ASPR TRACIE Technical Assistance Request

Request Receipt Date (by ASPR TRACIE): December 11, 2020
Response Date: December 16, 2020
Type of TA Request: Complex

Request:

ASPR TRACIE received a request for information related to the approval, allocation, distribution, and administration of vaccines to prevent COVID-19 within healthcare facilities.

Response:

The ASPR TRACIE Team reviewed existing resources, including those in our Mass Distribution and Dispensing of Medical Countermeasures, Influenza Epidemic/Pandemic, Ethics, and Responder Safety and Health Topic Collections and on our COVID-19 Resources Page. We also conducted a search online for relevant materials. Information from these materials are gathered and provided as points for consideration in this document.

The information below is intended to provide high level considerations for vaccination administration and planning in healthcare facilities.

Please refer to the Centers for Disease Control and Prevention's Coronavirus Disease 2019 webpage and the NIH COVID-19 Treatment Guidelines for the most up-to-date clinical guidance on COVID-19 outbreak management.

I. COVID-19 Vaccine Considerations

Vaccine Development and Approval: Development of a vaccine to prevent COVID-19 has proceeded at an unprecedented pace. Building on years of research on coronaviruses and with the support of purchase commitments from national governments, manufacturers focused on COVID-19 vaccine development and produced several vaccines authorized for use less than a year after the virus was first recognized.

- More than 200 vaccines are in development around the world using various technologies. Some of these technologies have been used in the past to prevent other illnesses, such as live attenuated vaccines for measles, inactivated vaccines for influenza, and protein sub-unit vaccines for pertussis. Some of the most promising COVID-19 vaccines use two newer technologies: viral vector-based vaccines (previously used for Ebola virus disease) and nucleic acid vaccines. The viral vector-based vaccines use well-established technology and elicit a strong immune response, but they are complex to manufacture and there are concerns that previous exposure to the vector may affect effectiveness. Nucleic

acid vaccines – including messenger RNA (mRNA) – are easier to manufacture and have no risk of triggering disease, but had previously only been approved for use in animals and some require ultra-cold storage.

- Each country has its own process for reviewing the safety and effectiveness of vaccine candidates and authorizing their use by the public.
- COVID-19 vaccines will not be administered in the U.S. until they are authorized by the Food and Drug Administration (FDA), likely via an Emergency Use Authorization (EUA). This does not constitute full approval or licensing for the vaccine but allows administration while an emergency declaration is in place when the current evidence favors the known benefit versus risk.
- China authorized the Petrovax vaccine for military use in June 2020 and authorized several other vaccines for emergency use in the months since. The Sinopharm vaccine authorized in China has also been approved by the United Arab Emirates and Bahrain. In August 2020, Russia authorized its Sputnik V vaccine for use. The Pfizer/BioNTech vaccine is the first mRNA vaccine to be authorized for human use for any disease and has been authorized or approved in the United Kingdom, Bahrain, Canada, the U.S., Mexico, Kuwait, Singapore, and Saudi Arabia as of December 14, 2020.
- Following its emergency use authorization in the U.S. by the FDA on December 11, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for the use of the Pfizer-BioNTech vaccine in those age 16 and older on December 13, 2020.
- Section II includes information on the status of vaccines authorized for use in the U.S. and vaccine candidates with promising results in late stage trials for which manufacturers may seek approval in the U.S. in the coming months.

Vaccine Options: While experience developing other vaccines suggests that many of the current COVID-19 candidates will not be approved for use, it is expected based on vaccine trials data released so far that several vaccines to prevent COVID-19 will eventually be available (see chart in Section II).

- Neither facilities being shipped vaccines, nor individuals that are being vaccinated may receive their preferred product, especially early in the vaccine distribution process when options are limited.
- The anticipated availability of multiple vaccines in 2021 will complicate decision-making for those ordering vaccines. Amounts of each vaccine available, booster dosing, the setting in which vaccines are administered, and the populations needing to be vaccinated will be factors to consider.
- Some vaccines may be more efficacious in certain populations than others. As more data becomes available, those ordering vaccine should maintain awareness of any emerging differences in effectiveness in specific populations, such as older adults or children, and place orders appropriate to the population they serve.
- As additional options become available, it may be possible to select a product with characteristics more suitable for the setting in which it will be administered. For

instance, supplies of vaccine requiring ultra-cold storage are expected to be directed to academic medical centers and large hospitals with the logistical capacity to manage them while vaccines that can be stored at refrigerator temperatures may be more suitable for physician offices or pharmacies.

Supply and Allocation: The initial supply of vaccine will be limited and will continue to grow as additional vaccines are approved and production increases.

- To encourage vaccine development, governments around the world made purchasing commitments that enabled manufacturers to begin producing vaccines prior to the completion of their clinical trials, thereby ensuring the availability of an initial, limited supply upon FDA authorization of each vaccine. Supplies will increase as production continues to ramp up and additional vaccines are authorized.
- Due to the initial limited supplies, a phased approach is necessary to prioritize which segments of the population are vaccinated first. Various governments and organizations have offered frameworks for the fair and ethical allocation of limited vaccine supplies, including the National Academies of Sciences, Engineering, and Medicine, ACIP, and the World Health Organization. Most of these frameworks include considerations for healthcare and other essential workers, older adults, and communities of color that have been disproportionately affected by the COVID-19 pandemic.
- In the U.S., ACIP identified approximately 24 million healthcare workers and residents of long-term care facilities as the highest priority groups for the initial allocation of COVID-19 vaccine.
- Of the first 6.4 million vaccine doses available in the U.S., the federal government is holding 500,000 doses in emergency reserve. 2.9 million doses were allocated to jurisdictions pro rata based on their population age 18 and older; the remaining 2.9 million doses will be shipped according to the same allocation for second doses. Shipment of ancillary supplies for the initial allocation to jurisdictions began on December 9, 2020.
- Because the initial supply is not sufficient to vaccinate all persons in ACIP's highest priority groups, additional sub-prioritization is needed at the state level as well as the sub-state level. For example, every hospital should prioritize the order in which all members of their staff are eligible for vaccination relative to their risk of exposure and risk of severe complications from COVID-19 (e.g., front line staff over the age of 60 who work on the Emergency Department or Intensive Care Units).
- At the current time, there are no specific recommendations for whether individuals who have already had confirmed COVID-19 disease should wait and be vaccinated at a later time.
- Effective prioritization requires an accurate understanding of the total number of persons in each prioritized group in a community/coalition.
- In the U.S., five federal agencies – the Bureau of Prisons, Department of Defense, Department of State, Indian Health Services, and Veterans Health Administration – have been allocated their own supply of vaccine to prioritize among their staff and populations

they serve. Additionally, federal agreements allow long-term care facilities to opt-in to having vaccine administered to their residents by CVS and Walgreens. Jurisdictions should consider these federal distribution efforts in their own prioritization decisions.

Transportation and Storage: Vaccines vary in their transportation and storage requirements, ranging from those that may be stored at normal refrigerator temperatures to those requiring ultra-cold storage. It is critical that those ordering vaccine understand the transportation and storage requirements associated with the ordered product and can support those requirements.

- Vaccine coordinators must be pre-identified at each shipping site to receive vaccine shipment and monitor its storage and supply.
- Due to its ultra-cold chain storage requirements, Pfizer developed shipping containers for its vaccine. Vaccine recipients should understand these shipping containers, including their size and weight, how long shipped vaccine can remain in the shipping container, how frequently the container may be opened, how to store vaccine once it is removed from the container, and plan for pelletized dry ice replenishment if required. Each shipment of this vaccine is expected to include 975 doses in multi-dose vials.
- Orders for other vaccines are expected to be a minimum of 100 doses per order. Health systems should consider central ordering for their affiliated hospitals, clinics, and other providers. Healthcare coalitions may have a role in coordinating orders and central shipping locations for participants, particularly in rural areas where facilities have limited staff and population served.
- Dry ice is a high demand product due to its use in vaccine shipments on top of its normal uses. Vaccine recipients should identify back-up sources of dry ice and train staff on the safe handling of dry ice. Have dry ice gloves in various sizes readily available.
- Emergency plans should account for the uninterrupted power supply needs of vaccine storage areas and identify generators or other back-up options to protect the vaccine supply in the event of a power outage.
- Many states require their boards of pharmacy to inspect freezers or mandate continuous monitoring of temperatures.

Logistics: In addition to the transportation and storage issues, vaccine distribution and administration involve numerous challenges.

- Vaccine providers must be pre-enrolled to be eligible for vaccine ordering and receipt. This requires outreach to recruit vaccine providers, completion of the enrollment process, and training on vaccine provider requirements, such as vaccine administration techniques and necessary reporting.
- Sites must be prepared to receive the vaccine itself and the ancillary supplies included in each kit. These kits do NOT include sharps containers, gloves, or bandages. Vaccine providers should understand what ancillary supplies will be provided and what additional supplies may be needed to support vaccine administration efforts.
- Security will be needed for both the vaccine storage site and the location where vaccine is administered.

- Each healthcare facility should have a plan that expands the vaccination of staff as supply increases. Various approaches may be used – including vaccinating on the unit/floor, operating a closed point of dispensing, scheduling appointments through occupational health services, or setting up a vaccine clinic – depending on the size of the facility, the number of staff, the amount of vaccine received, and other factors.
- Healthcare facilities should consider their full range of staffing needs. This includes not only vaccine providers, but also staff for planning, vaccine and related supply ordering, transport and storage, security, communications, finance, information technology, and administrative reporting. All staff should be trained on their expected roles.
- Healthcare facilities should review their workforce policies, including determining whether COVID-19 vaccination will be required.
- Use of multi-dose vials requires planning to avoid wastage.
- Vaccines administered under EUA will require the recipient review and provide consent. Ideally, these forms should be made available for review prior to the time of vaccination to speed the process.
- Include health care provider instructions for screening of patient's eligibility for vaccine based on ACIP contraindications and precautions recommendations.
- Most of the vaccines will require two doses at a different number of days between doses depending on the vaccine. Tracking is needed to ensure that individuals receive both doses of the same vaccine at the correct interval.
- Like in all vaccines, some localized and systemic side effects are expected with vaccines to prevent COVID-19. Healthcare facilities should ensure staff know how to report adverse events, have strategies in place to minimize their impact on operations (e.g., do not vaccinate an entire unit staff at the same time), and have paid time off and return to work policies in place for staff who experience symptoms post-vaccination.
- Extensive reporting requirements are in place to track both the vaccine and the vaccinated. Healthcare facilities and providers should understand reporting requirements and ensure systems are in place to support them.
- The success of the COVID-19 vaccination effort is dependent on accurate and effective communications among response partners and risk communication to the public. Healthcare coalitions may have a role in supporting information sharing among hospitals, clinics, physician offices, long-term care facilities, pharmacies, and other vaccine administration sites to ensure coordinated and equitable vaccine coverage in the community as supply increases. Additionally, consistent and coordinated risk communications can reduce confusion and build vaccine acceptance among the public as vaccine becomes available to other segments of the population.

Funding: Because the U.S. government is purchasing vaccines from the manufacturers, members of the public will not be charged for vaccines. However, there are costs associated with the mass vaccination effort.

- While individuals cannot be charged for the cost of the vaccine itself, they may be charged a vaccine administration fee. This administrative cost may be billed to the

individual's health insurer, Medicare, Medicaid, the Children's Health Insurance Program, or the COVID-19 Uninsured Program.

- The Centers for Disease Control and Prevention (CDC) awarded $200 million to the 64 jurisdictions required to submit COVID-19 vaccination plans yet the CDC Director estimated that $5.5-6 billion would be needed to distribute vaccine. The Adult Vaccine Access Coalition requested $8.4 billion to modernize immunization information systems, recruit and train the immunization workforce, promote mass vaccination, remove financial access barriers, and compensate providers for various costs.
- In addition to billing payers for vaccine administration costs, healthcare facilities and providers should accurately document all expenses related to COVID-19 vaccination planning and response efforts. Reimbursement and cost recovery may be available through the various federal and state programs established with COVID-19 relief funding.

II. FDA Approved Vaccines and Most Promising Candidates

The vaccine development and approval processes are fluid and information updates frequently. The information in this table is current as of December 14, 2020.

Vaccine Sponsor	Technology	Dosing	Effectiveness	Storage	Supply Forecast	Status
Pfizer/ BioNTech[1]	mRNA	2 doses 21 days apart	95% effective; common adverse reactions: injection site reactions, fatigue, headache, muscle pain, chills, joint pain, fever; and the second dose is associated with a higher incidence of side effects than the first; UK recommended against use in those with a history of anaphylaxis to a vaccine, food, or medicine	• Transportation & long-term storage at -70° Celsius • Developed shipping containers • Conducted pilot delivery program in 4 states	US purchased 100 million doses	• Authorized for use in the United Kingdom on December 2, Bahrain on December 6, Canada on December 9, Saudi Arabia on December 10, Mexico on December 11, Kuwait on December 13, and Singapore on December 14. The United Kingdom began administering the vaccine to prioritized healthcare workers and older adults on December 8. • Submitted request for emergency use authorization (EUA) to the Food and Drug Administration (FDA) on November 20. FDA's Vaccines and Related Biological Products Advisory Committee met to discuss the request on December 10. FDA issued an EUA on December 11. • ACIP issued an interim recommendation for use of the vaccine on December 13 for those 16 and older.
Moderna[2]	mRNA	2 doses 28 days apart	94.1% effective; common adverse reactions:	• Long-term storage at -20° Celsius	US agreed to purchase 200 million doses	• Submitted request for EUA to the FDA on November 30. FDA's Vaccines and Related Biological

[1] Pfizer-BioNTech COVID-19 Vaccine (BNT162, PF-07302048) Vaccines and Related Biological Products Advisory Committee Briefing Document
[2] Vaccines and Related Biological Products Advisory Committee Meeting Announcement

			injection site pain, fatigue, myalgia, arthralgia, headache, erythema/redness at injection site		if authorized; 20 million doses in U.S. by end of 2020; 85-100 million doses in U.S. plus 15-25 million doses outside the U.S. in the first quarter of 2021	Products Advisory Committee scheduled to discuss the request on December 17.
AstraZeneca/ Oxford University[3]	Non-replicating viral vector	2 doses		• Transportation and storage at 2-8° Celsius for up to 6 months	US supported development of at least 300 million doses	Phase 3 trials
Johnson & Johnson/ Janssen[4]	Non-replicating viral vector	Trials include 1 and 2 dose regimens		• Transportation and storage at 2-8° Celsius	US agreed to purchase 100 million doses if authorized, option for additional 200 million doses	Phase 3 trials
Novavax[5]	Protein sub-unit	2 doses		• Transportation and storage at 2-8° Celsius	US agreed to purchase 100 million doses if authorized	Phase 2 and 3 trials

[3] AZD1222 Oxford Phase III Trials Interim Analysis Results Published in the Lancet
[4] Johnson & Johnson Initiates Second Global Phase 3 Clinical Trial of Its Janssen COVID-19 Vaccine Candidate
[5] Novavax Announces COVID-19 Vaccine Clinical Development Progress

III. COVID-19 Vaccine Resources

General Vaccine Information

American Nurses Association. (2020). Guiding Principles for Nurses and the COVID-19 Vaccines.

This document identifies access, transparency, equity, efficacy, and safety as the guiding principles for the vaccination of nurses and other healthcare professionals.

ASPR TRACIE. (2020). Hospital Operations Toolkit for COVID-19: Administration – Vaccine Logistics. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response.

This section of the Hospital Operations Toolkit for COVID-19 discusses strategies for hospitals to administer allocated vaccine to their staff.

ASPR TRACIE. (n.d.). Influenza Epidemic/Pandemic Topic Collection. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response.

This Topic Collection helps healthcare professionals and emergency medical planners prepare for the next influenza epidemic or pandemic. The Vaccines section includes resources that are also relevant to the current COVID-19 pandemic.

ASPR TRACIE. (n.d.). Mass Distribution and Dispensing of Medical Countermeasures Topic Collection. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response.

This Topic Collection provides links to federal, state, local, and tribal programs and resources, lessons learned, plans, tools, and templates, courses, and guidance that can help planners address the need to effectively distribute and administer medical countermeasures (MCMs) to a large number of persons in a short period of time, particularly through mass dispensing efforts led by public health authorities.

Centers for Disease Control and Prevention. (2020). COVID-19 Vaccination. U.S. Department of Health and Human Services.

This page provides information for healthcare workers on getting vaccinated, preparing patients for vaccination, and finding additional COVID-19 vaccine resources.

Centers for Disease Control and Prevention. (2020). Vaccines. U.S. Department of Health and Human Services.

This landing page provides information for the public about COVID-19 vaccines, recommendations, administration plans, and safety. It also includes answers to frequently asked questions.

Michaud, J. and Kates, J. (2020). Distributing a COVID-19 Vaccine Across the U.S. – A Look at Key Issues. Kaiser Family Foundation.

This issue brief identifies key issues related to COVID-19 vaccine distribution. Issues discussed include: funding for vaccine distribution; supply, logistics, and monitoring; federal, state, and local authority over vaccine requirements; insurance coverage and out-of-pocket costs; addressing racial and ethnic disparities; and communication and trust.

Gavi. (2020). There are Four Types of COVID-19 Vaccines: Here's How They Work.

This page provides an overview of the four different COVID-19 vaccine types in development: whole virus, protein subunit, nucleic, and viral vector.

Pharmaceutical Supply and Payment Chain Coalition. (2020). Guiding Principles for Safe and Efficacious COVID-19 Vaccine Development, Distribution, Allocation, and Mass Immunization.

This statement by 17 organizations offers seven guiding principles related to COVID-19 vaccine. It calls for transparent and scientifically rigorous vaccine development, approval, and post-marketing surveillance processes; equitable allocation of vaccine; consistent and clear public engagement and communication; a well-coordinated national distribution strategy; accounting for the readiness of the local vaccination infrastructure and workforce; prioritization and promotion of COVID-19 vaccination; and ensuring affordability and access.

Vaccine Development and Approval

Bloomberg. (2020). Tracking the Coronavirus Vaccines That Will End the Pandemic.

This page tracks the development status of the most promising COVID-19 vaccine candidates and global purchasing commitments for each.

Food and Drug Administration. (2020). COVID-19 Vaccines. U.S. Department of Health and Human Services.

This landing page provides links to the latest information on the development and approval of COVID-19 vaccines.

Food and Drug Administration. (2020). Development and Licensure of Vaccines to Prevent COVID-19. U.S. Department of Health and Human Services.

This guidance document assists sponsors in the clinical development and licensure of vaccines to prevent COVID-19.

Food and Drug Administration. (2020). Emergency Use Authorization for Vaccines to Prevent COVID-19. U.S. Department of Health and Human Services.

This guidance document assists sponsors in understanding the data and information required to support the issuance of an emergency use authorization for a vaccine to prevent COVID-19.

Food and Drug Administration. (2020). The Path for a COVID-19 Vaccine from Research to Emergency Use Authorization. U.S. Department of Health and Human Services.

This graphic illustrates the key steps in the COVID-19 vaccine approval process.

Food and Drug Administration. (2020). Vaccine Development – 101. U.S. Department of Health and Human Services.

This webpage describes the steps that vaccine developers follow when seeking FDA approval of a vaccine.

London School of Hygiene and Tropical Medicine. COVID-19 Vaccine Tracker.

This frequently updated page provides a summary of vaccine candidates and trial timelines, key attributes of registered trials, a map of planning and ongoing efficacy trials, published safety, immunogenicity, and efficacy data, summary of vaccine distribution information, and frequently asked questions.

Milken Institute and First Person. (2020). COVID-19 Vaccine Tracker.

This frequently updated page offers data visualizations tracking all COVID-19 vaccines currently in development by their platform and phase of clinical testing. Other visualizations show how vaccines work, describe the phases of development, and illustrate manufacturing scenarios.

Oliver, S., Gargano, J., Marin, M., et al. (2020). The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine – United States, December 2020. Morbidity and Mortality Weekly Report.

This report documents the rationale supporting ACIP's interim recommendation to use the Pfizer BioNTech vaccine in persons age 16 and older.

U.S. Department of Health and Human Services. (2020). COVID-19 Vaccine Update.

This video describes how vaccines are developed, tested, and authorized for use. It features remarks from Dr. Anthony Fauci (National Institute of Allergy and Infectious Diseases), Dr. Moncef Slaoui (Operation Warp Speed), Dr. Stephen Hahn (Food and Drug Administration), and Dr. Robert Kadlec (Office of the Assistant Secretary for Preparedness and Response).

Vaccine Allocation

Ariadne Labs. (2020). Vaccine Allocation Planner for COVID-19. Brigham and Women's Hospital, Harvard T.H. Chan School of Public Health, and The Surgo Foundation.

This tool allows planners to enter the state population of prioritized groups, available COVID-19 vaccine doses, and allocation approach (proportional to population or according to two different vulnerability indexes) to view the distribution of vaccine across counties and population groups.

CEPI. (2020). COVAX: CEPI's Response to COVID-19.

This page describes the partnership of CEPI, Gavi, and the World Health Organization to make two billion doses of COVID-19 vaccine fairly and equitably accessible to participating countries.

Dooling, K., McClung, N., Chamberland, M., et al. (2020). The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine – United States, 2020. Morbidity and Mortality Weekly Report.

This report provides the rationale of the Advisory Committee on Immunization Practices in recommending that initial, limited supply of COVID-19 vaccine be allocated to healthcare workers and residents of long-term care facilities.

Emanuel, E., Persad, G., Kern, A., et al. (2020). An Ethical Framework for Global Vaccine Allocation. Science. 369(6509):1309-1312.

The authors of this article describe a three-phased Fair Priority Model for distribution of COVID-19 vaccine that prioritizes preventing urgent harms earlier. Phase 1 addresses premature deaths and other irreversible health effects, phase 2 addresses other enduring health harms and economic and social deprivations, and phase 3 addresses community transmission.

McClung, N., Chamberland, M., Kinlaw, K., et al. (2020). The Advisory Committee on Immunization Practices' Ethical Principles for Allocating Initial Supplies of COVID-19

Vaccine – United States, 2020. Morbidity and Mortality Weekly Report. 69(47):1782-1786.

The report identifies four ethical principles that guide the Advisory Committee on Immunization Practices' recommendations for initial allocation of limited COVID-19 vaccine: maximizing benefits and minimizing harms, promoting justice, mitigating health inequities, and promoting transparency.

The National Academies of Sciences, Engineering, and Medicine. (2020). Framework for Equitable Allocation of COVID-19 Vaccine. The National Academies Press.

This consensus study report offers a phased framework based on ethical and procedural principles for equitable allocation of COVID-19 vaccine that reduces severe morbidity and mortality and negative societal effects of the pandemic. In addition to the framework, the authors addressed implementation challenges related to program administration, risk communication and community engagement, vaccine acceptance, and global equity in allocation.

Toner, E., Barnill, A., Krubiner, C., et al. (2020). Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States. Johns Hopkins Bloomberg School of Public Health, Center for Health Security.

This report offers an ethical allocation framework and suggestions for vaccine distribution. The framework is based on wellbeing and promoting the common good; justice, fairness, and equity; legitimacy, trust, and sense of ownership in a pluralist society; combining and balancing ethical values and principles; adapting to changing conditions and evolving evidence; and linking ethical values and principles with policy goals and objectives.

World Health Organization. (2020). WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply.

This roadmap provides guidance on COVID-19 vaccine prioritization decisions within countries based on various epidemiological setting and vaccine supply scenarios.

World Health Organization. (2020). WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination.

This framework offers six core principles and twelve objectives to guide the prioritization of groups for COVID-19 vaccination when supply is limited.

Vaccine Distribution and Administration

American Society of Health-System Pharmacists. (2020). ASHP COVID-19 Vaccine Planning Tool for Pharmacists and Pharmacies.

This tool guides the involvement of pharmacists and pharmacy staff in institutional and community COVID-19 vaccine planning efforts. It addresses integration with institutional planning, vaccine supply and distribution, infrastructure, personnel, patient care, vaccine safety monitoring and surveillance, and legislative and regulatory controls.

Association of State and Territorial Health Officials. (2020). COVID-19 Vaccination Program Planning: A Checklist for State and Territorial Health Officials.

This checklist offers steps for health departments to take in preparation for the availability of a vaccine to prevent COVID-19.

Centers for Disease Control and Prevention. (2020). COVID-19 Vaccine Training Module. U.S. Department of Health and Human Services.

This online training module provides information to healthcare workers on COVID-19 vaccine approval and safety, storage, handling, administration, and reporting.

Centers for Disease Control and Prevention. (2020). COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. U.S. Department of Health and Human Services.

This playbook offers information to advise public health departments and their response partners on how to plan and operationalize their COVID-19 vaccination programs.

Centers for Disease Control and Prevention. (2020). Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations. U.S. Department of Health and Human Services.

This page provides guidance to inform vaccination clinic planning. It applies to both routine vaccination clinics as well as those established for emergencies, such as COVID-19. In addition to outlining activities necessary to operate a vaccination clinic, checklists are available for supplies and best practices.

Centers for Disease Control and Prevention. (2020). Interim Jurisdiction COVID-19 Vaccination Playbook Draft Executive Summaries. U.S. Department of Health and Human Services.

This page includes links to the executive summaries of the COVID-19 vaccination plans of state, territorial, and local public health agencies and their partners.

Centers for Disease Control and Prevention. (2020). Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination: Frequently Asked Questions. U.S. Department of Health and Human Services.

This page provides answers to frequently asked questions about the Pharmacy Partnership for Long-Term Care Program.

Centers for Disease Control and Prevention. (2020). Understanding the Pharmacy Partnership for Long-Term Care Program. U.S. Department of Health and Human Services.

This page describes the Pharmacy Partnership for Long-Term Care Program that enables participating pharmacies to provide COVID-19 vaccination onsite at long-term care facilities.

Centers for Disease Control and Prevention. (2020). Vaccine Storage and Handling Toolkit. U.S. Department of Health and Human Services.

This toolkit shares best practices for vaccine storage and handling. It includes an addendum focused on COVID-19 vaccines.

Centers for Medicare & Medicaid Services. (2020). COVID-19 Vaccine Policies and Guidance. U.S. Department of Health and Human Services.

This page links to toolkits on COVID-19 vaccine enrollment, coverage, reimbursement, and other information for healthcare providers, state Medicaid programs and Children's Health Insurance Programs, health insurers, and those helping consumers and beneficiaries.

Federal Emergency Management Agency. (2020). COVID-19 Pandemic: Vaccination Planning FAQ. U.S. Department of Homeland Security

This document answers frequently asked questions related to COVID-19 vaccination planning.

Health Industry Distributors Association. (2020). COVID-19 Vaccine Orders Will Include Needles and Syringes.

This alert summarizes the needles, syringes, alcohol prep pads, and personal protective equipment that will be included in ancillary kits accompanying COVID-19 vaccine shipments.

Indian Health Service. (2020). COVID-19 Pandemic Vaccine Plan. U.S. Department of Health and Human Services.

This plan details how the Indian Health Service will prepare for and distribute COVID-19 vaccine to its Direct Service facilities, Tribal health programs, and Urban Indian Organizations.

Michaud, J., Kates, J., Dolan, R., and Tolbert, J. (2020). States are Getting Ready to Distribute COVID-19 Vaccines. What Do Their Plans Tell Us So Far? Kaiser Family Foundation.

This issue brief describes a review of the 64 state, territorial, and local jurisdictional immunization program COVID-19 vaccine response plans submitted to the Centers for Disease Control and Prevention. The authors summarize how jurisdictions are identifying priority populations for vaccination, identifying a network of providers to administer vaccines, developing data collection and reporting systems to track vaccine distribution, and planning a communication strategy. Also included are links to all publicly available plans.

National Association of Counties. (2020). Key Considerations for Counties in COVID-19 Vaccine Distribution Plans.

This toolkit provides information to counties to inform planning for equitable local distribution of COVID-19 vaccine.

National Governors Association. (2020). Supporting an Equitable Distribution of COVID-19 Vaccines.

This report analyzes the initial drafts of jurisdictional COVID-19 vaccination plans submitted to CDC to identify key issues and promote promising practices.

Operation Warp Speed. (2020). From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine. U.S. Department of Defense and U.S. Department of Health and Human Services.

This document describes the strategy for distributing vaccine to all Americans, focused on engagement with the public and other stakeholders, vaccine distribution, safe administration, and monitoring distribution and administration.

Operation Warp Speed. (2020). Vaccine Distribution Process. U.S. Department of Defense and U.S. Department of Health and Human Services.

This graphic displays the vaccine distribution process from manufacturers to delivery sites.

Schoch-Spana, M., Brunson, E., Long, R., et al. (2020). The Public's Role in COVID-19 Vaccination: Planning Recommendations Informed by Design Thinking and the Social, Behavioral, and Communication Sciences. Johns Hopkins Bloomberg School of Public Health, Center for Health Security.

The authors – members of the Working Group on Readying Populations for COVID-19 Vaccines – offer five recommendations to advance public understanding of, access to, and acceptance of COVID-19 vaccines.

United Parcel Service. (2020). UPS Healthcare Enhances Dry Ice Production Capabilities, Launches Mobile Freezer Storage Units.

This press release announces the ability of UPS to produce up to 1,200 pounds of dry ice per hour to support COVID-19 vaccine storage in U.S. and Canadian hospitals, clinics, and other points of care. It also announces a collaboration with Stirling Ultracold to distribute portable ultra-low temperature freezers to support ultra cold chain requirements in smaller point of care facilities.

U.S. Department of Defense. (2020). DoD Announces COVID-19 Vaccine Distribution Plan.

This press release announces the Department of Defense's plan to distribute and administer COVID-19 vaccine to uniformed service members, dependents, retirees, civilian employees, and select contract personnel. It includes links to the Department's COVID-19 vaccine guidance and vaccine distribution and population schema.

U.S. Department of Health and Human Services. (2020). Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing.

This guidance allows state-licensed pharmacists to order and state-licensed pharmacists and registered pharmacy interns to administer COVID-19 vaccines under the Public Readiness and Emergency Preparedness Act when certain requirements are met.

U.S. Department of Health and Human Services. (2020). Trump Administration Partners with Chain and Independent Community Pharmacists to Increase Access to Future COVID-19 Vaccines.

This press release announces a partnership with pharmacy chains representing 60 percent of the pharmacies in the U.S. to increase the number of COVID-19 vaccinators and vaccination sites available across the nation.

U.S. Department of Health and Human Services. (2020). Trump Administration Partners with CVS and Walgreens to Provide COVID-19 Vaccine to Protect Vulnerable Americans in Long-Term Care Facilities Nationwide.

This press release announces the Pharmacy Partnership for Long-Term Care Program through which CVS and Walgreens agreed to provide and administer COVID-19 vaccines on site to residents of skilled nursing facilities, nursing homes, assisted living

facilities, residential care homes, and adult family homes as well as long-term care staff not already vaccinated via other efforts.

U.S. Department of Veterans Affairs. (2020). VA Announces Initial Plans for COVID-19 Vaccine Distribution.

This press release announces the 37 sites identified by the VA for prioritized vaccination of healthcare workers and veterans residing in long-term care units.

Vaccine Uptake and Safety

American Psychological Association. (2020). Building Vaccine Confidence Through Community Engagement.

This resource offers information to better understand attitudes and behaviors associated with vaccines. It offers strategies on building vaccination acceptance and confidence that will be important to the COVID-19 vaccination effort.

Centers for Disease Control and Prevention. (2020). Answering Patients' Questions. U.S. Department of Health and Human Services.

This page offers suggestions for how healthcare providers may answer patient questions about vaccination to prevent COVID-19.

Centers for Disease Control and Prevention. (2020). COVID-19 Vaccination Communication Toolkit for Medical Centers, Clinics, and Clinicians. U.S. Department of Health and Human Services.

This page includes materials that providers can use to communicate with patients about vaccination to prevent COVID-19. Materials include fact sheets, posters, stickers, slides, social media messages, videos, and communications guides.

Centers for Disease Control and Prevention. (2020). Post Vaccine Considerations for Healthcare Personnel. U.S. Department of Health and Human Services.

This page offers considerations for healthcare personnel with systemic signs and symptoms after receiving a vaccination for COVID-19.

Centers for Disease Control and Prevention. (2020). Post Vaccine Considerations for Residents. U.S. Department of Health and Human Services.

This page offers considerations for residents of long-term care facilities with systemic signs and systems after receiving a vaccination for COVID-19.

Centers for Disease Control and Prevention. (2020). Talking to Patients with COVID-19 Vaccines. U.S. Department of Health and Human Services.

This page offers communication strategies to aid healthcare providers in talking with their patients about vaccination to prevent COVID-19.