

June 19, 2022

To: Governors of California, Nevada, Oregon, and Washington State

- Governor Gavin Newsom, California
- Governor Steve Sisolak, Nevada
- Governor Kate Brown, Oregon
- Governor Jay Inslee, Washington

From: Arthur Reingold, MD, Chair, Western States Scientific Safety Review Workgroup

At its meeting on June 18, 2022, the Western States Scientific Safety Review Workgroup carefully reviewed the data presented to the U.S. FDA Vaccine and Related Biological Products Advisory Committee (VRBPAC) meeting on June 14-15, 2022 and to the U.S. C.D.C. Advisory Committee on Immunization Practices (ACIP) meeting held on June 17-18, 2022 and each committee's recommendations concerning the Moderna COVID-19 vaccine for infants and children 6 months through 5 years of age (2 vaccine doses) and the Pfizer BioNTech COVID-19 vaccine for infants and children 6 months through 4 years of age (3 vaccine doses).

The Workgroup noted that since March 2020 approximately 2,000,000 cases of COVID-19 have occurred among those less than 5 years of age in the U.S, resulting in approximately 20,000 hospitalizations and approximately 200 deaths, and that there have been a disproportionate number of COVID-19-related hospitalizations and deaths among African-American, Hispanic-Latino and Native American children in this age group.

The Workgroup reviewed the evidence concerning the safety, immunogenicity and efficacy of the Moderna COVID-19 2 vaccine dose series and Pfizer BioNTech COVID-19 3 vaccine dose series in infants and children in this age group. Completion of either vaccine series produced antibody levels similar to those achieved in individuals ages 18 -25 years for Moderna COVID-19 vaccine and 16-24 years for Pfizer BioNTech COVID-19 vaccine, respectively. Observed vaccine reactions among infants ages 6-12 months and children ages 1 through 5 years were consistent with reactions to other vaccines routinely recommended for use in these age groups.

The Workgroup also reviewed and discussed the data presented at the ACIP meeting from surveys of the opinions and plans of parents concerning COVID-19 vaccination of their infants and children 6 months to 5 years of age, as well as the discussion of the importance of ensuring both equitable access to and high uptake of COVID-19 vaccines among infants and children in this age group.

The Workgroup concluded that the available data strongly support the conclusion that the benefits of completing either the 2 vaccine dose Moderna COVID-19 series for infants and children 6 months through 5 years of age or the 3 vaccine dose Pfizer BioNTech COVID-19 vaccine for infants and children 6 months through 4 years of age substantially outweigh any known or likely risks. Immunization can be expected to reduce the numbers of COVID-19-related serious illnesses, hospitalizations, and deaths in infants and young children, while facilitating their participation in normal educational, social and recreational activities.

Given the relatively low uptake to date of COVID-19 vaccination among children and adolescents 5 -17 years of age, as well the results of surveys suggesting that many parents are not yet convinced of the need for COVID-19 vaccination in infants and children, the Workgroup calls on our states to devote substantial resources to multi-lingual, culturally diverse efforts to educate parents and to assist health care providers in conveying accurate information about the risks of COVID-19- illness, hospitalization and death in infants and young children and the benefits and risks of COVID-19 vaccine. These educational efforts should include information about the importance of vaccinating children who have already had a SARS-CoV-2 infection, because prior infection does not provide children with long-lasting protection against future COVID-19 illnesses; that COVID-19 vaccines can be co-administered with other pediatric vaccines; and that parents should discuss questions with their pediatric providers.

The Workgroup strongly encourages our states to strengthen existing efforts to ensure widespread, equitable access to age-appropriate COVID-19 vaccines among all vaccine-eligible individuals who have not yet been vaccinated or boosted, regardless of geographic location, socio-economic status, race and ethnicity, and immigration status. We must assure that all of our states' diverse communities are aware that now everyone over 6 months of age is recommended to receive COVID-19 vaccines.

The Workgroup also urges that our states' public health staff offer ongoing consultation to health providers administering COVID-19 vaccines to infants and young children on vaccine administration procedures.

Finally, the Workgroup continues to urge all healthcare providers and vaccine recipients to report any suspected adverse events following receipt of a COVID-19 vaccine to the Vaccine Adverse Events Reporting System (VAERS) and vaccine recipients to participate in the v-safe system because the various U.S. systems for monitoring the safety of vaccinations, including COVID-19 vaccines are important to sustaining confidence in immunization and guiding vaccination policy.

Respectfully submitted:

Members of the Western States Scientific Safety Review Workgroup:

Arthur Reingold, MD, Chair, UC Berkeley School of Public Health (*not in attendance at Western States meeting on June 18, 2022*)

California Members:

- Tomás J. Aragón, MD, DrPH, California Department of Public Health and State Health Officer (*not in attendance at Western States meeting on June 18, 2022*)
- Oliver Brooks, MD, Watts Healthcare
- Eric Goosby, MD, UCSF School of Medicine
- Rodney Hood, MD, UC San Diego Alumnus and National Medical Association (*not in attendance at Western States meeting on June 18, 2022*)
- Nicola Klein, MD, Ph.D., Kaiser Permanente Northern California
- Grace M. Lee, MD, MPH, Stanford Children's Health and Stanford University School of Medicine
- Bonnie Maldonado, MD, Stanford University School of Medicine and Stanford Children's Health
- Mark H. Sawyer, MD, UC San Diego School of Medicine and Rady Children's Hospitals
- Robert Schechter, MD, California Department of Public Health
- Peter G. Szilagyi, MD, MPH, UCLA Health and David Geffen School of Medicine
- Matt Zahn, MD, Orange County Health Care Agency (*not in attendance at Western States meeting on June 18, 2022*)

Nevada Members:

- Ihsan Azzam, MD, Ph.D., Chief Medical Officer, State of Nevada (*not in attendance at Western States meeting on June 18, 2022*)
- Kyle Devine, Bureau of Child, Family and Community Wellness
- Kristy Zigenis, COVID-19 Vaccine Manager

Oregon Members:

- Laura Byerly, MD, Virginia Garcia Memorial Health Center
- Louis J. Picker, MD, OHSU Vaccine and Gene Therapy Institute (*not in attendance at Western States meeting on June 18, 2022*)

Washington State Members:

- John Dunn, MD, MPH, Kaiser Permanente Washington
- Edgar K. Marcuse, MD, MPH, University of Washington School of Medicine