

Vaccine Updates

2/9/22

Moderna COVID-19 Vaccine Approval and Recommendation

- FDA announced approval of the Moderna Vaccine (Spikevax) on 1/31/2022.
- ACIP 2/4/2022 Meeting:
 - Moderna Phase 3 clinical trial study
 - 92% VE against hospitalization up to 5 months after the second dose
 - Several studies on mRNA vaccines and myocarditis
 - Higher than expected myocarditis rates after 2nd dose in males 18 – 49 years old
 - Majority of cases had resolution of symptoms, but some required hospitalization. No known vaccine-associated myocarditis deaths.
 - Ongoing long-term studies of outcomes of myocarditis.
 - The committee voted to recommend the Moderna vaccine for the primary series for individuals ages 18 years and older

Updates to Interim Clinical Considerations for Use of COVID19 Vaccines

- Clarification and updates on guidance for people who are moderately or severely immunocompromised
- Updates to recommendations on passive antibody products

REVISED COVID-19 Vaccination Schedule for People Who Are Moderately or Severely Immunocompromised

Vaccine	Vaccination Schedule			
Pfizer-BioNTech (ages 5 years and older)	1st dose	2nd dose (21 days after 1 st dose)	3rd dose (at least 28 days after 2 nd dose)	Booster dose* (at least 3 months after 3 rd dose)
Moderna (ages 18 years and older)	1st dose	2nd dose (28 days after 1 st dose)	3rd dose (at least 28 days after 2 nd dose)	Booster dose* (at least 3 months after 3 rd dose)
Janssen (ages 18 years and older)	1st dose	Additional dose† (at least 28 days after 1 st dose)		Booster dose* (at least 2 months after additional dose)

*Any COVID-19 vaccine can be used for the booster dose in people ages 18 years and older, though mRNA vaccines are preferred. For people ages 12–17 years, only Pfizer-BioNTech can be used. People ages 5–11 years should not receive a booster dose.

†Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used

Rationale for Revised Vaccination Schedule for Immunocompromised Persons

- Concern about initial immune response and loss of protection over time, particularly during high community transmission.
- Small studies show immunogenicity of a 4th dose when administered 1-3 months after the 3rd dose for immunocompromised persons.
- Studies in general population show immunogenicity of a booster as early as 3 months following a 2-dose primary series.

Revaccination for Certain Sub-Groups

- **Current** guidance: Limited to recipients of hematopoietic cell transplant (HCT) and chimeric antigen receptor (CAR)-T-cell therapy.
- **Revised** guidance: Recipients of HCT, CAR-T-cell, **or other B-cell depleting therapies** who received doses of COVID-19 vaccine **prior to or during treatment** should be revaccinated for doses received before or during treatment.
- Based on clinical judgement, revaccination may also be considered once immune competence is regained for people who received COVID-19 vaccine doses during **chemotherapy or radiation treatment**.

Case-by-Case Decision Making Based on Clinical Judgement

- On a case-by-case basis, providers who care for moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals **based on clinical judgement** when the benefits of vaccination are deemed to outweigh the potential and unknown risks.

Passive Antibody Products

Current guidance

Defer COVID-19 vaccination for:

- 30 days if product used for post exposure prophylaxis
- 90 days if product used for treatment
- No guidance for pre-exposure prophylaxis



Revised guidance

- No recommended deferral period
- However, tixagevimab/cilgavimab (EVUSHELD™) should be deferred for at least two weeks after vaccination

Benschop, et al. (2021). The effect of anti-SARS-CoV-2 monoclonal antibody, bamlanivimab, on endogenous immune response to COVID-19 vaccination. *medRxiv*. Preprint.
doi: <https://doi.org/10.1101/2021.12.15.21267605>

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- **FDA Advisory Committee Meeting to Discuss Request for Authorization of Pfizer-BioNTech COVID-19 Vaccine for Children 6 Months Through 4 Years of Age**

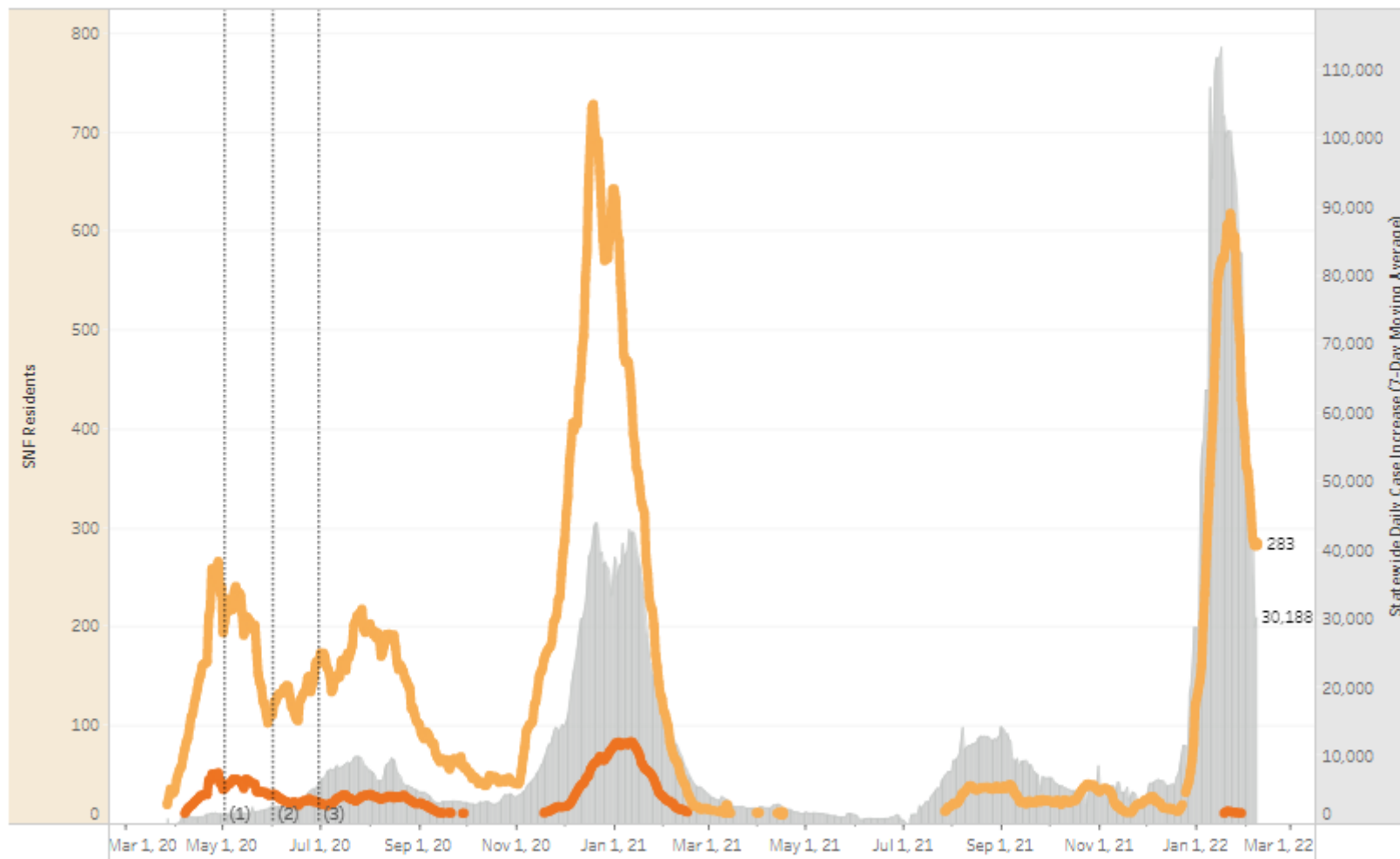
- [Press release](#)
- Meeting 2/15/2022, 8:30a-5p eastern time
- Livestream and webcast link: www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-february-15-2022-meeting-announcement

COVID-19 SKILLED NURSING FACILITIES TRENDS

SNF New COVID-19 Cases (7-Day Moving Average)

Statewide Daily Case Increase (7-Day Moving Average)

SNF COVID-19 Deaths (7-Day Moving Average)



(1) May 2-Predictive analytics are initiated.

(2) June 1-Mitigation plans are due from all SNFs, and baseline COVID-19 testing is initiated.

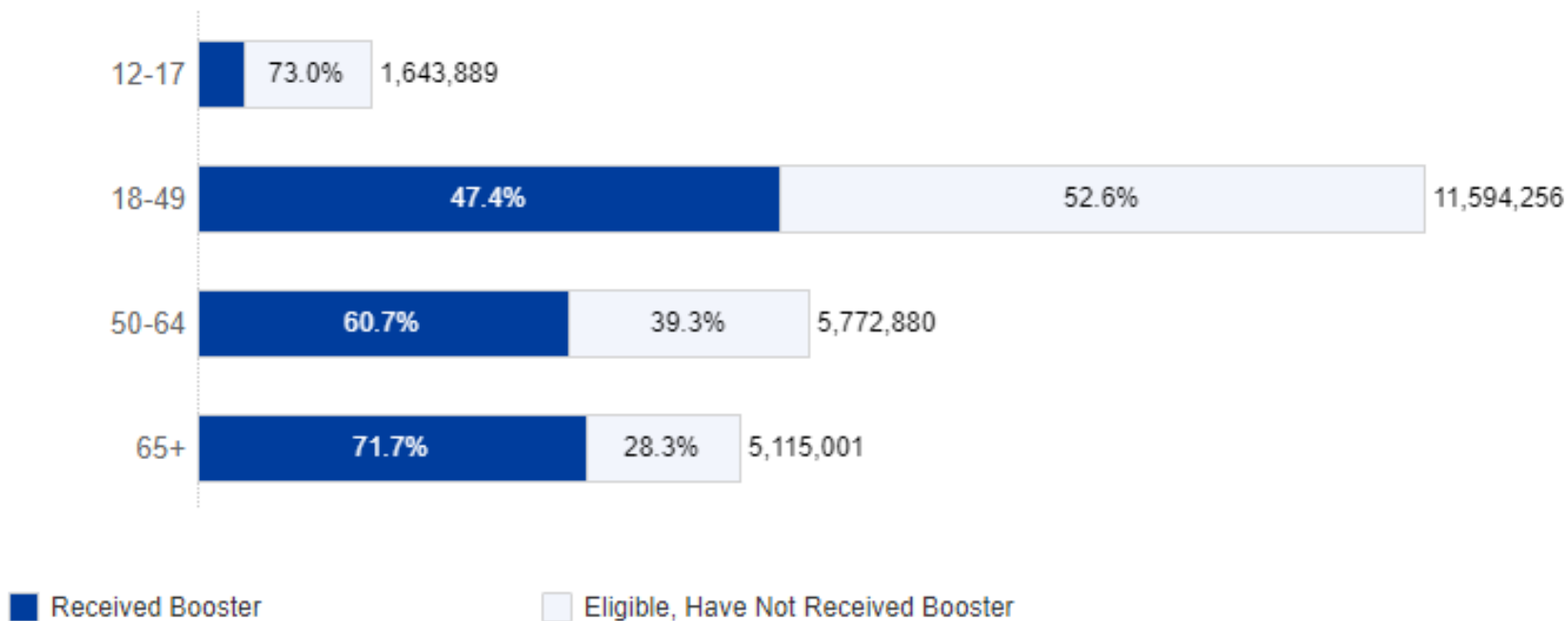
(3) June 30-Baseline testing is completed.

Booster Vaccinations in CA

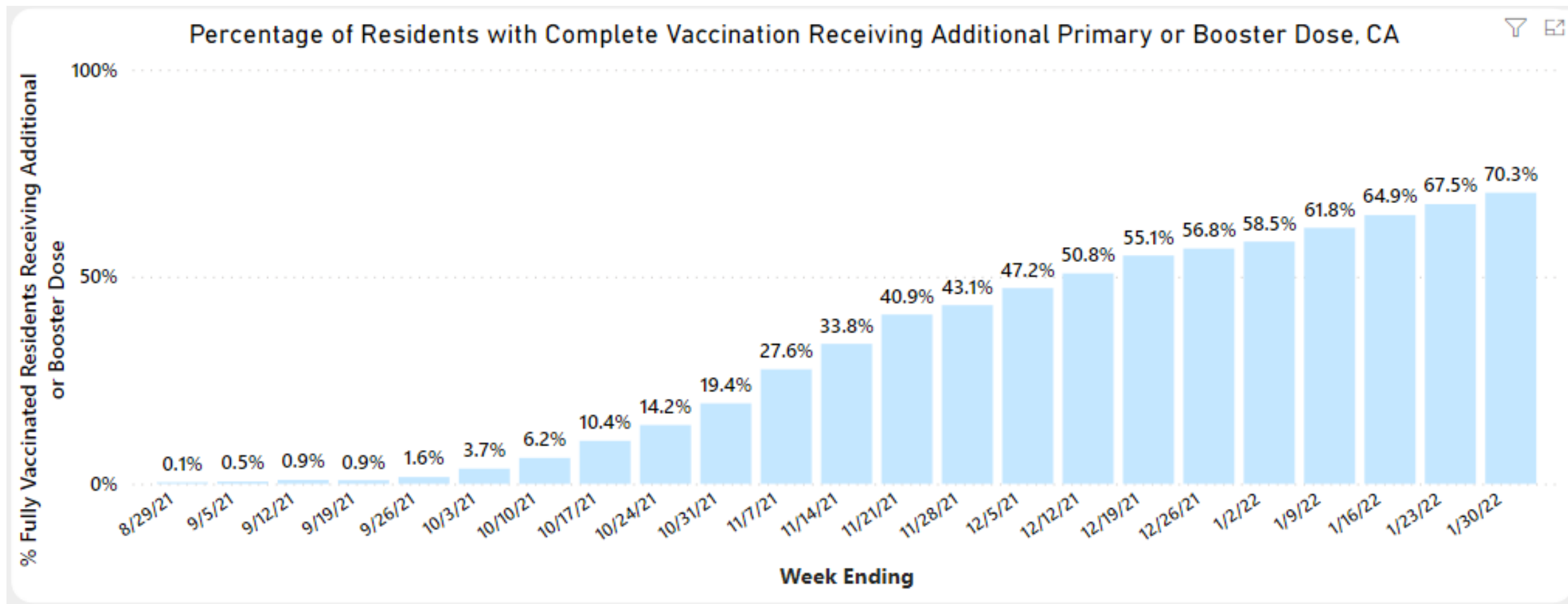
Vaccinated Status by Group

Select Category: Age
Select County: Statewide
Select Primary Series vs Booster: Booster Status

Booster status by age



SNF Booster Vaccinations: Residents



SNF Booster Vaccinations: Staff

