</u> in SNF setting
 - 124-bed SNF with outbreak late 2020
 - 34 treated
 - Average age >80
 - 17-fold reduction in risk of death

Molnupiravir

- Oral, 5 days, twice daily
- Can be used in patients with renal/hepatic impairment, or with significant DDI's with Paxlovid

- Real world <u>study</u> in Hong Kong, Lancet, 8/24/22
 - 1646 patients >65 hospitalized without O2 requirement treated with Molnupiravir
 - 43% risk reduction in disease progression

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)

<u>Test to Treat Playbook</u> 23

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
 - o 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 <u>HHS's Therapeutics Locator</u>

<u>Therapeutics Locator</u> 24

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
- 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

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 welltolerated



Recommendation

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

- Detailed <u>side by side comparison</u> of outpatient agents
- NIH Treatment guidelines

Additional Resources and Support



Type of Support

Description

Updated 8.30.22



General information

<u>CDPH COVID-19 Treatments Webpage</u> provides general information for healthcare providers, allocations, distribution and ordering, drug facts sheets, and additional resources

o CDPH COVID-19 Treatments Patient Flyer questions and answers on COVID-19 therapeutics



Clinical Guidance

<u>Test-to-Treat Playbook</u> clinical guidance and tools, distribution and logistics, data applications and availability, and best practices

Paxlovid Patient Screening Tool: Aid to support clinical decision making

Paxlovid Provider Info Sheet Summary of eligibility & effectiveness information



Questions

For general CDPH Therapeutics questions, please email COVIDRxProviders@cdph.ca.gov
For ordering, program inquiries, signing up new HPoP Accounts: please e-mail CDPHTherapeutics@cdph.ca.gov

Thank you!