

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

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

**WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP**

**MEETING #16 – Wednesday, July 7, 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 (Workgroup Member); **John Openshaw, MD**, Coronavirus Science Branch Clinical Team, California Department of Public Health.

**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

## **Workgroup Members Not Attending**

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

## **Welcome and Review Today's Agenda Topics**

*Arthur Reingold, MD, Chair*

Dr. Reingold welcomed Workgroup members.

Dr. Pan commented that this meeting does not follow action by ACIP and instead is convened to gather input on issues California and the Western States representatives are reviewing. The expertise of Workgroup members and consideration of available data are invaluable as the states develop their response to issues and questions. A written public statement will not be needed following the meeting. Several state staff are prepared to frame each issue prior to discussion.

## **Janssen/Johnson & Johnson Covid-19 Vaccine Protection against Delta Variant: Do J&J recipients need a booster for the Delta variant? Which vaccine(s) can be used as second dose for J&J recipients?**

*Arthur Reingold, MD, Chair*

*Rob Schechter, MD, CDPH*

Dr. Schechter presented available data on COVID-19 vaccine effectiveness against multiple SARS-CoV-2 variants for Janssen/Johnson and Johnson (J&J), Pfizer and Moderna COVID-19 vaccines. Dr. Schechter offered background on the types of data and findings from studies in several countries. He showed results on immunogenicity for J&J single-dose COVID-19 vaccine and Moderna and Pfizer two-dose COVID-19 vaccines. Data are available from neutralization assay studies performed by manufacturers using convalescent plasma and from Phase III COVID-19 vaccine clinical trials of vaccine effectiveness for several SARS-CoV-2 variants. Dr. Schechter also noted that, thus far, as the Delta variant has become more prevalent, the rate of COVID-19 illnesses in COVID-19 vaccine recipients in California has remained low.

Dr. Pan noted that COVID-19 cases among vaccinated individuals in California are stable at 0.03-0.04% of positive tests. Michelle Roberts noted that, in Washington state, cases of COVID-19 breakthrough infection in vaccinated individuals are also relatively few in number, about 2,500 cases among 3.8 million fully vaccinated people. The Oregon Health Authority has identified 1,790 COVID-19 breakthrough cases in vaccinated individuals. In Oregon to date, fewer than

11% of all vaccine breakthrough cases (n=191) have been hospitalized within two weeks of their positive test result and fewer than 2% have died (n=31).

<https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/data-tables/420-339-VaccineBreakthroughReport.pdf>.

<https://www.oregon.gov/oha/covid19/Documents/DataReports/Breakthrough-Report-07-2021.pdf>

Dr. Lee commented that the ACIP is currently not scheduled to discuss COVID-19 vaccine effectiveness for the Delta variant, although this may change. Workgroup members noted that the data are reassuring, although COVID-19 vaccine effectiveness will remain an ongoing concern as new variants emerge. Members commented that there is active discussion about the need for ongoing research and new studies of various types are being launched. For example, we can measure different types of antibodies to SARS-CoV-2, however there are insufficient data to know what the presence or absence of such antibodies means in terms of clinical protection. At this stage, we are not able to equate antibody titers with clinical protection, and we do not know whether the presence of antibody confers long-term protection. Workgroup members commented that there are not compelling data to change any of the current recommendations.

Dr. Aragon posed specific questions for consideration by the Workgroup:

1. Should people who received the J&J COVID-19 vaccine receive an mRNA COVID-19 booster, particularly in light of the Delta variant? Can individuals receiving the single-dose J&J COVID-19 vaccine choose to receive an additional COVID-19 vaccination?

Workgroup members confirmed that, based on available data, there is no reason to recommend a COVID-19 vaccine booster or additional mRNA COVID-19 vaccination for individuals who received the single-dose J&J COVID-19 vaccine. Members also noted that, under the EUA and federal provider agreement, providers are not currently permitted to administer additional COVID-19 vaccinations. There are questions about when a clinical trial of a COVID-19 booster vaccination for recipients of Pfizer or Moderna COVID-19 vaccine will proceed, however, current CDC recommendations do not include administration of a third dose of COVID-19 vaccine.

2. Is immunity due to natural COVID-19 comparable to vaccine-induced immunity for purposes of policy making? As policy, Israel considers either natural immunity or vaccination acceptable for admission to an event.

Workgroup members commented that the answer may depend on whether the goal is to prevent severe disease and hospitalization or to prevent transmission. It also may depend on the setting. For example, the answer for policy purposes may differ for a college campus vs. a congregate care or living facility. To discuss this policy question

more comprehensively, more information is needed concerning the context and goals for the policy.

**Follow-Up to Our June 23 Meeting: Immunity Post/Prior Infection Compared to Vaccination: Allow Proof of Prior Infection to = Proof of Vaccination as well as Public Health Policies re: masking, entry to events, etc.**

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

*John Openshaw, MD, CDPH*

- **Is there any difference in laboratory measures of immunity between vaccinated and naturally infected individuals?**
- **Are there real-world data comparing the rate of breakthrough SARS-CoV-2 infections in vaccinated individuals compared to naturally infected individuals?**

Dr. Openshaw presented data addressing the two questions related to vaccine-induced immunity and natural immunity from prior COVID-19. He noted that the data do not offer clear results. CDPH staff reviewed research findings comparing immunity in vaccinated individuals to control groups for J&J, Moderna and Pfizer COVID-19 vaccines. Results for the three COVID-19 vaccines indicate a slight increase in the neutralizing titer at day 28-35 among COVID-19 vaccine recipients compared to those with natural immunity from COVID-19. However, Dr. Openshaw noted the data limitations raise a question as to whether the findings are clinically meaningful. For example, neither COVID-19 vaccination nor a past history of COVID-19 is protective in all people, and conclusions are limited by a lack of comparison data. There are insufficient data or real-world studies with sufficient power to confirm the findings. Dr. Openshaw circulated a paper to Workgroup members outlining the available data. The paper also offers evidence that laboratory measures of immunity are boosted by a single dose of COVID-19 vaccine following COVID-19.

Members generally agreed there are many considerations that limit conclusions from these data. Members commented that the most important issue with regard to COVID-19 in a community remains the number of unvaccinated individuals. Stanford requires COVID-19 vaccination for all incoming students, and proof of antibody resulting from COVID-19 is not an acceptable basis for granting an exemption from the requirement to be vaccinated. Similarly, Oregon's state universities and private colleges have announced a COVID-19 vaccine requirement. While there are some exemptions, none are based on having had prior COVID-19. Washington representatives also weighed in that the state's colleges have COVID-19 vaccine requirements and there is no exemption based on prior COVID-19. A Nevada representative commented that they are waiting for full FDA approval to implement COVID-19 vaccine requirements. Full FDA approval is expected in Fall 2021 for the Pfizer COVID-19 vaccine and January 2022 for the Moderna COVID-19 vaccine.

There are infectious disease experts commenting publicly in the media that COVID-19 vaccine-induced immunity and natural immunity from prior infection are equivalent and should be treated the same. But there are insufficient data on which to base this conclusion. The variability and duration of the immune response to COVID-19 remains poorly characterized.

While California state law does not allow for new religious or personal belief exemptions from vaccines that are currently required to attend grades K-12, post-secondary institutions and systems in California may decide whether to permit exemptions to COVID-19 vaccination requirements; these decisions are not currently regulated by California law.

### **Advocacy for Pediatric Vaccine Data Collection and Timeline for EUA for Children under 12 years old**

*Arthur Reingold, MD, Chair*

*Erica Pan, MD, CDPH*

*Edgar K. Marcus, MD*

Dr. Pan noted that California Health and Human Services Agency wanted to solicit this group's perspective on whether the Western States should advocate to expedite COVID-19 vaccine EUA approval for children less than 12 years of age. The question has also been raised whether the states should advocate for a rapid timeline for full FDA approval of COVID-19 vaccines that already have an EUA for individuals 12 years of age and older.

Pfizer and Moderna have not yet completed trials and applied for an EUA for children less than 12 years of age, therefore, no FDA action can happen at this time. Members commented that advocacy could be counter-productive to assuring the public there is a rigorous process in place and make overcoming concerns about vaccine safety more difficult. One function of the Workgroup is to review safety data to overcome public concern about political pressure in the approval of COVID-19 vaccines. Members also noted that advocacy to move more quickly may have little or no impact on a bureaucracy already working on an aggressive timeline. Finally, some members noted that time is needed to obtain more data on myocarditis and pericarditis in youth following COVID-19 vaccination.

### **Next Steps and Next Meeting**

*Arthur Reingold, MD, Chair*

Dr. Pan and Dr. Aragon thanked the group for making time to meet and share their expertise. Dr. Reingold adjourned the meeting.