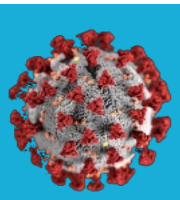
Commonwealth of Virginia
COVID-19 Accountability
Transport, Redistribution, Transfer & Waste



Introduction

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.

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 to -25°C) to ultra-cold (-60°C to -80°C in the freezer or within the dry ice shipping container in which product was received). Ongoing stability testing may impact these requirements.

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

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

VDH 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.

To minimize opportunities for breaks in the cold chain, most COVID-19 vaccines will be delivered from CDC's centralized distributor directly to the location where the vaccine will be stored and administered, although some vaccines may be delivered to secondary depots for redistribution. Certain COVID-19 vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site. If redistributing vaccines, providers must adhere to all cold chain requirements.

For more information, refer to the CDC Vaccine Storage and Handling Toolkit.

Transport vs Redistribution/Transfer

Transport refers to moving, or repositioning vaccine to a temporary vaccination site while maintaining the cold chain, for example, a vaccine clinic or event, after which the vaccine is returned back to its originating permanent storage location. Ownership does not change during transport, so no additional documentation is necessary.

Redistribution refers to planned or routine packing of vaccines by personnel who are familiar with qualified pack-out materials and temperature monitors, for shipment by a third-party vendor or transfer to a satellite vaccination site for permanent storage while maintaining the cold chain. Ownership of the vaccine changes as a result of redistribution, so documentation is required for vaccine accountability purposes. Redistribution is sometimes referred to as the hub-and-spoke model.

Transfer differs from redistribution in that it is unplanned. Transfers might be necessary due to excess supply, or imminent expiration. When a vaccine is transferred, ownership of the vaccine changes and documentation is required for vaccine accountability purposes.

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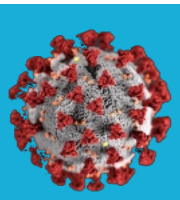

Transport - Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations

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

- The quantity of COVID-19 vaccine 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 the vaccine appropriately.
- 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 CDC Vaccine Storage and Handling Toolkit.
- 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 CDC Vaccine Storage and Handling Toolkit.
- At the end of the clinic day, temperature data must be assessed prior to returning vaccine to fixed storage units to prevent administration of vaccines that may have been compromised.

Redistribution (Redistribution Agreement and Plan Required)

Planned redistribution of vaccines is allowed, however, with the challenge of meeting cold chain requirements for frozen or ultra-cold vaccines, VDH will be judicious in its use of redistribution and limit any redistribution to refrigerated vaccines only.

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 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, vaccines 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 the VDH Division of Immunization, 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 for the sending facility/organization and have a fully completed and signed CDC COVID-19 Vaccination Provider Profile form for each receiving location.

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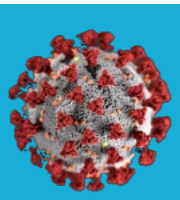

To redistribute COVID-19 vaccine, constituent products, and ancillary supplies to secondary sites, the organization agrees to:

1) *Sign and comply with all conditions as outlined in the CDC COVID-19 Vaccination Program Provider Agreement*
2) *Ensure secondary locations receiving redistributed COVID-19 vaccine, constituent products, or ancillary supplies also sign and comply with all conditions in the CDC COVID-19 Vaccination Program Provider Agreement*
3) *Comply with vaccine manufacturer instructions on cold chain management and CDC guidance in the CDC Vaccine Storage and Handling Toolkit*
4) *Document and make available any records of COVID-19 vaccine redistribution to secondary sites to jurisdiction's immunization program as requested, including dates and times of redistribution, sending and receiving locations, lot numbers, expiration dates, and numbers of doses*

Organizations planning for redistribution of COVID-19 vaccine must carefully assess the associated risks and costs (e.g., vaccine loss due to temperature excursions, purchase of vaccine-specific portable refrigerators and/or containers) before planning this activity.

CDC 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.

Provider agreement, profile form, and redistribution agreement (if applicable) must be thoroughly and accurately completed and retained on file for a minimum of 3 years, and made available to CDC upon request. For more information, visit VDH's COVID-19 Vaccine website.

Transfer (Transfer Documentation Required)
Unplanned movement or transfer of vaccine to another COVID-19 provider is also allowed when a provider is overstocked, or needs to mitigate waste due to expiration, for example. This must be coordinated through VDH or your Local Health Department. A redistribution agreement and plan are not required for vaccine transfers. The transfer must be approved by VDH for accountability purposes.

Waste/Excursions

Report unused/expired vaccine

Please promptly report any unused/expired vaccine. This helps CDC accurately monitor the amount of vaccine in the field. Keep in mind that there are no negative consequences for reporting waste, and it will not negatively impact future allocations.

CDC recognizes that unused expired vaccines are a normal part of any vaccination program, especially one of this scope and size. Use the "COVID19 Wastage Report Form" available on the VDH Vaccine Webpage for Healthcare Providers to report wasted vaccine.

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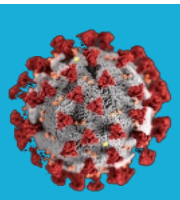

CDC is committed to helping jurisdictions and sites effectively and efficiently manage inventory and minimize the number of doses that go unused, including tracking vaccine expiration dates, and using vaccines in a timely manner. In order to do this, VDH encourages jurisdictions and providers to:

- Monitor expiration dates weekly, rotate stock as needed, and follow a "first in, first out" strategy to manage inventory.
- If nearing expiration, check posted manufacturer information for the most up to date expiration/extension information for vaccine lots.
- Based on the latest expiration information, REMOVE expired vaccine from the storage unit IMMEDIATELY. Do not give staff the opportunity to administer an expired vaccine.
    - If an expired vaccine is inadvertently administered, it is considered a vaccine administration error and requires reporting to VAERS and contacting the recipient to inform them of the error. The vaccine error may or may not require revaccination based on the manufacturers' guidance. Guidance on vaccine administration errors can be found in Appendix C of the CDC Interim Clinical Considerations for COVID-19 Vaccines.
- Vaccine disposal: dispose of the vaccine vial (with any remaining vaccine) and packaging as medical waste according to your local and state regulations. **Do NOT return vaccines in the thermal shipping container.**
- Check your vaccine stock using the CDC's Vaccine Lot Number and Expiration Date finder
    - Request access to a new COVID-19 Vaccine Lot Number report via CDC's Vaccine Code Set Management Service (VCSMS). This report includes COVID-19 vaccine lot numbers and expiration dates provided to CDC by the vaccine manufacturers. This report is updated daily and can be used to support vaccine administration, inventory management, and jurisdiction Immunization Information Systems (IIS). You must register to access the report.

Resources/References

- CDC Vaccine Storage and Handling Toolkit
- Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage
- COVID-19 vaccine product web pages and storage and handling summaries
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- CDC's Vaccine Lot Number and Expiration Date finder

Excursions

As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions (A "temperature excursion" is an event in which the COVID-19 vaccine is exposed to temperatures outside the range(s) prescribed for storage and/or transport) at any time, the temperature excursion should be documented and reported to the VDH Division of Immunization. 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. Vaccines that are non-viable according to stability data can be removed from storage and staged for recovery. COVID-19 vaccine that expires will need to be recovered. If/when a vaccination provider site has completed immunization activities with COVID-19 vaccine, appropriate storage of the vaccine must be maintained until it has expired or recovery guidance is issued stating otherwise.