Guidance for Satellite, Temporary, and Off-Site Clinics

California COVID-19 Vaccination Program

Repositioning is the transport of doses for administration at another setting when unused doses will be returned to the original facility at the end of the day. Satellite, temporary and off-site clinics are authorized to reposition COVID-19 vaccines without prior authorization because ownership is not changing hands. However, these situations require additional oversight and enhanced storage and handling practices. Use the following guidance and resources when planning.

Planning Clinics

CDC has provided the following guidance for planning clinics.

- Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations
- Considerations for Planning Curbside/Drive-Through Vaccination Clinics
- Accessibility at Drive-Through Medical Sites Fact Sheet | Checklist

Vaccine Orders

Vaccines should be shipped to the location where it will be administered to minimize potential breaks in the cold chain.

For large off-site events that can administer the minimum order: Ship vaccines to arrive at least the day before the event. Clinic must be able to store vaccines according to CDC's Vaccine Storage and Handling Toolkit.

For mobile clinics and PODs and temporary sites that lack a shipping address: Vaccines must be received at the primary location and transported to the clinic.

Vaccine Inventory Management

Never miss a vaccination opportunity because of fear of vaccine wastage! Vaccination wastage is an unavoidable aspect of large-scale vaccination programs. Do your best to follow clinical and inventory management best practices for vaccination to maximize vaccinations and minimize dose wastage where possible.

Continue to vaccinate all eligible recipients up to the end of the clinic—even if it means puncturing a vial! At the end of the day, report doses spoiled, expired or wasted and dispose of following local regulations and practice protocols.

Operational guidance when practical and feasible:

- Transport doses needed to meet the anticipated number of recipients for the clinic day/hours (e.g., 2000 ppl in 8-hour clinic = 250 ppl/hr.) and the ability of the vaccination provider to store, handle, and transport the vaccine properly; factor in average no-show rates and adjust the number of doses to transport.

- Don't remove more than 2 vials/vaccinator waiting to be pre-drawn.
- Don't draw up more than 1 vial/vaccinator at a time—even if it slows down your throughput times!
- Increase the number of runners to assist; use a flag system to indicate when a vaccinator is out of vaccine; don't try to estimate when vaccinators will run out.
- Create a standby list of patients you can call to come at the end of the day if there are leftover doses; consider patients scheduled to come in the next week or two; your local health department may have a list of standby patients to use.
- Fill no-show appointments with walk-ins or waitlist of nearby eligible residents; consider overbooking if data is available to support it.
- Towards the last couple hours of the day:
  - Only pre-draw for the number of clients in line.
  - Only remove the number of vials for clients in line at that moment.
- Leave time at the end of the day without scheduled patients so that you have time to bring any standby patients to the clinic as needed.
- Continue to vaccinate all eligible recipients up to the end of the clinic—even if it means puncturing a vial!

Transport

Follow product-specific transport guidance in CDC's Vaccine Storage and Handling Toolkit COVID-19 Addendum or EUA Fact Sheets by product (linked under "COVID-19 Vaccines Authorized for Emergency Use or FDA-Approved.")

The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours (e.g., if transport to an off-site clinic is 1 hour each way and the clinic runs for up to 6 hours). (Follow the manufacturer's guidance if it differs from this 8-hour timeframe.) The Vaccine Transport Time Tracker is available to help ensure transport time remains within limits.

Transport System Recommendations

Vaccines may be transported using a portable vaccine refrigerator with a data logger placed with the vaccines. (If a portable vaccine refrigerator is not available, use qualified containers and pack out.) Soft-sided containers specifically engineered for vaccine transport are acceptable.

Important. Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures.

	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System†	Yes	No
Manufacturer's Original Shipping Container	Yes (last resort only)	No
Food/Beverage Coolers	No	No

Qualified container & pack-out are specifically designed for use when packing vaccines for transport. They are passive containers that do not require a power source and are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time. For example, PCM refrigerated or frozen vaccine transport container.

Coolants for Transport

Phase change materials (PCMs) at 4°C to 5°C (39°F to 41°F) can also be purchased to maintain proper temperatures. Follow the manufacturer's instructions for use to reduce the risk of out-of-range temperatures during transport. Do not use frozen gel packs or coolant packs from original vaccine shipments to pack refrigerated vaccines. (Guidance to follow for Moderna vaccine.)

Data Loggers

Each transport container must be monitored with a data logger to ensure vaccines are not exposed to out-of-range temperatures that may impact vaccine viability.

Transporting Pre-Drawn Syringes

Vaccines should be drawn up only at the time of administration. General-use syringes are designed for immediate administration, not for storage. Contamination and growth of microorganisms can occur in syringes with predrawn vaccine that does not contain a preservative. In addition, vaccine components may interact with polymers in a plastic syringe over time, potentially reducing vaccine potency. Predrawing vaccines can also result in vaccine waste.

Even for off-site clinics, CDC recommends using manufacturer-filled syringes (MFSs) for large vaccination clinics. However, if transport of pre-drawn syringes is required, transport at refrigerator temperatures between 2°C and 8°C (35°F to 46°F) following guidance in USP COVID-19 Vaccine Handling Toolkit.

Transporting Diluents & Ancillary Supplies

Transport equal amounts of vaccines, diluents, and ancillary supplies (including vaccination record cards and PPE) for each receiving location.

Transport diluents with their corresponding vaccines so there are always equal amounts of vaccines and diluents for reconstitution. Follow the manufacturer's guidance for specific temperature requirements. If diluents stored at room temperature (20° C to 25° C [68° F to 77° F]) are going to be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines.

Never freeze diluents—not even during transport. Place an insulating barrier like bubble wrap between the diluents and conditioned water bottles or phase change materials.

Vaccine Transport Log

Bring two copies of the Vaccine Transport Log: (1) Record inventory and temperatures on the Vaccine Transport Log prior to departure and upon arrival. At the end of the day, (2) record remaining inventory and temperatures prior to departure and upon return to the primary location.

Preparation & Planning

Prepare transport containers following guidelines in CDC's Vaccine Storage and Handling Toolkit before removing vaccines from vaccine refrigerators or freezers.

Assemble transport supplies and set up data loggers first. Complete as much of the COVID-19 Vaccine Transport Log as you can. Once vaccines are packed, ensure the data logger is recording temperatures. Insert completed vaccine transport log into transport container before sealing.

Pack diluents and ancillary supplies including PPE separately.

Storing Vaccines at the Destination

Vaccines must be stored in storage units (e.g., refrigerators, freezers, or ultracold freezers) that maintain the manufacturer-recommended temperature range and meet guidance in CDC's Vaccine Storage & Handling Toolkit.

COVID-19 vaccines are sensitive to light. Ensure vaccines are protected from light during the clinic per the manufacturer's package insert.

Data Loggers Are Required

Vaccine temperatures must be monitored during the clinic using a digital data logger with a buffered probe (placed directly with vaccines) and a current and valid Certificate of Calibration Testing.

If Vaccines Are Stored in a Storage Unit at the Site

Review and record vaccine temperature data a minimum of 2 times during each clinic workday (preferably at the beginning and middle of an 8-hour shift) to ensure they remain at correct temperatures. (See sample COVID-19 Temperature Log.)

If Vaccines Cannot Be Stored in a Storage Unit at the Site

Additional steps must be taken to ensure vaccines are not affected by outdoor seasonal temperatures:

- keep vaccines in the portable vaccine refrigerator or qualified packout with a temperature monitoring device;
- place the data logger (with a probe in a thermal buffer) as close as possible to the vaccines;
- monitor and record temperatures hourly on the Hourly Temperature Log; and
- keep the container closed as much as possible.

Temperature Monitoring

Temperature data must be reviewed and documented according to guidance above (twice a day if stored in storage units, else hourly) and as documented in the COVID-19 Addendum to CDC's Vaccine Storage and Handling Toolkit.

At the End of the Clinic

Record temperatures at the end of the clinic day. Assess temperature data prior to returning vaccine to fixed storage units to prevent administration of vaccines that may have been compromised.

Reporting Temperature Excursions Off-Site

If vaccines are exposed to out-of-range temperatures at any time during the clinic, the affected vaccines must be labeled "Do not use" and stored at the required temperature until vaccine manufacturers make a viability determination. Report the temperature excursion at the end of the day.

Vaccine Preparation & Administration

Follow product-specific transport guidance in CDC's Vaccine Storage and Handling Toolkit COVID-19 Addendum or EUA Fact Sheets by product (linked under "COVID-19 Vaccines Authorized for Emergency Use or FDA-Approved.")

Calculate Beyond Use Dates for diluted or punctured vials and pre-drawn syringes. Always check expiration and beyond-use dates before preparation and administration.

Use pre-drawn syringes with the earliest discard time first to avoid waste. If pre-drawn syringes are used, consider the following manufacturer-released information supporting stability of vaccine in vials and in pre-drawn syringes.

See COVID-19 Vaccine Product Guide for summary chart of administration details.

Reporting Doses Administered

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and report doses administered daily.

Reporting Nonviable Doses

Manage your clinic inventory throughout the day to minimize spoiled or wasted doses. At the end of the day, report nonviable doses in myCAvax.

Disposal of Vaccine & Diluent

Dispose of expired or residual vaccine and diluent (never pool partial doses to make a full dose) in accordance with local regulations and practice protocols for disposing of regulated medical waste. **Janssen, Moderna, Novavax, and Pfizer** and vaccines do not contain hazardous components and may be disposed of in a pharmaceutical waste container, or a comingled pharmaceutical/Sharps waste container.

Resources

- Vaccine Storage and Handling Toolkit
- Vaccine Transport Log

- Hourly Temperature Log
- Reporting Temperature Excursion Worksheet
- Infection Control Guidance for Healthcare Professionals about Coronavirus