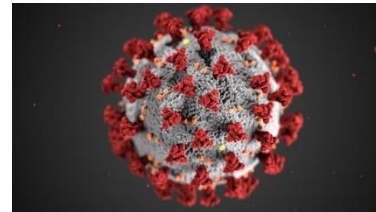


COVID-19 VACCINATION PROGRAM PLANNING ASSUMPTIONS FOR JURISDICTIONS

Many COVID-19 vaccine candidates are in development, and clinical trials are being conducted simultaneously with large-scale manufacturing. It is not known which vaccines will be approved. COVID-19 vaccination program plans must be flexible and accommodate multiple scenarios. For the purpose of initial planning, consider the following assumptions.



COVID-19 VACCINE

- Limited COVID-19 vaccine doses may be available by early November 2020, but COVID-19 vaccine supply will increase substantially in 2021.
- Initially available COVID-19 vaccines will either be approved as licensed vaccines or authorized for use under an [Emergency Use Authorization \(EUA\)](#) issued by the U.S. Food and Drug Administration (FDA).
- Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2° to 8°C) to frozen (-20°C) to ultra-cold (-60° to -80°C) temperatures, and ongoing stability testing may impact these requirements. *Note: These temperatures are based on information available as of August 26, 2020. Updated information will be provided as it becomes available.*
- Jurisdictions should develop strategies to ensure the correct match of COVID-19 vaccine products and dosing intervals. For most vaccines, two doses of COVID-19 vaccine, separated by either ≥ 21 or ≥ 28 days, will be needed for immunity, and second-dose reminders for patients will be necessary. Both doses will need to match each other (i.e., be the same vaccine product).
- Some COVID-19 vaccine products will likely require reconstitution with diluent or adjuvant at the point of administration.

COVID-19 VACCINE ALLOCATION

- The federal government will issue guidance on groups to prioritize for initial COVID-19 vaccination; populations of focus for initial COVID-19 vaccination will likely be:
 - Critical workforce that provides health care and maintains essential functions of society (see <https://www.cisa.gov/identifying-critical-infrastructure-during-covid-19>)
 - Staff and residents in long-term care and assisted living facilities
- Allocation of COVID-19 vaccine to jurisdictions will be based on multiple factors, including:
 - Populations recommended by the Advisory Committee on Immunization Practices (with input from the National Academy of Medicine)
 - Current local spread/prevalence of COVID-19
 - COVID-19 vaccine production and availability
- Jurisdictions should anticipate that allocations may shift during the response based on supply, demand, and risk.
- Each jurisdiction should plan for high-demand and low-demand scenarios.

COVID-19 VACCINATION PROVIDER OUTREACH AND ENROLLMENT

- To receive and administer COVID-19 vaccine and ancillary supplies, vaccination providers must enroll in the United States Government (USG) COVID-19 vaccination program, coordinated through their jurisdiction's immunization program, by signing and agreeing to conditions outlined in the *COVID-19 Vaccination Program Provider Agreement*.
- CDC will make this agreement available to each jurisdiction's immunization program for use in conducting outreach and enrolling vaccination providers. Jurisdictions will be required to maintain these agreements on file for a minimum of three years.
- Jurisdictions will be required to collect and submit to CDC information on each enrolled vaccination provider/site, including provider type and setting, patient population (i.e., number and type of patients served), refrigerated/frozen/ultra-cold temperature storage capacity, and logistical information for receiving COVID-19 vaccine shipments.

- Some multijurisdictional vaccination providers (e.g., select large drugstore chains, Indian Health Service [IHS], and other federal providers) will enroll directly with CDC to order and receive COVID-19 vaccine. These direct partners will be required to report vaccine supply and uptake information back to each respective jurisdiction. CDC will share additional information when available on these procedures to ensure jurisdictions have full visibility for planning and documentation purposes.
- Jurisdictions may choose to partner with commercial entities to reach the initial populations of focus.
- Routine immunization programs will continue.

To be determined:

- *Method of communicating provider enrollment and profile data between jurisdictions and CDC*
- *Specific multijurisdictional providers to be served directly by CDC*
- *Jurisdiction responsibility/involvement concerning multijurisdictional provider training*

COVID-19 VACCINE ORDERING AND DISTRIBUTION

- COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will share more information about reimbursement claims for administration fees as it becomes available.
- CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction immunization programs. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer.
- Jurisdiction-enrolled vaccination providers will follow the jurisdiction's vaccine ordering procedures.
- COVID-19 vaccination providers will be required to report ongoing COVID-19 vaccine inventory.
- Vaccine orders will be approved and transmitted in CDC's Vaccine Tracking System (VTrckS) by jurisdiction immunization programs for vaccination providers they enroll.
- Vaccine (and adjuvant, if required) will be shipped to provider sites within 24 hours of order approval by the immunization program, if supply is available. Ancillary supply kits and diluent (if required) will ship separately from the vaccine due to different cold chain requirements, but shipment will be timed to arrive with or before the vaccine.
- Ancillary supply kits will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators.
 - Each kit will include supplies needed to administer 100 doses of vaccine.
 - Jurisdictions may need to plan for additional PPE, depending on vaccination site needs.
 - For COVID-19 vaccines that require reconstitution with diluent or mixing adjuvant at the point of administration, these ancillary supply kits will include additional necessary syringes, needles, and other supplies for this purpose.
 - Sharps containers, gloves, bandages, and other supplies will not be included.
- Minimum order size for CDC centrally distributed vaccines will be 100 doses per order for most vaccines. Minimum order size for direct-ship vaccines may be much larger. CDC will provide more detail as it becomes available.
- Vaccine will be sent directly to vaccination provider locations for administration or designated depots for secondary distribution to administration sites (e.g., chain drugstores' central distribution).
- Once vaccine products have been shipped to a provider site, the federal government will not redistribute product.
- Jurisdictions will be allowed to redistribute vaccines while maintaining the cold chain. However, with the challenge of meeting cold chain requirements for frozen or ultra-cold vaccines, jurisdictions should be judicious in their use of redistribution and limit any redistribution to refrigerated vaccines only.
- Jurisdictions are not advised to purchase ultra-cold storage equipment at this time; ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice, can store vaccine for an extended period of time, and can be repacked for longer use. CDC will provide additional detail as it becomes available.

To be determined:

- *Frequency requirement for provider-level COVID-19 vaccine inventory reporting*
- *Vaccine disposal/recovery procedures*

COVID-19 VACCINE ADMINISTRATION DATA REPORTING

- Jurisdictions will be required to report CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours). CDC will provide information on these data elements to jurisdictions.
- All vaccination providers may be required to report and maintain their COVID-19 vaccination information on CDC's [Vaccine Finder](#).
- CDC's Vaccine Administration Management System (VAMS) will be available to jurisdictions/provider sites that need assistance in patient registration and scheduling, clinic flow, supply management, patient record management, and reporting.
- CDC has prioritized jurisdiction onboarding to the Immunization (IZ) Gateway* to allow Immunization Information Systems (IISs) to receive data directly from national providers, nontraditional vaccination providers, and VAMS, as well as to report vaccine administration data to CDC.
- Data Use Agreements (DUAs) will be required for data sharing via the IZ Gateway and other methods of vaccine administration data sharing with CDC, and will be coordinated by each jurisdiction's immunization program.

To be determined:

- *Jurisdiction responsibility/involvement concerning reporting of data from multijurisdictional providers*
- *Method and frequency for vaccination providers to report information to Vaccine Finder*

COMMUNICATION

- CDC will develop communication resources for jurisdictions to use with key audiences. These resources will be available on a public-facing website currently under development, but jurisdictions will likely need to tailor messaging and resources specific to special populations in their communities.
- CDC will work with national organizations to disseminate key messages.
- Communication and educational materials about COVID-19 vaccination provider enrollment, COVID-19 vaccine ordering, COVID-19 vaccine storage, handling, administration (i.e., reconstitution, adjuvant use, administration techniques), etc. will be available in a variety of formats.
- When vaccine supply is available for expanded groups among the general population, a national COVID-19 vaccine finder will be available on the public-facing [Vaccine Finder](#).
- A screening tool on the CDC website will help individuals determine their own eligibility for COVID-19 vaccine and direct them to the Vaccine Finder.

COVID-19 VACCINE SAFETY

- Clinically important adverse events following any vaccination should be reported to the Vaccine Adverse Event Reporting System ([VAERS](#)).
- Adverse events will also be monitored through electronic health record (EHR)- and claims-based systems (e.g., [Vaccine Safety Datalink](#)).
- Additional vaccine safety monitoring may be required under the EUA.

* The IZ Gateway is a portfolio of project components which share a common IT infrastructure. The IZ Gateway aims to rapidly onboard IISs to support readiness for COVID-19 vaccine response through data exchange, both among IIS and between IIS and federal providers, mass vaccination reporting and consumer access tools. The IZ Gateway aims to increase the availability and volume of complete and accurate immunization data stored within IIS and available to providers and consumers regardless of their jurisdictional boundaries.