Vaccine Management Guide

Oregon Vaccines for Children and Vaccine Access Program

The Ox Bow on the Deschutes River, Oregon

oregon
vaccines for children

CLINIC INFORMATION

Clinic name:	VFC PIN:	ALERT IIS number:

KEY STAFF

Responsible provider:
Primary vaccine contact:
Back-up vaccine contact:

OREGON
HEALTH
AUTHORITY

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immunization
program

ALERT
IMMUNIZATION INFORMATION SYSTEM

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Abbreviations

ACIP – Advisory Committee on Immunization Practices

ALERT IIS – ALERT Immunization Information System

CDC – U.S. Centers for Disease Control and Prevention

EUA – Emergency Use Authorization

FQHC – Federally Qualified Health Center

IIS – Immunization Information Statement

NCVIA – National Childhood Vaccine Injury Act

OHP – Oregon Health Plan

OIP – Oregon Immunization Program

RHC – Rural Health Clinic

VAERS – Vaccine Adverse Event Reporting System

VAP – Vaccine Access Program

VFC – Vaccines for Children program

VIS – Vaccine Information Statement

What to know before reading this guide

Is your clinic VFC-Only or VAP?

This Guide will discuss two types of enrolled clinics:

- **Vaccines for Children (VFC-only/Private)** sites. VFC-only (or "private") sites have a PIN beginning with the letter "P."
- **Vaccine Access Program (VAP/Public)** sites. VAP (or "public") sites have a PIN beginning with the numeral "0" (zero).

An update on COVID and Nirsevimab (Beyfortus RSV)

Both COVID and Nirsevimab (brand name "Beyfortus" – RSV antibodies for babies) are included in the Vaccines for Children Program. They must be stocked and offered to all children.

Nirsevimab (Beyfortus RSV) is not technically a vaccine. It is an antibody, but the U.S. Centers for Disease Control and Prevention (CDC) considers it an immunization.

For simplicity, this guide will use "vaccine" and "immunization" to mean the same thing. It will also include Nirsevimab under both terms unless stated otherwise.

Section 1: Overview of VFC and VAP

Clinics enrolled in the Oregon Vaccines for Children (VFC) program or Vaccine Access Program (VAP) must comply with the following requirements. More specific details on each requirement are found later in this guide.

Eligibility

- Screen patients at every immunization visit to find out if they are eligible for state-supplied vaccine or not.
- Record the vaccine eligibility code in the patient's medical record.
- Provide VFC vaccine only to children (through age 18) who are eligible.
- VAP providers who are a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) agree to:
  - Serve all underinsured children and adults who are eligible for 317-funded vaccine.
  - Vaccinate "walk-in" VFC-eligible children.[1]
- Pharmacies, urgent care, and school-located vaccine clinics agree to vaccinate all "walk-in" VFC-eligible children.[1]

Vaccine administration

- Offer all routinely recommended Advisory Committee on Immunization Practices (ACIP) vaccines for the clinic's patient population. Make non-routinely recommended ACIP vaccines available.
- Provide a current Information Statement in the patient's primary language. Do this for each vaccine before providing vaccine.
  - Most vaccines: Vaccine Information Statement (VIS)

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[1] "Walk-in" refers to any state-supplied vaccine-eligible child who asks for a vaccine, not just established patients. Providers do not have to serve patients without an appointment. If a provider's office policy is for all patients to make an appointment for vaccines, the policy applies to VFC/VAP patients as well.

- o Vaccines under Emergency Use Authorization: EUA Factsheet for Recipients and Caregivers
- o Nirsevimab (Beyfortus): Immunization Information Statement (IIS)

Billing

- Do not charge for the cost of a state-supplied vaccine administered to a VFC-eligible patient.
- Do not bill an administration fee higher than $21.96 to a patient who gets VFC or 317-funded vaccine.
- Waive administration fees if a patient who is eligible for VFC or 317-funded vaccine cannot pay.
- VAP providers may bill for state-supplied vaccine only at Oregon's cost (see Billable Vaccine Resources).

Oregon-specific standards

- Comply with standards in Oregon Administrative Rules 333-047 and 333-049:
  - o Report all immunizations to ALERT Immunization Information System (IIS). Use a valid vaccine eligibility code. Do this within 14 days of giving the vaccine.
  - o Use the ALERT IIS inventory and ordering modules to manage your vaccine stocks. Do this for both private and state-supplied vaccines.
  - o Make sure at least two clinic employees complete the online Vaccine Management Course at the Oregon Immunization Program (OIP) Training Portal every two (2) years.
- Comply with all standards for vaccine management in this guide. Standards include:
  - o A written plan for vaccine management.
  - o Use of storage equipment and thermometers that meet requirements outlined in this guide.
- Comply with state-supplied vaccine transfer and return policies.
- Comply with OIP's policy on vaccine borrowing.
- Make sure at least two clinic staff subscribe to the Oregon Immunization Partner Updates listserv. This listserv is the main way OIP lets VFC and VAP clinics know about program changes.

Temperature tracking

- Record minimum and maximum temperatures daily.
- Review digital data weekly.
- Notify OIP when state-supplied vaccine has been stored outside the appropriate temperature range. Do this by emailing vfc.help@odhsoha.oregon.gov
- Provide OIP with temperature logs when requested.

Records and reporting

- Communicate any changes to key staff in the Oregon Immunization Program within 30 days. For example, changes to:
    - The responsible provider (report immediately if the responsible provider leaves the role),
    - Primary vaccine contact, or
    - Back-up vaccine contact.
- Keep all records that relate to VFC and VAP for a minimum of three (3) years. This includes:
    - Borrowing logs,
    - Temperature logs,
    - Vaccine shipment packing lists, and
    - Vaccine storage troubleshooting records.
- Keep the current, signed Vaccine Management Guide in a place where it is easy to access. Recycle out-of-date materials – do not keep them in the clinic.
- Make sure all informational documents are up-to-date. Recycle out-of-date versions.
- Keep records that comply with the National Childhood Vaccine Injury Act (NCVIA).
- Recertify with the program each year. This includes reviewing and updating the VFC or VAP Provider Agreement and Profile.
- Make sure the primary and back-up vaccine coordinators complete the "Annual Vaccine Provider Overview Training" training module every year. This module is in the online OIP Training Portal.
- Take part in VFC/VAP program compliance visits. This includes unannounced storage and handling site visits.

Requirements apply to both state-supplied and privately purchased vaccine.

Section 2: Employee training plan

Note: Staff will get certificates for VFC/VAP-related trainings. Clinics must keep the most recent certificates on hand.

VFC training requirements			
Training	**Who should take it**	**How often**	**Website**
Review Vaccine Management Guide	All staff handling vaccine	Every year	n/a
Annual Vaccine Provider Overview Training	Primary and back-up vaccine coordinator	Every year	http://bit.ly/ ORVFCtraining
Vaccine management course	Primary and back-up vaccine coordinator (other immunizing staff recommended)	Every two years	
ALERT IIS standard user trainings	All staff accessing ALERT IIS	Once	http://bit.ly/ EnrollALERT
ALERT IIS super user	At least one person per clinic	Once	
ALERT IIS vaccine inventory	Anyone helping with inventory	Once	http://bit.ly/ ALERTInventory
ALERT IIS vaccine borrowing	Anyone helping with inventory	Once	
ALERT IIS reports (accountability, ad hoc, assessment, reminder/ recall, data monitoring, etc.)	Staff involved in quality assurance and improvement	When needed	http://bit.ly/ ReportsTraining
Clinic-specific training			
Training	**Who should take it**	**How often**	**Website**

VFC/VAP task list

VFC/VAP clinic staff must make sure that vaccine is appropriately stored and managed at all times.

Daily	Take minimum and maximum temperatures at the start of every clinic day.
	Document all immunizations.
Weekly	Download and review data from digital data loggers.
	Rotate vaccine stock.
Monthly	Do a vaccine inventory count.
	Adjust ALERT IIS inventory to match physical inventory.
	Troubleshoot any data quality issues you find due to inventory count.
	Run an Ad Hoc Report to review doses administered.
Every year	Complete provider recertification (January).
	Flu, RSV, and COVID vaccine management: • Prebook flu vaccine (January) and COVID vaccine and nirsevimab/Beyfortus RSV antibody (when notified via listserv) for upcoming season. • Return expired vaccine within six months of expiry.
	Review/update Vaccine Management Guide. Sign and date.
	Primary and back-up coordinators must take the Annual Vaccine Provider Overview Training.
Every other year	Take Vaccine Management Course Trainings (at least two staff).
	Participate in site visit and complete follow-up.
	Calibrate digital data loggers, including back-up data logger.
Every 3 years	Purge temperature log and borrowing log records older than 3 years.
As needed	Place vaccine orders (after you submit the reconciled inventory count).
	Document borrowed doses and pay them back within 90 days.
	Add private stock into ALERT IIS inventory upon receipt.
	Complete vaccine transfer documentation in ALERT IIS.
	Update Vaccine Information Statements (VIS), Immunization Information Statements (IIS), and Emergency Use Authorization Fact Sheets (EUAs).
	Submit temperature logs to OIP (when requested).
	Respond to out-of-range temperatures, contact OIP, and document in your clinic's vaccine storage troubleshooting record.
	Update clinic shipping hours in ALERT IIS.
	Report changes of key staff to OIP.
	Manage short-dated vaccine.

Section 3: Vaccine eligibility, billing, administration, and documentation

Vaccine eligibility coding

Providers must understand:

- What makes someone eligible,
- How to bill, and
- How to document.

Staff must:

- Screen all patients for VFC eligibility at every visit,
    - (Also screen for 317 eligibility at VAP sites)
- Record the eligibility category in the patient medical record, and
- Record every vaccine given in ALERT IIS.

Your clinic will use either the VFC-only/Private clinic coding chart or the VAP/Public clinic coding chart.

VFC-only/Private clinic PINs begin with a "P".

VFC-only/Private clinic coding chart			
Age	Definition	Eligibility codes	Vaccine stock
0 through 18	Oregon Health Plan (OHP) or Medicaid	M	VFC
	No insurance	N	VFC
	American Indian or Alaska Native	A	VFC
	Underinsured	F (FQHC or RHC only)	VFC
All ages	Privately insured children and all adults	B	Private
	OIP special projects (rarely used)	S	Special project

VAP/Public clinic PINs begin with a "0" (zero).

VAP/Public clinic coding chart			
Age	Definition	Eligibility codes	Vaccine stock
0 through 18	OHP or Medicaid	M	State
	No insurance	N	State
	American Indian or Alaska Native	A	State
	Underinsured	F (FQHC or RHC only)	State
19 +	Other state-supplied See 317 chart for eligibility requirements	O	State
All ages	Billable Privately insured children or adults with OHP or other insurance (No flu, MMRV, Varicella or Pfizer COVID)	B	State
	Locally owned (privately purchased vaccine, including flu, MMRV, Varicella, and Pfizer COVID for privately insured children and all adults)	L	Private
	OIP special projects (rarely used)	S	Special project

Billing

Billing for vaccine and administration fees			
Vaccine	Can you charge for the vaccine?	Administration fee	Waive fee if patient unable to pay
VFC vaccine	No	$21.96 per injection	Required
Privately purchased vaccine	Yes	Clinic-designated admin fee	Optional
Special projects	No	$21.96 per injection	Required
Billable vaccine (VAP clinics only)	Yes — OIP price	Clinic-designated admin fee	Optional
317 vaccine (VAP clinics only)	No	$21.96 per injection	Required

Notes on administration fees

- You **cannot** refuse to vaccinate an eligible child because of unpaid vaccine administration fees.
- Vaccine administration fees must be waived if the patient or family indicate they cannot pay.
- Unpaid administration fees may **not** be sent to collections.
- You **can** still bill Medicaid for a vaccine administration fee for a Medicaid-eligible child who gets state-supplied vaccines.
- If you bill after the date of service for a vaccine administration fee:
  - You can only send a single bill to patients who pay out-of-pocket (patients without insurance and not Medicaid-eligible).
  - The bill must be sent within 90 days of vaccine administration.

Billable vaccine for Vaccine Access Program (VAP) providers

VAP allows you to use state-supplied vaccine for privately insured children and insured adults.

OIP will bill you every three months for OIP-supplied vaccine given to "Billable" patients. Billable patients are:

- Privately-insured children and adults,
- Medicaid-covered adults, and
- Medicare-covered adults.

You will be charged according to OIP's current published price list.

Requirements

- OIP will bill providers every three months for doses of state-supplied vaccine administered to patients coded as B-Billable in ALERT IIS.
- OIP will bill the published price in effect at the time the vaccine dose is administered.
- Providers may not charge or bill more for the vaccine than the published price.
- Payment is due 30 days after the invoice date.
- Make sure billing claims match the pricing listed in the current OIP-published price list.

Important: be sure to code correctly. Eligibility coding in ALERT IIS keeps track of the vaccines administered to Billable patients. This is how OIP knows what to bill you for.

VFC-eligible children

- You will **not** be billed for **any** vaccines administered to VFC-eligible children.
- You will also not be billed for qualifying vaccines under the 317 program for uninsured adults.
- You must not charge patients for the cost of these vaccines.
- Make sure to code eligibility correctly.

Flu, MMRV, Varicella, & Pfizer COVID

Oregon does not provide flu, MMRV, Varicella, or Pfizer COVID as Billable vaccine for VAP children or adults. You must privately purchase these vaccines if you administer them to patients who are not eligible for VFC.

Documenting vaccine administration

All vaccine administration records must follow the National Childhood Vaccine Injury Act. This means they must have the following data:

- Address of clinic where vaccine was administered.
- Name, manufacturer, *and* lot number of vaccine administered.
- Date of administration.
- Name and title of the person who administered the vaccine.
- VIS publication date *and* date VIS was provided to patient.

Documenting adverse events

You must report all clinically significant adverse events that occur after administration of vaccines. Report them to the Vaccine Adverse Event Reporting System (VAERS). You must do so even if you are not sure whether the vaccine caused the adverse event. VAERS accepts all reports. This includes reports of vaccination errors.
There are two ways to file a VAERS report:

Online — https://vaers.hhs.gov/esub/index.jsp
When you use the online form, you must complete the report in a single session. It cannot be saved. This is the fastest method if you are able to complete it in one session.

PDF — https://vaers.hhs.gov/uploadFile/index.jsp
You can download and complete a PDF offline. Return to this webpage once you complete the form. Upload the form to finish the process. Use a computer where you can securely save documents that contain protected health information.

Before starting your VAERS report, make sure you have the following information:

- Patient information (age, date of birth, sex).
- Vaccine information (brand name, dose number, lot number).

- Date, time, and location administered.
- Date and time when adverse event started.
- Symptoms and outcome of the adverse event.
- Medical tests and laboratory results (if applicable).
- Physician's contact information (if applicable).

Adverse events involving just nirsevimab (RSV antibody / Beyfortus brand) should be reported to Medwatch rather than VAERS. This is because it is an immunization but not technically a vaccine. Adverse events involving nirsevimab **and** a true vaccine may be reported to VAERS alone.

Section 4: Inventory management

Managing your inventory

Clinics must keep enough inventory on hand for patients who are eligible <u>and</u> who are not eligible for state-supplied vaccine. Clinics should keep six weeks of vaccine supply. Plan orders in advance so you have enough vaccine to serve your patients but avoid unnecessary waste.

Clinics are required to:

1. Enter state-supplied and private vaccine stock into ALERT IIS inventory before administering doses.
2. Report all doses to ALERT IIS with an eligibility code and within 14 days of administration.
3. Count vaccine in the refrigerator and freezer. Compare the numbers to your ALERT IIS inventory monthly and adjust the numbers in ALERT IIS as needed. You must submit a reconciled inventory count in ALERT IIS within 14 days of placing an order.
4. Rotate vaccine stock to make sure that you use the vaccines that will expire first.

Receiving vaccine

Providers must be on site to receive state-supplied vaccine:

- At least one day a week,
- For at least four consecutive hours, and
- On a day other than Monday.

Fewer available hours will result in shipments being delayed until the correct days and hours are entered in ALERT IIS.

Deliveries will only be attempted during the hours and days you designate in ALERT IIS. Do not reject state-supplied vaccine shipments. Accept delivery and contact the Immunization Provider Help Desk as soon as possible if there is an issue.

1. Open your vaccine shipment immediately. Contact the Immunization Provider Help Desk if the shipment is received after the "receive by" date.
2. Check the temperature indicators (if included) in the shipping container. Make sure the vaccine stayed at the recommended temperature range during shipment. Contact the Immunization Provider Help Desk if the temperature indicators show exposure to out-of-range temperatures.
3. Be sure your delivery matches the packing slip and the ALERT IIS order transfer. Check:
   o Vaccine brands,
   o Expiration dates,
   o Lot numbers, and
   o Quantities.

   If your order is fulfilled in more than one shipment, the packing list will state what is in each box.
4. Place the vaccine into your refrigerator or freezer. Rotate vaccine stock to make sure the first vaccines you use are those that will expire first.
5. Accept the vaccine order transfer in ALERT IIS to add the order to your inventory.

Reconciling your inventory

Staff should:
- Count physical inventory at least monthly,
- Compare physical inventory to ALERT IIS inventory, and
- Adjust inventory in ALERT IIS to match.

Staff must reconcile inventory:
- No less than two weeks before placing an order, or
- More often, as part of data quality work.

To reconcile inventory:
1. Print inventory count list from ALERT IIS. Make sure all transfers have been accepted.
2. Compare quantity shown in ALERT IIS with physical inventory by lot number. Make a note of difference.

3. Troubleshoot inventory issues. Identify preventable errors, such as wrong lot numbers or inventory not entered in ALERT IIS.
   o Ad hoc report for inventory management training: http://bit.ly/ReportsTraining
4. Make any corrections you need to your ALERT IIS inventory.
   o Inventory adjustment tip sheet: http://bit.ly/adjustinventory
5. Submit your reconciled inventory count.
6. Develop a plan for avoiding preventable errors, and train staff.

Returning spoiled and expired vaccine

If you have spoiled or expired state-supplied vaccine, do not throw it away. You must return it to McKesson Distribution within six months of spoilage or expiration. Do this even if it shipped directly from the manufacturer. You may be required to replace vaccine spoiled or expired due to negligence.

To return state-supplied vaccine

Non-viable vaccine is any vaccine that cannot be administered to patients. This includes:

- **Expired vaccine**: vaccine that is past the expiration date. Once the expiration date has passed, you will receive a return label in the mail, usually within two weeks.
- **Spoiled vaccine**: vaccine that was stored incorrectly, is past its beyond use date (BUD) or was nonviable upon arrival. Once you adjust the quantity of the vaccine in ALERT IIS using the appropriate reason, you will receive a return label in the mail, usually within two weeks.
- **Wasted vaccine**: vaccine that has been opened or damaged but cannot be administered. For this, you will not receive a return label.

Your inventory in ALERT IIS will report all non-viable vaccine to OIP.

Do not return any punctured vials or uncapped syringes. Instead, dispose of any open and unusable vaccine in your sharps container, or in the way that is approved by your clinic.

Contact your private vaccine supplier for guidance on return or disposal of spoiled or expired private vaccine.

To correct your inventory – AFTER expiration – in ALERT IIS, create a new transfer of the expired vaccine to remove it from inventory:

- Under the **Inventory** menu, select **Manage Transfers**.
- Then click **New Transfer**.
- Select OIP Expired Vaccine Returns as the Receiving Organization for the transfer.
- To remove wasted or spoiled vaccine from ALERT IIS inventory, select **Modify Quantity** on the **Show Inventory** screen.

Tip Sheets:
How to Manually Adjust Inventory
Interpreting the Options in Modify Quantity of Vaccine Inventory

Short-dated vaccine

It is the clinic's responsibility to use vaccine before it expires. You should plan for short-dated vaccine at least three months before it expires. There are two options to use up the vaccine:

- **Option 1**: Run a Reminder/Recall report either in ALERT IIS or in an electronic health record for patients who are due or past due for the vaccine. ALERT IIS Reminder/Recall tip sheet: http://bit.ly/ReminderRecallRpt.
- **Option 2**: Transfer vaccine to another VFC clinic that can use the vaccine. Use the Oregon VFC Provider Map to find a nearby clinic: http://bit.ly/VFCProviderMap.

Staff at the Help Desk can help with either option.

Borrowing vaccine between state-supplied and private stock

In rare cases, vaccine providers can borrow between their state-supplied and private stock of vaccines. It's okay to borrow when:

- There are vaccine delivery delays.

- Vaccine is damaged in transit.
- There is a temporary vaccine shortage affecting vaccine distribution.
- You use short-dated vaccine to prevent vaccine expiration.
- You use private flu vaccine to vaccinate state-supplied vaccine-eligible children. (When state-supplied vaccine becomes available, replace borrowed private doses.)

It's **not** okay to borrow when:
- Doing so may result in no vaccine for state-supplied vaccine-eligible patients.
- It is routine.
- It is a repeated human error.
- You use state-supplied flu vaccine for a non-eligible patient.

What to do when you borrow or discover a borrow:
- Document every instance of borrowing on the borrowing log, available at http://bit.ly/VFCProviderResources.
- Update the ALERT IIS inventory to reflect the borrowing payback.
- Replace all doses within 90 days.
- Submit completed borrowing reports to OIP if requested.

How to discover borrows:
Some borrows happen on purpose or are caught when they happen. But some borrows happen by accident and have to be found.

The best way to find them is using the ad hoc list report in ALERT IIS. That report can be run and then sorted for doses ALERT identifies as a borrow (patient eligibility code is not appropriate for the vaccine funding source) and for doses which did not deduct from ALERT inventory ("null" doses) and so cannot be identified as a borrowed dose or not.

Learn about borrowing and using the ad hoc list report in the training portal: http://bit.ly/ALERTInventory

Section 5: Storage and handling

Refrigerator and freezer requirements

All vaccine storage units must meet the following requirements:

- The unit must be able to keep required vaccine storage temperatures:
    - » Refrigerator: 2°– 8° Celsius (36° – 46° Fahrenheit).
    - » Freezer: -50° to -15° Celsius (-58° to 5° Fahrenheit).
- The unit must be large enough to store the year's largest inventory while keeping the proper temperatures.
- Place a calibrated, digital data logger with a buffered probe in a central location in the unit.
- The unit must be dedicated to storage of vaccines (and other pharmaceuticals only as necessary).
  Food and beverages must **not** be stored in a vaccine storage unit. This practice results in opening the door too often, which destabilizes temperatures.
- **Never** use dorm-style refrigerators for vaccine storage under any circumstances.
- **Do not** use the freezer portion of a household fridge/freezer (household combination unit freezers that were relied on before July 1, 2024, are "grandfathered" in so long as they remain highly reliable).
- Separate and clearly label stocks bought privately and state-supplied vaccine.
- Plug storage units into ordinary outlets. **Do not** plug storage units into:
    - » Outlets controlled by a wall switch,
    - » Outlets with built-in circuit switches,
    - » Extension cords, or
    - » Surge protectors.
- Place "Do Not Unplug" stickers near the outlet and "Do not turn off" stickers on storage equipment's circuit breakers.
- You may not use new storage units until a week of temperature logs are approved by the Immunization Provider Help Desk.
- When you move storage units to a new location, monitor temperatures for 48 hours before you store vaccine in the unit.

- To help stabilize temperatures, place water bottles throughout the unit[2]:
  - » Against the walls of the unit,
  - » In the back of the unit,
  - » On the floor of the unit, and
  - » In the doors of the unit.

Refrigerator and freezer recommendations

- Use pharmacy or medical-grade storage units specifically designed for vaccine storage.
- Use stand-alone refrigerators and stand-alone freezer units only. Do not use the freezer portion of a household fridge/freezer to store vaccine. (OIP may not allow household units in the future.)
- Install plug guards or locks on outlets.
- Store vaccine in mesh trays or trays with holes that allow air circulation.
- Store vaccine in original box to prevent exposure to light.

Thermometer requirements

Clinics with state-supplied vaccines must keep one digital data logger for every vaccine storage unit. Each clinic must have at least one back-up digital data logger. These loggers must:

- Test for calibration at least once every two years or per manufacturer instructions. Certificates of calibration must include:
  - » Model number,
  - » Serial number,
  - » Calibration date, and
  - » Documentation of the instrument passing testing.
- Have a buffered temperature probe (glycol, glass beads, or similar).
- Be able to display a minimum and maximum temperature since the last check of the logger.

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[2] Water bottles are required for commercial and homestyle units; recommended for pharmaceutical units.

Thermometer recommendations

In addition to the above requirements, we strongly recommend data loggers have:

- An alarm for out-of-range temperatures.
- An accuracy of +/-0.5°C (+/-1°F).
- A low battery indicator.
- Memory storage for at least 4,000 readings.
- A logging interval set to once every 15 minutes.
- Be stored in the refrigerator when not in use so they are pre-chilled and ready to use.

For more information about refrigerators, freezers, and thermometers see our guides at http://bit.ly/VFCProviderResources

Temperature monitoring requirements

1. **Check and record minimum and maximum temperatures at the start of each clinic day** using your digital data logger. Temperatures must stay in the following ranges:
   - » Refrigerator: 2° to 8° Celsius (36° to 46° Fahrenheit).
   - » Freezer: -50° to -15° Celsius (-58° to 5° Fahrenheit).

   The following must be recorded in the temperature log:
   - » Exact time the temperature is checked, and
   - » The initials of the person who records it.

   Note: Minimum and maximum temperatures recorded must be those reached since the last time you checked and recorded temperatures. If your data logger has an automatic reset, you may have to review multiple measurement periods to capture all temperatures since you last reviewed them.

   Don't use current temperature twice per day: There is nothing wrong with checking temperature more than once per day, but the maximum and minimum temperature since the last reading should be recorded daily rather than current temperatures without information about maximums and minimums.

A tip sheet for reading your device is at: http://bit.ly/minmaxguide. Learn how to reset your min/max feature to take min and max temps since the last time, every time.

You can find temperature logs here: http://bit.ly/VFCProviderResources.

2. **Download and review data from digital data logger every week**:
   - » Preferably Monday mornings, or
   - » When you return to the clinic after a weekend or day closure. (Data may be saved on the cloud instead of downloading but must be reviewed.)

3. **Keep temperature monitoring documentation for three years.** This includes:
   - » Data from digital data loggers,
   - » Daily temperature logs,
   - » Data from alarm systems, and
   - » Vaccine storage troubleshooting records.

4. **Test your alarm system quarterly.** Do this by warming the probe to intentionally trigger the alarm. Document the results on your vaccine storage troubleshooting record.

Responding to out-of-range temperatures

If temperatures are out of range:

1. Restrict use of the refrigerator or freezer. Place a "Do Not Use" sign on the unit. Let your clinic's primary responsible staff know what happened.
2. Find out the cause and take action. The out-of-range temperature scenarios below show how you might handle different types of these cases.
3. Let the Immunization Provider Help Desk at 800-980-9431 or vfc.help@odhsoha.oregon.gov know what happened. (You don't need to let the help desk know if temperatures go out of range for less than half an hour, or less than one degree Celsius.)
4. Document the incident. Include:
    o   How long the temperature was out of range,
    o   Minimum and maximum temperatures,
    o   Steps taken to address the out-of-range temperatures, and
    o   Outcome. Do this in your vaccine storage troubleshooting record, available here: http://bit.ly/VFCProviderResources.

Out-of-range temperature scenarios

There is a slight temperature change due to an inventory count or door left open:

- Close the door. Recheck temperature in 30 minutes. Make sure it returned to the recommended temperature range.

The temperature is slightly out of range due to an unknown cause:

- Make a slight adjustment to the thermostat or follow your clinic's protocol. Recheck temperatures in 30 minutes.
- If temperatures return to the normal range, continue to monitor temperatures closely. Do this until you are sure you have not over-adjusted. Make sure your storage unit can maintain the appropriate temperature.
- If temperatures have not returned to normal range, move vaccine to a functioning unit.

The temperature is significantly out of range and your refrigerator or freezer seems to be malfunctioning:

- Move vaccine to a functioning storage unit. (See vaccine emergency plan.)
- Get the malfunctioning unit serviced. You may also want to contact the manufacturer of your vaccine storage equipment for help.

You suspect the out-of-range temperature is due to a malfunctioning thermometer (rather than a true change in temperature):

- Restrict use of the refrigerator or freezer. Place a "Do Not Use" sign on the unit. Let your clinic's primary responsible staff know.
- Place a back-up thermometer in the storage unit to confirm the temperature reading.

There is a power outage:

- Contact your power company to see how long the outage may last.
- Do not move your vaccine if the power outage is expected to last less than four hours. Most storage units will maintain temperatures during brief power outages as long as the door stays closed.
- If the power outage is expected to last longer than four hours, move the vaccine to your alternate storage facility. (See vaccine emergency plan.)

For all scenarios, notify the Help Desk if the temperature is out of range for:

- More than half an hour, or
- More than one degree Celsius (1.8 degrees Fahrenheit).

Off-site and mass vaccination storage requirements

Clinics that hold off-site or mass vaccination clinics must meet the storage and handling standards below. This makes sure the vaccine administered is safe and effective.

One person should be responsible for off-site clinic vaccination storage, including:

- Vaccine transport and inventory management plans,
- Portable storage unit operation,
- Off-site clinic temperature logs (http://bit.ly/VFCProviderResources), and
- Off-site clinic emergency plan.

Main clinic storage	Vaccine transport	Day storage	Vaccination station
• Holds multiple weeks' worth of vaccine stock. • Follows all state-supplied vaccine storage and handling requirements.	• No more than one day's worth of vaccine transported. • Use of purpose-built vaccine transport containers recommended. • If a purpose-built container is unavailable, transport according to transport instructions in emergency plan. • Include vaccine inventory count list. • Monitor temps using a digital data logger with a buffered probe. • Document minimum and maximum temps on arrival and after return to main clinic. • Unpack vaccines and move them to day storage immediately.	• Store only one day's worth of vaccine. • Use a purpose-built vaccine transport container or portable powered storage unit. • Units must be tested in advance to ensure ability to maintain required temps. • Include water bottles to ensure stable temps. • Monitor temps using a digital data logger with a buffered probe. • Take hourly temp readings and document minimum and maximum at end of day. • Download and review the temp logs at the end of event.	• No more than 10 doses or one hour's worth of vaccine should be stored at vaccination stations. • Store vaccine in a small cooler (lunch pail or similar size). • One or two conditioned water bottles in bottom. • Insulating layer between water bottles and vaccine. **Out-of-range temps** • Immediately relocate the vaccine to stable backup unit and label vaccines "Do Not Use." • Contact the Oregon Immunization Provider Help Desk (800-980-9431) to decide vaccine viability.

Section 6: Vaccine emergency plan

Activate your emergency plan and transport your vaccine to your alternate storage facility, if:

- The vaccine storage unit is out of range and will not return to the appropriate temperatures for four hours or more, or
- The temperature is far out of range, or
- Power outage due to fires, floods, ice, etc.

Emergency vaccine transport

Step 1: Gather materials	
- Hard-sided coolers, coolers built for vaccine transport, or foam vaccine shipping containers - Conditioned water bottles for refrigerated vaccine, frozen water bottles for frozen vaccine, or other transport material approved by OIP	- Insulating filler material - Cardboard - Digital data logger - Current vaccine inventory – ALERT IIS printout

Step 2: Arrange delivery with accepting clinic
Contact alternate storage facility with estimated time of arrival and length of storage time.

Step 3: Pack for transport
Use a Styrofoam or a hard-sided cooler at least 2 inches thick, designed for transporting vaccines.
Place a layer of conditioned frozen water bottles (for refrigerated vaccine) or frozen water bottles (for frozen vaccine) in the bottom of the transport container. To condition water bottles, run them under warm water for a few minutes. They should begin to thaw and the ice should spin freely inside the bottle.
Cover water bottles with a layer of cardboard.
Cover the layer of cardboard with 1–2 inches of filler material (e.g., bubble wrap or crumpled paper) to ensure vaccines do not touch the water bottles or shift during transport.

| |
|---|
| Place the vaccine in a plastic bag with a calibrated digital data logger (the display goes on the outside of the container). Place the bag on top of the filler material. |
| Place another layer, 1–2 inches, of filler material on top of vaccines. Top with another layer of cardboard. |
| Place another layer of conditioned frozen water bottles or frozen water bottles on top of cardboard. |
| Add vaccine inventory printout from ALERT IIS. |
| Fix any gaps in the container with filler material. Seal with packing tape. |
| Put digital data logger display on the outside of the container, on top of the lid. |
| Put "Rush! Vaccine Perishable" and "Do Not Freeze" stickers on the transport container. |
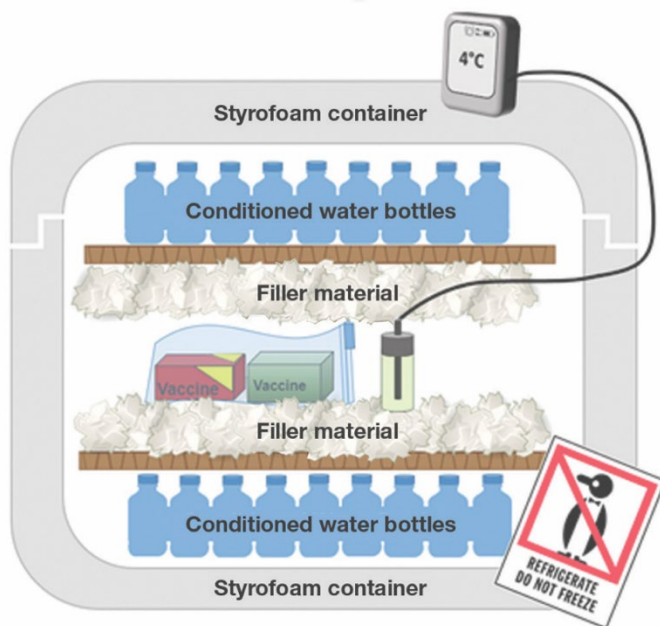
Step 4: Arrive at destination

Unpack and properly store vaccines.
Record minimum and maximum temperatures for the transport period.

Step 5: Document the event

When the vaccine is safely back at your clinic, document the transport in your vaccine storage troubleshooting record.
Contact the Immunization Provider Help Desk at 800-980-9431 to report the emergency before administering vaccine.

Transport and temperature guidelines

- When external temperatures are below 20°F or above 85°F, only transport if necessary. Before doing so, contact OIP.
- Do not leave the insulated container in an unconditioned location such as the trunk of a vehicle.
- Drive straight to the receiving site to minimize transport time.
- Do not use non-phase-change gel cold packs or dry ice to transport vaccine.
- Always use digital data loggers to monitor temperatures during transport.
- Frozen vaccine must be transported separately from refrigerated vaccine.
- When transporting ultra-cold frozen vaccine, step down to refrigerated temperature as recommended by the manufacturer and transport following refrigerated transport guidelines above. Mark vaccine with the "Beyond Use Date" (BUD).

Key phone numbers and information

- Write down storage unit details, key phone numbers, and other instructions.
- Primary and back-up staff should keep a copy of this information, building keys, and alarm codes in case emergency vaccine relocation or storage unit maintenance is required.

Vaccine storage equipment				
Unit type (e.g., freezer)	Location	Brand	Model #	Maintenance needs

Thermometers			
Primary or back-up	Brand	Model and serial #	Calibration due date

Important contact information	
Maintenance/repair company:	Phone number:
Power company:	Phone number:
Calibration company or laboratory:	Phone number:
Location of calibration certificates:	Location of back-up thermometers:
Location of Emergency Transport coolers and supplies:	

After-hours building access

Alarm codes and instructions:

Doors, locks, and keys:

Light switches and flashlights:

Circuit breaker location and instructions:

Generator instructions:

Location of generator and fuel:

Routine maintenance and generator testing instructions:

Alternative storage site

Facility name and contact person:	Phone number:
Address:	

Alternate storage site agreement

_____ [Site A] and

_____ [Site B]
agree that during a power outage or equipment failure, site A may store its vaccine and
other refrigerated pharmaceuticals in site B's refrigerator and freezer units.

Site A will contact site B before transporting vaccine. This agreement is effective as of
_____and will remain until modified or terminated as agreed by both sites.

_____
Signature of site A administrator or manager

_____
Date

_____
Signature of site B administrator or manager

_____
Date

You must update your clinic's vaccine management guide

- Each year,
- Whenever key staff changes, and
- Whenever there is a new guide.

Each time the guide is updated, the primary and back-up contacts must review and sign the guide. All staff who give vaccinations must also review and sign the guide. All clinic staff are responsible for ensuring the practice of proper vaccine management as outlined in this guide. The most current version is always available on the Oregon VFC website: http://bit.ly/VFCProviderResources

Date reviewed ___/___/___	Date reviewed ___/___/___
Primary contact signature:	Primary contact signature:
Back-up contact signature:	Back-up contact signature:
Additional staff signatures:	Additional staff signatures:

Oregon Vaccines for Children and Vaccine Access Program:
Vaccine Management Guide

You can get this document in other languages, large print, braille or a format you prefer. Contact the Oregon Health Authority Immunization Program at 800-980-9431. We accept all relay calls. Or you can dial 711.