

CDC COVID-19 Vaccination Playbook Supplement #1

Distribution Plan Update

November 25, 2020

CDC is working with other federal partners of <u>Operation Warp Speed</u> (OWS) to plan and implement a COVID-19 Vaccination Program. Operation Warp Speed's goal is to produce and deliver 300 million doses of safe and effective vaccines, with the initial doses available before the end of 2020. The following high-level distribution update is provided to aid jurisdictions to further refine their implementation plans. This approach for centralized vaccine ordering and distribution will be executed in phases by CDC in collaboration with jurisdictions, tribes, federal agencies receiving a direct allocation of vaccine, and commercial partners.

The information below covers four key topics:

- 1. Allocation
- 2. Ordering
- 3. Receipt, storage, and handling
- 4. Operational norms

The information within these sections will continue to evolve as new information becomes available.

Allocation:

COVID-19 vaccine will be allocated according to the following principles:

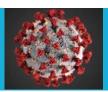
- Allocations will be calculated pro-rata based on the size of the jurisdiction's population and the quantity of ready-to-ship doses from manufacturer(s).
- Allocation amounts will be communicated to jurisdictions weekly. These allocations will be immediately available for ordering.
- If a jurisdiction does not order the full allocation, the remainder will roll over for future ordering. Unused allocations will not be reallocated to other jurisdictions.

For the two initial vaccine candidates, two doses will be required, and the same product must be used for both doses. Two-dose vaccine allocations will be managed in the following way:

- In coordination with vaccine manufacturers, CDC will reserve and store inventory of second-dose product to include in future allocations for ordering at the appropriate time (e.g., 2 weeks after first doses are ordered for a product requiring the second dose on Day 21).
- CDC does not expect jurisdictions or federal and commercial partners to maintain physical inventory of second-dose product (i.e., jurisdictions will not be expected to store product for 21–28 days to prepare for second-dose administration).

Ordering:

The COVID-19 Vaccination Program will utilize CDC's VTrckS system.



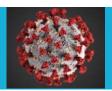
- 1. Each jurisdiction, federal agency, and commercial partner will receive allocations (order caps) weekly in VTrckS.
- 2. Jurisdictions, federal agencies, and commercial partners will submit orders for vaccination provider sites. These orders will be processed against the allocation (order cap).
 - a. Federal and commercial partners may pull order files from the Vaccine Provider Ordering Portal (VPoP) to upload into VTrckS.
- 3. Orders will be scheduled for delivery Monday through Friday.

Direct-Ship Vaccine (Vaccine A):

Jurisdictions are asked to identify locations to receive early shipments of this vaccine once the Food and Drug Administration (FDA) issues an Emergency Use Authorization (EUA) but before the Advisory Committee on Immunization Practices (ACIP) meets and makes recommendations for use and the recommendations are approved. This will ensure that product is available at the jurisdictional level and jurisdictions are ready to support vaccine administration after ACIP recommendations are issued and approved.

- A. The minimum order volume for Vaccine A is 975 doses.
- B. Each jurisdiction is asked to identify delivery sites to receive initial shipments of product. Jurisdictions can decide what quantity to order for each initial site (in 975-dose increments), based on what is feasible to administer.
 - Jurisdictions are encouraged to finalize site locations as soon as possible. Jurisdictions will be asked to confirm these sites once an EUA has been authorized.
- C. After ACIP recommendations have been approved, additional sites will be able to place orders against their jurisdiction's allocation. Vaccine will be delivered within 24-48 hours of order placement.
- D. Along with vaccine, each site will receive ancillary kits and an initial dry ice resupply:
 - Ancillary supply kits will include diluent and administration materials (including appropriate needles, syringes, alcohol swabs, and limited PPE). Ancillary supply kits will be automatically added to vaccine orders and do not require additional action or separate orders from jurisdictions/sites. CDC will provide details on dimensions of ancillary supply kits once the information is confirmed.
 - OWS will provide an initial dry ice resupply to facilitate storage in coordination with each vaccine shipment. Jurisdictions will have the option to allow sites to opt out of the

Final decisions about prioritization of populations will not be made until closer to implementation; jurisdictions should have multiple scenarios prepared for local distribution and administration.



initial dry ice resupply if desired. Sites will receive this initial dry ice resupply in coordination with receipt of the product, as they will need to replenish the dry ice upon product receipt. Further details about shipping and receipt of dry ice will be forthcoming.

Receipt, Storage, and Handling:

CDC is updated its *Vaccine Storage and Handling Toolkit*, to include a COVID-19 Vaccine Addendum, which will provide guidance on each vaccine product. CDC will also provide additional product-specific materials, including storage, handling and administration job aids. CDC will provide these resources as soon as possible.

The Vaccine Storage and Handling Toolkit can be found at: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html. General Additional web pages with clinical guidance will be added as COVID-19 vaccine products become available.

Vaccine A:

Thermal shipping containers with Vaccine A will arrive with a GPS-enabled temperature monitoring device that will monitor temperature excursions in transit as well as at the vaccination provider site, if used.

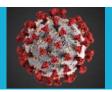
If a jurisdiction/site plans to store product in an ultra-low temperature (ULT) freezer, the jurisdiction/site must remove vaccine trays from the thermal shipping container before moving them to the freezer. The jurisdiction/site must then monitor the temperature inside the ULT freezer using standard protocol to ensure temperature excursions are identified quickly. Once the vaccine is removed from the thermal shipping container and put in the ULT freezer, the temperature monitoring device accompanying the vaccine can no longer be used; a digital data logger (DDL), or other appropriate monitoring method, will be needed.

A jurisdiction/site may also use the thermal shipping container for temporary storage of the vaccine. Instructions will be provided for monitoring vaccine temperatures in the thermal shipping container using the device that is available on the shipper (details will be forthcoming). In addition, storage and handling instructions for vaccine stored in the thermal shipper will be made available by the manufacturer and in CDC's storage and handling tool kit. Please also see Vaccine A information in the CDC Playbook.

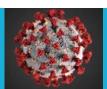
Operational Norms:

Jurisdictions should operate under the following assumptions and account for the following variables:

- Vaccine will be authorized by FDA (EUA).
- ACIP will make recommendations for vaccine use, including populations for phased allocation of initial doses.



- Vaccine is expected to be recommended in a phased approach by ACIP until supplies allow for broader administration.
- Jurisdiction and federal agency plans will need to be updated regularly as additional information becomes available and implemented in a timely manner.



Planning Appendix: The following materials are being provided to inform planning activities.

Chart 1: Vaccine A storage and handling guide

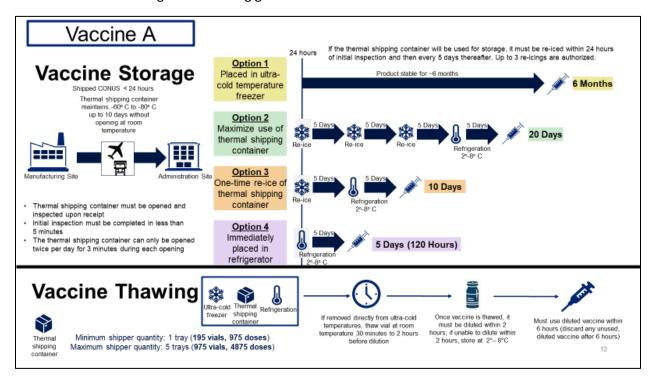
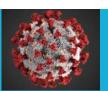


Chart 2: Vaccine A vaccination provider site archetypes for shipment timing and site planning

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

Chart 3: Vaccine B storage and handling guide

