For Internal Use Only, last edited 12.9.20

Internal Use Only – Updates in blue

TOPLINE MESSAGES FOR THE WEEK (DECEMBER 9)

- As case counts rise across the United States, implementation of a successful COVID-19 vaccination program becomes even more crucial. Vaccine planning, distribution, and administration are the next steps in the U.S. government's overall efforts to protect Americans, reduce the impact of the COVID-19 pandemic, and help restore some normalcy to our lives and our country.
- CDC continues to work with all 64 domestic jurisdictions on their readiness efforts. We know that there will be bumps in the road as the COVID-19 vaccination program is rolled out – that is to be expected. However, public health experts have extensive experience with vaccine distribution and administration and will work to quickly overcome obstacles.
    - The rollout of the COVID-19 vaccination program can be compared with the rollout of new software for phones – we expect some challenges, and we'll work quickly to meet them.
    - Jurisdictions are under immense stress at the moment – with COVID-19 cases increasing in nearly every state, planning for a large-scale vaccine rollout, and maintaining standard public health services. Their hard work and dedication are the reasons the COVID-19 vaccination program will be successful.
- Pfizer and Moderna have now submitted data for an emergency use authorization from FDA. FDA's independent advisory committee, the Vaccine and Related Biological Products Advisory Committee, is set to meet this week to discuss Pfizer's request for emergency use authorization and December 17 to discuss Moderna's request for emergency use authorization.
- Although we still have much to learn about these vaccines, the recent positive news means COVID-19 vaccines may be a tool, along with continued social distancing and mask wearing, to control the pandemic.
- Jurisdictions have started to notify the CDC of their intent to initiate the LTCF Federal Pharmacy partnership, which requires a two-week notification period. Jurisdictions are asked to specify the date on which it would like to turn the program on, and preference for product. More information on the Federal Pharmacy partnership can be found below.

CDC COVID-19 VACCINE MESSAGES

CONTENTS

UPDATES (IN BLUE BELOW IN THE SECTIONS AS WELL)

Vaccine Distribution

- CDC and OWS completed an end-to-end logistics test that shipped Pfizer vaccines to jurisdictions during the week of November 30.

Pharmacy – Long-Term Care Facilities

- On December 4, the list of participating facilities that will be served by the program was locked. All jurisdictions besides the U.S. Virgin Islands have opted into the program.
- Jurisdictions will need to provide at least a two-week notice to initiate the LTCF program. This period allows federal pharmacy partners to prepare for vaccine administration and coordinate with LTCF facilities. To begin the program, a jurisdiction must have an allocation of at least 50% of the required doses to cover the program within one week of providing notice.
- Jurisdictions will need to select which authorized vaccine will be used to support the program in their jurisdiction. Once activated, vaccine to support the program will come from jurisdictional allocations.
- The LTCF program will be split into two components:
    - In Part A, the program will perform vaccinations at skilled nursing facilities.
    - In Part B, the program will provide vaccinations at other facilities enrolled in the program such as assisted living facilities, continuing care residential facilities, etc.
- Jurisdictions can choose whether to start with Part A alone when activating the program or can opt to activate both Parts A and B simultaneously.
- CDC will provide jurisdictions with an estimated number of doses needed to cover Part A and Part B. Allocations that are not used as part of the program will be returned to the rest of the jurisdiction's allocation.

Administration, Storage, and Handling

- Pfizer's vaccine may be stored in its thermal shipper for up to 30 days if it receives a dry ice recharge every five days.
- Additional training materials on product-specific administration, storage, and handling topics will become available after the FDA issues an EUA.
    - For Pfizer, these may include a checklist for unpacking a delivery, beyond use date tracking labels for refrigerator storage, FAQs, a standing orders template, thermal shipping container temperature logs and a beyond use date tracking tool, temperature logs for ultra-cold units, vaccine preparation infographics, a vaccine administration summary, and a vaccine storage and handling summary.
    - For Moderna, these may include beyond use date tracking labels for refrigerator storage, FAQs, a standing orders template, temperature logs for freezer units, a vaccine administration summary, and a vaccine storage and handling summary.

EUA and Guidance for Industry

- VRBPAC is scheduled to convene on December 10 to discuss whether the Pfizer-BioNTech vaccine warrants issuance of an EUA. VRBPAC will meet again on December 17 to discuss the Moderna vaccine. Briefing materials that include clinical trials data will be available two days prior to each VRBPAC meeting.
- Once an EUA is issued, an EUA Letter of Authorization and EUA fact sheets will become available.
    - The Letter of Authorization describes the scope and criteria for EUA issuance.
    - EUA fact sheets will include one meant for healthcare providers and another meant for vaccine recipients and caregivers. Unlike a typical vaccine information statement (VIS), an EUA fact sheet is specific to one particular product (i.e. instead of referring to a class of vaccines).
- Although a patient's written informed consent is not required under an EUA, vaccination programs may choose to require written or verbal informed consent.
- As CDC and FDA monitor vaccine safety post-EUA, amendments to the EUA fact sheets may be posted on the FDA's website
- FDA cannot mandate that someone must receive a vaccine authorized under an EUA.

GENERAL KEY POINTS

- Operation Warp Speed is a partnership led by the U.S. government to help develop, manufacture, and distribute millions of COVID-19 vaccine doses as quickly as possible while ensuring those vaccines are safe and effective.
- Preparing to implement programs to provide safe and effective COVID-19 vaccines is a critical next step in efforts to immunize Americans, reduce the impact of the COVID-19 pandemic, and to help restore some normalcy to our lives and our country.
- We currently find ourselves in a complex and evolving landscape with respect to these vaccines, with multiple vaccines under development and some with characteristics that differ from the vaccines used year-round in the U.S.
- Anticipating that vaccine will first be available in limited doses, the Advisory Committee on Immunization Practices (ACIP) has described considerations for prioritization during the early phases of COVID-19 vaccination programs. ACIP will vote on prioritization for early doses of vaccine very soon after emergency approval is given by the U.S. Food and Drug Administration (FDA).
- Most vaccine products will be provided in 2-dose series, and some vaccine products will require special storage and handling (e.g., ultra-cold storage).
- Monitoring vaccine safety and building trust and educating healthcare providers will be critical to ensuring high vaccine coverage
- The end goal is for every person in the U.S. to get a COVID-19 vaccine. CDC and Operation Warp Speed efforts will work to:
    - Ensure safety and effectiveness of COVID-19 vaccines
    - Reduce mortality, morbidity, and incidence of COVID-19 disease
    - Help minimize disruption to society and economy, including maintaining healthcare capacity
    - Ensure equity in vaccine allocation and distribution
- The two vaccine candidates that have completed enrolling Phase III clinical studies in the United States were developed using a new vaccine technology employing messenger RNA (mRNA). When authorized or approved, these will be the first vaccines approved using mRNA technology.

IMPLEMENTATION – JURISDICTIONAL PLANNING

- CDC is working through existing U.S. jurisdiction programs to coordinate the distribution and administration of COVID-19 vaccines.
- On September 16, CDC released the first iteration of the *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations* that provides general interim guidance on how to plan and operationalize a vaccination response to COVID-19 within jurisdictions. This playbook was updated on October 29.
- Primary goals of ongoing planning efforts are to ensure high-priority groups are vaccinated early and to establish a foundation to ensure vaccine access to larger groups by working at the community level.

    - All jurisdictions submitted initial vaccination plans in mid-October, and CDC has provided feedback to jurisdictions on these plans. Focus is shifting to ensure readiness for Day 0 and planning for Days 1-30.
    - Jurisdictions are now confirming capacity and throughput with providers, preparing for Points of Dispensing (POD) setups, and running their own planning exercises.
- CDC posted the executive summaries of each plan, allowing for transparency and a general understanding of each jurisdiction's strategy. CDC is also working with jurisdictions to provide communication materials, assist with vaccine administration capacity calculations, and prepare readiness checklists.
- Initial vaccine allocation to jurisdictions will happen on a pro rata basis according to the jurisdiction's population.
- Operation Warp Speed is planning to deliver the first doses of vaccine after the FDA's Vaccine and Related Biological Products Advisory Committee (VRBPAC) has met and recommended that FDA authorize or approve a vaccine. In this way, vaccine can be administered soon after CDC's Advisory Committee on Immunization Practices (ACIP) makes recommendations.
- Jurisdictions have provided the locations where initial vaccine doses will be shipped.
- After that initial distribution of vaccine, jurisdictions will order from their weekly allocations.
    - A second dose will automatically be set aside for each first dose a jurisdiction orders.
    - Jurisdictions will be prompted to order the second dose through VTrckS.
- All vaccine will be ordered centrally through the vaccine tracking system VTrckS (see below).
- Jurisdictions and commercial or federal partners will place orders on behalf of providers.
- Jurisdictions must ensure that providers report vaccine administration data so that the jurisdiction can then transmit data to the CDC's IZ Gateway "Connect" component. Jurisdictions are not responsible for reporting data from federal agencies or commercial partners who receive vaccine allocations directly from CDC.

IMPLEMENTATION – FEDERAL ENTITY PLANNING

- Vaccine allocation to federal entities will not count against a jurisdiction's vaccine allocation.
- CDC is working with the following federal entities that will receive direct allocation of COVID-19 vaccines:
    - Federal Bureau of Prisons
    - Department of Defense
    - Department of State
    - Veterans Health Administration
    - Indian Health Service
- The allocation process for federal entities has yet to be determined.
- Federal agencies are planning to implement ACIP recommendations and will be included in early vaccine allocation and distribution.
- Federal agencies that are involved in the COVID-19 response but are not one of the five listed above that CDC is currently working with should work with immunization programs in their U.S. jurisdictions to ensure their staff is included in the plans for vaccination.

IMPLEMENTATION – TRIBES

- To ensure equitable access to COVID-19 vaccines, Tribal Nations will decide their vaccine allocation preferences—whether to receive vaccine through their jurisdiction or through the Indian Health Service (IHS).
- We want to be respectful of Tribal sovereignty and allow Tribes to make their own decisions on vaccine delivery.
- Tribal Nations have two options:
    - First, accessing vaccine through jurisdiction immunization programs:
        - I/T/U facilities that currently report vaccination data to the state immunization information system (IIS) may be able to use this existing process for COVID-19 vaccination reporting.

        - Jurisdiction decisions will affect the terms of who receives the vaccine, and potentially which vaccine is used, how it is distributed, and the amount that is received.
        - Working through immunization programs allows coordination of vaccination across the state in tribal and non-tribal populations.
    - Second, accessing vaccine through the Indian Health Service for delivery and distribution.

VACCINE DISTRIBUTION

- In August, CDC exercised a contract option with McKesson Corporation, which will serve as the central distributor for future COVID-19 vaccine(s) and related supplies. Centralized distribution allows the government full visibility, control, and ability to shift assets and use data to optimize vaccine uptake.
    - CDC has an existing contract with McKesson to support vaccine distribution for the Vaccines for Children (VFC) program.
    - McKesson has experience in this area, having distributed H1N1 vaccine during the H1N1 pandemic in 2009–2010.
- Once vaccines are allocated to a given jurisdiction or authorized partner, McKesson will deliver a specific amount of vaccine to a designated location.
    - Although vaccine distribution will be managed centrally, vaccines may be handled through more than one distributor, and distribution may expand to include additional organizations and providers.
    - HHS has also contracted with McKesson to produce, store, and distribute COVID-19 vaccine ancillary supply kits on behalf of the Strategic National Stockpile. Each kit will contain enough supplies to administer up to 100 doses of vaccine and will include:
        - Needles (various sizes for the population served by the ordering vaccination provider)
        - Syringes
        - Alcohol prep pads
        - Surgical masks and face shields for vaccinators
        - COVID-19 vaccination record cards for vaccine recipients
        - Needle information card
- This vaccine distribution system will be scalable to meet demand. Vaccine with ultra-cold storage requirements will be shipped directly from the manufacturer to vaccination provider sites.
- Initially, jurisdictions should anticipate that allocations will be less than demand until supply can catch up.
- CDC's Vaccine Tracking System (VTrckS) will be used for vaccine allocation and centralized distribution. VTrckS is a secure, web-based IT system that integrates the entire publicly funded vaccine supply chain from purchasing and ordering through distribution to participating state, local, and territorial health departments and healthcare providers.
    - Jurisdictions will place orders against their allocations in VTrckS. Those orders will be scheduled for delivery Monday through Friday.
    - Additional providers, including private partners (e.g., pharmacy chains) and other federal entities (e.g., the Indian Health Service), will be onboarded to enable allocation to and ordering directly by these partners
    - Through the linkage of a number of systems, information technology will also help direct people to locations where they can get vaccinated using VaccineFinder.org.
- Over time, distribution strategies will change as more vaccine becomes available and more people are recommended for vaccination.
- CDC and OWS completed an end-to-end logistics test that shipped Pfizer vaccines to jurisdictions during the week of November 30.
- COVID-19 vaccines will be allocated pro rata by population so that we ensure fair and equitable distribution across the U.S.

- As reported by Operation Warp Speed, enough vaccine to will be available to immunize 20 million people in the U.S. in December, that's 40 million doses, and 30 million people, 60 million doses in January, and 50 million people or a 100 million doses in February.

PHARMACY – LONG-TERM CARE FACILITIES

- The U.S. Department of Health and Human Services is partnering with CVS and Walgreens to offer on-site COVID-19 vaccination services for nursing homes and assisted living facilities residents once they are recommended to receive vaccine.
- The Pharmacy Partnership for Long-term Care (LTC) Program provides end-to-end management of the COVID-19 vaccination process, including cold-chain management, on-site vaccinations, and fulfillment of reporting requirements, to facilitate safe vaccination of this prioritized patient population, while reducing burden on facilities and jurisdictional health departments.
- The allocation of vaccine for LTCFs as part of the Pharmacy Partnership for Long-Term Care (LTC) Program is included in the pro rata population-based allocation for each jurisdiction. This is not an additional number of doses that will be allocated.
- Jurisdictions have control over when the LTC program will launch within their jurisdictions.
- The goal of the program is to safely and efficiently distribute vaccines to long-term care facility (LTCF) residents across the country and minimize the burden of vaccine handling, administration, and reporting when a COVID-19 vaccine becomes available.
- LTCF staff members who have not been previously vaccinated for COVID-19 (e.g., through satellite, temporary, or off-site clinics) will also be eligible for these services.
- This service will also be available in rural areas that may not have an easily accessible pharmacy.
- This program is available for residents in all LTCF settings, including skilled nursing facilities, nursing homes, assisted living facilities, residential care homes, and adult family homes.
- Vaccine allocations through this program will count against a jurisdiction's total allocation.
- This program is free of charge to LTCF. The pharmacy will:
    - Schedule and coordinate on-site clinic date(s) directly with each facility. Three total visits over approximately two months are likely to be needed to administer both doses of vaccine (if indicated) and vaccinate any new residents and staff.
    - Order vaccines and associated supplies (e.g., syringes, needles, personal protective equipment).
    - Ensure cold-chain management for vaccine.
    - Provide on-site administration of vaccine.
    - Report required vaccination data within 24 hours of administering each dose.
    - Adhere to all applicable Centers for Medicare & Medicaid Services requirements for COVID-19 testing for LTCF staff.
- Sign up for the LTC Pharmacy Program has ended.
- As of mid-November, over 26,000 facilities had signed up, including 99% of CMS-certified skilled nursing facilities.
- CDC expects the program services to continue on-site at participating LTCFs for approximately two months. After the initial phase of vaccinations, the facility can choose to continue working with the CVS or Walgreens partner that provided its initial on-site clinics or can choose to work with a pharmacy provider of its choice.
- On December 4, the list of participating facilities that will be served by the program was locked. All jurisdictions besides the U.S. Virgin Islands have opted into the program.
- Jurisdictions will need to provide at least a two-week notice to begin the LTCF program. This period allows federal pharmacy partners to prepare for vaccine administration and coordinate with LTCF facilities. To begin the program, a jurisdiction must have an allocation of at least 50 percent of the required doses to cover the program within one week of providing notice.
- Jurisdictions will need to select which authorized vaccine will be used to support the program in their jurisdiction. Once activated, vaccine to support the program will come from jurisdictional allocations.

- The LTCF program will be split into two components:
    - In Part A, the program will perform vaccinations at skilled nursing facilities.
    - In Part B, the program will provide vaccinations at other facilities enrolled in the program such as assisted living facilities, continuing care residential facilities, etc.
- Jurisdictions can choose whether to start with Part A alone when activating the program or can opt to activate both Parts A and B simultaneously.
- CDC will provide jurisdictions with an estimated number of doses needed to cover Part A and Part B. Allocations that are not used as part of the program will be returned to the rest of the jurisdiction's allocation.

PHARMACY – RETAIL AND COMMUNITY

- To maximize access to COVID-19 vaccines for all Americans, HHS is partnering with pharmacies across the U.S. to ensure all Americans have access to safe and effective COVID-19 vaccines when they are available.
    - Through the partnership with pharmacy chains, this program covers approximately 60% of pharmacies throughout the 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. The federal allocation to retail pharmacies will not cover every pharmacy within the United States.
    - Through the partnerships with network administrators, independent pharmacies and regional chains will also be part of the federal pharmacy program, further increasing access to vaccine across the country—particularly in traditionally underserved areas.
- More than 86% of people live within 5 miles of a community pharmacy, which means pharmacies can be a crucial public health partner to increase access and convenience of COVID-19 vaccines.
- As part of this program, the federal government will allocate and distribute vaccine products during Phase 2 to participating retail chain pharmacies and networks of independent and community pharmacies with a minimum of 200 stores.
    - Pharmacy partners will need to report their vaccine administration data to an immunization information system (IIS) or other external system.
- Jurisdictions will have access to vaccine supply and uptake data by store as part of this program, but jurisdictions may elect to opt out of having area pharmacies receive direct allocations.

VACCINE SAFETY

Vaccine Safety Monitoring

- Vaccine safety is a top priority for CDC.
- Vaccines are the best defense we have against infectious diseases.
- There is solid medical and scientific evidence that the benefits of approved vaccines far outweigh the risks.
- For over 30 years, vaccine safety surveillance and research has been used to actively monitor, identify, and address the side effects of vaccines in the U.S.
- The United States' long-standing vaccine safety system ensures vaccines are as safe as possible. As science advances and new information becomes available, this system will continue to improve.
- CDC works closely with other parts of the U.S. government to ensure the vaccines available in the United States are safe and effective.
- The U.S. government maintains the largest, most robust, and most advanced vaccine safety monitoring systems available in the world.
- Ensuring vaccines are safe is a critical process that begins during vaccine development and clinical trials and continues after vaccines are authorized or approved for use.
- For COVID-19 vaccines, CDC and federal partners will use a toolbox of existing and new monitoring systems for COVID-19 vaccine safety.
    - CDC will rely on existing systems that monitor the safety of vaccines every day, the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), and the Clinical Immunization

Safety Assessment (CISA) Project.
    - CDC has also developed a new, voluntary smartphone-based tool, v-safe, that uses text messaging and web surveys to provide personalized health check-ins after patients receive a COVID-19 vaccination. V-safe allows patients to report any side effects after COVID-19 vaccination to CDC in almost real time. It also gives them a convenient reminder to get their second COVID-19 vaccine dose if they need one.
    - CDC has also expanded its collaboration with the Advisory Committee on Immunization Practices (ACIP) to include a special ACIP COVID-19 Vaccine Safety Technical Sub-Group to review available vaccine safety data.
    - The ACIP COVID-19 Vaccine Safety Technical Sub-Group includes ACIP voting members, consultants, representatives, and technical experts from federal agencies involved in vaccine safety. The sub-group is advising CDC and other federal partners on planning and preparation for post-authorization/post-licensure safety monitoring of COVID-19 vaccines and will independently review and evaluate safety data.
- If potential safety issues with any COVID-19 vaccine are discovered, CDC will take the following steps:
    - Work with the Food and Drug Administration (FDA) and other vaccine safety partners to rapidly assess the potential safety issue.
    - Provide up-to-date vaccine safety information to ACIP. CDC routinely shares this kind of information for all vaccines. ACIP may recommend additional assessment and analysis, advise CDC on the balance between the benefit of COVID-19 vaccination and the risk of adverse events, or make changes to its recommendations.
    - Communicate vaccine safety information to the public in a timely and transparent manner.

VACCINE EFFECTIVENESS

- Before the U.S. Food and Drug Administration (FDA) determines whether to approve a vaccine or authorize a vaccine for emergency use, clinical trials are conducted to determine how well it works. This is known as effectiveness.
- After FDA approves a vaccine or authorizes a vaccine for emergency use, it continues to be studied to determine how well it works under real-world conditions. CDC and other federal partners will be assessing COVID-19 vaccine effectiveness under real-world conditions.
- CDC is preparing now so that further assessment of vaccine effectiveness can start as soon as COVID-19 vaccines either approved or authorized for emergency use by FDA.
    - Many of these assessments will build on existing CDC programs, such as the Emerging Infections Program, Coronavirus Disease 2019-Associated Hospitalization Surveillance Network (COVID-NET), and systems used to measure the effectiveness of influenza vaccines.
- The major reason for conducting vaccine effectiveness assessments is to make sure a vaccine protects people from getting sick under real life conditions, outside of the strict setting of a clinical trial.
    - Factors that can affect a vaccine's effectiveness can include things such as how a vaccine is transported and stored or even how patients are vaccinated.
    - Vaccine effectiveness can also be affected by differences in the ages or underlying medical conditions of people vaccinated in the real world compared to a clinical trial. Vaccine effectiveness assessments can also provide important information about how well a vaccine is working in groups of people not included or not well represented in clinical trials.
- CDC is coordinating with several other federal agencies to evaluate the effectiveness of COVID-19 vaccines, including CMS, DoD, FDA, IHS, and VHA.
- CDC is working to make sure vaccine effectiveness assessments include diverse groups of people, such as healthcare personnel, essential workers, older adults, and those living in nursing homes, people with underlying medical conditions, racial and ethnic minority groups, and tribal nations. It is important to measure how well COVID-19 vaccines work in groups of people who are at increased risk of getting COVID-19, as well as in those who are at increased risk of severe COVID-19 illness.

- For more information on ensuring vaccines work, visit https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness.html.

ACIP BACKGROUND

- The Advisory Committee on Immunization Practices (ACIP) is an independent federal advisory committee of medical and public health experts that provides advice and guidance to the CDC director on the most effective means to prevent vaccine-preventable diseases in the United States.
- ACIP develops written recommendations—subject to the CDC director's approval—for the routine administration of vaccines to both pediatric and adult populations.
- To inform its advice, ACIP considers disease epidemiology and disease burden, vaccine efficacy and effectiveness, vaccine safety, the quality of evidence reviewed, economic analyses, and implementation issues.
- ACIP deliberations provide a public and transparent opportunity for federally appointed independent experts to advise CDC on evidence-based vaccine policy.
    - ACIP meetings are open to the public and are typically held three times a year.
    - In exceptional circumstances, the CDC director may call an emergency meeting of ACIP. CDC has held three emergency meetings this year about COVID-19 vaccines, in addition to presentations at the regularly scheduled June meeting.
- ACIP comprises 15 voting members, eight ex-officio members, and 31 liaison representatives, who function under a chair and vice chair and are guided by a steering committee. To prepare for potentially FDA-authorized or approved COVID-19 vaccines, ACIP has established a COVID-19 Vaccine Work Group to help inform evidence-based approaches to COVID-19 vaccination policy, including an interim strategy for vaccination of groups in Phase 1.
- On December 2, the CDC Director signed Advisory Committee on Immunization Practices (ACIP) recommendations that vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a) should be offered to both 1) health care personnel (HCP) and 2) residents of long-term care facilities (LTCF).
- It is estimated there are 21 million people working in the healthcare industry and approximately 3 million people living in long-term care facilities.
    - HCP include all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials.
    - LTCFs provide a spectrum of medical and non-medical services to frail or older adults unable to reside independently in the community. These include:
        - Skilled nursing facilities: facility engaged primarily in providing skilled nursing care and rehabilitation services for residents who require care because of injury, disability, or illness.
        - Assisted living facilities: facility providing help with activities of daily living. Residents often live in their own room or apartment within a building or group of buildings.
- To date, more than 240,000 healthcare workers have contracted COVID-19, and 858 have died.
- According to estimates, deaths in long-term care facilities account for 40% of all COVID-19 deaths nationwide.
- These factors contributed to the committee's recommendation to prevent spread by protecting those on the front lines, healthcare workers treating COVID-19 patients, and protect the most vulnerable, those elderly persons living in long-term care facilities.
- The full recommendation was published in the MMWR on Thursday, December 3.
- ACIP will meet again following the Food and Drug Administration (FDA) authorization to vote on vaccine specific recommendations.
- Additionally, CDC published interim considerations for COVID-19 vaccination of healthcare personnel and long-term care facility residents to assist state, local, tribal, and territorial health officials and healthcare system administrators in planning the allocation of the initial doses of COVID-19 vaccine for HCP and LTCF residents.
    - These considerations will be updated as additional information becomes available.

- Summaries and slides from previous ACIP meetings are available online at https://www.cdc.gov/vaccines/acip/meetings/index.html.
- ACIP will meet next after VRBPAC has met (currently VRBPAC is planning to meet on December 10) and either recommended that FDA authorize or approve a COVID-19 vaccine.
- On November 23, an *MMWR* article titled "The Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020" was published as an Early Release.
    - The report describes the four fundamental ethical principles that will assist ACIP in formulating recommendations for the allocation of COVID-19 vaccine while supply is limited:
        - maximize benefits and minimize harms
        - promote justice
        - mitigate health inequities, and
        - promote transparency.
    - These principles can also aid state, tribal, local, and territorial public health authorities as they develop vaccine implementation strategies within their own communities based on ACIP's recommendations.

Sub-Prioritization of Phase 1A Priority Groups

- Initial supply of vaccine will be limited and there may be settings where the initial vaccine supply is insufficient to vaccinate everyone in a priority group and sub-prioritization is necessary.
- Additionally, given the storage requirements of mRNA vaccines, initial vaccine distribution may be limited to large healthcare systems with ultra-cold freezer capacity.
- Coordination between state and local health officials and healthcare administrators is needed to ensure vaccine access to HCP not affiliated with hospitals.
- Considerations for sub-prioritization of HCPs, of equal importance, include:
    - HCP with direct patient contact and thus who are unable to telework, including those who work in inpatient, outpatient, or community settings, who provide services to patients or patients' family members, or who handle infectious materials.
    - HCP working in residential care or long-term care facilities.
    - HCP with documented acute SARS-CoV-2 infection in the preceding 90 days may choose to delay vaccination until near the end of the 90 day period in order to facilitate vaccination of those HCP who remain susceptible to infection, as current evidence suggests reinfection is uncommon during this period after initial infection. Of note, previous SARS-CoV-2 infection, whether symptomatic or asymptomatic, is not considered a contraindication to vaccination and serologic testing for SARS-CoV-2 antibodies is not recommended prior to vaccination.
- Considerations for sub-prioritization among LTCF residents include:
    - Skilled nursing facilities should be prioritized among LTCFs as they provide care to the most medically vulnerable residents.
    - After skilled nursing facilities, consider broadening to other facilities, including:
        - Assisted living facilities
        - Intermediate care facilities for individuals with developmental disabilities
        - Residential care facilities
        - State Veterans Homes

Post-vaccination symptoms in HCP

- Based on available data, COVID-19 vaccination is expected to elicit systemic post-vaccination symptoms, such as fever, headache, and myalgias.
- While the incidence and timing of post-vaccination symptoms will be further informed by phase III clinical trial data, strategies are needed to mitigate possible HCP absenteeism and resulting personnel shortages due to the occurrence of these symptoms. Considerations might include:

    - Staggering delivery of vaccine to HCP in the facility so that personnel from a single department or unit are not all vaccinated at the same time. Based on greater reactogenicity observed following the second vaccine dose in phase I/II clinical trials, staggering considerations may be more important following the second dose.
    - Planning for personnel to have time away from work if they develop systemic symptoms following COVID-19 vaccination.
- Further considerations on the management of post-COVID-19 vaccination symptoms among healthcare personnel is under development.

PRIORITIZATION/VACCINE RECOMMENDATIONS

- If the FDA authorizes or approves a COVID-19 vaccine, ACIP will quickly hold a meeting to review all available data about that vaccine. From these data, ACIP will then vote on whether to recommend the vaccine and, if so, who should receive it. Included in ACIP's recommendations will be guidance on who should receive COVID-19 vaccines if supply is limited. Recommendations must go to the director of CDC for approval before becoming official CDC policy.
- ACIP has set the following goals for deciding who to recommend COVID-19 vaccines for if supply is limited:
    - Decrease death and serious disease as much as possible
    - Preserve functioning of society
    - Reduce the extra burden the disease is having on people already facing disparities
    - Increase the chance for everyone to enjoy health and well-being
- ACIP is considering four groups to possibly recommend COVID-19 vaccination for if supply is limited:
    - Healthcare personnel
    - Workers in essential and critical industries as defined by the Cybersecurity & Infrastructure Security Agency
    - People with certain underlying medical conditions
    - Older adults
- See the above section on ACIP to learn more about ACIP's recommendations for Phase 1a.
- Jurisdictions are planning for further prioritization within these groups when vaccine supplies are limited.
- Input from the public and the following professional groups is informing ACIP's discussions on who should receive COVID-19 vaccines if supply is limited:
    - Johns Hopkins Bloomberg School of Public Health: Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States
    - The National Academies of Sciences, Engineering, and Medicine: Framework for Equitable Allocation of COVID-19 Vaccine
    - World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE): WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination

ADMINISTRATION, STORAGE, AND HANDLING

- CDC is developing educational and training materials for health care providers related to COVID-19 vaccine storage, handling and administration based on ACIP recommendations, the ACIP General Best Practice Guidelines for Immunization, product information from vaccine manufacturers, and results of scientific studies.
- Ensuring that the cold chain–a system that maintains a vaccine's integrity from when it is manufactured to when it is administered–is a significant concern in any vaccination program.
- There are multiple vaccines in clinical trials that may be approved for use
- Currently one vaccine requires ultra-cold storage:
    - Ultra-cold vaccine will be shipped from the manufacturer in coolers that are packed with dry ice.
    - The Pfizer vaccine candidate requires ultra-cold storage (-60° to -80° C) or storage at 2-8° C for up to 5 days (120 hours). Once reconstituted, the vaccine can be at room temperature for up to 6 hours. Other vaccine candidates may not require ultra-cold storage and can be stored in standard -

15° to -25° C freezers. Pfizer's vaccine may be stored in its thermal shipper for up to 30 days if it receives a dry ice recharge every five days.
    - CDC understands and appreciates the operational complexities ultra-cold storage poses at the vaccination provider sites. Some COVID-19 vaccine products will require a very different storage and handling approach than a normal cold-state vaccine.
    - Jurisdictions are not advised to purchase ultra-cold storage equipment at this time. Ultra-cold vaccine will be direct shipped from the manufacturer in coolers that are packed with dry ice.
        - Storage and handling instructions for ultra-cold vaccine will address repacking these coolers for extended use.
        - Direct shipments to the vaccination provider site will be in 975-dose increments on a real-time, day to day basis.
- CDC will provide specific education and training materials to facilitate storage and handling of ultra-cold vaccine based on guidance from the vaccine's manufacturer. CDC has recently revised the COVID-19 Addendum to the *Vaccine Storage and Handling Toolkit*.
- Additional training materials on product-specific administration, storage, and handling topics will become available after the FDA issues an EUA.
    - For Pfizer, these may include a checklist for unpacking a delivery, beyond use date tracking labels for refrigerator storage, FAQs, a standing orders template, thermal shipping container temperature logs and a beyond use date tracking tool, temperature logs for ultra-cold units, vaccine preparation infographics, a vaccine administration summary, and a vaccine storage and handling summary.
    - For Moderna, these may include beyond use date tracking labels for refrigerator storage, FAQs, a standing orders template, temperature logs for freezer units, a vaccine administration summary, and a vaccine storage and handling summary.

DATA AND MONITORING

- Integrated IT systems —both public and private, as well as new and existing—are needed to ensure successful vaccine allocation, distribution, administration, monitoring, and reporting.

Vaccine Logistics and Administration

- Three systems support vaccine logistics and administration: the Vaccine Tracking System, Immunization Information Systems, and VaccineFinder.
- **(1) The Vaccine Tracking System (VTrckS)** is CDC's vaccine order management system, which supports routine vaccination with almost 80 million doses of vaccine annually.
    - CDC will use VTrckS as its platform for ordering all COVID-19 vaccines.
    - VTrckS users—the 64 state, local, and territorial public health jurisdictions and enrolled national provider organizations will use VTrckS to:
        - View vaccine allocations for each program
        - Place and manage vaccine orders for their providers
        - Generate reports throughout the vaccine distribution process, from vaccine order placement through distribution
        - Track vaccine shipments
    - As part of the overall IT infrastructure to support COVID-19 vaccination, VTrckS can receive or exchange data with the following systems or organizations:
        - VTrckS ExIS Portal: Jurisdictions and federal and commercial partners will connect with the portal or directly with VTrckS to submit vaccine orders, enrolled provider master data, as well as vaccine inventory, return, and wastage information. In return, VTrckS provides vaccine shipment data via downloads to the jurisdictional IIS.
        - McKesson, the VTrckS logistics contractor: McKesson receives orders from VTrckS, directs vaccine manufacturers to ship vaccines, and transmits vaccine shipment details from providers to VTrckS.

        - Federal data and reporting systems: The Immunization (IZ) Data Lake will receive data feeds from VTrckS related to provider data, orders, shipments, inventory, and allocations.
- **(2) Immunization Information Systems (IISs)** were formerly known as "immunization registries." The IISs vary by jurisdiction in their capacity to automate processes, handle large volumes of data, and capture high-quality data.
    - Vaccine recipients and enrolled providers use IISs to access people's vaccination records. The 64 jurisdictions use their IISs to support providers by:
        - Creating a centralized data repository for vaccination information specific to that jurisdiction
        - Approving vaccine orders from enrolled providers and submitting orders to VTrckS
        - Monitoring vaccine distribution and changes in vaccine inventory, including accounting for wasted, spoiled, expired, and transferred vaccine
        - Providing vaccination coverage assessments
    - Most IISs can:
        - Provide unidirectional or bidirectional data transmissions for providers
        - Connect with local/state Health Information Exchanges
        - Connect to the IZ Gateway to share and receive information from national providers and other IISs
    - In addition, IISs collect data from public and private healthcare provider organizations (e.g., electronic health records), health information systems (e.g., vital statistics, state Medicaid agencies), and pharmacies. IISs share these data with the IZ Gateway, CDC, and other jurisdictions if an agreement is in place. IISs also share vaccination records with healthcare providers and individuals.
    - As part of the overall IT infrastructure to support COVID-19 vaccination IISs connect with VTrckS, VAMS (see below for details), and federal data and reporting systems.
- **(3) The VaccineFinder website** helps people find providers who offer select vaccines. VaccineFinder also allows healthcare providers to list their vaccination locations in a centralized, searchable database and to track vaccine supply. VaccineFinder will serve two roles in the COVID-19 vaccination program:
    - Inventory reporting (required for all COVID-19 vaccine providers): Providers will report on-hand COVID-19 vaccine inventory each day through VaccineFinder.
    - Increase access to COVID-19 vaccines (optional for COVID-19 vaccine providers): Once there is enough supply, COVID-19 vaccination providers may choose to make their location visible on VaccineFinder, making it easier for the public to find provider locations that have doses available. CDC will direct the public to use VaccineFinder to find locations offering COVID-19 vaccine.
    - As part of the overall IT infrastructure to support COVID-19 vaccination, VaccineFinder sends data to and receives data from the IZ Data Lake.

Vaccine Data Collection and Reporting

- The IZ Gateway is a cloud-based message routing service intended to enable data exchange between IISs, other provider systems, and the IZ Data Lake. The IZ Gateway allows:
    - IISs to report data to the CDC Data Clearinghouse
    - Cross-jurisdictional queries and data exchange
    - Multijurisdictional providers to share data with multiple IISs via a central connection
    - VAMS data to be routed to the IIS where applicable

New Systems to Support COVID-19 Vaccination Clinics and Vaccine Administration

- Vaccine Administration Management System (VAMS) is an optional web-based application that supports planning and execution for temporary, mobile, or satellite COVID-19 vaccination clinics. VAMS has modules to support four specific user groups:
    - Public health jurisdictions: VAMS allows jurisdictions to provide end-to-end vaccination and manage vaccination clinics.

    - Healthcare providers: VAMS facilitates patient scheduling, vaccine administration workflow, and patient monitoring.
        - Note: VAMS does not support vaccine ordering. Ordering is done through the normal vaccine ordering process (i.e., VTrckS).
    - Employers/organizations: VAMS allows these groups to bulk input employees, who will receive an email to register in VAMS so they can schedule an appointment to receive a COVID-19 vaccination.
    - Vaccine recipients: VAMS provides an easy way for COVID-19 vaccine recipients to schedule vaccination appointments, receive a record of vaccination, and receive appointment reminders for the second dose of the specific vaccine they received if and when a second dose is needed.
- VAMS connects with IISs via federal and data reporting systems and sends data to IISs through the IZ Gateway or IZ Data Clearinghouse.

New Systems Developed for COVID-19 Vaccination Data Collection and Reporting

- **(1) The IZ Data Clearinghouse** is a cloud-hosted data repository that receives, deduplicates, and deidentifies COVID-19 vaccination data that are then used to populate the IZ Data Lake with deidentified data for analytics.
    - The IZ Data Clearinghouse allows healthcare providers to search for a patient, see what brand of COVID-19 vaccine they received, and see when they received their first dose of COVID-19 vaccine to ensure dose matching and appropriate vaccination intervals to complete the vaccine series.
- **(2) The IZ Data Lake** is a cloud-hosted data repository to receive, store, manage, and analyze deidentified COVID-19 vaccination data. CDC, jurisdictions, federal agencies, and pharmacy partners will use the IZ Data Lake to store and process administration, coverage, logistics, inventory, ordering, distribution, and provider data. VAMS, IISs, pharmacies, VTrckS, and VaccineFinder will provide data for the IZ Data Lake. The IZ Data Lake will also aggregate and analyze data and provide data summaries and analytics via these reporting hubs:
    - Data Storefront
    - Department of Health and Human Services' HHS Protect data hub
    - Operation Warp Speed's Tiberius platform, a COVID-19 vaccine distribution planning, tracking, modeling, and analysis application

COVID-19 VACCINE STATUS

Pfizer and its partner BioNTech

- On December 2, the United Kingdom authorized the use of Pfizer and BioNTech's COVID-19 vaccine and will begin vaccinating people in certain priority groups next week.
- On Friday November 20, Pfizer and its partner BioNTech announced they submitted a request to the FDA for EUA of their mRNA vaccine candidate, BNT162b2 against SARS-CoV-2.
- Earlier Pfizer and its partner BioNTech announced that its first interim efficacy analysis has found its vaccine candidate is more than 90% effective. The study enrolled over 43,000 participants and has not uncovered any serious safety concerns.
    - Study enrolled 43,538 participants, and no serious safety concerns have been observed.
    - The company is planning to submit for Emergency Use Authorization (EUA) to the FDA planned for soon after the required safety milestone is achieved.
    - Clinical trial is going to continue through to final analysis at 164 confirmed cases in order to collect further data and characterize the vaccine candidate's performance against other study endpoints.

Moderna

- On December 2, Moderna announced that it would soon begin testing its coronavirus vaccine in children ages 12 through 17. In a post on clinicaltrials.gov, the study plans to include 3,000 children, with half receiving two shots of vaccine four weeks apart, and half getting placebo shots of salt water.

- Moderna announced that its first interim efficacy analysis has found its vaccine candidate is 94.5% effective. The study enrolled over 43,000 participants and has not uncovered any serious safety concerns. Moderna's trial includes 30,000 participants.
    - Based on these interim safety and efficacy data, Moderna applied for an Emergency Use Authorization (EUA) with the FDA on November 30.
    - Moderna also plans to submit applications for authorizations to global regulatory agencies.
    - Clinical trial is going to continue through to final analysis at 164 confirmed cases in order to collect further data and characterize the vaccine candidate's performance against other study endpoints.
    - By the end of 2020, Moderna expects to have approximately 20 million doses ready to ship in the U.S. and remains on track to manufacture 500 million to 1 billion doses globally in 2021, including 100 million to 125 million doses in the first quarter of the year.

AstraZeneca

- AstraZeneca recently issued a press release reporting results from its Phase III clinical trial in Brazil and the United Kingdom indicating strong vaccine effectiveness among participants.

mRNA vaccines

- mRNA vaccines are being held to the same rigorous safety and effectiveness standards as all other types of vaccines in the United States. The only COVID-19 vaccines the Food and Drug Administration (FDA) will make available for use in the United States (by approval or emergency use authorization) are those that meet these standards. mRNA vaccines do not use the live virus that causes COVID-19. They cannot give someone COVID-19.
- mRNA never enters the nucleus of the cell, which is where our genetic material (DNA) is kept. The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.
- This means the mRNA vaccines do not affect or interact with our DNA in any way.

EUA AND GUIDANCE FOR INDUSTRY

- Data and information needed to support the issuance of an Emergency Use Authorization (EUA) by FDA were outlined in recently-released guidance from FDA entitled "Emergency Use Authorization for Vaccines to Prevent COVID-19 (October 2020)".
- Data to support an EUA request for an investigational COVID-19 vaccine that must be submitted to FDA include the following:
    - Chemistry, manufacturing, and controls information (CMC)
    - Nonclinical data and information
    - Clinical data and information
    - Administrative and regulatory information
- Key information and data should be submitted to a relevant investigational new drug application (IND) or cross-referenced master file prior to submission of an EUA request in order to facilitate FDA's complete and timely review, including convening the Vaccines and Related Biological Products Advisory Committee (VRBPAC).
    - FDA's VRBPAC reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines that are intended for use in the prevention of human diseases, and, as required, any other products for which FDA has regulatory responsibility.
    - VRBPAC will convene open sessions on COVID-19 vaccines with meeting materials available on FDA's website. Sessions include general discussion of the development, authorization, and/or licensure of vaccines to prevent COVID-19. FDA expects to convene an open session of FDA's VRBPAC prior to the issuance of any EUA for a COVID-19 vaccine, to discuss whether the available data support authorization of an EUA for the specific vaccine under review.
    - VRBPAC is scheduled to convene on December 10 to discuss whether the Pfizer-BioNTech vaccine warrants issuance of an EUA. VRBPAC will meet again on December 17 to discuss the Moderna

vaccine. Briefing materials that include clinical trials data will be available two days prior to each VRBPAC meeting.

- The guidance also discusses FDA's current thinking regarding the circumstances under which the issuance of an EUA would be appropriate including the safety and efficacy data to support an EUA.
- Once an EUA is issued, an EUA Letter of Authorization and EUA fact sheets will become available.
    - The Letter of Authorization describes the scope and criteria for EUA issuance.
    - EUA fact sheets will include one meant for healthcare providers and another meant for vaccine recipients and caregivers. Unlike a typical vaccine information statement (VIS), an EUA fact sheet is specific to one particular product (i.e., instead of referring to a class of vaccines).
- Although a patient's written informed consent is not required under an EUA, vaccination programs may choose to require written or verbal informed consent.
- As CDC and FDA monitor vaccine safety post-EUA, amendments to the EUA fact sheets may be posted on the FDA's website.
- FDA cannot mandate that someone must receive a vaccine authorized under an EUA.

MISCELLANEOUS

Cost

- COVID-19 vaccine will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers.
- Providers can bill for an office visit when administering COVID-19 vaccine if the visit meets the criteria for office visit coding under a recipient's plan.
- Vaccine providers will be able to charge an administration fee. However, participating vaccine providers must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay COVID-19 vaccine administration fees or coverage status, as stated in the CDC Provider Agreement.
    - Vaccine providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient.
    - For uninsured patients, the vaccine provider can seek reimbursement for an administration fee from the HRSA Provider Relief Fund.
- Immunization cooperative agreement funds may be used by the awardee to pay for redistributing vaccines. However, provider organizations cannot purchase equipment or contract with a vendor for redistribution and then bill the immunization program or federal government for those costs.

COVID-19 Vaccination and Pregnant Women

- Evidence suggests that pregnant women are potentially at increased risk for severe COVID-19-associated illness and death compared to non-pregnant women, underscoring the importance of disease prevention in this population.
- Given the predominance of women of child-bearing age among the healthcare workforce, a substantial number of HCP are estimated to be pregnant or breastfeeding at any given time. Currently, there are no data on the safety and efficacy of COVID-19 vaccines in these populations to inform vaccine recommendations.
- Further considerations around use of COVID-19 vaccines in pregnant or breastfeeding HCP will be provided once data from phase III clinical trials and conditions of FDA Emergency Use Authorization are reviewed.