California Health and Human Services Agency (CHHS)

California Department of Public Health (CDPH)

WESTERN STATES SCIENTIFIC SAFETY REVIEW WORKGROUP

April 13, 2021 - 2:00 – 3:00 pm

April 14, 2021 6:00 – 7:30 pm

COMBINED MEETING SUMMARY

Workgroup Members

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

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

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:

Candice McDaniel, Health Bureau Chief, Bureau of Child, Family, and Community Wellness

Ihsan Azzam, MD, Chief Medical Officer, Division of Public and Behavioral Health

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

Consultants:
Bobbie Wunsch, Founder and Partner, Pacific Health Consulting Group

Workgroup Members Not Attending: April 13, 2021
John Dunn, MD, Medical Director for Preventive Care and Head of Immunization Program, Kaiser Permanente Washington
Louis Picker, MD, Associate Director of Oregon Health & Science University's Vaccine and Gene Therapy Institute

Workgroup Members Not Attending: April 14, 2021
Rodney Hood, MD, Trustee, Alliance Healthcare Foundation
Candice McDaniel, Health Bureau Chief, Bureau of Child, Family, and Community Wellness

April 13, 2021 Meeting Summary
Arthur Reingold, MD, Chair
Tomas Aragon, MD
Erica Pan, MD

Dr. Reingold welcomed members of the Western States Scientific Safety Review Workgroup. He thanked members for convening at short notice both today and tomorrow (April 13 and 14, 2021) for discussions related to the Johnson & Johnson/Janssen (J&J) COVID-19 vaccine. On April 13, 2021, CDC and FDA announced a recommended pause in use of the Johnson & Johnson/Janssen COVID-19 vaccine. An excerpt of a joint statement from CDC and FDA is below.

Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine
The following statement is attributed to Dr. Anne Schuchat, Principal Deputy Director of the CDC and Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research

As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. CDC and FDA are reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred among women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination. Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given.

CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to further review these cases and assess their potential significance. FDA will review that analysis as it also investigates these cases. Until that process is complete, we are recommending a pause in the use of

this vaccine out of an abundance of caution. This is important, in part, to ensure that the health care provider community is aware of the potential for these adverse events and can plan for proper recognition and management due to the unique treatment required with this type of blood clot.

Dr. Aragon thanked members for convening and reviewed the steps taken in California to communicate the pause in use of the J&J COVID-19 vaccine. He noted that J&J COVID-19 vaccine is about 4% of total vaccine supply in California. Dr. Pan asked members who serve on the Advisory Committee on Immunization Practices (ACIP) to offer comment on the discussions.

Dr. Grace Lee reviewed the discussion of the ACIP Vaccine Safety Technical (VaST) Subgroup on vaccines that met April 12, 2021 and the ACIP COVID-19 Vaccines Workgroup meeting today (April 13, 2021). She commented on the immediate need to communicate with health care providers to increase awareness about information surrounding the adverse events. She noted that a change in screening and clinical management of patients experiencing adverse events following J&J COVID-19 vaccination may improve outcomes. Specifically, in the case of blood clot disorders following recent COVID-19 vaccination, providers should follow different guidelines than standard clinical management for blood clots.

Dr. Peter Szilagyi provided a summary of the policy options discussed at ACIP:

a) Continue use of J&J – only 6 cases nationally.
b) Focus use of the J&J vaccine in populations over age 50 years or in some other sub-populations.
c) Pause longer, perhaps 2-4 weeks to gather additional information and identify any additional cases.

Dr. Szilagyi commented that it is important for public reassurance to communicate that the vaccine surveillance systems are working and that the recommended pause in use of the J&J COVID-19 vaccine is to convene experts to review the data because safety is paramount. There is no finding to date that the J&J COVID-19 vaccine is causally related to the occurrence of blood clots in the six cases. The pause in use of the J&J COVID-19 vaccine results from an abundance of caution

Workgroup members noted the six cases of blood clots following J&J COVID-19 vaccination in the United States occurred after more than six million vaccinations, making it extremely rare. The six cases were all in women, one of whom died. These adverse events generally have occurred 6-13 days following vaccination. The Workgroup discussed the importance of public and clinician communication that is transparent and underscores the rare occurrence of adverse events following receipt of the J&J COVID-19 vaccine. In particular, there is a need to support clinician awareness of the facts, given that clinical management of blood clots following COVID-19 vaccination differs from standard clinical management.

The Workgroup adjourned and will reconvene tomorrow, April 14, 2021 to discuss the full ACIP meeting scheduled for the same day.

April 14, 2021 Meeting Summary
Welcome
Arthur Reingold, MD, Chair

Dr. Reingold welcomed the Western States Scientific Safety Review Workgroup. He asked members of the Advisory Committee on Immunization Practices (ACIP) meeting to offer a summary of today's meeting related to the recommended pause in use of the Johnson & Johnson/Janssen (J&J) COVID-19 vaccine.

Dr. Grace Lee reviewed that the ACIP Vaccine Safety Technical (VaST) Subgroup on vaccines met April 12, 2021 and the ACIP COVID-19 Vaccines Workgroup met April 13, 2021. The full ACIP met today, April 14, 2021. ACIP discussed the data available, noting that there are remaining elements of data to be collected. There will be another meeting of ACIP in 7-10 days to review additional data related to the population risk and individual risk/benefit and make a recommendation. The options include:

a) Reinstate the use of J&J COVID-19 vaccine.
b) Mitigate the risk by limiting use of the J&J COVID-19 vaccine to certain groups.
c) Stop the use of J&J COVID-19 vaccine.

In addition, it is important for clinicians to have more information so they can treat appropriately and improve outcomes.

Workgroup members discussed the available data and whether it will be possible to assess the risk of the blood clot disorder following COVID-19 vaccine. The background rate of this disorder in the population is not well understood and therefore the denominator for any calculation of a relative risk is difficult to determine. In addition, the potential association of clotting following receipt of the vaccine with other risk factors is difficult to assess with only six cases. The J&J COVID-19 vaccine is currently being used only in the United States.

The Workgroup discussed possible risk mitigation by segmenting the population recommended to receive the J&J COVID-19 vaccine. More time is needed to review data and identify possible cases prior to entertaining a potential risk mitigation strategy. Other Workgroup members noted that this demonstrates that the surveillance system for blood clots following immunization is working.

Dr. Andrew Leavitt, a Hematology/Oncology physician from University of California, San Francisco, joined as an expert guest to discuss issues related to the reported adverse events. Dr. Leavitt provided input and responded to questions posed by Workgroup members related to the clinical presentation of adverse events following COVID-19 vaccination. Discussion included

issues related to gender, implications of the timing of adverse events following vaccination, potential underlying conditions that could trigger adverse events and various other aspects of venous thromboembolism. The Workgroup discussed whether there are ways to improve the outcomes for individuals who experience these adverse events.

Dr. Reingold polled representatives from the states to comment on whether a statement on this topic is needed or requested. California, Nevada, Oregon and Washington representatives weighed in that there is no expectation of a statement on this topic at this time given ACIP has delayed their recommendation until additional data is available.

Workgroup members emphasized that the known adverse events are quite rare and members explored the question of tolerance for risk related to receipt of this and other vaccines. The Workgroup also discussed how the risk of vaccine-related adverse events compares to the risk of COVID-19 disease. Finally, the Workgroup discussed the challenges of equity worldwide posed by the J&J pause, given that other vaccines are less available outside the US.

The Workgroup summarized the timeline for the pause in the J&J COVID-19 vaccine. ACIP's goal is to collect as much information as possible and avoid an inordinately long pause. The 7-10 days is needed so a good decision can be made that is likely to hold over time. The overall message is that safety is paramount and oversight bodies are taking the events seriously.

Dr. Pan thanked everyone for the additional time and input on this complex topic. The Workgroup will reconvene as needed.