COUNTY OF IMPERIAL
PUBLIC HEALTH DEPARTMENT

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HEALTH ADVISORY

Recommendations for a third m-RNA Vaccine Dose for Moderately to Severely Immunocompromised Individuals

Over the last few days, the U.S Food and Drug Administration has expanded the Emergency Use Authorization (EUA), and the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) have recommended a third dose of m-RNA vaccines in certain immunocompromised individuals. The Western States Scientific committee has also voted to support this recommendation and their statement should be available soon. The science that formed the basis for the decisions and details of the recommendations can be found below.

The science is based on serologic responses in organ transplant recipients- there are no current data available on clinical outcomes or in other immunocompromised populations. However, the recommendations include guidelines on how to identify other patients who could have an "equivalent level of immunocompromise" and are therefore eligible for a third dose. The guidelines and discussion around them do not allow for additional doses in other populations, such as those who are over the age of 65, or who have other conditions that make them high-risk for complications of COVID-19, unless they are also immunocompromised. This is being considered by the FDA and ACIP, and there may be additional recommendations for this larger group in the future. Of note, the J&J Janssen vaccine is not included in this recommendation due to insufficient data for review. Therefore, additional doses of either J&J Janssen vaccine or an m-RNA vaccine in persons who received the J&J Janssen vaccine as a primary series are not

recommended at this time. Studies are ongoing regarding additional doses of J&J Janssen vaccine and additional recommendations for these patients may be forthcoming.
More than 3 vaccine doses are not authorized, and serology testing is not recommended to determine if an individual needs a third dose or after a dose to determine response from vaccine. It is important to remember that the vaccine agreements that were signed by organizations to procure vaccine for administration, require that the EUAs be followed exactly. The process toward full FDA approval of the COVID vaccines continues to move forward and may be done in the next few weeks for the current EUAs-approved age groups. Full FDA approval will allow for much more flexibility for clinicians and patients by allowing "off-label" use. It is important to note that individuals who are immunocompromised, regardless of their decision to receive or not a third dose, should continue follow all other public health recommended preventive measures, such as social distancing, use of mask including indoors or in crowded outdoor settings, as well as avoiding crowds and poorly ventilated indoor spaces. The California Department of Public Health (CDPH) will be making available additional information, including that pertaining to operational issues related to My Turn that will allow for third-dose appointments. Proof of immunocompromise, such as a doctor's note, is not required and self-attestation of eligibility is acceptable documentation.

FDA
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised

ACIP
https://www.cdc.gov/vaccines/acip/meetings/slides-2021-08-13.html

CDC Guidance
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html

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