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CALTCM COVID-19 Webinar Series

November 8, 2021

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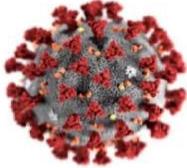
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Webinar Faculty

Namrita Gogia, MD

Internist

Primary Care Physician

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Webinar Faculty

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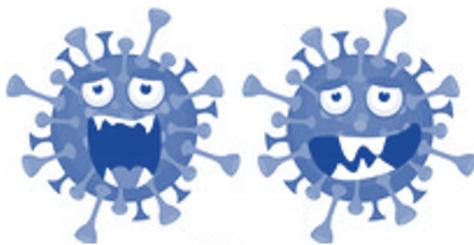
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The Booster & the Beast

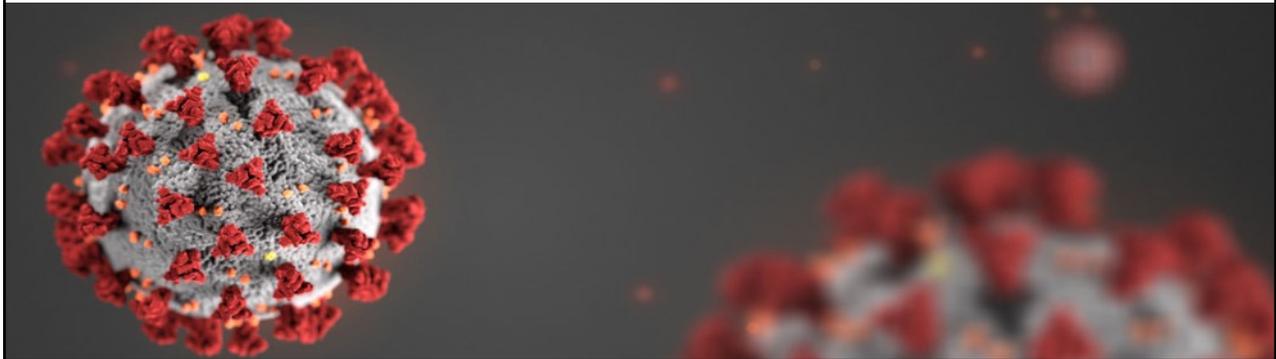


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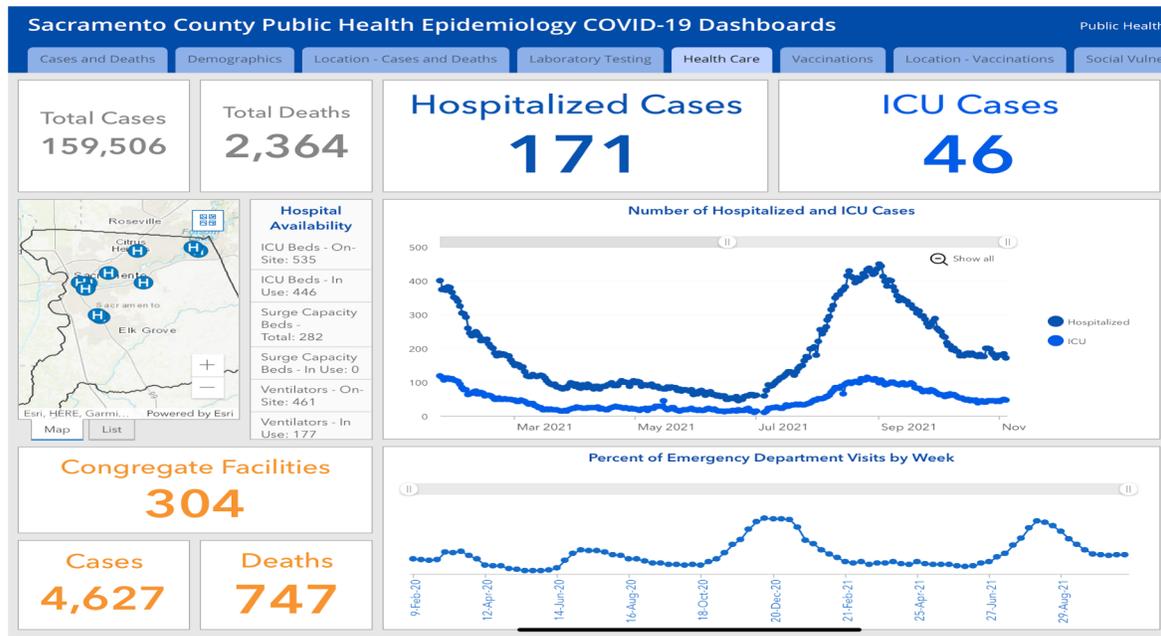
CALTCM COVID UPDATES

Namrita Gogia, MD
11/8/21



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As of November 8th, 2021



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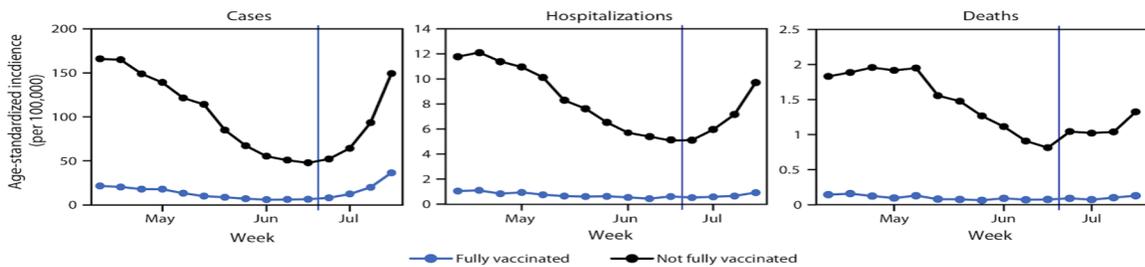
Vaccines Work

People who are fully vaccinated are roughly 10 times less likely to be hospitalized and 11 times less likely to die from Covid-19, according to a recent study from the C.D.C.

Among the more than 187 million Americans who have been fully vaccinated, there have been 7,178 deaths, according to the C.D.C. Eighty-five percent of those deaths have been in people 65 or older. -NYT

Morbidity and Mortality Weekly Report

FIGURE 2. Weekly trends in age-standardized incidence* of COVID-19 cases, hospitalizations,† and deaths,§ by vaccination status¶ — 13 U.S. jurisdictions,** April 4–July 17, 2021



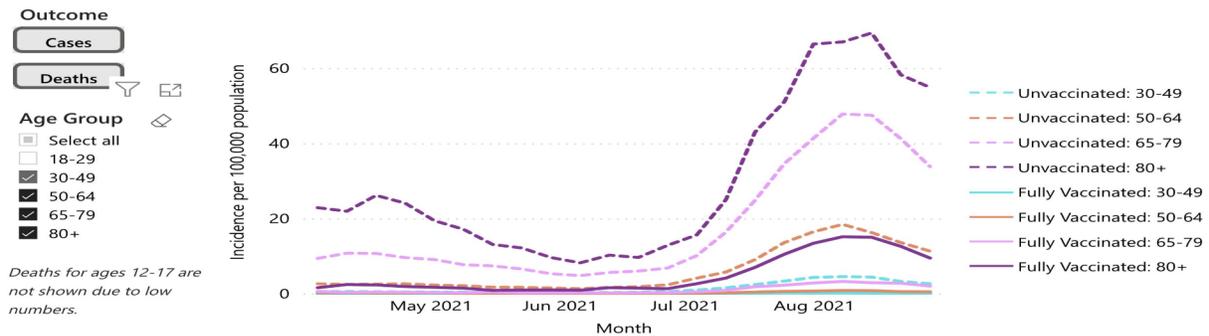
* Rates are standardized by age, according to the enumerated 2000 U.S. Census age distribution. Blue vertical lines indicate when the B.1.617.2 (Delta) variant reached

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CDC Adds New Data Measures

Rates of COVID-19 Deaths by Vaccination Status and Age Group

April 04 - September 04, 2021 (16 U.S. jurisdictions)



Deaths for ages 12-17 are not shown due to low numbers.

In August, unvaccinated persons had:

6.1X	AND	11.3X
Greater Risk of Testing Positive for COVID-19		Greater Risk of Dying from COVID-19
compared to fully vaccinated persons		

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Three studies: Risk of infection increases after 6 months, but protection against severe disease persists

Levin and colleagues performed monthly assessments of anti-spike IgG and SARS-CoV-2 neutralizing antibodies in 3808 immunized Israeli healthcare workers. They found that IgG antibodies peaked 4–30 days after the second dose, then consistently declined during the 6-month study period. Neutralizing antibody titers also fell, but the rate of decline was steeper from 1–3 months than 3–6 months. Decreases in both IgG and neutralizing antibodies were greater with older age, male sex, ≥ 2 comorbidities, and autoimmune disease or immunosuppression.

Chemaitelly and colleagues used a test-negative, case-control study design to evaluate vaccine effectiveness among 947,035 BNT162b2 recipients in Qatar. Effectiveness against SARS-CoV-2 infection peaked at 77% within the first month after complete vaccination, then progressively declined to 20% during months 5–7. In contrast, effectiveness against COVID-19 hospitalization and death attained at least 96% within the first month and did not drop throughout 6 months.

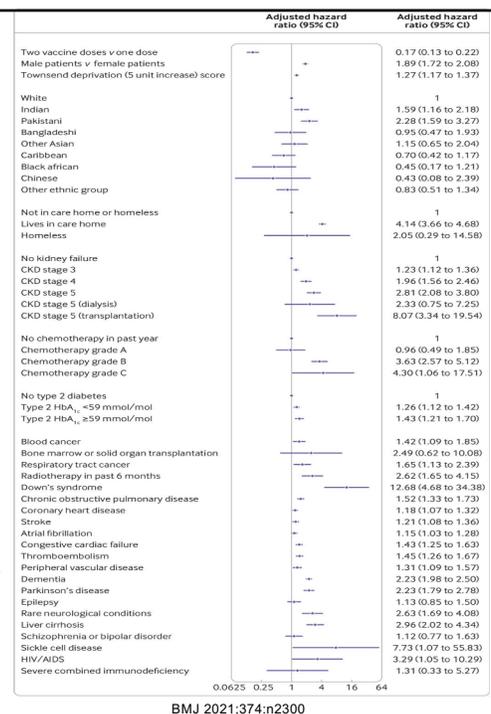
Tartof and colleagues assessed BNT162b2 effectiveness in 3,436,957 individuals in the Kaiser Permanente Southern California healthcare system. Throughout the 6-month study, 184,081 SARS-CoV-2 infections and 12,130 COVID-19 hospitalizations occurred. Effectiveness against infection fell from 88% during the first month to 47% after the fifth month. Effectiveness against hospitalization was 87% at 1 month and 88% at 5 months. Protection against infection with the Delta variant was similar to that against other variants within the first month (93% and 97%, respectively), then declined over time compared with other variants (53% and 67%; comparison not significant).

Richard T. Ellison III, MD, reviewing Levin EG et al. N Engl J Med 2021 Oct 6 Chemaitelly H et al. N Engl J Med 2021 Oct 6
Tartof SY et al. Lancet 2021 Oct 4

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Boosters: Why and Who?

- The benefits of a COVID-19 booster dose may include
 - reduced risk of SARS-CoV-2 infection
 - reduced risk for severe COVID-19 and morbidity from the disease
 - reduce transmission of the virus to other people
- Considerations:
 - Risk for severe infection related to underlying conditions. A person's risk of severe COVID varies by type, number, and level of control of specific medical conditions as well as other yet to be defined variables. Pregnant people may receive a COVID-19 vaccine booster.
 - Potential impact of SARS-CoV-2 infection. SARS-CoV-2 infections that are not severe may still lead to morbidity (e.g., post-COVID-19 symptoms). A person's individual circumstances should also be considered; these may include living with/caring for a person who is medically frail or immunocompromised.
 - Risk of exposure to SARS-CoV-2 and Risk of developing infection: Occupation? Living situation? When was primary series given? Serologic testing is not recommended as part of R/B analysis.



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Updates From VRBPAC

Moderna

- Boosters at 6 months
- Booster dose is half dose
- Criteria same as Pfizer booster dose

J&J

- “Booster” at 2 months
- All JJ recipients are eligible
- Discussion with certain patients to opt for mRNA vs adenovector

FIGURE. Serum anti-receptor binding domain and anti-spike immunoglobulin G levels 2-6 weeks after full vaccination among healthy adult volunteers — three hospitals in three U.S. states,^{6,†} April-June 2021

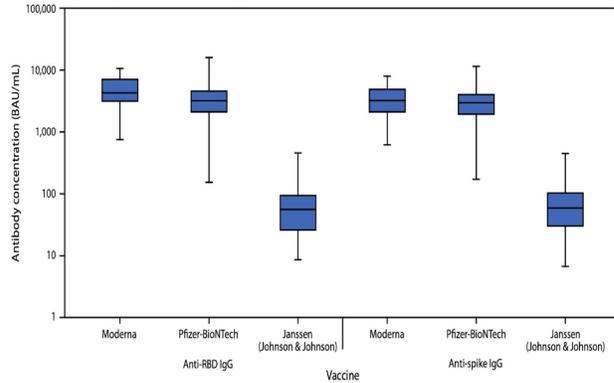


TABLE. COVID-19 vaccine effectiveness^a against laboratory-confirmed COVID-19–associated emergency department and urgent care clinic encounters and hospitalizations^b among adults during SARS-CoV-2 8.1.617.2 (Delta) variant predominance,^b by outcome, age group, and vaccine — nine states,^c June–August 2021

Outcome	Total	No. of SARS-CoV-2-positive tests (prev %)	VE, % (95% CI)
All adults (aged ≥18 yrs), any COVID-19 vaccine			
COVID-19 hospitalizations			
Unvaccinated (ref)	6,960	1,316 (18.9)	—
Fully vaccinated**	7,676	235 (3.1)	86 (82–89)
COVID-19 ED/UC encounters			
Unvaccinated (ref)	10,872	3,145 (28.9)	—
Fully vaccinated**	7,359	512 (7.0)	82 (81–84)
COVID-19 hospitalizations, any COVID-19 vaccine, by age			
Age group = 18–74 yrs			
Unvaccinated (ref)	5,708	1,185 (20.8)	—
Fully vaccinated**	4,551	134 (2.9)	89 (85–92)
Age group = ≥75 yrs			
Unvaccinated (ref)	1,252	131 (10.5)	—
Fully vaccinated**	3,125	101 (3.2)	76 (64–84)
COVID-19 hospitalizations by COVID-19 vaccine			
BNT162b2 (Pfizer-BioNTech)			
Unvaccinated (ref)	6,960	1,316 (18.9)	—
Fully vaccinated**	4,243	135 (3.2)	80 (73–85)
mRNA-1273 (Moderna)			
Unvaccinated (ref)	6,960	1,316 (18.9)	—
Fully vaccinated**	2,975	70 (2.4)	95 (92–97)
Ad26.COV2.S (Janssen)			
Unvaccinated (ref)	6,960	1,316 (18.9)	—
Fully vaccinated**	458	30 (6.5)	60 (31–77)

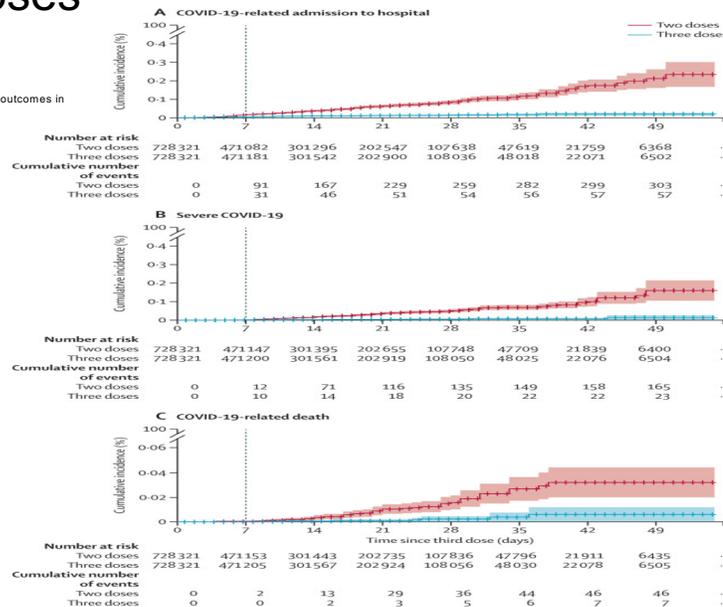
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Two Doses vs Three Doses (Pfizer)

Effectiveness of a third dose of the BNT162b2 mRNA COVID-19 vaccine for preventing severe outcomes in Israel: an observational study. Lancet. Published: October 29, 2021

1,158,269 individuals were eligible to be included in the third dose group. Following matching, the third dose and control groups each included 728,321 individuals. Participants had a median age of 52 years and 51% were female. The median follow-up time was 13 days in both groups.

Vaccine effectiveness evaluated at least 7 days after receipt of the third dose, compared with receiving only two doses at least 5 months ago, was estimated to be 93% (231 events for two doses vs 29 events for three doses) for admission to hospital, 92% (157 vs 17 events) for severe disease, and 81% (44 vs 7 events) for COVID-19-related death.



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Homologous vs Heterologous Booster Doses

In a study conducted by the National Institutes of Health, researchers organized nine groups of roughly 50 people each. Each group received one of the three authorized vaccines, followed by a booster. In three groups, volunteers received the same vaccine for a boost. In the other six, they switched to a different brand.

The researchers found that those who got a Johnson & Johnson shot followed by a Moderna booster saw their antibody levels rise 76-fold within 15 days, whereas those who received another dose of Johnson & Johnson saw only a fourfold rise in the same period. A Pfizer-BioNTech booster shot raised antibody levels in Johnson & Johnson recipients 35-fold.

Group	1			2			3			4			5			6			7			8			9		
Primary EUA Immunization Vaccine	Janssen Ad26.COV2-S			Moderna mRNA-1273			Pfizer/BioNTech BNT162b2			Janssen Ad26.COV2-S			Moderna mRNA-1273			Pfizer/BioNTech BNT162b2			Janssen Ad26.COV2-S			Moderna mRNA-1273			Pfizer/BioNTech BNT162b2		
Booster	Moderna mRNA-1273 100-mcg			Pfizer/BioNTech BNT162b2 30-mcg			Janssen Ad26.COV2-S 5x10 ¹⁰ vp			Moderna mRNA-1273 100-mcg			Pfizer/BioNTech BNT162b2 30-mcg			Janssen Ad26.COV2-S 5x10 ¹⁰ vp			Pfizer/BioNTech BNT162b2 30-mcg			Moderna mRNA-1273 100-mcg					
IgG Serum Binding Antibody (Binding Antibody Units/mL)																											
Wildtype (S-2P-WA-1)																											
N at Study Day 15	51			50			50			50			49			50			50			48			48		
Day 1 GMT* (95% CI)†	57.1 (44.6-73.2)			859.2 (668.3-1104.6)			356.6 (262.5-484.5)			71.3 (47.9-106.2)			638.8 (513.7-794.2)			320.6 (250.7-410.1)			75.1 (54.8-102.8)			534.4 (444.8-642.0)			223.5 (177.4-281.7)		
Day 15 GMT (95% CI)	3203.1 (2499.5-4104.9)			6799.8 (5771.8-8010.9)			6155.0 (4895.4-7738.7)			326.0 (235.8-450.7)			3029.4 (2433.2-3771.7)			1904.7 (1497.8-2422.2)			2549.5 (2038.1-3189.3)			5195.6 (4433.1-6089.3)			3409.1 (2760.6-4209.8)		
Day 29 GMT (95% CI)	2803.1 (2263.3-3471.7)			5917.4 (5070.4-6905.9)			5170.2 (4156.9-6430.6)			368.6 (290.8-467.4)			4560.1 (3544.2-5867.2)			2599.6 (2085.9-3239.9)			In process			In process			In process		
Percentage with two-fold rise at Day 15 (95% CI)	100.0% (93.2-100.0%)			96.0% (86.3-99.5%)			98.0% (89.4-99.9%)			86.0% (73.3-94.2%)			83.7% (70.3-92.7%)			92.0% (80.8-97.8%)			98.0% (89.4-99.9%)			100.0% (92.6-100.0%)			100.0% (92.6-100.0%)		
Geometric mean	56.1			7.9			17.3			4.6			4.7			6.2			32.8			9.7			14.9		
fold rise (95% CI)	(40.7-77.2)			(6.2-10.1)			(13.3-22.4)			(3.7-5.7)			(3.6-6.2)			(4.7-8.1)			(24.6-43.8)			(8.0-11.8)			(11.8-18.9)		
Neutralizing Antibody Titer (International Unit (IU)/mL)																											
D614G ‡																											
Day 1 GMT (95% CI)	8.9 (6.2-12.8)			88.7 (67.7-115.9)			24.8 (18.0-34.2)			7.6 (4.9-11.8)			61.7 (45.0-84.6)			18.6 (13.4-25.7)			9.4 (6.4-13.6)			57.6 (45.0-73.7)			21.4 (15.3-30.0)		
Day 15 GMT (95% CI)	676.1 (517.5-883.3)			901.8 (727.5-1117.8)			785.8 (596.4-1035.2)			31.42 (22.3-44.3)			382.1 (290.5-502.5)			216.4 (157.8-296.9)			341.3 (239.6-486.3)			677.9 (559.4-821.3)			446.7 (340.3-586.3)		
Day 29 GMT (95% CI)	431.7 (322.6-577.6)			700.0 (568.6-861.8)			495.7 (370.4-663.4)			In process			In process			In process			In process			In process			In process		
Percentage with four-fold rise at Day 15 (95% CI)	100.0% (93.2%-100.0%)			86.0% (73.3%-94.2%)			100.0% (92.9%-100.0%)			50.0% (35.5-64.5%)			61.2% (46.2-74.8%)			82.0% (68.6-91.4%)			98.0% (89.0-99.9%)			93.8% (82.8-98.7%)			97.9% (88.9-99.9%)		
Day 15 geometric mean	75.9 (55.0-104.8)			10.2 (8.0-12.8)			31.7 (23.8-42.2)			4.2 (3.0-5.8)			6.2 (4.5-8.5)			12.5 (8.7-17.9)			35.1 (23.9-51.6)			11.5 (9.0-14.8)			20.0 (14.6-27.4)		
fold rise (95% CI)	(55.0-104.8)			(8.0-12.8)			(23.8-42.2)			(3.0-5.8)			(4.5-8.5)			(8.7-17.9)			(23.9-51.6)			(9.0-14.8)			(14.6-27.4)		

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Vaccinating Children

- 18+ yo Pfizer, JJ, Moderna
- 12-16 yo Pfizer
- 5-11 yo Pfizer

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A Service of Dignity Health Medical Foundation

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Benefits of Vaccinating Young Children

- Severe illness has been uncommon in 6 million children positive for COVID
- 5217 cases of multisystem inflammatory syndrome in children (MIS-C) and 46 MIS-C deaths have been reported as of 10/4
- The risk of severe illness and death is greater for children older than 10 years. Although the percentage of severe illness among pediatric cases is small, as infections increase, so too will the number of children who become seriously ill.
- At least 1.9 million children aged 5 to 11 years have been infected. 8300 of them have been hospitalized, a third of whom needed intensive care.
- Nearly 100 children aged 5 to 11 years have died, making COVID-19 among the leading causes of death in this age group.
- Hospitalization rates among children aged 5 to 11 years are 3 times higher for Black, Hispanic, or Native American children than for White children, with rates of 45 to 50 per 100 000 children vs 15 per 100 000 children, respectively.
- Data from adolescents suggest that Pfizer vaccinations for children 5 to 11 years old will likely prevent most hospitalizations and deaths
- Vaccinating children 5 to 11 years of age may lower transmission in families, schools, and communities.

Moss WJ, Gostin LO, Nuzzo JB. Pediatric COVID-19 Vaccines: What Parents, Practitioners, and Policy Makers Need to Know. JAMA. Published online November 05, 2021. doi:10.1001/jama.2021.20734

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FDA Briefing Summary: Pfizer Vaccine 5-11 yo

- The Pfizer's study in kids (5-11yo) (about 3000 vaccinated and 1500 placebo), but well done.
- They looked at 10mcg dose of Pfizer (adult dose is 30mcg) given twice, 21 days apart.
- The first cohort (~1500 vaccinated, 750 placebo) was followed for a longer duration (2 months after second dose), the second cohort was added later when the FDA asked Pfizer to expand their study population so the median duration of follow up is less (2 weeks after second dose).
- There was no evidence of myocarditis in the vaccinated group. The antibodies that the 5-11 year olds made were robust and comparable to the average titers made by vaccinated 16-25 year olds.
- There were 3 cases of Covid in the vaccinated group and 16 cases in the placebo group. None of the cases were severe.
- We don't know what strains the Covid cases were but suspect they were delta since they occurred in the July-August timeframe.
- The most common adverse reactions were pain at the injection site, fatigue, headache and occurred at a median time of about 2 days after vaccination

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Oral Therapeutics for COVID-19

Molnupiravir

- No peer rev data. Just statement from company re: phase III interim analysis
 - Participants:symptom onset w/in 5 days. Participants had at least one risk factor associated with poor disease outcome.
 - Molnupiravir reduced the risk of hospitalization or death by approximately 50%
 - 7.3% of patients who received molnupiravir were either hospitalized or died through day 29 following randomization (28/385) vs 14.1% of placebo-treated patients (53/377)
 - No deaths in molnupiravir group (through day 29) vs. 8 deaths in patients who received placebo
- Study stopped early due to positive results (Intended size was 1550 participants)
- Consistent efficacy against all variants

Paxlovid

- The Pfizer medicine, known by the code name PF-07321332 or simply '332, reduced hospitalization by 89% compared to placebo when given with the HIV drug ritonavir within three days of symptom onset
- The medicine also reduced the chance that patients would die. There were 7 deaths out of 385 patients in the placebo group, and none in the 389-patient group that received the medicines. Pfizer plans to market '332 under the brand name Paxlovid

Courtesy of Eric Topol	Molnupiravir (Merck)	Paxlovid (Pfizer)
Efficacy in high-risk patients, reduction of hospitalizations/deaths at 28 days	50% 14.1 vs 7.3%	89% 8.2 vs 0.7%
Deaths in placebo vs drug	8 vs 0	7 vs 0
Duration of therapy (twice daily)	5 days	5 days
Given with co-drug to promote half-life	No	Yes, ritonavir
Repurposed	Yes, Equine encephalitis Planned to test for RSV, influenza, redirected	No, Covid specific New chemical entity adapted from an anti-SARS molecule
Mechanism	Nucleoside analog; Induces mutations	Inhibits Mpro, not mutagenic
Active against all variants	Yes	Yes
Cost	~\$700	~\$700

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CALTCM White Paper on Nursing Home Staffing

- We are the **medical voice for long term care in California**
- Public policy committee developed this White Paper
 - Made recommendations based on evidence-based literature
 - Not our intention to debate the financial impact of our recommendations
 - Current huge workforce shortage issues
 - Where will staff come from?
- **We stand for quality care in nursing homes**
- We understand there are many issues that have put NH care in a precarious state
- Issues MUST be debated
- Does not change the existing evidence
- **Our White Paper presents the evidence**

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California's
Nursing
Home
Residents
Have Faced
an Ongoing
Humanitarian
Crisis



- > 60,000 resident COVID-19 infections
- 10,000+ deaths (conservatively)
- < 1% of the population
- Wildly disproportionate percent of California deaths from COVID-19
- NH residents are "human beings who deserve to be treated with respect and dignity."

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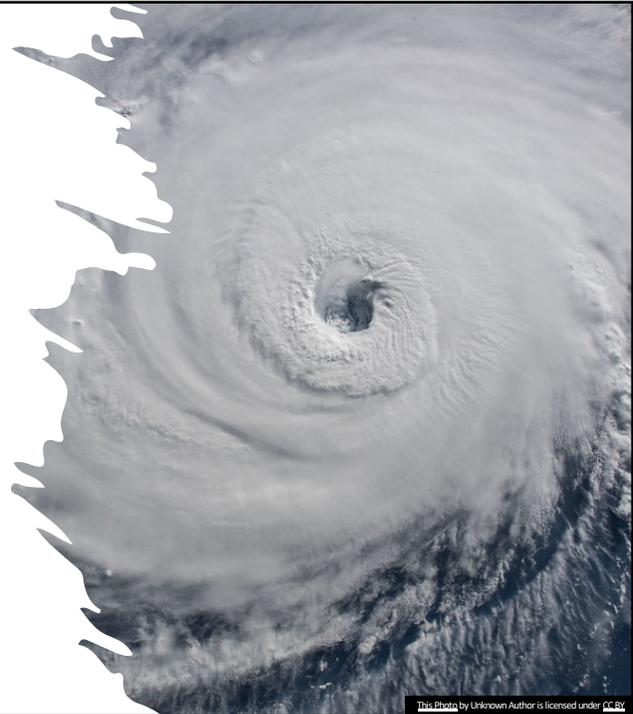
Overview



- Pre-existing quality issues
- Inequities and disparities
- Positive relationship between the quality of nursing home care and staffing
 - certified nursing assistants (CNAs)
 - registered nurses (RNs)
 - total nurse staffing
- Low nurse staffing levels
 - associated with poor quality of care
 - abuse and neglect
- Disparities
 - Racial and ethnic minorities reside in nursing homes with
 - limited financial resources
 - low staffing levels
 - high number of deficiencies
 - 9% of White nursing home residents live in "lower-tier" homes, compared to an estimated 40% of Black nursing home residents

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“Now is not the time for additional “studies” to assess the importance of appropriate staffing levels. The combination of inadequate staffing and disparities can only lead to more tragic situations and outcomes, such as those recently seen during the latest hurricane in Louisiana.”



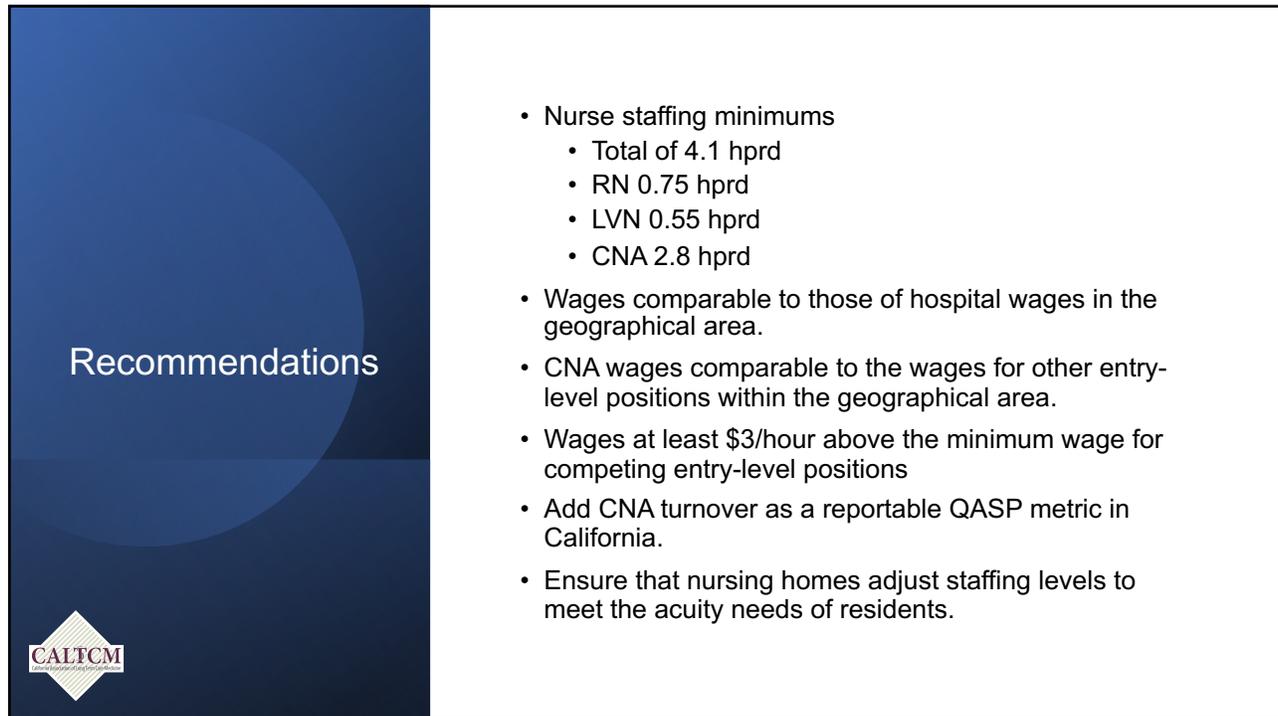
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The Pandemic
Has Profoundly
Confirmed and
Reinforced the
Evidence-Based
Literature on the
Impact of
Inadequate
Staffing



- NHs with RN staffing < 0.75 RN hours per resident day (hprd) were 2x likely to have residents with COVID infections.
- Higher total nurse staffing hours reduced NH residents' COVID infection rates by half
- Facilities in California with higher RN staffing reduced COVID death rates by half.
- Higher RN staffing levels (other states) a/w fewer COVID-19 outbreaks and deaths.
- NHs w/ COVID-19 outbreaks among staff or residents were more likely to report staff shortages.
- NHs with higher RN staffing levels before the pandemic and those with higher overall quality ratings were less likely to report nursing staff shortages.

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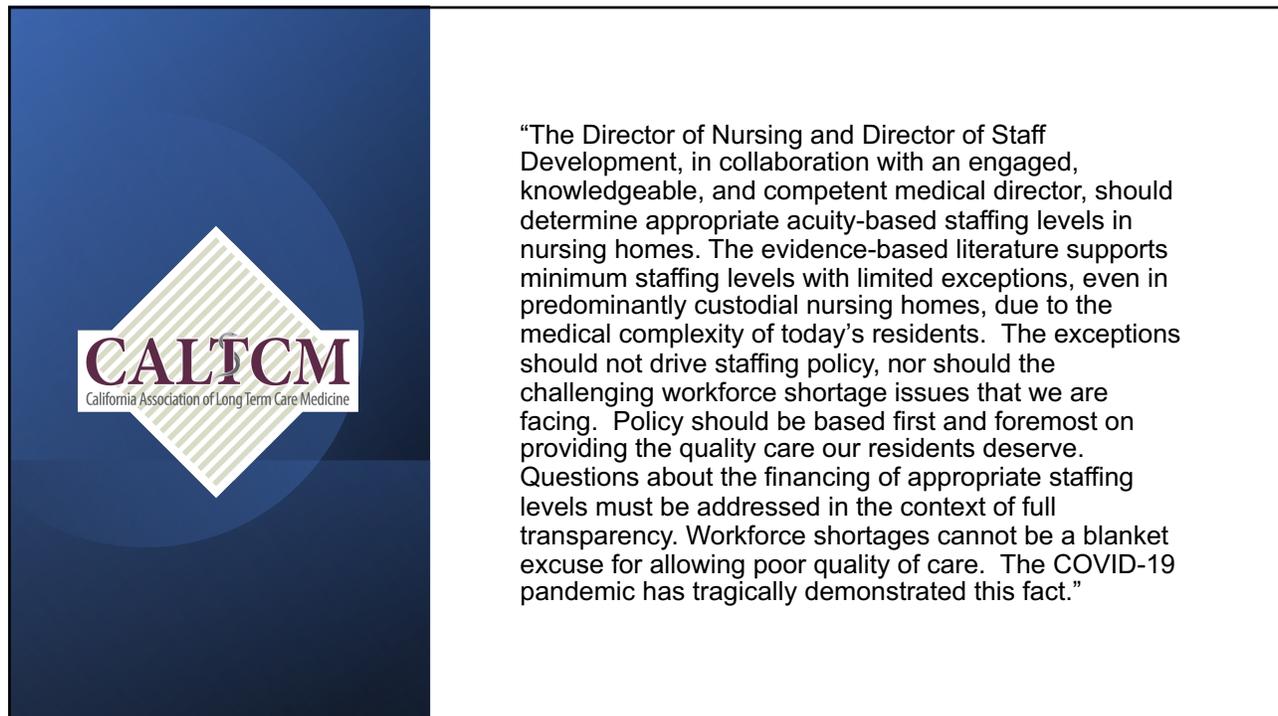


Recommendations

- Nurse staffing minimums
 - Total of 4.1 hprd
 - RN 0.75 hprd
 - LVN 0.55 hprd
 - CNA 2.8 hprd
- Wages comparable to those of hospital wages in the geographical area.
- CNA wages comparable to the wages for other entry-level positions within the geographical area.
- Wages at least \$3/hour above the minimum wage for competing entry-level positions
- Add CNA turnover as a reportable QASP metric in California.
- Ensure that nursing homes adjust staffing levels to meet the acuity needs of residents.



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“The Director of Nursing and Director of Staff Development, in collaboration with an engaged, knowledgeable, and competent medical director, should determine appropriate acuity-based staffing levels in nursing homes. The evidence-based literature supports minimum staffing levels with limited exceptions, even in predominantly custodial nursing homes, due to the medical complexity of today’s residents. The exceptions should not drive staffing policy, nor should the challenging workforce shortage issues that we are facing. Policy should be based first and foremost on providing the quality care our residents deserve. Questions about the financing of appropriate staffing levels must be addressed in the context of full transparency. Workforce shortages cannot be a blanket excuse for allowing poor quality of care. The COVID-19 pandemic has tragically demonstrated this fact.”



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CAMPUS AND LOCAL TECHNICAL COLLEGE MODEL

Questions are the path to learning

November 8, 2021