

**California Health and Human Services Agency (CHHS)**

**California Department of Public Health (CDPH)**

**WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP**

**MEETING #15 – Wednesday, June 23, 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; **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; **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

**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 Today's Agenda Topics**

*Arthur Reingold, MD, Chair*

Dr. Pan thanked the group for its flexibility and engagement. She noted that Dr. Aragon was confirmed by the Senate as State Public Health Officer today. Workgroup members expressed their congratulations. She commented that it would be helpful for the Workgroup to issue a brief statement regarding its review of the evidence presented at the meeting of the CDC Advisory Committee on Immunization Practices (ACIP) meeting today concerning cases of myocarditis and pericarditis among recipients of COVID-19 mRNA vaccines.

**Update from ACIP Meeting Discussion and Recommendations on Vaccines for 12-15 Year Olds and Western States Guidance to Governors (including risk/benefits of mRNA Vaccines and Update on Myocarditis)**

*Arthur Reingold, MD, Chair*

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

Dr. Lee summarized the proceedings of the ACIP meeting earlier today. She reported that ACIP determined, based on the data, that there is likely an association between myocarditis and pericarditis and receipt of COVID-19 mRNA vaccine. Data from the Vaccine Safety Datalink (VSD) and the Vaccine Adverse Event Reporting System (VAERS) were consistent, with myocarditis and pericarditis occurring most commonly in males under 30 years of age and within several days of the second COVID-19 mRNA dose. The timing and clustering of the cases was compelling. The qualitative features and phenotype of the cases are distinct from typical viral myocarditis and pericarditis. ACIP concluded there is a strong need to ensure follow up medical care for individual cases. ACIP reached unanimous agreement that the benefits of COVID-19 vaccination outweigh the risks and that COVID-19 mRNA vaccination should continue among those age 12 years of age and older following CDC recommendations. The ACIP agreed that continued monitoring and data collection are warranted.

Workgroup members discussed whether any data are available related to the incidence of myocarditis and pericarditis following COVID-19 mRNA vaccination in older age cohorts, such as those age 30-39 years of age and those age 40 years of age and older. While analysis is ongoing, existing data do not indicate a significant risk of myocarditis and pericarditis in older adults.

There was discussion about the need for additional benefit-risk analysis, specifically the morbidity and mortality associated with COVID-19 infection in youth age 12 years of age and older who are eligible for COVID-19 vaccination. In addition, one member reported receiving questions about whether to delay administration of the second COVID-19 vaccination in children, especially male children. Members noted that it is important to note that the AAP, AMA and other groups endorse continuing to follow the CDC recommended COVID-19 vaccination schedule.

Members discussed the need for continued efforts to vaccinate everyone age 12 and older and referenced the fact that morbidity and mortality from COVID-19 disease are continuing among youth 15-30 years of age. Moreover, COVID-19 hospitalization rates have not dropped in this age group, as they have in older age groups, perhaps due to the lack of success in reaching this age group with COVID-19 vaccination. Members recommended that the written statement from the Workgroup continue to encourage COVID-19 vaccination, including for males 15-30 years of age.

Workgroup members discussed their recommendation to continue to follow the current evidence-based recommendations for COVID-19 vaccination. There was agreement that the evidence does not support a change at this time; however, transparency is critical to maintain trust. In addition, public communication should indicate that additional data concerning myocarditis and pericarditis following receipt of COVID-19 vaccines may support change in the recommendation in the future. Other members agreed with staying the course and continuing to monitor new data as they become available.

Dr. Reingold asked for input from members about priority messages to include in the Workgroup statement. Members commented that the CDC statement is clear and should be endorsed. The statement should also make note of the fact that the Workgroup conducted its own review. The Workgroup language should be accurate yet not use the word “mild” to describe the myocarditis or pericarditis because that determination is subjective. It is accurate that most of the cases of myocarditis and pericarditis following receipt of COVID-19 mRNA vaccine appear to resolve with minimal treatment. One member recommended the statement include language indicating that the risk of myocarditis and pericarditis from COVID-19 in youth 12-15 years of age is greater than the risk of myocarditis and pericarditis from the COVID-19 vaccine. Members also discussed whether the statement should recommend withholding the second COVID-19 dose in people who experienced a reaction to the first dose and decided it is premature to comment on this issue.

Members offered unanimous agreement that, based on evidence available at this time, myocarditis and pericarditis in recipients of the vaccines are extremely rare side effects, and that most cases of myocarditis and pericarditis in vaccine recipients are self-limited, with individuals typically recovering on their own or with minimal treatment. The Workgroup concluded that the known benefits of administering COVID-19 mRNA vaccine outweigh the very small risk of myocarditis and pericarditis following receipt of the COVID-19 mRNA vaccine. After

its own review of the evidence, the Workgroup endorses the CDC ACIP statement. The Workgroup also recommends ongoing monitoring for and reporting to VAERS of any suspected cases of myocarditis and pericarditis, as well as other adverse events following receipt of COVID-19 vaccine, be continued.

A draft statement will be circulated to members for comment by the end of day June 24, 2021, with a request for input and suggested edits by the morning of June 25, 2021.

### **Immunity Following/Prior SARS-CoV-2 Infection Compared to Immunity Following Vaccination: Allow Proof of Prior Infection to Serve as Proof of Immunity**

*Erica Pan, MD, MPH, California State Epidemiologist*

Dr. Pan requested input about whether proof of prior SARS-CoV-2 infection is sufficient to demonstrate immunity in the place of vaccination. Workgroup members commented that there are data to indicate that SARS-CoV-2 infection provides immunity for at least 30-90 days; however, there are insufficient data concerning immunity beyond that time. The level of immunity is challenging to document, and the CDC currently recommends COVID-19 vaccination for those who have had previous SARS-CoV-2 infection. In addition, immunity against the new COVID-19 variants generated by prior SARS-CoV-2 infection is unknown. Oregon requires vaccination verification to be without a mask indoors, and past SARS-CoV-2 infection is not considered sufficient evidence of immunity. On June 30, 2021 the requirements for masks in most indoor locations in Oregon will sunset, with masks continued to be recommended for those not fully vaccinated or those who are immunocompromised. Washington will remove mask requirements in most indoor environments when vaccination rates reach 70% coverage with one dose or after June 30, 2021.

### **Update on Other Issues Posed by Members**

*Arthur Reingold, MD, Chair*

*Edgar K. Marcuse, MD*

A suggestion was made that a future Workgroup meeting agenda include a discussion on what data will be needed in order to recommend COVID-19 immunizations for children 5-11 years of age and for those under 5 years of age.

### **Next Meeting**

*Arthur Reingold, MD, Chair*

Dr. Reingold noted that the Workgroup has no meetings scheduled at this time. The Workgroup will be convened to advise the Western States Governors as requested.