Vaccine Storage and Handling 2017

Vaccine Management

This document is an adaptation of the CDC Vaccine Toolkit to be used as a Vaccine Management Plan Reference Guide. 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: http://www.health.ri.gov/immunization/for/providers/

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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 repairing vaccines and administering vaccines 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 recommended for all vaccines.
• Vaccine storage unit must be large enough to store year’s largest vaccine inventory (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.
Vaccine Storage

- 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.

Combination/household style
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 minimum of a 30-day supply. (maximum 120-day supply)
- Monitor expiration dates and rotate stock. Use vaccines that expire sooner first.
- If vaccines are four months or less from expiring and will not be used before the expiration date:
  - Locate another SSV-enrolled provider who is willing to accept vaccines transferred for use. (Note: Opened, multi-dose vials cannot be transferred to another practice).
  - Record transfer information in OSMOSSIS.
  - Use vaccine transport protocols when transferring vaccines.
- Never use expired vaccine or diluent.
- Report expired or wasted vaccines via OSMOSSIS immediately. **Return labels will be emailed directly from McKesson** – please check your junk, spam, or clutter folders.

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.
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.
- If you are using a paper log, record the time and the initials of the person checking each unit.
- Keep temperature logs for three years.

If the temperature is outside the recommended range, take **IMMEDIATE ACTION** by contacting each vaccine manufacturer:

**Merck:** 1-800-672-6372 (Gardasil, MMR, MMRV, Varicella, Pedvaxhib, pneumovax 23)

**Pfizer:** 1-800-934-5556 (Prevnar 13)

**Glaxo, Smith, Kline:** 1-888-825-5249 (Pediarix, Infanrix, Kinrix, Havrix, Engerix B, Bexsero, Rotarix, Boostrix)

**Sanofi:** 1-800-822-2463 (Menactra, Adacel)

Have the following information for manufacturers so they can make a determination about continuous use of vaccine that was out of the recommended temperature range:

- Lot number, NDC code(s), and expiration date(s) for each vaccine;
- Number of minutes the vaccine(s) were out of temperature range;
- The lowest/highest temperature of the excursion and how long the vaccine(s) were at that temperature;
- Current temperature reading

Next Steps

1. Ask each pharmaceutical manufacturer to send your practice, via email, the confirmation number and guidance for use.
2. Submit all information to your RIDOH Immunization Program Representative.
3. Use OSMOSSIS to report and return vaccines - DO NOT DISCARD vaccines unless instructed to do so by RIDOH.
4. Order replacement vaccines. Note: Before ordering additional vaccines, the practice must show unit temperatures within appropriate range for **at least 48 hours** or documentation of replacement of the unit involved in the temperature excursion.
Certified Calibrated Thermometers

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

- 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?

- In addition to a twice daily visual check, the cloud must be checked daily.
- When checking the cloud, you will see any breaches in temperature(s) that need to be addressed.

*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. 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 Disaster Plan. The written plan must be accessible to all staff and present to the Immunization Program Representative at each routine site assessment.
• The plan should include identification of a back-up site, with a generator, should the practice 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 assure 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 calling manufacturers and reporting any loss to the Office of Immunization.

Do not allow vaccines to remain in a non-functioning unit for an extended period of time. If you are unsure of how long the power interruption will last, refer to your practice’s Vaccine Storage Disaster Plan.
Vaccine Deliveries
It is important to establish routine, systematic procedures for handling vaccine shipments.

Arrange for vaccine deliveries to be made only when the vaccine coordinator or alternate coordinator is on duty. (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.
- Vaccines that require diluents will arrive in the same shipping container as the diluents.
- For varicella-containing vaccines, the diluents should be in a separate compartment of the same container.
- 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.
- Immediately store vaccines in the proper vaccine storage unit.
  1. Rotate vaccines. Use vaccines that will expire sooner first.
  2. Label vaccines (i.e. Pedi/State, Adult/State, or Adult/Private).
  3. Be sure there is appropriate space between boxes of vaccines for airflow.
If there are any discrepancies with the packing slip or concerns about the shipment:

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

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. Follow and enter information as required.
4. IMPORTANT: If a practice is not listed in the dropdown box, DO NOT transfer vaccine to them.
5. Pack vaccines for transport using the guidelines provided.
6. Once received, the borrower must log in to OSMOSSIS to receive the transfer.