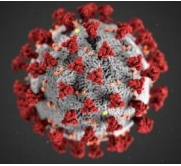


COVID-19 Vaccination Plan Template for Hospitals



COVID-19 VACCINATION PLAN TEMPLATE FOR HOSPITALS



The Maryland Department of Health Center for Immunization created the COVID-19 Vaccination Plan template to assist with development of a hospital's COVID-19 vaccination plan. Hospitals should use this template when developing and reviewing their COVID-19 vaccination plans.

While this guidance may help guide plan development, it is not comprehensive, and hospitals are reminded to carefully review the October 16, 2020 [Maryland COVID-19 Vaccination Plan](#) as well as other CDC guidance and resources when developing their plans.

Name of COVID-19 Hospital Vaccination Campaign Contact:

Title:

Email:

Phone:

Name of Person Responsible for Vaccine Storage:

Title:

Email:

Phone:

Name of Person Responsible for Submission of Vaccine Related Data:

Title:

Email:

Phone:

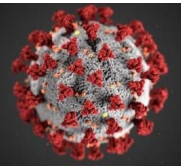
Name of Person Responsible for Vaccine Security

Title:

Email:

Phone:

COVID-19 VACCINATION PLAN TEMPLATE FOR HOSPITALS



Section 1: Phased Approach to COVID-19 Vaccination

Due to changing vaccine supply levels at various points during the COVID-19 Vaccination Program, planning needs to be flexible but as specific as possible to accommodate a variety of scenarios. A key point to consider is that vaccine supply will be limited at the beginning of the program, so the allocation of doses must focus on vaccination providers and settings for vaccination of limited critical populations as well as outreach to these populations. The vaccine supply is projected to increase quickly over the preceding months, allowing vaccination efforts to be expanded to additional critical populations and the general public. It is important to note that recommendations on the various population groups to receive initial doses of vaccine could change after the vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors. Final decisions are being made about use of initially available supplies of COVID-19 vaccines by FDA and the Advisory Committee on Immunization Practices. These decisions will partially depend upon the proven efficacy of the vaccines coming out of Phase 3 trials, but populations of focus for initial COVID-19 vaccination may include:

- Healthcare personnel (paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials)
- Non-healthcare essential workers
- Adults with high-risk medical conditions who possess risk factors for severe COVID-19 illness
- People 65 years of age and older

Instructions:

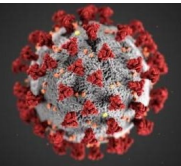
A. Describe how your hospital will identify/prioritize individuals to be vaccinated during the two phases of COVID-19 vaccine administration:

Phase 1: Potentially Limited Doses Available

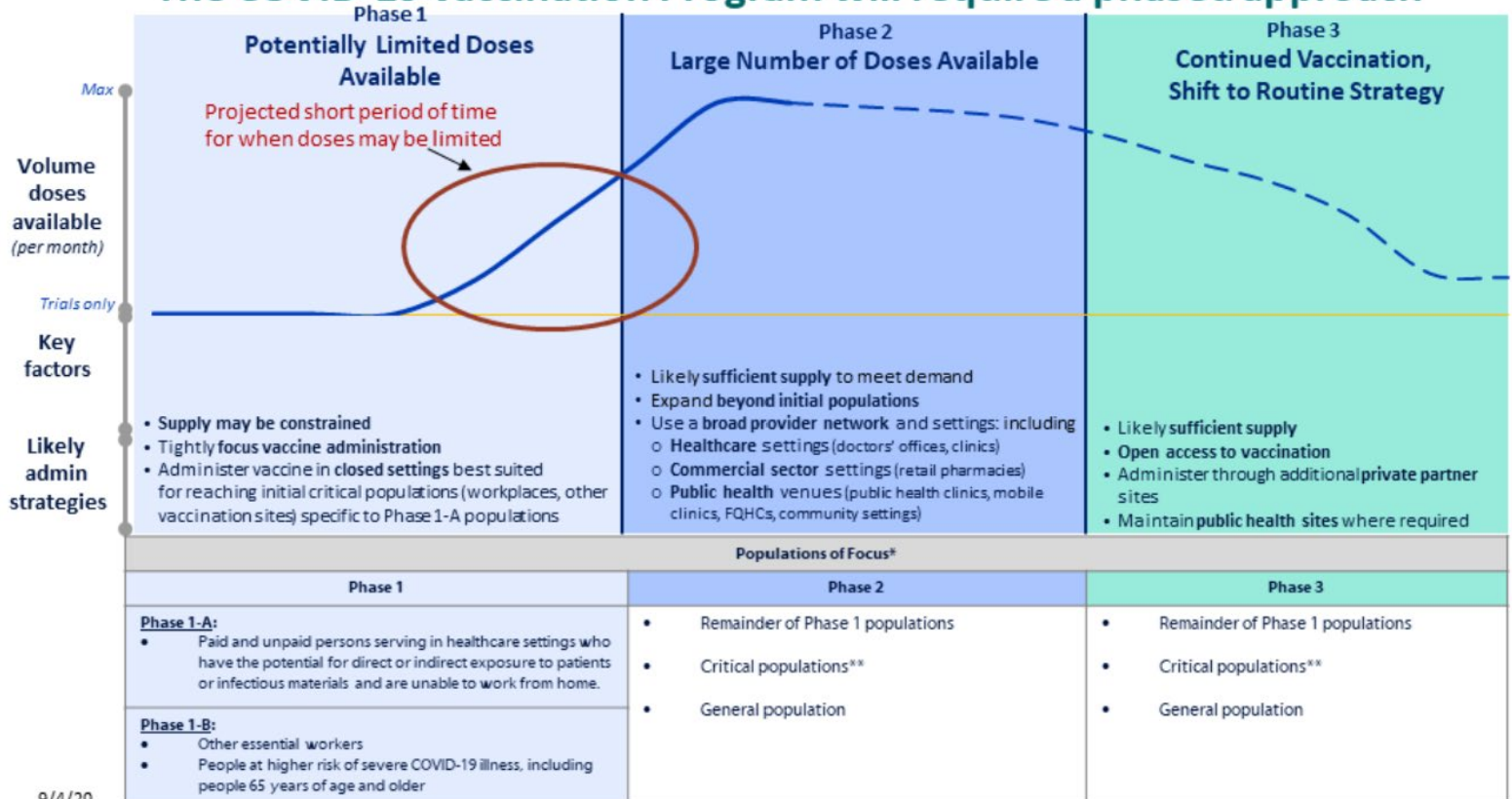
Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand

B. Describe how your hospital will identify subpriority groups if vaccine is not available for your entire first priority group.

COVID-19 VACCINATION PLAN TEMPLATE FOR HOSPITALS



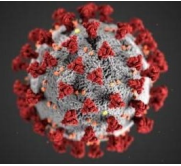
The COVID-19 Vaccination Program will require a phased approach



*Planning should consider that there may be initial age restrictions for vaccine products.

**See Section 4: Critical Populations for information on Phase 1 subset and other critical population groups.

COVID-19 VACCINATION PLAN TEMPLATE FOR HOSPITALS



Section 2: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

Allocation

The federal government will determine the amount of COVID-19 vaccine designated for each state. The Maryland immunization program, Center for Immunization (CFI) will then be responsible for managing and approving orders from hospitals using this allotment. The amount allotted will change over time, which may be based on critical populations recommended for vaccination by ACIP (with input from NASEM), COVID-19 vaccine production and availability, and overall population of the jurisdiction. The CFI will develop allocation methods for critical populations of focus in early- and limited supply scenarios. Prior to receiving an initial vaccine supply, hospitals should determine COVID-19 vaccine order allowances based on:

- Critical populations identified in Section 1 including possible subpriority groups
- Vaccine storage and handling capacity
- Vaccination capacity to administer vaccines to minimize the potential for wastage of vaccine, constituent products, and ancillary supplies

Ordering

Hospitals enrolled/registered in the COVID-19 vaccination program will order COVID-19 vaccines through CFI. During Phase 1 of the vaccination program, when there is limited vaccine supply for critical populations, CFI will order first and second doses of vaccine on behalf of the hospitals based on the critical populations served by the hospital, the hospital's capability to store and handle various COVID-19 vaccine products, and existing inventory. There will be no need for hospitals to "hold in reserve" vaccine for second dose use as CDC will provide vaccine supply for second doses as needed. During phase 2, hospitals will order COVID vaccine directly through ImmuNet, Maryland's Immunization Information System.

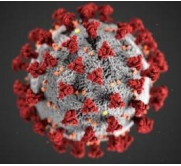
The minimum order size and increment for centrally distributed vaccines will be 100 doses per order; though early in the response, ultra-cold (-60°C to -80°C) vaccine (if authorized for use or approved) may be shipped directly from the manufacturer in 975-dose increments. See appendix for information on shipping & handling of the vaccine A (Pfizer) and vaccine B (Moderna) vaccine product. CFI will share more information on other vaccine products as it becomes available.

CFI will order the first available/approved COVID-19 for hospitals. Requests to delay healthcare worker vaccination for a specific vaccine brand/formulation will not be honored.

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders.

A. For centrally distributed vaccines, each kit will contain supplies to administer 100 doses of vaccine, including:

COVID-19 VACCINATION PLAN TEMPLATE FOR HOSPITALS



- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 105 per kit (ranging from 1–3 mL)
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit
- Vaccine needle guide detailing the appropriate length/gauge for injections based on route, age (for children), gender, and weight (for adults)

If a COVID-19 vaccine that requires mixing with diluent is ordered and shipped from CDC's centralized distributor, a mixing kit that includes the necessary needles, syringes, and alcohol prep pads will also be automatically added to the order. Hospitals will have the option to opt out of receiving the administration and mixing kits.

B. For vaccines that are shipped directly from the manufacturer, a combined kit will be included. This combined kit will include administration supplies (as noted above), mixing supplies, and vials of diluent to prepare the vaccine for use. Because it contains diluent, providers will not have the option to opt out of requesting this combined ancillary kit.

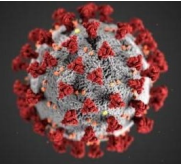
Ancillary supply kits will **not** include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.

Distribution

COVID-19 vaccines and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will use its centralized distribution contract to fulfill orders for most vaccine products and associated ancillary supplies. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site. Hospitals should ensure accurate and complete shipping information (e.g., shipment address, provider contact information, shipping hours) is available in ImmuNet for all vaccine shipments. To support more efficient distribution of vaccines, hospitals should offer full-day receiving hours to the extent possible. When that is not possible, locations identified to receive vaccine and ancillary supply shipments must be available during a 4-hour window on a weekday other than Monday to receive those shipments.

COVID-19 vaccine (and diluent, if required) will be shipped to vaccination provider sites within 48 hours of order approval. Because of cold chain requirements, ancillary supply kits (and diluent, if applicable) will ship separately from vaccine but should arrive before or on the same day as vaccine. The federally contracted vaccine distributor uses validated shipping procedures to maintain COVID-19 vaccine cold chain and minimize the likelihood of vaccine loss or damage during shipment. Once a vaccine product

COVID-19 VACCINATION PLAN TEMPLATE FOR HOSPITALS



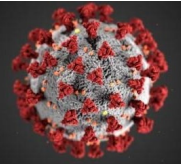
has been shipped to a COVID-19 vaccination provider site, the federal government will neither redistribute the product nor take financial responsibility for its redistribution.

Whenever possible, vaccine should be shipped to the location where it will be administered to minimize potential breaks in the cold chain. However, there may be circumstances where COVID-19 vaccine needs to be redistributed beyond the identified primary CDC ship-to sites (i.e., for orders smaller than the minimum order size or for large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations). In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers may be allowed, if approved by CFI, to redistribute COVID-19 vaccine, if validated cold-chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling. These entities must sign and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement (available from CFI) for the sending facility/organization and have a fully completed and signed CDC COVID-19 Vaccination Provider Profile form for each receiving location.

Hospitals should be extremely judicious in allowing redistribution and limit any redistribution to refrigerated vaccines only. CFI may occasionally allow local transport of vaccines from one location to another within their jurisdictions, if adherence to cold chain and tracking requirements are maintained. CDC/MDH does not pay for or reimburse jurisdictions, COVID-19 vaccination provider organizations, facilities, or other entities for any redistribution beyond the initial designated primary CDC ship-to location, or for any vaccine-specific portable refrigerators and/or qualified containers and pack-outs.

Instructions:

- A.** *Describe your hospital's plans for allocating/assigning allotments of vaccine throughout the jurisdiction using information from Sections 1 and 2. Include allocation methods for populations of focus in early and limited supply scenarios as well as the variables used to determine allocation.*
- B.** *Describe your hospital's procedures for ordering COVID-19 vaccine, including entering/updating provider information in ImmuNet.*
- C.** *Describe hospitals plans for monitoring COVID-19 vaccine wastage and inventory levels.*



Section 3: COVID-19 Vaccine Administration Capacity

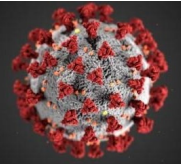
Occupational health settings, temporary vaccination clinics, and closed PODs may be particularly useful for vaccination of hospital employees and other select critical populations early in the COVID-19 vaccination response when vaccine supply may be limited. Hospitals should understand their overall potential COVID-19 vaccine administration capacity, using a variety of COVID-19 vaccination provider types and settings. “Vaccine administration capacity” is defined as the maximum achievable vaccination throughput regardless of public demand for vaccination. If a hospital has a good understanding of its vaccine administration capacities, then planners can generate rough estimates of COVID-19 vaccine administration capacity and their ability to reach various COVID-19 vaccination coverage goals.

Important elements to consider in estimating vaccination capacity:

- Estimated number of existing vaccination providers in the hospital
- Estimated potential weekly COVID-19 vaccine administration capacity (throughput)
- Existing vaccine administration capacity during seasonal influenza or other high vaccination periods
- Infection control measures (i.e., scheduling, distancing, donning and doffing personal protective equipment, cleaning/sanitation procedures) that may slow the vaccination process
- Timing and duration of COVID-19 vaccination provider participation due to changes in staffing or other resources throughout the response or staff experiencing post vaccination symptoms
- First available COVID-19 vaccine (shipped fall 2020) is likely to require ultra-cold storage; be shipped in thermal shippers containing minimum of 975 doses (maximum of 4,875); have 20 day shelf-life in original thermal shipper if recharged with dry ice, 5 days if refrigerated; each vaccine encounter estimated to take up to 10 minutes (a routine influenza vaccination takes 2-3 minutes).

Instructions:

- A. Describe how your hospital has or will estimate vaccine administration capacity based on hypothetical planning scenarios for ultra cold vaccine.*
- B. Describe your capacity to vaccinate ~1,000 people in under five days with ultra cold vaccine (if no ultra cold storage on site); include clinic staffing, space location for large mass clinic, clinic security, use of electronic systems to eliminate data entry/paper consent forms.*
- C. Describe your capacity to schedule 1,000 patients in 5-10 days to receive ultra cold vaccine.*
- D. Will your hospital allow non-hospital employees to be vaccinated at hospital clinics?*
- E. Describe your plan to partner with the local health department to ensure healthcare worker vaccination.*



Section 4: COVID-19 Vaccine Storage and Handling

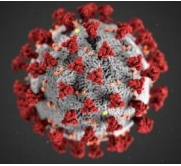
COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness. Hospitals should ensure appropriate vaccine storage and handling procedures are established and followed. It is expected that cold chain storage and handling requirements for COVID-19 vaccine products will vary in temperature from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold (-60°C to -80°C) in the freezer or within the dry ice thermal shipper in which product was received (see appendix). For a reliable cold chain, three elements must be in place:

- Well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

Every hospital vaccine storage unit must have a temperature monitoring device. MDH/CDC recommends digital data loggers (DDLs). As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions at any time, the temperature excursion should be documented and reported according to CFI's current procedures (see MarylandVFC.org). The vaccines that were exposed to out-of-range temperatures must be labeled "do not use" and stored at the required temperature until further information on usability can be gathered or further instruction on disposition or recovery is received.

Instructions:

- A.** *Describe how your hospital plans to ensure adherence to COVID-19 vaccine storage and handling requirements, including cold and ultra cold chain requirements, at all levels:*
 - 1.** *Vaccine A (Pfizer) - Ultra cold vaccine storage shipping containers can be recharged with dry ice to extend use of the container for up to 20 days.*
 - 2.** *Vaccine B (Moderna) - Expected to be stable at refrigerated temperatures for 30 days.*
- B.** *If your hospital has ultra cold storage capability, describe the amount of available storage capacity to hold ultra cold vaccine trays, 9" x 9", with 975 doses.*
- C.** *Does your hospital have a vendor to supply dry ice if needed for ultra cold storage (CDC will send a supply of dry ice along with the first shipment of ultra cold vaccine)? Hospitals with ultra cold storage can decline the dry ice shipment.*
- D.** *Describe how your hospital will secure all COVID-19 vaccine doses to prevent theft or misplacement.*



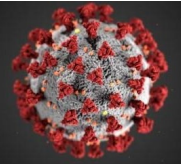
Section 5: COVID-19 Vaccine Administration Documentation and Reporting

COVID-19 vaccination accountability and documentation will be necessary for determining vaccination coverage in Maryland, ensuring the elimination of disparities, providing residents with documentation of vaccination for employment/school purposes, and providing updates on vaccine supply. MDH and CDC have established a list of required data elements that must be collected with each COVID-19 vaccination and reported to MDH/ImmuNet and CDC within 24 hours of administration, as required by the [CDC COVID-19 Program Provider Enrollment Agreement](#). Required data elements include data elements currently being reported to ImmuNet and two new COVID vaccination fields:

- Administered at location: facility name/ID
- Administered at location: type
- Administration address (including county)
- Administration date
- CVX (Product)
- Dose number
- Recipient race
- Recipient ethnicity
- IIS recipient ID
- IIS vaccination event ID
- Lot number: unit of use and/or unit of sale
- MX (manufacturer)
- Recipient address
- Recipient date of birth
- Recipient name
- Recipient cell/mobile phone number
- Recipient email address
- Recipient Occupation (Direct patient care or Non-direct patient care)*
- Recipient sex
- Sending organization
- Vaccine administering provider suffix
- Vaccine administration site (on the body)
- Vaccine expiration date
- Vaccine route of administration
- Vaccination series complete

*New element for COVID vaccination

COVID-19 VACCINATION PLAN TEMPLATE FOR HOSPITALS

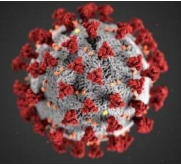


Hospitals have the option of utilizing their own EHR or PrepMod to capture and report the required data elements for Phase 1 vaccinations. PrepMod is a web-based application that supports planning and execution for temporary, mobile, or satellite COVID-19 vaccination clinics. PrepMod manages priority populations from employers and organizations, recipient scheduling, clinic setup, vaccine inventory, and recipient notifications. PrepMod is distributed by the Maryland Partnership for Prevention and licensed to the State of Maryland for hospital use, at no charge to the hospital. PrepMod is cloud hosted on AWS hosting environment. Access to PrepMod requires multi-factor authentication for all users and associated roles. Roles and associated recipient data visibility are enforced by MDH role-based permissions, with role assignment managed by MDH superuser platform administrators, jurisdictional administrators, and clinic administrators.

For information on PrepMod or additional information on the required vaccine data elements please email mdh.covidvax@maryland.gov

Instructions:

- A.** *Describe the system your hospital will use to collect COVID-19 vaccine doses administered data.*
- B.** *Describe how your hospital will ensure each COVID-19 vaccination clinic is ready and able (e.g., staff is trained, internet connection and equipment are adequate) to report the required COVID-19 vaccine administration data elements to ImmuNet every 24 hours.*
- C.** *Describe the steps your hospital will take to ensure real-time documentation and reporting of COVID-19 vaccine administration data from satellite, temporary, or off-site clinic settings.*
- D.** *Describe how your hospital will monitor provider-level data to ensure each dose of COVID-19 vaccine administered is fully documented and reported every 24 hours.*



Section 6: COVID-19 Vaccination Second-Dose Reminders

For most COVID-19 vaccine products, two doses of vaccine, separated by 21 or 28 days, will be needed. Because different COVID-19 vaccine products WILL NOT be interchangeable, a vaccine recipient's second dose must be from the same manufacturer as their first dose. Second-dose reminders for vaccine recipients will be critical to ensure compliance with vaccine dosing intervals and achieve optimal vaccine effectiveness. Some COVID-19 vaccine products may have a short window in which to receive the second dose to prevent the possibility of having to restart the vaccination series.

Multiple methods should be implemented to provide second dose reminders:

- Hospitals should make every attempt to schedule a patient's second-dose appointment when they get their first dose. Many hospital pharmacies and healthcare systems have their own systems for patient notifications and reminders, some using functionality within their electronic health record systems.
- Hospitals should work with occupational health providers and partners to consider the most appropriate and effective method of issuing second-dose reminders.
- COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. Vaccination providers must complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each patient who receives a vaccine to ensure a basic vaccination record is provided. The card provides room for a written reminder for a second-dose appointment.
- MDH will use email and SMS text message-based systems to notify vaccine recipients of the need to schedule a second dose.

Instructions:

- A.** *Describe all methods your hospital will use to remind COVID-19 vaccine recipients of the need for a second dose, including planned redundancy of reminder methods.*

Appendix

Appendix B: COVID-19 Vaccination Scenarios for Jurisdictional Planning—Phase 1, Q4 2020 (updated 10/29/2020)

The planning scenarios described below should be used by state and local jurisdictions to develop operation plans for early COVID-19 vaccination when vaccine supply may be constrained. The scenarios describe potential COVID-19 vaccine requirements, early supply estimates in the event that a vaccine is authorized under EUA, and populations that may be recommended for vaccination during this early period. These scenarios are designed to support jurisdictional, federal, and partner planning, but they are still considered hypothetical. The COVID-19 vaccine landscape is evolving and uncertain, and these scenarios may change as more information is available.

Planners should assume that by January 2021, significantly more COVID-19 vaccine may be available for distribution and plans will need to evolve to address additional vaccine availability. Please refer to COVID-19 vaccine planning assumptions and additional guidance from the Centers for Disease Control and Prevention.

Scenario 1: FDA has authorized vaccine A for Emergency Use Authorization (EUA) in 2020

Availability Assumptions

Vaccine availability under EUA by			
Candidate	End of Nov 2020	End of Dec 2020	Notes
Vaccine A	10M–20M doses	20M–30M doses	Ultra-cold (-70°C) storage requirements, for large sites only

Distribution, Storage, Handling, and Administration Assumptions

Vaccine A	
SHIPMENT <i>3 separately acquired components (mixed on site)</i> 1. Vaccine <ul style="list-style-type: none">2 mL multidose vials (5 doses/vial)Direct to site from manufacturer (on dry ice) in thermal shipping containerThermal shipper estimated specs: 400 mm X 400 mm X 560 mm, (15.75" X 15.75" X 22.0")Each shipper can hold up to 5 trays, and each tray will hold up to 195 vials.Tray (i.e., "pizza box") estimated specs: 229 mm X 229 mm X 40 mm (9" X 9" X 1.6") 2. Diluent and ancillary supply kits (for administration and mixing) <ul style="list-style-type: none">Direct to site from the federal government (at room temperature) 3. Thermal shipper should be returned after use. Instructions for mail-back and labels will be forthcoming.	ON-SITE VACCINE STORAGE <i>Ultra-Cold Temp Frozen (-60°C to -80°C)</i> <ul style="list-style-type: none">Freezer units capable of ultra-cold temperatures (UCTs)The shipping container (thermal shipper) may be used to store vaccines:<ul style="list-style-type: none">Once received (day 1), the thermal shipper should be replenished with pelleted dry ice within 24 hours.Shippers should be replenished with dry ice every 5 days thereafter to maintain required temperature.Total amount of dry ice needed per thermal shipper "recharge" is ~23 kg.On day 15, transfer the vaccine to refrigerated temperatures (2–8°C). Use within 5 days (120 hours).Shippers may only be opened two times a day.Temperature monitoring must be in alignment with CDC guidance, irrespective of re-icing.<ul style="list-style-type: none">Thermal shipper may be monitored using a temperature probe on the container, in alignment with guidance provided by CDC and information provided by the manufacturer.Direct handling of dry ice needed for recharging the containers will require the use of appropriate PPE. <i>Thawed but NOT diluted (2°C to 8°C)</i>

<p>ORDERS</p> <p><i>Large quantities, to large provider sites only</i></p> <ul style="list-style-type: none"> • Minimum order: ~1,000 doses • Maximum order: ~5,000 doses 	<ul style="list-style-type: none"> • Product may be removed from ultra-cold storage or thermal shipper, thawed, and stored at 2°C–8°C for up to 5 days (discard unused doses after 5 days). • Cannot return to ultra-cold storage or thermal shipper once thawed <p>Diluted (room temperature)</p> <ul style="list-style-type: none"> • If removed directly from ultra-cold temperatures, vaccine must be thawed ~30 minutes at room temperature before dilution. • Once vaccine is thawed, it must be diluted within 2 hours. If unable to dilute within 2 hours, store at 2°C–8°C. • Must use diluted vaccine within 6 hours (discard any unused, diluted vaccine after 6 hours) <p>ADMINISTRATION</p> <p><i>2-dose series (21 days between doses)</i></p> <ul style="list-style-type: none"> • On-site mixing required; dilute with diluent just prior to administration; all 5 doses must be administered within 6 hours of dilution; remainder of diluted vaccine should be discarded. • Administer by intramuscular (IM) injection.
<p>INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINATION PROVIDER SITES</p> <p>NOTE: <i>Primary vaccination provider sites may consider providing vials to other sites. HOWEVER, all cold chain requirements should be maintained and logged in accordance with the information provided above.</i></p> <p>Healthcare personnel — public health clinics, closed points of dispensing (PODs), temporary/off-site vaccination clinics + potential for mobile clinics</p> <p>Other essential workers — public health clinics, closed PODs, temporary/off-site vaccination clinics + potential for mobile clinics</p> <p>Adults with underlying medical conditions and people 65 years of age and older — open PODs in strategic locations, potential for mobile clinics at long-term care facilities (LTCFs) or partnership with pharmacy on-site clinics for LTCFs, correctional/detention facilities, and other congregate settings</p>	

Additional Considerations for Early Vaccination Planning

- “Healthcare personnel” includes paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to people with COVID-19 or infectious materials.
- Jurisdictions should plan for real-time shipment of doses.
- Vaccination provider sites (during Phase 1) will not be required to store vaccine products beyond the period of time. Vaccine A can be stored in the ultra-cold thermal shipper or at refrigerated temp (2°C–8°C, see “Thawed but NOT diluted” section).
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on vaccination provider sites that can reach critical populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine A; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the critical populations as possible, given vaccine product storage and handling requirements. For example, Vaccine A may be administered by mobile clinics if multiple mobile clinics are planned over a short period of time to ensure sufficiently high throughput. Vaccine A may also be placed in healthcare systems and support multiple clinics in one system (where product can be shared and repositioned from one site to another at 2°C–8°C).
- Ensure equitable access for adults with underlying medical conditions and people 65 years of age and older who are part of other critical populations. Additional vaccination provider sites may be required to reach these populations.

Scenario 2: FDA has authorized vaccine B for EUA in 2020

Availability Assumptions

Vaccine availability under EUA by			
Candidate	End of Nov 2020	End of Dec 2020	Notes
Vaccine B	~10M doses	~15M doses	Central distributor capacity required (-20°C)

Distribution, Storage, Handling, and Administration Assumptions

Vaccine B	
SHIPMENT <i>2 separately shipped components</i> Vaccine <ul style="list-style-type: none"> To central distributor (at -20°C) Multidose vials (10 doses/vial) Ancillary supply kits <ul style="list-style-type: none"> Direct to site from USG (at room temperature) 	ON-SITE VACCINE STORAGE <i>Frozen (-25°C to -15°C until ready for use)</i> Note: This is a narrower range than for varicella-containing vaccines. <i>Refrigerated (2°C to 8°C)</i> <ul style="list-style-type: none"> Must use within 7 days if the vial has not been entered Thaw before use: <ul style="list-style-type: none"> Thaw in refrigerated conditions between 2°C to 8°C for 2 hours. Let vial stand at room temperature for 15 minutes before administering. Alternatively, thaw at room temperature between 20°C to 25°C for 1 hour. After thawing, do not return vial to the freezer. <i>Room temperature</i> <ul style="list-style-type: none"> The total time between removal from refrigeration and administration should be no more than 12 hours. Once the vial has been entered, it must be used within 6 hours (discard any unused vaccine after 6 hours).
ORDERS <i>Central distribution capacity</i> <ul style="list-style-type: none"> Required by Dec 2020 Maintained at -20°C 	ADMINISTRATION <i>2-dose series (1 month between doses)</i> <ul style="list-style-type: none"> No on-site mixing required Once thawed, swirl vaccine gently prior to withdrawing a dose. Do NOT shake. Administer by intramuscular (IM) injection.
INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINATION PROVIDER SITES <i>Healthcare personnel</i> — healthcare clinics + healthcare occupational health clinics + public health clinics, closed PODs, temporary/off-site vaccination clinics + mobile clinics <i>Other essential workers (specifics TBA)</i> — occupational health clinics + hospital clinics + public health clinics, closed PODs, temporary/off-site vaccination clinics <i>Adults with underlying medical conditions and people 65 years of age and older</i> — commercial pharmacy partners + mobile clinics	

Additional Considerations for Early Vaccination Planning

- “Healthcare personnel” includes paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to people with COVID-19 or infectious materials.
- Jurisdictions should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine B can be stored at 2–8°C.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach critical populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine B; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the prioritized populations as possible, given limitations with the product.
- Ensure equitable access for adults with underlying medical conditions and people 65 years of age and older who are part of other critical populations. Additional vaccination provider sites may be required to reach these populations.

Scenario 3: FDA has authorized vaccines A and B for EUA in 2020

Availability Assumptions

Vaccine availability under EUA by			
Candidate	End of Nov 2020	End of Dec 2020	Notes
Vaccine A	10M–20M doses	20M–30M doses	Ultra-cold (-70°C), for large sites only
Vaccine B	~10M doses	~15M doses	Central distribution capacity required (-20°C)
Total	20M–30M doses	35M–45M doses	

Distribution, Storage, Handling, and Administration Assumptions

Vaccine A	
SHIPMENT <i>3 separately acquired components (mixed on site)</i> 1. Vaccine <ul style="list-style-type: none"> 2 mL multidose vials (5 doses/vial) Direct to site from manufacturer (on dry ice) in thermal shipping container Thermal shipper estimated specs: 400 mm X 400 mm X 560 mm (15.75" X 15.75" X 22.0") Each shipper can hold up to 5 trays, and each tray will hold up to 195 vials. Tray (i.e., "pizza box") estimated specs: 229 mm X 229 mm X 40 mm (9" X 9" X 1.6") 2. Diluent and ancillary supply kits (for administration and mixing) <ul style="list-style-type: none"> Direct to site from the federal government (at room temperature) 3. Thermal shipper should be returned after use. Instructions for mail-back and labels will be forthcoming.	ON-SITE VACCINE STORAGE <i>Ultra-Cold Temp Frozen (-60°C to -80°C)</i> <ul style="list-style-type: none"> Freezer units capable of ultra-cold temperatures (UCTs) The shipping container (thermal shipper) may be used to store vaccines: <ul style="list-style-type: none"> Once received (day 1), the thermal shipper should be replenished with pelleted dry ice within 24 hours. Shippers should be replenished with dry ice every 5 days thereafter to maintain required temperature. Total amount of dry ice needed per thermal shipper "recharge" is ~23 kg. On day 15, transfer the vaccine to refrigerated temperatures (2°C to 8°C). Use within 5 days (120 hours). Shippers may only be opened two times a day. Temperature monitoring must be in alignment with CDC guidance, irrespective of re-icing. <ul style="list-style-type: none"> Thermal shipper may be monitored using a temperature probe on the container, in alignment with guidance provided by CDC and information provided by the manufacturer. Direct handling of dry ice needed for re-icing the containers will require the use of appropriate PPE. <i>Thawed but NOT diluted (2°C to 8°C)</i> <ul style="list-style-type: none"> Product may be removed from the ultra-cold storage or thermal shipper, thawed, and stored at 2°C to 8°C for up to 5 days (discard unused doses after 5 days). Cannot return to ultra-cold storage or thermal shipper once thawed

	<p><i>Diluted (room temperature)</i></p> <ul style="list-style-type: none"> • If removed directly from ultra-cold storage, vaccine must be thawed ~30 minutes at room temperature before dilution. • Once vaccine is thawed, it must be diluted within 2 hours. If unable to dilute within 2 hours, store at 2°C–8°C. • Must use diluted vaccine within 6 hours (discard any unused diluted vaccine after 6 hours)
<p>ORDERS</p> <p><i>Large quantities, to large provider sites only</i></p> <p>Minimum order: ~1,000 doses</p> <p>Maximum order: ~5,000 doses</p>	<p>ADMINISTRATION</p> <p><i>2-dose series (21 days between doses)</i></p> <ul style="list-style-type: none"> • On-site mixing required; dilute with diluent just prior to administration; all 5 doses must be administered within 6 hours of dilution; remainder of diluted vaccine should be discarded. • Administer by IM injection.
<p>PRIORITIZED POPULATIONS AND ANTICIPATED VACCINATION PROVIDER SITES</p> <p><i>Healthcare personnel</i> — public health clinics, closed PODs, temporary/off-site vaccination clinics + potential for mobile clinics</p> <p><i>Other essential workers (specifics TBA)</i> — public health clinics, closed PODs, temporary/off-site vaccination clinics + potential for mobile clinics</p> <p><i>Adults with underlying medical conditions and people 65 years of age and older</i> — commercial pharmacy partners, open PODs in strategic locations, potential for mobile clinics at LTCFs, correctional/detention facilities, and other congregate settings</p>	
<p>Vaccine B</p>	
<p>SHIPMENT</p> <p><i>2 separately shipped components</i></p> <p>Vaccine</p> <ul style="list-style-type: none"> • To central distributor (at -20°C) • Multidose vials (10 doses/vial) <p>Ancillary supply kits</p> <ul style="list-style-type: none"> • Direct to site from USG (at room temperature) 	<p>ON-SITE VACCINE STORAGE</p> <p><i>Frozen (-25°C to 15°C until ready for use)</i></p> <p>Note: This is a narrower range than for varicella-containing vaccines.</p> <p><i>Refrigerated (2°C to 8°C)</i></p> <ul style="list-style-type: none"> • Must use within 7 days if the vial has not been entered. • Thaw before use: <ul style="list-style-type: none"> • Thaw in refrigerated conditions between 2°C to 8°C for 2 hours. Let vial stand at room temperature for 15 minutes before administering. • Alternatively, thaw at room temperature between 20°C to 25°C for 1 hour. • After thawing, do not return vial to the freezer. <p><i>Room temperature</i></p> <ul style="list-style-type: none"> • The total time before administration and after removal from the refrigerator should be no more than 12 hours. • Once the vial has been entered, it must be used within 6 hours (discard any unused vaccine after 6 hours).

ORDERS <i>Central distribution capacity</i> <ul style="list-style-type: none"> Required by Dec 2020 Maintained at -20°C 	ADMINISTRATION <i>2-dose series (1 month between doses)</i> <ul style="list-style-type: none"> No on-site mixing required Once thawed, swirl vaccine gently prior to withdrawing a dose. Do NOT shake. Administer by intramuscular (IM) injection
INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINATION PROVIDER SITES <i>Healthcare personnel</i> — healthcare clinics + healthcare occupational health clinics + public health clinics, closed PODs, temporary/off-site vaccination clinics + mobile clinics <i>Other essential workers (specifics TBA)</i> — occupational health clinics + hospital clinics + public health clinics, closed PODs, temporary/off-site vaccination clinics <i>Adults with underlying medical conditions and people 65 years of age and older</i> — commercial pharmacy partners + mobile clinics	

Additional Considerations for Early Vaccination Planning

- “Healthcare personnel” includes paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to people with COVID-19 or infectious materials.
- Jurisdictions should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine A can be stored in the ultra-cold shipment box or Vaccine B can be stored at 2–8°C.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach prioritized populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine A and Vaccine B; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the prioritized populations as possible, given the limitations with the product. For example: Vaccine A may be administered through mobile clinics if multiple mobile clinics are planned over a short period of time to ensure sufficiently high throughput.
- Ensure equitable access for adults with underlying medical conditions and people 65 years of age and older who are part of other critical populations. Additional vaccination provider sites may be required to reach these populations.

Vaccine A (Pfizer) Shipping/Storage Information

Direct Shipment to Points of Vaccination

Direct Shipments* to Vaccination Center by Transport Courier



Pfizer has designed a distribution model which is built on a flexible just in time system to ship the vaccine from manufacturing site and/or storage facility directly to the points of vaccination.

*COVID Vaccine supply chain model is a drop ship direct from Pfizer manufacturing sites to the designated locations by the governments.
Markets with no Pfizer commercial legal entity: Product ownership transfer at port of entry for governmental customer importation and in-market distribution

Temperature & Location Tracking During Transportation



- Each thermal shipper has reusable GPS enabled temperature monitoring device which will be enabled when the shipper is packed.
- All shipments will be tracked via the onboard GPS monitoring device to ensure end-to-end distribution within required temperatures.
- Shipments will be executed under the management of Pfizer Quality processes and controls to ensure that upon ownership transfer, product has arrived under acceptable conditions.
- Temperature records of the shipments can be shared with upon request.

Thermal Shippers may have slight differences depending on manufacturer.

Product Packaging Overview

1. Primary Packaging



2 mL Type 1 glass
preservative-free

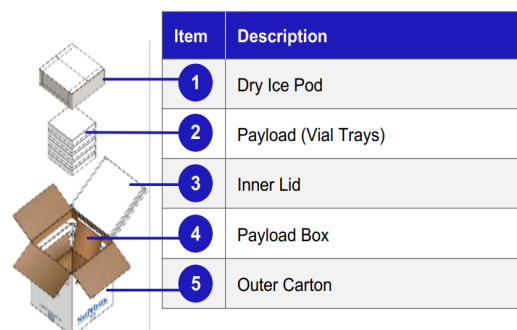
- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 5 doses per vial after dilution

2. Secondary Packaging “Single Tray”



- Single tray holds 195 vials
- 975 doses per tray
- A smaller tray, containing 25 vials (125 doses) is in development with estimated availability in early 2021

3. Tertiary Container: Thermal Shipper



Thermal Shippers may have slight differences depending on manufacturer.

- Minimum 1 tray (975 doses) or up to 5 trays (4875 doses) stacked in a payload area of the shipper
- Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT -75+15°C (-103° to 5°F) up to 10 days if stored at 15°C to 25°C (5° to 77°F) temperatures without opening
- Thermal shippers are reusable and designed to be a temporary storage containers by replenishing dry ice.

Temperature Controlled Storage Selection Guide

An **Ultra Low Temperature Freezer (ULTF)** is the preferred storage option, and is ideal when a Point of Care site...

- Seeking the preferred storage option which allows for up to 6 months of shelf life
- Is concerned about variability in number of full-time immunizers available and/or variability in patient flow (e.g. walk-ins)
- Is unable to secure dry ice, or meet the handling requirements associated with the use of a thermal shipper as a temporary storage device
- Already has capacity in an existing ULTF or can support substantial expenditures (i.e. cost for ULTF)

A **Thermal Shipper** is ideal when a Point of Care site...

- Doesn't have access to an ULTF
- Meets all requirements defined in the Pfizer Storage and Handling Guidelines
- Has at least 2 full-time immunizers and, is concerned about administering 975 doses in 5 days
- Has consistent and reliable access to dry ice

A **Refrigerator** is ideal when a Point of Care site...

- Has at least 4 full-time immunizers and, is expecting to administer at least 975 doses every 5 days
- Is concerned about ordering/ handling dry ice shipments

Cold Storage Comparison

Cold Storage Limitations	ULTF (6 months)	Thermal (15 Days)	Fridge (5 Days)
Availability of Full-time Immunizers	No Restriction	Minimum 2 Immunizers	Minimum 4 Immunizers
Anticipated Patient Flow	Minimum 960 patients in 6 months	Minimum 960 patients in 15 days	Minimum 960 patients in 5 days
Allows for Variability in Patient Flow (e.g. walk-ins)	Yes	No	No
Requires Dry Ice Ordering/ Handling	No	Yes	No
Additional Site Expenditures Investment¹	\$\$	\$	\$

¹Expenditures are based on estimates for ULTF procurement and dry ice procurement.
Note: Assumes immunizers are working 8 hours a day, and vaccinating 6 patients an hour

Ultra-Low Temperature Freezer

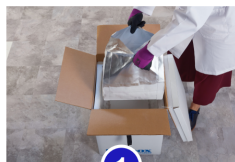
Temperature

- Store as frozen liquid at $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$ ($-94^{\circ}\text{F} \pm 50^{\circ}\text{F}$) for long term storage up to 6 months.
- Different size of ULT freezers are may be available for purchase by points of vaccination
- A small size (under or over the countertop ULT Freezers can store as much as 30K doses).



Illustrative Only

Product Transfer



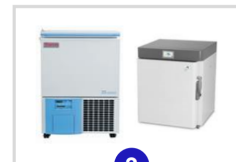
1

Remove Dry Ice Pod from shipper



2

Take out Vial Tray(s) from Payload Box and transfer to ULT Freezer



3

Monitor Freezer Temperatures

Transfer of product from the thermal shipper must be done in less than 5 minutes to prevent premature product thawing

Thermal Shippers may have slight differences depending on manufacturer.

*Product temperature must always be monitored to ensure adherence to temperature requirements for different storage conditions are being met in alignment with site Standard Operating Procedures.

Please note that it is possible that the final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping requirements, but this deck reflects the Company's current understanding based on the totality of available data currently. Current as of September 8, 2020.

Refrigerator Usage

Product Removal

When removing a tray from the thermal shipper, minimize the time the shipper is open (≤ 1 minute)

If less than a full tray is needed, remove the number of vials needed from the tray as quickly as possible and return the tray to frozen storage. Trays should not be exposed to room temperature for more than a few minutes, as the vials can thaw very quickly

Vials should be transferred into a secondary container for safe transportation

Gloves allowing manual dexterity should be worn while handling frozen vials.

Refrigerator Usage

Product Thawing

Either: Transfer the frozen vials immediately to a refrigerator at 2 to 8 °C (35.6° to 46.4°F).

An entire tray will take about 3 hours to thaw; a smaller number of vials may thaw more quickly

Or: Vials needed for immediate can be thawed at room temperature (30 minutes); room temperature hold time is no more than 2 hours

Vials thawed at room temperature form condensation on the outside of the vial, so thawing in a secondary container is recommended

Vials may be stored in the refrigerator prior to dilution for up to 5 days (120 hours)

Vials may be held at room temperature for no more than 2 hours prior to dilution.

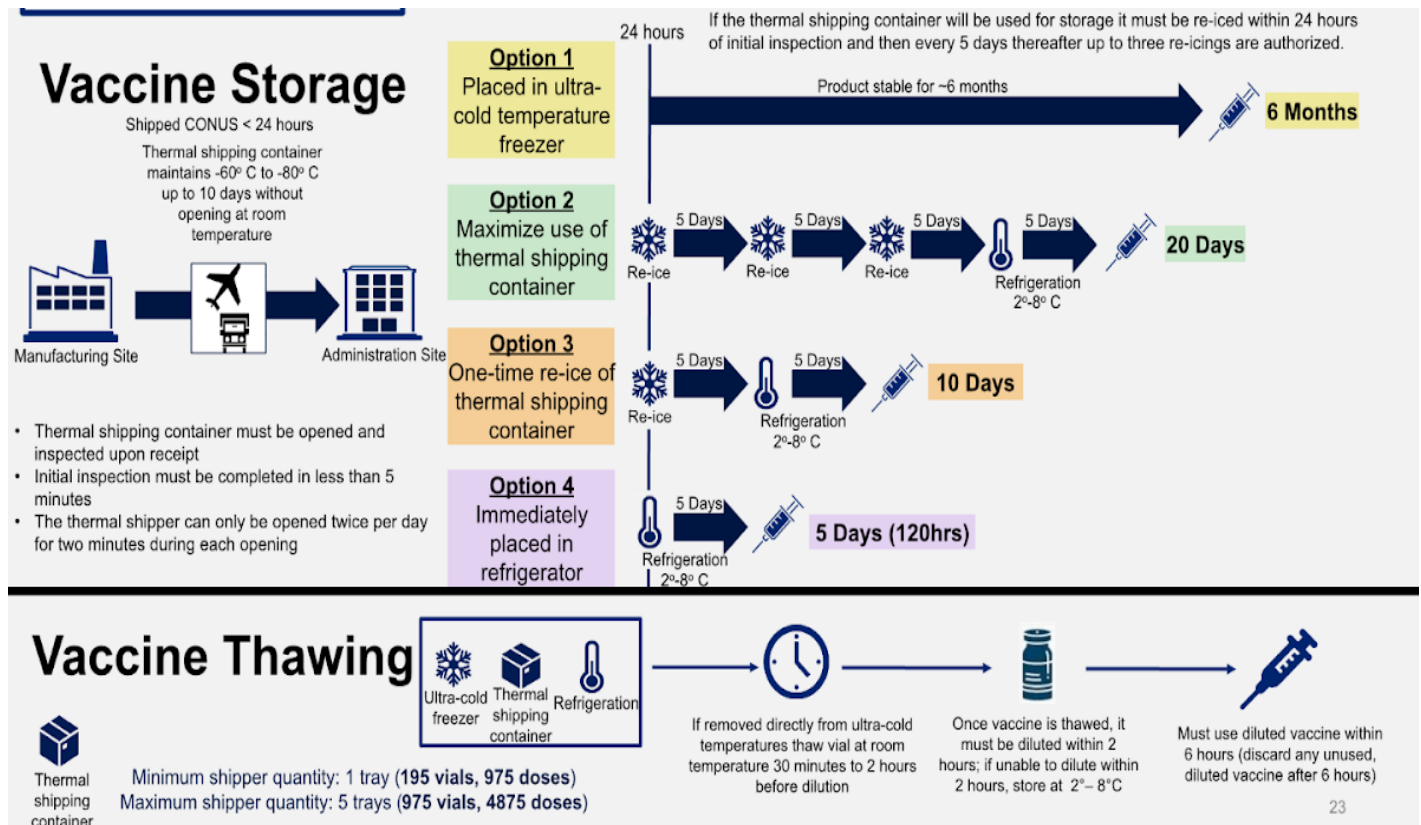
Product Refrigeration

Product can be stored at 2 to 8 °C (35.6° to 46.4°F) refrigerator up to 120 hours (5 days).

Diluted Product Storage

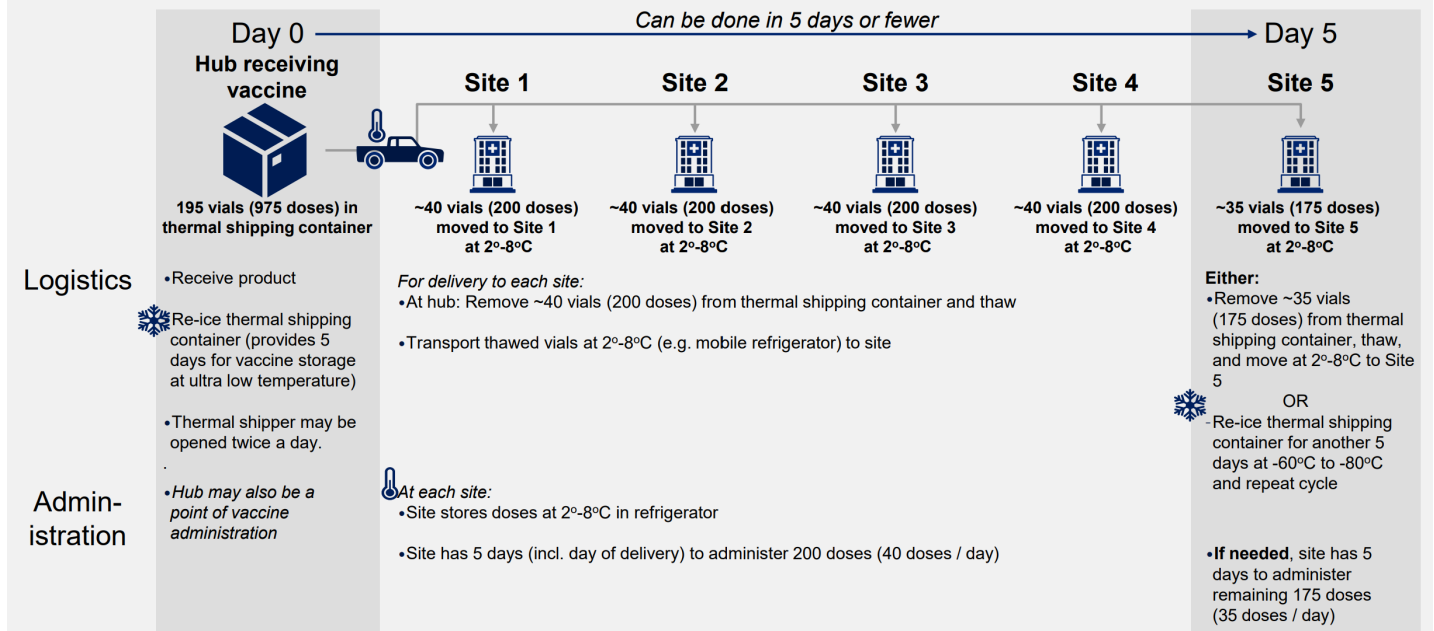
Diluted product must be used in 6 hours from the time of dilution, stored between 2°C to 25°C (35.6° to 77°F).

Vaccine A: Thermal Shipper Infographic



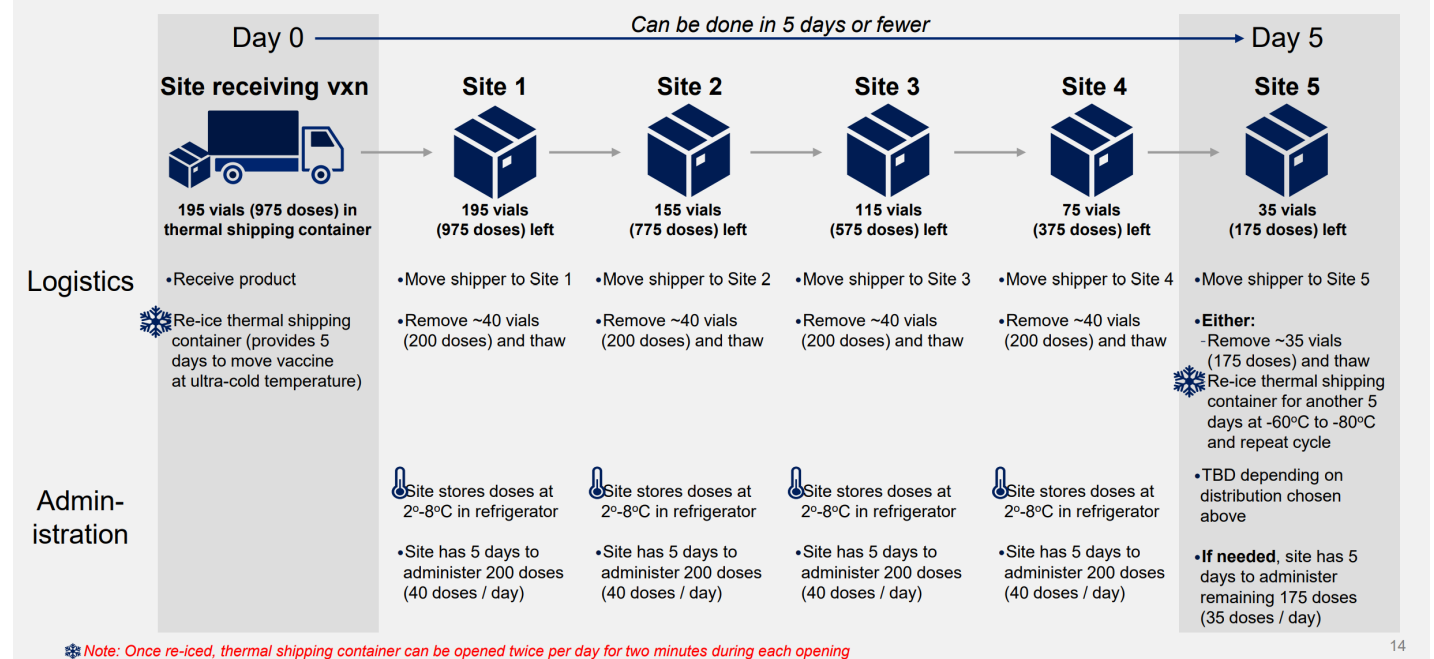
Vaccine A Example: Hub and Spoke Model, Delivery at 2-8°C

Illustrative example, using one-time re-ice of thermal shipping container








Vaccine A Example: Mobile Delivery Using Thermal Shipping Container



Illustrative example, using one-time re-ice of thermal shipping container



Site Types for Vaccine A Product

Vaccination provider site	Ordering assumptions			Operating assumptions				
	Order size	Storage conditions	Patient flow	Number of immunizers	Patients per immunizer	Hours per day	Vaccines per day	Shipment model
 A – large outpatient center (mass vx)	1 tray (975 doses)	Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	~500/day	10 immunizers	6 patients/hour (~10 min/Vx)	8 hours	480 vaccinations	1 tray; 2-3 times per week
 B – hospital or outpatient center	1 tray (975 doses)	Ultra-cold freezer, Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	4 immunizers	6 patients/hour (~10 min/Vx)	8 hours	192 vaccinations	1 tray; every week
 C – large hospital with affiliated outpatient center	5 trays (4,875 doses)	Ultra-cold freezer, Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	7 immunizers (hospital outpatient clinic)	6 patients/hour (~10 min/Vx)	8 hours	340 vaccinations	1 tray; 1-2 times a week
 D – outdoor parking lot vaccination hub at large retail pharmacy	1 tray (975 doses)	2-8C fridge, for product estimated at site (5 days)	~200/day	5 immunizers	6 patients/hour (~10 min/Vx)	N/A	240 vaccinations	1 tray; every week
 E – mobile vaccination in targeted geographic areas	5 trays (4,875 doses)	2-8C fridge, for product estimated in mobile unit (5 days)	Variable	3 immunizers	6 patients/hour (~10 min/Vx)	Not specified	150 vaccinations	1 tray; every week

Site Types for Vaccine A Product

Vaccination provider site	Ordering assumptions			Operating assumptions				
	Order size	Storage conditions	Patient flow	Number of immunizers	Patients per HCP	Hours per day	Vaccines per day	Shipment model
 F – large indoor spaces not used during pandemic (convention hall)	5 trays (4,875 doses)	Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	10 immunizers	6 patients/hour (~10 min/Vx)	8 hours	480 vaccinations	2-3 trays; every week
 G – Drive-through vaccination clinic	3 trays (2,925 doses)	Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	10 immunizers	6 patients/hour (~10 min/Vx)	8 hours	480 vaccinations (by 7 days)	2-3 trays; very week

Vaccine Candidate B (Moderna)

mRNA-1273 packaging during EUA

