DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Advisory Committee on Immunization Practices (ACIP)

Summary Report
December 1, 2020
Atlanta, Georgia

Final - November 27, 2020

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Centers for Disease Control and Prevention
Atlanta, Georgia 30329
December 1, 2020

	AGENDA ITEM	PRESIDER/PRESENTER(s)
Tuesday, December 1, 2020		
2:00	**Welcome & Introductions**	Dr. José Romero (ACIP Chair) Dr. Amanda Cohn (ACIP Executive Secretary, CDC)
	Coronavirus Disease 2019 (COVID-19) Vaccines	
	Introduction	Dr. Beth Bell (ACIP, WG Chair)
	Allocation of initial supplies of COVID-19 vaccine: Phase 1a	Dr. Kathleen Dooling (CDC/NCIRD)
	Clinical considerations for populations included in Phase 1a	Dr. Sara Oliver (CDC/NCIRD)
	Post-authorization safety monitoring update	Dr. Tom Shimabukuro (CDC/NCEZID)
	Discussion	
4:00	***Break***	
4:10	Public Comment	
4:40	**VOTE**	
	Allocation of initial supplies of COVID-19 vaccine: Phase 1a	Dr. Kathleen Dooling (CDC/NCIRD)
5:00	**Adjourn**	

Acronyms

CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus disease 2019
NCIRD	National Center for Immunization & Respiratory Diseases [of CDC/OID]
NCEZID	National Center for Emerging and Zoonotic Diseases [of CDC/OID]
WG	Work Group

Acronyms

AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
AAPA	American Academy of Physician Assistants
ACHA	American College Health Association
ACIP	Advisory Committee on Immunization Practices
ACNM	American College of Nurse Midwives
ACOG	American College of Obstetricians and Gynecologists
ACP	American College of Physicians
ADEs	Adverse Drug Events
ADL	Activities of Daily Living
AE	Adverse Event
AECI	Adverse Events of Clinical Interest
AESI	Adverse Events of Special Interest
AGS	American Geriatric Society
AHIP	America's Health Insurance Plans
AIM	Association of Immunization Managers
ALF	Assisted Living Facilities
AMA	American Medical Association
AMDA	American Medical Directors Association
AOA	American Osteopathic Association
APhA	American Pharmacists Association
ASTHO	Association of State and Territorial Health Officers
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CISA	Clinical Immunization Safety Assessment
CISA	Cybersecurity and Infrastructure Security Agency
CMS	Center for Medicare and Medicaid Services
COI	Conflict of Interest
COU	Clinical Operations Unit
COVID-19	Coronavirus Disease 2019
COVID-NET	Coronavirus Disease 2019-Associated Hospitalization Surveillance Network
CoVPN	COVID-19 Prevention Network
CSTE	Council of State and Territorial Epidemiologists
DFO	Designated Federal Official
DHA	Defense Health Agency
DoD	Department of Defense
DSMB	Data Safety Monitoring Board
DVA	Department of Veterans Affairs
ED	Emergency Department
EMS	Emergency Medical Services
EtR	Evidence to Recommendation
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
GRADE	Grading of Recommendation Assessment, Development and Evaluation
HCoVs	Human Coronaviruses
HCP	Healthcare Personnel / Providers

HCW	Healthcare Workers
HHS	(Department of) Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Resources and Services Administration
ICU	Intensive Care Unit
IDSA	Infectious Disease Society of America
IHS	Indian Health Service
IIS	Immunization Information Systems
IRB	Institutional Review Board
ISD	Immunization Services Division
ISO	Immunization Safety Office
ISTM	International Society for Travel Medicine
LTCF	Long-Term Care Facilities
MedDRA	Medical Dictionary for Regulatory Activities
MERS	Middle East Respiratory Syndrome
MMWR	*Morbidity and Mortality Weekly Report*
mRNA	Messenger Ribonucleic Acid
NACCHO	National Association of County and City Health Officials
NACI	National Advisory Committee on Immunization Canada
NAM	National Academy of Medicine
NAPNAP	National Association of Pediatric Nurse Practitioners
NAS	National Academy of Sciences
NASEM or the National Academies	National Academies of Sciences, Engineering, and Medicine
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
NCHS	National Center of Health Statistics
NCIRD	National Center for Immunization and Respiratory Diseases
NFID	National Foundation for Infectious Diseases
NHSN	National Healthcare Safety Network
NIH	National Institutes of Health
NMA	National Medical Association
NPI	Non-Pharmaceutical Intervention
NVSN	New Vaccine Surveillance Network
NVAC	National Vaccine Advisory Committee
OID	Office of Infectious Disease
OIDP	Office of Infectious Disease Policy and HIV/AIDS
OWS	Operation Warp Speed
PCR	Polymerase Chain Reaction
PHAC	Public Health Agency Canada
PICO	Population, Intervention, Comparison, Outcomes
PIDS	Pediatric Infectious Disease Society
PPE	Personal Protective Equipment
QI	Quality Improvement
RCA	Rapid Cycle Analysis
RCT	Randomized Controlled Trial
RNA	Ribonucleic Acid
rRT-PCR	Real-Time Reverse Transcription Polymerase Chain Reaction

RT-PCR	Reverse Transcriptase Polymerase Chain Reaction
SAE	Serious Adverse Event
SAHM	Society for Adolescent Health and Medicine
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus-2
SHEA	Society for Healthcare Epidemiology of America
SLU	Saint Louis University
SME	Subject Matter Expert
SNF	Skilled Nursing Facilities
SVI	Social Vulnerability Index
US	United States
USG	US Government
VA	(US Department of) Veteran's Affairs
VA ADERS	Veteran's Affairs Adverse Drug Event Reporting System
VAERD	Vaccine-Associated Enhanced Respiratory Disease
VAERS	Vaccine Adverse Event Reporting System
VaST	ACIP COVID-19 Vaccine Safety Technical Subgroup
VE	Vaccine Efficacy
VE	Vaccine Effectiveness
VHA	Veterans Health Administration
VIS	Vaccine Information Statement
VRBPAC	Vaccines and Related Biological Products Advisory Committee Meeting
V-SAFE	Vaccine Safety Assessment for Essential Workers
VSD	Vaccine Safety Datalink
WG	Work Group

Opening Session

José Romero, MD, FAAP
ACIP Chair

Amanda Cohn, MD
Executive Secretary, ACIP / CDC

Dr. Romero called to order the December 1, 2020 emergency meeting of the Advisory Committee on Immunization Practices (ACIP), the primary purpose of which was to discuss and vote on allocation of initial supplies of Coronavirus Disease 2019 (COVID-19) Vaccine: Phase 1a.

Dr. Cohn welcomed everyone and indicated that copies of the slides being presented during this meeting were available on the ACIP website and had been made available through a ShareFile link for ACIP Voting, Liaison, and *Ex-Officio* members; videos of the live webcast would be posted on the ACIP website approximately 1 week after the meeting; meeting minutes also would be posted on the ACIP website, generally within 90-120 days of the meeting; and that a brief summary from the previous week's meeting had been posted to the ACIP website.

In terms of meeting logistics, participants were instructed to raise their hands virtually when Dr. Romero opened the floor for discussion and to disable their video or mute their phone lines to reduce issues with the Zoom connection. Dr. Cohn explained that during the discussion period, the order in which Dr. Romero would take questions would be first from ACIP Voting Members, second from *Ex Officio* and Liaison member representatives, and then from the audience. The plan was to stay on schedule with the meeting agenda as much as possible. Participants on the Zoom platform were instructed to disable their videos for the duration of the meeting, with the exception of the discussion and vote session during which time the voting ACIP members would turn on their videos.

The meeting's oral and written public comment practices are designed to accommodate increased public interest in ACIP's work, maximize opportunities for comments, make public comments more transparent and efficient, and create a fair process for assigning limited oral public comment time. More than 75 requests for public comment were made. Given that many more individuals registered to make oral public comments than could be accommodated, selection was made randomly via a lottery for 10 individuals to make public comment prior to the vote. Those individuals who were not selected and any other individuals wishing to make written public comments were instructed to submit them through https://www.regulations.gov using Docket Number CDC-2020-0121, which would be open through December 3, 2020. Those who submitted public comments to the ACIP mailbox or to individuals were instructed to submit those comments through the docket as well. Further information on the written public comment process can be found on the ACIP website. Dr. Cohn emphasized that public comments for this meeting should focus on the vote for allocation of initial supplies of COVID-19 Vaccine: Phase 1a.

As a reminder, ACIP members agree to forgo participation in certain activities related to vaccines during their tenure on the committee. For certain other interests that potentially enhance a member's expertise while serving on the committee, CDC has issued limited conflict

of interest (COI) waivers. Members who conduct vaccine clinical trials or serve on data safety monitoring boards (DSMBs) may present to the committee on matters related to those vaccines, but are prohibited from participating in committee votes on issues related to those vaccines. Regarding other vaccines of the concerned company, a member may participate in discussions with the provision that he/she abstains on all votes related to that company. At the beginning of each meeting, ACIP members state any COIs.

Dr. Romero conducted a roll call of ACIP members, during which the following COIs were declared:

- ❑ Dr. Robert Atmar is serving as the Co-Director of the Clinical Operations Unit (COU) of the National Institutes of Health (NIH)-funded Infectious Diseases Clinical Research Consortium (IDCRC) that is working within the COVID-19 Prevention Network (CoVPN) to evaluate Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) vaccine candidates in Phase 3 clinical trials, including those produced by Moderna, AstraZeneca, Janssen, Novavax, and Sanofi. He has participated in the Moderna Phase 3 trial.

- ❑ Dr. Sharon Frey is employed by Saint Louis University (SLU), which has a Vaccine Treatment Evaluation Unit (VTU) that is part of the IDCRC. She is currently serving as the Site PI for the Moderna and Janssen Phase 3 COVID-19 vaccine clinical trials.

- ❑ Dr. Paul Hunter owns a small amount of stock in Pfizer and has received a small grant from Pfizer to conduct a quality improvement (QI) project on pneumococcal vaccines.

Given that the recommendations under consideration were generalizable to all vaccine manufacturing companies and that no specific vaccine products were being recommended, all voting ACIP members were permitted to participate in the discussion and vote during this meeting.

A list of Members, *Ex Officio* Members, and Liaison Representatives is included in the appendixes at the end of the full minutes for the December 1, 2020 ACIP meeting.

Coronavirus Disease 2019 (COVID-19) Vaccines

Introduction

Beth Bell, MD, MPH
ACIP, COVID-19 Vaccine WG Chair
Clinical Professor, Department of Global Health
School of Public Health, University of Washington

Dr. Bell introduced the COVID-19 Vaccines session. She began by taking a moment to recognize that this is a particularly difficult time with an average of one COVID-19 death per minute in the United States (US), meaning that 180 people would have died from COVID-19 by the end of the meeting—a somber reminder that that they were acting none too soon. ACIP is responding to the ongoing pandemic and accelerated vaccine development through the scheduling of additional meetings. As a reminder, ACIP convened an emergency meeting on November 23, 2020 during which the Evidence to Recommendations (EtR) framework was

discussed. When considering a recommendation, the EtR framework is used by ACIP as an explicit and transparent method for assessing the quality of the evidence related to benefits and harms and consideration of additional factors or domains. In this case, the domains included the Public Health Problem, Resource Use, Equity, Values, Acceptability, and Feasibility. In addition, the ACIP's COVID-19 Work Group (WG) meets weekly.

The topics considered by the WG since the November 23rd ACIP meeting included additional discussions pertaining to Phase 1a populations and clinical considerations for populations included in Phase 1a. Dr. Bell emphasized that two COVID-19 vaccine manufacturers recently announced their filings with the Food and Drug Administration (FDA) for Emergency Use Authorization (EAU): Pfizer/BioNTech on November 20, 2020 and Moderna on November 30, 2020. Dr. Bell indicated that the agenda for the December 1, 2020 ACIP meeting would include presentations on the following topics:

- ❑ Allocation of Initial Supplies of COVID-19 Vaccine: Phase 1a
- ❑ Clinical Considerations for Populations Included in Phase 1a
- ❑ Post-Authorization Safety Monitoring Update
- ❑ Public Comment Focused on Phase 1a Allocation
- ❑ Vote: Allocation of Initial Supplies of COVID-19 Vaccine: Phase 1a

Allocation of Initial Supplies of COVID-19 Vaccine: Phase 1a

Kathleen Dooling, MD MPH
Co-Lead ACIP COVID-19 Vaccine WG
Medical Officer, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

Dr. Dooling indicated that this session would revisit phased allocation of COVID-19 vaccine in order to answer the following policy question, "Should HCP and LTCF residents be offered COVID-19 vaccination in Phase 1a?" During the ACIP meeting on November 23rd, the WG reviewed evidence in three domains to inform allocation decisions. For the science pillar, the WG group examined COVID-19 disease burden, as well as the balance of benefits and harms in each group. Of course, details of the Phase III data will further inform this area when they become available. For implementation, the WG took into consideration the values, acceptability, and feasibility of implementation in each target group. Finally, the WG considered the ethical principles that apply to each group, which are to maximize benefits and minimize harms, promote justice, mitigate health inequities, and promote transparency throughout the policy process. The WG then used these three pillars to evaluate the proposed groups for Phase 1 vaccination. ACIP discussed phased allocation with health care personnel (HCP) and long-term care facility (LTCF) residents in Phase 1a, essential workers who do not work in healthcare in Phase 1b, and adults with high-risk medical conditions and adults ≥ 65 in Phase 1c. In order to address the policy question before the ACIP for a vote during this meeting, the rest of this presentation focused on HCP and LTCF residents.

To review who these groups include, HCP are defined as "essential workers paid and unpaid serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials." There are approximately 21 million HCP working in settings such as hospitals, LTCF, outpatient settings, home healthcare, pharmacies, Emergency Medical Services (EMS), public health, and others. The second group under consideration are residents of LTCF. About 3 million adults in the US live in LTCF, which provide a spectrum of medical and non-medical services, usually to frail or older adults unable to reside independently in the

community. There are several different categories of LTCF, including skilled nursing facilities (SNF). In general, SNF provide higher acuity care, including rehabilitation services. There are also assisted living facilities (ALF), where residents are provided help with activities of daily living (ADL) but may live in their own room or apartment within that facility. Other residential care facilities may provide specific services or cater to specific populations.

With respect to the science, as of November 30th, there have been at least 243,000 confirmed COVID-19 cases with 858 COVID deaths among HCP. LTCF modeling that was presented to ACIP in August predicts more cases and deaths averted at a facility by vaccinating staff compared to vaccinating residents. COVID-19 exposure, both inside and outside of the healthcare setting, results in absenteeism due to quarantine, infection, and illness. Vaccination has the potential to reduce HCP absenteeism. Older adults in congregate settings are disproportionately affected by COVID-19. LTCF facility residents and staff accounted for 6% of cases and 40% of deaths in the US, despite the fact that LTCF residents account for less than 1% of the US population. The SNF population is approximately 1.3 million and as of November 15th, had experienced almost half a million confirmed and probable cases and more than 69,000 COVID-associated deaths. ALF are home to approximately 800,000 residents across the nation. Although surveillance is less systematic for these types of facilities, 27,965 confirmed and suspected cases were reported across 23 states and more than 5,469 deaths were reported across 20 states. Based on the Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET) surveillance system, 31.4% of hospitalized patients aged 65 to 74 were admitted from a LTCF and 48.7% of hospitalized COVID patients 75 and older were admitted from a LTCF.

Turning to implementation considerations, a Harris Poll was completed in August during which survey respondents were asked which groups should receive priority when a COVID-19 vaccine is available. Survey respondents most strongly supported early allocation of vaccine to healthcare workers and seniors. While not expected to exactly predict COVID-19 uptake, influenza vaccine among HCP may offer some indication of COVID-19 vaccine acceptance. Overall, influenza vaccine coverage is high among HCP, with the highest rates of uptake among hospital workers and lower rates among workers in a long-term care setting. Another early indication of LTCF acceptance of COVID-19 vaccination is the overwhelming response to the Pharmacy Partnership for Long-term Care (LTC) Program. The CDC is partnering with two national pharmacy chains to offer on-site COVID-19 vaccination services for residents and staff of SNF and ALF. To date, 99% of SNF nationwide have enrolled in this program. The program provides end-to-end management of the COVID-19 vaccination process, including cold-chain management, on-site vaccination, and fulfillment of reporting requirements. But even with the Pharmacy Partnership for LTC Program, COVID-19 vaccination implementation and achieving high levels of coverage in the long-term setting will still be challenging. Based on a simulation of 1- and 2-dose coverage among SNF residents over time, even if acceptance is high and 3 vaccination visits are made, because of the high turnover, the proportion of current residents who are vaccinated decreases over time. The situation will improve when vaccine is readily available in the community and adults can be vaccinated prior to admission.

Pertaining to ethics, vaccinating HCP supports the principle of maximizing benefits and minimizing harms for what the WG is calling the “multiplier effect.” In other words, protection of HCP leads to preservation of healthcare capacity and better health outcomes for all. Vaccinating health care workers promotes justice because HCP put themselves at risk and will be essential to carry out the vaccination program. Vaccinating HCP also has the potential to mitigate health inequities because the group includes a broad range of occupations inclusive of low wage earners and racial and ethnic minority groups. Vaccinating long-term care residents maximizes

benefits by directly preventing disease in a high-risk group and minimizes harms by potentially reducing the burden on hospitals. The federal Pharmacy Partnership for LTC Program can promote justice by facilitating equal access to vaccine across most LTCF. The program has the potential to mitigate health inequities by reaching LTCF across the socioeconomic spectrum. In summary, the WG felt that early vaccination of both HCP and LTCF residents was strongly supported by science, implementation, and ethical consideration.

There are several additional important considerations for Phase 1a. It is important to remember that the proposed recommendation represents interim guidance for Phase 1a. Allocation policy will need to be dynamic and adapted as new information such as vaccine performance and supply and demand become clear. To that end, gating criteria will be needed to move expeditiously from one phase to the next as demand saturates. It is important to keep in mind that following vaccination, measures to stop the spread of SARS-CoV-2, such as masks and social distancing, will still be needed. Ultimately, this interim allocation is a short-term measure. The US Government (USG) has stated its commitment to making COVID-19 vaccines available to all residents who want them as soon as possible. During the last ACIP meeting, a number of important issues were raised that the WG wanted to recap before the vote. For HCP, ACIP members and liaisons expressed a need for guidance on sub-prioritization of HCP when vaccine supply is very limited in the beginning, to address vaccination in pregnant or lactating HCP, and to consider how to approach expected reactogenicity following vaccination. For LTCF residents, ACIP members requested more information on consent and assent within the facilities and plans on interpretation of reactogenicity and safety monitoring in this specific population.

Discussion Points

Dr. Atmar pointed out that one of the arguments for performing vaccination in LTCFs during the prior meeting was that both HCP working in the unit or facility and the residents could be vaccinated at the same time. He asked whether the pharmacy partnership would vaccinate only HCP or would vaccinate the residents as well and what the potential advantages might be for vaccinating both simultaneously.

Dr. Dooling responded that the Pharmacy Partnership for LTC Program will vaccinate residents as well as staff in the facility.

Recalling a slide from earlier that looked at 1 and 2 doses of vaccine, Dr. Frey asked whether there is any evidence of efficacy after administration of a single dose of vaccine at this time.

Dr. Dooling replied that there is no evidence at this time, but this is one of the questions they will be asking of the Phase III data once these becomes available.

Dr. Atmar observed that it seemed that there might be a challenge in LTCFs with the declining population and wondered what the implementation plans would be to keep and complete vaccination in that setting.

Dr. Dooling agreed that it would be a challenge, but indicated that the pharmacies that have signed up for this program have agreed to make 3 separate visits to the facility in order to vaccinate all persons who wish to be vaccinated. This will be less of a challenge when vaccine is more available in the community.

Dr. Goldman (ACP) thanked the committee and staff for all their hard work and consideration on this difficult issue. Concerning Phase 1 prioritization, especially healthcare workers and guidance on sub-prioritization, with the outpatient community physician and small private practice truly being the backbone of the healthcare system, he is pleased to see it is considered in healthcare in the first phase. However, it is important to look at the outpatient offices as being most at risk. A recent study out of the University of Pennsylvania showed small community and outpatient physicians may be at a higher risk of death than the inpatient. While Intensive Care Unit (ICU) physicians might see sicker patients, they also may have greater access to personal protective equipment (PPE) compared to small offices. Dr. Goldman expressed great concern about the ability for small and private practices to acquire vaccination doses, especially from large healthcare systems. Additionally, the office staff are critical to running small practices, almost as much as the physician. They truly are the frontline workers. He expressed hope that the committee would consider this in the guidance and sub-prioritization, especially in terms of vaccine distribution for those offices whose physicians are not employed by hospitals and not associated with large healthcare systems, to ensure that the vaccines are truly getting to the people on the frontlines who need it the most—more specifically, the small private independent community primary care physicians.

Dr. O'Leary (PIDS) agreed with Dr. Goldman's point about outpatient providers and added that consideration also should be given to other people who work outside of hospitals like home health aides and Emergency Medical Services (EMS), and that plans should be made for those providers as well.

Dr. Sanchez agreed that with sub-prioritization, a lot of which will likely be left to jurisdictions, the availability of PPE will be critical in terms of what sub-specialties and what practices they should be allocated to first.

Dr. Fryhofer (AMA) emphasized the importance of making sure that small community practices have access to COVID-19 vaccines.

Dr. Romero pointed out that there would be some data in Dr. Oliver's next presentation that would deal with this.

In terms of science, Dr. Duchin added that the transmission dynamics of COVID-19 also suggests that those providers who care for patients earlier in their course of illness may be at higher risk, including outpatient HCP. This also is supported by information CDC recently published.

Regarding sub-prioritization, Dr. Bernstein asked whether it was envisioned that HCP in LTCFs would receive vaccine if supply is constrained before giving it to the residents or if there was another prioritization scheme.

Dr. Cohn said she would assume that most planning around LTCFs would have LTCFs vaccinate both residents and HCP working in these facilities at the same time, but some jurisdictions will likely start with HCP and then vaccinate residents. This will be dependent on supply and local context.

Ms. Bahta said she had similar concerns about making sure that the staff at LTCFs are being vaccinated. They too are often less equipped in terms of PPE and certainly have experienced a major burden of disease.

Ms. Léger (AAPA) recalled that in previous discussions, there was mention of high turnover of the residents of LTCFs, usually within a 30-day time period. This raised a question about implementation and follow-up of those residents for their second dose and the challenge that may result.

Dr. Cohn said this highlighted one of the many challenges with ensuring high coverage in LTCFs among residents and staff. The turnover among LTCF residents tends to represent a portion of resident turnover, with the additional residents being more long-term. There will need to be additional visits to the LTCFs. There are data systems in place to support those individuals who leave the facility in getting a second dose. That still will be a challenge, particularly in the first couple of months of vaccination when locations where people can be vaccinated will be more limited.

Dr. Gluckman (AHIP) endorsed the efficiency that could be gained by co-administering residents and HCP at the same site at the same time. Given the relatively small number, it will not likely have a meaningful impact on delaying vaccination for other populations such as essential health workers or others who would be phased in at a later place. The logistics can be overcome with thoughtful planning. For instance, it seems that the SNFs could schedule people for one of the subsequent second or third days that the pharmacy is coming on-site again, and then it would just be a transportation issue.

Dr. Szilagyi agreed that it would be efficient to vaccinate the residents and the HCP simultaneously. He asked what was known about the number of COVID deaths between those who cycle through quickly versus those who stay longer-term in LTCFs.

Dr. Cohn responded that they did not have these data readily available, but would acquire them and report back to the committee.

Dr. Gluckman (AHIP) pointed out that some of the patients in LTCFs are there for acute medical illnesses for which they need short-term help. From a health education point of view, many patients need short-term help with conditions such as sepsis, post-pneumonia care, congestive heart failure. People who have joint replacements are not in LTCFs as much as they used to be. He thought perhaps short-term residents would not be at most risk.

Dr. Frey pointed out that if people in LTCFs, particularly the elderly, are going to be batch vaccinated, a lot of guidance will be needed post-vaccination to evaluate symptoms, adverse events, or side effects. If the elderly suffer from fatigue or even a little fever, people worry about them having underlying infections. If there are more than just a few people suffering from those side effects, it perhaps could cause issues in a facility. Dr. Dooling indicated that the next presentation would address specific guidelines around managing symptoms.

Dr. O'Leary (PIDS) requested clarification regarding whether the recommendation would pertain to only adult LTCFs or if pediatric facilities would be involves as well since the Pfizer vaccine may go down to 16 years of age.

Dr. Dooling indicated that the recommendation on which they would be voting during this meeting pertained to adults. The specifics of the age cutoff will be determined once a specific vaccine has been authorized.

Considerations for Populations Included in Phase 1a

Sara Oliver MD, MSPH
Co-Lead ACIP COVID-19 Vaccine WG
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

Dr. Oliver presented clinical consideration for populations discussed for the potential inclusion in Phase 1a, HCP and LTCF residents. This included sub-prioritization, reactogenicity, and considerations for implementation. One or more COVID-19 vaccines may be authorized by the FDA for use in December. However, the initial doses of any COVID-19 vaccine will be limited. There is expected to be a constrained supply environment for some months, which will require the best use of available vaccine. By the end of December, the number of doses available will be approximately 40 million, enough to vaccinate around 20 million people. However, that will not all be available at the same time. Approximately 5 to 10 million doses per week are anticipated post-authorization, which could lead to a need for sub-prioritization of the initial populations, at least for the first several weeks.

Where sub-prioritization of HCP is needed, individuals with direct patient contact who are unable to telework should be considered. This includes personnel who provide services to patients or patients' family members and persons who handle infectious materials. This can also include both inpatient and outpatient settings. Consideration also should be given to personnel working in residential or LTCFs and personnel without known infection in the prior 90 days. Reinfection appears uncommon during the initial 90 days after symptom onset preceding infection. However, serologic testing is not recommended prior to vaccination. For pregnant or breastfeeding women, as has been discussed over the last several ACIP meetings, 75% of the healthcare workforce are female and there are approximately 330,000 HCP who are pregnant or recently postpartum at the time of vaccine implementation. Data demonstrate potentially increased risk for severe maternal illness and preterm birth due to COVID-19 disease. However, this must be balanced with the fact that there are no data on the use of mRNA vaccines in pregnant or breastfeeding women. The WG is awaiting Phase 3 data and FDA assessment and the EUA conditions of use. Once reviewed, further guidance is anticipated around the use of COVID-19 vaccines in pregnant or breastfeeding Phase 1a populations.

Reactogenicity post-vaccination will be a concern among vaccinated HCP. There will be additional data soon from the Phase III trials. Current data from the Phase I/II trials with vaccine doses used in the Phase III trials indicated that systemic symptoms are more common after the second dose. It is important to note that the numbers are quite small. There are several considerations for implementation among HCP. Healthcare systems and public health should work together to ensure vaccine access for HCP who are not affiliated with hospitals, which could include home health, community services, or broad practice types. Next, consideration should be given to staggering vaccination of personnel from similar units or positions. In addition, consideration should be given to planning for personnel to have time away from clinical care if HCP experience systemic symptoms post-vaccination. On that issue, there is additional CDC guidance forthcoming that describes the approach to systemic symptoms in HCP after COVID-19 vaccination. This will provide detailed information on how to handle these systemic symptoms and HCP. This guidance will be available on the CDC website before any vaccine doses are administered. Regarding clinical consideration for LTCF residents, as mentioned before, LTCFs provide a spectrum of medical and non-medical services to frail and older adults unable to reside independently in the community. SNF and ALF are both considered types of LTCF. SNF are engaged primarily in providing skilled nursing care and rehabilitation services for

residents who require care because of injury, disability, or illness. ALF provide help with ADL; however, residents often live in their own room or apartment within buildings or groups of buildings.

Regarding COVID-19 disease among the LTCF, as of November 26th, there have been around 730,000 COVID-19 cases and 100,240 deaths among LTCF residents and staff. As of mid-November, SNFs reported nearly 500,000 cases and 70,000 deaths through the Centers for Medicare & Medicaid Services (CMS). Reporting varies for ALF, but through October 15th, 23 states reported nearly 28,000 cases and 20 states report around 5500 deaths. Therefore, where sub-prioritization of LTCF is needed, consideration should be given to SNF which care for the most medically vulnerable residents. Then after SNF, consideration could be given to broadening to other facility types, including ALF, residential or intermediate care facilities, or state Veterans Homes.

While there are no data from LTCF residents specifically on reactogenicity for the older adult populations, there are data from the Phase I/II trials among community-dwelling older adults ≥71 years of age in the Moderna trials and 65-85 years of age in the Pfizer trials. Systemic symptoms are generally lower among the older adult population. The one severe reaction post-dose 2 in the Moderna trial was a report of Grade 3 fatigue. There are considerations for implementation among LTCF residents. Federal pharmacy partners supporting the LTCF program will be required to adhere to all EUA conditions of use, including providing fact sheets to recipients. In addition to the fact sheets for staff and residents getting vaccinated, they will be provided to families and medical proxies as applicable. CDC also will provide language clarifying that while there are available data on safety and efficacy among adults 65 and older, there are no data on individuals in LTCF. Importantly, consent or assent will be obtained from residents or families or medical proxies and documented in the patient's chart as is standard practice for other vaccines.

In summary, sub-prioritization may be required with an initial limited supply of vaccine. Implementation of vaccination programs for HCP will need to consider reactogenicity post-vaccination and additional guidance is forthcoming from CDC. Reactogenicity appears lower in the older adult population for mRNA vaccine, but there are no reactogenicity data in LTCF residents specifically. Safety monitoring, which will be described in detail in our next presentation, will be critical post-authorization for all populations in Phase 1a, especially LTCF residents.

Discussion Points

Dr. Atmar offered a cautionary comment about comparing the community-dwelling older adults to younger adults living in the community, pointing out that 2 out of 12 verses 1 out of 12 is hardly reassuring. He did not think any conclusions could be drawn about the relative frequencies of side effects based on this limited dataset. While the data from the Phase III trial should provide a lot more information, it is much too early to draw conclusions about the relative reactogenicity of the vaccine in these two different age groups.

Dr. Hunter commended the notion of not vaccinating everybody who works on a particular unit at the same time. The convenience of vaccination unit-by-unit would be pretty high within a healthcare system, but that could wipe out that unit for an entire day 2 to 3 days later when people have their reactogenicity. That level of detail will be highly valuable for those who are going to be administering vaccinations.

Dr. Hunter added that this also applies to emergency personnel as mass vaccination could result in a shortage of EMTs in a community.

Dr. Sanchez suggested separating lactating mothers from pregnant woman. Although there may not be safety or transmission data on lactation, it is known that women with COVID-19 can breastfeed safely. HCP working on the frontline who recently gave birth and are at risk should be vaccinated and continue breastfeeding as well.

Dr. Maldonado found it helpful to think about how to allocate vaccine across healthcare systems. In thinking about the science, implementation, and ethics, sub-allocation comes into play in much more granular ways when looking at the tiered approach to these smaller allocations of vaccine. She requested guidance on how and when to weigh age greater than 65 years, versus risk of exposure, versus racial and ethnic disparities, versus risk for community transmission at home among HCP. She wondered whether the bottom line was to prevent transmission in the hospital setting, among HCP specifically, and/or community transmission. These are very entangled concepts to which people would look to CDC and ACIP for further guidance.

Dr. Szilagyi added that he is on multiple groups trying to sub-prioritize within healthcare systems and everybody is looking for guidance from ACIP or CDC. He emphasized the importance of guidance and the balance between being specific enough to help health systems, but allowing, suggesting, and encouraging some flexibility because health systems know their own populations the best. He asked whether there be a discussion about coordination with SHEA or other groups that are also in this space working on guidance for healthcare facilities and sub-prioritization.

Dr. Cohn indicated that about 40 million doses are anticipated initially. That would be enough to cover approximately 15 and 20 million individuals and would cover a large portion of healthcare workers by the end of December. Approximately 5 to 10 million doses are anticipated each week thereafter. In essence, sub-prioritization is likely to be needed for a limited period of time in this population.

Dr. Oliver added some context around WG discussions about this. Protection for HCP is related to both direct protection for that individual as well as for the health care system as a whole. Each individual health care system is going to need to figure out whether they need additional sub-prioritization based on the doses and staff that they have, as well as weighing privacy and protection for the individual HCP.

Dr. Hunter asked for clarification regarding whether it was anticipated that 20 million people could be vaccinated with the 40 million doses by the end of December or that the doses would be available to be distributed by the end of December.

Dr. Cohn clarified that if jurisdictions and providers place orders, they will be available and it is anticipated that most of those doses will be distributed. This relates to the storage and handling requirements, but jurisdictions have very detailed plans about how to ensure maximizing doses in clinics. That being said, it will not be 40 million doses equals 20 million people vaccinated because there will be some dose mismatching in some areas.

Dr. Messonnier added that in discussions with the jurisdiction, most believe that they can vaccinate all of their healthcare workers within 3 weeks. That is certainly dependent upon the workforce and the hope that there will be support for the vaccine among them. From an

operational standpoint, most jurisdictions are planning far less than 3 weeks. The goal is to vaccinate health care workers quickly.

Dr. Drees (SHEA) indicated that SHEA is very interested in working with CDC with regard to healthcare worker sub-prioritization and managing the reactogenicity of the vaccines in this population, and that work has started already. Because of the characteristics of the vaccine, a high throughput, centralized vaccine distribution system would be ideal. However, this is at odds with staggering vaccine across different units and departments, as well as requesting that people schedule their vaccine before they have a day off already scheduled. Those things are going to be very challenging to manage logistically. From a large healthcare system perspective, she will not be able to manage which people in which units get vaccines on which days. They are going to have to manage that at the unit level as much as possible. She thinks the smaller hospitals are going to have a really hard time. For instance, a 100-bed hospital will have to order enough vaccine to vaccinate their entire staff within a day or two. Given that this may not be feasible with smaller staffs, there is going to be a need for a lot of partnerships between local and state health departments and smaller hospitals to distribute the vaccine in a way that makes sense and allows them to stagger it over time.

Dr. Poehling commented that the reactogenicity data available from two trials was particularly helpful as everybody is looking to identify how best to move these forward. It does highlight the importance of staggering, which is not going to be easy.

Ms. McNally asked how the EUA fact sheet for recipients differs from a Vaccine Information Statement (VIS), how often the EUA fact sheets will be updated with the accumulation of new data, and whether the EUA fact sheet has a public comment session like a VIS.

Dr. Cohn indicated that the EUA fact sheet will be very similar to a VIS in terms of overlapping content, though it will be formatted differently. VISs are also reviewed and coordinated with the FDA. There is not a public comment period for an EUA fact sheet. It is developed as part of the EUA authorization between FDA and the manufacturer. The EUA fact sheet is given to all vaccine recipients, not just those working within LTCFs. There are fact sheets for providers and the individuals receiving the vaccine. Another difference between the VIS statements and the EUA fact sheets is that each product will have an individual EUA fact sheet. The VIS is specific to the types of the disease a vaccine prevents or the type of vaccine. An individual will receive the EUA fact sheet for the vaccine product that they receive, which is part of the EUA package. Providers will be trained rapidly on how to provide vaccines under an EUA, including ensuring that patients have the fact sheet.

Dr. Fink added that the EUA fact sheet will be updated with any new information the FDA considers important to allow vaccine recipients to understand the benefits, risks, and options related to use of the vaccine under the EUA. The timeframe for updates will depend on when information is received by the FDA that warrants a change.

Dr. Lee asked whether there would be differences in the benefit/risk counseling that is intended with the EUA fact sheet and whether it would be reasonable to have one that is tailored to LTCFs that would be different from generic fact sheets specific to a healthier population.

Dr. Cohn indicated that the EUA fact sheets that are FDA-authorized and sent by the manufacturer will be the same for every individual. However, CDC is developing specialized toolkits for communications materials that will provide additional information and context around COVID vaccination specific to each product that should be available soon. The first one to roll

out will be specifically for healthcare systems vaccinating HCP. The second one will be the LTCF toolkit, which will have information about what vaccination means for LTCF residents and their family members.

Dr. Lee expressed gratitude to CDC for the development of the implementation toolkits. She recognized how challenging it is to develop these communications in the absence of having the Phase III clinical trial data in hand. She also recognized that providers and healthcare delivery systems need to partner with CDC, states, and jurisdictions in order to support these communications. This will be an iterative process in part because everything is happening on such a compressed timeline.

Dr. Atmar asked whether there any Institutional Review Board (IRB) reporting requirements if there are AEs. Dr. Fink indicated that the EUA, if issued, would lay out requirements for AE reporting.

Ms. Stinchfield, (NAPNAP) commented on some of the practical considerations of sub-prioritization, which she is already working on in her healthcare institution. The total employee population at Children's Minnesota is 5300, with 3300 direct care providers. While they have employees' month and day of birth, the year is not included in their files for age discrimination reasons. They also may not have race and ethnicity. Because they do not have employee medical records and personal medical histories in the occupational health setting, they can only go down so far in terms of sub-prioritization among mostly direct and indirect patient care providers. In thinking about asking the other 2000 employees to hold, it was helpful to know that they were talking about weeks rather than months in terms of giving people the guidance on when to expect their doses. There is a lot of enthusiasm and understanding the timeframe is really helpful.

Dr. Duchin indicated that as a member of the COVID-19 Vaccine WG, he wanted to make sure that the ACIP voting members were clear about whether they thought the level of sub-stratification guidance was adequate given what is expected in terms of supply. With all due respect, it is never possible to predict the future. Supply issues may go on longer than anticipated. In case supply is insufficient to meet demand, consideration should be given to whether ACIP feels that the sub-stratification guidelines are adequate or if there should be further guidance around equity or other considerations in determining who receives vaccine first. For example, should more facilities be given fewer doses or should fewer facilities be given more doses?

Dr. Lee said she certainly believed that the WG's goal in Phase 1a with regard to HCP is to preserve the workforce and health care capacity regardless of where exposure occurs. She feels strongly that this includes those who need to be in the workplace interacting with patients, families, and staff for their job function. This includes clinical support services such as nursing assistants, medical aids, environmental services, food services, frontline staff who all are critical to the delivery of healthcare. She is very mindful of the equity considerations and the importance of making sure it reflects the distribution of the workforce early on in terms of those who must attend work in person to function in their jobs. Medical conditions of health care workers and age are clearly going to be important in Phase 1c. Her concern about the equity issue is that if people are asked to self-disclose, it may inherently create some unintended inequities in that some healthcare workers are more easily able to self-advocate and feel comfortable in their position in being able to declare medical conditions. She worries that creating that as a construct might unintentionally create more inequity in that if lower-wage workers do not feel comfortable self-disclosing medical conditions, they may effectively not be

put in the front of the line as they should be. At least in some institutions and in the national data, lower-wage workers are faced with higher rates of infection in the community or the workplace. If there are supply issue for a longer period of time, it will be important to make sure there is a focus on Phases 1b and 1c. The workforce who cannot stay home and shelter in place until the spring or summer, certainly as they meet 1c conditions, should be vaccinated in that phase. However, there is a portion of the workforce who can work from home without going into the workplace until spring or summer who she would have a hard time personally allocating to early on when she knows that there are so many individuals who are in need.

Dr. Hunter said he was thinking of a process related to venues and gathering people who are making the decisions at the venue level; that is, the unit of the healthcare delivery itself. Perhaps those people could be brought together in some type of forum every week or so to discuss the issues they are facing with allocation on a state, federal, and/or national organizational level and consider how to interpret the general guidelines that the ACIP votes on. This could address how to have enough specificity in ACIP recommendations while at the same time having enough flexibility to implement them.

Dr. Goldman (ACP) emphasized the need for guidance, oversight, and detailed gating criteria for large hospital systems receiving huge amounts of vaccine to distribute vaccine to the small and community practices. It would be a shame for a large system to vaccinate everyone including those not necessarily at risk, such as those working in the IT department who are not in patient care but are employed by a hospital, versus getting vaccine out to small/community practices where it is needed. In rural areas, there may be many physicians, practices, providers, et cetera who do not even know where to go to get the vaccines or who is distributing them if it is only being localized to large healthcare systems.

Dr. Fryhofer (AMA) asked whether there is a place on the EUA forms for patients to sign. She is concerned about ensuring that the frail elderly really understand what they are getting and what the side effects might be. If these patients are not able to sign on their own, she wondered whether there would be outreach to family members, or whomever has their power of attorney, to sign for them. She emphasized Dr. Goldman's concerns about the importance of community outreach to HCP who might not work in the hospital to ensure that they get vaccines.

Dr. Messonnier said that CDC agreed to the concern about ensuring that the frail elderly and their families understand the vaccine that they are getting. There is a special provision in the LTCF program to ensure that this occurs. There was a detailed presentation during a previous meeting, for which CDC can resend the slides. This is a space where CDC has been very concerned. Part of the issue is that everybody must be pulling together and working together to ensure that messages are harmonious. As Dr. Cohn said, a big effort for CDC in the next two weeks is to get out as much communication material as possible. The plan is to ensure that ACIP is fully briefed on CDC's efforts so that they can then brief their counterparts.

Regarding sub-prioritization, Dr. Sanchez pointed out that importance of including recommendations for individuals who are receiving biologics.

COVID-19 Vaccine Post-Authorization Safety Monitoring Update

Dr. Tom Shimabukuro
CDC COVID-19 Vaccine Task Force, Vaccine Safety Team
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Shimabukuro presented a COVID-19 vaccine post-authorization safety monitoring update in the context of the various safety monitoring systems that are available, which he described in detail and with respect to HCP and LTCF residents specifically. The systems are listed in this table depicting the populations they include and level of coverage for HCP and LTCF residents:

Monitoring Systems and Populations

	Monitoring systems	Population	Healthcare workers	LTCF residents
early	**VAERS** (CDC & FDA) VA ADERS DoD VAECS CDC NHSN	General U.S. population, VA and DoD patient populations, NHSN acute care and long-term care facilities	Yes	Yes
early	**V-safe** (CDC)	All COVID-19 vaccine recipients eligible	Yes	Limited
later	**VSD** (CDC)	Insured patients in VSD sites	Yes	Limited
later	**FDA-CMS**	Medicare recipients (90+% of 65 y/o in the U.S., including 650K LTCF residents)	Limited	Yes
later	**BEST & PRISM** (FDA)	Insured patients in BEST & PRISM sites	Yes	Limited
later	**VA EHR & data warehouse**	Enrolled VA patients	Limited	Yes
later	**DoD DMSS**	Active duty military (limited info on beneficiaries [i.e., family members, retirees])	Yes	Limited
later	**Genesis HealthCare** (Brown U. & NIH-NIA)	Long-term care facility residents (~35,000 long stay residents)	No	Yes

To be more specific on safety monitoring in LTCF residents, the Vaccine Adverse Event Reporting System (VAERS) is the nation's early warning system for vaccine safety and will be the system that captures information on LTCF residents the quickest and provides the quickest data for CDC and FDA on safety in this particular demographic. VAERS includes all 320 million US residents as a covered population. This includes all ages, races, occupations (including healthcare workers) states/jurisdictions, healthy people, those with chronic health problems, long-term care facility residents, older adults living in the community, et cetera.

The Veteran's Affairs Adverse Drug Event Reporting System (VA ADERS) is the VA's spontaneous reporting system. Although VA healthcare workers may not be enrolled as VA patients, many of them are vaccinated in occupational health at the VA and will be eligible to be captured by the VA ADERS. It also includes the 8,000 residents per day in VA LTCFs. A Veterans Health Administration (VHA) directive from 2020 established a national policy for reporting, monitoring, and surveillance of adverse drug events (ADEs). By policy, vaccine AE reports captured in the VA ADERS are reported to VAERS.

The National Healthcare Safety Network (NHSN) captures a weekly count of doses administered by product type. There are roughly 17,000 LTCFs in NHSN. It includes aggregate voluntary reporting of vaccine doses administered and counts of non-specific AEs. Importantly, NHSN includes guidance on reporting AEs to VAERS with a link to the VAERS website where reporting can be done electronically. Instructions are included to enter the NHSN organization identification (orgID) number in box 26 of the VAERS form. Coding NHSN reports by site allows CDC to make queries and identify those reports that originated from NHSN sites.

Through the Pharmacy Partnership Program for LTCF vaccination, pharmacy partners may vaccinate in a substantial percentage of LTCFs/ This can provide early denominator information in LTCF residents, which can improve the accuracy of reporting rate estimates. Outreach to pharmacy partners on VAERS reporting is planned.

FDA's Rapid Cycle Analysis (RCA) in the Center for Medicare and Medicaid Services (CMS) data includes about 92% of the US elderly including approximately 650,000 LTCF residents. The data will be refreshed weekly with weekly sequential analyses. Because the data are refreshed and the analyses are done, that is a separate issue from the data actually accumulating. For CMS fee-for-service, the average data lag is around 4 weeks. The average data lag can be up to 5 to 6 weeks for hospitalizations. In the VA electronic health record data warehouse, historically 60% of VA patients who receive influenza vaccinations are 65 years and older. That translates into about 1.56 million older adults vaccinated for influenza annually in recent years. There are also 8,000 LTCF residents per day captured in the VA EHR data warehouse. The data will be refreshed weekly with weekly sequential analysis. For the VA, there is an approximate 1-week average data lag and up to about 4 weeks for hospitalization.

For CDC RCA in the VSD, there are about 1.8 million older adults in 9 integrated healthcare systems that comprise the VSD. Again, the data refresh weekly with weekly sequential analyses. There is an approximate 1 to 2 week average data lag and up to around 6 weeks for hospitalization. The data lag for hospitalization for these systems is primarily due to the hospital stay. These are average lags as some hospitalizations are longer than others. Once the patient is discharged, the processing of the data and entering that into the database for these systems is fairly rapid.

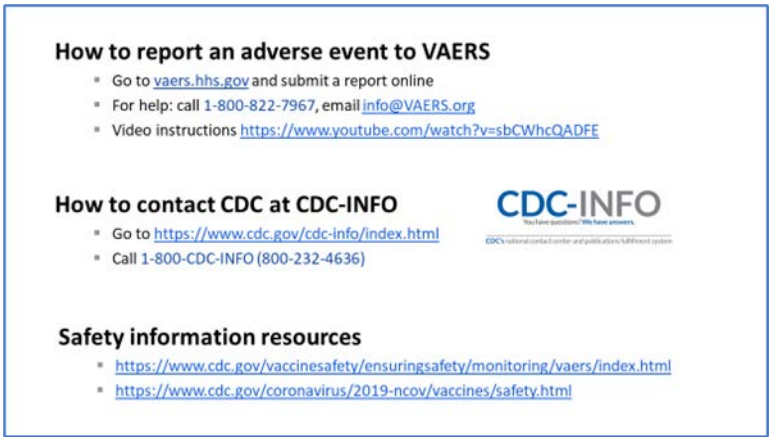
There are plans to do case evaluations of AEs. Some of the planned activities include rapid processing and review of reports to VAERS classified as "serious" and adverse events of special interest (AESI). FDA reviews all reports that are classified as "serious" and CDC will be reviewing a selected list of AESIs for which the reports and accompanying medical records will be reviewed. The processing times for COVID-19 will be 1 day for death reports, 3 days for serious reports, and 5 days for non-serious reports. There also will be an investigation of clusters of adverse events of clinical Interest (AECI) by a multidisciplinary CDC team if necessary and clinical case reviews by the CDC Clinical Immunization Safety Assessment (CISA) project.

In terms of coordination, communication, and implementation, the Vaccine Safety Technical Sub-Group (VaST) was built off lessons learned from H1N1. The terms of reference and composition are finalized and the VaST is ready to begin reviewing data once implementation commences. It is co-chaired by an ACIP member and a National Vaccine Advisory Committee (NVAC) member. It has ACIP and NVAC representation, includes independent expert consultants, federal agency ex officio members, and liaisons from the VA and Department of Defense (DoD). The post-implementation objectives of VaST are to review, evaluate, and interpret post-authorization/ approval COVID-19 vaccine safety data; service as the central hub for technical subject matter experts (SMEs) from federal agencies conducting safety monitoring to share safety surveillance data; advise on analyses, interpretation, and data presentation; and to liaise with the ACIP COVID-19 Vaccines WG on issues of safety data presentations to the ACIP and application of safety data to policy decisions. It is important to understand that safety monitoring does not stop with tracking alone.

CDC is ramping up communications efforts in anticipation that vaccine soon will be distributed, available, and administered in priority groups. These efforts include distributing communication materials to state health officials, HCP, and health care systems; providing up-to-date information on the website; and conducting ongoing partner outreach and engagement to raise awareness of V-SAFE and the VAERS requirements to include healthcare provider professional organizations, public health partners, healthcare organizations and other private sector partners, long-term care partners, and pharmacy partners.

In summary, early data on COVID-19 vaccine safety in healthcare workers will be available primarily through V-SAFE, VAERS, and systems that report into VAERS. Early data on safety in LTCF residents will be mainly available through VAERS and systems that report into VAERS. VAERS is a long-standing established safety monitoring system that is critical to monitoring new vaccines during the early uptake period. It is also critical to monitoring influenza vaccine every season when a 150 million doses or so are administered in a very compressed time window of several months. Large-linked database monitoring systems, such as CDC's Vaccine Safety Datalink (VSD), will provide safety data when vaccines become more widely available in priority groups and in the general population. Efforts are ongoing to increase awareness and provide information needed to CDC's partners for safety monitoring.

ACIP, public health and health care providers, and the public should feel assured that the systems are in place to collect safety data. There are validated methods to rapidly analyze the data, processes in place to respond to safety signals when detected, and trusted partnerships are well-established. To strengthen vaccine safety efforts, Dr. Shimabukuro specifically called upon: 1) CDC's public health partners to promote participation in V-SAFE, promote reporting to VAERS, and communicate with partners on vaccine safety; and 2) healthcare providers to inform patients about V-SAFE and encourage them to participate, report AEs to VAERS, and communicate with patients about vaccine safety. He shared the following links:



Discussion Points

Dr. Messonnier reiterated the importance that CDC places on the safety of vaccines. FDA will not authorize a vaccine and ACIP will not recommend a vaccine unless they are convinced, based on the Phase III clinical trials, that the vaccines are very safe. But everyone knows that vaccine safety does not stop there, especially for these vaccines. CDC is going to hold itself to an exceedingly high standard for safety monitoring after a vaccine is authorized and when it is rolled out more broadly. Dr. Shimabukuro, his team, and a vast array of scientists across the USG and among CDC's partners have done an incredible job of enhancing existing vaccine

safety systems to meet this challenge. They have done a great job of trying to anticipate gaps in the system and fill them. But as Dr. Shimabukuro pointed out, vaccine safety systems are partly dependent on the stakeholders in the health systems, public health departments, and the public reporting AEs. Especially in this initial phase, she implored everybody in the community to work together to help ensure the safety of these vaccines. It may mean extra work for some groups that have to report through other systems as well as through these systems, but these early phase are crucial.

Dr. Ault asked what has been proposed to encourage people to be involved in the V-SAFE program since that seems to be the quickest way to get safety data.

Dr. Shimabukuro indicated that CDC is ramping up communications efforts to get the message out to its public health partners, the provider community, and pharmacy partners, and other about the importance of V-SAFE in capturing early information on vaccine safety. They soon will push this out strongly and will try to get the message out as broadly as possible to those who are vaccinating or those who partner with CDC who vaccinate. This mostly involves reaching out to partner organizations, professional societies, public health partners, pharmacy partners, and others who are going to be directly involved in vaccination.

Dr. Cohn added that the health system and health care provider communication toolkit will include information about how to enroll patients in V-SAFE and information about the program and tips for encouraging patients to enroll.

Dr. Poehling thanked Dr. Shimabukuro for this really important conversation highlighting the importance of the initial assessment of safety, as well as following the safety of all vaccines that are administered. She requested additional information about V-SAFE in terms of how that data will be monitored and the confidentiality of reporting through this system.

Dr. Shimabukuro indicated that operationally, an information sheet will be available in different formats, including a URL and scannable QR code. The individual patient enrolls themselves by either typing in the URL or scanning this QR code. It takes them to a registration sites and there is a limited amount of information a person puts in to register. There is a confirmation step and place to enter the vaccine. Once someone is registered, CDC sends messages with a weblink that takes them to an electronic survey. For the first week of vaccination, CDC does daily check-ins where recipients are asked about local and systemic reactogenicity and some health impact questions. The local and systemic reactogenicity questions and some other questions are fed into a database that has all of the federal IT security and privacy protections. That information is available to the CDC staff who are doing the safety monitoring. For those who have a health impact question, CDC is going to use the cell phone numbers from the registration to reach out to them and take a VAERS report. That report will actually go into VAERS, the spontaneous reporting system that is subject to all of the security requirements and Health Insurance Portability and Accountability Act (HIPAA) as well. Vaccinated individuals should be confident that private information will be protected and that it will be used for safety monitoring purposes only. That will be reviewed and presented to the VaST regularly and analyzed in the context of signal detection.

Dr. Zahn (NACCHO) said that as a local public health person, he will be extremely enthusiastic to get out information about the need to report. The general message needs to be, “If something happens to you or your patients, report it.” However, the need to have a smartphone in order to use V-SAFE complicates the message. In terms of messaging, providers are going to hear about V-SAFE and they going to hear about VAERS. Clarifying which system to use for which

situations and what to tell patients to report seems very important. While CDC will be conducting outreach to pharmacies and pharmacists regarding AEs in the reporting in the context of vaccinating in LTCF, they are going to take the responsibility to vaccinate. However, the people who are caring for them at their facility or their primary providers are the ones who are going to be identifying and reporting those issues. Therefore, it seems really important to communicate to SNF or LTCF staff about how they are supposed to report these events. Obviously, NHSN is one resource.

Dr. Shimabukuro agreed that this raised a good point that needs clarification and probably a better explanation in CDC's communication material. V-SAFE is really an interaction between the patient and CDC through which patients are reporting information to CDC. Beyond the first week of looking at local and systemic reactogenicity, the patient will be answering health impact questions that pertain to three things: Did you miss work? Were you unable to do certain daily activities? Did you seek or receive health care? Checking any one of those triggers an active telephone follow-up with that patient during which CDC would perform an assessment. If the patient or the patient's provider has not already submitted a VAERS report, that also would be completed over the phone. He agreed that CDC's message to providers should be to encourage reporting of any clinically significant adverse health events in addition to the EUA reporting requirements, even if they are not sure if the vaccine caused it. That would be irrespective of whether the person is enrolled in V-SAFE. If it happens that two reports are made, CDC has ways of identifying and consolidating the reports.

Dr. Foster (APhA) expressed gratitude for the enormous effort that has gone into the planning, and asked whether a mechanism has been built in for reporting at LTCFs and whether the facilities would be reporting back to the pharmacists or would be making reports themselves.

Dr. Shimabukuro said that based on the comments from Drs. Zahn and Foster, CDC would probably need to revise that. Maybe this would include awareness for providers and pharmacy partners, and specific guidance on AE reporting targeted to the HCP who are going to be interacting with these patients on a daily basis following immunization.

Dr. Maldonado requested further information about where VaST fits within the workflow of all of the various systems.

Dr. Shimabukuro explained that VaST is a group of external experts and that this forum is the central hub for the federal agencies that are doing the monitoring in the systems. Information from the systems will be provided to VaST for feedback on data interpretation, analyses, and maybe even further signal assessment. For example, RCA is done in the VSD. If an RCA signal is detected, it would be further assessed in the VSD and CDC would possibly even engage with FDA colleagues to determine if further signal assessment could be done in the CMS data. CDC will be meeting regularly with the VaST group to present data from these systems on signal detection and signal assessment and so that they can provide feedback to CDC. If a signal is detected, it is likely that the VaST, ACIP COVID-19 WG, and ACIP would be involved in the process in terms of receipt and discussion of this information. There potentially may be some type of policy decision, which might involve public health or regulatory action if necessary. That is a separate process. What the VaST is going to do is intimately linked. During an upcoming ACIP meeting, CDC can further delineate the step-by-step process of what will be done if there is a signal. It is anticipated that there will be signals that will need to be assessed because of the various populations, which may or may not be related to the vaccine. There will be many more signals than there will be actual AEs that need to be assessed.

Dr. Lee added that she and Bob Hopkins are Co-Chairs of the VaST sub-group. The goal is to review the data from all of these systems as it is coming in. She thought Dr. Shimabukuro outlined nicely that the timing of the availability of the data will likely be staggered. However, the plan is for those data to be reviewed on a regular basis at least weekly at this point pending the availability of data. It is anticipated that the VaST sub-group, which reports to the ACIP COVID-19 Vaccines WG, will do so on a regular basis and that this information, through the COVID-19 Vaccines WG, will be brought forth to ACIP. She agreed that it would be helpful to present the processes that are in place for the framework for evaluating signals, which is signal detection, signal refinement, and signal evaluation. They can definitely bring that forward next time. Similar to what was done during H1N1, this is anticipated to be a robust process. There are a lot of safety systems available, but the way she is thinking about this right now from a healthcare provider perspective is that V-SAFE focuses on individual patients. The role of care providers is to support and facilitate vaccinees to enroll in V-SAFE so that they can self-report what is going on post-vaccination. This is a patient-directed system. In addition, the goal is to ensure that all HCP are aware of how to report any potential AEs that may occur into VAERS. VAERS is co-managed by CDC and FDA, but that would be specific to providers and asking them to take action. The third layer that is important to highlight is the NHSN, which is a national safety surveillance network that has been in place for decades. Over 4700 acute care facilities and 17,000 LTCF in the US are NHSN users. It is going to be important to encourage facility-level reporting, different from patient-level and provider-level reporting, that encourages acute care facilities and LTCFs to support efforts to report not only doses administered, but also any clinically significant safety events that occur. That would address some of the questions and issues that were raised earlier regarding the connection between LTCFs and pharmacies, recognizing that those systems are coming online for the acute care facilities sooner compared to the LTCFs. Sharing this aggregate information with NHSN and linking it to VAERS will be incredibly helpful for the safety monitoring system overall.

Dr. Talbot pointed out that while their pediatric colleagues are very well-versed in VAERS, their adult colleagues are not. Family practice physicians are included because they expand the gap, but internists and geriatricians rarely have any knowledge about VAERS. What concerns her is that the people who work at LTCFs are not actually represented around the circle. The American Geriatrics Society (AGS) is there, but not the American Medical Directors Association (AMDA). She asked what has been done to reach out to other groups beyond ACIP liaisons and how many VAERS reports have actually been entered from LTCFs in the last year.

Dr. Shimabukuro said that CDC's communications folks are planning substantial outreach to partners, including long-term care partners, geriatric care partners, OB/GYNS, and other vaccinators. They certainly recognize the need to get the word out as rapidly and as broadly as possible on the availability and importance of VAERS and VAERS reporting. As far as how many reports have come from LTCFs, that is captured on the VAERS form though he did not have the total number of reports on hand. The category is more combined, so it could be LTCFs and community living facilities for older adults and it may not be possible to split these apart. CDC will look at this and will report back to ACIP, and will attempt to assess this by vaccine type as well.

Dr. Dooling added that many of the important constituents who will need to be plugged into VAERS to ensure its success for this program are represented as liaisons on the ACIP COVID-19 WG. CDC will continue to inform them and have them inform their liaison constituents.

Dr. Bernstein wondered whether CDC could work with cell phone carriers to have V-SAFE offered for download now the way updates are made for software and then practice teaching examples could be created so that vaccine recipients in the near future can begin to learn about V-SAFE and hit the ground running for their own individual safety monitoring after being vaccinated.

Dr. Shimabukuro said he would take this question back to CDC's technical experts at V-SAFE to see what they think about that.

Dr. Romero pointed out that in educating the public regarding these vaccines safety systems, it is going to be a very important to provide culturally and linguistically appropriate information to the general public so that they understand what this is all about and they enter data as appropriate. This is critical going forward in order to capture all signals that could arise from the use of these vaccines.

Dr. Hayes (ACNM) said she would submit suggestions for organizations that are not ACIP liaisons to ensure they are communicated with. She asked whether the app and consent forms are being translating into multiple languages other than just English and if so, how many languages.

Dr. Shimabukuro clarified that the V-SAFE program is not an app like on a cell phone. It is actually a text messaging program that includes a link to a survey. There are plans to translate the messages and survey into a variety of languages, with the first being Spanish.

Dr. Cohn added that V-SAFE and the survey, among other CDC products, will be translated into 5 languages. She emphasized that in addition to the 30 ACIP liaison organizations, CDC has hundreds of partners that they need to engage, listen to, educate, and talk to about all of this. They have very strong partnerships across the healthcare sector that have been solidified over the past year with the pandemic and they will ensure that extensive outreach is done beyond the ACIP community. She assured everyone that they absolutely take the advice and understand the importance of ensuring that CDC's outreach materials speak to HCP and others recommended to be vaccinated, to ensure that the communication materials are culturally appropriate and at a reading level that is accessible across the educational background of the health care community.

Interim Recommendation: Proposed Language for Phase 1a Allocation

Kathleen Dooling, MD MPH
Co-Lead ACIP COVID-19 Vaccine WG
Medical Officer, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

Dr. Dooling observed that they had seen the evidence and engaged in some very detailed discussions pertaining to critical considerations and safety in the rollout of future COVID vaccines. She asked the ACIP members to take a step back and look once again at the policy question at hand, "Should HCP and residents of LTCF be offered COVID-19 vaccination in Phase 1a?" and posed the following interim recommendation language:

When a COVID-19 vaccine is authorized by FDA and recommended by ACIP, health care personnel[§] and residents of long-term care facilities[¶] should be offered vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a)

[§]Health care personnel are defined as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials
¶ Long-term care facility residents are defined as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently.

Discussion Points

Dr. Poehling made a motion, which Dr. Ault seconded, to approve the proposed language.

Dr. Kimberlin (AAP Red Book) reminded everything that he asked at the November 23rd ACIP meeting for confirmation that people who work in LTCFs are considered HCP and was told that they are. He requested at least a verbal confirmation of that if not actually putting them in one of the little sub-bullets to explain that more directly.

Dr. Dooling confirmed that LTCF staff are included as HCP under the definition displayed and the details, including that group, will be included in a future *MMWR*. Other groups, such as EMS, community health, et cetera will be discussed in greater detail as well. The long-term care definition that they are going by, which is listed, refers to facilities that are providing medical and personal care. Occasionally, those are provided within a corrections facility and those would be included.

Dr. Atmar said that while he had no issue with the HCP, he remained somewhat concerned about including residents of LTCF in the Phase 1a group because of the lack of both safety and efficacy data in that patient population. He was somewhat persuaded by the support of the AGS and others and the information provided about the ease of administration at the same time to the resident population as vaccinations are being provided to the HCP working in that area. He was somewhat concerned about the issue that Dr. Talbot raised about the safety reporting. While plans are in place to do the monitoring, there is a potential for a lag of information arriving. It will be particularly important that as planned, the LTCFs be asked to participate vigorously in the VAERS program. Staffing to do that may be an issue and he is still worried about this group, although he was leaning toward including it.

Dr. Hunter said he was very strongly supportive of the interim recommendation as written, assuming that the sub-prioritization discussed earlier would be captured in guidance that is written as part of the publication of this vote in the *MMWR*. He asked how soon that might be available, especially to healthcare systems that are going to be needing that to do the prioritizations.

Dr. Oliver indicated that the clinical considerations, including sub-prioritizations that were discussed earlier in the day, would be summarized and posted on the CDC website, the ACIP website, and under the recommendation, including the HCP and LTCF information.

Ms. Howell (AIM) indicated that AIM surveyed 64 of its members regarding whether they would like LTCF residents included in Phase 1a with HCP. The turnaround was short, so there were only 19 responses. However, 14 responded that they would like long-term care residents included in Phase 1a, mostly for logistical reasons and concerns about uptake with vaccination among staff in long-term care. The one question or clarification that would be helpful is regarding the definition of LTCF. Ms. Howell thinks that many have been planning for skilled and assisted living. After today's meeting, Ms. Howell stated that she was getting the impression that it also may include group homes and then it was just mentioned that it might also include

corrections. Now she is also wondering about homeless shelters. If additional clarification could be provided on the definition of long-term care, that would be helpful.

Dr. Dooling clarified that LTCFs are primarily focusing on SNF and assisted living with an implied priority for SNF first and moving on to assisted living as vaccine supply dictates. It is understood that gating criteria will be needed to move from one phase to the next. As shown previously, it possible that they may be working on assisted living while moving into other phases.

Dr. Sanchez pointed out that as worded “HCP and residents of long-term facilities” would say that is the HCP of the long-term facilities. He suggested those two be separated as: 1) HCP; and 2) Residents of LTCF.

Dr. Szilagyi expressed strong support for this interim recommendation, including both HCP and residents of LTCF. There is incredibly high-risk among residents of LTCFs. While there is some concern over the modeling studies suggesting that vaccinating the HCP around the residents is more effective, if more protection could be added by vaccinating the residents, that swayed him. He was very impressed with the safety monitoring systems being designed and emphasized that the transparency with consent and assent in the LTCFs will be really important. That also swayed him to express strong support for this recommendation.

Ms. Bahta added her support if this interim recommendation and thanked the two CDC leads for such a well-thought-out process that they took to get to this point.

Dr. Hahn (CSTE) observed that most LTCF residents and potentially workers would be vaccinated through the pharmacy contract. His understanding for his immunization program is that it takes 2 weeks for the state request process to start and be turned on. Vaccine is not on their doorstep at this point, but there is a possibility that states will be hamstrung by the delay in getting vaccination started and will struggle to implement this recommendation. He wondered whether somebody could address that from a practical standpoint of trying to be fair in getting this started so that health care workers and long-term care residents are being offered vaccinations at the same time.

Dr. Cohn clarified that the intent of the vote for this meeting was to provide guidance and recommendations for health departments to place their orders for COVID-19 vaccine and determine how they want to implement this guidance at state and local levels. It is anticipated that if a state chooses to turn on a pharmacy program for LTCF residents in the first few days or week of the program, there would be enough time between the end of this week and vaccine availability. Substantial delays in that program are not anticipated, but it will be determined at the jurisdiction level how orders are placed.

Dr. Frey weigh in in favor of group 1a as it was currently categorized with healthcare workers and people living in LTCF. She thinks it is crucial to maintain health care capacity for vaccinating health care workers, but it also is important to prevent severe disease and death in the group that is at highest risk for those complications, and that includes the people in the LTCF. She was less concerned about risk early on in those in LTCFs because typically lesser immune responses are seen in this group in general. But this is an unknown platform that is being testing in thousands of people, and there is not a lot of good safety data at this time post-second vaccination. She remains concerned about vaccinating this group, but still thinks it is the appropriate thing to move forward and vaccinate the healthcare workers and folks in the LTCF

simultaneously in order to get the job done more quickly, keeping in mind oversight of safety at the same time.

Vote: Allocation of Initial Supplies of COVID-19 Vaccine: Phase 1a

Kathleen Dooling, MD MPH
Co-Lead ACIP COVID-19 Vaccine WG
Medical Officer, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

Dr. Dooling posted reworded language in accordance with feedback received during the previous session, explaining the rewording clarified the intent of the interim recommendation. Because the change was minor, a new motion and second were deemed unnecessary.

Motion/Vote: Interim COVID-10 Vaccine Recommendation Phase 1a

Dr. Poehling made a motion and Dr. Ault seconded to approve the revised language reading, "When a COVID-19 vaccine is authorized by FDA and recommended by ACIP, vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a) should be offered to both 1) health care personnel[§] and 2) residents of long-term care facilities[¶]."

§Health care personnel are defined as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials.
¶ Long-term care facility residents are defined as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently.
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No COIs were declared. The motion carried with 13 affirmative votes, 1 negative votes, and 0 abstentions. The disposition of the vote was as follows:

13 Favored:	Atmar, Ault, Bahta, Bell, Bernstein, Frey, Hunter, Lee, McNally, Poehling, Romero, Sanchez, Szilagyi
1 Opposed:	Talbot
0 Abstained:	N/A

Following the vote, Dr. Romero invited ACIP members who wished to do to reflect on the rationale for their votes:

Dr. Bernstein said that his decision to include the HCP in Phase 1a was straightforward. In contrast, the decision to include LTCF residents was initially a challenging one for him, especially when vaccine supply is initially constrained. Coupled with controlling resident direct contact with outside visitors and use of appropriate mitigation, he was thinking that vaccinating only staff was likely to notably minimize coronavirus exposure to LTCF residents. However, reflecting further on the data that has been presented over the last several months moved him to change his thinking on LTCF residents. In particular, LTCF residents and staff account for 6% of COVID cases and 40% of the deaths in the US. A majority of the COVID-related hospitalizations in those 75 years and older have been from LTCF. The systemic reactogenicity of the vaccine in a relatively small number of older adults appeared lower among the older age population in Phase I and Phase II trials, although LTCF populations were not included. While vaccination should be strongly encouraged, it is likely that vaccine uptake among LTCF staff will vary considerably, which is not ideal for limiting resident exposure. Lastly, there are federal pharmacy partners in place to help implement LTCF programs for residents. For all these reasons, he was in support of this policy question.

Dr. Talbot emphasized that she has struggled with this recommendation throughout these meetings. She has spent her career studying vaccines in older adults. Vaccines have traditionally been tested in a young, healthy population with the hope that they would work in frail older adults. Entering this realm of hoping it works and hoping it is safe concerns her on many levels, particularly for this vaccine. One concern is that there is less reactogenicity, which also means there is less immunogenicity. She also does not feel that the safety network for LTCF is strong enough and that work remains to be done. If time is going to be spent educating anyone, HCP are going to be incredibly important to vaccinate. It is known with influenza that there is a little impact on vaccinating residents, but major impact on vaccinating health care workers. She emphasized that she was still struggling with this and that it was not an easy vote. She expressed her hope that this would highlight that LTCF residents are a population who needs many vaccines, not just COVID-19. It is important to find ways of developing and testing vaccines to prolong the quality of life of LTCF residents. She stressed that she has no reservations for HCP taking this vaccine. There are amazing data about a respiratory vaccine that have never been seen before. It is incredibly exciting and she wants HCP to know that she has no reservations about them taking the vaccine whatsoever. She thanked ACIP for letting her serve and said she was very glad it is a village and not one person.

Dr. Bell reflected on the weight of the decision made during this meeting and the process upon which they are embarking. While they all would like to know more, they go through a process, evaluate carefully every bit of information available to them, and then comes a time when they need to act. She found the consistency with which all of her colleagues on the ACIP essentially had the same way of looking at the evidence that was available to them and settling on the same conclusions was testament not only to the fidelity of the process, but also to the soundness of the thinking for this moment. She thanked her colleagues for continuing to work through this to reach this point.

Dr. Romero reminded everyone that the WG and ACIP have spent 8 months discussing and evaluating the data. Whatever they have asked for has been presented to them and has been clearly discussed, both in the WG and in a public setting. Their discussions have been transparent and their motives clear. As stated previously, they are using the principles of maximizing benefits and minimizing harms, promoting justice, and mitigating health inequities. Those who are in the area of public health at this time see the growing number of cases that are coming before them. They see the growing number of HCP who have become infected, some of whom have unfortunately passed away. They see that individuals living in LTCF are at exceptional risk for morbidity and mortality due to this virus and disease. He believes that his vote reflects maximum benefit, minimum harm, promoting justice, and mitigating the health inequalities that exist with regard to distribution of this vaccine. It is because of that that he voted in favor of this recommendation. He expressed gratitude to the WG leads, Chair, and members of CDC from whom the WG and ACIP receive support. He stressed what an incredible honor it is has been to serve and how humbled he feels to lead ACIP.

Dr. Messonnier thanked the public and everyone listening to this incredibly important meeting. For all those who are anxiously awaiting a vaccine, she expressed her hope that this vote would get them one step closer to the day they can all feel safe again and the pandemic is over. In conclusion of the meeting, she thanked Dr. Romero for presiding over this meeting and for his work over the past year guiding the ACIP.

Certification

Upon reviewing the foregoing version of the December 1, 2020 ACIP meeting minutes, Dr. Jose Romero, ACIP Chair, certified that to the best of his knowledge, they are accurate and complete. His original, signed certification is on file with the Management Analysis and Services Office (MASO) of CDC.

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