Health Advisory:

Additional COVID-19 Vaccine Dose for mRNA Vaccine Recipients with Immune Compromise

August 18, 2021

Situational Update

FDA amended its Emergency Use Authorizations (EUA) and Fact Sheets for Pfizer-BioNTech and Moderna COVID-19 Vaccines to allow administration of an additional (3rd) dose at least 28 days following completion of the 2-dose series in solid organ transplant recipients and those with an "equivalent level" of immune compromise. The age groups authorized to receive the additional dose are the same as those authorized to receive the primary series (Pfizer-BioNTech age ≥ 12 years; Moderna age ≥ 18 years).

CDC updated its guidance for COVID-19 vaccination of persons with immune compromise stating that an additional dose of an mRNA COVID-19 vaccine "should be considered" for persons with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive treatment or medication.

Western States Scientific Safety Review Workgroup has endorsed the CDC guidance, noting that individuals should discuss the benefits and risks of an additional dose of mRNA COVID-19 vaccine with a healthcare provider, and that an individual's medical care team is in the best position to determine the degree of immunocompromise in relation to the recommended COVID-19 vaccination schedule.

FDA did not similarly amend the EUA for Johnson & Johnson (J&J) vaccine and CDC, citing a lack of sufficient data at present, has not recommended additional doses for J&J recipients with immune compromise.

Definition of an Additional Dose

CDC has stated that an ***additional dose after an initial primary vaccine series*** is defined as administration of an additional vaccine dose when the initial immune response following a primary vaccine series is likely to be insufficient; and that a ***booster dose*** is a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time.

Federal and state guidance on the need for and timing of COVID-19 booster doses are currently in development and we are following closely.

Additional Dose for Immunocompromised Persons Who Received mRNA Vaccine

According to recent data, persons with moderate to severe immunosuppression have a lower immune response to vaccination and lower vaccine effectiveness after a 2-dose mRNA vaccine series compared to non-immunocompromised persons, and are more susceptible to breakthrough infections and severe COVID-19. Limited data also indicate that an additional dose of mRNA vaccine is likely to be safe and will enhance the immune response in some, but not all, immune compromised recipients

In accordance with CDC guidance, SFDPH endorses the administration of an additional (3rd) COVID-19 mRNA vaccine dose to patients with moderate to severe immune compromise whose first 2 doses were Pfizer-BioNTech or Moderna COVID-19 vaccine. Specific examples of qualifying conditions or treatments cited by CDC include:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Ideally, patients with immune compromise will be able to consult with their primary or specialty medical professional and if appropriate, receive an additional dose of mRNA vaccine through that channel. Health systems and clinics are encouraged to create access to consultation and additional mRNA vaccine doses for these patients.

In settings where input of the individual's clinical team is not available, individuals requesting 3rd doses of mRNA vaccine may self-attest they have one of the above or an equivalently immunocompromising condition or treatment.

In accordance with CDC guidance, the additional dose of mRNA product should be given at least 28 days following completion of the 2-dose series. There is no maximum interval between 2nd and 3rd doses, and a person should not receive more than 3 doses in total. The third dose should be the same vaccine product as the initial 2-dose series, but if that same product is not available, the other mRNA product may be administered. Serologic or cellular immune testing to assess immune response to vaccination has not been validated in this context and is not recommended at this time.

Counseling Regarding Non-Pharmaceutical Prevention Measures

All immune compromised persons, including those receiving an additional mRNA vaccine dose, should be counseled about the potential for reduced immune response to COVID-19 vaccine and the need to follow current non-pharmaceutical prevention measures, including wearing a mask, maintaining social distancing, and avoiding crowds and poorly ventilated indoor spaces. Their close contacts who are not immune compromised should be strongly encouraged to complete a standard COVID-19 vaccination regimen.

Additional Dose for Immunocompromised Persons Who Received J&J Vaccine

Western States Scientific Safety Review Workgroup offers this guidance regarding immune compromised patients who received the J&J COVID-19 vaccine:

"The Workgroup recognizes that the ACIP did not provide guidance for similarly immunosuppressed patients who received the Janssen COVID-19 vaccine … the Workgroup advises individuals whose immune systems are moderately to severely compromised and who received the Janssen COVID-19 vaccine to consult with their health care providers. The Workgroup believes clinicians should weigh the potential risk of COVID 19 infection and the unknown potential risks and benefits of a dose of an mRNA vaccine for each such patient and also consider the potential organizational and professional risks of the unauthorized administration of a supplementary dose of an mRNA vaccine. Should a clinician choose to recommend the patient consider a supplementary dose of an mRNA vaccine in these circumstances, the patient should be informed that the recommendation exceeds current FDA and CDC guidance and is based on the clinician's individualized medical judgment."

SFDPH Supplemental Dose Accommodation for J&J Vaccine Recipients

SFDPH is continuing to accommodate special requests to receive a single supplemental dose with an mRNA vaccine product, from J&J COVID-19 recipients who are San Francisco residents or who received their J&J dose in San Francisco, and who have consulted with a health care provider about the risks and benefits of such supplemental vaccination. See SFDPH Health Advisory dated 8/6/2021.

This accommodation, while available at SFDPH-operated vaccination sites, does not constitute guidance or a recommendation by SFDPH, and non-SFDPH providers have no obligation to follow suit.

The accommodation process does not require that individuals attest to specific medical circumstances, and therefore does not exclude J&J vaccine recipients with moderate to severe immune compromise.

Additional Information

Application Deadline and Eligibility Extended for CALVAX Grant Funds

September 10, 2021 is the new deadline to apply.

Eligibility now includes student health centers, university health centers, and K-12 schools, as well as medical Independent pharmacies and medical practices with <200 physicians.

Eligible entities are strongly encouraged to apply, as COVID-19 vaccination efforts are expected to be ongoing, and the success of our efforts to vaccinate children and adults requires an "all-hands-on-deck" approach.

See https://www.phcdocs.org/Programs/CalVaxGrant. Up to $55,000 in support can be requested. Application assistance is available; email: CCC-Distribution@sfdph.org

Resources

Patient-Facing Info on Additional Doses for Immunocompromised Persons

- CDC: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html
- CDPH:https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/ThirdVaccineDoseQandA.aspx)

CDC COVID Vaccination Guidance for Clinicians
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

CDPH Program Info https://eziz.org/covid/

FDA COVID vaccine site
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

SF Dashboard https://sf.gov/data/covid-19-vaccinations