California Health and Human Services Agency (CHHS)

California Department of Public Health (CDPH)

COVID 19 VACCINE SCIENTIFIC SAFETY REVIEW WORKGROUP

December 17, 2020 - 5:00pm – 6:30pm

MEETING SUMMARY

Workgroup Members Attending

Tomas Aragon, MD, Health Officer, City & County of San Francisco; **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; **Rob Schechter, MD**, Chief, California Department of Public Health, Immunization Branch; **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

Tricia Blocher, Deputy Director, Office of Emergency Preparedness, California Department of Public Health; **Erica Pan, MD**, Interim State Health Officer; **Ron Chapman**, MD, MPH, Former Director, 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

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

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
Laura Hogan, Senior Health Consultant, Pacific Health Consulting Group

Welcome, Review Agenda and Focus of Workgroup
Arthur Reingold, MD, Chair

Dr. Reingold welcomed everyone for a discussion of the Moderna COVID-19 vaccine.

Review Learnings from VRBPAC Meeting Today

Arthur Reingold, MD, Chair
All Members

Dr. Reingold asked Dr. Mark Sawyer, as temporary voting member of the Vaccine and Related Biological Products Committee (VRBPAC), to update members on the VRBPAC discussion today of the safety and efficacy of the Moderna COVID-19 vaccine. Dr. Sawyer commented that there was no controversy related to the efficacy or safety of the Moderna vaccine. The vote for Emergency Use Authorization (EUA) was unanimous, with abstentions that were not related to safety or efficacy.

Dr. Sawyer reported that VRBPAC members discussed the safety implications of anaphylaxis following administration of the COVID-19 vaccine due to the report of two cases in Alaska and earlier cases reported in Britain following administration of the Pfizer vaccine. Thus far, few details about the cases are available. There were no cases of anaphylaxis in either the Pfizer or Moderna COVID-19 clinical trials. CDC has issued guidance about who should avoid the vaccine until more is known.

Workgroup members discussed reported cases of Bell's palsy in the vaccine group in both the Pfizer and Moderna clinical trials and shared data on the baseline incidence of Bell's palsy.[i] Members agreed that, as of this date, it remains unknown whether there is an association between receipt of COVID-19 vaccine and Bell's palsy, and it is not at a level of concern to change the recommendation that COVID-19 vaccines are safe and effective. The incidence of Bell's palsy and anaphylaxis post vaccination will be important to monitor as COVID-19 vaccine is administered to large numbers of people.

The discussion of Moderna's COVID-19 vaccine at VRPBAC noted hypersensitivity reactions at the injection site, including hives, that were identified in the clinical trial. There was also a lengthy discussion at VRPBAC on the implications of continuing the randomized clinical trials to preserve the blinded clinical trial for additional time. VRBPAC indicated that blinded trials should not continue and that placebo recipients should receive the COVID-19 vaccine when they would otherwise be eligible for vaccine in their community. Workgroup members noted there would be little added value of an additional 3-6 months of observation and that continuing a placebo group is perhaps unethical.

Contrasting the Pfizer and Moderna COVID-19 vaccines, members noted that the Moderna vaccine has less stringent cold storage requirements; a lower incidence of fever reported after the second dose; and an interval of four weeks between doses compared to an interval of three weeks between doses for the Pfizer vaccine. The most important difference is the less stringent storage requirement for the Moderna vaccine. There was greater axillary swelling noted after receipt of the Moderna vaccine, which will be important for clinicians to communicate so that people are prepared for this possibility. Members voiced confidence that ongoing surveillance will identify any adverse events, as well as noting the fact that these clinical trials have been much larger than most other vaccine trials.

The FDA is expected to issue the EUA within 24 hours. The CDC Advisory Committee on Immunization Practices (ACIP) will meet Saturday. The Workgroup will convene following the ACIP meeting for further discussion and a vote. If the vote by Workgroup members is to recommend the use of the Moderna COVID-19 vaccine, the Workgroup will review a draft statement to forward to the Western States Governors.

Format for Moderna COVID-19 Vaccine DRAFT Statement to Governors and Timeline

Art Reingold, MD, Chair
Tricia Blocher, Deputy Director, Office of Emergency Preparedness, CDPH

There will be a vote during the Saturday evening meeting following the FDA issuance of an EUA and ACIP review. Dr. Reingold will prepare a draft statement and circulate for review prior to the Saturday meeting to ensure timely follow up if the vote is to proceed. Dr. Reingold asked members to identify any reservations they may have about moving forward. No one raised any reservations at this juncture.

Our Saturday Meeting and ACIP Meeting(s)

Workgroup Members on ACIP
Art Reingold, MD, Chair

The ACIP meeting is scheduled for Saturday, December 19 from 8 am to 4 pm. The Workgroup will meet Saturday at 5 pm to discuss its recommendation. If they conclude the Moderna COVID-19 vaccine is safe and effective, the Workgroup will review and finalize the statement to the Western States Governors during the Saturday evening meeting. The timing for sending the statement will be similar to the previous one, either late Saturday night or early Sunday morning, so as not to delay vaccine distribution in our State.

Closing Comments and Adjourn
Arthur Reingold, MD, Chair

Dr. Reingold thanked the members for a good discussion.

[i] Epidemiologic and clinical features of Bell's palsy among children in Northern California. Rowhani-Rahbar A, Baxter R, Rasgon B, Ray P, Black S, Klein JO, Klein NP.Neuroepidemiology. 2012;38(4):252-8. doi: 10.1159/000338303. Epub 2012 Jun 5.PMID: 22678408 https://www.karger.com/Article/FullText/338303

Bell's palsy and influenza(H1N1)pdm09 containing vaccines: A self-controlled case series. Wijnans L, Dodd CN, Weibel D, Sturkenboom M.PLoS One. 2017 May 3;12(5):e0175539. doi: 10.1371/journal.pone.0175539. eCollection 2017. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0175539