California Health and Human Services Agency (CHHS)

California Department of Public Health (CDPH)

WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP

January 17, 2021 - 7:30pm – 9:00pm

MEETING SUMMARY

Workgroup Members Attending

Rodney Hood, MD, Trustee, Alliance Healthcare Foundation; **Nicola Klein, MD**, Director, Kaiser Permanente Vaccine Study Center; **Grace Lee, MD**, Professor of Pediatrics and Associate Chief Medical Officer for Practice Innovation, Stanford Children's Health; **Bonnie Maldonado, MD**, Professor and Chief of the Division of Infectious Diseases, Department of Pediatrics, Stanford Medicine; **Arthur Reingold, MD**, School of Public Health Division Head of Epidemiology and Biostatistics, University of California, Berkeley; **Mark Sawyer, MD**, Infectious Disease Specialist, Rady Children's Hospital; **Peter Szilagyi, MD**, Professor and Vice Chair for Clinical Research, Department of Pediatrics and Mattel Children's Hospital; **Matt Zahn, MD,** Medical Director, Communicable Disease Control Division, Orange County Health Care Agency

Workgroup Members Not Attending

Eric Goosby, MD, Distinguished Professor of Medicine and Director of the Center for Global Health Delivery, University of California, San Francisco;

California State Representatives Attending

Tomas Aragon, Director California Department of Public Health and State Health Officer; **Erica Pan, MD**, Deputy Director for the Center for Infectious Disease and California State Epidemiologist; **Rob Schechter, MD**, Chief, California Department of Public Health, Immunization Branch

Western States Representatives Attending

STATE OF WASHINGTON:

John Dunn, MD, Medical Director for Preventive Care and Head of Immunization Program, Kaiser Permanente Washington

Edgar Marcuse, MD, MPH, FPIDS, Emeritus Professor, Pediatrics, University of Washington

STATE OF NEVADA:

Ihsan Azzam, MD, Chief Medical Officer, Division of Public and Behavioral Health

Candice McDaniel, Health Bureau Chief, Bureau of Child, Family, and Community Wellness

STATE OF OREGON

Laura Byerly, MD, Chief Medical Officer, Virginia Garcia Health Center

Louis Picker, MD, Associate Director of Oregon Health & Science University's Vaccine and Gene Therapy Institute

Consultants:
Bobbie Wunsch, Founder and Partner, Pacific Health Consulting Group
Laura Hogan, Senior Health Consultant, Pacific Health Consulting Group

Welcome and Review Today's Agenda
Arthur Reingold, MD, Chair

Dr. Reingold welcomed everyone and asked Dr. Pan to offer introductory comments. Dr. Pan thanked members for convening at short notice and commented that the meeting was requested to gather guidance from the Western States Scientific Safety Review Workgroup about the potential to extend the COVID-19 vaccine interval between dose one and dose two.

Dr. Pan reported that California recently issued guidance that providers may use 50% of the COVID-19 vaccine supply labeled for second doses as first doses and then continue to receive new vaccine supply for second doses. CDC approved this approach and several states have implemented it to speed the pace of vaccinations. Dr. Pan reiterated that CDPH is not advocating to change the guidance that all patients receive the second dose - not advocating to stop administering the second dose.

Dr. Pan asked the Workgroup for its recommendation on whether there is an extended interval beyond the current guidance of 21 days for Pfizer COVID-19 vaccine and 28 days for Moderna COVID-19 vaccine that the Workgroup could recommend.

There was lengthy member discussion about the efficacy and safety of extending the interval between dose one and two of the COVID-19 vaccines. Members discussed the expected flow of vaccine supply based on recent federal statements. Members commented that the "flow approach" approved by the CDC relies on consistent, reliable vaccine supply; however, the information about when vaccine supply will arrive has not been reliable.

Several members commented that there are no data regarding the safety and efficacy of an extended interval. Practically speaking, there is variation in when people receive the second dose and, in some cases, the interval may be longer than the recommended interval. However, members expressed that if the recommended guidance were changed to extend the interval by two weeks or six weeks or another time period, the extended interval would become standard practice. Given the normal variation that occurs due to a missed appointment or other delay, this would extend the interval between doses even farther and become very concerning, given the absence of data to support this change. Moreover, changing guidelines creates confusion,

causes some people to have a false sense that they are protected after one dose, when they may not be, and may increase hesitancy to receive vaccinations.

Members reiterated that people are not fully vaccinated until they have had two doses. In particular, people in phase 1 are at high risk of exposure, disease and death, and there should be significant concern about delaying the second dose. If for whatever reason there is a delay in administering the second dose beyond the recommended interval, the CDC Advisory Committee on Immunization Practices (ACIP) recommends that the second dose be administered and a third dose should not be given.

Members offered input to a recommended statement about extending the interval between doses: The recommended interval should remain within the window studied in the respective clinical trials. The second dose should be given at 21 days after the first dose for Pfizer and 28 days after the first dose for Moderna. If the exact schedule cannot be achieved, vaccination should occur as close as possible to the recommended interval, and there is no need to give a third dose.

Members reviewed the ACIP guidance and noted there is no indication that the Workgroup should deviate from the ACIP recommendations.
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html#Administration

Administration
The mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:

- *Pfizer-BioNTech (30 µg, 0.3 ml each): 3 weeks (21 days) apart*
- *Moderna (100 µg, 0.5 ml): 1 month (28 days) apart*

Persons should not be scheduled to receive the second dose earlier than recommended (i.e., three weeks [Pfizer-BioNTech] or one month [Moderna]). However, second doses administered within a grace period of four days earlier than the recommended date for the second dose are still considered valid. Doses inadvertently administered earlier than the grace period do not need to be repeated. There is no maximum interval between the first and second doses for either vaccine. Therefore, if the second dose is administered >3 weeks after the first Pfizer-BioNTech vaccine dose or >1 month after the first Moderna vaccine dose, there is no need to restart the series. Vaccine administration errors should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Dr. Reingold asked for partner states to offer thoughts. Nevada's participating member commented it is not a good moment to make changes. The state receives only 36,000 doses per week, and we are already seeing vaccine hesitancy. The member from Oregon agreed that the

ACIP recommendation should continue to be our standard. There is concern that if an extended interval is recommended, the implementation may result in even longer time intervals between doses. Washington's representative also commented that no change to the recommended interval is warranted at this time.

Dr. Pan commented that it is helpful to receive this input and hear the thinking of the Workgroup. She commented that she is hearing there is no scientific basis for an extension of the interval. A statement indicating the Workgroup reviewed this topic and there are no data to support a change to the recommended interval between COVID-19 vaccine dose one and dose two, citing the ACIP recommendation, which would be helpful.

Next Meetings, Closing Comments and Adjourn
Arthur Reingold, MD, Chair

Dr. Reingold will draft a brief statement by tomorrow morning and distribute to the Workgroup for review. The statement to reiterate ACIP guidance should be final by end of day tomorrow.