



Vaccine Storage and Handling 2019

*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**

Revised February 2019

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.

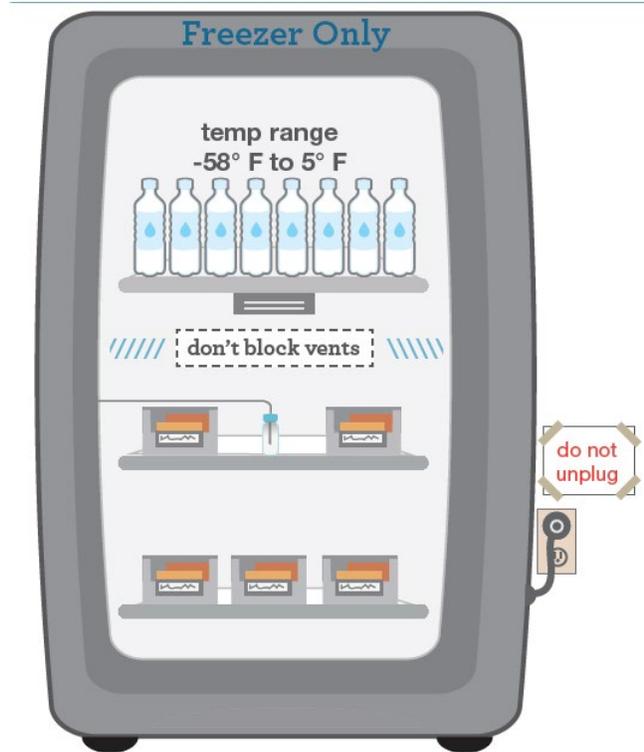
Vaccine Storage and Handling Guidelines

- 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.