Vaccine Storage and Handling Guide
2021

This document is an adaptation of CDC’s Vaccine Toolkit.
Complete information on vaccine storage and handling can be found at:
www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Rhode Island Department of Health Immunization Resource Manual:
www.health.ri.gov/immunization/for/providers

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Contents
Cold Chain........................................................................................................................................... 3
Vaccine Storage and Handling Guidelines ............................................................................................ 3
Vaccine Storage Requirements ............................................................................................................ 3
Vaccine Inventory Control .................................................................................................................. 5
Temperature Monitoring .................................................................................................................... 6
Temperature Reviews for Processing Orders ....................................................................................... 7
Certified Calibrated Thermometers .................................................................................................... 8
Emergency Vaccine Packing and Transport ......................................................................................... 9
Vaccine Deliveries ............................................................................................................................. 10
    Checking the Condition of the Deliveries ....................................................................................... 10
Transferring Vaccines ......................................................................................................................... 11
    Storage issue or impending storm .................................................................................................. 11
    Lending or borrowing .................................................................................................................... 11
COVID-19 Vaccine ............................................................................................................................. 12
    Pfizer ............................................................................................................................................. 12
    Moderna .......................................................................................................................................... 15
    Janssen (Johnson & Johnson) ....................................................................................................... 17
Cold Chain

The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal conditions. The cold chain relies on three main elements:

- Well-trained personnel.
- Reliable transportation and storage equipment.
- Efficient management procedures.

Vaccine Storage and Handling Guidelines

- Practices are required to have an assigned primary coordinator and a back-up coordinator to manage storage and handling responsibilities.

- All staff assigned to vaccine storage and handling responsibilities must complete the You Call the Shots Vaccine Storage and Handling training modules found at: https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp

Vaccine Storage Requirements

- Stand-alone refrigerator and freezer units are required for all vaccines.
- The vaccine storage unit must be large enough to store the year’s largest vaccine inventory (usually flu season).
- Vaccine storage units must be dedicated to vaccines only. No food, beverages, or bodily fluids for laboratory testing can be stored with vaccines.
- Dorm-style refrigerators* are not acceptable for vaccine storage.
- Avoid storing other medications and medical supplies with vaccines. If you do not have a separate refrigerator for other medicines and supplies, store these items below vaccines on a different shelf. Storing items on different shelves helps to prevent medical errors.

*A dorm style refrigerator is classified as any size refrigerator with one external door and a freezer within the refrigerator compartment. Per the Centers for Disease Control and Prevention (CDC), all vaccines stored in a dorm-style unit will be deemed non-viable and will need to be returned.
Combination/ Household Style

**DO**
- Do make sure the refrigerator door is closed!
- Do replace crisper bins with water bottles to help maintain consistent temperature.
- Do label water bottles "Do Not Drink."
- Do leave 2 to 3 inches between vaccine containers and refrigerator walls.
- Do post "Do Not Unplug" signs on refrigerator and near electrical outlet.

**DON’T**
- Don’t use dormitory-style refrigerator.
- Don’t use top shelf for vaccine storage.
- Don’t put food or beverages in refrigerator.
- Don’t put vaccines on door shelves or on floor of refrigerator.
- Don’t drink from or remove water bottles.
Temperature:
- Store refrigerated vaccines between 36°F and 46°F (optimal storage temperature is 40°F/41°F).
- Store frozen vaccines between -58°F and +5°F.

- Clearly label the designated space for each vaccine.
- ALL vaccines should be kept in original boxes and NOT loose in bins.
- Keep vaccines two to three inches away from walls and other boxes.
- Do not store vaccines in the door, at the bottom, or in drawers of refrigerators or freezers.
- Water bottles/blocks should be stored in each of the vaccine units.
- Post Do Not Unplug stickers above/near/next to electrical outlets.
- Place thermometer probe in the center of the unit.

Vaccine Inventory Control
- Conduct a vaccine inventory at least once per week and when vaccine is delivered.
- Avoid stocking excessive vaccine supplies. Limit inventory to a 60-90 day supply for monthly vaccines and two to four weeks for flu vaccines.
- Monitor expiration dates and rotate stock. Use vaccines that expire sooner first.
- If vaccines will expire before they will be used:
  - Locate another SSV-enrolled provider who is willing to accept vaccines transferred for use. Opened, multi-dose vials cannot be transferred to another practice.
  - Record transfer information in OSMOSSIS BEFORE vaccines are removed from the practice. Vaccines cannot be transferred to any practice not listed in OSMOSSIS.
  - Use vaccine transport protocols when transferring vaccines.
- Never use expired vaccine or diluent.
- Report expired or wasted vaccines via OSMOSSIS (please read instructions in OSMOSSIS to help choose correct option) immediately. Return labels will be emailed directly from McKesson – please check your junk, spam, or clutter folders if you do not see an email from McKesson in your inbox.
Temperature Monitoring

Manually check temperatures twice a day even if you are using a continuous temperature recording device.

- Check once at the opening of business and once at closing.
- Log into the CLOUD at the start of each day to assess the minimum and maximum temperatures. If using a paper log, record the min/max on the log.

If the temperature is outside of the recommended range:

1. **Do not use** vaccines in the affected unit.
2. Contact your Immunization Team Representative (ITR) immediately.
3. If needed, your ITR will email you a response worksheet. Complete and return the worksheet.
4. Your ITR will review manufacturer guidance to determine viability of the vaccines.

If vaccines are determined to be viable, a mark or sticker should be placed on each box. In the event of additional excursions, vaccines with a previous history of an excursion will need to be identified.
Temperature Reviews for Processing Orders

DECLINED Orders:
A vaccine order will be declined if all the information needed to approve the order (e.g. temperature logs) is not received within five business days of when the order is placed. The Immunization Team Representative (ITR) will contact the practice in a timely manner to get the needed information.

No Temperature Log:
If there is no temperature data (e.g. if the logger is offline) for the practice, the person reviewing the order will email the practice, cc’ing the ITR, to let the practice know that it needs to submit the temperatures. If the practice does not submit the temperatures within five business days, the order will be DECLINED. The ITR is encouraged to promptly contact the practice and ask for the temperature logs to prevent a DECLINE. Note: Faxed temperature logs will no longer be accepted starting January 2018; data logger uploads will be required.

HOLD Orders:
An order will be placed on HOLD if it is received with current temperature excursions. This is done because any changes to vaccine viability stemming from an excursion will affect inventory and ordering needs. When an order is placed on HOLD, the order status in OSMOSSIS is changed from SUBMITTED to HOLD. All data entered for the order is retained. When the person reviewing the order notices that there are temperatures out of appropriate range, the person will email the practice, cc’ing the ITR, to let the practice know of the excursion (as it appears), include the Temperature Excursion Response Worksheet link, and request that the practice submit the worksheet to the designated ITR.
Certified Calibrated Thermometers

The CDC requires that vaccine providers use continuous temperature monitoring devices (data loggers) to monitor vaccine temperatures onsite, during transport, and at mass/community clinics.

All SSV providers are eligible to receive a LASCAR state-supplied continuous temperature monitoring system from RIDOH.

- LASCAR temperature monitoring devices are cloud-based and require Wifi internet service.
- Although the LASCAR unit records temperatures on a continuous basis, storage unit checks MUST be completed twice daily.

When checking the storage unit, please note the following:

- ✓ Are unit doors securely closed?
- ✓ Has the unit been accidentally unplugged?
- ✓ Check the display reading on the LASCAR unit for alarms and Wifi connection.
- ✓ Is the glycol bottle in the center of the unit?

*Providers are responsible to have the temperature units calibrated every two years.*

Note: Practices are not required to use the state–supplied temperature monitoring device. However, any practice who purchases their own device must purchase a 24/7 continuous monitoring device that meets CDC guidelines for certified thermometers.
Emergency Vaccine Packing and Transport

- Develop and keep a current **Vaccine Storage Emergency Preparedness Plan**. The written plan must be accessible to all staff and presented to the Immunization Program Representative at each routine site assessment visit.

- The plan should include identification of a back-up site, with a generator, where the practice will store its vaccines should it experience equipment failure or a power outage.

**Emergency procedures may be necessary for:**

- Equipment failure
- Impending emergency
- Power outages

If power loss is short-term (usually two hours or less), storage temperatures can usually be maintained by water bottles in the refrigerator and by frozen coolant packs in the freezer, depending on the room temperature) during the time of outage. To help ensure safe temperatures during an outage:

- **Do not open storage unit** until power is restored.
- Continue to monitor temperatures of each unit.
- When power is restored, if temperatures are outside of recommended ranges, document duration of inappropriate temperature exposure and follow procedures for reporting any loss to the Office of Immunization.

Do not allow vaccines to remain in a non-functioning unit for an extended period. If you are unsure of how long the power interruption will last, activate your practice’s Vaccine Storage Emergency Preparedness Plan.
Vaccine Deliveries

It is important to establish routine, systematic procedures for handling vaccine deliveries. Arrange for vaccine deliveries to be made only when the vaccine coordinator or alternate coordinator is in the office. Consider holidays, vacations, staff schedules, and changes in hours of operation.

All staff members (including non-medical staff) must be aware of the importance of maintaining the vaccine cold chain, and need to immediately notify the vaccine coordinator when vaccines arrive so that the vaccines can be handled and stored properly.

Checking the Condition of the Deliveries

- Examine the shipping container and its contents for any signs of physical damage.
- Cross-check the contents with the packing slip to make sure they match.
- Check the vaccine lot numbers and expiration dates to be sure that you have not received any vaccines or diluents that have already expired or will expire within four months.
- Check that the correct amount and type of diluents have been shipped.
- Check the hot/cold temperature strips to determine if vaccines or diluents have been exposed to temperatures outside the recommended range.
- Check that the vaccines were stacked properly. There should be an insulating barrier (bubble wrap or Styrofoam pellets) between the vaccines and the refrigerated or frozen coolant packs.
- Vaccines that require diluents will arrive in the same shipping container as the diluents. For varicella-containing vaccines, the diluents should arrive in a separate compartment of the same container.
- Immediately store vaccines in the proper vaccine storage unit and do the following:
  1. Rotate vaccines. Use vaccines that will expire sooner first.
  2. Label vaccines (e.g. Pedi/State, Adult/State, or Adult/Private).
  3. Be sure there is appropriate space between boxes of vaccines for adequate airflow.
If there are any discrepancies with the packing slip or concerns about the shipment:

- Mark or label the vaccines in question. Separate from the other vaccines.
- Store the vaccines under appropriate conditions.
- **Do not use** the vaccines.
- Call the RIDOH Office of Immunization for guidance within four hours of delivery.

### Transferring Vaccines

#### Storage issue or impending storm

1. Notify the transfer site when and how much vaccine you will need to store.
2. Provide a list of all vaccine quantities, lot numbers, and expiration dates. Be sure to keep a copy for yourself.
3. When packing vaccine, follow guidelines as specified in this guide.
4. If your practice has lost power or if your unit is unstable, do not retrieve vaccines until your storage unit is operating under proper temperatures.

#### Lending or borrowing

Lending or borrowing vaccines must begin in the OSMOSSIS system by the lender.

1. Log in to OSMOSSIS using your SSV login or KIDSNET username and password.
2. Select the **TRANSFER VACCINE TO ANOTHER PRACTICE** option.
3. Enter information as required. If a practice is not listed in the dropdown box, **DO NOT** transfer vaccine to them.
4. Pack vaccines for transport using the guidelines provided.
5. Once received, the **borrower** must log in to OSMOSSIS to receive the transfer.
COVID-19 Vaccine

The COVID-19 vaccines have special storage and handling considerations. This guide will be updated as new vaccines are approved.

Pfizer

The complete CDC Pfizer COVID-19 vaccine training module can be found at https://www2.cdc.gov/vaccines/ed/covid19/pfizer/index.asp

Staff should review the manufacturer’s guidance located here https://www.cvdvaccine-us.com/

The Pfizer COVID-19 vaccine must be stored at ultra-low temperatures, between -80°C and -16°C (-112°F and -76°F). It is shipped in a thermal shipping container with dry ice pellets. Each thermal shipping container contains:

- Up to 5 trays of vaccine. Each tray contains 195 multidose vials.
- A Controlant GPS-enabled temperature monitoring device (TMD) to monitor temperatures in the container. TMD will continue to monitor temperatures on site if storing vaccine in the thermal shipping container.

Staff should review the dry ice safety information found here https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/dry-ice-safety-hcp.pdf

The Pfizer thermal shipping container must be unpacked in a specific manner:

1. Press the “Stop Shipment” button on the Controlant TMD for 5 seconds.
2. If light turns green, continue to unpack the vaccine and continue to step 3.
3. **Do not open the trays!**
   a. Inspect trays
   b. Count the number of trays
4. If storing vaccine in an ultra-low temperature (ULT) freezer, return unopened trays to storage within 5 minutes.
5. Do not open the vial trays or remove vials until ready to thaw/use the vaccine.
6. If light turns red, wait for the e-mailed status report on the vaccine. Contact the manufacturer immediately if the vaccine cannot be used.

The Pfizer COVID-19 vaccine can be stored in a ULT freezer or in the thermal shipping container.
If storing in a ULT freezer, you must use a DDL with a probe designed specifically to measure ultra-cold temperatures.

If stored in the thermal shipping container:

*Dry ice will be sent to replenish the container for the first time.*

**The thermal shipping container must be returned to Pfizer within 30 days!** After 30 days, the vaccine can be transferred to and stored in the refrigerator.

The vaccine may also be stored in the refrigerator for **up to 5 days.**
If storing in the refrigerator, you must use an approved DDL. Please see the section titled **Certified Calibrated Thermometers** for more information on appropriate DDLs.

**Thawing**

*Once a vial of the Pfizer COVID-19 vaccine is touched, it starts to thaw* and must be either thawed in the refrigerator or at room temperature.

- **Refrigerator:** Between 2°C and 8°C (36°F and 46°F)
  - ✓ 25 to 195 vials may take 2 to 3 hours to thaw in the refrigerator.
  - ✓ Fewer number of vials will take less time.
- **Room temperature:** Up to 25°C (77°F) between 30 minutes and 2 hours
  - ✓ Vials at room temperature must be mixed within 2 hours or returned to the refrigerator.
- Do NOT refreeze thawed vaccine.
Modernas

The complete CDC Moderna COVID-19 vaccine training module can be found at https://www2.cdc.gov/vaccines/ed/covid19/moderna/index.asp

The Moderna COVID-19 vaccine will arrive frozen between -25°C and -15°C (-13°F and 5°F). Each shipment contains 100 doses of vaccine. When unpacking the shipping container:

1. Examine the package for damage.
2. Open the box and remove the TagAlert monitor next to the vaccine.
3. Check the TagAlert for temperature excursions during transit.
4. Press and hold the blue “start and stop” button for 5 seconds.
5. Read the indicator status. If the:
   a. Left arrow points to a green checkmark, the vaccine is ready to use. Store the vaccine at proper temperatures immediately.
   b. Right arrow points to an X mark: The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label DO NOT USE! Call the phone number indicated in the instructions or your Rhode Island Department of Health Immunization Team Representative (ITR) immediately.

If you are storing the Moderna COVID-19 vaccine in the freezer, it must be:

- Stored between -25°C and -15°C (-13°F and 5°F)
- Stored in the original carton
- Protected from light
- Do not store with dry ice!

If storing the Moderna COVID-19 vaccine in the refrigerator, it must be:

- Stored between 2°C and 8°C (36°F and 46°F)
- Stored in the original carton or similar container.
- Protected from light.

The Moderna COVID-19 vaccine can only be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days.

You must monitor the temperature of the freezer and/or refrigerator using an approved DDL. Please see the section titled Certified Calibrated Thermometers for more information on appropriate DDLs.
Thawing

The vaccine may be thawed in the refrigerator or at room temperature.

- Refrigerator: Between 2°C and 8°C (36°F and 46°F) for 2 hours and 30 minutes
- Room temperature: Between 15°C and 25°C (59°F and 77°F) for 1 hour
- Vials that have not been punctured may be kept between 8°C and 25°C (46°F and 77°F) for up to 12 hours. Do NOT refreeze thawed vaccine.
**Janssen (Johnson & Johnson)**

The complete CDC Janssen (Johnson & Johnson) COVID-19 vaccine training module can be found at [https://www2.cdc.gov/vaccines/ed/covid19/janssen/index.asp](https://www2.cdc.gov/vaccines/ed/covid19/janssen/index.asp)

The Janssen COVID-19 vaccine will arrive refrigerated between 2°C and 8°C (36°F and 46°F). When unpacking the shipping container:

1. Examine the shipment for signs of damage.
2. Each shipment contains two temperature monitors. Open the box and remove both monitors.
   - The WarmMark monitor is located under the frozen gel packs at the top of the cooler.
   - The FreezeMark indicator is located inside the inner box, next to the vaccine.
3. Remove the instruction card for each temperature monitor immediately. Follow the guide on the back of each card to read the monitors.
4. The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:
   - Scan the QR code on the outer carton, or
   - Call 1-800-565-4008, or
   - Visit [www.vaxcheck.jnj](http://www.vaxcheck.jnj).
5. Write the expiration date on the carton.

**Refrigeration**

You must monitor the temperature of the or refrigerator using an approved DDL. Please see the section titled **Certified Calibrated Thermometers** for more information on appropriate DDLs. See next page for guidance on room temperature storage.

The Janssen COVID-19 vaccine can be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) or at room temperature between 9°C to 25°C (47°F to 77°F). **Do not freeze!**

- **Unpunctured vials** of the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) until the expiration date.
  - Keep the vials in their original package to protect from light and keep track of the expiration date (write the expiration date on the carton).
- **Punctured vials** can be kept refrigerated between 2°C and 8°C (36°F and 46°F) for up to 6 hours and at room temperature between
Room Temperature

The Janssen COVID-19 vaccine may be kept at room temperature between 9° C to 25° C (47° F to 77° F) for the following time frames:

- Punctured vials for 2 hours
- Unpunctured vials for 12 hours