COVID-19 Vaccine Provider Training

2022
Part 2: Storage
Modules

- Maintaining the Vaccine Storage Cold Chain
- Temperature Monitoring Devices (TMDs) and Digital Data Loggers (DDLs)
- On-Site Vaccine Storage
- Off-Site Vaccine Storage
- Temperature Excursions
Maintaining the Vaccine Storage Cold Chain
Maintaining the Vaccine Storage Cold Chain

• Vaccines **must** be stored at temperatures according to the manufacturers’ instructions.

• Once vaccines arrive at your facility, it is the responsibility of your office to maintain the cold chain until a patient receives the vaccine.

• When vaccines are not stored at the correct temperature, it could reduce the effectiveness of the vaccine and may not protect patients from COVID-19 infection.
Cold Chain
TMDs and DDLs
DDLs or TMDs are Required

- All providers must use an approved DDL or TMD in all on-site and off-site vaccine storage units.
- Providers must maintain current calibration for all DDLs or TMDs.
  - Certificates of calibration must be kept on file and documented in NMSIIS.
TMDs

• Certain types of TMDs have significant limitations and should **not** be used to measure temperature in a storage unit.

• CDC does **NOT** recommend the following TMDs:
  - Alcohol or mercury thermometers, even if placed in a fluid-filled, biosafe, liquid vial
  - Bimetal stem TMDs
  - TMDs used for food
  - Chart recorders
  - Infrared TMDs
  - TMDs that do not have a current and valid Certificate of Calibration Testing

• DDLs are recommended for best practices.
DDLs continuously record the temperature in a storage unit.

Data from the logger can be downloaded onto the computer and analyzed to determine if the temperatures have remained in required ranges.

If temperatures went out of range (i.e., temperature excursions), this data will help the manufacturer determine if the vaccine is still okay to use.
The 3 Modes of a VFC-400 DDL

1. Ready Mode:
The DDL has no data logged but is ready to start.
The 3 Modes of a VFC-400 DDL

2. Recording Mode:
The DDL is actively recording temperatures. When the DDL is in the storage unit you always want it in recording mode.
The 3 Modes of a VFC-400 DDL

3. Stopped Mode:
The DDL was recording but has now been stopped.

It also means there is data on the DDL.

Once in stopped mode, the data is uploaded to the computer.

The DDL is then re-configured for continued use.
Reading Temperatures

A check mark, in the upper left corner, means that the temperature has been within normal range.

- In addition, if the audible alarm is not beeping, this indicates that the temperature has been within normal range.
Reading Temperatures

An X, in the upper left corner means the temperature has been **out of range**.

- The audible alarm should be sounding as well.

Press the “Review” button to view the minimum and maximum temperatures.
DDL Downloads

Dock your DDL onto your docking station to upload the temperature data to your computer.

Three files should be saved on your computer:

1. Ltd. or Log Tag file
2. PDF file
3. CSV file (this file type can be uploaded into NMSIIS)

Note: Instructions for downloading data and uploading is in NMSIIS under the “Reports” tab.
Battery Replacement

The end of battery life is indicated by a low battery symbol.

- Each DDL contains an extra Lithium battery.

- Battery access sits behind the square white label on the back of the DDL.

- If you have replaced your battery, place your DDL back onto the docking station.
  - Prior to placing it back on your storage unit, your DDL must be reset.
Re-Calibrating DDLs

• DDLs must be re-calibrated before the expiration date.

• All DDLs must always be replaced as a complete kit (not including docking stations).

• The dedicated cord for a DDL is to never be used with any other DDL.
  • The cords are only calibrated to each specific DDL.
On-Site Vaccine Storage
On-site Vaccine Storage Units

- Stand-alone refrigerators and freezers are preferred for vaccine storage compared to combination refrigerator/freezer units.
- Frozen vaccine must be stored in a stand-alone freezer.
- If using a combination unit, *only* the refrigerator section may be used, and only as long as appropriate storage temperature can be maintained.
On-site Vaccine Storage Units

• Dormitory style units (which have a freezer within the body of the refrigerator) are never allowed for vaccine storage.

• Make sure the storage unit has enough space to store the largest inventory you might have without crowding.

• New vaccine storage units must be monitored and approved by Immunization Program staff prior to placing vaccine in the unit.
On-Site Refrigerator and Freezer Set-up

• Place DDL probe in the center of the storage unit.

• Ensure temperatures meet storage requirements:
  • Refrigerator
    • Between 36° and 46°F (2° and 8°C)
  • Freezer
    • Between -58° and 5°F (-50° and -15°C)
  • Ultra-Cold Freezer
    • Between -130° and -76°F (-90° and -60°C)
On-Site Refrigerator and Freezer Set-up

- Place water bottles in the door and floor of the unit to ensure temperature stability (*if possible*).
- Store vaccine in their original boxes and protect from light.
  - If original boxes are not available or if units have glass-fronted doors, use opaque bags or other opaque containers that will shield vaccines from light.
On-Site Refrigerator and Freezer Set-up

• Organize vaccine by product, funding type (e.g., blended, adult, pediatric or private purchase) and expiration date, placing shorter-dated vials in front.

• Do NOT store food or place vaccine in the door, drawers, or floor of the unit.
On-Site Refrigerator and Freezer Set-up

Storage unit temperatures may need to be adjusted over time.

- Temperature adjustments should be:
  - Made by the primary or back-up coordinator, based on information from the TMD and temperature monitoring log.
  - Done at a time that is not busy and/or when the unit door is not being frequently opened and closed.
On-Site Refrigerator and Freezer Set-up

- Post warning signs to warn staff **not** to adjust storage unit temperatures.

![Warning Signs](image_url)
Vaccine Power Supply

• Do **NOT** use:
  • Extension cords.
  • Power strips or surge protectors that are controlled by an on/off switch.
  • Electric outlets controlled by a light switch.
  • Outlets with built-in circuit switches.
Vaccine Power Supply

- Post “DO NOT UNPLUG” signs on the outlet and warning stickers on the breaker box.
On-Site Temperature Monitoring Responsibilities

• Record the minimum and maximum temperatures each morning and actual readings twice per workday (at the start and end of the day).

• Identify acceptable and unacceptable temperature readings (temperature excursions) on the DDL.
On-Site Temperature Monitoring Responsibilities

• Providers are required to upload temperature readings into NMSIIS **weekly**.
  - If you are unable to upload into NMSIIS, temperature logs (both written and digital) must be e-mailed to COVIDdata.compliant@state.nm.us on a **weekly basis**.
Off-Site Vaccine Storage
Off-Site/Transport Vaccine Storage Units

- Recommended off-site and transport vaccine storage units include:
  - Portable vaccine refrigerators, freezers, or ultra-cold freezers.
  - Qualified containers and pack-outs.
- These units **must** maintain appropriate temperatures for the type of vaccine and intended storage condition.
- Do **NOT** use the manufacturers’ original *shipping container* or food/beverage coolers for transport or for off-site clinics.
Vaccine Transport Preparation

1. Ensure cooler inserts have been stored at proper temperatures and length of time, and properly inserted into the transport containers.

2. For DDL(s) that will be used in the transport container(s), store them in the on-site refrigerator before inserting them into the unit for transport.
   • The probe should remain in the transport container when not in use.

3. Label the DDL(s) that you plan to use for transport (e.g., Transport 1).
Vaccine Transport Preparation

4. Do not place vaccine in the transport container(s) until reaching and maintaining a correct temperature.

5. Ensure the DDL:
   • Probe is directly placed with the vaccine
   • Always remains on
   • Always remains with the vaccine

Note: A back-up cooler and DDL is highly recommended in case the primary transport container’s temperature goes out of range.
Off-Site Vaccine Preparation

1. Take only the amount of vaccine needed for the workday.
2. Document the brand, lot numbers, and expiration dates of each vaccine.
3. Label vaccine type (i.e., Adult or Pediatric).
4. Keep vaccine in original boxes if possible.
During Transport and While Off-site

1. Transport container(s) should be placed in the passenger compartment of the vehicle.
   - Do not place transport container(s) in the bed of the truck or trunk of the vehicle.
   - Hatch back trunks of vehicles can be used.

2. Keep DDL(s) turned on and in the transport container(s) with the vaccine.

3. Protect the vaccine from light.

4. Keep the lid closed and ensure temperatures are stable.

5. Keep the transport container(s) packed per manufacturer instructions.
6. Record temperatures hourly on a NM Outreach/Offsite Temperature Log.

7. Address temperature excursions immediately.

8. Remove only the amount of vaccine that is needed for preparation.
Post Event

1. Ensure the vaccine temperatures in the transport container(s) are within the appropriate range.

2. Place the remaining vaccine back in the on-site storage unit and label the vaccine with the date and time last used.

3. Place the transport container inserts back into the on-site storage unit.
Post Event

4. Download the data from the DDL and save the file to your computer.

5. Review the DDL report to ensure vaccines were at acceptable temperatures throughout the event.
   • If a temperature excursion occurred, follow the COVID Troubleshooting Record instructions, to be described later.
Post Event

6. Upload the temperature report to NMSIIS.

7. Document how many doses were administered and wasted for each lot number in NMSIIS.
Temperature Excursions
Temperature Excursions

• An out-of-range temperature incident, also called a temperature excursion, is when a storage unit experiences any temperature outside the recommended range for the vaccine.

• If a temperature excursion occurs, immediately contact the Help Desk at 833-882-6454 and COVIDdata.compliant@state.nm.us for guidance.
  • Properly store and isolate COVID vaccine that may have been affected by the excursion and mark “Do Not Use.”
  • Fill out the COVID Troubleshooting Record (TSR) form.
    • Completion of all steps listed on the TSR form are required.
COVID-19 Troubleshooting Record

Follow all steps listed under "What To Do" on previous page to ensure the safety of all vaccines. Incomplete or hand-written Troubleshooting Records will be rejected. DO NOT administer, discard, or return any vaccines until instructed to do so by the NM Immunization Program.

Date TSR Completed: 

Provider Information
Site Name: 
Site PIN#: 
Site prepared by: 
Email address: 

Site’s Primary COVID-19 vaccine contact name: 
Site’s Secondary COVID-19 vaccine contact name: 
Email: 
cell phone: 

Event Details (ALL ARE REQUIRED)
Date Range of event: From: 
To: 
Time span of event: From: 
To: 
Description and cause: provide a detailed description of the incident, including the cause (door left ajar, power outage, etc.): 

<table>
<thead>
<tr>
<th>Refrigerator</th>
<th>Freezer</th>
<th>Ultra-low Transport/storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event involved refrigerator</td>
<td>Event involved freezer</td>
<td>Event involved ultra-low transport</td>
</tr>
<tr>
<td>Min. Temp:</td>
<td>+Min. Temp:</td>
<td>+Min. Temp:</td>
</tr>
<tr>
<td>+Max. Temp:</td>
<td>+Max. Temp:</td>
<td>+Max. Temp:</td>
</tr>
<tr>
<td>No Temperature Data recorded</td>
<td>No Temperature Data recorded</td>
<td>No Temperature Data recorded</td>
</tr>
</tbody>
</table>

*From data logger files

1. Complete the second page of the COVID-19 Troubleshooting Record
2. Obtain and attach written advice from all manufacturers
3. Locate the .pdf version of the temperature log/s from data logger/s involved in the event
4. Email this completed document, the manufacturer’s WRITTEN advice, and your temperature files to coviddata.compliant@state.nm.us

Immunization Program Staff Only:

VT tracks Return ID: 
Date Return uploaded: 
By: 

COVID-19 Troubleshooting Record

*Fizer 800-438-1985 or www.PfizerMedinfo.com

<table>
<thead>
<tr>
<th>Vaccine Name / NDC</th>
<th>Lot #</th>
<th># of Doses</th>
<th>Advice Given</th>
<th>Manufacturer's response*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rem: COVID-19 / 52247-1000-01</td>
<td></td>
<td></td>
<td>OK to Use / Do NOT Use</td>
<td></td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Moderna 866-MODERN 866-663-3762</td>
<td></td>
<td></td>
<td>OK to Use / Do NOT Use</td>
<td></td>
</tr>
</tbody>
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*DO NOT administer, discard, or return any vaccines until instructed to do so by the NM Immunization Program.
# Temperature Excursion Overview

<table>
<thead>
<tr>
<th>Take Care of the Vaccine</th>
<th>Document the Incident</th>
<th>Evaluate the Data</th>
<th>Report</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Isolate</strong> the vaccine.</td>
<td><strong>Immediately</strong> restart the DDL if temperatures are not recording.</td>
<td><strong>Dock the DDL</strong> and analyze the report.</td>
<td><strong>Follow the instructions on the TSR form.</strong></td>
</tr>
<tr>
<td><strong>Label</strong> “DO NOT USE”.</td>
<td><strong>Document:</strong></td>
<td><strong>Upload the data into NMSIIS.</strong></td>
<td><strong>Contact the manufacturer(s) for guidance.</strong></td>
</tr>
<tr>
<td>Begin stabilizing temperatures in refrigerator or freezer.</td>
<td>• Date/Time</td>
<td></td>
<td><strong>Email completed TSR form to the Immunization Program.</strong></td>
</tr>
<tr>
<td>If unable to stabilize temperatures, move vaccine to another approved COVID storage unit.</td>
<td>• Duration</td>
<td></td>
<td><strong>Wait for further instruction from the Immunization Program before using affected vaccine.</strong></td>
</tr>
<tr>
<td></td>
<td>• Minimum and maximum temperature</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Description of what happened</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Contact

- NMSIIS Help Desk (833) 882-6454

<table>
<thead>
<tr>
<th>CONTACT INFO</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:COVID.Vaccines@state.nm.us">COVID.Vaccines@state.nm.us</a></td>
<td>COVID-19 Vaccine Record requests; Provider COVID-19 Vaccine Order status; NMSIIS assistance.</td>
</tr>
<tr>
<td><a href="mailto:COVID.Therapeutics@state.nm.us">COVID.Therapeutics@state.nm.us</a></td>
<td>Provider questions regarding COVID oral therapeutics (Molnupiravir and Paxlovid); COVID PrEP (Evusheld); mAB; or Remdesivir</td>
</tr>
<tr>
<td><a href="mailto:COVIDData.compliant@state.nm.us">COVIDData.compliant@state.nm.us</a></td>
<td>COVID-19 vaccine storage and handling questions, temperature log and onboarding Vaccine Plan submissions.</td>
</tr>
<tr>
<td><a href="mailto:COVID.testing-doh@state.nm.us">COVID.testing-doh@state.nm.us</a></td>
<td>For Provider questions on testing and test supplies</td>
</tr>
</tbody>
</table>