

California Health and Human Services Agency (CHHS)

California Department of Public Health (CDPH)

WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP

MEETING #22 – Tuesday, November 2, 2021 – 5:00pm – 6:00pm

MEETING SUMMARY

Workgroup Members Attending

STATE OF CALIFORNIA

Tomas Aragon, MD, Dr.PH, Director California Department of Public Health and State Health Officer; **Oliver Brooks, MD**, CMO, Watts Health Care; **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; **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; **Rob Schechter, MD**, Chief, California Department of Public Health, Immunization Branch; **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.

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

Workgroup Members Not Attending

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

Consultant

Bobbie Wunsch, Founder and Partner, Pacific Health Consulting Group

Welcome and Review of Today's Agenda Topics

Arthur Reingold, MD, Chair

Dr. Reingold welcomed Workgroup members. The agenda for the meeting is to review the data and recommendations for Pfizer COVID-19 vaccine for children ages 5-11 years old.

COVID-19 Vaccines for Children Ages 5-11 Years Old

Arthur Reingold, MD, Chair

Grace Lee, MD, Stanford Children's Health

Dr. Lee and other Workgroup members summarized the data and discussions from the Federal Drug Administration's Vaccine Related Biological Products Advisory Committee (VRBPAC) on October 26, 2021 and the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunizations Practices (ACIP) on November 2, 2021.

ACIP posed the following for its review: *Should vaccination with Pfizer-BioNTech COVID-19 vaccine (2-doses, 10µg, IM) be recommended for children 5–11 years of age, under an Emergency Use Authorization?*

Dr. Lee summarized the ACIP discussion. Workgroup members commented that the data were compelling and well presented. ACIP also reviewed statements submitted by the American Academy of Pediatrics, the American Academy of Family Physicians and other provider organizations in strong support of recommending the Pfizer COVID-19 vaccine for children 5-11 years of age. There was a unanimous vote of ACIP in favor of the recommendation for Pfizer COVID-19 vaccine (2-doses, 10µg, IM) to be recommended for children 5–11 years of age.

Data highlighted by the Workgroup as compelling included:

- Children are at least as likely to be infected with SARS-CoV-2 as adults; over 1.9 million reported cases.
- Children 5-11 years of age are at risk of severe illness from COVID-19, with >8,300 COVID-19 related hospitalizations as of mid-October.
- Secondary transmission from young school-aged children occurs in household and school settings.
- Indirect Impact of COVID-19 in children 5-11 years of age:
 - Worsening of mental or emotional health.
 - Widening of existing education gaps.
 - Decreased physical activity and increased body mass index (BMI).
 - Decreased healthcare utilization.
 - Decreased routine immunizations.

- Increase in Adverse Childhood Experiences (ACEs).
- Loss of caregivers.

Workgroup members discussed issues that may concern the public related to COVID-19 vaccination in this age group, including the risk of myocarditis. Workgroup members reiterated that myocarditis following COVID-19 immunization is a rare event and that the available data are from adolescents and adults receiving a 30ug dose of Pfizer-BioNTech COVID-19 vaccine, while the dose in the pediatric (5–11 year old) age group is 10ug. No cases of myocarditis occurred during the clinical trials in 5–11 year olds (N=3,082 with at least 7 days of follow up reported); however, the data from the trial are limited by the number of individuals studied. One member noted that this recommendation is based on a consistent type and quantity of data that are generally available in support of approval of new vaccines. The extremely large sizes of the trials of COVID-19 vaccines in adults are not the norm.

Workgroup members also discussed data showing that only 50% of parents surveyed planned to vaccinate their children 5-11 years of age against COVID-19. The narrative over time in the public sphere has downplayed the risk of COVID-19 disease among young children. The data concerning direct and indirect COVID-19 harm to children are powerful.

The Workgroup discussed issuing a statement to the Western States' Governors and highlighted possible messages to include:

- Summarize the COVID risk in this age group; the burden is compelling
- The Workgroup reviewed the available data on efficacy, safety and benefits/risks
- Safety data are compelling
- Benefits of COVID-19 vaccination clearly outweigh risks
- Important to reference myocarditis as a possible concern, with the conclusion that COVID-19 vaccination benefits greatly outweigh risks
- There is a rigorous and ongoing adverse event following immunization surveillance system in place
- Clear statement on the need for equity in distribution of COVID-19 vaccinations
- Prevention efforts in children return pay off in terms of health and other benefits for many years.

Timing of Statement and Next Steps

Arthur Reingold, MD, Chair

All Western State representatives weighed in that a statement from the Workgroup is needed for immediate distribution. A draft statement will be distributed to the Workgroup for review and comment tonight to be finalized by tomorrow morning, November 3, 2021.

Dr. Lee commented that VRBPAC and ACIP members have received many questions related to their role in vaccine mandates. ACIP does not issue mandates or recommendations on mandates. She noted that public health representatives may want to prepare messaging to

address questions following the Western States statement, given there are existing immunization mandates in states.