California Health and Human Services Agency (CHHS)

California Department of Public Health (CDPH)

WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP

April 8, 2021 - 6:00pm – 7:30pm

MEETING SUMMARY

Workgroup Members Attending

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

Nicola Klein, MD, Director, Kaiser Permanente Vaccine Study Center
Rodney Hood, MD, Trustee, Alliance Healthcare Foundation
Ihsan Azzam, MD, Chief Medical Officer, Division of Public and Behavioral Health

California State Representatives Attending

Tomas Aragon, MD, Dr.PH, 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:

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

Welcome and Review Today's Agenda
Arthur Reingold, MD, Chair
Erica Pan, MD, California State Epidemiologist

Dr. Reingold welcomed the Western States Scientific Safety Review Workgroup. Dr. Pan thanked members for joining. Dr. Aragon introduced the agenda for the meeting and offered framing remarks.

Revisit Second Dose Recommended Interval Strategy – Request from Secretary Mark Ghaly, MD, California Health and Human Services Agency
Arthur Reingold, MD, Chair
Tomas Aragon, MD, Dr.PH, Director, California Department of Public Health and State Health Officer and Erica Pan, MD, MPH, State Epidemiologist

Dr. Aragon opened the discussion by commenting that there have been recurring questions and media coverage related to the second dose recommended intervals for mRNA COVID-19 vaccines. Therefore, Secretary Ghaly requested that the Western States Scientific Safety Review Workgroup (Workgroup) offer input to the state. Dr. Aragon also noted that there are logistical and implementation considerations related to any change in the recommended intervals.

Dr. Pan acknowledged that the Workgroup has discussed this previously. However, staff are being asked to reconsider delaying the second dose of mRNA COVID-19 vaccines in order to accelerate delivery of first doses. This issue has been raised again recently in relation to data reported from recent CDC effectiveness studies in the United States, and the United Kingdom, and other countries adopting a delay in administering the second dose. Dr. Pan commented that the discussion in California is to potentially delay the second dose by two weeks, remaining within CDC guidelines. Dr. Pan asked the Workgroup for opening comments related to the dose interval and any likely impact on COVID-19 variants related to changing the dose interval. For context, Dr. Pan noted the following:

> CDC: Extended inter-dose intervals have been adopted by other national vaccine advisory groups and proposed by individuals in the U.S. as a strategy to increase 1- dose coverage during a time when demand exceeds supply
>
> Current guidance: "The second dose should be administered as close to the recommended interval as possible. However, if it is not feasible to adhere to the recommended interval, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be scheduled for administration up to 6 weeks (42 days) after the first dose."

Members of the Workgroup offered initial input. One dose of the mRNA COVID-19 vaccines does offer some protection, yet having a second dose offers the full benefit of vaccination documented in the clinical trials. Members noted that the effect of the boost from a second dose of an mRNA COVID-19 vaccine on in vitro SARS-CoV-2 neutralization varies across the different variant strains identified to date. Others commented that there is not an evidence-base to support a change in the current strategy and that there are operational risks related to making this change, in that such a change may lead to public confusion, disruption to current vaccination operations and increased numbers of individuals who do not receive the second dose. One member noted that the CDC guidance already includes a window for the second vaccine dose to be scheduled for administration up to six weeks following the first dose.

Dr. Pan answered a member's question by commenting that she is not aware of any other states having made a change to the recommended interval between doses established in clinical trials. She also reported that California is sequencing SARS-CoV-2 viruses from 4-5% of COVID-19 cases and the predominant strain, approximately 60%, is the West Coast Variant.

Many members weighed in that there are unknowns and risks associated with any change and there is no evidence to support a change. Currently, there are lower levels of COVID-19 disease and hospitalizations, reducing the potential urgency for any change. As one member noted, the Workgroup bases its decisions on evidence, not on expert opinion.

Tomas Leon, PhD epidemiologist from the California Department of Public Health offered a presentation on the likely impact of delaying the second dose. He began with the reasons for considering the change, as discussed by the Workgroup. In California, delaying the second dose by two weeks would allow up to 2.8 million additional doses to potentially be used as first doses by July 1, 2021. Having 2.8 million additional first doses sooner would result in reaching 90% vaccination coverage in the state one week earlier than projected if the current dose intervals are maintained. Dr. Leon then presented data on the impact of dose spacing on COVID-19 cases under different sets of assumptions. While there were variations in case rates based on the scenarios, the impact of increasing dose spacing was minimal. The possible effects of changing the vaccine schedule on recipient confusion or loss to follow up were not assessed.

Members asked clarifying follow-up questions. The two-dose vaccination completion rate in California is 83% for the Moderna vaccine and 85% for the Pfizer vaccine. There was also discussion about the assumptions in the models.

Dr. Reingold then asked for each state to weigh in on the question of changing the recommended interval for the mRNA COVID-19 vaccine second dose.

Oregon has not implemented any change to the recommended interval, although staff are asked frequently about whether the state should delay the recommended interval for the second dose of mRNA COVID-19 vaccines. The predominant variant in Oregon is also the California strain, which is different from the B117 variant that is predominant in the Midwest or East Coast.

Nevada has received similar inquiries but has also not made any change to the recommended interval. There was one region in Nevada that did temporarily extend intervals, followed by a course correction to get them back on track. For Nevada, the confusion created by that experience underscored that a change to the recommendation is likely to lead to confusion and might not have a beneficial effect.

Dr. Reingold asked if the Workgroup was unanimous in its recommendation not to make any change to the second dose recommended interval, and all members present concurred.

Dr. Pan and Dr. Aragon thanked the Workgroup for the discussion. They commented that, in light of new information from other countries, updated effectiveness data in the United States, and the questions surfacing here in the United States, it was helpful to revisit the topic and have a thorough discussion of the science and the operational considerations related to changing the second dose interval.

Forecasting Discussion of Vaccines for Children 12 – 15 Years of Age
Arthur Reingold, MD, Chair
Tomas Aragon, MD, Dr.PH, Director, California Department of Public Health and State Health Officer and Erica Pan, MD, MPH, State Epidemiologist

Workgroup members reported on what they understood was the likely timing and process for FDA approval to administer COVID-19 vaccine to youth ages 12-15 years. Pfizer is expected to submit additional data to the FDA in April 2021 and Moderna will likely submit data in May 2021. The process will not require a separate Emergency Use Authorization (EUA). Instead, if approved, the FDA is expected to add this age group to the existing EUA for the vaccines.

There is currently no information about whether a separate Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting will review this topic. The CDC Advisory Committee on Immunization Practices (ACIP) is expected to discuss the benefits of COVID-19 vaccine for youth ages 12-15 years whenever the FDA adds them to the existing EUA.

Workgroup discussion also included a forecast of whether COVID-19 vaccination might be made mandatory for school entry in Fall 2021. Some colleges have already announced plans to require COVID vaccinations of students as soon as Fall 2021. Mandatory vaccination may require that the vaccines have received full FDA approval (i.e. Biologics License Application BLA), not just an EUA. Both Pfizer and Moderna have plans to seek a BLA, although the timing of their submissions to FDA remains uncertain. In addition to timing, there may be other considerations that make mandatory vaccination requirements challenging for the upcoming 2021-22 school year.

The Workgroup briefly discussed reports of a cluster of incidents of post-COVID-19 vaccination dizziness, light headedness, and nausea in multiple states. There were no reports of such

incidents in California at the time of this meeting. Members noted that the severity and medical significance of this type of incident are difficult to assess, given the type of symptoms experienced. Most cases resolved within the post-vaccination observation times recommended as standard procedure.

Discussion about Possible Impact on Generation of SARS-CoV-2 Mutations of Vaccination of Individuals Incubating the Disease
Arthur Reingold, MD, Chair
Rob Schechter, MD, Chief, Immunizations Branch, CDPH

Dr. Pan requested that members offer input about whether there is an increased risk of generating variants of SARS-CoV-2 if a person is vaccinated while incubating COVID-19 disease, in context of considering "ring" vaccination or post-exposure prophylaxis with COVID-19 vaccine.

Members commented that receiving a COVID-19 vaccination while incubating the disease is unlikely to produce new variant mutations. It is very likely that some individuals receiving COVID-19 vaccines are incubating the disease, given that some individuals develop COVID-19 in the 7-10 days following vaccination.

Next Steps and Timing of Statement(s)and Adjourn
Arthur Reingold, MD, Chair

There is no new information on when Astra Zeneca vaccine data might be submitted to the FDA for EUA approval; therefore, the next meeting of the Workgroup cannot be scheduled at this time.

A short statement will be issued on the Workgroup's recommendation not to make any change in the second dose interval.