COVID-19 Update for Skilled Nursing Facilities:

Updated (Bivalent) Booster Recommendations & More

September 9, 2022

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Los Angeles County Department of Public Health Acute Communicable Disease Control Program



Disclosures

There is no commercial support for today's webinar.

Neither the speakers nor planners for today's webinar have disclosed any financial interests related to the content of the meeting.

This webinar is meant for skilled nursing facilities and is off the record. Reporters should log off now.



DISCLAIMER

• This is a rapidly evolving situation so the information being presented is current as of today (09/09/22), so we highly recommend that if you have questions after today you utilize the resources that we will review at the end of this presentation.



Presentation Agenda

- Local COVID-19 Trends
- Updated Bivalent Booster
- Action Plan for Los Angeles County SNFs
- COVID Vaccine FAQs
- Reporting on State/Federal Surveys
- Q and A

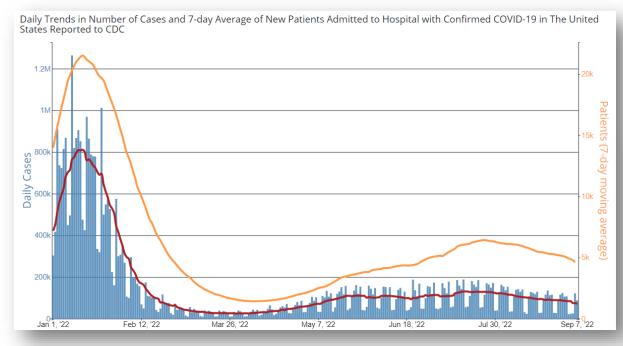


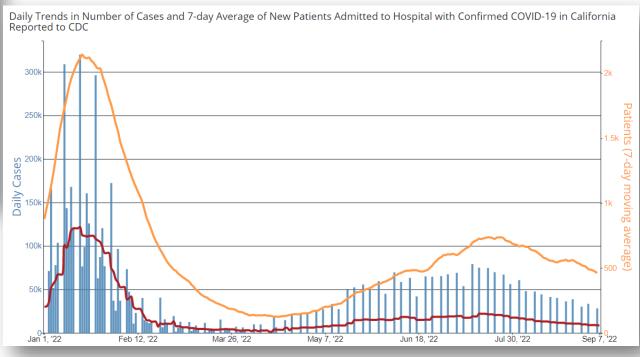
Local COVID-19 Trends

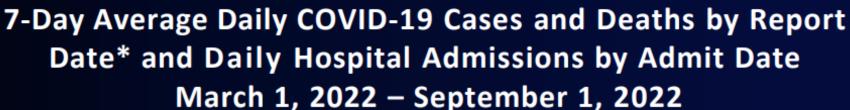


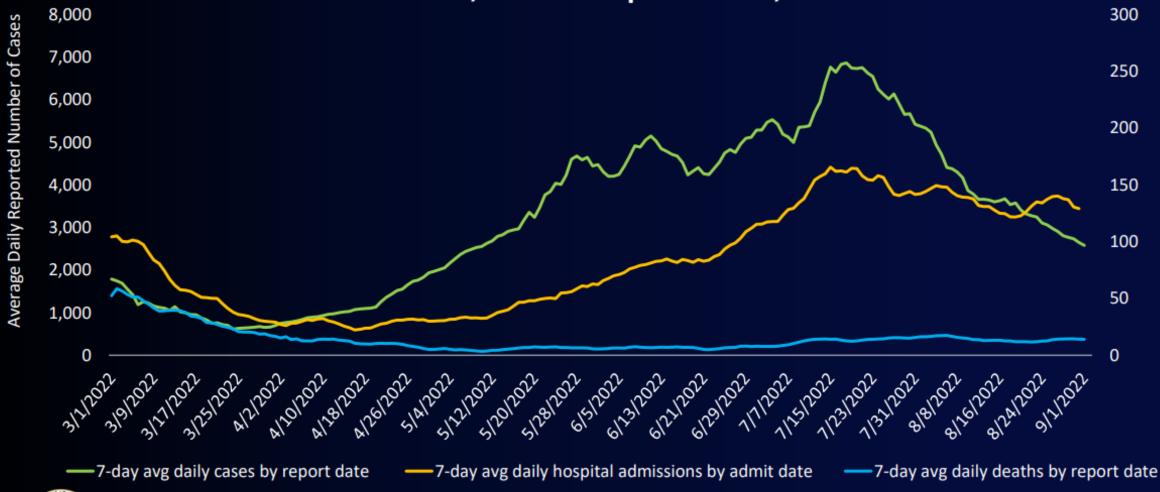


National & State Trends in COVID-19 Cases and New Hospitalizations









covid19.lacounty.gov

9/1/2022

Hospital admission data from 8/23/22 onward is subject to change.

Deaths

of

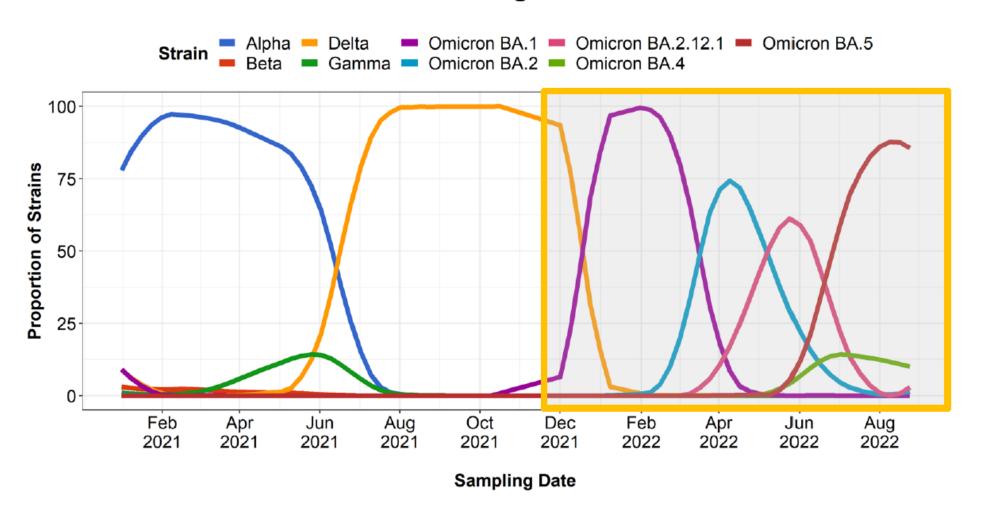
Average Daily Reported Number

and Average Daily Hospital Admissions

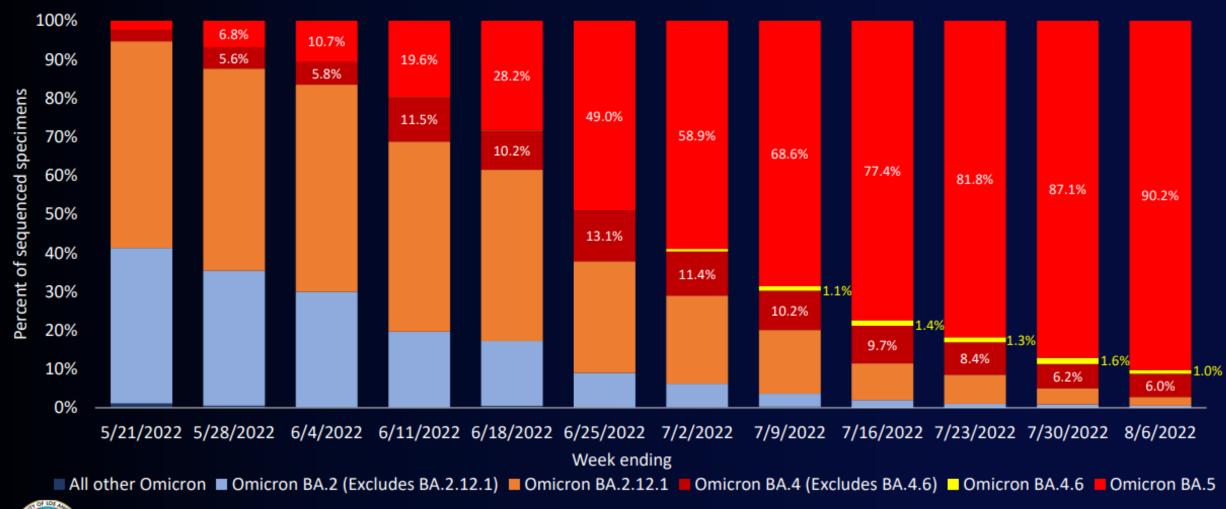
*Case and death values include data from Long Beach and Pasadena.



USA circulating strains trend



SARS-CoV-2 Variants as a Percentage of All Specimens Sequenced for Baseline Variant Surveillance



covid19.lacounty.gov

8/25/2022

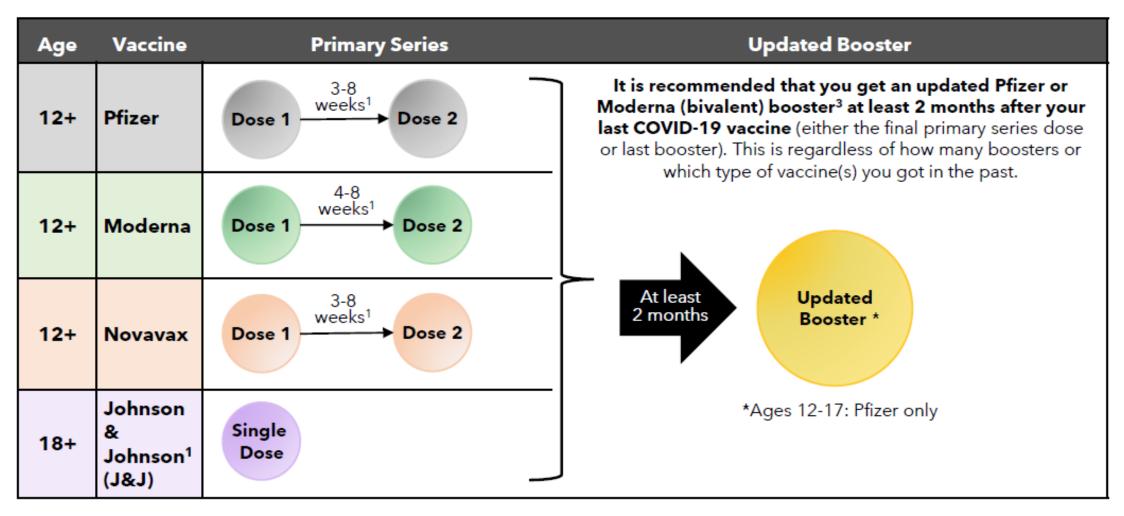


Updated (Bivalent) COVID-19 Booster: *Interim Clinical Considerations*



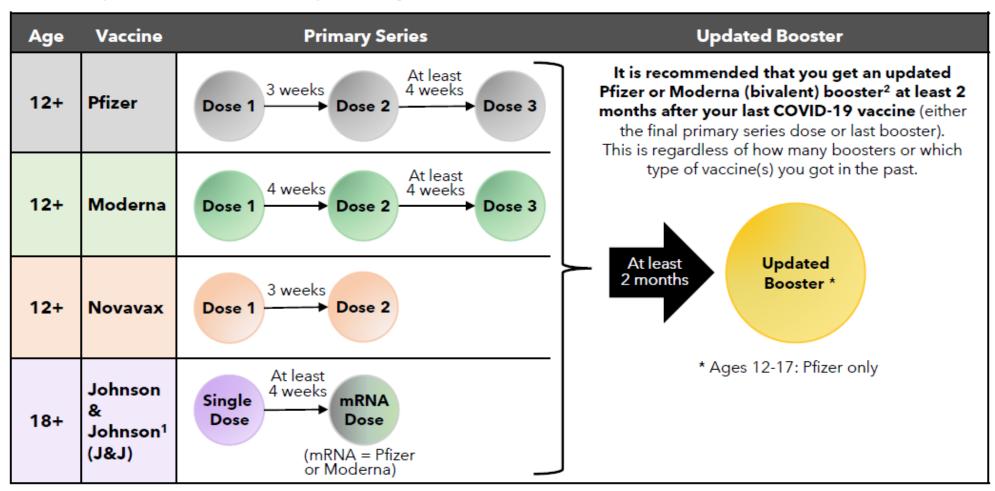


Updated COVID-19 Vaccine Schedules: People Ages 12+





Updated COVID-19 Vaccine Schedules: Immunocompromised People Ages 12+





Fall Booster "Reset": Updated (Bivalent) Booster Recommendations

- Recommendations are simplified
- Change from dose counting to 1 bivalent booster for everyone eligible 12 years+
 - Same recommendation for immunocompromised individuals
 - 12-17yo: eligible for Pfizer bivalent booster
 - ≥18yo: eligible for Pfizer or Moderna bivalent booster
- If eligible, a bivalent booster dose should be administered regardless of total number of doses already received

COVID-19 Vaccination History	Time since last dose	Next dose
Primary series*	At least 2 months	1 updated (bivalent) booster dose
Primary series* + 1 original (monovalent) booster	At least 2 months	1 updated (bivalent) booster dose
Primary series* + 2 original (monovalent) boosters	At least 2 months	1 updated (bivalent) booster dose

^{*}Primary series could be 1-3 doses depending on manufacturer type and immunocompromised status of the individual



Original (monovalent) Pfizer and Moderna COVID-19 Vaccines

- FDA removed authorization of original (monovalent) vaccines from Pfizer and Moderna for use as booster doses as of Aug 31, 2022
 - LAC DPH sent email notification out to all SNFs same day
- Communicate with your LTC pharmacy if any monovalent vaccine was administered as a booster after Aug 31, 2022.
 - May need to be reported as vaccine administration error to <u>VAERS</u>
- Only monovalent vaccines are approved/authorized for primary series doses

Bivalent vaccine incorrectly administered for the primary series	Bivalent Pfizer-BioNTech vaccine: Do not repeat dose.
	Bivalent Moderna vaccine: Repeat dose immediately (no minimum interval)⁵ because administration of the booster dose will result in a lower-than-authorized dose.
Monovalent vaccine incorrectly administered for a booster dose (if bivalent booster indicated)	 In general, do not repeat dose. However, providers may administer 1 bivalent booster dose as a repeat dose based on clinical judgement and patient preference. In this case, space the repeat dose after the dose given in error by at least 2 months.



What's the evidence behind booster doses?





What's the review and authorization process?

June 28, 2022:

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted in favor of including Omicron component in COVID-19 vaccines for booster doses administered in fall 2022.



August 31, 2022:

FDA issued Emergency
Use Authorizations
(EUAs) for Pfizer and
Moderna Bivalent
COVID-19 vaccines for
use as boosters



September 1, 2022

CDC's Advisory
Committee on
Immunization
Practices (ACIP) met
to review evidence
and passed
recommendations for
Pfizer and Moderna
bivalent boosters



September 3, 2022

Western States
Scientific Safety
Review Workgroup
supported the same
recommendations

^{1.}VRBPAC Recommendations: https://www.fda.gov/vaccines-blood-biologics/update-covid-19-vaccine-booster-composition

^{2.}FDA issued EUAs for bivalent vaccines: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use
3.CDC ACIP September 1, 2022 meeting: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-09-01-02.html



What evidence was reviewed?

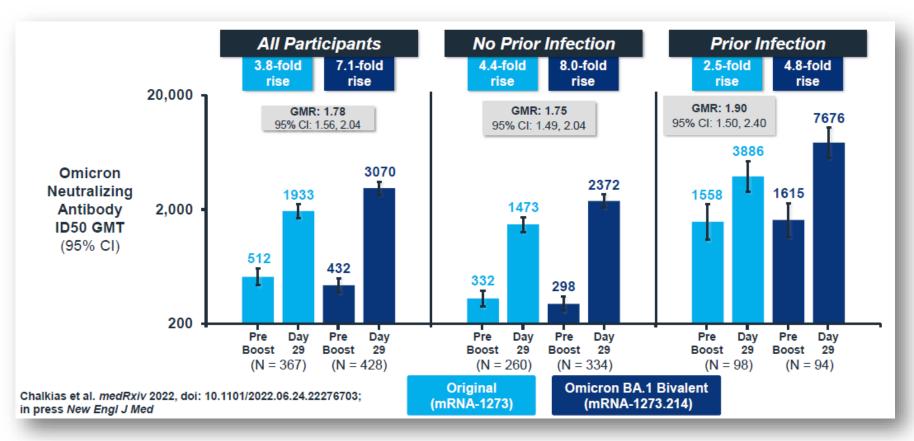
- Data from using COVID-19 mRNA vaccine technology for nearly 2 years and over 600 million doses in the US alone
 - Extensive vaccine effectiveness studies as well as robust post-authorization safety data across multiple platforms
- Clinical (human) data from bivalent COVID-19 vaccine formulations in >1700 persons
 - Studies from both manufacturers (Moderna and Pfizer) and National Institutes of Health (NIH)
 - >1400 persons received bivalent vaccines with Omicron component specifically
- Other fancy studies: antigenic cartography, antibody studies, modeling data

A LOT of evidence!!!



Updated bivalent vaccines resulted in significantly higher neutralizing titers compared with monovalent vaccines even in persons with prior

infection

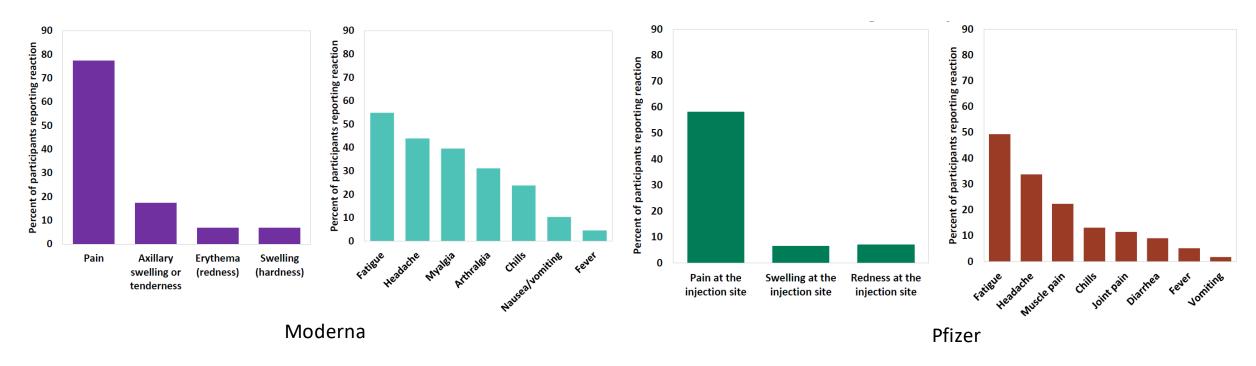


Met superiority criteria with or without prior infection on day 29



What about "side effects"?

- Post-vaccination symptoms (local and systemic reactogenicity) from updated bivalent booster are the same as the original monovalent vaccines
- Indicate the body is responding appropriately to the vaccine and are expected



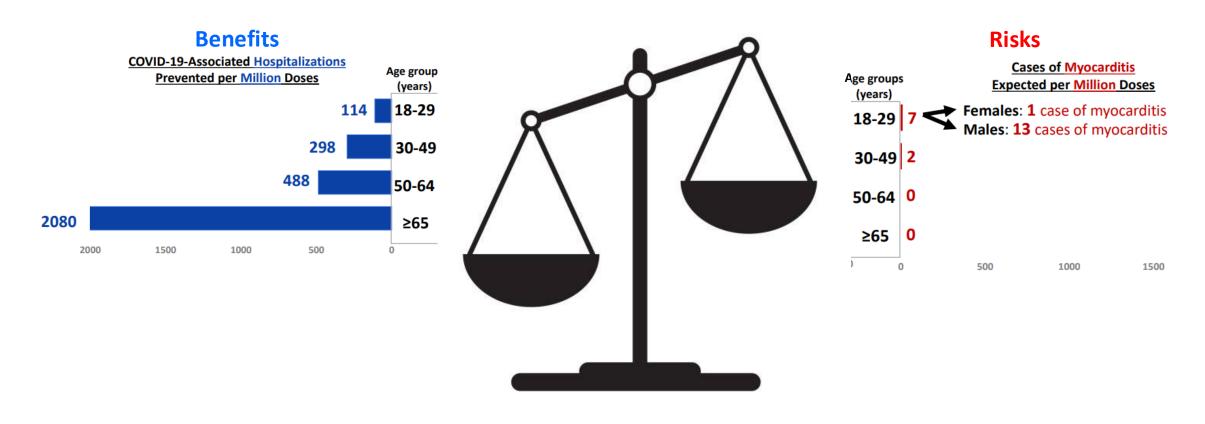


What about "side effects"?

- No deaths were reported for either Moderna or Pfizer bivalent booster vaccines
- No grade 4 (potentially life threatening e.g., anaphylaxis) adverse events were reported for either Moderna or Pfizer bivalent booster vaccines
- Minimal to no grade 3 (severe) adverse events
 - Most commonly local redness at site of injection and fatigue
- **No** adverse events of special interest (myocarditis, pericarditis, Bell's palsy) were reported for either Moderna or Pfizer bivalent booster vaccines



Benefits of booster doses greatly outweigh risks





Are there long-term effects from the booster vaccine?

- No, long-term side effects are not likely.
- Based on what we know from other vaccines, any side effects usually begin to appear within six weeks of getting vaccinated.
- No concrete evidence of long-term effects from COVID-19 vaccines after almost 2 years of use and after billions of people have received COVID-19 vaccines across many demographics

VS

Well documented long-term effects from COVID-19 infection fo people of all ages

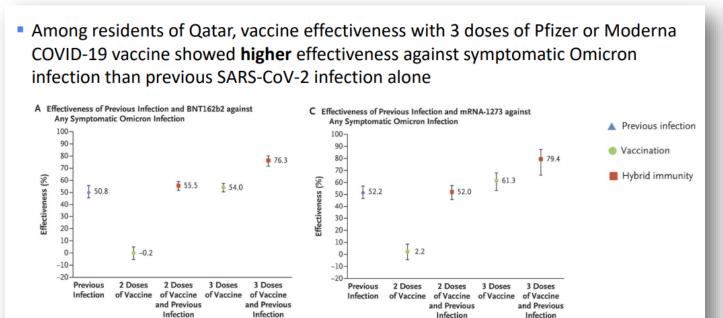
Risk of adverse cardiac outcomes (myocarditis, pericarditis) were 1.8-5.6
 times higher after SARS-CoV2 infection vs after Pfizer/Moderna COVID-19
 vaccination even among highest risk group of males 12-17yo



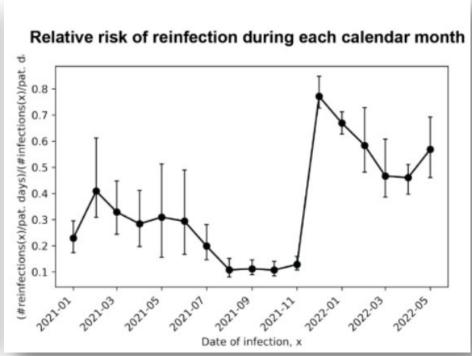


What if I've already had COVID-19 infection?

Yes, you should still get the booster dose.



Altarawneh HN, Chemaitelly M, Ayoub HH, et.al. Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections. N Engl J Med 2022; 387:21-34



 Omicron variant has shown to have high re-infection rates after a prior COVID infection, so it's even more important now to get a booster dose.

Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced Immunity: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-09-01/08-COVID-Oliver-508.pdf

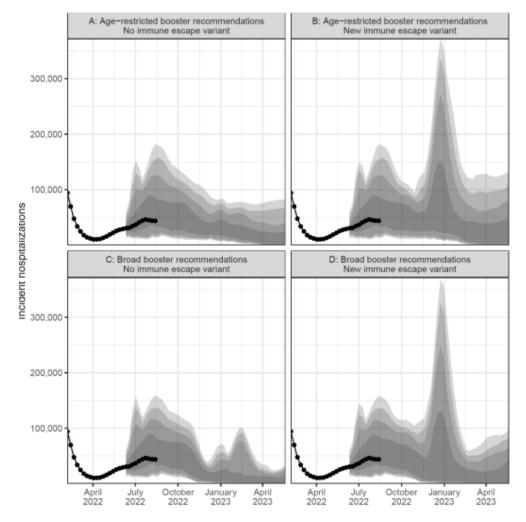


Do younger adults (<50 years old) really need to get the updated booster?

Round 14: National ensemble projection intervals - Hospitalizations

Round 14

Regardless of presence of a new variant, flu-like vaccine uptake in individuals ages ≥18 years would lead to a >20% reduction in hospitalizations and >15% reduction in deaths versus a recommendation for individuals ages ≥50 years only





Do we really need to start now? It's only September.

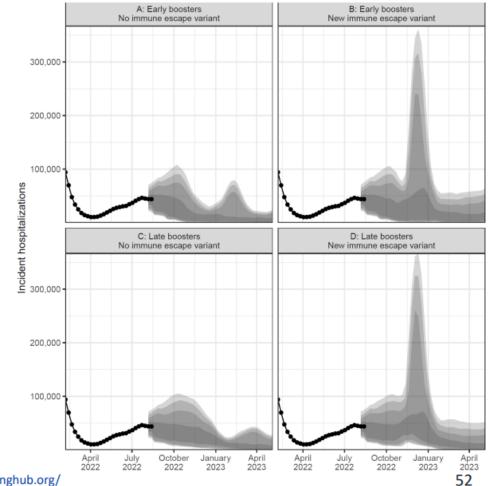
Round 15: National ensemble projection intervals - Hospitalizations

Round 15

Absent a new variant, boosters to individuals ages ≥18 years in September could prevent

137,000 more hospitalizations¹ and

9,700 more deaths² compared to boosters in November



¹95% Confidence Interval: 21,000-251,000

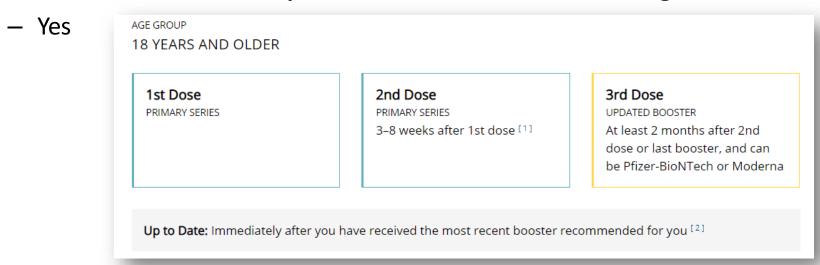
²95% Confidence Interval: 500-19,000

https://covid19scenariomodelinghub.org/



COVID-19 Vaccine FAQs

Does the definition for "up to date" vaccination status change?



- Important because upcoming SNF guidance heavily relies on "up to date" vaccination status
- Is the updated bivalent booster required for healthcare personnel working in SNFs?
 - Not at this time, but may change...
 - They are highly encouraged
 - Facilities must still actively offer



State of California—Health and Human Services Agency California Department of Public Health



AFL 22-09

February 24, 2022

TO: All Facilities

SUBJECT: Coronavirus Disease 2019 (COVID-19) Vaccine and Booster Recommendations for Clinically Eligible Individuals

All Facilities Letter (AFL) Summary

The California Department of Public Health (CDPH) recommends facilities offer COVID-19 vaccinations and booster doses to clinically eligible individuals.

The circulation of more transmissible recent variants of the SARS-CoV-2 virus has led to surges in COVID-19 cases. The majority of COVID-19 hospitalizations and deaths are occurring in unvaccinated individuals. The emergence of the Omicron variant further demonstrates the importance of vaccination, boosters, and other prevention efforts, including testing and masking, to protect eligible individuals (patients/residents), staff, and the community from COVID-19.

This AFL reminds facilities of the importance of offering and encouraging COVID-19 vaccinations, including booster doses, to clinically eligible individuals, especially those at highest risk of morbidity and mortality, at all interactions across the healthcare continuum. The following three vaccines

https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-22-09.aspx

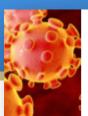


Health Officer Order updated July 25, 2022 clarifies facilities must offer all recommended additional and booster doses to SNF residents and staff

13. Offer, Track and Report COVID-19 Immunizations, as Directed by LAC DPH

- a. The Facility must offer COVID-19 immunization, including all recommended additional and booster doses, as the vaccine is made available to the facility to all residents and Facility staff including directly employed staff and staff not directly employed by the Facility, paid and non-paid, who regularly enter Facility premises one time per week (7 days) or more.
 - For residents who have been discharged or transferred to another facility by the time the second dose is due, the Facility that administered the first dose should ensure follow-up to offer the second dose.
 - ii. For staff who no longer regularly work at or visit the Facility that administered the first dose by the time the second dose is due, the same Facility should ensure follow-up to offer the second dose if requested.

Health Officer Order for the Control of COVID-19: Prevention of COVID-19 Transmission in Skilled Nursing Facilities Revised 7/25/2022 Page 6 of 9



Coronavirus Disease 2019



Guidelines for Preventing & Managing COVID-19 in Skilled Nursing Facilities

This webpage is specifically intended for the med Click here to visit DPH's COVID-19 webpage for the

On this page Updated 7-5-22	Quick li
Summary of Recent Changes	• LA
• Introduction	thi
COVID-19 Vaccination Guidance	wh
 COVID-19 Prevention - General and 	res
Administrative Practices	Im
 Communal Dining, Group Activities, and 	ho
Visitation	us
COVID-19 Testing	hig
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• Infection Prevention and Control Guidance	• Inf
Healthcare Personnel Monitoring and Return	• LA
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Inter-facility Transfers	• LA
Resources	foi

Track, Increase, and Maintain COVID-19 Vaccination & Booster Coverage

- All facilities must track all vaccine doses, including additional primary and booster doses, for all staff and
 residents including verifying vaccination status of new staff hires and new admissions. If a person's
 vaccination status is not verified, they are considered unvaccinated.
 - a. It is recommended that facilities maintain the following information at minimum in secure/encrypted electronic documents (such as a password protected spreadsheet) for all current residents in a single file and all current staff in a single file:
 - 1) vaccination status (e.g., up to date, fully, partially, un-vaccinated, or not yet assessed)
 - 2) the dates of all vaccination doses, including additional primary and booster doses, OR date the person declined. This will a) help facilities anticipate when individuals are due for additional primary or booster doses, b) help facilities' ability to efficiently implement guidance in this document that depends on vaccination status, and c) allow for easier reporting on vaccination surveys from Public Health, CDPH, and/or NHSN.
- 2. All facilities should increase and maintain vaccination coverage, including boosters, for both staff and residents by re-offering the vaccine, providing education, hosting listening sessions including to persons who have previously declined, etc. Please see Best Practices for Improving Vaccination in SNFs of for more detailed strategies including building vaccine confidence. Also, as per CMS QSO 21-19-NH Interim Final Rule COVID-19 Vaccination Immunization Requirements for Residents and Staff of, facilities must document when COVID-19 vaccine education took place and provide samples of educational materials used for both staff and residents.

http://publichealth.lacounty.gov/acd/ncorona2019/healthfacilities/snf/prevention/



COVID-19 Vaccine FAQs

- Does the COVID-19 including updated booster dose need to be spaced out by 14 days with other vaccines (e.g., influenza)?
 - No. COVID-19 vaccines may be administered without regard to timing of other vaccines, including simultaneous administration of COVID-19 vaccine and other vaccines on the same day.
 - If multiple vaccines are administered at a single visit, administer each injection in a different injection site.
 - Co-administration with influenza vaccine (when available) is actually highly encouraged
- Do providers still need to observe 15 minutes post-vaccination?
 - 15-minute observation period is now optional
 - Vaccination providers should <u>consider</u> a 15min observation period for adolescents (risk of syncope) and 30min observation for those with history/at risk for anaphylaxis, immediate allergic reactions, etc.



Action Plan for SNFs in Los Angeles County





Updated Bivalent Booster Plan for Los Angeles County SNFs

- Public Health is directing all SNFs in Los Angeles County to immediately start offering the updated bivalent booster to all eligible residents and staff.
- All SNFs in LA County must have had at least 1 (preferably multiple) vaccine clinic
 administering the updated bivalent booster to eligible individuals by October 7, 2022 (4 weeks
 from today).
 - Assess all residents and staff for their eligibility and interest to receive the updated bivalent booster.
 - 2. Obtain consent.
 - Verbal consent is accepted. Document verbal consent in chart (residents).
 - Consider advance "opt-out" consent for future booster doses to relieve administrative burden.
 - 3. Reach out to your <u>long-term care (LTC) pharmacy</u> to schedule for delivery of doses.
 - Expect a call from Public Health offering mobile vaccine assistance.
 - SNFs may use BOTH their LTC pharmacy and Public Health's mobile vaccine team.
 - Provide past/future booster clinic dates to <u>Public Health callers</u>.





COVID-19 Vaccine/Booster Resources for LA County SNFs



1) Continue to FIRST utilize LTC pharmacy

- EVEN when your Public Health Nurse/Outbreak Investigator has referred your facility to Public Health's MVT (mobile vaccine team)
- Ok to hold clinics with both MVT and with supply from your LTC pharmacy. One does not preclude the other!
- 2) If there any issues with accessing vaccine from your LTC pharmacy (e.g., type is not available, unable to meet minimum dose requirement), then either:
 - Fill out a referral form here (ONLY for SNFs):
 https://forms.office.com/g/TsThXceFX2; OR
 - Contact our SNF team at Public Health:
 COVID-LTC-Test@ph.lacounty.gov



Reporting Up to Date with COVID-19 Vaccines



Reporting Up to Date on CDPH Survey Weekly Reporting

- "Up to date" on the CDPH weekly survey includes any staff or resident who has completed their primary vaccine series doses and recommended booster if enough time has passed
 - For ages 12+, one booster dose of bivalent COVID-19 vaccine is recommended at least 2 months after the last COVID-19 vaccine dose (either the final primary series dose or the last booster). This is regardless of how many boosters or which type(s) of vaccine they received in the past).
- if it has been <2 months since their last dose, they are up to date
- if it has been >2 months since last dose AND
 - they do NOT have an updated booster (bivalent), they are NOT up to date
 - they DO have an updated booster (bivalent), they ARE up to date

CDC Up to Date COVID-19 Vaccine Recommendations: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html



Reporting Up to Date on CDPH Survey Weekly Reporting

CDPH

Cumulative number of those with completed primary vaccine series, who are up to date with COVID-19 vaccine

NHSN

Question 5 (Up-to-date Residents)	Of the residents in question #2, this question asks about individuals who are up to date with COVID-19 vaccination. Please review the current definition of up to date: https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-May2022-508.pdf
	Please review FAQs on additional and booster doses for examples on how to categorize various individuals based on the number of doses they've received and when they received these doses: FAQs on Reporting COVID-19 Vaccination Data NHSN CDC

Data Fields	Instructions for Completion	
5. *Cumulative number of residents in	Required. Enter Cumulative number of residents in question #2 who	
question #2 who are up to date with COVID-	are up to date with COVID-19 vaccines according to the definition,	
19 vaccines	found here:	
	https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-	
	May2022-508.pdf.	
	STATE OF THE PARTY	

All SNFs must Track and Report "Up to Date" status for ALL:

- Residents
- EmpHCP: Number of employed HCP
- **LIPHCP**: Number of licensed independent practitioner HCP
- **VolHCP**: Number of adult student/trainee and volunteer HCP
- OCPHCP: Number of other contract personnel

Please remember all responses should be cumulative — meaning report the total number who are up to date for residents and staff in your facility, not just those new during the reporting week.



Resources





COVID-19 Resources for Skilled Nursing Facilities in Los Angeles County

- Contact to update your facility's point of contact (e.g., to receive email updates):
 LACSNF@ph.lacounty.gov
- Contact for COVID-19 guidance questions in SNFs: LTC_NCoV19@ph.lacounty.gov
- Contact for COVID-19 Vaccination resource questions, including questions about your LTC pharmacy or Public Health's Mobile Vaccine resource: <u>COVID-LTC-Test@ph.lacounty.gov</u>

 LAC DPH COVID-19 SNF Past Webinar Slides & Recordings: http://publichealth.lacounty.gov/acd/SNFWebinarArchive.htm



COVID-19 Resources for Skilled Nursing Facilities in Los Angeles County

Los Angeles County Public Health

- Guidelines for Preventing & Managing COVID-19 in Skilled Nursing Facilities:
 http://publichealth.lacounty.gov/acd/ncorona2019/healthfacilities/snf/prevention/
- COVID-19 Infection Prevention Guidance for Healthcare Personnel:
 http://publichealth.lacounty.gov/acd/ncorona2019/healthfacilities/HCPMonitoring/
- Interfacility Transfer Rules: http://publichealth.lacounty.gov/acd/NCorona2019/InterfacilityTransferRules.htm

CDPH:

- CDPH All Guidance Documents by Topic (including State Public Health Officer Orders):
 https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Guidance.aspx
- 2022 AFLs: https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LNCAFL22.aspx
- 2021 AFLs: https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LNCAFL20.aspx
- 2020 AFLs: https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LNCAFL21.aspx

• CDC, NIH:

- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
- NIH Anti-SARS-CoV-2 Monoclonal Antibodies: https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-monoclonal-antibodies/



Questions and Answers

