California Health and Human Services Agency (CHHS)

California Department of Public Health (CDPH)

WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP

MEETING #19 – Monday, August 30, 2021 – 5:00pm – 6:00pm

MEETING SUMMARY

Workgroup Members Attending

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; **Rob Schechter, MD**, Chief, California Department of Public Health, Immunization Branch; **Matt Zahn, MD,** Medical Director, Communicable Disease Control Division, Orange County Health Care Agency; **Nicola Klein, MD**, Director, Kaiser Permanente Vaccine Study Center; **Peter Szilagyi, MD**, Professor and Vice Chair for Clinical Research, Department of Pediatrics and Mattel Children's Hospital;

California State Representatives Attending

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

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

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

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

Tony Lapiz, MPH, Health Policy Advisor, Office of Governor Kate Brown

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; **Rodney Hood, MD**, Trustee, Alliance Healthcare Foundation; **Karissa Loper**, Health Bureau Chief, Bureau of Child, Family, and Community Wellness; **Mark Sawyer, MD**, Infectious Disease Specialist, Rady Children's Hospital.

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. Today's agenda will focus on the Advisory Committee on Immunization Practice (ACIP) meeting discussion August 30, 2021, related to the FDA approval of the Pfizer BioNTech COVID-19 vaccine. In addition, the Workgroup will discuss information from ACIP for a COVID-19 vaccine booster framework.

Update from ACIP Meeting on August 30, 2021: Discussion and Recommendations on FDA Approval of Pfizer BioNTech COVID-19 vaccinations for individuals 16 years old of age and older
Arthur Reingold, MD, Chair
Grace Lee, MD, Stanford Children's Health

Dr. Lee provided an update from the ACIP meeting held on August 30, 2021. ACIP reviewed data, including presentations on safety and efficacy, adverse events and benefit-risk assessment and an update from the Vaccine Adverse Events Reporting System (VAERS) team on myocarditis following COVID-19 vaccination. The VAERS team reported there is follow-up tracking and data collection at three- and six-months for individual cases of myocarditis reported following vaccination. Summary conclusions included:

- COVID-19 incidence and hospitalization rates are increasing among young individuals, and projections are that this increase will continue.
- Myocarditis occurs rarely after mRNA vaccination, at higher rates in young males.
- Benefits of COVID-19 mRNA vaccinations outweigh risks, based on an assessment presented for adolescents (Pfizer-BioNTech) and young adults (Pfizer-BioNTech and Moderna) to ACIP on June 23, 2021.

Dr. Lee reported that ACIP members voted unanimously for full approval, Biologics License Application (BLA), for the Pfizer BioNTech (Pfizer) COVID-19 vaccine in individuals 16 years of age and older. There are no changes to current vaccine guidance based on the BLA approval for the Pfizer COVID-19 vaccine.

Workgroup members discussed a statement made by a CDC COVID Task Force official during the ACIP meeting in which it was indicated that the Pfizer COVID-19 vaccine BLA should not be assumed to confer the flexibility for clinical discretion (e.g. off-label prescribing) that is standard practice following BLA approval of a vaccine. The statement emphasized that current guidelines included in provider agreements for COVID-19 vaccine administration should be strictly followed for the Pfizer COVID-19 vaccine going forward. Representatives from the four western states reported that the CDC has provided similar information to states. There are no known examples of enforcement efforts of the federal provider agreement.

COVID-19 Vaccine Booster Framework
Arthur Reingold, MD, Chair
Grace Lee, MD, Stanford Children's Health

At a previous meeting, the Workgroup discussed and issued a statement on administration of an additional dose of Pfizer COVID-19 vaccine for immunocompromised populations due to insufficient immune response following the vaccine series in such individuals. This Workgroup meeting is to consider a framework for vaccine booster doses for all individuals who received COVID-19 vaccination if studies indicate that the immune response to the primary series wanes over time.

ACIP held an initial discussion concerning the data required to determine whether booster doses are needed, effective and feasible. ACIP meetings are scheduled in September to consider additional data and determine whether to recommend booster doses of COVID-19 vaccines.

The Workgroup discussed potential guidelines for administration of booster doses that incorporate lessons learned to date. A priority is to minimize COVID-19 related hospitalizations and deaths. Workgroup members agreed that a simple and straightforward framework for administration of booster doses, consistent with the initial guidance during the roll-out of COVID-19 vaccines, will facilitate implementation, especially given the wide range of clinicians and sites now administering COVID-19 vaccines. The Workgroup noted that the key criteria for the vaccine booster framework should prioritize the elderly and time elapsed since COVID-19 immunization.

The Workgroup also discussed the challenge for clinicians in having only Pfizer COVID-19 vaccine available for booster vaccinations. Some members voiced concern about the uncertain timing of the BLA licensure for the Moderna COVID-19 vaccine. Most urgently, members noted their concern that there is currently no clinical guidance for second doses of vaccines for recipients of Janssen/Johnson & Johnson (J&J) COVID-19 vaccine, and it is unclear whether necessary studies that will result in timely recommendations are underway.

Workgroup members voiced that this is an equity concern, given that significant numbers of individuals received the J&J COVID-19 vaccine, including incarcerated persons, agricultural workers, health care workers and others who chose the single-dose COVID-19 vaccine. The Workgroup discussed options for how to elevate the urgency of the need for guidance. Some suggested the requirement to administer the same COVID-19 vaccine for boosters might be amended to allow individuals who did not receive Pfizer COVID-19 vaccine to receive it as a booster, regardless of the vaccine used for the primary series.

Timing of Statement and Next Steps
Arthur Reingold, MD, Chair

Representatives from the four western states commented that there is no expectation of a statement from the Workgroup at this time. ACIP did not issue a recommendation on boosters and will likely meet again within weeks to offer guidance. A statement from the Workgroup may be useful following the guidance from ACIP.