

Lesson 4

Guidance on Storage & Handling

Note: Formalized training will be released after vaccine product approval to provide vaccine-specific storage and handling, vaccine administration, and operational guidance.

Note: CDC is updating “*You Call the Shots*” (web-based module), *Epidemiology and Prevention of Vaccine-Preventable Diseases*, “*Vaccine Storage and Handling Toolkit*” and “*Keys to Storing and Handling Your Vaccine Supply*” video.

All vaccine inventory must be managed in accordance with storage and handling requirements specific to each vaccine. 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.

CDC is developing tools to help providers store, manage, and handle the different vaccine products once they are approved, including guidelines for storage equipment, temperature monitoring, use of thermal shipping containers as temporary storage for ultra-cold vaccine products, vaccine transport, etc.

Vaccine storage and handling procedures will be finalized by manufacturers once vaccine products are approved. Enrolled providers will be notified as materials are made available.

Cold Chain Storage

It is expected that cold chain storage and handling requirements for COVID-19 vaccine products will vary in temperature and include **refrigerated** (2°C to 8°C), **frozen** (-15°C to -25°C), and **ultra-cold** (-60°C to -80°C) either in freezers or within the dry ice thermal shipper in which product was received. Ongoing stability testing may impact these requirements.

Note: These temperatures are based on preliminary information provided by vaccine manufacturers. Updated information will be provided once vaccines are approved.

For a reliable cold chain, three elements must be in place:

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

The cold chain begins at the COVID-19 vaccine manufacturing plant, includes delivery to and storage at the COVID-19 vaccination provider site, and ends with vaccine administration. Local health departments and vaccination providers are responsible for maintaining vaccine quality from the time a shipment arrives at a vaccination provider site until the dose is administered.

Storage & Handling (continued)

To minimize opportunities for breaks in the cold chain, most COVID-19 vaccines will ship from CDC's centralized distributor directly to the location where the vaccines will be stored and administered. Certain COVID-19 vaccine products, such as those with ultra-cold temperature requirements, will ship directly from the manufacturer to the vaccination provider site.

For guidance on vaccine transfers and transport, please refer to the vaccine management lesson.

Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations

Satellite, temporary, and off-site clinics in collaboration with community or mobile vaccinators may assist jurisdictions in providing equitable access for COVID-19 vaccination. However, these situations require additional oversight and enhanced storage and handling practices.

The quantity of COVID-19 vaccines transported to a satellite, temporary, or off-site COVID-19 vaccination clinic should be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and transport vaccines appropriately. This is essential to minimizing the potential for vaccine wastage and spoilage.

COVID-19 vaccines may be transported—not shipped—to a satellite, temporary, or off-site COVID-19 vaccination clinic setting using vaccine transportation procedures outlined in the upcoming COVID-19 addendum to CDC's *Vaccine Storage and Handling Toolkit*. The procedures will include transporting vaccines to and from the provider site at appropriate temperatures, using appropriate equipment, as well as monitoring and documenting temperatures.

- ✓ Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.
- ✓ Temperature data must be reviewed and documented according to guidance in the upcoming COVID-19 addendum to CDC's *Vaccine Storage and Handling Toolkit*.
- ✓ At the end of the clinic day, temperature data must be assessed prior to returning vaccines to fixed storage units to prevent administration of vaccines that may have been compromised.
- ✓ As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions at any time, the temperature excursion must be documented and reported according to federal guidance and following the state's immunization program procedures (to be developed once vaccine products are approved). Vaccines 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.

CDC Resources:

- [Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](#)
- [Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist](#)