

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

**Advisory Committee on
Immunization Practices (ACIP)**



**Summary Report
September 22, 2020
Atlanta, Georgia**

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Final - September 21, 2020**MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)**

Centers for Disease Control and Prevention

Atlanta, Georgia 30329

September 22, 2020

<u>AGENDA ITEM</u>	<u>PRESIDER/PRESENTER(s)</u>
Tuesday, September 22, 2020	
10:00 Welcome & Introductions	Dr. José Romero (ACIP Chair) Dr. Amanda Cohn (ACIP Executive Secretary, CDC)
10:30 Coronavirus Disease 2019 (COVID-19) Vaccines	
Introduction	Dr. Beth Bell (ACIP, WG Chair)
Overview of COVID-19 vaccine safety	Dr. Grace Lee (ACIP)
Enhanced vaccine safety surveillance	Dr. Tom Shimabukuro (CDC/NCEZID)
Vaccine implementation	Dr. Nancy Messonnier (CDC/NCIRD)
12:00 Lunch	
12:45 Disparities among COVID-19 Epidemiology	Dr. Megan Wallace (CDC/NCIRD)
Overview of vaccine equity and prioritization frameworks	Dr. Sara Oliver (CDC/NCIRD)
2:00 Break	
2:15 Phase 1 allocation for COVID-19 vaccine: Work Group considerations	Dr. Kathleen Dooling (CDC/NCIRD)
3:30 Break	
3:45 Public Comment	
4:30 Adjourn	

Acronyms

CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
COVID-19	Coronavirus disease 2019
DoD	Department of Defense
DVA	Department of Veterans Affairs
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

AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ACA	Affordable Care Act
ACHA	American College Health Association
ACIP	Advisory Committee on Immunization Practices
ACOG	American College of Obstetricians and Gynecologists
ACP	American College of Physicians
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
AI/AN	American Indian/Alaskan Native
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
AMA	American Medical Association
AOA	American Osteopathic Association
APhA	American Pharmacists Association
ASPR	Assistant Secretary for Preparedness and Response
ASTHO	Association of State and Territorial Health Officers
ATS	American Thoracic Society
BEST	Biologics Effectiveness and Safety
CDC	Centers for Disease Control and Prevention
CEA	Cost-Effectiveness Analysis
CEPI	Coalition for Epidemic Preparedness Innovations
CFR	Code of Federal Regulations
CISA	Clinical Immunization Safety Assessment
CISA	Cybersecurity and Infrastructure Security Agency
CKD	Chronic Kidney Disease
CMS	Center for Medicare and Medicaid Services
COI	Conflict of Interest
COU	Clinical Operations Unit
COVID-19	Coronavirus Disease 2019
CoVPN	COVID-19 Prevention Network
CVD	Cardiovascular Disease
DFO	Designated Federal Official
DHA	Defense Health Agency
DoD	Department of Defense
DSMB	Data Safety Monitoring Board
EHR	Electronic Health Record
EMS	Emergency Medical Services
ET	Eastern Time
EtR	Evidence to Recommendation
EUA	Emergency Use Authorization
FDA	Food and Drug Administration

GRADE	Grading of Recommendation Assessment, Development and Evaluation
GSK	GlaxoSmithKline
HAIs	Healthcare-Acquired Infections
HHS	(Department of) Health and Human Services
IDCRP	Infectious Disease Clinical Research Program
ICU	Intensive Care Unit
IDSA	Infectious Disease Society of America
Ig	Immunoglobulin
IHR	International Health Regulation
IHS	Indian Health Service
IIS	Immunization Information Systems
JHSPH	Johns Hopkins Bloomberg School of Public Health
LTCF	Long-Term Care Facilities
MedDRA	Medical Dictionary for Regulatory Activities
MMRV	Measles, Mumps, Rubella, and Varicella
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
mRNA	Messenger Ribonucleic Acid
MIS-C	Multisystem Inflammatory Syndrome in Children
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
NHIS	National Health Interview Survey
NHSN	National Healthcare Safety Network
NMA	National Medical Association
NYC	New York City
OCR	Office for Civil Rights
OWS	Operation Warp Speed
PCR	Polymerase Chain Reaction
PHAC	Public Health Agency Canada
PhRMA®	Pharmaceutical Research and Manufacturers of America®
PIDS	Pediatric Infectious Disease Society
PPE	Personal Protective Equipment
RNA	Ribonucleic Acid
SAGE	Strategic Advisory Group of Experts on Immunization
SAHM	Society for Adolescent Health and Medicine
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus-2

SDOH	Social Determinants of Health
SHEA	Society for Healthcare Epidemiology of America
SLU	Saint Louis University
SME	Subject Matter Expert
SPEAC	Safety Platform for Emergency vACcines
SVI	Social Vulnerability Index
TA	Technical Assistance
US	United States
VA	(US Department of) Veteran's Affairs
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
VRBPAC	Vaccines and Related Biological Products Advisory Committee Meeting
V-SAFE	Vaccine Safety Assessment for Essential Workers
VSD	Vaccine Safety Datalink
VTU	Vaccine Treatment Evaluation Unit
WG	Work Group
WHO	World Health Organization

Call To Order, Welcome, Overview, Announcements, & Introductions

José Romero, MD, FAAP
ACIP Chair

Amanda Cohn, MD
Executive Secretary, ACIP / CDC

Dr. Cohn called to order the September 22, 2020 meeting of the Advisory Committee on Immunization Practices (ACIP), indicating that it was ACIP's third emergency meeting to discuss Coronavirus Disease 2019 (COVID)-19 vaccines. She welcomed everyone participating by Zoom or watching via the live webcast.

She indicated that copies of the slides for this meeting would be available until 5:00 PM Eastern Time (ET) on the ACIP website at the following URL:

<https://www.cdc.gov/vaccines/acip/meetings/slides-2020-09.html>

Dr. Cohn explained that at the end of the meeting, the slides would be removed from the site, made 508-compliant, and returned to the website within approximately 4 weeks of the meeting. Additionally, the slides to be presented during this meeting were made available through a ShareFile link for ACIP Voting, Liaison, and *Ex-Officio* members. The live webcast videos will be posted approximately 4 weeks following the meeting, and the meeting minutes are posted to the ACIP website generally within about 120 days following 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. If running early, a break would be taken until time for the next item on the agenda.

The next regularly scheduled ACIP meeting also will be virtual. That meeting will be convened on October 28-29, 2020. This will once again be a virtual meeting and it is anticipated that the agenda for this meeting will cover both COVID-19 vaccines as well as other routine business.

Dr. Cohn explained that this meeting's oral and written public comment processes were 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. For this meeting, one oral public comment period would be held in the afternoon beginning at approximately 3:45 PM. Additionally, written public comments may be made via regulations.gov using Docket Number ID CDC-2020-0093. Information on the written public comment process, including information about how to make a public comment, can be found on the ACIP website.

As noted in the ACIP Policies and Procedures manual, 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, 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. 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 and prior to each vote, if any, ACIP members state any COIs. While ACIP members would be stating their COIs at the beginning of this meeting, no votes were scheduled that would prohibit members who declared COIs from participating in the meeting.

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.
- ❑ Dr. Sharon Frey is employed by Saint Louis University (SLU). SLU has a Vaccine Treatment Evaluation Unit (VTU) that is part of the IDCRC. She is currently working with the CoVPN on the Moderna COVID-19 vaccine trials and anticipates working on the Janssen trial and others in the future.
- ❑ Dr. Paul Hunter owns a small amount of stock in Pfizer and has received a small grant from Pfizer to conduct a quality improvement project on pneumococcal vaccines.
- ❑ Dr. Pablo Sánchez receives grant support from Merck for research focused on global antibiotic use, which is soon ending.

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

Coronavirus Disease 2019 (COVID-19) Vaccines

Introduction

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

Dr. Bell introduced the session and provided a few brief updates. As a reminder, during the August 26, 2020 meeting, ACIP reviewed the following:

- Moderna's mRNA COVID-19 Vaccine Clinical Development
- Pfizer/BioNtech's mRNA COVID-19 Vaccine Clinical Development
- Overview of Post-Marketing Safety Surveillance
- Epidemiology of Individuals at Increased Risk of Severe COVID-19 Disease
- WG Interpretation
- Prioritization and WG Next Steps

Since that time, the COVID-19 Vaccine WG has been meeting weekly. Topics covered during the August WG meetings included the following:

- Review of Published COVID-19 Vaccine Prioritization and Allocation Frameworks
- Qualitative Research on a Future COVID-19 Vaccine
- Clinical Development Program for a COVID-19 Vaccine, Including Data from Phase I/II Clinical Trials and Plans for Phase III Clinical Trials
- Racial and Ethnic Disparities in COVID-19 Testing, Exposure, Severity, and Impact
- Association Between Social Vulnerability and Risk of Becoming a COVID-19 Hotspot
- Proposal for Ethics/Equity Framework for COVID-19 Vaccine Allocation
- Further discussions regarding COVID-19 vaccine allocation

Dr. Bell indicated that the agenda for the September 22, 2020 ACIP meeting would include presentations on the following topics:

- Overview of COVID-19 Vaccine Safety
- Enhanced Vaccine Safety Surveillance
- Vaccine Implementation
- Disparities in COVID-19 Epidemiology
- Overview of Vaccine Equity and Prioritization Frameworks
- Phase 1 Allocation for COVID-19 Vaccine: WG Considerations

Regarding considerations for prioritization of COVID-19 vaccines, Dr. Bell noted that two of the presentations would be particularly relevant, including disparities among COVID-19 disease and a proposal for ACIP's Ethics & Equity Framework and a review of groups for allocation of initial COVID-19 vaccine. Moving forward in future sessions, the WG envisions continuing to discuss the Evidence to Recommendation (EtR) Framework for COVID-19 vaccines, review additional manufacturer data as they become available, and prepare for independent review of safety and efficacy data from Phase III clinical trials.

In terms of the status of vaccines globally, over 200 COVID-19 vaccines are currently under development. Within the United States (US), there are two vaccines in Phase III clinical trials that are actively enrolling. There is one vaccine in Phase III clinical trials, which is currently on hold. There are three vaccines in Phase I/II clinical trials that are actively recruiting. The two vaccines in Phase III clinical trials that are actively recruiting are the mRNA-1273 vaccine from Moderna and the BNT162b2 vaccine from Pfizer/BioNtech. The Moderna mRNA-1273 Phase III trial reported 25,296 participants enrolled as of 9/16/2020, with 28% of the participants enrolled being from "diverse communities." The Pfizer/BioNtech BNT162b2 vaccine trial reported 31,928 participants enrolled as of 9/21/2020, with 26% of participants enrolled having "diverse backgrounds." Pfizer/BioNtech has proposed expansion of its clinical trial to 44,000 participants.

Additional COVID-19 vaccines in human clinical trials in the US include the University of Oxford/AstraZeneca vaccine, which is currently on hold, and three other trials that are currently recruiting. These include a non-replicating viral vector vaccine by Janssen Pharmaceutical, a protein subunit vaccine by Sanofi/GlaxoSmithKline (GSK), and a protein subunit vaccine by Novavax. There also are a number of vaccines in human clinical trials outside of the US that are actively recruiting. There are six inactivated candidate vaccines currently recruiting in trials throughout the world. There are nine viral vector vaccines, most of which are still in Phase I/II trials with the exception of the University of Oxford/AstraZeneca and a vaccine manufactured in Russia that are in Phase III trials. There are six protein subunit vaccines in human clinical trials outside of the US being studied in Australia, Taiwan, and South Africa. There are three mRNA and four DNA vaccines in human clinical trials outside of the US in parts of Europe, South Korea, Singapore, Japan, and India.

In terms of the path forward for ACIP to vote on and make COVID-19 vaccine recommendations, the WG is meeting weekly as mentioned to review Phase I/II data from manufacturers as the data become available and to design the structure for independent data review that will occur once Phase III data are available. Once data are available from Phase III clinical trials, the ACIP WG will conduct independent reviews of safety and efficacy data using the EtR Framework and the Grading of Recommendation Assessment, Development and Evaluation (GRADE) system. Based on this data review, the WG will present policy options to the full ACIP. The ACIP makes recommendations about Food and Drug Administration (FDA) licensed or authorized vaccines. If and when an FDA decision is announced about a particular vaccine, the ACIP will convene an emergency meeting with a public comment session. The ACIP will review the safety and efficacy data using the GRADE system and the EtR framework. The ACIP will then vote on recommendations for the vaccine and the populations for use. Notably, the ACIP recommendations could be more targeted or detailed than the FDA “Conditions of Use” that accompany licensure. After an ACIP vote, the ACIP submits the recommendations to the CDC Director. If those recommendations are accepted, they are published in the *Morbidity and Mortality Weekly Report (MMWR)* and become official CDC policy.

Overview of COVID-19 Vaccine Safety

Grace M. Lee, MD MPH

Chair, ACIP COVID-19 Vaccine Safety Technical Subgroup

Associate CMO, Stanford Children’s Health

Professor of Pediatrics, Stanford University School of Medicine

Dr. Lee provided an overview of the COVID-19 vaccine safety activities on behalf of the ACIP COVID-19 Vaccine Safety Technical Subgroup (VaST). She emphasized that safety is not the absence of risk. Everyone takes risks every day, whether it is getting on a plane to see loved ones or going outside for a walk when it is fire season on the west coast. Safety is actually about finding an acceptable balance of benefits and risks.

There are two independent advisory committees that review vaccine safety on a regular basis. The Vaccines and Related Biological Products Advisory Committee (VRBPAC) provides advice to the Commissioner of the FDA. VRBPAC evaluates data concerning the safety, effectiveness, and appropriate use of vaccines for which the FDA has regulatory responsibility. ACIP provides advice and guidance to the Director of the CDC. ACIP provides recommendations on the use of

vaccines in the U.S. civilian population based on disease epidemiology, vaccine safety, vaccine efficacy and effectiveness, the quality of the evidence reviewed, economic analyses, and implementation issues.

Vaccine safety data are routinely considered by ACIP WGs. The role of ACIP is to deliberate about benefit-risk balance and recommendations for use. ACIP is routinely updated on post-market safety and effectiveness data for vaccines, and modifies those recommendations as needed. Decision-making is intended to be a dynamic process as new data and evidence emerge. For COVID-19 vaccines, a separate safety group was assembled in June 2020 to support the COVID-19 Vaccines WG and the full ACIP on the safety of COVID-19 vaccines in development, post-authorization, and post-licensure.

The VaST includes three ACIP members (Lee, Bell, Talbot); seven consultants with expertise in coronavirus immunology, clinical trials, vaccine safety, pregnancy, and risk communication (Belongia, Daley, Edwards, Kuldorff, Riley, Perlman, and Viswanath); and *Ex Officio* members (CDC, FDA, DoD, VA, IHS, HRSA, HHS, NIH, BARDA). Dr. Lee extended gratitude to the CDC Lead, Dr. Tom Shimabukuro, for his leadership of this group.

The terms of reference for VaST that were developed in May 2020 are to serve as the central hub for technical subject matter experts (SMEs) to: 1) review and interpret pre-authorization/pre-licensure SARS-CoV-2 vaccine candidate safety data; 2) review and interpret post-authorization/post-licensure SARS-CoV-2 vaccine safety data; and 3) provide advice and guidance on presenting post-authorization/post-licensure SARS-CoV-2 vaccine safety data to the COVID-19 Vaccines WG, the full ACIP, and the general public.

VaST convened its kickoff meeting on June 8, 2020, which was then followed by an overview on June 22nd of vaccine-associated enhanced respiratory disease (VAERD) as an outcome; this potential adverse event (AE) is important in the selection of vaccine candidates to minimize a theoretical risk of VAERD. On July 2nd, VaST had the opportunity to meet with global vaccine safety colleagues to discuss potential adverse events of special interest (AESI), a case definition in progress for VAERD, and standardized Brighton Collaboration templates. They then had four full meetings discussing the capabilities of post-marketing vaccine safety surveillance systems for monitoring the safety of COVID-19 vaccines, including the Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), Clinical Immunization Safety Assessment (CISA), Center for Medicare and Medicaid Services (CMS), FDA, Veteran's Affairs (VA), Department of Defense (DoD), Indian Health Service (IHS), National Healthcare Safety Network (NHSN), and Vaccine Safety Assessment for Essential Workers (V-SAFE). VaST also recently discussed frameworks for risk communication.

Two key statements have been endorsed by VaST. First, VaST asked its colleagues whether safety monitoring for Phase III clinical trials should be harmonized in terms of definitions for AESIs and/or duration of follow-up. The group said "yes" that harmonization is critical for timely evaluation. It would allow for the combination of data, if appropriate, by maximizing the sample size for any given AESIs. It would also allow for the comparison of safety across different vaccine platforms and trials, if appropriate, and enable the dynamic assessment of benefit-risk balance. The group also felt that harmonizing with international standards, such as the Brighton Collaboration, would be preferred. Similar to the FDA guidance on COVID-19 VE that was published in the summer, the group felt that FDA guidance is needed on vaccine safety standards. The COVID-19 vaccine clinical trials that are in progress or planned are currently

proposed to include between 30,000 to 50,000 participants per trial. These trials are designed for efficacy, but also can be designed for safety, if sufficient follow-up is allowed. For example, rotavirus vaccine trials were specifically designed with safety as a primary endpoint. The minimum duration of follow-up needed to assess safety, or the benefit-risk balance, depends upon the types of AEs events and the associated risk intervals.

The second question VaST asked of their colleagues pertained to whether safety monitoring for post-authorization or post-licensure safety surveillance systems should be harmonized. There was general agreement that it is critical for timely evaluation similar to clinical trials. Common protocols, outcome definitions, risk windows, and approaches to severity grading can support rapid evaluation of statistical signals. However, it is recognized that different systems may have different capabilities, such as billing versus electronic health record (EHR) data, to identify exposures or outcomes and that systems may need to align rather than fully harmonize in certain instances.

The group felt that the capability for timely evaluation of statistical signals is crucial for vaccine confidence, and that coordination across post-market safety surveillance systems is recommended similar to the experience with H1N1 vaccine safety. As a reminder, near real-time safety surveillance systems are designed to optimize sensitivity. Therefore, statistical signals should be expected in a robust monitoring program. Two examples include syndromic surveillance performed in four states which identified 62 alerts corresponding to 17 distinct signals, but only two true clusters of illness were detected. More specifically, in the VSD, Yih and colleagues published their experience of monitoring safety for five different vaccines, following five to seven AESIs per vaccine. While 10 statistical signals occurred, 9 were spurious; only one was a true signal that led to a revised ACIP recommendation for measles, mumps, rubella, and varicella (MMRV) vaccine. Timely and thorough investigations of statistical signals are needed to distinguish true associations.

VaST adopted the Safety Platform for Emergency vACcines (SPEAC) classification of AESIs. SPEAC is a collaboration between the Coalition for Epidemic Preparedness Innovations (CEPI) and the Brighton Collaboration. They anticipate bringing prioritizations forward in future meetings. General AEs of interest are those typically monitored for vaccines such as anaphylaxis. Platform-specific (e.g., mRNA, viral vector, adjuvanted) AESIs of interest will be based on the findings from clinical trials. Population-specific AESIs of interest might include multisystem inflammatory syndrome in children (MIS-C) in children.

At this point, it is anticipated that there will be a transition in the role of VaST. During the current pre-authorization or pre-licensure phase, VaST will remain focused on discussing prioritized AESIs; discussing common protocols for enhanced passive and active surveillance; discussing approaches to signal refinement and evaluation; and reviewing and refining membership of the data review group in the post-authorization or post-licensure phase. Once vaccine candidates are licensed or authorized for use, VaST will prospectively review, evaluate, and interpret the safety data from ongoing clinical trials in near real-time and from passive, enhanced passive, and active surveillance systems. VaST will advise on signal refinement, signal evaluation activities, and data presentation to ACIP and the public.

In order to succeed at this task, VaST highlighted six conditions for success. First, the ability to capture vaccine exposure in vaccine safety surveillance systems is needed. Clarity is needed not only on the distribution processes and the documentation of vaccines administered, but also to ensure that this information can and will be linked to outcome data in systems that are planning surveillance of COVID-19 vaccines. Second, the ability to define background rates of AESI in the general population and among those with COVID-19 disease is necessary for success. This is challenging, but reliance on background rates is important to understand what typical rates might look like. COVID-19 has changed the way that patients utilize health services, which makes it particularly challenging. Understanding rates among those with COVID-19 disease is important because some of the outcomes they hope to monitor are actually seen with COVID-19 disease. In order to best assess the benefit-risk balance, it will be important to have information on rates following disease as well as post-vaccination. Third, it will be necessary to minimize conflicts of interest among members of the data review group. Fourth, VaST believes that a learning health system's approach to vaccine is needed with shared review and shared learning across all COVID-19 vaccine safety surveillance systems. Fifth, the VaST has requested and been granted the ability for the data review group to discuss findings independently. Six, a well-developed communication plan will be needed on safety issues throughout the lifecycle of vaccines. Strong collaborations and partnerships will be needed in order to meet the needs of ACIP, provider organizations, and the public.

In closing, systems have been designed to detect safety signals. It is how those signals are collectively handled that will define the country's ability to respond to COVID-19.

Discussion Points

Dr. Fryhofer (AMA) asked whether the Department of Health and Human Services (HHS) Secretary also is involved in the process after the CDC recommendations are sent to the CDC Director.

Dr. Cohn indicated that CDC would confirm this. Typically, under the Federal Advisory Committee Act (FACA), the CDC Director makes the final decision and informs the HHS Secretary.

Dr. Goldman (ACP) stressed the importance of taking safety very seriously to ensure public confidence in the process and applauded the COVID-19 Vaccines WG and the VaST in their strong work for examining the detailed processes in order to have a safe and effective vaccine.

Dr. Whitley-Williams (NMA) observed that Dr. Lee's slide on population-specific AESIs, the high-risk groups listed included children, pregnant women, the elderly, and those with co-morbidities. Although not applicable for all vaccine-preventable diseases, but certainly with COVID-19, certain under-represented populations have been disproportionately affected. Therefore, she wondered why under-represented minorities were not included in the population-specific list of AESIs.

Dr. Lee indicated that at this time, VaST is focused more on the general and platform-specific AESIs primarily because until they have the Phase III clinical trial data for all sub-populations, it will not be possible to assess which sub-populations of specific interest there will be. She expressed appreciation for Dr. Whitley-Williams raising the issue and emphasized that this was not a final list per se. Under-represented populations and those disproportionately affected by

COVID-19 disease are certainly a population under consideration. They will look at the clinical trials as they enroll diverse populations to determine whether there might be any differences between under-represented minorities versus others.

Enhanced Safety Monitoring for COVID-19 Vaccines in Early Phase Vaccination

Tom Shimabukuro, MD, MPH, MBA
Immunization Safety Office
Vaccine Safety Team
CDC COVID-19 Vaccine Planning Unit (VPU)
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Shimabukuro provided an overview of enhanced vaccine safety monitoring for COVID-19 vaccines in early phase vaccination. The challenge identified for safety monitoring in early recipients is that during the early phase of a national COVID-19 vaccination program, the initial doses may be distributed to specific groups such as healthcare personnel (HCP) and other essential workers. In this scenario, activities to enhance traditional vaccine safety monitoring systems such as VAERS will be necessary. The response will include preparing traditional monitoring systems as best as possible, conducting active surveillance in early recipients through smartphone- and email-based web surveys, and obtaining vaccination and safety monitoring data from healthcare facility and long-term care facility (LTCF) surveillance.

As a reminder, VAERS is the U.S. national spontaneous reporting or passive surveillance system early warning safety monitoring system that is co-managed by the CDC and the FDA. Anyone can submit a report to VAERS. Manufacturers are required to submit reports to VAERS of AEs that come to their attention. Reporting is now 100% electronic either through the VAERS portal for public report or through the electronic submission gateway for manufacturers. VAERS essentially has the entire U.S. population of roughly 320 million US residents covered for safety monitoring for all ages, races, states, healthy people, those with co-morbidities, et cetera. In recent years, VAERS has received approximately 60,000 reports per year or just over 1000 reports per week.

VAERS serves as the nation's early warning system to detect possible safety issues with U.S. vaccines, and traditionally has provided initial data on the safety profile of new vaccines when they are introduced for use in the population. COVID-19 vaccine report processing times will be quick. Processing times will be 1 day for reports of death, 3 days for reports classified as serious, and 5 days for reports classified as non-serious. These timeframes are from the time the reports are received until the time they become available to the CDC and FDA for analysis. CDC and FDA receive updated datasets daily. During routine times each morning, the CDC and FDA receive a "Data Extract," which is basically a refresh of the entire VAERS database.

In terms of VAERS analysis for COVID-19 reports, FDA scientists will review all VAERS reports classified as "serious" per routine. Attempts are made to follow-up on all serious reports to get medical records and other medical documentation. Based on the Code of Federal Regulations (CFR), a "serious" report is defined as a report of "death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly or birth defect." CDC scientists will review VAERS reports for AESIs. The CDC and FDA coordinate on the analysis of VAERS data and both agencies conduct data mining. The following is a preliminary list of

VAERS AESIs, which is subject to change and could expand or contract depending upon the results of the Phase III clinical trials and surveillance data in the post-authorization period as it begins to accumulate:

Preliminary list of VAERS AESIs	
▪ COVID-19 disease	▪ Seizures / convulsions
▪ Death	▪ Stroke
▪ Vaccination during pregnancy	▪ Narcolepsy / cataplexy
▪ Guillain-Barré syndrome (GBS)	▪ Autoimmune disease
▪ Other clinically serious neurologic AEs (group AE)	▪ Anaphylaxis
– Acute disseminated encephalomyelitis (ADEM)	▪ Non-anaphylactic allergic reactions
– Transverse myelitis (TM)	▪ Acute myocardial infarction
– Multiple sclerosis (MS)	▪ Myocarditis / pericarditis
– Optic neuritis (ON)	▪ Thrombocytopenia
– Chronic inflammatory demyelinating polyneuropathy (CIDP)	▪ Disseminated intravascular coagulation (DIC)
– Encephalitis	▪ Venous thromboembolism (VTE)
– Myelitis	▪ Arthritis and arthralgia (not osteoarthritis or traumatic arthritis)
– Encephalomyelitis	▪ Kawasaki disease
– Meningoencephalitis	▪ Multisystem Inflammatory Syndrome in Children (MIS-C)
– Meningitis	
– Encephalopathy	
– Ataxia	

To demonstrate how quickly VAERS can accumulate data and characterize the safety profile of a new vaccine when it is authorized or approved and begins to be used in the population, Influenza A (H1N1) 2009 vaccines were licensed in mid-September 2009. They did not become available until well into October 2009. The analytic period for an analysis published in the *MMWR* on December 4, 2009 was through November 24, 2009. This is a matter of weeks from when CDC and FDA began conducting enhanced surveillance for H1N1 vaccines to the time this was published. The take-home message for this initial MMWR report was that the data were reassuring and that the safety profile for H1N1 vaccines was similar to that observed for season influenza vaccines.

Moving on to enhanced monitoring programs to meet the challenge of COVID-19, V-SAFE is a smartphone-based text, text-to-web survey, and email-to-web survey active surveillance program for early vaccine recipients. It uses contact information, including phone numbers from the registration process for COVID-19 vaccination of essential workers. This could be up to 20 million people during the first few months of a vaccination program. Health checks of vaccine recipients will be conducted via text messages and email. These will be conducted daily during the first week post-vaccination and weekly thereafter for 6 weeks post-vaccination. Active telephone follow-up will be conducted with persons reporting a clinically important AE during any V-SAFE health check. These health checks are basically text messages that are sent out to the vaccinated individuals who can respond either by text, by clicking on a link to fill out a web survey, or by email in cases where there are no phone numbers. A VAERS report will be taken during telephone follow-up, if appropriate.

CDC will have access to registered individuals. Upon notification that an individual has been vaccinated, CDC will begin the text messaging process. There is bidirectional communication of CDC reaching out to the vaccinated individual and them sending information back to CDC via the mechanisms described. Based on the responses received from vaccinated individuals, if any clinically important VE is reported by the vaccinated person, CDC will then transmit information to the existing VAERS call center to follow-up via phone with the individual and to complete a VAERS report if appropriate. Per usual, those VAERS reports will go to the CDC and FDA. Here is a sample of a text that an individual would receive during the first week when receiving daily text messages:

The image shows a text message form with two main sections. The left section is titled 'Symptoms check' and contains several sub-sections for reporting symptoms: 'Site Reaction', 'Infection (Body System) Reactions', 'Fatigue or weakness', 'Nausea', and 'Redness or tenderness'. Each sub-section has a 'Check all that apply' checkbox and a list of symptoms with radio buttons for severity (Mild, Moderate, Severe). The right section is titled 'Health Impact' and asks 'Did any of the symptoms or health conditions you reported TODAY cause you to (check all that apply)?'. It includes three checkboxes: 'Miss work?', 'Be unable to do your normal daily activities?', and 'Get care from a doctor or other healthcare professional?'. Below these is a 'What type of healthcare visit did you have?' section with checkboxes for 'Virtual health or email health consultation', 'Outpatient clinic or urgent care illness visit', 'Emergency room or emergency department visit', and 'Hospitalization'. A note at the bottom of the right section says 'If your symptoms bothered you, we encourage you to report your experience to the Vaccine Adverse Event Reporting System (VAERS)'. A blue bracket on the left side of the 'Health Impact' section points to the three checkboxes and is labeled 'Defines clinically important'.

The important component of this in terms of active follow-up for clinically important AEs occurs on the righthand side in that if an individual checks any one of the 3 boxes defined as clinically important, it would constitute a clinically important AE and would trigger the cascade of action where CDC sends the contact information to the call center for follow-up to take a VAERS report. While the clinically important AE in the text is fairly general, the VAERS report will be specific and will go through the normal VAERS process in which detailed information is collected on the signs and symptoms and goes through a Medical Dictionary for the Regulatory Activities (MedDRA) coding process.

CDC has validated the basic text messaging collection methods for vaccine safety monitoring. Smartphone-based safety monitoring of early COVID-19 vaccine recipients will allow for the estimation of rates of local and systemic reactogenicity and rates of clinically important AEs following immunization. Smartphone-based safety monitoring of early COVID-19 vaccine recipients will allow for the comparison of observed rates of AEs with background rates in the population and with known rates following other types of vaccinations such as influenza.

To describe enhanced VAERS reporting using the National Healthcare Safety Network (NHSN) sites, COVID-19 vaccine safety surveillance and facilitated VAERS reporting for healthcare workers and long-term care facility (LTCF) residents will occur through NHSN. NHSN is a CDC surveillance system with the principle purpose of monitoring healthcare-acquired infections (HAIs). The NHSN sites will track weekly vaccine doses administered by dose number in healthcare workers and LTCF residents, which is denominator data. The NHSN sites are well-

positioned to identify AEs among COVID-19 vaccine recipients at their sites, which is the numerator data. VAERS staff will match reports in VAERS to NHSN sites using facility address information, which means that the CDC can identify reports originating from NHSN facilities. This allows for calculation of crude overall reporting rates and AE-specific reporting rates.

To describe some of the established monitoring systems for a general vaccination program, national monitoring systems are robust and timely. VAERS reports are received and processed within days of program implementation. The CISA Project conducts case reviews upon request from U.S. healthcare providers. For the VSD and VA EHR monitoring systems, data are available on patients within a couple weeks of their encounter with the medical system. For FDA CMS data monitoring, which includes 650,000 nursing home residents, data may be available within several weeks of an encounter with a medical system. For FDA's Biologics Effectiveness and Safety (BEST) and Sentinel and other large insurer/payer databases, data availability is variable depending upon the source, but can be available within a couple of weeks to several months of encounter with a medical system.

In summary, VAERS will play an important role in characterizing the safety profile of COVID-19 vaccines in the early stages of a vaccination program. Signal detection is of paramount importance, but VAERS data can also provide reassurance if no concerning safety signals are detected, as in the case of H1N1 for which CDC was able to characterize the basic safety profile of the H1N1 vaccines relatively quickly. Additional systems such as V-SAFE and NHSN will enhance traditional vaccine safety monitoring systems, such as VAERS. Traditional large-linked database systems such as VSD, CMS, and VA EHR will quickly accumulate safety data when vaccines become widely available.

Discussion Points

In terms of V-SAFE, Dr. Szilagyi emphasized that the effectiveness of such a monitoring program depends upon adherence to the daily texts and responses and requested information about the experience that people have had with responding to those daily texts.

Dr. Shimabukuro indicated that much of the work with text monitoring at CDC has been done in the CISA Project. The response rates have been relatively high. In fact, rates have been surprisingly high in pregnancy studies. While he could not say that this would be generalizable to V-SAFE, generally speaking, the response rates for text monitoring and vaccine safety programs have been fairly good. This is a different situation, given that it is a much bigger program. Specifically, for the follow-up of clinically important AEs, multiple attempts will be made to engage the person to obtain information on those. For V-SAFE, not following up might be an indication of the absence of AEs. While they need to be careful about how they interpret these, based on previous experience with text monitoring, CDC is hopeful that response rates will be decent.

Dr. Szilagyi said it was reassuring to him that many HCP, including himself, already are participating in daily symptom monitoring systems within their own healthcare systems as are teachers and many other essential workers. People seem to be getting used to quick daily monitoring.

Dr. Atmar asked whether V-SAFE is opt-in or opt-out, exactly how participants would be recruited to do this, and whether this is envisioned as a condition for receipt through an EUA. He emphasized that with all of the discussion going on around the country and some people expressing concerns about the process of assessing the effectiveness and safety of these vaccines, continued monitoring of safety after the vaccine has been rolled out could be viewed by some with concern. They want the public to be reassured that any vaccine that is rolled out has gone through the appropriate review process and that this collection of additional safety information is what is done with all vaccine products, but is voluntary for those who will be the initial recipients of the vaccine.

Dr. Shimabukuro explained that for V-SAFE, they are essentially borrowing or leveraging information that is being collected as part of the registration process to identify essential workers for scheduling and for reminder recall. Part of the registration process is going to be to inform individuals that there is going to be outreach from CDC doing these health checks as part of the V-SAFE process. There will be an opt-out for these text messages. For example, when people are contacted initially after the vaccination, they will have the opportunity to opt-out. Being engaged in the program in general will be part of the registration process, which is broader than just vaccine safety. There are plans to develop some physical or electronic educational materials to be distributed at the point of service about what is being done, why it is important, and why participation would be appreciated.

Dr. Poehling expressed appreciation for the thoughtful approach to making sure everybody is included, including under-represented minorities. She asked whether there are plans to assess enrollment rates based on race and ethnicity and how the NSHN reflects the broader community and particularly under-represented minorities.

Dr. Shimabukuro indicated that he would have to get back to the group on the capture of racial data because they are essentially piggybacking onto the initial registration process and he did not know if these variables are being collected. There are tens of thousands of sites involved in NHSN across the country, including acute care facilities and LTCF. While he was not aware specifically if NHSN is representative of the population as far as race and ethnicity, there are many facilities, a large population, and a wide reach across the US.

Dr. Goldman asked Dr. Shimabukuro to comment on how he sees the role of community physicians in the reporting process or the enhanced reporting process.

Dr. Shimabukuro stressed that public reporting for VAERS is largely voluntary. It depends on members of the public submitting reports. Anyone can send a VAERS report, including patients, parents, caregivers, and HCP. It is very important that reports are submitted from HCP. Reporting of AEs is encouraged following immunization for any clinically important or clinically serious AE, or any AE regardless of whether the person is sure that the vaccine caused the AE. There will be education and outreach to HCP. They are a very important partner in vaccine safety monitoring and the information they provide in VAERS reports tends to be of high quality. CDC wants to make HCP and facilities aware of the importance of VAERS and receiving quick data in order to characterize the safety profile early.

Dr. Drees asked whether facilities would be asked to report raw numbers for both the numerator and denominator, or if they plan to ask for healthcare worker-level or recipient-level information for the numerator. NHSN facilities are very familiar with reporting raw numbers, which they do for influenza each year. Asking for patient-level or healthcare worker level data would be a significantly bigger ask, particularly for those that do not have an electronic capture system.

Dr. Shimabukuro indicated that NHSN reporting will be aggregate numerator and aggregate denominator with instructions and guidance of how to report the numerator into VAERS. This is traditional NHSN style reporting and will not be individual line list type data. At this point, the frequency of data reporting will be weekly. However, those discussions are still occurring.

Dr. Finley requested clarification regarding whether a condition for receipt of COVID-19 vaccine will be that the patient consents to allow their personal health information to be shared with CDC.

Dr. Cohn indicated that this would not be required.

Dr. Coyle (AIRA) asked whether it would be fair to assume that the information regarding the text message is going to come from the data clearinghouse that states will be leveraging for this.

Dr. Shimabukuro indicated that the actual sending of the text messaging would be from CDC or its information technology (IT) contractors and partners who are helping, not from the individual states.

Dr. Cohn added that the phone numbers for the text messaging will come from the registration process through multiple IT systems connecting state registration processes. However, no additional private information will be shared.

Ms. McNally asked whether CDC anticipates any feasibility challenges to the launch of V-SAFE in terms of timing or technical development, given the scale of this. She also wondered whether the programs referenced on Slide 14 were on the same scale as this.

Dr. Messonnier noted that those questions could be better answered during the next session, which would be more specifically about implementation.

COVID-19 Vaccine Implementation Planning Update

**Janell Routh, MD, MPH
CAPT, USPHS
Deputy, Implementation Planning Unit
Vaccine Task Force
Centers for Disease Control and Prevention**

Dr. Routh explained that the Implementation Planning Unit consists of 3 teams, one that works specifically with jurisdictions on their planning process, one that is focused on planning for critical populations, and one that is working with CDC's federal partners to help them administer vaccines to their respective populations. There is likely to be a relatively short period of time when vaccine doses will be limited, so CDC is directing its state, jurisdictional, and Tribal

partners to think about vaccine planning in 3 phases: 1) the first 3 to 6 weeks during which limited dosing will be available for prioritized populations; 2) a time during which there begins to be an increase in a large number of doses that will help to vaccinate other critical populations; and 3) a time during which there are sufficient doses for the population, when the emphasis switches to distributing vaccine to a broader population with a specific emphasis on populations that may require special consideration around distribution and equitable access.

To assist states, jurisdictional partners, and Tribal nations in this phased rollout of vaccine, CDC released the *COVID-19 Vaccination Program Interim Playbook for Jurisdictional Operations* (the "Playbook") on September 16, 2020 with guidance for states to begin this planning process. In terms of some of the work that greatly informed the Playbook content, it builds on experiences from longstanding relationships that CDC staff in NCIRD have had with Immunization Managers across the US. It also leverages lessons learned from seasonal influenza campaigns, routine vaccination, campaigns, and prior outbreak-associated vaccination programs such as H1N1. That said, CDC recognizes that the COVID-19 response will be much more complex.

This longstanding expertise helped to design a piloting effort that CDC put forth during the summer to help inform the Playbook content. In August 2020, CDC and Operation Warp Speed (OWS) staff met with 5 jurisdictions to assess their COVID-19 vaccine-specific plans. They selected North Dakota, Florida, California, Minnesota, and Philadelphia because of their diversity, size, and geography of their populations. In-person and virtual sessions were conducted with these jurisdictions, which allowed them to talk through the challenges in distributing COVID-19 vaccine. The feedback from these meetings helped to inform this interim Playbook. Other federal participants included the Indian Health Service (IHS) and the Assistant Secretary for Preparedness and Response (ASPR).

To highlight a few common themes that arose among all pilot sites, COVID-19 vaccination is going to be a resource-intensive endeavor, likely beyond what most jurisdictions currently have available. Jurisdictions are balancing significant COVID-related responsibilities with other routine immunization programs. Social distancing adds significant logistical complexity into COVID-19 vaccination event planning, so it is important to make sure that social distancing and infection control practices are implemented as part of vaccine rollout. Clear and transparent communication from CDC to jurisdictions is critical. Information gaps can challenge planning; therefore, it is important to quickly identify those gaps in order to solve problems before vaccine is rolled out. CDC began rolling out enhanced technical assistance (TA) to jurisdictions a couple of weeks prior to this meeting, which should help to mitigate some of the communication challenges. Technology concerns are persistent and significant. It is necessary to provide specific technical expertise in that area to make sure that jurisdictions are connected across the four avenues of vaccine release (i.e., allocation, distribution, administration, and tracking).

Public confidence in the vaccine process rates among the highest concerns for jurisdictions. The Implementation Planning Unit is doing some work to overcome vaccine hesitancy. Border communities (along city/state borders) highlight the need for clear guidance from CDC so that neighboring jurisdictions do not differ in their approaches to vaccination. To address that, CDC is standing up regional calls so that all of the 10 HHS Regions have an opportunity to come together to talk through issues that might be specific to their regions. Specific and uniform federal guidance on those to vaccinate in the earliest days of vaccine availability will lead to less complexity and fewer questions at the state/city levels. The prioritization list is driving a lot of the

current conversations. Vaccine allocation should consider the critical populations jurisdictions expect to vaccinate and not simply be based on their populations.

The Playbook released on September 16, 2020 has 15 sections that walk through all aspects of distribution and administration. This includes sections on engaging partners and establishing a COVID-19 Vaccination Program Implementation Committee to enhance the development of plans, reach of activities, and the risk crisis response in communicating message and delivery. One thing they tried to emphasize in the planning committees is to make sure that there is representation at the jurisdiction, local, and Tribal levels. One important aspect of the Playbook is that it stresses collaboration in working not only across the jurisdiction, but also with the local level partners, public health emergency preparedness programs, emergency management agencies, healthcare coalitions, industry groups, policymakers, and community vaccine providers to ensure that there is a well-represented committee that can think through these plans carefully.

The Playbook has sections that address how vaccine will be allocated, ordered, and distributed and how vaccine inventory will be managed. Most jurisdictions are planning to enroll vaccine providers to place orders using systems and procedures routinely used for ordering publicly funded vaccines, though some jurisdictions may have augmented systems for that. It is important to understand that this interim Playbook is a living document. CDC plans to update the content regularly as more information is learned about what vaccines will be available and when they will be released. Some updates that will be coming shortly will be additional information on reaching out to critical populations like LTCF; those who need special consideration for distribution and access like communities of color, rural populations, and those at increased risk for severe outcomes from COVID-19, such as the elderly.

As previously mentioned, the CDC is implementing a system of enhanced TA to support this planning. The idea is to have daily interaction with jurisdictional partners to understand their TA needs and where they are in the development and implementation of COVID-19 vaccination plans. The teams consist of CDC Immunization Program Officers with a lot of expertise working with jurisdictional partners. The teams are augmented by IT SMEs. CDC received 10 DoD OWS liaisons who have special expertise in logistics, supply, and IT support to help augment these teams and provide additional TA to the states. Teams are organized by HHS Region and are expanding to include support and coordination with regional federal staff as well. Some of the tasks for which the teams are responsible will be to:

- Collect and analyze metrics on jurisdictional capacity
- Provide direct TA to individual jurisdictions
- Facilitate cross-jurisdictional regional communication and collaboration so regions can learn from each other and think of creative ways to solve problems
- Train jurisdictions on the use of OWS' Tiberius application and CDC's internal dashboard to improve their microplanning and allocation processes
- Review and approve jurisdictional COVID-19 vaccination response plans, which is expected to occur rapidly after the plans are submitted to CDC
- Support phased implementation of jurisdictional vaccination response

Every jurisdiction is heavily involved in their plan development. Even though the Playbook only went out the week before, states and jurisdictions have been thinking about this for quite some time and many have nearly completed their plans. Even though the TA is ongoing, the amount

of time already put into the planning process is very impressive. As noted, weekly calls will be held with all 64 jurisdictions and regional calls will continue to cross-populate ideas across the different regions. CDC also is collecting a series of metrics to ensure that jurisdictions are on track with their vaccination planning and to help identify areas that may need additional support.

In terms of next steps, work will continue with commercial partners and federal entities who may receive direct allocations to expand access to all populations. It will be necessary to pull in all resources. This is not just a jurisdictional effort alone. Jurisdictions also are being asked to collect vaccine provider agreements and onboard providers to be able to receive and administer vaccine, with a particular emphasis on providers who serve critical populations. Certainly, with the early effort in Phase 1 having limited vaccine doses, the emphasis is on jurisdictions focusing on enrolling providers who can rapidly vaccinate populations of focus as soon as vaccine is available. This would include providers at large hospitals and health systems, mobile vaccination providers, satellite or temporary clinics, occupational health clinics, and critical access hospitals to ensure that the HCP population is saturated. In the next phase, jurisdictions are being asked to think critically about increasing the provider pool to include providers who can help expand equitable access to other critical populations and the general public. They are being encouraged to seek providers with connections in Tribal communities, rural health, and community health centers. Next is to enumerate critical populations who may be prioritized for early vaccine allocation or require special consideration for distribution and access. Jurisdictions are being asked to help CDC rapidly understand the number of HCP in jurisdictions so that they can plan accordingly.

Next is to begin engaging with community stakeholders to address vaccine hesitancy. Even as CDC works to develop a national strategy to address hesitancy, they know that most of that work will take place at the state and local levels. In addition to the communications staff who are currently working in the Task Force on an overall national plan, the Implementation Planning Unit has a team working on developing in-depth concepts of operations for populations that they think may have increased vaccine hesitancy. They are working to engage stakeholders at a national level that can then be translated down to the state and local levels so that they can begin the necessary work to strengthen overall immunization programs and COVID vaccination programs. Certainly, they will draw on lessons learned from their influenza colleagues since these populations are most similar to those most likely to be first prioritized for COVID vaccination. Finally, CDC is working with state, jurisdictional, and Tribal partners to ensure that data systems have processes in place to monitor vaccine distribution, uptake, demand, and wastage. CDC has an end-to-end data initiative underway that will ensure jurisdictions will have the visibility of COVID vaccine supply, and the data needed to accurately administer doses of vaccine, including second doses. Several new data systems are being finalized to help with collection, monitoring, and visualization of data necessary to mount a successful campaign (e.g., the OWS Tiberius platform, CDC's internal dashboard, and other systems that jurisdictions can use to better track vaccines).

Discussion Points

Dr. Talbot said she could not imagine that the final cold storage requirements would be known for this vaccine before the deadline for the jurisdictions to complete and submit their plans. Also unknown are the best populations for efficacy and safety. With that in mind, she asked why the deadline is October 16th and if it is a hard deadline. It seems like there should be time to build connection with local officials. To have a deadline with no data seems somewhat premature.

Dr. Routh agreed that the planning process is iterative. CDC is working with a current set of assumptions that was released to states in August. They are constantly learning more about vaccine products, storage and handling, et cetera and are anticipating some information about prioritized groups to come later. They are asking states to plan based on these assumptions, but they know the plans will be constantly improving and changing as new information is learned. The October 16th deadline was set based on the cooperative agreement regulations that states would return a plan to CDC 30 days after the Playbook was released. Given the fact that the Playbook was released on September 16th, they set October 16th as a deadline to be able to review the state plans. Again, states are being asked to think broadly. In their plans, they should have contingencies for whether there is an ultra-cold product only or more than one vaccine product becomes available. By thinking across that spectrum, when there is finally an answer, they can take a plan off of the shelf and run with it as soon as possible. Again, this is an iterative process and CDC is providing as much TA as possible to help states think through various scenarios. Although there is an October 16th deadline to return a plan, CDC will continue to work with its jurisdictional partners across the coming weeks and months to ensure that those plans are tailored as more information is available.

Dr. Messonnier added that it is important to understand that CDC has a lot of goals, one of which is to be ready on the first day that it is possible to actually distribute vaccines. Their colleagues in OWS say they expect there to be vaccine as early as November. Therefore, everyone needs to be ready so that there is no delay in distributing that vaccine. That early phase is close upon them. She asked everyone to think about planning in terms of phases. Based on data provided by their colleagues in OWS, CDC developed some scenarios they think are most likely. Moving out into 2021, more vaccines will be available and certainly more doses will be available. When CDC thinks about planning, they are thinking about not only the phase that is rapidly upon them, but also the second phase moving into 2021. They must be ready for the first phase imminently, but also recognize that in a lot of ways logistically, the movement of so much vaccine so quickly for the entire population is much more logistically challenging. Therefore, they must get started on that now.

Dr. Hunter found the Playbook to be very helpful to those involved in implementation because it gives local and state health departments some guidelines to allocate vaccines on a micro level to venues being stood up by local health departments, healthcare organizations, community organizations, and pharmacies that will serve and vaccinate the kinds of groups the ACIP will be prioritizing. This helps connect the dots between what ACIP will eventually vote on, who the high-risk groups are, and the venues where many of those people will present. He commended CDC in being practical about that in the Playbook. The one thing he did not see is security at the sites. He is concerned about the threats of violence that have been perpetrated against leaders of public health that have led in part to the resignation of Commissioners of Health and the potential for disruption at vaccination events. He wondered if those issues will be addressed in future iterations of the Playbook.

Dr. Routh reported that CDC conducted a tabletop exercise with OWS in which they went through vaccine administration at a clinic site and thought through the security concerns. She agreed that the Playbook needs an update to address this, which CDC will be working to provide.

Dr. Bell requested further information about the tracking systems in terms of the kind of information that will be collected, the timing, who will assess the data, and other considerations.

Part of inspiring public confidence is having a mechanism for accountability, being able to report the status of vaccination and who is getting vaccinated and highlighting the issues that are developing early. She was happy to hear that CDC and OWS are working on various tracking methods.

Dr. Routh said that they are in the process of finalizing a lot of these data systems to be able to roll them out through jurisdictions to help with their planning and tracking. It will be possible to give an update during a future ACIP meeting. Many of the jurisdictions will be using their Immunization Information Systems (IIS) either as they currently exist or in an augmented form to help with tracking. For jurisdictions that may choose not to use this or for clinics that may not have access to an IIS, CDC is in the final stages of developing a vaccine administration management system for use at standalone clinics that will provide similar features to an IIS and will allow providers to schedule appointments, register patients, and provide second dose reminders. This system is anticipated to be rolled out around the end of October. With regional teams, CDC will be able to provide some enhanced TA to support jurisdictions in getting up to speed with those systems. The OWS Tiberius platform will be rolled out to help states and jurisdictions do their microplanning. There is a microplanning tool and a dosing allocation tool that should be very useful. That system will also provide some additional visualization and tracking moving forward into the implementation process.

Ms. McNally asked whether there is a firm date for the launch of the V-SAFE program.

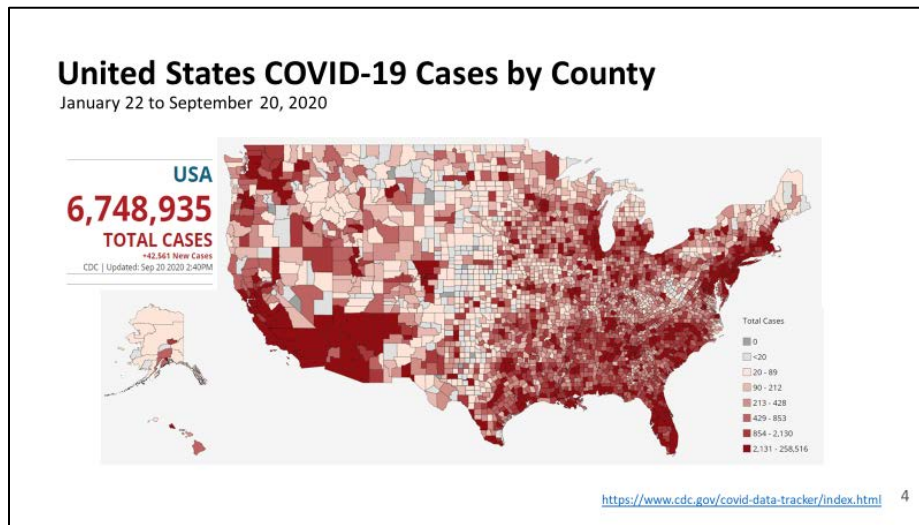
Dr. Messonnier indicated that the plan is to launch the V-SAFE program that Dr. Shimabukuro described with the first distribution of vaccines. Trial runs and backstopping will be done to ensure that there are no flaws in the system. CDC partly developed that system with an expectation, based on ACIP deliberations, of the first groups who would be prioritized for vaccination, which is HCP. A follow-up presentation can be provided during another ACIP meeting about the end-to-end data systems. It all comes together where there is a tool that people can use to register the vaccination sites to help with clinic management. There is the V-SAFE tool for people to enroll in sites. The data are then rolled over so that they populate the registry system and then finally dump back in so that state and local health departments can use it and CDC gets an extract of it so that they can keep track of uptake and ensure that vaccine is being allocated appropriately. Explaining how all of these systems work together can be added to the agenda for the next meeting.

Disparities in COVID-19 Incidence, Severity, and Outcomes

Megan Wallace, DrPH, MPH
Epidemic Intelligence Service Officer
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

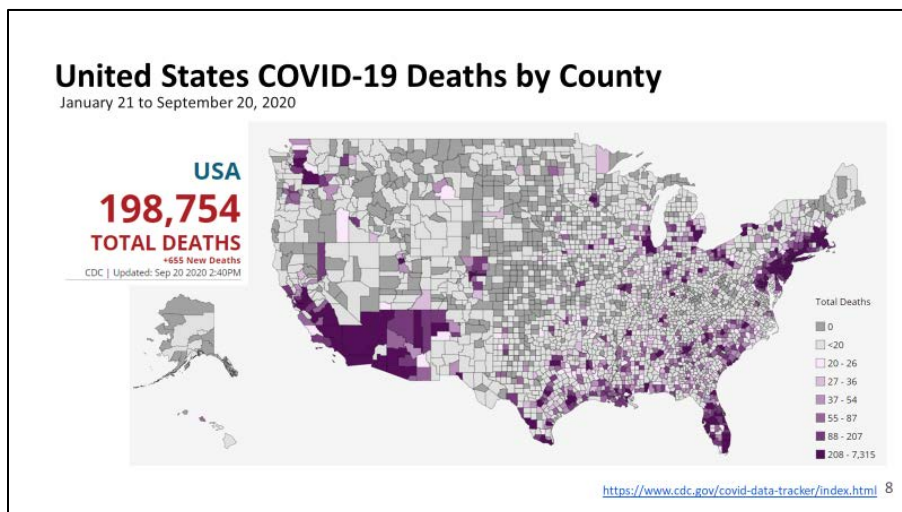
Dr. Wallace presented a brief update on U.S. COVID-19 epidemiology and data on disparities in COVID-19 incidence, severity, and outcomes, including disparities among racial and ethnic minority groups, that are driven by social determinants of health (SDOH).

As of September 20, 2020, a total of 6.7 million US COVID-19 cases have been reported to CDC. This map shows the cumulative case count by county, with the darker red representing larger numbers of cases:



In terms of the trends in the number of COVID-19 cases reported per day in the US, nationally cases peaked in mid-July and have been decreasing over the past 2 months. Based on the number of specimens tested for SARS-CoV-2 using a molecular assay and reported to CDC by public health laboratories, nationally, the percentage of specimens testing positive for SARS-CoV-2 has continued to decrease since mid-July. During Week 37, the overall percent positive at public health laboratories was 4.5%. Among commercial laboratories reporting to CDC, the percentage of specimens testing positive also has been decreasing since mid-July. During Week 37, the percent positive was 4.8%.

As of September 20, 2020, a total of 198,754 deaths due to COVID-19 have been reported to CDC. This map shows the cumulative number of deaths by county, with the darker purple representing large numbers of deaths:

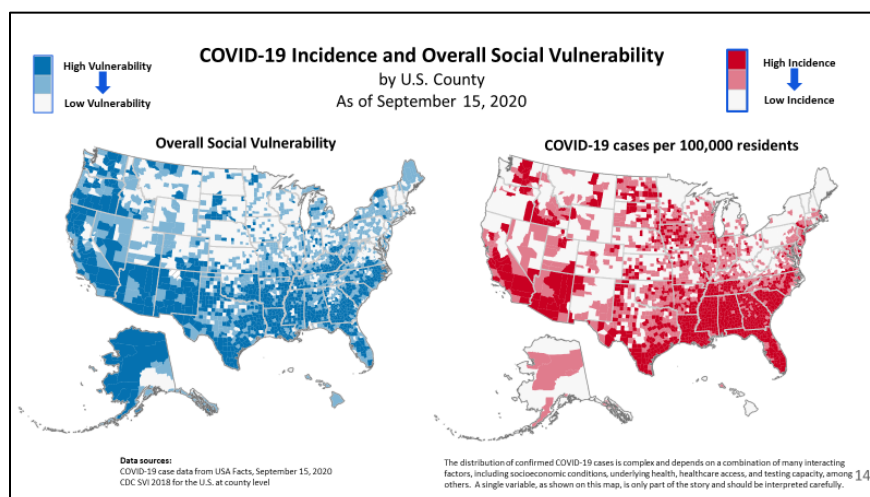


In terms of trends in the number of COVID-19 deaths reported per day in the US, nationally, deaths peaked first in mid-April and again in early August and have been decreasing over the past month. Regarding trends in pneumonia, influenza, and COVID-19 mortality, the National Center for Health Statistics (NCHS) collects death certificate data from Vital Statistics offices for all deaths occurring in the US. Based on death certificate data available as of September 17, 2020, the percentage of deaths attributed to pneumonia, influenza, or COVID-19 for the week ending September 12th is 6.2%. While lower than the percentage for the previous week, it remained above the epidemic threshold and likely will increase as more death certificates are processed.

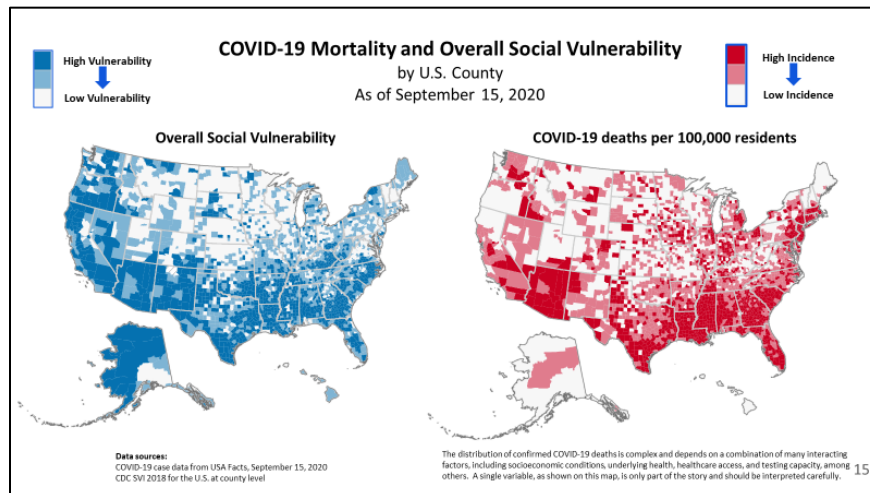
As shared in previous ACIP meetings, certain factors such as older age and having certain underlying medical conditions increases a person's risk of severe COVID-19 disease. There is also increasing evidence that disparities in COVID-19 incidence, severity, and outcomes are occurring among people facing inequities in SDOH. SDOH are conditions in the places where people live, learn, work, and play that affect a wide range of health risks and outcomes. These broadly include economic stability; education; social and community context; health and healthcare; and housing, neighborhood, and built environment.

The Social Vulnerability Index (SVI) was developed by the CDC to identify communities that are at highest risk and may need the most support before, during, and after a public health emergency such as a pandemic. It is a measure of SDOH using U.S. Census Data and ranks each county and census tract on 15 social vulnerability factors and groups them into four related themes: Socioeconomics, Housing Composition and Disability, Representation of Racial and Ethnic Minority Groups, and Housing and Transportation.

The map on the left displays the SVI with those counties displayed in dark blue having the highest vulnerability. The map on the right displays COVID-19 cases per 100,000 residents with darker red representing counties with the highest COVID-19 incidence. These maps follow similar geographic patterns, indicating that many communities with high social vulnerability experience a high incidence of COVID-19:



Here, the map on the left remains the same and the map on the right now displays COVID-19 deaths per 100,000 residents, with darker red representing counties with the highest incidence of death. Again, COVID-19 death rates also follow similar geographic patterns to high social vulnerability:



Using data from the SVI and U.S. county-level COVID-19 cases from June 1-June 25, 2020, a recent analysis examined associations between social vulnerability and the risk of becoming a COVID-19 hotspot, and among hotspot counties, described COVID-19 incidence after hotspot detection by level of social vulnerability. COVID-19 hotspots are counties with rapidly increasing COVID-19 incidence, identified using standard criteria developed by CDC. SVI scores were categorized as quartiles (Q) based on their distribution among all U.S. counties, overall and by urbanicity. Counties in Q1 had the lowest social vulnerability and counties in Q4 had the highest vulnerability. This study showed that the probability of becoming a COVID-19 hotspot was 2.4 times higher for counties with the highest social vulnerability compared to counties with the lowest social vulnerability. This effect became even more pronounced in less urban areas. For example, in non-metropolitan areas, the probability of becoming a COVID-19 hotspot was more than 15 times higher for areas with the highest social vulnerability. This was particularly true for sub-scores related to racial and ethnic minority residents and housing composition, which led them to analyze these factors further. Comparing the relative risk of becoming a COVID-19 hotspot by components related to racial and ethnic minorities and housing composition, counties at or above the national median percentage of racial and ethnic minority groups had an increased risk of becoming a COVID-19 hotspot compared to counties below the national median percentage. The association was particularly pronounced in non-metropolitan areas where the risk of becoming a hotspot was more than 8 times higher among counties with a higher percentage of racial and ethnic minority groups. The percentage of housing structures with ≥ 10 units or crowded structures increased the risk of becoming a hotspot only in metropolitan counties. The percentage of households with more people than rooms or crowded households increased risk more in non-metro counties. In terms of the incidence of COVID-19 among hotspot counties by SVI quartile for the 14 days after detection as a hotspot, compared with less socially vulnerable counties (Q1-Q3), areas with the highest social vulnerabilities (Q4) continued to have markedly higher COVID-19 incidence [Dasgupta et al, CDC COVID-19 Response Team: Manuscript in *MMWR* clearance].

There is increasing evidence that some racial and ethnic minority groups are being disproportionately affected by COVID-19. These disparities are seen in the disproportionate number of cases, hospitalizations, and deaths among these groups. Racial and ethnic minority groups represent 40% of the total U.S. population, but nearly 60% of COVID-19 cases. Based on case level data reported by health departments to CDC for approximately 5 million cases, among Hispanic or Latino, Black, and multiple or other race groups, the percentage of cases was higher than the percentage of the total population. This indicates a disparity in COVID-19 cases among some racial and ethnic minority groups.

In another analysis among 79 U.S. counties identified as a hotspot between June 5-18, 2020, 76 counties had a disproportionately high number of cases among racial and ethnic minority groups. In terms of the differences between the proportion of cases and proportion of the population and hotspot counties with disparities among racial and ethnic minority groups, if a group makes up 20% of the population of a county on average but 40% of COVID-19 cases, the difference would be 20%. The difference ranged from 4.5% for Native American Hawaiian and other Pacific Islanders to almost 40% in American Indians/Alaska Natives (AI/AN) [Moore et al, COVID-19 State, Tribal, Local, and Territorial Response Team, August 2020 <https://www.cdc.gov/mmwr/volumes/69/wr/mm6933e1.htm>].

Disparities in severe COVID-19 disease are observed by the differences in COVID-19 associated hospitalizations among racial and ethnic minority groups. COVID-NET is a population-based surveillance system collecting laboratory-confirmed COVID-19 associated hospitalizations in 14 states. In terms of the age-adjusted cumulative rate of hospitalizations by week reported to COVID-NET, as of MMWR Week 35 or August 29th, hospitalization rates among AI/AN, Black, and Hispanic persons were more than 3 times the rate among White and Asian persons. Racial and ethnic disparities in COVID-19 hospitalization rates among racial and ethnic minority groups occur in both young and older age groups. In younger adults 18-49 years of age, hospitalization rates among AI/AN and Hispanic persons were higher. In older age groups ≥ 65 years of age, hospitalizations were higher among Black persons. Racial and ethnic minority groups represent 40% of the U.S. population, but nearly 50% of COVID-19 deaths. Among Black and multiple/other racial groups, the percentages of deaths were higher than the percentage of the total population indicating a disparity in COVID-19 deaths among these groups. In terms of the differences between the percent of COVID-19 deaths and the weighted population distribution by race and ethnicity and age group from death certificate data, persons reported as Hispanic, Black, and AI/AN all experienced disparities in COVID-19 deaths in the age groups less than 65 years, with the greatest disparities observed in the youngest age groups.

Regarding data on race and ethnicity by age group among a convenience sample of 10,000 COVID-19 deaths that occurred during February 12-April 24, 2020 in 16 health jurisdictions, the median age was 71 years among Hispanic decedents, 72 years among all other race decedents, and 81 years among White decedents. The percentages of COVID-19 decedents who were less than 65 years in Hispanic or other race groups were more than twice those that were White [Modified from: Wortham et al, 2020, <https://www.cdc.gov/mmwr/volumes/69/wr/mm6928e1.htm>].

Some of the many inequities and SDOH that put racial and ethnic minority groups at increased risk of getting sick and dying from COVID-19 include discrimination; healthcare access and utilization gaps; occupation in higher risk settings; education, income, and wealth gaps; and housing that is crowded or lacks basic services. For example, in New York City (NYC), the percentage of COVID-19 tests increased significantly with the increasing percentage of White residents [Lieberman-Cribbin et al, September 2020, <https://doi.org/10.1016/j.amepre.2020.06.005>].

Some racial and ethnic minority groups are more likely to be employed in essential industries or in occupations with frequent exposure to infections and in close proximity to others. For example, a study by Hawkins and colleagues showed that 38% of Black persons are likely employed in an essential industry compared to 27% of White persons [Hawkins, May 2020: <https://doi.org/10.1002/ajim.23145>].

In terms of the association between poverty, representation of racial and ethnic minority groups, and COVID-19 rates using data from 10 U.S. urban centers, counties with more poverty (defined as those counties with a poverty rate above the median of the dataset) had higher COVID-19 rates. These rates increased with increasing percentage of racial and ethnic minority groups. In counties with more poverty and a population that was more than 44.5% racial and ethnic minority groups, the COVID-19 rate was nearly 8 times that of counties with substantially White populations [Adhikari et al, July 2020, doi:10.1001/jamanetworkopen.2020.16938].

In a large health system in Louisiana, SDOH such as residence in a low-income area and insurance type were independently associated with increased odds of COVID-19 hospitalization. Black race also was independently associated with an increased odds of COVID-19 hospitalization [Price-Haywood EG et al. N Engl J Med 2020;382:2534-2543].

Racial and ethnic minorities are disproportionately impacted by the COVID-19 pandemic. Black, Native American, and Hispanic persons reported elevated levels of suicidality, depressive symptoms, and fear of COVID-19. Non-Hispanic Black persons are more likely to experience loss of a close relative due to COVID-19 than non-Hispanic White persons. Non-Hispanic Black and Hispanic persons are more likely to report food insecurity during the COVID-19 pandemic [Source: Fitzpatrick et al, June 2020, <https://doi.org/10.1111/sltb.12655>; Verdery et al, July 2020, <https://doi.org/10.1073/pnas.2007476117>; Wolfson and Leung, June 2020, doi: 10.3390/nu12061648].

In summary, as of September 20th, over 6.7 million cases of COVID-19 have been diagnosed and over 198,000 COVID-19 associated deaths have been reported in the US. Racial and ethnic minority groups are being disproportionately affected by COVID-19, including increased risk of infection, hospitalization, and deaths. Inequities in SDOH put racial and ethnic minority groups at increased risk of getting sick and dying from COVID-19.

Discussion Points

Dr. Szilagyi observed that the depiction of racial and ethnic disparities was very sobering. He wondered whether social vulnerability could be overlaid with the proportion of all COVID-19 cases that are in large metropolitan areas, medium metropolitan areas, and non-metropolitan areas—thinking about non-metropolitan areas being at higher risk of social vulnerability.

Dr. Dasgupta indicated that they looked at incidence in metropolitan versus non-metropolitan areas. Interestingly, there was a shift in higher incidence in less urban areas during the summer months. Incidence was higher in non-metropolitan areas as well as small and medium metropolitan areas compared with large metropolitan areas. Strikingly, SVI scores were higher among those areas as well. There was a shift in the proportion of counties with high social vulnerability that were identified as hotspots in the summer months as well. These particular hotspot areas continue to have high incidence, especially among socially vulnerable areas.

Dr. Whitley-Williams (AMA) suggested working to understand whether bias is playing a role in this. For instance, assessing ethnicity in terms of how many of the patients who died never made it to the hospital or how many of these patients were seen at a healthcare facility or by a HCP and sent home.

Dr. Wallace indicated that they would determine whether they have any data to address the potential for bias playing a role and will get back to the group. Many of the studies have found that among a population already hospitalized, many of the disparities are not seen in deaths. Disparities in deaths are driven a lot by disparities in incidence. However, there is probably more they could look into regarding this.

Dr. Oliver added that from a surveillance standpoint, COVID-NET is limited to patients who are hospitalized. Dr. Wortham's *MMWR* included any type of COVID-related death that had been reported from any site. Looking at the difference between those two would be assessing the difference in the people hospitalized, while acknowledging the larger question that there are likely additional disparities that could come with lack of healthcare access as well.

Dr. Lee wondered how SVI information could inform implementation efforts and asked whether vaccine distribution would be tracked to these communities.

Dr. Cohn said that CDC has been thinking about ways to use this type of data to help jurisdictions and commercial and private partners to ensure access and availability of vaccine in these targeted areas when vaccine is widely available. Ensuring access and demand and working with community and local stakeholders in these vulnerable communities will be very important.

Dr. Poehling asked whether there has been a sub-analysis of hotspots with incarcerated populations and in meat packing plants.

Dr. Oliver indicated that there are specific groups within the response who are looking at these populations. Some of their data have been presented previously in terms of correctional facilities and cases associated with workplace outbreaks.

Dr. Gluckman noted that over time there have been some advances in therapy, which could result in a reduction in disparities.

Dr. Fryhofer (AMA) emphasized that these disparities are striking and disturbing. The FDA issued special guidance on June 30, 2020 for the vaccine makers to include diverse populations in all study phases. Of the two vaccines ACIP has reviewed, one has only 28% and the other only 26% diversity as they heard earlier in the day. Perhaps those percentages should be increased to 40% racial and ethnic minorities to better reflect the general population. Efforts

should be made now to instill confidence in these vaccines among racial and ethnic minority groups so that when there is a vaccine they will be willing to take it.

Dr. Oliver reported that in discussions with FDA and manufacturers, ACIP has continued to reiterate that the composition of these clinical trials should mirror the population of the US.

Dr. Cohn added that ensuring that all individuals, including racial and ethnic minorities, are confident in getting the vaccine will be crucial to the success of the vaccine program. CDC has implemented community-level engagement with regard to influenza vaccine and is hoping that a lot of the work done in that space will help with COVID-19 vaccine engagement. Based on everything they have learned over the last year, it is imperative to engage communities at a very local level in addition to ensuring that messages are culturally competent, targeted, empathetic, clear, and accurate in terms of the information provided. The efforts to increase vaccine confidence is likely to expand more rapidly when there are data about the vaccines to incorporate into the messaging. Right now, messaging is in the preparation phase and is very broad. When there are safety and efficacy data that they can message, there will be a big push to ensure that these communities understand the messages and are hearing them from people who they trust.

Dr. Romero added that the message must begin now. It cannot wait until the vaccine is on the precipice of being released. Speaking from his own experience, the advisory groups that advise the Arkansas Department of Health have reported that there is an extreme lack of confidence in this vaccine among under-represented minorities. He has been trying to reach out to the Latino population by providing specific targeted talks to leaders of that group.

Dr. Arthur (BIO) wondered whether it would be possible to have a breakdown of the racial and ethnic differences in the populations by metropolitan and non-metropolitan areas. She said her suggestion was intended to understand specifically which racial and ethnic groups comprise the populations under each geographic description. For example, are the populations in non-metro areas largely Native American or is the distribution between the communities largely the same across all races?

Dr. Dasgupta said that there is a larger proportion of racial and ethnic minorities in large metropolitan areas compared with smaller, less urban areas.

Dr. Frey agreed with Drs. Fryhofer and Romero that the country must be extremely proactive in educational pieces for racial and ethnic minority populations, essential workers, and people of low socioeconomic means so that individuals will be confident about taking vaccines. She would like to know who actually does this work, at what level it is done, the types of efforts being made, and when this will begin. Perhaps a presentation to ACIP on this would be beneficial.

Dr. Cohn indicated that multiple entities will contribute to activities to increase confidence at the state, local, Tribal, community, non-governmental, and governmental levels. CDC hears the message that this work needs to begin now, and it is beginning in many communities.

Dr. Eckert (AGOC) asked whether there are any data about the pregnancy status of the women presented in the disparities data and maps so that they could ascertain whether the same trends are following for pregnant women.

Dr. Oliver indicated that this specific issue will be addressed during a future ACIP meeting once the information is assembled to present.

Dr. Lee took a moment to recognize their CDC colleagues who are working incredibly hard behind the scenes to stand up multiple systems and communication processes in this extremely challenging climate. While she agreed that it is challenging to communicate around vaccines and vaccine confidence without actually having the clinical trial data in hand, perhaps one thing they could do together would be to continue to emphasize the process for decision-making and how much emphasis they are all placing on transparency and the importance of that. Trusted voices will definitely be needed from providers, community leaders, and others to convey confidence in vaccines. She expressed her hope that working with liaison organizations going forward would continue to be a strength. She recognized that this goes well beyond CDC and emphasized the importance of working together to support what is needed.

Dr. Messonnier recognized that this is a challenging time for everyone, but that they all believe that COVID-19 vaccines could be a very important part of the solution. The groundwork will be very important to ensure that people are ready, willing, and confident when vaccines become available.

Dr. Bell said she liked the idea of the SVI because it integrates so many different factors and ties in closely with geography. She asked about the extent to which anyone at CDC thinks that it is feasible to use the SVI as a tool in implementation planning.

Dr. Cohn thinks it is quite feasible and these factors can all be incorporated into local planning to provide information to programs to help target their efforts. Local and state programs know their communities, frequently even more than the data show. Combining the expertise of local and state programs with the power of understanding some of the data based on SVI is very important and will be implemented.

Dr. Foster asked whether any analyses have been performed with regard to behavioral compliance, such as masking, to ascertain the degree of protection people who got sick were using or not using to protect themselves. He hears a lot of people say that they do not believe this, and they will not wear a mask.

Dr. Oliver indicated that aspects within the response have examined that broadly, but they have not presented that directly to ACIP at this point. There are communications and messaging on CDC's Home Page that could help to address that.

Ms. Bahta said that being on the local side of planning, they know what venues and avenues can be used to provide messages. However, the many national messages right now make it very difficult to provide the context around what is really occurring. As mentioned before, the title "Operation Warp Speed" scares a lot of people. It would be helpful if national leaders from FDA and CDC could talk about what that means in plain language. Being able to visualize what this means might assuage people's anxiety about COVID-19 vaccination.

Overview of Vaccine Equity and Prioritization Frameworks

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Dr. Oliver reminded everyone that ACIP has discussed the inclusion of ethics and equity principles as a part of the process to identify proposed groups for early COVID-19 vaccination. As a first step, the WG reviewed frameworks and published literature related to COVID-19 vaccine allocation. Several groups have published frameworks for early vaccine allocation, including the World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE), the Johns Hopkins Bloomberg School of Public Health (JHSPH), and the National Academies of Science, Engineering and Medicine (NASEM).

The [WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination](#) includes both national and global considerations with the six core values principles of: human well-being, equal respect, global equity, reciprocity, legitimacy, and national equity. In this framework, the priority groups were not ranked and were relatively broad. They include populations with significantly elevated risk of being infected, such as healthcare workers, employment categories unable to physically distance, or persons living in crowded conditions. They also include populations with elevated risk of severe disease or death, including older adults, groups with comorbidities, and sociodemographic groups at disproportionately higher risk of severe disease and death.

The purpose of the JHSPH [Interim framework for COVID-19 Vaccine Allocation and Distribution in the United States](#) is to identify candidate groups for serious consideration as priority groups, and demonstrate how ethical principles and objectives can be integrated to produce an ethically defensible list of candidate groups. The authors note the importance of transparency and a fair process; equity, including access to healthcare; and community outreach and engagement. The structural organization of the JHSPH framework includes three ethical values linked to seven ethical principles. Those are then linked to 11 policy goals, which are linked to 12 objectives, which ultimately lead to the priority groups. The ethical values include promoting the common good; treating people fairly and promoting equality; and promoting legitimacy, trust, and a sense of ownership in a pluralistic society.

In terms of JHSPH's priority groups for Tier 1, first are those most essential in sustaining the ongoing COVID-19 response, including frontline HCP caring for COVID-19 patients, frontline emergency services personnel, vaccine manufacturing, diagnostics, and public health workers. Next are those at greatest risk of severe illness and death and their caretakers, including adults 65 years of age and older and those who care for them, others at increased risk of severe disease, frontline LTCF providers, and HCP caring for patients with high risk conditions. Third in Tier 1 are those essential to maintaining core societal functions, including public transportation, food supply workers, and teachers.

The groups included in Tier 2 of the JHSPH framework are those involved in broader health provision, including other HCP and pharmacy staff; those who face barriers to access to care, including those living in remote locations; those needed to maintain other essential services, including deployed military, police and fire, Transportation Security Administration (TSA) and

border security; and finally, those whose living or working conditions give them elevated risk of infection, including those living in congregate settings.

The NASEM [Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine](#) defines their purpose as being to develop an overarching framework for vaccine allocation to assist policy makers in domestic and global health communities in planning for equitable allocation of vaccines. They note the expectation that the framework will inform decisions by health authorities, including ACIP. They were asked to consider criteria for setting priorities for equitable allocation, and how to apply the criteria to determine the 1st tier of recipients. The major elements of the NASEM framework structure are an overarching goal, allocation criteria, and allocation phases. NASEM identified six foundational principles:: maximize benefits, equal regard, mitigate health inequities, fairness, evidence-based, and transparency. They state that their overarching goal is to maximize societal benefit by reducing morbidity and mortality caused by transmission of COVID. Their allocation criteria are based on the risk of acquiring infection, risk of severe morbidity and mortality, risk of negative societal impact, and risk of transmitting disease.

Their vaccine allocation phases are: 1) Phase 1a, or a “jumpstart phase,” which includes high risk workers in healthcare facilities and first responders; 2) Phase 1b, which includes people of all ages with underlying conditions that put them at significantly higher risk, defined as two or more CDC designated medical conditions, and older adults living in congregate settings; 3) Phase 2, which includes critical workers at substantial risk of exposures, teachers and school staff, people with any underlying condition, all older adults, people in homeless shelters or group homes, and people in prisons/jails/detention centers; 4) Phase 3, which includes young adults, children, and the remainder of essential workers; and 5) Phase 4, which includes everyone not previously vaccinated.

Here are the three frameworks in one table and organized by the four groups ACIP has previously discussed: HCP, other essential workers, persons with underlying medical conditions, and adults ≥65 years of age:

Group	Johns Hopkins	National Academies	WHO
Healthcare personnel	<p>Tier 1: Frontline healthcare personnel including LTCF providers; EMS</p> <p>Tier 2: HCP & staff with direct, non-COVID patient contact; pharmacy workers</p>	<p>Phase 1a: Frontline healthcare personnel including LTCF providers; EMS</p> <p>Phase 2: Other healthcare personnel</p>	Priority groups unranked
Other essential workers	<p>Tier 1: Public transport, food supply workers; teachers & school workers. Workers necessary for pandemic support: (e.g. vaccine manufacturers; public health workers/support)</p> <p>Tier 2: Frontline infrastructure; warehouse/delivery/postal; deployed military; police & fire; TSA and border security; high-density or high-contact jobs</p>	<p>Phase 1a: Police, fire</p> <p>Phase 2: Critical infrastructure at risk of exposure; teachers and school staff incl childcare workers</p>	
Underlying medical conditions	<p>Tier 1: Those with elevated risk of serious disease; members of social groups experiencing disproportionately high fatality rates</p>	<p>Phase 1b: Significantly higher risk (≥2 CDC designated conditions)</p> <p>Phase 2: Moderately higher risk (1 CDC condition)</p>	
Adults ≥65 years of age	<p>Tier 1: Adults ≥65 years including those living with or providing care to them</p>	<p>Phase 1b: Older adults in congregate settings</p> <p>Phase 2: All older adults not in Phase 1</p>	

The WHO priority groups included all four of these populations, but were unranked, so further details are not able to be provided. For HCP, both Hopkins and NASEM placed “frontline” HCP in Tier 1 or Phase 1, with other HCP included in the next Tier or Phase. Among other essential workers, teachers and school workers are in Tier 1 of the Hopkins framework, but in NASEM’s Phase 2. Hopkins included police and fire in Tier 2 while NASEM placed them in Phase 1a. For adults with underlying medical conditions, Hopkins includes all in Tier 1; NASEM includes those with two or more underlying conditions in Phase 1b, and adults with one underlying condition in Phase 2. For adults 65 years of age and older, Hopkins includes them in Tier 1 and NASEM includes those in congregate settings in Phase 1b and all others in Phase 2.

The ACIP COVID-19 Vaccines WG interpretation of the frameworks when they were presented and discussed was as follows: all published frameworks identify HCP as important for early phase vaccine allocation. However, after HCP, all frameworks have large population sizes for the next doses of vaccine. The populations in Tier 1 or Phase 1 likely have 50 million individuals or more, which may be more than initially available vaccine doses. The WG also felt that many of the identified populations contain operational or implementation difficulties. For both frameworks, essential workers are split across different Tiers and Phases, which could be difficult to implement. In addition, the identification and delivery of vaccine to only those with two or more underlying medical conditions would be very difficult to operationalize. Finally, both frameworks separate out “frontline” HCP from other HCP. However, the epidemiology of COVID-19 disease among HCP demonstrates that that cases and risk of disease extend beyond only “frontline” HCP.

Equity was considered as a crosscutting consideration for all three of the frameworks. Hopkins discussed the importance of promoting equity and social justice; the NASEM discussed using CDC’s SVI; and WHO stated that these vaccines should contribute to equitable protection of people around the world.

ACIP has proposed an ethics/equity framework for COVID-19 vaccine allocation. The purpose of the framework is to assist ACIP in the identification of early recipients for allocation of COVID-19 vaccine in the setting of a constrained supply. The goals are to minimize death and serious disease, preserve the functioning of society, reduce disproportionate burden on those with existing disparities, and increase equity of opportunity to enjoy health and well-being. After discussions with SMEs and with the ACIP COVID-19 Vaccines WG, the five proposed ethical principles for the ACIP ethics/equity framework are: maximize benefits and minimize harms, equity, justice, fairness, and transparency.

First, the ethical principle to *maximize benefits and minimize harms* includes minimizing death and serious disease, addressing the obligation to promote public health and promote the common good, balanced with the obligation to respond and care for persons, and based on the best available science. The *equity* principle will help orient discussions to make sure that vaccine allocation reduces, rather than increases, health disparities and ensures that everyone has a fair and just opportunity to be as healthy as possible. The *justice* principle involves a commitment to remove unfair, unjust, and avoidable barriers to good health and well-being that disproportionately affect the most disadvantaged populations, as well as intentionally ensuring that groups, populations, and communities affected by a policy are being treated fairly. The *fairness* principle includes a commitment to fair stewardship in the distribution of a scarce resource, with equitable distribution of benefits and burdens; not exacerbating existing disparities in health outcomes; providing equal opportunity to access vaccine; and consistency

in implementation. Finally, *transparency* is essential to building and maintaining public trust during vaccine program planning and implementation. Achieving transparency requires that the supporting principles and processes for allocation decisions are clear, understandable, and open for review. This involves to the degree possible, given the urgency of the response, that public participation in the creation and review of the process is recognized and honored and that all recommendations are evidence based, with information used to make recommendations publicly available.

All ACIP recommendations for COVID-19 vaccines must be ethically principled, evidence-based, and feasible for implementation. GRADE and the EtR framework will be used to ensure recommendations are evidence-based. Dr. Dooling's upcoming presentation will have further discussions around whether the recommendations are feasible for implementation. The remainder of this talk will focus on the steps taken to make sure ACIP recommendations are ethically principled.

Dr. Oliver next walked through the four populations discussed previously, using the proposed framework. SMEs and the WG felt that the transparency principle was more about the process than each individual population, and as such would be more of a foundational principle across the entire framework. In addition, all ACIP recommendations are evidence-based and this serves as an overarching principle.

First, for HCP:

Application of ethical principles to potential early COVID-19 vaccine recipient groups				
← Evidence Based →				
Group	Maximize benefits	Equity	Justice	Fairness
Healthcare personnel (~20M)	Essential for response May decrease transmission to patients, coworkers, community ¹ Decrease COVID-19 morbidity and mortality in some HCP • ~40% have high risk condition or ≥65 years of age ² May be in low redundancy jobs where absenteeism may compromise/stop care	Overrepresentation of some racial or ethnic minority groups and lower income earners • Seroprevalence of SARS-CoV-2 higher among Hispanic and non-Hispanic Black HCP ³ • Larger proportion of staff at LTCF female and non-Hispanic Black persons; disproportionately lower-wage workers ⁴	HCP recommended for early phase vaccination have an equal opportunity to access vaccine Definition of HCP includes "paid and unpaid persons serving in healthcare settings"	Can help reduce disparities in health outcomes Acknowledges increased risk of COVID-19 exposure due to essential nature of work
Transparency Engagement with partners and key stakeholders; Discussion at public meetings				

¹Slayton. Modeling allocation strategies for the initial COVID-19 Vaccine Supply. ACIP meeting Aug 26, 2020
²Gibson. J Gen Int Med 2020 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7314425/?report=reader>
³Self et al MMWR. https://www.cdc.gov/mmwr/volumes/69/wr/mm6925e2.htm?_cid=mm6925e2_a
⁴Oliver. Epidemiology of COVID-19 in essential workers, including healthcare personnel. ACIP meeting July 29, 2020

Under *maximize benefits*, HCP are essential for the response. Protecting HCP may decrease transmission to patients, coworkers, and the community and may decrease morbidity and mortality among this population. Nearly 40% of HCP have a high risk condition or are 65 years of age and older. HCP may serve in low redundancy jobs where absenteeism may compromise care. Under *equity*, there is an over-representation of some racial or ethnic minority groups and lower income earners. Seroprevalence of SARS-CoV-2 is higher among Hispanic and non-Hispanic Black HCP, and a larger proportion of staff at LTCF are female, non-Hispanic Black persons and disproportionately lower-wage workers. Under *justice*, HCP recommended for early phase vaccination should have equal opportunity to access the vaccine. In addition, the definition of HCP is broad and includes paid and unpaid persons serving in healthcare settings. Under *fairness*, vaccination of HCP could help reduce disparities in health outcomes and it

acknowledges the increased risk of exposure due to the nature of work. Finally, *transparency* involves engagement with partners and key stakeholders, as well as discussion at public meetings.

Next moving to other essential workers:

Application of ethical principles to early potential COVID-19 vaccine recipient groups				
← Evidence Based →				
Group	Maximize benefits	Equity	Justice	Fairness
Other essential workers (~60M)	Essential for response and/or functioning of society May decrease transmission to work and community contacts May decrease outbreaks in some work settings/sectors ¹ <ul style="list-style-type: none"> Food/agricultural processing plants Correctional facilities 	Overrepresentation of minority groups in subsets of essential workers ¹ <ul style="list-style-type: none"> Accounted for 87% of cases in meat and poultry processing plants¹ 73% of cases in workplace outbreaks in Utah² 	Essential workers recommended for early phase vaccination have an equal opportunity to access vaccine	Can help reduce disparities in health outcomes Acknowledges increased risk of COVID-19 exposure due to high density workplaces; frontline nature of work; and inability to work remotely
Transparency Engagement with partners and key stakeholders; Discussion at public meetings				
<small>¹Oliveir. Epidemiology of COVID-19 in essential workers, including healthcare personnel. ACIP meeting July 29, 2020 ²Bui et al. MMWR: https://www.cdc.gov/mmwr/volumes/69/ww/mm6933e3.htm?_cid=mm6933e3_w</small>				

Under *maximize benefits*, their work is essential for the response or functioning of society. Protection of other essential workers may decrease transmission to work and community contacts and could decrease outbreaks in some work settings or sectors such as food and agricultural plants and correctional facilities. Under *equity*, there is an overrepresentation of minority groups in some sectors of essential workers, with racial or ethnic minority populations representing nearly 90% of cases in meat or poultry processing plants, and 73% of cases in workplace outbreaks in Utah. Under *justice*, workers should have an equal opportunity to access vaccine. Under *fairness*, vaccination of essential workers could help reduce disparities in health outcomes and it also acknowledges the increased risk of exposure due to high density workplaces and the inability to work remotely. Transparency remains a foundational principle.

Next are adults with high-risk medical conditions:

Application of ethical principles to potential early COVID-19 vaccine recipient groups				
← Evidence Based →				
Group	Maximize benefits	Equity	Justice	Fairness
Adults with high-risk medical conditions (>100M)	Reduce risk of COVID-19 morbidity and mortality <ul style="list-style-type: none"> 60% of hospitalized adults and 80% of hospitalized adults who died had ≥3 high-risk conditions¹ 	Racial and ethnic minority groups have increased prevalence of high-risk conditions <ul style="list-style-type: none"> Non-Hispanic Black adults have highest prevalence of obesity (39.8%), followed by Hispanic adults (33.8%) and non-Hispanic White adults (29.9%)² Prevalence of underlying medical conditions higher in counties in the Southeastern United States and in rural counties ³	Persons recommended for early phase vaccination have an equal opportunity to access vaccine	Can help reduce disparities in health outcomes
Transparency Engagement with partners and key stakeholders; Discussion at public meetings				
<small>¹McClung. Epidemiology of COVID-19 in essential workers, including healthcare personnel. ACIP meeting August 26, 2020 ²Combined data from 2017-2019, BRFSS https://www.cdc.gov/obesity/data/obesity-and-covid-19.html ³Razzaghi et al. MMWR: https://www.cdc.gov/mmwr/volumes/69/ww/mm6929a1.htm?s_cid=mm6929a1_w</small>				

Under *maximize benefits*, protection among adults with high-risk conditions could reduce morbidity and mortality: 60% of hospitalized adults and 80% of adults who died had three or more underlying conditions. Under *equity*, racial and ethnic minority groups have increased prevalence of many high risk conditions, with data on obesity presented in the table. In addition, the prevalence of underlying medical conditions is higher in counties in the Southeastern US and rural communities, where the SVI is generally higher. Under *justice*, persons recommended for early phase vaccination should have an equal opportunity to access vaccine. Under *fairness*, providing vaccine to adults with high-risk medical conditions can help reduce disparities in health outcomes. Again, transparency is a foundational principle.

And finally, for adults 65 years of age and older:

Application of ethical principles to potential early COVID-19 vaccine recipient groups				
← Evidence Based →				
Group	Maximize benefits	Equity	Justice	Fairness
Adults ≥65 years of age (~53M)	Reduce risk of COVID-19 morbidity and mortality <ul style="list-style-type: none"> Adults ≥65 years of age represent 16% of cases, but nearly 80% of deaths¹ 	Hispanic and non-White decedents under-represented among COVID-19 deaths in adults ≥65 years of age ²	HHS Office for Civil Rights says age not recommended for use in ventilator/resource allocation ³	<p>“Healthy older person who can shelter in place is at different risk from a medically vulnerable older person in crowded housing”⁴</p> <p>“Age should never be used to exclude someone categorically from a standard of care, nor should age ‘cut-offs’ be used in allocations”⁵</p>
Transparency Engagement with partners and key stakeholders; Discussion at public meetings				

¹McClung. Epidemiology of COVID-19 in essential workers, including healthcare personnel. ACIP meeting August 26, 2020
²Wortham et al. MMWR https://www.cdc.gov/mmwr/volumes/69/wr/mm6928e1.htm?_cid=mm6928e1_w
³<https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf>
⁴Persad G, Peek MS, Emanuel EJ. JAMA. See <https://jamanetwork.com/journals/jama/fullarticle/2770684>.
⁵American Geriatric Society Public Comment to National Academies of Science, Engineering and Medicine

Under *maximize benefits*, providing vaccine to this population could reduce morbidity and mortality. Adults 65 and older represent 16% of cases, but nearly 80% of deaths. However, there are other things to consider in this population. Under *equity*, Hispanic and non-White decedents are under-represented among COVID-19 deaths in adults 65 years of age and older. Under *justice*, the HHS Office for Civil Rights (OCR) has stated that a strict age cut-off or age-based criterion alone is not recommended for use in ventilator or resource allocation. Under *fairness*, Persad and co-authors have stated that a “healthy older person who can shelter in place is at different risk from a medically vulnerable older person in a crowded housing environment.” The American Geriatric Society (AGS) submitted a statement to NASEM after their draft framework was released stating that “age should never be used to exclude someone categorically from a standard of care, nor should age cutoffs be used in allocations.” This public comment shows the importance of transparency as a foundational principle as well.

The next steps are to continue to progress the development of an ACIP ethics/equity framework. The WG is happy to receive input from ACIP regarding the five proposed ethical principles and their application. The WG is also planning further discussions about application of the framework to “Phase 1” allocation discussions and future recommendations. In addition, there are discussions around how ethics and equity can formally be incorporated into the EtR framework for COVID-19 vaccines, and hopefully, more broadly to other vaccines as well.

Discussion Points

Dr. Szilagyi expressed his support for the five proposed ethical principles for the ACIP ethics/equity framework of: maximize benefits and minimize harms, equity, justice, fairness, and transparency. He thinks these are the right principles and that they overlap very nicely with the best components of the SAGE, Hopkins, and NASEM models. One of the challenges is that they must remember that over months, the vaccine supply will increase. Therefore, these decisions would have to be made for a shorter time period. There is wide diversity of risk within each of these groups, but it is very difficult to figure out the actual risk for an individual person. Some sort of a principle is needed that follows the rules of simplicity and offers the ability to identify individuals.

As the WG Chair, Dr. Bell encouraged other ACIP members and liaisons to weigh in on their sense of whether this is heading down the right track and if they feel that a framework like this would help them. While she completely agreed with what Dr. Szilagyi said about not wanting to be so totally focused on something that hopefully will last a relatively short period time, showing that they have thought about all of these issues very carefully and are transparent about it will be helpful for inspiring public confidence.

Dr. Poehling agreed that this is exactly the type of information needed to think clearly about how to maximize the benefit and minimize the harm. This is a very transparent way to do this. She agreed with all of the principles and thought it was an excellent start.

Dr. Hunter also agreed with the principles. He pointed out the importance of understanding who would apply these principles early. Hopefully, it will not be the individual clinician or nurse at the point-of-care dealing with an individual patient or client. Instead, it should be used on a more programmatic level at the state and local health department and healthcare system levels with flexibility to decrease potential conflict at the point-of-care between the vaccinators themselves so there can be some flexibility at the site. In order to increase confidence in general and gain trust and cooperation, political leaders and scientific experts together need to come to consensus behind this. Unified delivery of messages that are evidence-based recommendations and these unified principles are the way to go and will make the jobs of ACIP and state health departments much easier.

Dr. Fryhofer (AMA) thanked ACIP for the thoughtful and methodical process they went through with respect to these principles. Weigh in from the WHO/SAGE, Hopkins, NASEM, and AGS added credibility to this process. She expressed great appreciation for the *transparency* foundational principle mentioned. The AMA had an opportunity to weigh in on the NASEM recommendation. She clarified that under the four-phase approach, physicians, healthcare staff, and private practices involved in direct patient contact and who are, therefore, at increased risk of exposure, should be eligible for vaccine in Phase 1. These physicians and HCP may not have access to personal protective equipment (PPE) that physicians and others have in larger facilities.

Dr. Atmar found this to be an outstanding framework that set the groundwork for the difficult work ahead, which is further deciding how to roll out the vaccine to various groups. He echoed

Dr. Szilagyi's comment about trying to keep it simple to implement and Dr. Hunter's comments about the importance of guidance. His own healthcare system has begun to struggle with how

vaccine that becomes available should be allocated within the healthcare system. They are racing against time to be prepared to do this, but there is still the very real challenge of trying to figure out within these groups how to further sub-divide.

Phase 1 Allocation COVID-19 Vaccine: Work Group Considerations

Kathleen Dooling, MD MPH

**National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention**

Dr. Dooling presented WG considerations for Phase 1 allocation of COVID-19 vaccines. The WG envisions the overall goals of a COVID-19 vaccine program to be to: 1) ensure the safety and effectiveness of COVID-19 vaccines; 2) reduce the transmission, morbidity, and mortality of COVID-19 disease; 3) help minimize disruption to society and the economy, including maintaining healthcare capacity; and 4) ensure equity in vaccine allocation and distribution. From the beginning, the WG established guiding principles to help achieve these goals. The first guiding principle is that safety is paramount. Second, clinical trials should be inclusive. Third and fourth, and most pertinent to this presentation, are the desire for efficient distribution of vaccine and flexibility within national guidelines.

As mentioned a number of times throughout the day, administration of COVID-19 vaccines will require a phased approach. Once a vaccine is approved for use, there likely will be insufficient supply to meet demand. In August, ACIP heard about cold-chain storage and handling requirements of -70° and -20° Celsius, which may require specialized equipment and high throughput in clinics. In the second and third phases of this vaccine rollout, sufficient vaccine supply and a broadening of the implementation strategies to reach everybody who wants to be vaccinated are anticipated. This session focused on the first phase, that projected short period of time when vaccine doses may be limited and administration will need to be targeted, and how the objectives of the program can best be achieved during this period.

During the August emergency meeting, ACIP members voiced support for HCP to be offered vaccine during Phase 1a. Phase 1b groups included essential workers outside of healthcare, adults with high-risk medical conditions, and adults 65 years and older. The Phase 1b groups were further explored during the September meeting, with a review of their risk for COVID-19, the overlap between groups, their racial and ethnic composition, and a summary of the WG considerations for each group. These two questions were posed for ACIP to consider while hearing the presentation:

- If constrained vaccine supply necessitates sequencing of groups in Phase 1b, what are the most important information gaps we need to fill for ACIP to make sequencing recommendations?
- What is the correct balance of national guidance and local flexibility?

As mentioned, there was broad support from ACIP for inclusion of HCP in Phase 1a of a COVID-19 vaccine program. HCP are defined as “all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials.” The estimated population for this group is 17 to 20 million people in the US. Although not exhaustive, some examples include HCP who work in hospitals, LTCFs (including assisted

living and skilled nursing facilities), outpatient, home health care, pharmacies, Emergency Medical Services (EMS), and public health.

In terms of information that either supports early allocation of doses to HCP or will pose a challenge, equity considerations support early vaccination of broadly defined HCP as there is high representation of racial minority groups in some healthcare settings, such as long-term care and home health care. As heard in the previous talk, all values-based allocation frameworks the WG reviewed included HCP in their earliest allocations. Feasibility considerations mostly support HCP as at least large healthcare systems have occupational health departments to facilitate vaccine clinics, and they may also have -80°C freezers. However, it will be more challenging to reach rural healthcare facilities, LTCF, small independent clinics, and home health care workers. Importantly, it will not be possible to assess the benefits or possible harms of any particular COVID vaccine until the clinical trials are complete.

Regarding Phase 1b essential workers, not including healthcare workers, the Cybersecurity and Infrastructure Security Agency (CISA) within the Department of Homeland Security (DHS) is responsible for creating a list of workers who are essential to continue critical infrastructure and maintain the services and functions Americans depend on daily. Their guidance acknowledges that workers who cannot perform their duties remotely and must work in close proximity to others should be prioritized for mitigation measures. It is also important to recognize that sub-categories of essential workers may be prioritized differently in different jurisdictions depending upon local needs. The estimated population for this group, not including HCP, is 60 million people. Although not exhaustive, some examples include workers in industries such as food and agriculture, transportation, education, energy, water and wastewater, and law enforcement.

Although few specific surveillance systems for COVID-19 exist within critical industries, there are numerous examples of outbreaks affecting these workers. By July 2020, hundreds of outbreaks had been documented in meat and poultry processing plants affecting thousands of workers¹. Similarly, corrections and detention facilities' residents and staff have been hard-hit^{2,3}. In New York City (NYC), seroprevalence among correctional facility workers and fire department workers on the frontlines exceeded those of the general population⁴ [¹*MMWR* July 10, 2020 https://www.cdc.gov/mmwr/volumes/69/wr/mm6927e2.htm?s_cid=mm6927e2_w; ²UCLA COVID-19 Behind Bars Data Project <https://law.ucla.edu/academics/centers/criminal-justice-program/ucla-covid-19-behind-bars-data-project>; ³Hagan et al. *MMWR* – projected publication date August 7. Results of mass testing for SARS-CoV-2 in 16 prisons and jails—Six U.S. jurisdictions, April–May 2020;⁴<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-07/COVID-06-Oliver-508.pdf>].

There is a significant proportion of essential workers who also have high-risk medical conditions that range from about 30% of essential workers with obesity to about 2% with chronic kidney disease (CKD). It is estimated that more than a third of essential workers have a medical condition putting them at high-risk for severe COVID-19 disease. Essential industries may vary by the prevalence of high-risk medical conditions among their workers. For example, transit and postal workers have a slightly higher than average risk of cardiovascular disease (CVD) while workers in trucking have a disproportionate prevalence of obesity and diabetes¹. The racial and ethnic composition also varies among essential industries. Racial and ethnic minorities account for about 37% of US adults, but more than 50% of transit workers and utility workers. In fact, compared to all workers, Black workers are over-represented among frontline industries.

Hispanic workers are over-represented in industries such as trucking, warehousing, and building cleaning services. Despite performing work essential to the functioning of society, 23% of essential workers live in low-income families defined as income less than two times the poverty line. Moreover, 10% of essential workers have no health insurance. That reaches as high as 30% in industries such as cleaning services. There is also overlap between essential workers and older adults. Approximately 16% of essential workers are either 65 or older themselves or live with someone who is ² [¹https://www.cdc.gov/mmwr/volumes/69/wr/mm6936a3.htm?s_cid=mm6936a3_w; ² Source: American Community Survey. CEPRs Analysis of American Community Survey, <https://cepr.net/a-basic-demographic-profile-of-workers-in-frontline-industries/>].

The WG's summary of the considerations for essential workers are that overall, equity considerations support early vaccination of essential workers as there is high representation of racial and ethnic minorities and many workers may be in low-income families or have no health insurance. Although all values-based frameworks the WG reviewed recognized essential workers for early vaccinations, they differed in their prioritization of specific industries. It is still largely unknown how essential workers value COVID-19 vaccination. In terms of feasibility, essential workers are generally mobile and vaccine points of dispensing may be deployed to work sites. Because essential industries vary by jurisdiction, states will likely have to make prioritization decisions which will exercise local flexibility. On the other hand, prioritization exercises will increase workload and create the potential for differences from state-to-state. Finally, the acceptance of COVID-19 vaccine among essential workers is not precisely known.

Moving to the Phase 1b group of persons with high-risk medical conditions, focusing on adults with medical conditions at higher risk for severe COVID-19, the estimated population for this group is over 100 million adults in the US. This is a rough estimate and may change as evidence is gained about the conditions which confer risk. The [current list of conditions](#) includes: cancer, CKD, chronic obstructive pulmonary disease (COPD), immunocompromised state from solid organ transplant, obesity defined as body mass index (BMI) of 30 or greater, serious heart conditions (heart failure, coronary artery disease, or cardiomyopathies), sickle cell disease, type 2 diabetes mellitus. The [percentage of adults with selected medical conditions](#) ranges from approximately 31% with obesity to 3% with CKD.

In terms of risk for COVID-19 disease, nearly 90% of hospitalized adults had at least one high-risk medical condition and over 60% have three or more¹. Obesity, CKD, diabetes, and hypertension are associated with hospitalization for COVID-19². Among hospitalized COVID-19 patients, the adjusted rate ratios for underlying medical conditions associated with death ranged from 1.19 for diabetes to 1.39 for immunosuppression³ [¹https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html; ²Ko et al. *Clinical Infectious Diseases*, ciaa1419, <https://doi.org/10.1093/cid/ciaa1419>; ³Kim et al, *Clinical Infectious Diseases*, ciaa1012, <https://doi.org/10.1093/cid/ciaa1012>].

The prevalence of selected underlying conditions varies by race and ethnicity. For example, the prevalence of diagnosed cancer, CKD, and CVD is either similar across all racial and ethnic groups or higher in whites. Whereas the prevalence of diabetes and obesity was highest among American Indians and Alaska Natives [National Center for Health Statistics, National Health Interview Survey, 2018. Estimates were not available for Hawaiian/other Pacific Islanders or for CKD among American Indian/Alaska Native populations].

In summary, the WG's considerations for high-risk medical conditions are that equity may be challenged by early vaccination of adults with high-risk medical conditions because diagnosis of these conditions may require access to healthcare. All of the allocation frameworks that were reviewed support persons with high risk medical conditions as early phase vaccine recipients. Supporting feasibility of vaccination, persons with medical conditions are often connected with healthcare. On the other hand, the number of people in this group is greater than 100 million and likely will require some prioritization if vaccine supply is constrained. This will be difficult considering the high degree of overlap between conditions like obesity and diabetes. Moreover, assessing medical eligibility within the context of a mass vaccination clinic is logistically challenging. In terms of acceptability, this group has moderate influenza vaccine coverage, but it is not yet known how this group will view acceptability or value Phase 1 receipt of COVID-19 vaccine.

Turning to Phase 1b adults ≥ 65 years of age, this group is estimated at approximately 53 million persons in the US. This accounts for approximately 16% of the U.S. population. Of note, approximately 3 million persons currently live in LTCF¹. In terms of COVID risk, adults 65 years and older represent 16% of COVID-19 cases but nearly 80% of COVID-19 deaths². Adults 65 years and older have the highest cumulative rate of COVID-19 associated hospitalizations³. Older age is the strongest independent risk factor for in-hospital death⁴. Hispanic or Latino persons account for almost 18% of the total U.S. population, but only 8% of the population 65 and older. Of this group, 77% are white and racial minority groups all comprise a smaller fraction of people 65 years of age and older compared to their proportion in the overall population. According to the National Health Interview Survey (NHIS) approximately 39% of adults 65 and older have a medical condition that puts them at high risk for severe COVID-19 disease [¹United States Census Bureau <https://www.census.gov/topics/population/older-aging.html> <https://www.cdc.gov/nchs/fastats/nursing-home-care.htm>; ²<https://www.cdc.gov/covid-data-tracker/index.html#demographics>; ³https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html; ⁴Kim *et al*, *Clinical Infectious Diseases*, c1aa1012, <https://doi.org/10.1093/cid/c1aa1012>; <https://www.census.gov/library/publications/2018/acs/acs-38.html>].

When considering early vaccination of adults 65 and older, a challenge to equity is the under-representation of racial and ethnic minorities among older persons. Some allocation frameworks support the early vaccination of older persons, especially those living in congregate settings, while other frameworks suggest that older persons living at home and without underlying medical conditions should be vaccinated in Phase 2. In terms of feasibility, persons 65 and older usually have access to Medicare and a high proportion have a regular place they receive healthcare. However, if mass vaccination clinics are necessary, mobility and social distancing may be difficult for some in this age group. As for acceptability, older adults have moderate influenza vaccine coverage. However, it is not yet known how this group will view acceptability or value early vaccination with COVID-19 vaccine.

To recap, the WG has reviewed the worker considerations of three possible groups for Phase 1b vaccine allocation. The WG has articulated some key unknowns, which hamper more detailed sequencing for these groups. First, there are multiple vaccine characteristics that are not yet known such as the magnitude and balance of benefits and potential risks; the storage, distribution, and handling for cold-chain requirements that have ramifications for implementation; and whether vaccine efficacy and immunogenicity will be different in younger versus older recipients. Another unknown regards whether the vaccine will be approved under an Emergency Use Authorization (EUA) or licensure and which populations may be covered.

Finally, the number of doses that will be available at the time of approval and the rate of scale-up are unknown.

As for next steps, the WG will continue to build scientific understanding of the epidemiology of the Phase 1 groups, modeling the impact of various vaccination strategies, and interpretation of early clinical trials safety data and plans for post-marketing safety monitoring. The WG will prepare the EtR framework for vaccines in Phase 3 clinical trials, including preparing an equity domain, gathering evidence on the value and acceptability domains among others, GRADEing safety and efficacy from Phase 3 data as it becomes available, and preparing policy options for ACIP consideration. Dr. Dooling requested discussion and input on the two questions she posed earlier for ACIP's consideration.

Discussion Points

If constrained vaccine supply necessitates sequencing of groups in Phase 1b, what are the most important information gaps we need to fill for ACIP to make sequencing recommendations?

- ❑ Be very clear about serious COVID infection and death and separating that as the outcome from COVID infection:
 - For example, many essential workers in some groups who do not have chronic conditions or who are younger may have a very high likelihood of infection and a higher or lower likelihood of mortality.
 - For this particular question, it may not be possible to answer the impact on those with severe disease versus transmission. The reason this might be important is that there may be a greater focus on preventing severe morbidity and mortality in some populations but preventing transmission in other populations.
- ❑ It is interesting that none of the paradigms specifically called out older adults or staff in LTCF facilities, given the evidence that was presented previously at another meeting about the importance of vaccinating staff around them. This is one group within those ≥ 65 years of age who might be an important subgroup to call out.
- ❑ It could be beneficial to better understand what percent of hotspots have been due to essential workers and perhaps focus on these workers:
 - This could decrease transmission, morbidity, and mortality; increase societal and economic benefits; and address equity.
 - Thinking about how large the pool of essential workers is, it might make sense to move essential workers in hotspots into Phase 1a. This might also address some of the concerns people have about making sure there is a priority for disadvantaged populations; using the SVI might have more impact. Getting 80 million doses in addition to the 20 million is going to de-prioritize essential workers in hotspots.

- ❑ It is important to understand acceptability in each of the groups:
 - Determine how to figure in the limited acceptance that some of these groups may have.
 - Perhaps some mathematical modeling could help to ascertain varied rates of acceptance of the vaccine, which will in turn impact distribution and administration.
- ❑ There appears to be overwhelming support for and wholehearted agreement with the principles of the frameworks presented and how consistent the WG's proposed principles are with those:
 - In terms of the exploration of the EtR, these principles for prioritizing groups should be used for allocation, distribution, and administration in order to get the vaccine to the prioritized groups and actually into them.
- ❑ Perhaps V-SAFE, which will initially roll out among HCP, could be used among additional essential workers as well.
- ❑ Early on when there is constrained supply, it is going to be very difficult for state and local health immunization program directors to allocate the vaccine that they have control over to particular venues in terms of deciding which ones to go with first:
 - Within Phase 1b, it could be beneficial to have as much differentiation and information as possible to rank them. Perhaps a ranked list of the smallest sub-group divisions possible would be helpful.
 - The benefit-risk balance is unknown for all of the vaccines. For example, if the benefit-risk balance in adults over 65 looks quite different than in younger adults, that might influence the ordering and vice versa. If a benefit-risk balance is extremely favorable versus moderate, that also may influence the approach that might be taken to maximize the benefits and risks in any given population. This will depend upon the characteristics of the vaccines.
- ❑ In low-income areas, access to facilities that can provide the vaccine may be more challenging:
 - Consider placing more emphasis on mobile van distribution to ensure vaccine access in disadvantaged populations
- ❑ In terms of prioritizing groups and the implementation process, consideration should be given up front to the importance of operationalizing access to second doses to ensure that the vaccines doses administered are effective.
- ❑ An important information gap is that it is unknown how the pediatric population fits into the equation, but it is likely to factor in since they will not be immunized, but certainly will interface with all of these groups of adults.

Considering all the groups discussed, what is the correct balance of national guidance and local flexibility?

- ❑ There must be some degree of local flexibility within the boundaries of the guidelines that ACIP establishes, in part because this will be important in delivering vaccine to a number of the significant groups listed. While there has to be some degree of flexibility, the boundaries should be respected.
- ❑ One argument for greater national guidance is because it is at this level where there is the greatest transparency. Transparency is not always quite as good at the intermediate and local control levels.
- ❑ This is a delicate and important question in terms of the national conversation and guidance. The easier the guidance can be made to follow and implement, the better it will be. There likely will need to be some local flexibility, but the more similar and transparent guidance is across the country, the better the process will go.
- ❑ There seem to be some clear domains that should be at the national level. For instance, guidance on the benefit/risk for transmission, hospitalizations, and deaths can be transmitted nationally. Guidance for VE early on, interim, the entire population, and those over 75 years of age could be at the national level. However, it is at the local level that local public health officials will need to know whether they are a hotspot or not, and that will change over time. Local authorities will know the prevalence among various kinds of essential workers. For example, some areas have many meat packing facility essential workers and other areas do not have any. Those at the local level will know their delivery mechanisms, practical aspects of implementation, and perhaps the values of the population. There must be a balance between national guidelines and local flexibility.
- ❑ The idea that hotspot analyses can be used to make decisions about how to target vaccines is somewhat troubling given that hotspot analyses do not predict very far out and may not predict out past the second dose of vaccine if it is a 28-day vaccine that then takes another week to be effective. There may be other reasons to target hotspots, such as helping to ensure that people understand the risks. Nevertheless, it is important to be careful how this is communicated to state and local health departments so that it is not inappropriately suggested that these current vaccines would be a short-term tool for controlling outbreaks.
- ❑ The reality is that what is occurring at the local level has to drive the response for the community and local public health, so flexibility is critical.
- ❑ National guidance can provide high-level recommendations or principles that drive implementation, but the local level is where the implementation actually happens. Preserving the autonomy of local leaders who are critical in supporting implementation in their areas will be very important. Perhaps implementation metrics could be developed for accountability. For instance, one metric could focus on measuring equity in terms of distribution and administration. Think about the SVI as a tool for this rather than focusing on hotspots, which come and go and might not be predictable in sufficient time to get vaccine distributed in advance. Communities at risk are well-known independent of disease activity and should be advocated for as priority populations.

- ❑ National guidance is very important in terms of the delicate issue of balance. There is currently an imbalance and it seems that much more national guidance is needed at this point. At the same time, operationalizing national guidance and allowing for flexibility at the local level are also important.
- ❑ This vaccine is unlikely to be used for hotspots as it will not be feasible given the way the vaccine needs to be stored, drawn up, and used. Flexibility for local planning seems to pertain more to whether the community has strawberry farms, meat packing plants, or something else. The idea is to keep workers safe who cannot work from home.
- ❑ Consideration also must be given to how vaccines will be distributed among states. It seems that disease prevalence and hotspots will be important considerations in terms of how many doses are delivered to states so that they can then use the flexibility needed to deliver to local communities.
- ❑ It is very clear that these first vaccines are not amenable to outbreak control. Therefore, it is not convincing that hotspot analysis would play a major role in decision-making. Part of the decision regarding allocation will be driven by the ACIP recommendations. In the absence of specific information about the vaccine and priority groups, it is difficult to say exactly how vaccine will be allocated. But as state and local health departments know, in order to do planning, CDC has given states the broad outlines of some scenarios that are thought to make sense in terms of prioritization as a starting point. Part of what CDC looks to ACIP for is to help the agency by making those very specific recommendations.
- ❑ While national guidance is important, there must be some local flexibility because there are likely to be marked differences in vaccine uptake even among those considered to be higher risk individuals.
- ❑ While national guidance is important and necessary, it is important to be careful that the level of guidance is not too granular such that it bogs down or paralyzes vaccination campaigns because of complex decision-making, data gathering, and paperwork. It would be best for states and communities to plan how they are going to distribute and administer the vaccines such that the process is as efficient as it can be. This would need to be done before they are shipped to distribute and administer. Early planning will be most effective and efficient and too much oversight is not always the best choice.
- ❑ The AMA submitted a paper to the WG based on the *AMA Code of Medical Ethics: Allocating Scarce Vaccine Supplies in a Public Health Crisis*. One of the topics that was raised in this document is distribution based on the geography of need and perhaps in some instances that might be preferable ethically to putting foundational values into play. The geography of need requires an approach that determines the number of vaccine doses provided based on identifying those communities where, based on the available evidence, access to vaccine supplies could reasonably be expected to have the greatest effect. Such decisions might take into account such factors as known emerging hotspots and structural factors that influence the risk and rate of transmission, such as population density, demographics, and living conditions. This approach is different from what is normally done, would require an infrastructure for data collection, and likely would demand new channels of

communication and coordination. This would involve things that could only be accomplished by looking at this at a local level.



Certification

Upon reviewing the foregoing version of the September 22, 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

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Centers for Disease Control and Prevention
Advisory Committee on Immunization Practices
July 1, 2019 – December 31, 2020**

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