

California Health and Human Services Agency (CHHS)

California Department of Public Health (CDPH)

WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP

May 12, 2021 – 7:00pm – 8:30pm

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

California State Representatives Attending

Tomas Aragon, MD, Dr.PH, Director California Department of Public Health and State Health Officer; **Erica Pan, MD, MPH**, 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

Karissa Loper, MPH, Health Bureau Chief, Nevada Department of Health and Human Services

STATE OF OREGON

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

Consultant:

Bobbie Wunsch, Founder and Partner, Pacific Health Consulting Group

Welcome and Review of Today's Agenda

Arthur Reingold, MD, Chair

Dr. Arthur Reingold welcomed the members of the Western States Scientific Safety Workgroup. Dr. Erica Pan, California State Epidemiologist thanked the members for again convening on short notice to advise the state.

Update from ACIP Meeting Discussion and Recommendations on COVID-19 Vaccines for 12-15 Year Olds and Western States Guidance to Governors

Arthur Reingold, MD, Chair

Grace Lee, MD, Stanford Children's Health and ACIP Member

Dr. Grace Lee, a current member of the Advisory Committee on Immunization Practices (ACIP), summarized the findings and discussions presented at its meeting earlier today. The study protocol for the Pfizer COVID-19 vaccine was amended for use in those 12-15 years of age, at the same dose and schedule as in adults, to understand safety and efficacy of the Pfizer COVID-19 vaccine in this age group. Dr. Lee reported that the efficacy data were reassuring (VE = 100%). There were no severe cases of COVID-19 and no deaths reported among vaccine recipients. The reactogenicity profile was similar to that reported in the 16-25 years old age cohort, including local reactions at the injection site and systemic events such as fatigue, headache, and fever. No safety concerns were identified, although lymphadenopathy was reported by a small number of vaccine recipients. There was discussion of the racial and ethnic representation in the trial and ACIP members requested follow up data on this issue. Overall, ACIP concluded that the immunogenicity and efficacy data support the use of the Pfizer-BioNTech COVID-19 vaccine in adolescents 12-15 years of age.

A phased approach to vaccinating those 12-15 years old will allow states and providers flexibility as they transition from mass vaccination sites to vaccine administration in provider offices and primary care clinics.

Recommendation from American Academy of Pediatrics (AAP) Board to CDC/ACIP re: Vaccine Timing after COVID-19 Vaccines

Bonnie Maldonado, MD, Stanford University School of Medicine

Dr. Maldonado provided background on the recommendation from the AAP Board to the CDC. More than 1.5 million youth age 12-17 years have had COVID-19 ([Sarah Oliver, MD, MSPH, May 12, 2021 presentation ACIP](#)) and many youth are behind in receiving other recommended vaccinations

The AAP recommends COVID-19 vaccination for all adolescents 12 years of age and older who do not have contraindications using a COVID-19 vaccine authorized for use in their age group. A press release statement was issued by AAP, that reads, in part:

The AAP supports giving other childhood and adolescent immunizations at the same time as COVID-19 vaccines, particularly for children and teens who are behind on their immunizations. Between the

substantial data collected on the safety of COVID-19 vaccines, and the extensive experience with non-COVID-19 vaccines which shows the immune response and side effects are generally similar when vaccines are given together as when they are administered alone, the benefits of co-administration and timely catch up on vaccinations outweigh any theoretical risk. AAP recommends that children and adolescents catch up on all vaccinations that may have been delayed during the pandemic.

Clarifying questions:

- Is the AAP recommendation intended to apply to pre-school age children?
- Did the trials include any examination of co-administration of COVID-19 vaccine with other vaccines?

Dr. Maldonado clarified that the AAP recommendation applies only to those age 12 years and older. She also reported that the study did not include or report data on concomitant vaccination.

Members noted that the Vaccine Adverse Events Reporting System (VAERS) can collect data about other vaccinations within 14 days of COVID-19 vaccination and concomitant vaccination; however, this is not common practice when reporting an adverse event via VAERS. Pediatricians are requesting additional guidance because it has not been standard practice to screen patients for recent COVID-19 vaccination prior to administering other vaccinations.

The Workgroup discussed the fact that the CDC is changing its recommendation on co-administration of COVID-19 vaccines with other vaccines for all age groups. In the absence of data about safety or immunogenicity, the Workgroup will not issue a separate recommendation on this topic and defers to the CDC recommendation:

- *Due to the novelty of the COVID-19 vaccines, the previous recommendation was to administer COVID-19 vaccines alone, with a minimum interval of 14 days before or after administration of any other vaccine, to better understand any adverse reactions.*
- *However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently authorized by FDA for use under EUA.*
- *Extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.*
- *COVID-19 vaccine and other vaccines may now be administered without regard to timing. This includes administration of COVID-19 vaccine and other vaccines on the same day, as well as administration within 14 days.*

Dr. Reingold requested input from members about their agreement with a recommendation that the Pfizer-BioNTech COVID-19 vaccine is safe and effective for individuals 12-15 years of age. He also requested that members speak to whether the recommendation should include a statement about concomitant vaccine administration or vaccination within 14 days of other vaccinations for those 12-15 years of age.

There was unanimous agreement on the recommendation that the Pfizer-BioNTech COVID-19 vaccine is safe and effective for use in individuals 12-15 years of age.

There was also unanimous agreement on deferring to CDC regarding co-administration of COVID-19 vaccine with other vaccines.

Members discussed the timing of a statement and the request from the Governors for an immediate statement from the Workgroup, tonight if possible. Given the late hour, the Workgroup prepared a short statement on the safety and efficacy of the Pfizer-BioNTech COVID-19 vaccine for individuals 12-15 years of age.

Some Workgroup members spoke to the need for monitoring of data related to the safety profile of COVID-19 vaccination when given with or within 14 days of other vaccines. Others noted that millions of COVID-19 vaccinations have now been administered and many were likely administered within 14 days of another vaccine. There have not been reports of adverse events connected to the co-administration of COVID-19 vaccine with other vaccines. In addition, it is important going forward to make COVID-19 vaccination available in physician offices and clinics. Representatives from all states weighed in that they are rapidly enrolling smaller, office locations. States are working on packaging and distributing the vaccines in boxes containing fewer doses to make it easier to implement COVID-19 vaccination in office and clinic locations.

Update on Other Issues Discussed at ACIP

Arthur Reingold, MD, Chair

There was a discussion of the Janssen/Johnson & Johnson (J&J) COVID-19 vaccine at ACIP. ACIP confirmed its recommendation for use of the J&J COVID-19 vaccine, including a warning of rare clotting events for women 18-49 years of age.

In response, CDPH has developed a fact sheet to ensure that people know there is a choice of COVID-19 vaccines. <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Get-the-Facts-on-Vaccines.aspx>

Dr. Reingold queried the group as to whether to revisit the previous statement on the J&J COVID-19 vaccine. The Workgroup discussed the topic and agreed not to revisit the previous statement on Janssen/Johnson & Johnson vaccine.

Next Steps and Next Meeting

Arthur Reingold, MD, Chair

Workgroup members discussed the elements of a statement to the Governors of each participating state.

The Workgroup finalized the following statement for immediate release.

The Western States Scientific Safety Review Workgroup, after a thorough review of the evidence from the clinical trial of the Pfizer-BioNTech COVID-19 vaccine for those 12-15 years of age, concludes the vaccine is safe and effective in this age group and supports its use. Expanding COVID-19 vaccination to anyone 12 years of age and above will both protect those who are vaccinated and contribute to control of the COVID-19 pandemic in our states.