California Health and Human Services Agency (CHHS) California Department of Public Health (CDPH)

COMMUNITY VACCINE ADVISORY COMMITTEE (CVAC)

MEETING #4 - December 16, 2020 - 3:00pm - 6:00pm

MEETING SUMMARY

Committee Members Attending

Fred Buzo, AARP; Jacob Snow, American Civil Liberties Union Northern California (ACLU); Alia Griffing, American Federation of State, County and Municipal Employees (AFSCME); Susan de Marois, Alzheimer's Association; Andrew Nguyen, Asian Americans Advancing Justice – Los Angeles; Dr. Chang Rim Na, Asian and Pacific Islander American Health Forum (APIAHF); Dr. Ron Williams, Association of California School Administrators (ACSA): Jeff Luther, MD, California Academy of Family Physicians (CAFP); Michael Dark, California Advocates for Nursing Home Reform (CANHR); Lisa Mancini, California Association of Area Agencies on Aging (C4A); Carolyn Pumares, California Area Indian Health Service; Heather Harrison, California Assisted Living Association (CALA); Dean Chalios, California Association for Health Services at Home (CAHSAH); Joe Diaz, California Association of Health Facilities (CAHF); Charles Bacchi, California Association of Health Plans (CAHP); Michael Wasserman, MD, California Association of Long-Term Care Medicine (CALTCM); David Lown, MD, California Association of Public Hospitals and Health Systems (CAPH); Vicky Reilly, California Association of Rural Health Clinics (CARHC); Chuck Helget, California Association of Veteran Service Agencies; Veronica Kelley, California Behavioral Health Directors Association (CBHDA); Rhonda M. Smith, California Black Health Network; Preston Young, California Chamber of Commerce; Eric Sergienko, MD, California Conference of Local Health Officers (CCLHO); Virginia Hedrick, California Consortium for Urban Indian Health, Inc. (CCUIH); Mary McCune, California Dental Association (CDA); Christina N. Mills, California Foundation for Independent Living Centers (CFILC); Jackie Garman, California Hospital Association (CHA); Orville Thomas, California Immigrant Policy Center (CIPC); Catherine Flores-Martin, California Immunization Coalition; Mitch Steiger, California Labor Federation; Amanda McAllister-Wallner, California LGBTQ Health and Human Services Network; Leza Coleman, California Long-Term Care Ombudsman Association (CLTCOA); Lance Hastings, California Manufacturers & Technology Association (CMTA); Hendry Ton, California Medical Association (CMA); Rocelyn de Leon-Minch, California Nurses Association (CNA); Kiran Savage-Sangwan, California Pan-Ethnic Health Network (CPEHN); Susan Bonilla, California Pharmacists Association (CPHA); Andie Martinez Patterson, California Primary Care Association (CPCA); Michel Feyh, California Professional Firefighters; Jose R. Padilla, California Rural Legal Assistance, Inc. (CRLA); Debra Schade, California School Boards Association (CSBA); Pamela Kahn, California School Nurses Organization (CSNO); Loriann DeMartini, CEO: California Society of Health-System Pharmacists (CSHP); Carol Green, California State Parent Teachers Association (CAPTA); Lisa Constancio, California Superintendent of Public Instruction; Laura Kurre, California Teachers Association (CTA); Shannon Lahey, Catholic Charities California; Esther Bejarano, Comite Civico del Valle; Vivian Reyes, American College of Emergency Physicians; Kim Saruwatari, County Health Executives Association of California (CHEAC); Andy Imparato, Disability Rights California; Silvia Yee, Disability Rights Education and Defense Fund (DREDF); Kristin Weivoda, Emergency Medical Services Administrators of California (EMSAC); Liugalua (Liu) Maffi, Faith in the Valley; Pastor J. Edgar Boyd, First African Methodist Episcopal Church; Melissa Stafford-Jones, First Five Association; Anthony Wright, Health Access; Lisa Hershey, Housing California; Naindeep Singh, Jakara Movement; Denny Chan, Justice in Aging; Jeffrey Reynoso, Latino Coalition for a Healthy California: Genevieve Flores-Haro, Mixteco Indigena Community Organizing Project (MICOP); Jodi Hicks, Planned Parenthood Affiliates of California (PPAC); Tia Orr, Service Employees International Union (SEIU) California State Council; G Perdigones, Service Employees International Union Local 1000 (SEIU 1000) (Unit 17-Nurses); Aaron Carruthers, State Council on Developmental Disabilities; Brian Mimura, The California Endowment; Gabriella Barbosa, The Children's Partnership; Diana Tellefson-Torres, UFW Foundation; Matthew Maldonado, United Domestic Workers (UDW/AFSCME); Maria Lemus, Vision y Compromiso; Crystal Crawford, Western Center on Law and Poverty; Amber Baur, Western States Council: United Food and Commercial Workers (UFCW) California

Committee Members Absent

Brianna Lierman, Local Health Plans of California (LHPC); **Thomas J. Kim, MD,** California Rural Indian Health Board (CRIHB)

California State Representatives Attending

Erica Pan, MD, MPH Interim State Health Officer; **Nadine Burke Harris, MD, MPH,** California Surgeon General

Public Attending

There were 76 members of the public attending by phone, including 2 on the Spanish line, and 564 viewed the meeting by YouTube livestream.

Committee Co-Chairs

Dr. Erica Pan, MPH Acting State Health Officer

Dr. Nadine Burke Harris, MPH, California Surgeon General

Consultant

Bobbie Wunsch, Founder and Partner, Pacific Health Consulting Group

Welcome, Purpose of Today's Meeting, Co-Chairs' Opening Comments and Meeting Logistics

Erica Pan, MD, MPH, Acting Public Health Officer, CDPH, Co-Chair Nadine Burke Harris, MD, MPH, California Surgeon General, Co-Chair Bobbie Wunsch, Founder and Partner, Pacific Health Consulting Group

Dr. Pan thanked the committee for its participation and input. Today California reported a record high number of cases — over 53,000 reported today alone. This is more than three times higher than the peak in July. The state continues to monitor Intensive Care Unit (ICU) beds and staffing capacity. The San Francisco area is now below the 15% threshold of ICU capacity with only 12.9% of beds available, which will trigger a stay-at-home order on December 17. Statewide, only 4.1% of intensive care capacity is available. The state is mobilizing to request additional staffing through federal and international resources and implementing alternative care sites to reduce ICU demands. A focus needs to be on protecting the health care system over the next several weeks as the vaccination campaign gets underway.

Dr. Burke Harris welcomed the committee and thanked everyone for their participation. Attendance has been incredible and participation has been robust. It is the participatory community process the state intended. Dr. Burke Harris shared that today's meeting would focus on updates from two members of the Western States Scientific Safety Review Workgroup and initial discussions on community engagement and vaccine acceptability. This group already has provided important recommendations on community engagement and messaging, especially for vulnerable communities. The meeting will focus on gathering more of this valuable input. There will also be a full discussion today regarding Phase 1b - Essential Workers. Dr. Burke Harris thanked the group for using the Zoom chat function to complement the verbal feedback.

Bobbie Wunsch reminded the committee that meetings are intended to be interactive and reiterated the group guidelines. A reminder that chairs have requested no substitutes or delegates, but that staff can join via public line (English/Spanish) or YouTube livestream. The American Sign Language (ASL) interpreters were introduced and she offered a reminder on available closed captioning. Materials are available on the CDPH website and public comment can be submitted via email at COVID19VaccineOutreach@cdph.ca.gov. Public comments are shared verbatim with the committee the day before the meeting and posted on the website.

Review Public Comments since December 9, 2020 Meeting #3

Bobbie Wunsch, Founder and Partner, Pacific Health Consulting Group

Bobbie Wunsch summarized 142 public comments received between December 7-14:

- 1 person asked to be included as a member of the CVAC
- 131 were requesting that a wide range of workers be prioritized as Tier 1 of Phase 1b

- 5 comments related to the safety of the vaccine and the ability of certain individuals to give informed consent, particularly those living in long-term care facilities
- 2 questions about how to offer and obtain vaccines
- 3 people over age 78 recommending vaccines for essential workers before seniors

Update from Western States Scientific Safety Review Workgroup on Pfizer BioNTech COVID-19 Vaccine EUA

Grace M. Lee, MD, MPH, Stanford Children's Health and Stanford University School of Medicine, Member, CDC Advisory Committee on Immunization Practices (ACIP) and Member, Western States Scientific Safety Review Workgroup

Mark H. Sawyer, MD, UC San Diego School of Medicine and Rady Children's Hospital, Member, FDA Vaccine and Related Biological Products Advisory Committee (VRBPAC) and Member, Western States Scientific Safety Review Workgroup

Dr. Sawyer offered an overview of the process that the FDA Vaccine and Related Biological Product Committee (VRBPAC) uses to make vaccine recommendations. First, the pharmaceutical company submits a package of information from the clinical trial to the FDA. FDA staff then reviews the data and re-analyzes it to ensure the conclusions are sound. They present this information to VRBPAC, comprised of experts from across the US not associated with government organizations. VRBPAC reviews the data and asks questions of manufacturers and the FDA. They entertain public comment, have extensive discussion and make a recommendation to the FDA. Dr. Sawyer stated that the process with the Pfizer COVID-19 vaccine last week seemed identical to past reviews and he is confident no short cuts were taken.

After the FDA authorizes or approves use of a vaccine, the Advisory Committee on Immunization Practices (ACIP) weighs in to provide a recommendation to the CDC Director on the use of the vaccine in the US population. ACIP is also an independent federal advisory committee of experts and one consumer representative. The ACIP's COVID-19 workgroup has met over 27 times since March and has had at least nine open public meetings with the full ACIP. The evidence-to-recommendations framework employed by ACIP considers the epidemiology, public health burden, benefits-risk balance, values of the population being vaccinated, acceptability to key stakeholders, resource use, and feasibility and implementation issues. In the case of the COVID-19 process, the group has included not just the science but an ethical framework for allocation, including health equity, as well as implementation issues unique to each vaccine candidate. The ACIP workgroup has been meeting frequently and is now starting to meet daily. Dr. Lee commented that the compressed timeline is necessary given the impact of the pandemic, and she strongly endorses the finding of a very strong benefit-risk balance of the Pfizer COVID-19 vaccine. ACIP unanimously voted to recommend the Pfizer

COVID-19 vaccine last weekend. The Western States Partners Scientific Safety Review Workgroup independently reviewed and evaluated the data with a focus on safety and efficacy and also recommended the use of the Pfizer COVID-19 vaccine. The Moderna COVID-19 vaccine will follow this review process during December 17-19.

Both the Pfizer and Moderna vaccine trials have focused on enrolling diverse populations. Nearly 40,000 trial participants have participated in each trial, including 3,500 African Americans, 1,600 Asian Americans and 10,000 Latinx individuals. The efficacy was similar across age groups, gender, race/ethnicity and co-morbidities. Common side effects include local pain and tenderness at the injection site as well as fever; fatigue; headache; and muscle aches. These are short-lived up to a few days and are more frequent after the second dose. Side effects are less frequent in older adults. Side effects like this are common and reflect the body's immune response to the vaccine. ACIP anticipates anaphylaxis may occur in rates of 1-3 per million doses similar to other vaccines or antibiotics. ACIP is looking to experts for more context, counsel and diagnoses around these reactions.

Vaccine safety does not end with approval or authorization. After every new vaccine is approved, safety is monitored through a variety of surveillance systems. A newer system, v-safe, is a text messaging and web survey tool from CDC to check in with vaccine recipients following COVID-19 vaccination. All healthcare providers are requested to enter adverse events into the Vaccine Adverse Event Reporting System (VAERS) database. ACIP is committed to reviewing data as it comes in and re-evaluating its recommendations as needed and appropriate.

Dr. Sawyer stated that across these committees, 40-50 independent experts from around the country have come to the same conclusions - no substantial concerns about the Pfizer COVID-19 vaccine's safety or efficacy.

Questions and Comments from Members

Congregate Care Settings

- Is the CVS /Walgreen's federal partnership going to include the state's 7,300 Residential Care Facilities for the Elderly (RCFEs)?
- The allocation of vaccines via the federal vaccine distribution program is lacking information such as number of doses available, what Skilled Nursing Facilities (SNFs) will receive and the process for determining who will receive vaccine first within the in a SNF. How many of the 327,000 doses will be distributed to SNFs via CVS/Walgreen's?
- The process for vaccinating SNF residents needs more clarity. Can we take some time at a CVAC meeting to unpack the details about vaccine logistics and distribution within long-term care facilities? This will help CVAC members communicate accurate information.
- For Phase 1a, are residents of long-term care facilities within prisons included?
 - o CDPH: Yes.

- Logistically, it makes more sense to focus vaccination of nursing home staff and residents on the Moderna vaccine, which was part of the reason LA County opted out of the Pfizer vaccine because it's easier to stagger the Moderna vaccine and because they want more flexibility than the CVS and Walgreen's rollout plans allow.
- We can't rush the process of education. When it comes to frontline nursing home staff we must respect, honor and value the concerns of those who are not confident. Only after we hear their concerns can we effectively engage them in education.
- Doses are showing up as early as next week, and it's critically important to hear from
 residents about their concerns and learn their motivations directly. Our decision to
 prioritize residents of long-term care facilities will not be as impactful if we do not utilize a
 tailored outreach strategy for them.

Vaccine Data on Specific Populations

- ACIP has raised concerns about the scarcity of vaccine data on residents in long-term care facilities. Can you share more, especially as it might affect messaging for this population?
 - Or. Lee: Clinical trials have been focused on adults not living in long-term care facilities. There is not yet data based on medically fragile populations. Waiting for this data would take quite some time, and given high mortality rates in this population, the benefit: risk balance seems to weigh in favor of vaccinating these populations with ongoing monitoring. Because this population will have a higher mortality rate at baseline than other same-aged people, it will be important to carefully assess information about adverse events and not draw conclusions based on coincidental events not attributable to the vaccine. Dr. Sawyer stated that the FDA reached the same conclusion.
- If 16 and 17 year-olds are vaccinated in later phases, could they build immunity to go to college in the fall?
 - Dr. Sawyer: The FDA reviewed the age groups of the clinical trials. That age group
 had a smaller representation but the committee assumed these adolescents were
 not that different from 18 or 19-year-olds; therefore, the benefit: risk seems to be in
 favor of vaccinating this group. No other vaccines have shown a disproportionate
 reaction rate in middle or later adolescence.
- Do you feel comfortable with the representation of the demographic groups in the clinical trials and can we translate this into our messaging to address vaccine hesitancy?
 - Dr. Sawyer: Diversity has been emphasized since the beginning of these vaccines for the first time ever. There has been a reasonable, not perfect, effort to ensure diversity in the clinical trials. Based on data, there is no signal to suggest there is any discrepancy in safety or effectiveness in any sub-group. We will continue to monitor this as the vaccine rolls out.
- What are the committees saying about safety and efficacy for people with allergies or preexisting conditions?

- People with intellectual and developmental disabilities (IDD) have many concerns about vaccine safety. Can you tell us what is known about the co-morbidities of people in the vaccine trials and what we can say about safety and drug interactions?
 - o Dr. Lee: Pfizer data has been published in the New England Journal of Medicine. A large percentage of those with co-morbidities included obesity, respiratory and cardiac disease or diabetes. The efficacy of the vaccines was quite high in those with co-morbidities even compared to healthy adults. Among the populations we continue to study are those with immunosuppression. Although the data on people with IDD and other disabilities are not as robust, a lot of these individuals are also at elevated risk for severe disease and death, so the benefit: risk balance seems to weigh in favor of vaccination. Post-release databases will allow us to understand effectiveness or side effects better in unique populations. The overall preponderance of evidence suggests that people with IDD should do just as well but this will need ongoing study. Also, adults with IDD are not receiving the services they need right now which is a further rationale to vaccinate early.
- Messengers need to know the vaccine risks for specific groups. Is there an effort to learn
 this granular information or is this an opportunity for people in any sub-groups to be
 vaccinated early in order to generate more knowledge?
 - O Dr. Lee: ACIP has recommended the vaccine for 16-year-olds and older with no contraindications, per the FDA Emergency Use Authorization, and leaving the decision to individuals. There will be healthcare personnel and essential workers with these various co-morbidities and we think the benefits outweigh known and unknown risks. The various federal agencies will monitor safety in broad populations and are asking the manufacturers to study longer term effectiveness and observational data in more diverse populations. Dr. Lee is not aware of specific trials enrolling other groups except for pregnant women and young children. Many communities have clinical registries where sub-groups contribute their data to capture as much information as possible. Dr. Lee offered to find out more about these registries for people with disabilities.
- What about co-morbidities of mental illness or substance use disorder, including those using Medication Assisted Treatment?
 - Dr. Sawyer: At the FDA level, the data were not that granular; people with those underlying risk factors were not identified or stratified. There's no reason to think a different safety profile would apply but ongoing experience will shed more light.
- It would be great if the state invested some resources in monitoring the impacts on nursing home residents and collecting data.

Safety & Efficacy

• Is it true that immunity with a single dose is approximately 50-60%? What mitigation measures should be provided between first and second dose?

- O Dr. Sawyer: Both studies were designed to only study what happens after two doses. The preliminary data suggests effectiveness of 50-70% range but these were not studied thoroughly. Even after two doses, people still need to mask and follow social distancing because we don't know yet if the vaccines reduce transmission. We will learn more about transmission in the coming months.
- Is there any consideration in the initial months of scarcity of using the limited supply to vaccinate a greater number of people more quickly?

Vaccine and Impact Timing

- A Pfizer representative said last week their primate trials showed "some intermittent prevention of upper respiratory infection" and that they would do continued studies on the preventive effects.
 - Or. Sawyer: Pfizer's clinical trial will continue for two years, following all participants. They will pull out a subset to see if they are asymptomatic, infected and could potentially transmit the virus. Their animal model data suggested that this might be the case but it's insufficient to reach any conclusion. We will probably learn from the healthcare workers being vaccinated because some of them are being tested weekly; this will demonstrate whether we can rely on the vaccines to reduce transmission. The Moderna vaccine trials are studying transmission and preliminary results suggest some reduced transmission risk.
- How soon can we see a drop of COVID cases, provided we start vaccination this week? Is there a timeline and projection of decrease in trend of the COVID-19 cases and mortality?

Phase 1a Questions

- Are privately paid long-term care workers included in Phase 1a and if so how do they know they are prioritized, where do they go for vaccination, and will they have to "prove" that they are in a prioritized population?
- What are the plans to vaccinate healthcare workers who don't work in hospitals but in settings such as clinics, dental offices and pharmacies? Is there a plan for this level of distribution?
- Where do the state guidelines to local health jurisdictions place nurses and other healthcare workers working in educational settings in the tiers?
 - CDPH: Detailed Phase 1a Recommendations are here:
 https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/CDPH-Allocation-Guidelines-for-COVID-19-Vaccine-During-Phase-1A-Recommendations.aspx
- How are the workers in each tier being notified they qualify for a vaccine? How will CVS or other partners administering the vaccine know the worker is actually in a qualified tier?
 Specifically how will In-Home Supportive Services (IHSS) workers and clients be notified?
- It will be helpful to get specifics about Phase 1a and what is being decided at the county level so that groups can mobilize locally as needed.

Vaccination Safety, Reporting and Logistics

- The CDC has asked all vaccinators to adopt and distribute information about v-safe. Is there a plan to incorporate this vaccine response notification system with vaccine distribution?
- Will there be trained experienced medical professionals onsite or available by phone when administering the vaccine in case there are side effects requiring medical attention?
 - o Some members offered protocols from their own healthcare facilities.
- CVS/Walgreen's are planning to use pharmacy techs and interns to administer the vaccine because the federal government expanded their scope. This is not allowable by California Board of Pharmacy but if this changes it will require training, and physical demonstration of vaccine technique and direct pharmacist supervision.
- Vaccine reporting mechanisms will need to be able to take comments from diverse populations and accept reports in various formats (e.g., online, video calls, etc.). We have heard concerns from parents of adults with disabilities who are non-verbal and are worried about their children being able to understand and communicate adverse vaccine reactions.

Bobbie Wunsch assured the group that the Scientific Safety Review Workgroup is large, committed and amazing. She thanked Drs. Lee and Sawyer on behalf of the committee. Dr. Burke Harris echoed this thanks.

Initial Discussion of Community Engagement and Vaccine Acceptability

Nadine Burke Harris, MD, MPH, California Surgeon General Kathleen Kelly Janus, Office of the Governor Maricela Rodriguez, Office of the Governor Suanne Buggy, CDPH

Dr. Burke Harris introduced the next topic. She shared a new logo – *Vaccinate ALL 58* – highlighting the importance of rolling out vaccines across all California counties in order to end the pandemic. To engage communities across California, it will be important to tailor our messaging and methodologies, especially for vulnerable communities.

Dr. Burke Harris shared the key principles grounding message development and this work:

- An acknowledgement of complex and nuanced personal and community experiences, and an understanding that lived experiences shape willingness to accept the vaccine;
- A commitment to engagement by partnering with all our diverse communities across the state to share knowledge and information about the COVID vaccines; and
- **Action** by providing everyone living in California with culturally competent, fact-based messages so they can make an informed decision to vaccinate.

She then asked the committee to share their high-level feedback on these principles, including suggestions for improvement.

Questions and Comments from Members

Principles

- The principles should include influences arising due to historic, sociocultural, environmental, health system/institutional, economic or political factors; Influences arising from personal perception of the vaccine or influences of the social/peer environment; It might be helpful to explicitly acknowledge histories of racism and homophobia that has led to distrust of institutions and systems.
- We should acknowledge that the speed of vaccine development is unique and may contribute to vaccine hesitancy.
- Safety is among the most important factor for disabled communities. Ideally we can address safety with transparency while being inclusive.
- Can we be explicit about including people with disabilities when diversity is mentioned?
- Principle #2 could go one step further to state that we will <u>follow the lead</u> of our communities, since they are the experts.
- We should learn from "gatekeepers" within community ethnic or cultural groups.
- Most members appreciated the principles and many raised questions about how engagement with community groups would occur.
- Engagement can sometimes be tokenizing if action isn't taken. There could be a close tie-in between engagement and the action principles to uplift that piece.
- To increase public trust we should add something about transparency.
- The action principle should also state that messaging be linguistically accessible considering the language diversity of our state.
- There needs to be two way dialogue: information on the vaccine from scientific perspective and information from the community about that community.
- We need to go beyond culturally competent to culturally informed and cultural humility.

Outreach, Messaging and Vaccinate ALL 58 Materials

- Language access is important; is there a plan for broader accessibility in multiple languages?
 Is there an opportunity to learn from the work done by Complete Count in the Department of Social Services Immigrant Service Program about trusted messengers, number of touches, extra investments for certain communities and partners with deep ties?
 - CDPH: Yes, the state is planning to engage the Census infrastructure via Complete Count. It will partner with trusted messengers across the state to reach vulnerable communities.
- Language needs to be accessible to all readers, at or below a 5th grade reading level, with pictures or graphics to display the message; and readable for those with low health literacy.
- It is critical to not just engage but <u>learn from</u> community partners about who are trusted messengers and what messages work. This has not yet been explored in aging communities, and vaccines are about to land through CVS and Walgreen's. The "who" is really important.

- Can videos include American Sign Language?
- It would be useful to include members of groups such American Indians/Alaska Natives in Public Service Announcements and Vaccinate ALL 58 materials.
- CALTCM has been developing a toolkit: https://www.caltcm.org/covid-19-vaccine, https://vimeo.com/caltcm/review/491006904/db45fe807d
- The Berkeley Media Studies Group put out a vaccination communications paper:
 http://www.bmsg.org/resources/publications/communicating-covid-19-vaccines-guidance-and-sample-messages-for-public-health-practitioners/. And this guide to communicate about the vaccine (centering equity).
- I wonder how many people know that California has 58 counties and would wonder what the number referred to. *Vaccinate All CA* might be as effective.
- It would be helpful for school communities to have materials with teachers, other school staff, and parents/guardians who are essential workers included.
- It's important to message the thoroughness of the research and testing of vaccines within diverse populations.
- Specific and targeted messaging on the vaccine should include funding opportunities for American Indian tribes, Indian Health Programs and community-based organizations (CBOs).
- CBOs with deep knowledge of their communities should be included in the education and support process as we begin vaccinations. It is not too late to integrate CBOs in a real way to deploy community leaders, promotoras and others as partners.
- We must let people know that side effects are expected.
- There's a myth that the first vaccines will be replaced by safer ones so debunking that is important these first few months.
- Pharmacists are highly trusted so if we can provide materials for pharmacists to build their confidence they will share this with patients and others.
- We hope that the resources CDC is creating for patients and providers will be a dynamic process that includes opportunities to learn and talk about benefits and risks.
- Asian/Pacific Islander communities have had a positive response when a healthcare
 provider that belongs to a church congregation talks to the congregation and leaves their
 contact information.
- It will help to have a variety of ways to explain vaccine content and how it was developed.
- Within tribal communities, community health representatives are trusted members that can bridge both medical and traditional beliefs and build confidence in the vaccine.
- Can other state agencies and departments beyond Public Health help connect our data systems to support outreach, engagement and more?
- Faith communities can play an important role in messaging; however, many indigenous communities in California have experienced historical trauma when it comes to religious groups and have remaining distrust. It is important to message in a more secular way to these communities unless it known that members of a specific American Indian/Alaska Native community are open to receiving messaging within a religious context.

Dr. Burke Harris thanked the group for their ideas, engagement and wisdom. She added that the meeting today includes key people from CDPH and the Governor's Office, who are leading these efforts in message development. She introduced Maricela Rodriguez, Suanne Buggy and Kathleen Kelly Janus. Dr. Burke Harris shared that staff will benefit from hearing CVAC input and will use it in developing messages and strategies for engagement and communication.

Vaccine Barriers and Hesitancy Factors

Dr. Burke Harris asked the group what it perceives as the most common barriers and vaccine hesitancy factors among high-risk communities. They shared the following:

- Family members of Alzheimer's patients in long-term care have not seen their loved ones in months, are concerned about their frailty, and don't have a clear idea about safety. We need to include adult children and spouses in messaging since they will make decisions and have concerns about their loved ones' resilience.
- The Latinx immigrant community is mistrustful of the US government. Many families have mixed immigrant status which may create barriers to trust. Many families live in poverty and lack health insurance, so a big question for them is who will pay for the vaccine. Public charge is another concern for immigrants that want to legalize so we should include information about this in our outreach.
- There are a lot of concerns in communities of color. Unions want to help as trusted messengers with materials and talking points.
- We should be proactive in trying to understand vaccine hesitancy. People are asking about whether the vaccine is safe given their specific pre-existing conditions. The more information we have, the more we can share, and encourage them to talk to their providers. We shouldn't expect individuals to find the answers themselves.
- A lot of workers have safety concerns about side effects and want to be sure they can ask these questions of immunizers and that they are well trained and informed to answer them with appropriate protocols in place.
- Workers also have concerns about HIPAA violations and what employers learn and share outside the normal employment context. They are also worried about potential retaliation if they need and use additional sick leave.
- Among those with mental illness, especially paranoia, getting an injection from the federal government can be problematic. But many trust their mental health clinicians and see them as separate from the medical profession, which they often associate with 5150s, hospitalization and restraints.
- Indigenous farmworkers are saying they will not take the vaccine because they don't
 know what's in it and are afraid of getting sick. It feels too experimental and they worry
 it will do more damage than good. Many prefer to use home remedies like teas and
 herbs and lack medical homes but go to clinics they trust that feel similar to Mexico.
 Cost is a factor as is the potential impact to work. There is also a stigma attached to
 COVID-19 and the vaccine.

- Many communities will only go to a doctor when something is wrong, not for prevention. This requires outreach, and patient navigators can be helpful. For trusted messengers to do this work successfully will require investments in language access.
- We need to ensure that any reporting mechanisms feel safe for undocumented populations.
- People are afraid and desire reassurance they can trust. There are many avenues for trust-building among existing relationships. Many people are connected to staff in their clinic in primary care health home. Nurses and Medical Assistants are often from their communities and we should empower them.
- Concerns within LGBTQ communities include: safety; fairness; distrust of health care
 institutions given historic mistreatment; how the vaccine will interact with pre-existing
 conditions, like HIV or autoimmune disorders; questions about long-term impacts and
 long-term effectiveness; and stories circulating in our communities such as false-positive
 HIV tests in one of the vaccine clinical trials, which stokes fear and stigma.
- Many are turning to natural medicines from home countries as protection.
- A barrier for people with significant disabilities is the current link to access through congregate living.
- Many people do not want to be early adopters but prefer to wait until they have more trusted feedback on safety.
- Others are waiting for herd immunity rather than expose themselves to unknown risks.
- Youth and youth adults may not see themselves as high risk but may live in communities highly impacted by COVID.
- LGBTQ people, especially women, are less likely to have a regular doctor or receive preventive care. They may not know where to go for the vaccine.
- Logistical barriers include geographic access to the vaccine in rural and outlying areas, transportation, time and disability access.
- American Indian communities have significant issues of historical distrust and injustice.
- The following barriers have been identified among farmworkers: safety and speed of vaccine development; cost; accessibility (preference for locations outside the workplace); fear of losing work if they suffer adverse effects; and what documentation will be needed, especially among the undocumented.
- Individuals may feel pressured or shamed into taking the vaccine when their concerns haven't been adequately addressed.
- Safety and "rushing" the approval of the vaccines.
- Personal and historic experience with mistreatment in health care; historical medical trauma from testing and forced medical treatment.
- The chilling effect of the current federal administration.
- The impact of side effects on family.
- Costs related to adverse reaction and other hidden costs.

- Single parents of people with disabilities are concerned there will be no one to help them if their child or children have an adverse reaction.
- Distrust of pharmaceutical companies, government, medicine and science.
- There are active disinformation efforts, spread more widely than ever on the Internet.
- Digital literacy is a barrier if vaccine appointments are made online; alternative ways to make appointments will be paramount. CBOs can be helpful in navigating this process.
- People with substance use disorders are concerned for safety due to co-morbidities like liver disease and Hepatitis.

Vaccine Motivations and Acceptance

Dr. Burke Harris then asked a second question of the group: What are the perceived motivations for vaccine acceptance among high-risk communities? Committee responses:

- We need to first hear people's concerns before we try to explain the positives or respond to their questions. People need to feel heard. If we don't, people will blame us later. White professionals in particular need to put themselves in others' shoes and be patient. We can motivate by hearing, respecting, honoring and valuing them.
- Some tribal members inoculate themselves with plants indigenous to the region which connects the strategy to a familiar cultural framework. We can emphasize that vaccinations play a part in traditional medicine.
- The church community can be helpful. Farmworkers in Riverside County responded to the Catholic Church more than other community-based organizations and COVID testing increased tenfold when the Catholic Archdiocese announced its support.
- Among unsheltered populations, if a homeless service provider goes with medical staff they
 are much more likely to get COVID testing or a flu vaccine. Many people experiencing
 homelessness are more likely to listen to someone with whom they've built a trusted
 relationship. Because there is a great fear of getting COVID and dying, homeless service
 workers are building a narrative that the vaccine will help create better outcomes for them.
- Educators want to get back to the classroom and public education is vital to California's full recovery. This vaccine adds a layer of protection for safe, equitable, in-person instruction. There's an interconnectedness with schools at the center of many communities. Health equity and education equity are inextricably linked. Many parents are concerned about safety and choosing distance education, especially in communities of color. Vaccinating whole schools together with students and families will help provide wraparound protection and signal greater confidence. Prevention and mitigation measures also continue to be critical and will signal greater confidence in programs.
- Black and Brown families are getting information from the news, church and then sharing among inter-generational and extended families. One motivation will be representation of small diverse communities (e.g., Polynesian and American Samoans).
- The good of the community is a very strong motivation and it's important to understand what this means for different people by listening to them. The community needs not just

vaccination but also physical distancing, masks, testing, limiting large gatherings, etc. The concept of community includes different ages and identities; it is not just superficial.

- Restoring family visitation is a powerful motivator for long-term care residents.
- Older adults say they will get vaccinated to protect and help their family members.
- We are learning more by asking patients at outpatient clinics what made them accept the flu vaccine and what additional information will help them accept the COVID vaccine.
- Community Health Center staff and providers want to be safe, feel safe and protect their families and communities.
- Love is a motivator. Family and caregivers of people with intellectual and developmental disabilities will get vaccinated so they can care for and protect their loved ones.
- Many want the pandemic and restrictions to end so the world can get back to normal.
- Outpatient clinic staff can wear buttons to show that they have accepted vaccines themselves. Talking to these staff can be a motivator.
- Schools and teachers can be credible messengers. Some school districts are seeking to volunteer themselves as vaccination sites.
- Those with substance use disorders are being motivated to get the vaccine in order to ensure access into residential treatment.
- A message of social solidarity and being part of a bigger effort is key to norm change.
- Many have a self-interested motive. But if the message is that they still have to wear a
 mask, socially distance, and still can't do "normal" things, I worry about the impact. It would
 be good to message that if people get a vaccine, things will return to normal more quickly.
- The Faith community is a really important partner and trusted messenger.
- Children are a motivator. We have heard from indigenous Mixtec-speaking community members that they are on the fence, but would get the vaccine for themselves to protect their children. They will also vaccinate to ensure their children have access to school.
- People want to protect their elderly parents.
- A motivator will be making the vaccine free and easy to access, and with access to care and (paid) time off for side effects, for both doses. The vaccine should be available during off hours in trusted accessible locations.
- There is a family-focused pro vaccine group called VaccinateCalifornia.org. They can be very effective to help support and normalize the process.
- Community Health Centers should customize Vaccinate ALL 58 images and messages.
- Decreased morbidity and mortality is a strong motivating factor.
- Having an established and trusted source of care and information.

Dr. Burke Harris thanked the committee and introduced Maricela Rodriguez from the Governor's Office, who shared information about the communications campaign. Maricela commented that this feedback was extremely helpful and noted that she worked on the Census project and other relevant efforts. The state does plan to leverage those learnings and the networks of trusted messengers that have been developed. Maricela shared a video that the

Governor unveiled this week which is an animated version of the Vaccinate ALL 58 logo. The goal and thinking behind this brand is to have an opportunity to encourage local engagement from the beginning. Based on preliminary information, the campaign is clearly about the vaccine, is positive, empowering and conveys a light at the end of the tunnel. The Governor's Office is translating the tagline into various languages and will include county logos. They have also created a toolkit to highlight the safety and effectiveness of the vaccine, manage expectations about the phased distribution, and the need to continue practicing safety precautions given the current surge. Other languages beyond English and Spanish are pending and will be available soon on the state's COVID website. The toolkit includes fact sheets, graphics and testimonials as well as a video "explainer" with detailed information and history about the vaccine. They are collecting stories to share since these are also part of a peer-topeer and trusted messenger strategy. Content will be in-language and responsive to reading levels and hopefully other graphics. The information loop will be very important – not just providing reliable actionable information early but also hearing from communities so that misinformation and other barriers can be addressed. Maricela emphasized that CVAC participation is needed to shape and amplify the campaign and toolkit. She expressed her gratitude for all the CVAC help and feedback.

Dr. Burke Harris thanked the group and summarized that a key to vaccine confidence is trusted relationships, providers and relationships.

Discussion of Phase 1b Updated Data on Essential Workers, Update on Timing of Vaccine Distribution to Essential Workers, and Recommendation Regarding Phase 1b Tier 1 of Essential Workers from Drafting Guidelines Workgroup

Oliver Brooks, MD, Co-Chair, Drafting Guidelines Workgroup Robert Schechter, MD, MPH, CDPH, Co-Chair Drafting Guidelines Workgroup Ron Chapman, MD, MPH, CDPH

Vaccine Supply Update

Dr. Burke Harris introduced Dr. Schechter to update the group on vaccine supply and address questions raised at the last meeting.

Dr. Schechter shared the sequence of meetings to review the Moderna candidate vaccine, starting December 17. First, the FDA VRBPAC will meet to review the vaccine data for safety and efficacy, and consider recommending authorization. If VRBPAC recommends authorization, the FDA leadership will review the data and consider the VRBPAC recommendation in its decision to authorize. On Saturday December 19, ACIP will review the data and vote on a recommendation. If they recommend use of the Moderna vaccine then shortly thereafter the Western States Partners Scientific Safety Review Workgroup will convene and review the information to make its statement on safety and efficacy to the governors of the four states.

In addition, the ACIP has an emergency meeting on Sunday December 20 to discuss which groups to consider recommending for Phase 1b and beyond in Phase 1.

Data on the Moderna vaccine shows that of the 14,000 participants that received vaccine, about 94% overall and 86% of those 65 and older did not get sick. Rates were similar for at-risk adults with co-morbidities such as hypertension or diabetes. Effectiveness rates were also similar for across race and ethnic groups. Dr. Schechter also shared slides demonstrating the numbers of each race/ethnic group participating in the clinical trials.

The safety data for the Moderna vaccine is similar to the Pfizer vaccine. There are frequent minor reactions that include sore arms, fatigue, headache and muscle pain, more so after the second than first dose. Although a few severe allergic reactions were noted in the United Kingdom among recipients of the Pfizer vaccine, there were none observed in the clinical trials.

Current estimates show California receiving 327,000 doses of the Pfizer vaccine by mid-December; 2 million (cumulative) by the end of December (this estimate is lower than prior estimates and will include both Pfizer and Moderna, if authorized); 4+ million by the end of January and up to 20+ million by the end of April. He then discussed questions raised at the last CVAC meeting:

- 1. Where do people with co-occurring conditions or disabilities who are high risk but not living in congregate settings fall in the prioritization?
 - CDPH: These populations are a great concern but are not currently being prioritized for Phase 1a or 1b.
- 2. Explain again how the pharmacy distribution to long term care facilities will work and when it will start?
 - CDPH: <u>This</u> website describes the program at length. Starting December 28, teams under CVS and Walgreen's will begin to immunize the current rosters for most of the skilled nursing facilities in California. Each team is set up to provide first and second doses over three visits to residents and staff at those facilities. These doses will be part of the doses CDC has allocated for California and 80,000 doses of the Pfizer vaccine have been set aside to start this program.
- 3. How will any group of essential workers receive notification that they qualify to receive the vaccine? How will home-based caregivers/IHSS workers be notified that it's their turn for the vaccine?
 - Workers will be notified in a variety of ways e.g., health departments, providers, health plans, unions, employers, community-based organizations, or a combination of these methods. The CDPH communications plan will include media and public service announcements about eligibility and timing,

- 4. How will immunizers/employers generate, validate, receive lists of employees eligible for vaccines? How will workers verify their eligibility?
 - This will vary. There will be some immunization efforts at worksites, which is the most straightforward. In other settings there may be clinic appointments or voucher systems, including use of appointment software. There may be other methods that rely on the honor system.
- 5. What role will health plans play in the process of notifying essential workers?
 - This will also depend. All plans have ways to broadcast general messages and some may have ways to target those in specific occupations or sectors.
- 6. Can the State and/or employers make the vaccine mandatory in order to work?
 - There cannot be a federal mandate for any vaccine under the EUA; however, states and private entities <u>may</u> impose mandates. CDC has not taken a position on the advisability of making mandates.

Phase 1b Continuing Discussion to Prioritize Workers

Dr. Burke Harris introduced Drs. Brooks and Chapman. She reminded the committee that its prior comments have been shared with the Drafting Guidelines Workgroup which reviewed and discussed them. In particular, they discussed the issues of intersectionality raised by the CVAC. Today the workgroup is presenting guidance about Phase 1b – Essential Workers. She reminded the group that the focus is on employment <u>sectors</u>, not individual occupations at this point. Members were sent a listing of these sectors as identified by the Governor's order.

Dr. Brooks showed a slide showing the distribution of essential critical infrastructure workers by sector. The updated figure for this population is 11.9 million – two thirds of the state population. Beyond the messaging principles Dr. Burke Harris shared, the state is still following the foundational principles of safety, transparency and equity. In terms of prioritizing among essential workers, CVAC suggested four criteria: Societal impact, Impact on economy, Equity, and Occupational exposure. Examples were shared for each criterion. The Drafting Guidelines Workgroup agree with these criteria and that intersectionality is important for consideration.

Dr. Schechter then spoke about the workgroup's deliberation on the various sectors. They reviewed the criteria against the different sectors and reviewed presentations and data on economic impact, occupational exposure, risk and equity. There was consensus from the group that three sectors rose to the top of Phase 1b (in no priority order):

- Education & Child Care (1.4 million)
- Emergency Services (1.1 million)
- Food and Agriculture (3.4 million)

(Total 5.9 million people, 10-12 million doses)

Within education and children care, included would be child care workers (formal and informal), preschools, K-12, higher education and trade schools.

Within emergency services, workers include non-medical first responders, law enforcement, fire fighters, child and youth services, shelters, non-residential social services for the elderly and people with disabilities, durable goods merchants including safety devices, and justice and safety activities.

Food and agriculture includes a broad number of settings and occupations from manufacturing and slaughtering to grocery stores and markets, food and drinking establishments, pharmacies and drug stores, warehouse clubs, community food services, nurseries/florists and sawmills.

The workgroup has reviewed potential criteria for sub-prioritization if doses are scarce. Its partial list for consideration, in no particular order, includes the following, many of which were previously considered under the category of occupational exposure:

- Risk of severe disease or death
 - o Advanced age or underlying medical conditions
- Inability to work at home
- Economic necessity of higher-risk work
- Reside or work in disadvantaged communities disproportionately affected by the pandemic
- Likelihood of spreading disease to workers and the public

In summary, the workgroup is recommending to start with these three essential sectors using the above criteria for sub-prioritization as needed.

Another consideration will be how to reach these prioritized workers once there is agreement. This will need to include outreach, education and counseling, as well as providing access to the vaccine in an expanding mix of locations (routine sites for care, designated clinics, workplaces). Partnerships in the community will be crucial for all these steps.

ACIP will meet this weekend to discuss additional prioritization for Phases 1b and 1c. While California groups are independent of the ACIP, they will be following these national experts and public comment closely. The Drafting Guidelines Workgroup will review the CVAC discussion as well as the deliberations and recommendations of ACIP and other groups and will consider which sub-prioritization criteria might be feasible in accordance with California principles.

Dr. Burke Harris thanked Drs. Schechter and Brooks for the work of the Drafting Guidelines Workgroup. Ms. Wunsch noted that California expects 4 million doses by the end of January.

Questions and Comments from Members

Congregate Care Settings

- There are questions and concerns from ombudsmen in assisted living facilities (ALFs). When will the pharmacy partnership be activated for the ALFs? Will there be in-person vaccination events for the smaller facilities or how will the vaccine be distributed? The lack of transparency with local health departments is frustrating for families and ombudsmen.
 - CDPH: The pharmacy partnership is structured in two parts: Part A for SNFs and Part B for ALFs and related facilities. The state is looking closely at activating the Part B partnership which would impact the smaller assisted living facilities. There should be a decision shortly. Dr. Brooks reminded the committee that this does not represent a lack of transparency but the fact that some decisions have not yet been made.

Logistics

- There is no easy or perfect approach to identifying and vaccinating essential workers. Health plans may or may not have the relevant information. Plans and providers should not be in the position of telling people no.
- Can you clarify how the sub-prioritization process will interact with the sectors?
 - CDPH: As with healthcare workers, we may need criteria that can be used practically and efficiently to sort between worthy recipients of scarce vaccine – using age, medical conditions or other factors. More details will follow soon.
- The time between the current scarcity and the moment of surplus is concerning. If we are not clear or the process is too complex, it may lead to public mistrust. Social solidarity is helpful in the beginning but it will dissolve if things appear to be unfair or undermine equity. Can we create more simplicity and clarity to reduce county-level decision-making? A few bad stories in the media could really hurt our efforts. Can there be simpler approaches within or beyond these sectors e.g., age-based or place-based?
 - o CDPH: We'll be parsing the Tier 1 sector of Phase 1b soon and then adding others.
- All these principles will evaporate if we move forward in a decentralized way with county discretion and if states don't give directives to counties with some enforcement.
 - CDPH: Local health departments have the challenging job of getting these dose allocations and implementing the guidelines as they direct the doses to healthcare workers, congregate settings and then vaccination sites for essential workers. The expectation is that providers and LHDs who receive vaccine will sign a contract with the federal government saying they will abide by federal and state laws and recommendations. This is very complicated and there will need to be some local flexibility and discretion based on diverse economics, epidemiology and other circumstances. Future meetings may include hearing from local health departments.
- Those administering vaccines need training on administration; to be prepared for anaphylactic shock and have protocols and protections when they face angry people.
- Can we have some discussion about how the prioritization will be translated into an action plan or work plan that deals with these various challenges?

Specific Workers and Sectors

- Most firefighters are paramedics or emergency medical technicians (EMTs). Will they be included in Phase 1a or Phase 1b?
 - o CDPH: If they are providing health services, they would be included in Phase 1a.
- The emergency services sector should also include non-profit social services.

Education

• It would be great to save some portion of an in-person school year.

Closing Comments and Adjourn

Erica Pan, MD, MPH, Acting State Health Officer, Co-Chair Nadine Burke Harris, MD, MPH, California Surgeon General, Co-Chair

Dr. Burke Harris thanked all those involved in this process for a broad and robust discussion. Thanks to the teams for rapidly incorporating the input of this committee, reflecting CVAC comments in the Drafting Guidelines Workgroup, and bringing their responses forward. This all improves California's response and vaccine allocation strategy. Dr. Burke Harris thanked everyone for their time, input, candor and commitment.

Next Meetings

- ❖ December 23, 2020 from 2:00 4:00pm* Please note change from original December 21 time to allow Drafting Guidelines Workgroup time to meet after the ACIP emergency meeting and before CVAC
- ❖ January 6, 2021 from 3:00 − 6:00pm
- ❖ January 20, 2021 from 3:00 − 6:00pm
- ❖ February 3, 2021 from 3:00 6:00pm
- ❖ February 17, 2021 from 3:00 6:00pm