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

Advisory Committee on Immunization Practices (ACIP)

Summary Report
November 23, 2020
Atlanta, Georgia

Final - November 19, 2020

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Centers for Disease Control and Prevention
Atlanta, Georgia 30329
November 23, 2020

	AGENDA ITEM	PRESIDER/PRESENTER(s)
Monday, November 23, 2020		
12:00	**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)
	EtR Framework: Public Health Problem, Resource Use and Equity Domains Discussion	Dr. Sara Oliver (CDC/NCIRD)
1:15	***Break***	
1:30	EtR Framework: Values, Acceptability and Feasibility Domains Discussion	Dr. Sara Oliver (CDC/NCIRD)
2:30	***Break***	
3:00	Phased Allocation of COVID-19 Vaccines Discussion	Dr. Kathleen Dooling (CDC/NCIRD)
4:30	***Break***	
4:40	**Public comment**	
5:00	**Adjourn**	

Acronyms

CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
COVID-19	Coronavirus disease 2019
EtR	Evidence to Recommendations Framework
FDA	Food and Drug Administration
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
NCHHSTP	National Center for HIV, Hepatitis, STD and TB Prevention [of CDC/OID]
NCIRD	National Center for Immunization & Respiratory Diseases [of CDC/OID]
NCEZID	National Center for Emerging and Zoonotic Diseases [of CDC/OID]
NIAID	National Institute of Allergy and Infectious Diseases
OIDP	Office of Infectious Disease and HIV/AIDS Policy
SAGE	Strategic Advisory Group of Experts
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
WG	Work Group
WHO	World Health Organization
VE	Vaccine Effectiveness

Acronyms

ACIP	Advisory Committee on Immunization Practices
AE	Adverse Event
CDC	Centers for Disease Control and Prevention
CISA	Cybersecurity and Infrastructure Security Agency
COI	Conflict of Interest
COU	Clinical Operations Unit
COVID-19	Coronavirus Disease 2019
CoVPN	COVID-19 Prevention Network
DHS	Department of Homeland Security
DSMB	Data Safety Monitoring Board
ED	Emergency Department
EHR	Electronic Health Record
ET	Eastern Time
EtR	Evidence to Recommendation
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
HCP	Healthcare Personnel / Providers
HCW	Healthcare Workers
HHS	(Department of) Health and Human Services
ICU	Intensive Care Unit
IDCRP	Infectious Disease Clinical Research Program
LTCF	Long-Term Care Facilities
MMWR	*Morbidity and Mortality Weekly Report*
mRNA	Messenger Ribonucleic Acid
NCIRD	National Center for Immunization and Respiratory Diseases
NIH	National Institutes of Health
OWS	Operation Warp Speed
PI	Principal Investigator
POD	Point Of Dispensing
PROGRESS-Plus System	Place of Residence, Race/Ethnicity, Occupation, Gender/Sex, Religion, Education
QI	Quality Improvement
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus-2
SDOH	Social Determinants of Health
SES	Socioeconomic Status
SLU	Saint Louis University
SNF	Skilled Nursing Facilities
SUD	Substance Use Disorder
UK	United Kingdom
US	United States
USG	US Government
VE	Vaccine Efficacy
VE	Vaccine Effectiveness
VRBPAC	Vaccines and Related Biological Products Advisory Committee Meeting
VTU	Vaccine Treatment Evaluation Unit

Opening Session

Welcoming Remarks

Robert R. Redfield, MD
Director, Centers for Disease Control and Prevention
Administrator, Agency for Toxic Substances and Disease Registry

Thank you very much and good afternoon. Thank you for giving me an opportunity to join you for this introduction. I wanted to start by just reflecting on a quote that has been very important to me in my life. I mentioned it to a number of CDC staff. It is a quote of President Teddy Roosevelt's that I think is appropriate at this point in time and it says, "It is not the critic who counts: not the man [and I'll paraphrase or woman] who points out how the strong man stumbles or where the doer of deeds could have done better. The credit belongs to the man [or woman] who is actually in the arena, whose face is marred by dust and sweat and blood, who strives valiantly, who errs and comes up short again and again, because there is no effort without error or shortcoming, but who knows the great enthusiasms, the great devotions, who spends himself [or herself] for a worthy cause . . ." [23 April 1910, Sorbonne, France].

I say that because I believe each of you are devoted to a worthy cause as we are right now trying to get a safe and effective vaccine to the American public. As the case counts rise across the United States, the implementation of the COVID-19 Vaccine Program is really more crucial than it has ever been before. I know our nation looks to you all to give your thoughtful and wise advice and recommendations as we stand now and face growing cases across our nation, complicated more by cold weather, the holiday season, and the increased strain on our health system across this nation.

So, I really just wanted to take a moment to thank you for your service and just underscore how important the thoughtful work that you are doing now to give the best guidance to these new vaccines, which really, it's very exciting that we now will have I think soon two vaccines available to distribute to the American public. I just want to thank you for being in the arena and making the tough decisions based on the data and your best thoughtful advice that you will give to see how this vaccine can begin to be distributed and ultimately, I believe, will ameliorate this pandemic that we face in the months ahead. So, that's what I really wanted to say, Amanda, and thank you for giving me the chance to make a comment to begin your meeting.

Dr. Redfield, this is Jose Romero, the Chair. I want to thank you on behalf of all the members and myself for those words and those thoughts. I think we will carry those with us through the next weeks as we come to recommendations for this vaccine. We understand the importance of this and we welcome the opportunity to improve the health and well-being of the American public. So, thank you very much to those kind words with the introduction and encouragement.

Dr. Redfield: Thank you. Thank you, Jose, and thank you for your leadership. God bless.

Call to Order, Overview, & Introductions

José Romero, MD, FAAP
ACIP Chair

Amanda Cohn, MD
Executive Secretary, ACIP / CDC

Dr. Romero officially called to order the November 23, 2020 emergency meeting of the Advisory Committee on Immunization Practices (ACIP), the primary purpose of which was to discuss Coronavirus Disease 2019 (COVID-19) Vaccine in terms of the Evidence to Recommendations (EtR) Framework and phased allocation of COVID-19 vaccines.

Dr. Cohn welcomed everyone and indicated that copies of the slides being presented during this meeting would be available until late afternoon 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 will be posted on the ACIP website approximately 1 week after the meeting. Meeting minutes will be posted on the ACIP website, generally within 90-120 days of the meeting.

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.

The ACIP is, at its heart, a public body. Engagement with the public and transparency in the processes are vital to the committee's work. As part of this commitment, ACIP has strengthened and written public comment process to maximize opportunities for comment and make public comment more transparent and efficient. For this meeting, one oral public comment period was scheduled for approximately 4:45 PM Eastern Time (ET). People interested in making oral public comments submitted a request online in advance of the meeting. Priority is given to advanced requesters. When more people request to speak than can be accommodated, a blind lottery is conducted to determine who the speakers will be. Speakers selected in the lottery for this meeting were notified in advance of the meeting. Any members of the public can also submit written public comments via https://www.regulations.gov using docket number docket ID CDC-2020-0117. Information on the written public comment process, including information about how to make a comment, can be found on the ACIP meeting website.

Members of the ACIP 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 that specific vaccine product. 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 announced the publication of "The Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020" in the *Morbidity and Mortality Weekly Report* (*MMWR*), which can be found at the following URL: https://www.cdc.gov/mmwr/volumes/69/wr/mm6947e3.htm. The primary author on this publication is Dr. McClung and includes multiple members of the ACIP COVID-19 Vaccine Workgroup (WG), as well as the Chair of the WG, Dr. Bell, and the two Co-Leads, Drs. Oliver and Dooling. This publication outlines the ethical principles that were used for identifying 4 groups for initial vaccine allocation. These groups have not been stratified as of yet and will not be stratified until a final vote is taken. As pointed out by Dr. Bell, the COVID-19 Vaccine WG Chair, this will not be done until vaccines are authorized by the Food and Drug Administration (FDA). The groups identified at this time were selected based on the available scientific data, vaccine implementation considerations, and ethical principles. In no particular order, they are: Healthcare Personnel (HCP); Other Essential Workers; Adults with High-Risk Medical Conditions; and Adults ≥65 Years of Age, Including Residents of Long-Term Care Facilities (LTCFs).

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 also has served as a Co-Investigator on the Moderna vaccine 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 Principal Investigator (PI) for the Moderna and Janssen 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.

A list of Members, *Ex Officio* Members, and Liaison Representatives is included in the appendixes at the end of the full minutes for the November 23, 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 for the November 23, 2020 emergency ACIP meeting, which focused on ACIP's continued response to the ongoing pandemic and accelerated vaccine development. She reminded everyone that during the October 30, 2020 emergency meeting, ACIP reviewed the following topics:

- ❑ Updates from Vaccines and Related Biological Products Advisory Committee Meeting (VRBPAC) Meeting
- ❑ Development Programs from 2 COVID-19 Vaccine Manufacturers
- ❑ Updates on Vaccine Implementation and Communication Plans
- ❑ Post-Authorization Safety Monitoring
- ❑ Ethical Principles and Modeling Strategies for Initial Allocation of COVID-19 Vaccines
- ❑ Updates to Immunity and Epidemiology
- ❑ WG Interpretation of Data
- ❑ Policy Questions, EtR Framework and Outcome

The COVID-19 Vaccine WG continues to meet on a weekly business. The topics this group has covered during November include the following:

- ❑ Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine
- ❑ Current Evidence for Each Domain in EtR Framework
- ❑ Further Discussions Around Initial Allocation Recommendations

Dr. Bell indicated that during this session, presentations would be provided in the following topic areas:

- ❑ EtR Framework: Public Health Problem, Resource Use, and Equity Domains
- ❑ EtR Framework: Values, Acceptability, and Feasibility Domains
- ❑ Phased Allocation of COVID-19 Vaccines

Dr. Bell reminded everyone that over 200 COVID-19 vaccines are currently under development. Within the US, 4 vaccines are in active Phase III clinical trials and 6 are in active Phase I/II clinical trials. Based on information provided from the manufacturers in their press releases, there is information about the efficacy of 2 messenger ribonucleic acid (mRNA) vaccines from the Phase III trials. The Pfizer/BioNTech BNT162b2 vaccine trial in a final analysis of 170 cases found 162 cases in the placebo group and 8 cases in the vaccine group, yielding a point estimate of 95% efficacy 7 days post-dose 2. The report and press release gave a 94% efficacy estimate in adults ≥65 years of age. There were 10 severe cases, 9 of which were in the placebo group. The DSMB found no serious safety concerns and an EUA was submitted to the Food and Drug Administration (FDA) by Pfizer/BioNTech on Friday November 20, 2020. The

data on the mRNA-1273 vaccine from Moderna reported an interim analysis of 95 cases of which 90 cases were in the placebo group and 5 cases were in the vaccine group, yielding a point estimate of 94.5% efficacy 2 weeks post-dose 2. There were 11 severe cases all of which were in the placebo group. The DSMB found no serious safety concerns and the manufacturer reports that they plan to submit an EUA soon. Also noteworthy is that AstraZeneca/University of Oxford put out a press release earlier in the morning reporting early results of their Phase III trials in the United Kingdom (UK) and Brazil.

In addition to these vaccines, there is a Janssen viral vector non-replicating vaccine with a 1-dose schedule that is currently recruiting. Novavax has completed enrollment of their Phase I/II trial of a protein subunit vaccine, and Sanofi/GSK is still recruiting on their Phase I protein subunit vaccine. Merck has a replicating viral vector vaccine in Phase I/II trials and Vaxart has a non-replicating viral vector vaccine in Phase I, both of which are recruiting. Inovio has a DNA plasmid vaccine in Phase 1 and Aivita has an AuDentric cell vaccine in Phase I/II. Neither of these is recruiting yet. There are 4 inactivated vaccines, 1 protein subunit vaccine, and 3 non-replicating viral vector vaccines in Phase III trials outside of the US that are actively recruiting. There is 1 non-replicating viral vector vaccine in Phase II/III, 7 non-replicating viral vector vaccine candidates in Phase I/II, 1 RNA vaccine in Phase II/III clinical trials, and 7 RNA vaccine candidates in Phase I/II outside of the US.

EtR Framework: Public Health Problem, Resource Use, and Equity Domains

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 on the EtR framework which she explained is a structure to describe information considered in moving from evidence to ACIP vaccine recommendations. It also provides transparency around the impact of additional factors on deliberations when considering a recommendation. As a reminder, ACIP will undergo deliberations for 2 separate policy questions:

1) Should a specific COVID-19 vaccine be recommended?
2) To whom should early allocation of COVID-19 vaccine be recommended?

She noted that the EtR framework would be used for the first policy question regarding whether the vaccine should be recommended for the US population, and that there would further allocation discussions in afternoon after the EtR framework presentation.

These are the domains used for EtR, with each domain having either one or several questions for which ACIP will provide judgment:

EtR Domain	Question
Public Health Problem	• Is the problem of public health importance?
Benefits and Harms	• How substantial are the desirable anticipated effects? • How substantial are the undesirable anticipated effects? • Do the desirable effects outweigh the undesirable effects?
Values	• Does the target population feel the desirable effects are large relative to the undesirable effects? • Is there important variability in how patients value the outcomes?
Acceptability	• Is the intervention acceptable to key stakeholders?
Feasibility	• Is the intervention feasible to implement?
Resource Use	• Is the intervention a reasonable and efficient allocation of resources?
Equity	• What would be the impact of the intervention on health equity?

To help make these questions easier, “the vaccine” or “the intervention” in question will be changed to “COVID-19 vaccine X” to be replaced by a specific vaccine name later. “The problem” also will be replaced with “COVID-19 disease.”

For the Benefits and Harms domain, which specifically discusses data for safety and efficacy, the Phase III clinical trial data will be used to inform this domain so it was not discussed further during this session. A new addition to the EtR framework is the Equity domain. The 3 domains discussed during this presentation included: Public Health Problem, Resource Use, and Equity. The Public Health Problem will not be impacted by individual vaccine characteristics. The overall Resource Use domain will have minimal impact currently by individual vaccine characteristics, although this will likely change over time. Additionally, the Equity domain will be impacted by individual vaccine characteristics. Dr. Oliver noted that her second presentation on the EtR Framework would focus on the Values, Acceptability, and Feasibility domains, all of which will be impacted by individual vaccine characteristics.

The presentations during this meeting focused on the current evidence and WG discussions around each EtR domain for future COVID-19 vaccines, and the identification of areas where the EtR judgment may vary by individual vaccine characteristics. While no vote was scheduled for this meeting, once the Phase III clinical trial data and an FDA decision are available, the EtR framework for a specific vaccine will be presented. It is expected that the information will continue to evolve, so the EtR framework and vaccine recommendations will be evaluated continually and updated as needed.

The main question associated with the Public Health Problem is, “Is COVID-19 disease of public health importance?” The additional questions to help inform this discussion include the following:

- ❑ Are the consequences of COVID-19 serious?
- ❑ Is COVID-19 urgent?
- ❑ Are a large number of people affected by COVID-19?
- ❑ Are there disadvantaged groups or populations disproportionately affected by COVID-19?

For each domain, the WG will be reviewing the available evidence to help answer questions addressed by the domain. For the Public Health Problem, as of November 21, 2020, there have been over 12 million cases of COVID-19 in the US, with a cumulative incidence of 3670 per 100,000 population. The cumulative hospitalization rate between March 1 and November 14, 2020 was nearly 230 per 100,000 population. Among those hospitalized, nearly one-third required intensive care and 15% died. As of November 21, 2020, there have been 255,076 COVID-19 associated deaths reported in the US and estimates of the SARS-CoV-2 infections fatality ratio ranged from 0.5% to 1.4%. There are other biologic factors associated with increased incidents, including age and the presence of underlying medical conditions, which have been presented in earlier ACIP meetings. Based on the review of the epidemiology data presented here, as well as the epidemiology data that have been presented at prior ACIP meetings, the WG judgment was that “Yes” COVID-19 disease is of public health importance.

The primary question for the Resource Use domain is, “Is COVID-19 vaccine X a reasonable and efficient allocation of resources?” The additional questions include:

- ❑ What is the cost-effectiveness of COVID-19 vaccine X?
- ❑ How does the cost-effectiveness change in response to changes in context, assumptions, et cetera?

The WG reviewed estimates of economic costs related to COVID-19 vaccinations, disease outcomes, and disease mitigation activities in coordination with National Center for Immunization and Respiratory Diseases (NCIRD) and ACIP’s lead economist. To summarize the available evidence, this involves the balance of the cost of COVID-19 disease and the cost of COVID-19 vaccines. For the cost of disease, it has been estimated that if 20% of the US population is infected with COVID, the direct medical costs could be $163 billion. Health-related costs of COVID-19 disease (including premature deaths, long-term health impairment, and mental health impairment) have been estimated at $8.5 trillion. In terms of the costs associated with COVID-19 vaccines, the US Government (USG) has committed at least $10 billion to Operation Warp Speed (OWS) for the provision of vaccines. In addition, vaccine doses purchased with US taxpayer dollars will be given to the American people at no cost.

The WG interpretation is that there are no published cost-effective analyses currently available. The precise cost-effective analysis and economic impact of vaccination depends on a number of factors that are currently unknown, including the duration of vaccine protection, vaccination coverage levels, and implementation costs associated with a large vaccination program. The WG concluded that cost-effectiveness may not be a primary driver for decision-making during a pandemic and for a vaccine used under EUA. However, this will need to be reassessed for future recommendations. At this time, the differences by individual vaccine characteristics is minimal relative to the overall scale of the pandemic. However, when cost-effectiveness is reassessed for routine implementation, individual vaccine characteristics will need to be taken

into account. Based on these discussions, the WG felt that "Yes" COVID-19 vaccine X is a reasonable and efficient allocation of resources.

The primary question for the new Equity domain is, "What would be the impact of COVID-19 vaccine X on health equity?" The additional questions include the following:

- Are there groups or settings that might be disadvantaged in relation to COVID-19 disease burden for receipt of COVID-19 vaccine X?
- Are there other considerations that should be made when implementing the COVID-19 vaccine X program to ensure that inequities are reduced whenever possible, and that they are not increased?

For a review of the available evidence on equity, the WG first worked to identify groups who might be disadvantaged in relation to COVID-19 disease burden or receipt of a COVID-19 vaccine X. This was done building upon other work that has been done in this area using a PROGRESS-Plus system, which is an acronym to identify factors associated with unfair differences in disease burden such as place of residence, race or ethnicity, occupation, gender or sex, religion, education,), social capital, disability, or other. A review of the scientific and gray literature was conducted in addition to reviewing CDC COVID-19 response data and resources.

Data from several specific populations were used to inform this discussion. While comprising only 40% of the US population, racial and ethnic minorities comprise 50% of COVID cases and 45% of COVID-19 deaths. Age-adjusted hospitalization rates are approximately 4 times higher among racial and ethnic minority groups compared to compared to non-Hispanic White persons. Inequities in social determinants of health (SDOH) put racial and ethnic minority groups at increased risk of COVID disease, including discrimination, lack of healthcare access, over-representation among essential workers, low-income, and crowded housing. Regarding people living in poverty or with high social vulnerability, COVID-19 cumulative case rates are 1.5 times higher in high versus low poverty counties and 1.3 times higher in counties with high versus low social vulnerability. Regarding essential workers, large outbreaks have been reported in multiple essential industries (food and agriculture, manufacturing, construction, wholesale trade). Racial and ethnic minority populations are disproportionately represented in subsets of essential workers. There are disadvantaged groups of note, including justice-involved persons, persons experiencing homelessness, persons with disabilities, persons with substance use disorders (SUDs), and sexual and gender minorities.

There were additional considerations for the equity domain. Although COVID-19 vaccines will be provided at no cost, personal investments in time and travel to obtain the vaccine may be a barrier for some groups. Importantly, characteristics of specific vaccines, including the storage and handling requirements, have the potential to greatly impact equitable distribution of COVID vaccines. Ultimately, the WG felt that equity could not be adequately assessed apart from these characteristics and had different assessments for the impact of health equity for different vaccines.

There are additional considerations that should be made when implementing the COVID vaccine X program to ensure that inequities are reduced whenever possible and that they are not increased. The WG discussed various considerations, including ways to identify groups disproportionately affected by COVID-19 or who face health inequities; undertake focused outreach and education; identify and address barriers to vaccination; and conduct active follow-up of disadvantaged groups to ensure completion of a 2-dose series or consider 1-dose COVID vaccines for group or follow-up may be difficult.

The WG felt that the successful implementation of a COVID-19 vaccination program and confidence in COVID-19 vaccines are pivotal to reducing health inequities. A quote that resonated with the WG representing the importance of an equitable implementation of the COVID-19 vaccine programs states, "…increasing the availability of an effective intervention within a country or region is not necessarily enough to reduce inequities. The intervention has to be accessible, acceptable, effective in, and used by the most disadvantaged groups within that population to be truly effective at reducing inequities in health" [O'Neill J, Tabish H, Welch V, et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. J Clin Epidemiol. 2014; 67: 56-64].

When reviewing available data on the equity of COVID-19 as well as characteristics associated with individual vaccines, the WG group discussed the impact of COVID-19 vaccine X on health equity. Specifically, for a vaccine with ultra-cold chain requirements limiting where a vaccine could be provided, there was concern that this particular vaccine when considered alone would probably reduce health equity. However, a vaccine that could be used in a broad range of vaccine providers for 1-dose vaccines could probably increase health equity.

The WG invited the ACIP to provide input on the 3 domains discussed in this presentation, with the discussion divided by individual domain.

Discussion Points

Public Health Problem Domain

- ❑ There was strong consensus from the committee that the data presented clearly demonstrates that COVID-19 disease is a serious public health problem and additional data/information on the public health problem is not needed before a vote.

Resource Use Domain

- ❑ There was strong consensus from the committee that sufficient information has been presented to date on resource use without the need at this time for a specific cost-effectiveness analysis.
- ❑ The committee agreed that cost-effectiveness may not be a primary driver for decision-making in the setting of a pandemic.
- ❑ The committee recognized that as additional vaccines become available for use with different levels of effectiveness for potentially different populations or subgroups, analysis of cost-effectiveness and economic impact will become more important and may be necessary to pursue further.

Equity Domain

- It behooves the nation to invest the necessary resources to make sure that if there are only one or two vaccine products, it will be possible to provide equitable access to all populations.

- Local considerations about implementation will have a large impact on equity and the populations that are reached with vaccine:
  - Equity and implementation are intertwined. Local and state health authorities require adequate resources to distribute COVID-19 vaccines to the most affected communities and ensure equitable access.
  - Local decisions about selection of initial administration venues and potential recipients will be critical for maximizing equity.
  - Although some vaccines have challenging handling and administration requirements such as cold-chain requirements, this should not preclude support, access, acceptability, and use of vaccine regardless of characteristics in order to help ensure equitable access. Additional guidance may be needed to make this clear to local jurisdictions as they begin to use vaccine.

- It is essential to ensure that the equity domain also includes age equity so that there are pediatric children of color and well as children of all ages.

- Focused outreach and education are critical:
  - Several hundred years ago, a medical professional said that the amount of resources devoted to a health problem should be proportionate to the need. The need is not just a healthcare need, it is also a social need. Difficulty in access is a need, so more resources must be devoted to subgroups of the population who have greater difficulties with respect to access.
  - There are studies showing that minority populations are less interested at this point in a future COVID vaccine.
  - Providers are a trusted source of information.
  - Information should be tailored to specific groups.
  - Low perceived acceptance should not result in reduced allocation to areas and populations, but rather in increased efforts and resources for focused outreach and education to improve vaccine acceptance.
  - To reach groups who normally do not seek information from public health's usual means of transmission, it may be necessary to identify thought leaders or influencers in communities who have the ability to change the current perception of the vaccine.
  - Willingness to receive vaccine is modifiable, especially in the setting of a pandemic.
  - Early experience with vaccine will be very important to increase interest and demand. It will be critical to collect information on everyone who is vaccinated in terms of the vaccination itself and any AEs.
  - Transparency is essential to improve trust and acceptability.

EtR Framework: Values, Acceptability, and Feasibility Domains

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 the EtR framework for the Values, Acceptability, and Feasibility domains again acknowledging that all of these domains will be impacted by individual vaccine characteristics.

The first question for the Values domain is, "Does the target population feel that the desirable effects are large relative to the undesirable effects?" Additional questions include the following:

- How does the target population view the balance of desirable versus undesirable effects?
- Would patients feel that the benefits outweigh the harms and burden?
- Does the population appreciate and value COVID-19 vaccine X?

The second question in the Values domain is, "Is there important uncertainty about, or variability in, how much people value the main outcomes?" Addition question related to this primary question include:

- How much do individuals value each outcomes in relation to the other outcomes?
- Is there evidence to support those value judgments?
- Is there evidence that the variability is large enough to lead to different decisions?

For the Values domain, the WG conducted a review of the scientific literature focusing on vaccine intent, confidence, and attitude with these search terms: SARS-CoV-2/COVID-19 string; vaccine string; intent, confidence, hesitancy, attitude, belief, accept, choice, decision, refusal. The search included scientific articles, news media and reports, and preliminary findings from CDC work, including a vaccine intent survey and focus group discussions.

The overall acceptability of COVID-19 vaccine was moderate. The proportion intending to receive the COVID-19 vaccine ranged from 42% to 86%. While nearly all of these surveys were performed prior to news for any specific vaccine, one survey was conducted after Pfizer's 90% efficacy announcement, after which a large proportion of people indicated their belief that the vaccine would be safe (68%) and effective (71%). Many surveys reported anticipated benefits to vaccinations to protect self, family, and community; prevent infection and severe illness; and return to normal life. Vaccine intensions varied by time, population, and vaccine characteristics with a decline from May to September. Acceptance was lowest among Black respondents and highest among Asian respondents. Acceptance was greater with higher SES, history of prior influenza vaccine or higher COVID-19 risk perception, higher VE, and strong healthcare provider recommendations. Based on a combination of 26 surveys, vaccine intent has declined since the initial surveys in the spring. However, surveys conducted in November appear to rebound slightly with higher acceptance. Based on 6 surveys that provided COVID-19 vaccine acceptance by race/ethnicity, vaccine acceptance was lowest among Black respondents. Some surveys showed lower acceptance in Hispanic respondents compared to White respondents, and Asian respondents reported the highest acceptability.

To summarize the available evidence for the Values domain, common reasons for not planning to receive a COVID-19 vaccine include concern for side effects, uncertainty of vaccine efficacy (VE), and low risk perception of COVID-19 or severe disease. A high VE was preferred. For many focus groups, most were open to receiving the vaccine, but many preferred not to be first. Many reported concerns that the vaccine approval process was fast. Limitations for these surveys include that they were conducted prior to an available vaccine or any specific data about the vaccines. Also, convenience samples for surveys or focus groups may not be representative of the entire US population. Broadly across national surveys, many adults reported intentions to receive a COVID-19 vaccine with a desire to protect themselves and their community and return to normal. However, concerns were raised around side effects, unknown efficacy, and the speed of the process. Intentions varied substantially by race, ethnicity, and SES.

The WG also discussed several strategies to consider for overcoming barriers to vaccine acceptance. This included engaging trusted sources, developing communication materials that are culturally appropriate, ensuring that providers have information on vaccines and vaccine recommendations, educating throughout specific communities and jurisdictions, and educating non-clinical staff around the benefits of vaccine. In terms of the WG interpretation for the first question, the plurality of the group felt that the answer to that is “Probably Yes” but also that it varies by vaccine, population, and over time. Not surprisingly when asked the second question regarding whether there was important uncertainty about or variability in how much people value the outcomes, the WG felt that there was “Important Uncertainty or Variability” or “Probably Important Uncertainty or Variability.”

In terms of the Acceptability domain, the main question is, “Is COVID-19 vaccine X acceptable to key stakeholders?” Additional questions include:

- Are there key stakeholders who would not accept the distribution of benefits and harms?
- Are there key stakeholders that would not accept the undesirable effects in the short-term for the desirable effects (benefits) in the future?

For this domain, the WG conducted a review of scientific literature and a review of preliminary findings from CDC evaluations of COVID-19 vaccine attitudes, including a survey with state health officers, focus groups with nurses, and online surveys of HCP. They also looked at broader stakeholders, including professional societies and workers unions and considered stakeholder opinions regarding programmatic, financial, and ethical aspects. There are no published provider knowledge, attitudes, and practices surveys. State health officers voiced concerns with vaccine hesitancy, safety, and communications. Seven different focus groups with nurses demonstrated that most supported prioritizing nurses, but some were reluctant to get vaccinated, especially nurses belonging to racial or ethnic minority groups. Another vaccine survey among HCP showed that 63% reported that they would get the vaccine once available. Information from the nurses survey demonstrates moderate acceptability of COVID-19 vaccine where 63% were confident that the vaccine would be safe and effective, but only 34% would voluntarily receive the vaccine.

To summarize the available evidence overall, all jurisdictions have submitted vaccine implementation plans, demonstrating at least some level of acceptance with the vaccine. Large and small pharmacy chains are participating in COVID-19 vaccine programs. State health officers had concerns around hesitancy, safety, and communications. Nurses reported a low percent to receive the vaccine. The WG overall felt that a COVID-19 vaccine X was "Probably Yes" acceptable to key stakeholders, but that it varies among the stakeholders.

The primary question associated with the Feasibility domain is, "Is COVID-19 vaccine X feasible to implement?" Additional questions include the following:

- ❑ Is the COVID-19 vaccine X program sustainable?
- ❑ Are there barriers that are likely to limit the feasibility of implementing COVID-19 vaccine X or require consideration when implementing it?
- ❑ Is access to COVID-19 vaccine X an important concern?

The WG discussed several barriers to implementation including financial barriers, complexity of recommendations, access to healthcare or vaccine providers, and vaccine storage and handling requirements. For financial barriers, all COVID-19 vaccines will be provided to the US population free of charge. However, health systems or health departments could incur the cost for vaccine implementation in clinics. Multiple vaccines under EUAs could make overall COVID-19 vaccine recommendations complex. Individual vaccine recommendations may contribute to complexity, including variations in the number of doses or the vaccine schedules. Population access to healthcare or vaccine providers could be limited in rural or other hard-to-reach areas. The range of providers providing a vaccine could be impacted by cold-chain storage requirements, populations with proven safety or efficacy, and populations recommended to receive the vaccine. Vaccines with ultra-cold requirements will be unable to be integrated into individual provider practices. However, vaccines with refrigerator temperature requirements will be easier to integrate. A large minimum size of orders could be a barrier to implementation. In many populations, requirements for a 2-dose series will be difficult.

The WG discussed that while these barriers to implementation might be insurmountable in traditional circumstances, there are innovative solutions to overcome these barriers including expanding funding opportunities, pharmacy partnerships, technology that includes second dose reminders, unique packing containers to maintain ultra-cold temperatures without a freezer, and detailed state micro-planning. Taking these barriers and the novel solutions into account, the WG felt that COVID-19 vaccine X is "Probably" feasible to implement.

This table shows all of the EtR domains discussed during this session. It is worth noting that many of the aspects where the WG did not reach a singular conclusion will be informed by specific vaccine characteristics or data in the weeks to follow:

EtR Domain	Question	Work Group Judgments
Public Health Problem	Is COVID-19 disease of public health importance?	Yes
Values	Does the target population feel the desirable effects are large relative to the undesirable effects?	Probably Yes/ Varies
	Is there important variability in how patients value the outcomes?	Important/ probably important uncertainty
Acceptability	Is the intervention acceptable to key stakeholders?	Probably Yes/ Varies
Feasibility	Is the intervention feasible to implement?	Probably Yes/ Varies
Resource Use	Is COVID-19 vaccine X a reasonable and efficient allocation of resources?	Yes
Equity	Does COVID-19 vaccine X have the potential to increase health equity?	Probably reduced/ Probably increased*

* *Judgment differed by COVID-19 vaccine

Before beginning discussions around the specific EtR domains, the WG wanted to let ACIP know that the WG is working its way through various proposed clinical considerations before there any specific vaccine recommendations. As discussed during the last ACIP meeting, pregnancy and breastfeeding were not felt to be contraindications to receiving a COVID-19 vaccine if individuals were otherwise recommended to receive a vaccine in early allocation phases. Given that prior mRNA vaccines have not been licensed, mRNA vaccines have not been studied in pregnant women. Regarding prior infection, again as was discussed during the last ACIP meeting, vaccination is recommended regardless of prior infection and testing for antibodies is not recommended prior to vaccination. However, while vaccine supplies are constrained, the WG discussed that vaccination of persons with recent prior infection may be delayed. However, the duration of protection after infection is unknown. Other topics have been or will be discussed by the WG for future presentations. These include co-administration with other vaccines, vaccine dosing schedules and intervals, and the impact of vaccine reactogenicity for HCP. These topics will not all require a specific ACIP vote, but would be included as interim clinical guidance.

ACIP was then invited to provide input individually on the domains of Value, Acceptability, and Feasibility.

Discussion Points

Values Domain

- Declines in vaccine intent are relatively recent and are likely mutable or modifiable:
  - Concerns among the populations who appear hesitant about a COVID-19 vaccine were predominantly about safety and vaccine characteristics.
  - As more data become available about these factors, it may be possible to modify intent.
  - There was agreement with strategies to overcome barriers and the notion that the barriers are modifiable.

- Patients need to know what to expect in terms of the potential for arm soreness, fatigue, body aches, fever, having to stay home from work, et cetera (e.g., reactogenicity reflects immune response to the vaccine) which can improve the likelihood of completing a 2-dose series. Perhaps term could be utilized that are less frightening to people such as "response" instead of "reaction."

- People who seek vaccine and value getting vaccine early will be important for messaging and increasing vaccine uptake by subsequent groups of recipients.

Acceptability Domain

- Trust and transparency are critically important to acceptability:
  - Some headway has been made on this by Moderna and Pfizer posting their protocols online and the FDA posting guidelines on what will be required to consider EUA.
  - HCP should get vaccinated to set an example and practitioners should begin having conversations with their patients early.

- In thinking about equity, it may be necessary to reconsider expanding the definition of "stakeholders" to include businesses and employers other than healthcare.

- It is important to remember that communities do not see vaccine as a categorical program, so thought must be given to this in the context of the COVID-19 response overall:
  - There will be a need to continue other mitigation measures and to support communities that desperately need economic assistance now to comply with isolation and quarantine and to meet the needs of mitigation to businesses and employees who are losing income and their jobs.
  - When talking to businesses and employees, they want to hear holistically how they are being supported in coping with COVID-19. To speak about vaccines without addressing other very pressing needs and not having the resources to do that is problematic in terms of acceptability.

Feasibility Domain

- Although COVID-19 vaccine will be provided at no cost, there are other costs that must be considered that have the potential to impact feasibility:
  - Some clinics providing tests are charging administrative fees to patients, which has been a barrier to others getting tested. The same could be true with vaccines, so it is important to ascertain how people can access vaccines without having to pay for an office visit and administrative fees.
  - Work is underway to address potential administrative costs associated with vaccine receipt which can be a deterrent (e.g., for uninsured patients, Prep ACT funding will allow for providers to be reimbursed for administrative costs).
  - Personal investments in time and travel (e.g., time off from work to be vaccinated or vaccine-associated side effects) may be a barrier for some, particularly for hourly workers who are not paid if they do not work.
  - There is a potential that an entire workforce could be impacted if everyone is vaccinated within a week and a significant portion experience fever. For instance, an entire Intensive Care Unit (ICU) could be incapacitated if the majority are vaccinated simultaneously and experience AEs. CDC does have a group working on this and this type of feasibility issue can be addressed in the clinical guidelines.

- While the focus should be on targeting people susceptible to COVID-19, screening of individuals for prior infection (i.e., presence of antibodies) should not be done:
  - Delaying vaccination for people with documented prior infection could be considered, although information on the duration of protection following natural infection is limited.
  - All of the clinical trials being conducted are assessing baseline antibody for evidence of prior infection. Hence at some point, there will be information about whether persons who had evidence of prior infection developed disease and whether the vaccine protected them.

- The committee emphasized that adequate funding must be available to deliver a vaccination program that is feasible to implement, values equity, and addresses issues of accessibility and acceptability. ACIP urged the relevant authorities to allocate parallel investment in the vaccine distribution and implementation structure to ensure that the accomplishments of the significant $10 billion investment over the last 9 to 11 months in vaccine research and development are fully realized.

- Communication between healthcare providers/healthcare systems and local public health authorities is essential throughout the vaccination program.

- Public/private partnerships at the local, state, and federal levels can be extremely beneficial.

- It will be imperative to engage a variety of stakeholders early to anticipate potential feasibility issues that may arise and identify strategies to mitigate these.

- The need for provider and patient educational materials and guidance is crucial. CDC noted that a health care provider toolkit and other materials will be available in the near future.

Phased Allocation of COVID-19 Vaccines

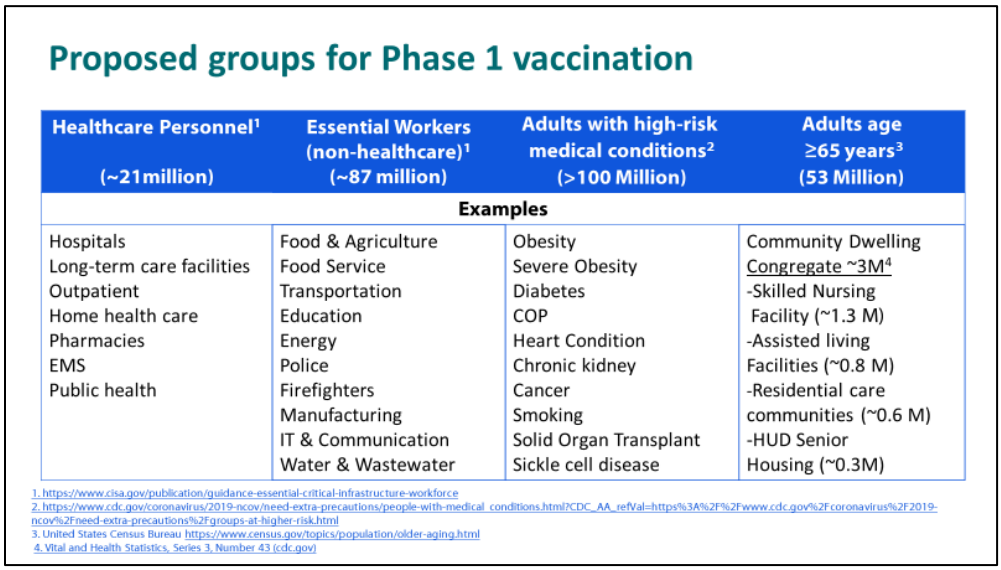
Kathleen Dooling, MD MPH
Co-Lead ACIP COVID-19 Vaccine WG
Medical Officer, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

Dr. Dooling presented on the phased allocation of COVID-19 vaccines. One there is a vaccine approved for use, there likely will be a period when there is insufficient vaccine to meet demand. Given that, the objective for this session was to select groups for COVID-19 vaccine allocation in Phase 1a,1b, and 1c. In the previous two presentations, Dr. Oliver led the group through the domains of the EtR. Those determinations will lead to a decision on recommendations for any given vaccine in order to answer Policy Question #2, “Which groups should be recommended to receive COVID-19 vaccine X during Phase 1?” Dr. Dooling modified the approach to focus on the pillars of science, implementation issues, and ethical considerations that inform this important question.

As for the science pillar, the WG examined COVID-19 disease burden and 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 of the target group and the feasibility of implementation in each of the groups. The ethical principles were presented to ACIP and supported by members during the last ACIP meeting. The principles aim to maximize benefits and minimize harms, promote justice, mitigate health inequities, and promote transparency throughout the vaccine policy process. These three pillars will be used to evaluate the proposed groups for Phase I vaccination. These groups are HCP, essential workers outside of healthcare, adults with high-risk medical conditions, and adults who are 65 years and older.

Recall that during the August emergency ACIP meeting, ACIP members expressed support for vaccinating HCP in Phase 1a. 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, LTCFs, outpatient settings, home health care, et cetera. Essential workers are "Those who work outside of healthcare, continue critical infrastructure, and maintain services and functions Americans depend on daily." The Cybersecurity and Infrastructure Security Agency (CISA), within the Department of Homeland Security (DHS) is tasked with creating the list of critical and essential workers that includes the sectors listed here:



Proposed groups for Phase 1 vaccination

Healthcare Personnel[1] (~21million)	Essential Workers (non-healthcare)[1] (~87 million)	Adults with high-risk medical conditions[2] (>100 Million)	Adults age ≥65 years[3] (53 Million)
Examples			
Hospitals Long-term care facilities Outpatient Home health care Pharmacies EMS Public health	Food & Agriculture Food Service Transportation Education Energy Police Firefighters Manufacturing IT & Communication Water & Wastewater	Obesity Severe Obesity Diabetes COP Heart Condition Chronic kidney Cancer Smoking Solid Organ Transplant Sickle cell disease	Community Dwelling Congregate ~3M[4] -Skilled Nursing Facility (~1.3 M) -Assisted living Facilities (~0.8 M) -Residential care communities (~0.6 M) -HUD Senior Housing (~0.3M)

1. https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce
2. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical_conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html
3. United States Census Bureau https://www.census.gov/topics/population/older-aging.html
4. Vital and Health Statistics, Series 3, Number 43 (cdc.gov)

The guidance acknowledges that workers who cannot perform duties remotely and must work in close proximities to others should be prioritized for mitigation measures. It also is important to recognize that sub-categories of essential workers may be prioritized differently in different jurisdictions, depending on local needs. The estimated population for this group is 87 million, but it should be noted that this is a very rough estimate and may be revised as workplaces evolve and find innovative ways to protect their workers and allow work at a distance. Next are adults with medical conditions at high-risk for severe COVID-19. The estimated population for this group is over 100 million adults. The conditions that put people at risk are being constantly refined according to the evidence and updated on the CDC website. Finally, adults 65 years of age and older number approximately 53 million. This group can be thought of as older adults living in the community and those who are living in congregate settings. About 3 million adults in the US live in congregate settings, such as skilled nursing facilities (SNF), assisted living, residential, and Housing and Urban Development (HUD) housing. The COVID-19 pandemic has taken a tremendous toll on this group, which will be examined in greater detail later on in the presentation.

To summarize the WG's considerations supporting vaccination HCP in Phase 1a. With respect to science, as of November 21st, there have been more than 220,000 confirmed COVID-19 cases among HCP with 822 deaths. COVID-19 exposure that occurs both inside and outside healthcare settings result in absenteeism either due to quarantine, infection, or illness. Vaccination has the potential to reduce HCP absenteeism. LTCF modeling demonstrates that more cases and deaths can be averted at the facility by vaccinating staff compared to vaccinating residents. Implementation considerations support the selection of HCP as acute care HCP routinely have high uptake of influenza vaccine and high vaccine acceptance. Many acute healthcare facilities have the equipment and expertise to carry out large-scale vaccination with a vaccine that requires ultra-cold storage. From an ethical perspective, vaccinating HCP with a safe and effective COVID-19 vaccine maximizes benefits by preserving health care services essential to the COVID-19 response and the overall health care system. Also, the HCP group is inclusive of all job types and health care settings and is racially and ethnically diverse.

Given ACIP's prior support of early allocation of vaccine to HCP, Dr. Dooling focused the remainder of the presentation on the remaining groups in Phase 1 by examining these groups through the lens of science, implementation, and ethics and highlighting the relevant differences. In terms of the science, national estimates of COVID-19 incidents of confirmed cases by age group show that COVID-19 incidents is highest in young adults. On the other hand, COVID mortality rates are highest in older adults. The national estimates of death per 100,000 population rises steeply after age 55. In terms of data on the proportion of COVID-associated hospitalized patients who were admitted from a LTCF, more than 30% of hospitalized patients aged 65 to 74 were admitting from a LTCF and more than half of hospitalized COVID-19 patients 75 years of age and older were admitted from a LTCF.

A published paper featuring COVID-Net data shows that risk for COVID-19-associated hospitalization increased with the number of underlying medical conditions. Compared to people without underlying medical conditions, adults with one or more conditions were significantly more likely to be hospitalized with COVID-19. That risk increased if a person had multiple conditions. Older adults living in the community also were more likely to be hospitalized for COVID-19 compared to younger adults. However, in this adjusted analysis, the magnitude of association for older age was smaller compared to having multiple comorbidities. It should be noted that persons living in long-term care were excluded from this analysis[1]. In contrast, among persons already hospitalized for COVID-19, risk of in-hospital death increased dramatically with age, with adjusted rate ratios ranging from 6 to 11 in age groups that were 65 years of age and older[2] [[1]Ko, Sept 2020, doi: 10.1093/cid/ciaa1419; [2]Kim *et al*, 2020, https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1012/5872581].

These data together demonstrate that older adults in congregate settings are disproportionately affected by COVID-19. LTCF residents and staff accounted for 6% percent of cases and 39% 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 8th had experienced approximately 470,000 confirmed and probable cases and more than 67,000 deaths. Assisted living facilities are home to approximately 800,000 residents nationally. Although surveillance is less systematic for this setting, states have reported thousands of cases and deaths among these residents.

To review the modeling data that were presented to the ACIP in October, the question was "What is the potential impact of preventing COVID-19 infections and deaths of initially allocating vaccine to one of the following groups after vaccinating HCP in Phase 1a?". The analysis was updated with a vaccine effectiveness (VE) input of 90% in younger and older adults and to reflect the current epidemiology. Full methods can be reviewed at the ACIP website at this link: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-10/COVID-Biggerstaff.pdf

In terms of the population-wide averted infections after 6 months from the beginning of the start of the vaccine program using an infection-blocking vaccine, assuming that there is no asymptomatic infection or transmission among vaccinated persons, initially vaccinating high-risk adults or essential workers in Phase 1b averts approximately 1% to 3% more infections compared to targeting persons 65 and older. Under the same timeline and assumptions of vaccine performance, but instead considering averted deaths, initially vaccinating adults 65 and older in Phase 1b averts approximately 0.5% to 2% more deaths compared to targeting high-risk adults or essential workers. If the extreme scenario is considered whereby the vaccine does not prevent asymptomatic infections or transmissions at all and only prevents disease, the overall percent of a population-wide averted deaths is much lower. Initially vaccinating adults 65 and older in Phase 1b averts approximately 2% to 6.5% more deaths compared to targeting high-risk adults or essential workers.

The WG concluded that the differences between the three strategies is minimal. Ethical principles and implementation considerations may greatly contribute to the selection of the optimal sequence in Phase 1b and beyond. The largest impact in averting deaths and infections is the timing of vaccine introduction in relation to increases in COVID-19 cases. This emphasizes the need to continue non-pharmaceutical interventions, such as wearing masks and social distancing. This analysis will continue to be updated as more information is collected. The factors that will inform interpretation of modeling going forward include estimates of VE in older adults and the vaccine's ability to prevent asymptomatic infection and transmission. In summary, the WG felt that the COVID-19 burden is high throughout the population and that the differences between sequencing strategies in terms of infections and deaths prevented was small.

Looking at the pillar of implementation, Dr. Dooling shared results depicting survey responses of intent to receive a COVID-19 vaccine as of September. Note that this was prior to any information publicly available about VE. Overall, 62% of survey respondents indicated that they were either absolutely certain, very likely, or somewhat likely to get a COVID-19 vaccine when it became available if it was available at no cost. The proportion was slightly higher for adults with high-risk medical conditions compared to those without those medical conditions, and higher in adults 65 years and older compared to younger adults. In a Harris Poll conducted in August, survey respondents supported the early allocation of COVID-19 vaccine to the groups proposed for Phase 1, with the strongest support for healthcare workers and seniors.

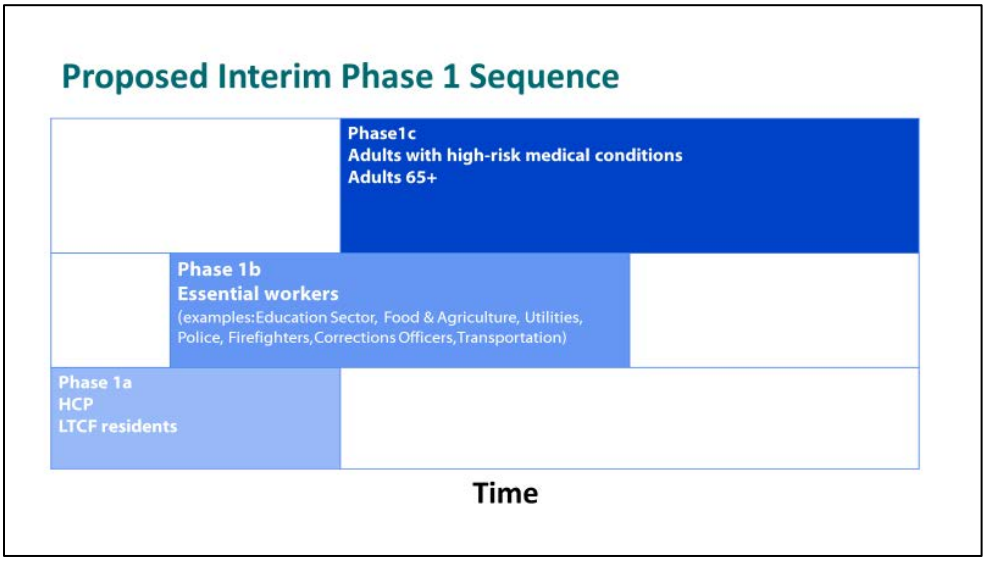
The WG considered a number of feasibility issues. For essential workers, it will be challenging to reach workers in rural locations, shift workers, those with multiple jobs, or those working in small cohorts. Jurisdictional approaches to overcome those challenges include on-site occupational clinics, pharmacy delivery, and health department point-of-dispensing (POD) strike teams. Most jurisdictions have and allocation micro-plan, which includes prioritization among non-healthcare essential workers and they are prepared for the period during which vaccine supply is limited. For adults with high-risk medical conditions, one of the biggest challenges may be determining eligibility. Healthcare homes, such as provider offices or pharmacies, could be better suited to verify the underlying medical conditions. Unfortunately, minimum size of vaccine orders and storage and handling requirements may preclude involvement of small clinics. For many, including adults 65 years and older, long distances to travel to central clinics and the necessity of large high-throughput clinics may be challenging. It should be noted that a federal pharmacy program has already been established to reach LTCF residents. Values, considered to be a combination of intent to get the vaccine and the values of the population, increased from essential workers to adults with high-risk medical conditions to older adults. Feasibility was thought to be slightly higher for essential workers and older adults than those with high-risk conditions. Overall, the WG felt that implementation would be easiest among older adults.

This is an application of the ethical principles to the three groups under discussion. The ACIP was introduced to this application during the October meeting. Additional details can be found in the MMWR publication that Dr. Romero announced during the opening session:

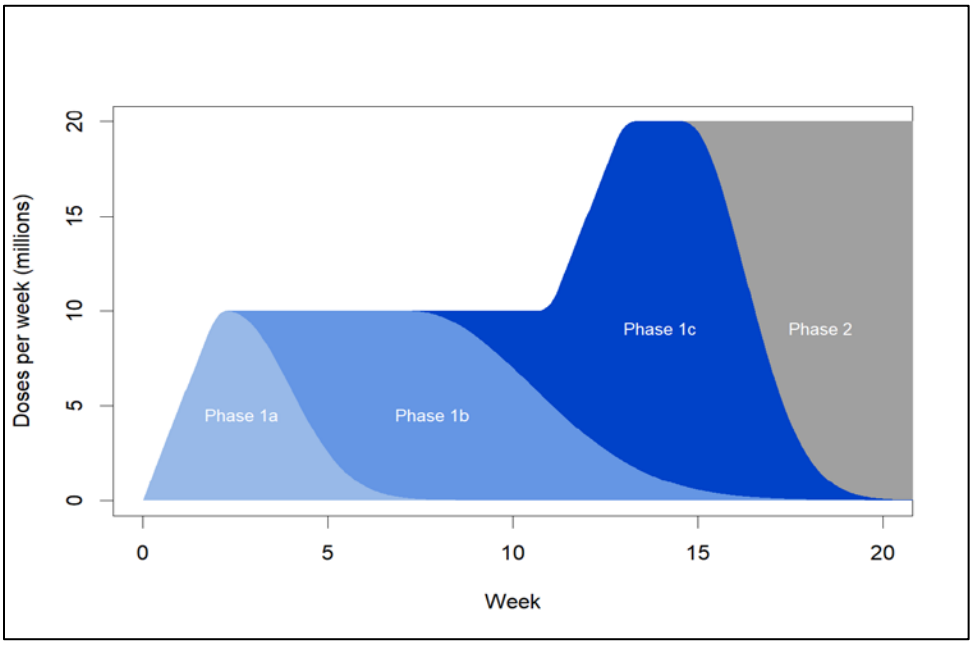
Ethical Principle	Essential Workers (non-healthcare) (~87 million)	Adults with high-risk medical conditions (>100 Million)	Adults age ≥65 years (53 Million)
Maximize benefits and minimize harms	Preserves services essential to the COVID-19 response and overall functioning of society "Multiplier effect"	Reduces morbidity and mortality in persons with high burden of COVID-19 disease and death	Reduces morbidity and mortality in persons with highest burden of COVID-19 hospitalization and death
Promote justice	-Workers unable to work from home (↑exposure risk) -Promotes access to vaccine and may reduce barriers for workers with low vaccine uptake	Will require focused outreach to those with limited or no access to healthcare	Will require focused outreach to those who experience barriers to access healthcare
Mitigate Health inequities	-Racial and ethnic minority groups disproportionately represented in many essential industries -~1/4 of essential workers live in low-income families	Increased prevalence of some medical conditions in race/ethnic minority groups & persons in rural areas -Diagnosis of medical conditions requires access to healthcare	-Highest incidence and mortality in congregate living --Racial and ethnic minority groups under-represented among adults ≥65

The darker green color indicates stronger support for that ethical principle. For essential workers, the WG noted that early vaccination of this group would strongly support maximizing benefits and minimizing harms, promote justice, and mitigate health inequities. Vaccinating adults with high-risk medical conditions moderately supported maximizing benefits and promoting justice. There were concerns that diagnosis of medical conditions may favor those who already have access to healthcare. The WG felt that early vaccination of adults 65 and older would strongly support maximizing benefits and minimizing harms. There were concerns that the racial and ethnic groups that have been disproportionately affected by COVID so far are underrepresented in this group.

The WG took all of this into consideration and here is the Proposed Interim Phase 1 sequence, which represents the majority of WG opinion:



As previously indicated, Phase 1a would include HCP. The WG also felt that given the burden of disease, likely benefits, implementation, and ethics supported the inclusion of LTCF residents in Phase 1a as well. The proposed Phase 1b includes essential workers, such as those who work in the education and childcare sector, food and agricultural, utilities, police, firefighters, corrections officers, and those who work in transportation. The proposed Phase 1c group includes adults with high-risk medical conditions and adults 65 years of age and older. This is an example of a schema depicting how the Phase 1 sequence might roll out over time:



There are two important things to note here. First, the phases will likely overlap in time and it will not be necessary to vaccinate 100% of one group before moving on to the next. Second, as more vaccine supply is expected in later months, this will allow broader and faster coverage.

There are some additional important WG considerations. The schema presented here presents an interim phase one sequence allocation policy that will need to be dynamic and adapted as new information, such as vaccine performance and supply/demand, become clearer. To that end, gating criteria will be needed to move expeditiously from one phase to the next as demand saturates. The WG reinforced that reaching essential workers may be challenging and will require jurisdictions to identify critical sectors at risk and optimal strategies to reach them. It is important to keep in mind that following vaccination, measures to stop the possible 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 USG has stated its commitment to making COVID-19 vaccines available to all residents who want them as soon as possible. At this time, the ACIP members were invited to provide specific feedback on Phases 1a, 1b, and 1c.

Discussion Points

Phase 1a
Long-Term Care Facility Residents

- ❑ Because LTCF residents were not enrolled in COVID-19 vaccine trials, safety and efficacy data are not available to assess the benefits and harms of COVID-19 vaccines in this group.

- ❑ Influenza VE is known to be reduced in older compared with younger adults and could be reduced for COVID-19 vaccines as well. However, even reduced VE could result in benefits, such as reduced COVID-19-related hospitalizations in this group and ease of the burden on strained healthcare systems.

- ❑ Reactogenicity following receipt of COVID-19 vaccine could lead to medical evaluation and treatment in this group and the potential for unnecessary harm.

- ❑ Baseline mortality among LTCF residents is high. Deaths temporally associated with receipt of COVID-19 vaccine during the early phases of vaccine distribution will be difficult to evaluate and could reduce overall public confidence in the safety of COVID-19 vaccines. Similar issues may arise following vaccination of people with high-risk medical conditions in phase 1c.

- ❑ Vaccinating both LTCF residents and staff on-site would offer efficiency in operations, likely would result in increased vaccine coverage, and likely would decrease intra-facility transmission between staff and residents.

- ❑ If consideration is given to delaying vaccination for previously infected individuals, some LTCF residents and staff have been previously infected with SARS-CoV-2.

- ❑ It was stated that 30% of LTCF residents turn over every 30 days. However, a subsequent written communication to the committee noted that "…many nursing homes have both short-stay residents that are there for post-acute care rehab, and longer-stay residents that reside there. Both populations would not be difficult to track in terms of second COVID-19 vaccine dose…hospitals in some states are still using nursing home post-acute care for COVID-19 convalescent care."

- Many LTCF staff and other HCP live in higher-risk communities. Vaccinating them can help to protect the health of others in their community.

- Some committee members indicated that provision of information to LTCF staff as well as to residents and their family members about COVID-19 vaccines, including available safety data and the lack of vaccine trial data for LTCF residents, would help to address their concerns if it was accompanied by consent for vaccination.

Health Care Personnel

- Given the limited amount of vaccine that will be available in the first few weeks based on estimates from OWS, all HCP cannot be vaccinated initially so subsets of HCP will need to be targeted. Possible examples noted by committee members included frontline HCP, HCP who cannot work remotely or who have inadequate PPE, and older HCPs and those with high-risk medical conditions.

- The need for clear guidance on prioritization of subsets of HCP was emphasized. The initial shipments of vaccine will likely go to tertiary care facilities due to the requirement for storage at ultra-cold temperatures. However, the risk for acquiring SARS-CoV-2 is higher for HCP working in the community at LTCFs.

- Among state health officials there is strong support for vaccinating HCP due to increased opportunities for exposure and the important role they play in the response.

Phase 1b

- There was strong agreement with inclusion of essential workers (non-healthcare) in Phase 1b, given that they are fundamental in the response to COVID-19.

- By nature of their jobs and often close proximity to one another, many essential workers are at increased risk and should be given the opportunity to be vaccinated early on.

- Participants applauded the emphasis on equity and identifying that the racial, ethnic, and low-come disparities, and the impact of COVID-19 warrants prioritization of such workers.

- Racial and ethnic minority groups are disproportionally represented in many essential industries and live in communities that are disproportionally affected. This offers an opportunity to really impact equity.

Gating Criteria

- This will be a dynamic process and they do not want to find themselves in a situation in which available vaccine is not being used as efficiently as possible:
  - Given all of the discussions and data reviewed about hesitancy and the willingness to be vaccinated, especially early on, not everybody in any given group is going to want to be vaccinated.
  - As demand is saturated in one group, it will be necessary to be ready to move onto the next group before 100% coverage is attained to ensure that vaccine is used as effectively as possible.
  - Clear guidance is going to be needed on gating criteria.

Overall Summary

- Of the 14 ACIP voting members, 12 expressed that they support Phases 1a, 1b, and 1c as presented.

- Overall, there was general agreement among the ACIP members with the proposed interim Phase 1 sequence, with 2 members expressing a desire for better data to inform recommendations about including LTCF residents in Phase 1a.

- All 14 ACIP voting members indicated agreement with essential workers as Phase 1b.

- Multiple stakeholders also agreed with the proposed interim Phase 1 allocation sequence.

Certification

Upon reviewing the foregoing version of the November 23, 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.

ACIP Membership Roster

Department of Health and Human Services
Centers for Disease Control and Prevention
Advisory Committee on Immunization Practices
July 1, 2019 – December 31, 2020

CHAIR
ROMERO, José R., MD, FAAP
Professor of Pediatrics
Horace C. Cabe Endowed Chair in Infectious Diseases Director,
Pediatric Infectious Diseases Section
University of Arkansas for Medical Sciences and Arkansas Children's Hospital
Director, Clinical Trials Research
Arkansas Children's Hospital Research Institute
Little Rock, AR
Term: 10/30/2018-06/30/2021

EXECUTIVE SECRETARY
COHN, Amanda, MD
Senior Advisor for Vaccines
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Atlanta, GA

MEMBERS
ATMAR, Robert L., MD
John S. Dunn Clinical Research Professor in Infectious Diseases
Departments of Medicine and Molecular Virology & Microbiology
Baylor College of Medicine
Chief, Infectious Diseases Service
Ben Taub General Hospital, Harris Health System
Houston, TX
Term: 7/1/2016 – 6/30/2020

AULT, Kevin A., MD, FACOG, FIDSA
Professor and Division Director
Department of Obstetrics and Gynecology
University of Kansas Medical Center
Kansas City, KS
Term: 10/26/2018 – 6/30/2022

BAHTA, Lynn, RN, MPH, CPH
Immunization Program Clinical Consultant
Infectious Disease, Epidemiology, Prevention & Control Division
Minnesota Department of Health
Saint Paul, Minnesota
Term: 7/1/2019 – 6/30/2023

BELL, Beth P., MD, MPH
Clinical Professor
Department of Global Health, School of Public Health
University of Washington
Seattle, WA
Term: 7/1/2019 – 6/30/2023

BERNSTEIN, Henry, DO, MHCM, FAAP
Professor of Pediatrics
Zucker School of Medicine at Hofstra/Northwell
Cohen Children's Medical Center
New Hyde Park, NY
Term: 11/27/2017-06/30/2021

FREY, Sharon E., M.D.
Professor and Associate Director of Clinical Research
Clinical Director, Center for Vaccine Development
Division of Infectious Diseases, Allergy and Immunology
Saint Louis University Medical School
Saint Louis, MO
Term: 11/27/2017-06/30/2021

HUNTER, Paul, MD
Associate Professor of Family Medicine and Community Health
University of Wisconsin School of Medicine and Public Health
Associate Medical Director
City of Milwaukee Health Department
Milwaukee, WI
Term: 7/1/2016 – 6/30/2020

LEE, Grace M., MD, MPH
Associate Chief Medical Officer for Practice Innovation
Lucile Packard Children's Hospital
Professor of Pediatrics, Stanford University School of Medicine
Stanford, CA
Term: 7/1/2016 – 6/30/2020

MCNALLY, Veronica V., JD
President and CEO
Franny Strong Foundation
West Bloomfield, Michigan
Term: 10/31/2018 – 6/30/2022

POEHLING, Katherine A., MD, MPH
Professor of Pediatrics and Epidemiology and Prevention Director,
Pediatric Population Health
Department of Pediatrics
Wake Forest School of Medicine
Winston-Salem, NC
Term: 7/1/2019 – 6/30/2023

SÁNCHEZ, Pablo J., M.D.
Professor of Pediatrics
The Ohio State University – Nationwide Children's Hospital
Divisions of Neonatal-Perinatal Medicine and Pediatric Infectious Diseases
Director, Clinical & Translational Research (Neonatology)
Center for Perinatal Research
The Research Institute at Nationwide Children's Hospital
Columbus, Ohio
Term: 7/1/2019 – 6/30/2023

SZILAGYI, Peter, MD, MPH
Professor of Pediatrics
Executive Vice-Chair and Vice-Chair for Research
Department of Pediatrics
University of California, Los Angeles (UCLA)
Los Angeles, California
Term: 7/1/2016 – 6/30/2020

TALBOT, Helen Keipp, MD
Associate Professor of Medicine
Vanderbilt University
Nashville, TN
Term: 10/29/2018 – 6/30/2022

EX OFFICIO MEMBERS

Centers for Medicare and Medicaid Services (CMS)
HANCE, Mary Beth
Senior Policy Advisor
Division of Quality, Evaluations and Health Outcomes
Children and Adults Health Programs Group
Center for Medicaid, CHIP and Survey & Certification
Centers for Medicare and Medicaid Services
Baltimore, MD

Food and Drug Administration (FDA)
FINK, Doran, MD, PhD
Deputy Director, Clinical, Division of Vaccines and Related Products Applications Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
Silver Spring, MD

Health Resources and Services Administration (HRSA)
RUBIN, Mary, MD
Chief Medical Officer
Division of Injury Compensation Programs
Rockville, MD

Indian Health Service (IHS)
WEISER, Thomas, MD, MPH
Medical Epidemiologist
Portland Area Indian Health Service
Portland, OR

Office of Infectious Disease and HIV/AIDS Policy (OIDP)
KIM, David, MD CAPT,
US Public Health Service Director Division of Vaccines
Washington, DC

National Institutes of Health (NIH)
BEIGEL, John, M.D.
Associate Director for Clinical Research
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases (NIAID) Bethesda, MD

LIAISON REPRESENTATIVES

American Academy of Family Physicians (AAFP)
ROCKWELL, Pamela G, DO
Associate Professor, Department of Family Medicine,
University of Michigan Medical School
Medical Director, Dominos Farms Family Medicine Ann
Arbor, MI

American Academy of Pediatrics (AAP)
MALDONADO, Yvonne, MD
Senior Associate Dean for Faculty Development and Diversity
Professor of Pediatrics and Health Research and Policy
Chief, Division of Pediatric Infectious Diseases
Stanford University School of Medicine
Stanford, CA

American Academy of Pediatrics (AAP)
Red Book Editor
KIMBERLIN, David, MD
Professor of Pediatrics
Division of Pediatric Infectious Diseases
The University of Alabama at Birmingham School of Medicine
Birmingham, AL

American Academy of Physician Assistants (AAPA)
LÉGER, Marie-Michèle, MPH, PA-C Senior
Director, Clinical and Health Affairs
American Academy of Physician Assistants
Alexandria, VA

American College Health Association (ACHA)
CHAI, Thevy S, MD
Director of Medical Services
Campus Health Services
University of North Carolina at Chapel Hill
Chapel Hill, NC

American College Health Association (ACHA) (alternate)
MCMULLEN, Sharon, RN, MPH, FACHA
Assistant Vice President of Student & Campus Life for Health and Wellbeing
Cornell Health
Ithaca, NY

American College of Nurse Midwives (ACNM)
HAYES, Carol E., CNM, MN, MPH Lead
Clinician
Clinical Quality Compliance and Management
Planned Parenthood Southeast
Atlanta, GA

American College of Nurse Midwives (ACNM) (alternate)
MEHARRY, Pamela M., PHD, CNM
Midwifery Educator, Human Resources for Health
In partnership with University of Rwanda and University of Illinois, Chicago

American College of Obstetricians and Gynecologists (ACOG)
ECKERT, Linda O., MD, FACOG
Professor, Department of Obstetrics & Gynecology
Adjunct Professor, Department of Global Health
University of Washington
Seattle, WA

American College of Physicians (ACP)
GOLDMAN, Jason M. MD, FACP
Affiliate Assistant Professor of Clinical Biomedical Science, Florida Atlantic University, Boca Raton, Florida
Private Practice
Coral Springs, FL

American Geriatrics Society (AGS)
SCHMADER, Kenneth, MD
Professor of Medicine-Geriatrics
Geriatrics Division Chief
Duke University and Durham VA Medical Centers
Durham, NC

America's Health Insurance Plans (AHIP)
GLUCKMAN, Robert A., MD, MACP
Chief Medical Officer, Providence Health Plans
Beaverton, OR

American Immunization Registry Association (AIRA)
COYLE, Rebecca, MSEd
Executive Director, AIRA
Washington, DC

American Medical Association (AMA)
FRYHOFER, Sandra Adamson, MD
Adjunct Associate Professor of Medicine
Emory University School of Medicine
Atlanta, GA

American Nurses Association (ANA)
RITTLE, Charles (Chad), DNP, MPH, RN

Assistant Professor, Nursing Faculty
Chatham University, School of Health Sciences
Pittsburgh, PA

American Osteopathic Association (AOA)
GROGG, Stanley E., DO
Associate Dean/Professor of Pediatrics
Oklahoma State University-Center for Health Sciences
Tulsa, OK

American Pharmacists Association (APhA)
FOSTER, Stephan L., PharmD CAPT (Ret)
U.S.P.H.S.
Professor, College of Pharmacy
University of Tennessee Health Sciences Center
Memphis, TN

Association of Immunization Managers (AIM)
HOWELL, Molly, MPH Immunization Program Manager
North Dakota Department of Health
Bismarck, ND

Association for Prevention Teaching and Research (APTR)
McKINNEY, W. Paul, MD
Professor and Associate Dean
University of Louisville School of Public Health and Information Sciences
Louisville, KY

Association of State and Territorial Health Officials (ASTHO)
SHAH, Nirav D, MD, JD
Director
Maine Center for Disease Control and Prevention
Augusta, ME

Biotechnology Industry Organization (BIO)
ARTHUR, Phyllis A., MBA
Senior Director, Vaccines, Immunotherapeutics and Diagnostics Policy
Washington, DC

Council of State and Territorial Epidemiologists (CSTE)
HAHN, Christine, MD State
Epidemiologist
Office of Epidemiology, Food Protection and Immunization Idaho
Department of Health and Welfare
Boise, ID

Council of State and Territorial Epidemiologists (CSTE) (alternate)
LETT, Susan, MD, MPH
Medical Director, Immunization Program
Division of Epidemiology and Immunization
Massachusetts Department of Public Health
Boston, MA

Canadian National Advisory Committee on Immunization (NACI)
QUACH, Caroline, MD, MSc
Pediatric Infectious Disease Specialist and Medical Microbiologist
Medical Lead, Infection Prevention and Control Unit
Medical Co-director – Laboratory Medicine, Optilab
Montreal-CHUM
Montreal, Québec, Canada

Infectious Diseases Society of America (IDSA)
BAKER, Carol J, MD
Professor of Pediatrics
Molecular Virology and Microbiology
Baylor College of Medicine
Houston, TX

International Society for Travel Medicine (ISTM)
BARNETT, Elizabeth D, MD
Professor of Pediatrics
Boston University School of Medicine
Boston, MA

National Association of County and City Health Officials (NACCHO)
ZAHN, Matthew, MD
Medical Director, Epidemiology
Orange County Health Care Agency
Santa Ana, CA

National Association of County and City Health Officials (NACCHO) (alternate)
DUCHIN, Jeffrey, MD
Health Officer and Chief, Communicable Disease Epidemiology and Immunization Section
Public Health - Seattle and King County
Professor in Medicine, Division of Allergy and Infectious Diseases
University of Washington School of Medicine and School of Public Health
Seattle, WA

National Association of Pediatric Nurse Practitioners (NAPNAP)
STINCHFIELD, Patricia A., RN, MS, CPNP
Director, Infectious Disease/Immunology/Infection Control
Children's Hospitals and Clinics of Minnesota
St. Paul, MN

National Foundation for Infectious Diseases (NFID)
SCHAFFNER, William, MD
Chairman, Department of Preventive Medicine
Vanderbilt University School of Medicine
Nashville, TN

National Foundation for Infectious Diseases (NFID) (alternate)
DALTON, Marla, PE, CAE
Executive Director & CEO
National Foundation for Infectious Diseases (NFID)
Bethesda, MD

National Medical Association (NMA)
WHITLEY-WILLIAMS, Patricia, MD
Professor and Chair
University of Medicine and Dentistry of New Jersey
Robert Wood Johnson Medical School
New Brunswick, NJ

Pediatric Infectious Diseases Society (PIDS)
O'LEARY, Sean, MD, MPH
Associate Professor of Pediatrics
Pediatric Infectious Diseases
General Academic Pediatrics
Children's Hospital Colorado
University of Colorado School of Medicine

Pediatric Infectious Diseases Society (PIDS) (alternate)
SAWYER, Mark H, MD
Professor of Clinical Pediatrics
University of California, San Diego School of Medicine
San Diego, CA

Pharmaceutical Research and Manufacturers of America (PhRMA)
ROBERTSON, Corey, MD, MPH
Senior Director, US Medical, Sanofi Pasteur
Swiftwater, PA

Society for Adolescent Health and Medicine (SAHM)
MIDDLEMAN, Amy B., MD, MSEd, MPH
Professor of Pediatrics
Chief, Section of Adolescent Medicine
University of Oklahoma Health Sciences Center
Oklahoma City, OK

Society for Healthcare Epidemiology of America (SHEA)
DREES, Marci, MD, MS
Chief Infection Prevention Officer & Hospital Epidemiologist
ChristianaCare
Wilmington, DE
Associate Professor of Medicine Sidney Kimmel Medical College at Thomas Jefferson University
Philadelphia, PA