

Most Common VFC Site Visit Findings

Marie Martinez

June 25, 2024

VFC Sites



Goals! After participating in this session, you should be able to:

• List three things that will be reviewed during a VFC Site Visit.

 Identify the five components needed in the temperature logs.

Describe how to properly store vaccine.



Vaccines for Children is over 30 years old!



- Bill Clinton signed the Omnibus Budget Reconciliation Act of 1993, making VFC law.
- Started as a response in a resurgence of measles in the U.S.
- Betty Bumpers & First Lady Rosalynn Carter attempted to take the Every Child By 74 (months) campaign nationwide in 1974.
- They went on to found "Every Child by Two" in 1991.
- Found assistance for childhood immunizations with the Clintons.





PRO	VIDER AGREEMENT
	eive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of myself and all the ioners, nurses, and others associated with the health care facility of which I am the medical director or ilent:
1.	I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.
	I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:
2.	A. Federally Vaccine-eligible Children (VFC eligible) 1. Are an American Indian or Alaska Native; 2. Are enrolled in Medicaid;
	 Have no health insurance; Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.
	B. State Vaccine-eligible Children In addition, to the extent that my state designates additional categories of children as "state vaccine-eligible", I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 funded doses) to such children.
	Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are <u>not</u> eligible to receive VFC-purchased vaccine.
3.	For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless: a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child; b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

I will maintain all records related to the VFC program for a minimum of three years and upon request make these

records available for review. VEC records include, but are not limited to VEC screening and eligibility.





Your VFC Compliance Site Visit



- Every 18-24 months
- Lasts about 2-3 hours
- Will be contacted by a site visitor to schedule a date and time
- Email will contain a checklist for what will be reviewed
- They will be reviewing 10 charts they have randomly selected.







List of findings we frequently see:



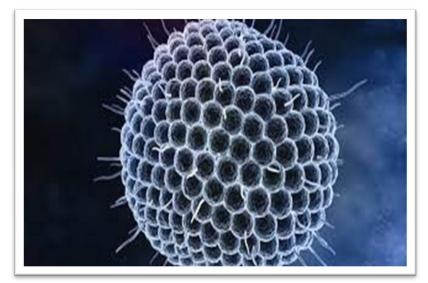
Documentation issues

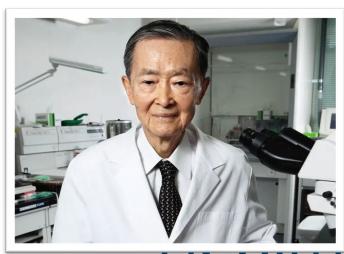
Vaccine storage & handling

Temperature Logs



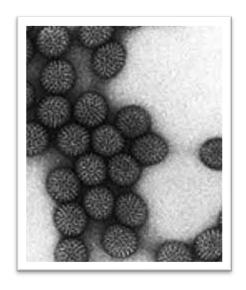
Borrowing/Eligibility Codes





Documentation

- Updating your Vaccine Management Guide
- Updating ALERT:
 - Addresses, and
 - VFC Primary Coordinator & Back-up Coordinator
- Training requirements every 2 years
- Documentation requirements in patient charts

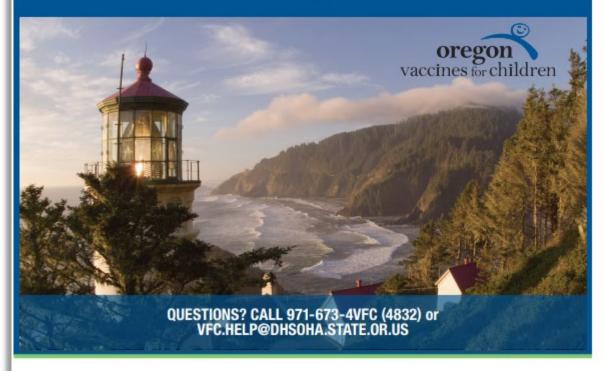








Oregon Vaccines for Children Vaccine Management Guide



CLINIC INFORMATION

Clinic name:

KEY STAFF	3	
Responsible provider:	(b) (d)	
Primary VFC contact:		
Back-up VEC contact:		

VFC PIN:

ALERT IIS number:





VFC task list

VFC clinic staff must ensure that vaccine is appropriately stored and managed at all times.

Daily tasks	Take once daily minimum and maximum temperatures. Do so at the start of the day.
	Document all immunizations.
Weekly	Download and review 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 discover due to inventory count.
Annually	VFC Recertification (January).
	Flu vaccine management:
	Prebook flu vaccine for upcoming season (January)
	Return expired flu vaccine (July)
	Review/update Vaccine Management Guide, sign and date.
	Take VFC overview and self-assessment training (primary and back-up contacts).
Every other year	Take Vaccine Management Trainings (at least two staff).
	The trainings cover:
	Storing vaccines
	Preparing vaccines, and
	Administering vaccines.
	Complete a VFC site visit.
	Calibrate thermometers.
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 of inventory.
	Complete vaccine transfer documentation in ALERT IIS.
	Update VIS.
	Submit temperature logs to Oregon Immunization Program (when requested).
	Respond to and document temperature excursions in your clinic's vaccine storage
	troubleshooting record.
	Update clinic shipping hours in ALERT IIS.
	Report changes of key staff to VFC program.
	Manage short-dated vaccine.



Pro Tip:

Translate this into a schedule on your calendar





VFC task list

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	Manage short-dated vaccine.			

Bigger Pro Tip:

results come from checking inventory more than once per month



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Another Excellent Pro Tip:

Translate this into a schedule on your calendar





You must update your clinic's vaccine management guide:

- Annually
- Whenever key staff changes, and
- . Whenever requested by the Vaccines for Children (VFC) program.

At that time, primary and back-up contacts as well as all staff who give vaccinations must review and sign the guide. All clinic staff are responsible to ensure 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:





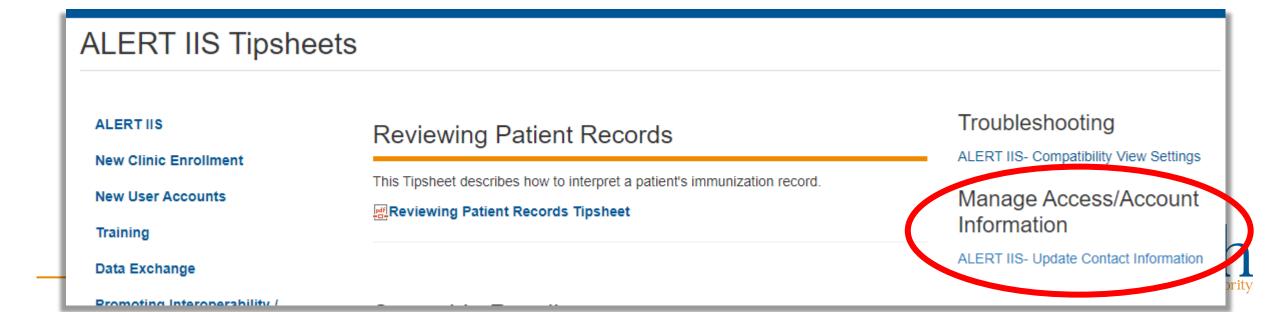


VFC Personnel

- Trainings Completed
- Documentation that training is complete

ALERT Contact Information

- Updated in ALERT?
- ALERT Tipsheet



Patient Record Documentation

Site Visitor will review 10 patient charts. They will be preselected at random by the Site Visitor.

- Patient Name
- Patient DOB
- Patient's VFC Eligibility Status
- Address of Clinic

- Name, Lot #, Manufacturer of vaccine
- Name and Title of individual administering the vaccine
- Date when VIS/IIS was given and VIS/IIS publication date

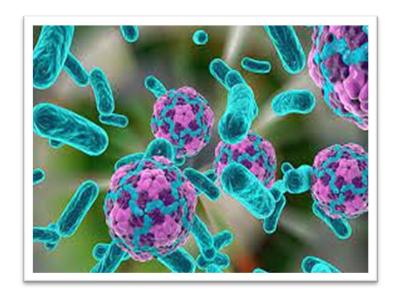




Vaccine Storage & Handling

- Refrigerators, Freezers and Ultra-cold storage
- Electrical outlets
- Emergency Plan
- Full suite of ACIP vaccines









Co	Temperature Log for Refrigerator - Celsius Days 1-15
	Days 1-15

Monitor	temperatures	closely!

Write your initials below in "Staff initials" and note the time in "Exact Time."
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If any out-of-range temps, see instructions to the right.
 Keep this documentation, data logger logs, and vaccine storage troubleshooting.

Monthly rear.	VPC FIII.
Facility Name:	

Take action if temp is out of range—too warm (above 8°C) or too cold (below 2°C).

1. Label the vaccines "Do Not Use". Store vaccine in proper conditions as quickly as possible. Do not discard vaccines unless directed to by the Oregon Immunization Program.

2. Call the Oregon VFC Helpdesk at 971-673-4832 to determine vaccine viability and next steps.

3. Document the event on your clinic's Vaccine Storage Troubleshooting Record.

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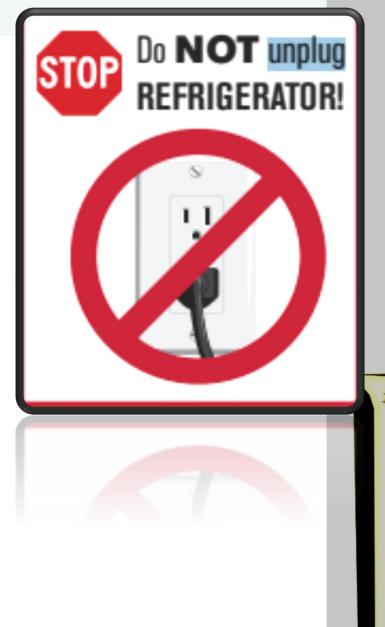


















What happens when the lights go out?

Emergency Plan:

- Have a plan ready to go
- Should be easy for anyone to understand
- Template in the Vaccine Management Guide

Section 6: Vaccine emergency plan

After-hours building access		
Alarm codes and instructions:		
Doors, locks and keys:		
,		
Light switches and flashlights:		
Light switches and hashiights:		
Circuit breaker location and instructions:		
Generator instructions:		
Location of generator and fuel:		
Routine maintenance and generator testing ins	otwictions.	
Routine maintenance and generator testing his	istructions:	
Alternative storage site		
Facility name and contact person:	Phone number:	
rading frame and contact person.	Thoro number.	
Address:		
71441000		





Section 6: Vaccine emergency plan

Key details: phone numbers, codes, etc.

Key phone numbers and information

Write down storage unit details, key phone numbers and other instructions. Primary and backup staff should keep a copy of this information along with 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						

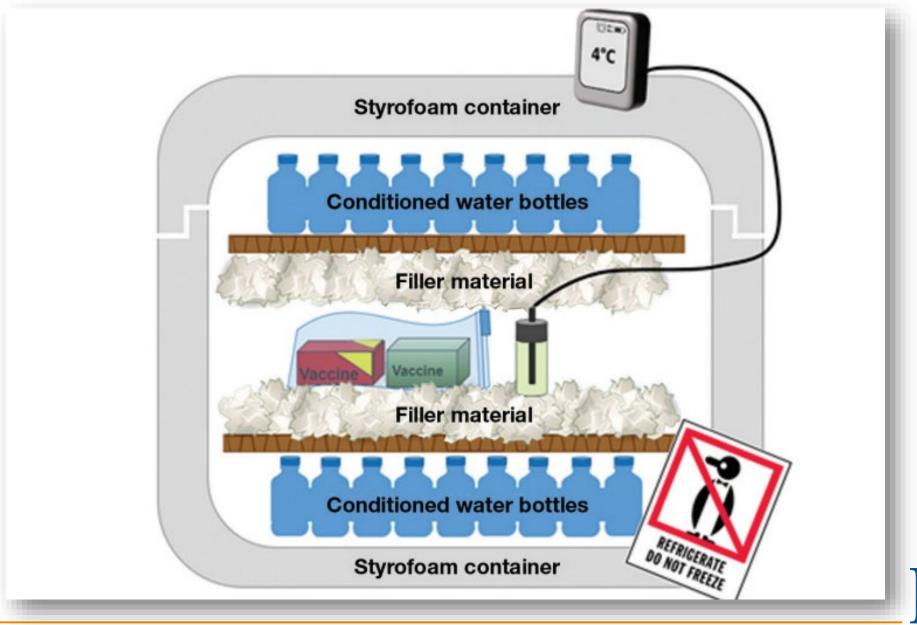
Thermometers			
Primary or back-up	Brand	Model/serial #	Calibration due date

Important contact information			
Maintenance/repair company:	Phone number:		
Davis conserve	Dhana sumbar		
Power company:	Phone number:		
Calibration company/laboratory:	Phone number:		
Location of calibration certificates:	Location of back-up thermometers:		





VACCINE MANAGEMENT GUIDE Page 18

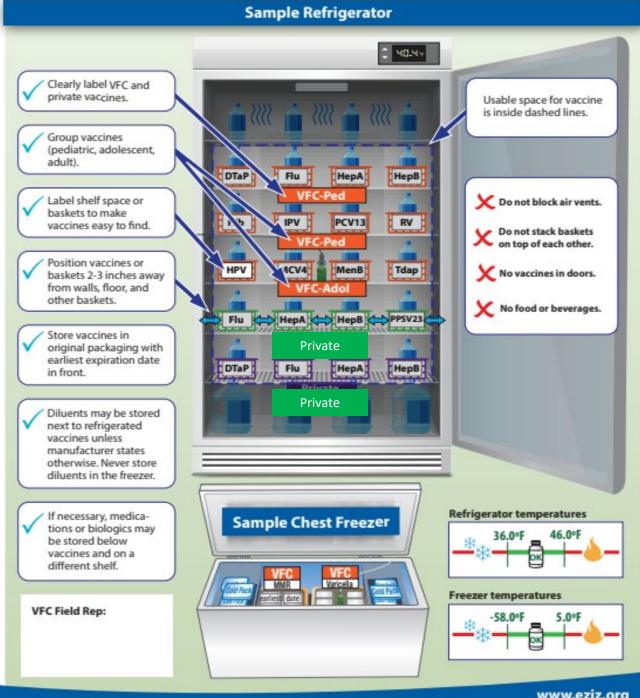






To fully ensure the safety of vaccines, equipment should include a recommended unit with enough space to accommodate your maximum inventory without crowding.

https://www.cdc.gov/vaccines/ hcp/admin/storage/toolkit/stor age-handling-toolkit.pdf

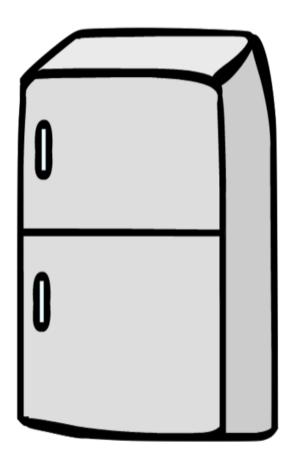






Good or bad?







Good or bad?







Both Good and Bad

GOOD:

- Centrally placed probe,
- Separated in baskets,
- Enough room for airflow



BAD:

- VFC vs Private stock labeling is not evident
- Close to being too crowded





Good or Bad?









Way tooFULL







Good or Bad?







Oh, the HUMANITY!

VERY BAD!









Lab Grade Unit





Good
or
Bad?



Lab Grade Unit









Good or bad?







Good or bad?



BAD!









BAD

or

BAD?







BAD

or

BAD?







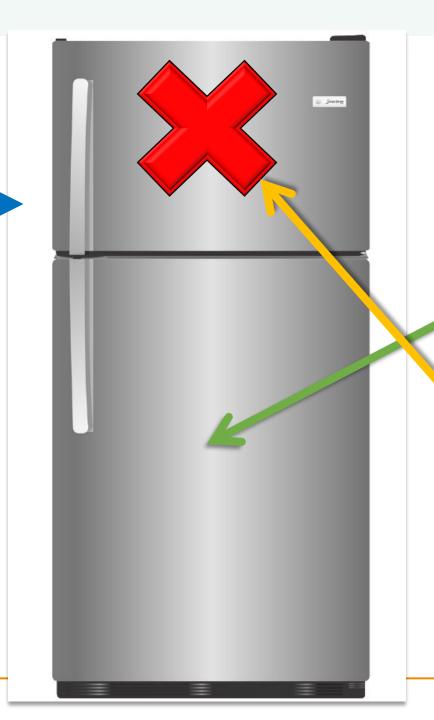


Good
or
Bad?





Freezer compartment for storage will not be allowed for **new enrollees** after July 1, 2024









Full Vaccine Suite



VFC Required Vaccines	In Stock	Nonroutine ACIP Approved Vaccin	In Stock	VFC Required Therapeutics	In Stock
COVID-19	No	MenB	No	RSV	No
Diphtheria	No	PPSV23	No		
НерА	No				
НерВ	No				
Hib	No				
HPV	No				
Influenza	No				
IPV	No				
MenACWY	No				
MMR	No				
PCV13, 15, 20	No				
Varicella	No				
Tetanus	No				
Pertussis	No				
Rotavirus	No				

Any seasonal vaccines during respiratory season (e.g., flu, RSV)

COVID-19 & RSV are new additions to the ACIP recommended vaccines/immunizations



Temperature Logs







Co	Temperature Log for Refrigerator - Celsius Days 1-15
	Days 1-15

Month/Year:	VFC Pin:	
Facility Name:		

oregon
immunization
program

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials" and note the time in "Exact Time."
- Record the maximum and minimum temperatures at the beginning of each clinic day. Max and min are the highest and lowest temps reached since the last time you checked them. Documenting the current temperature is optional.
- 3. If any out-of-range temps, see instructions to the right.
- Keep this documentation, data logger logs, and vaccine storage troubleshooting records for three years.

Take action if temp is out of range—too warm (above 8°C) or too cold (below 2°C).

- Label the vaccines "Do Not Use". Store vaccine in proper conditions as quickly as possible. Do not discard vaccines unless directed to by the manufacturer (COVID-19 vaccine) Oregon Immunization Program (all other vaccines).
- For COVID-19 vaccine, call the manufacturer. For other vaccines call the OIP Helpdesk at 971-673-4832 to determine vaccine viability and next steps.
- 3. Document the event on your clinic's Vaccine Storage Troubleshooting Record.

Day o	of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff	Initials															
Exact	Time															
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	Danger! Ten	nperature	s above 8"	C are too w	varm! Call	the Manuf	facturer (C	OVID-19 va	accine) or	OIP Helpde	sk (all oth	er vaccine	s - 971-673	-4832) im	mediately!	
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	2°C															



But why do you need **both** the temperature data and the daily temperature logs?

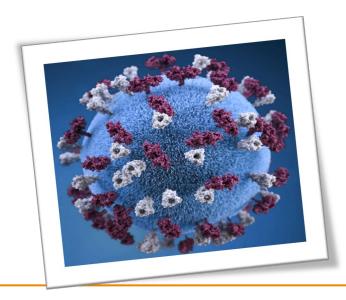






But why do you need **both** the temperature data and the daily temperature logs?

- 1. Sometimes, the data cannot be found, a good back-up.
- 2. It activates a daily check









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2. Record the maximum and minimum temperatures at the beginning of each	1. Lä
clinic day. Max and min are the highest and lowest temps reached since the last	poss
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4. Keep this documentation, data logger logs, and vaccine storage troubleshooting	Help
records for three years.	3. D

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- 1. Fill out every day you are open & have clinic staff
- 2. Reset min/max on data logger after reading
- 3. Keep for 3 years







program ure Log for Refrigerator - Celsius

Month/Year: March/202

TJ McChu

Facility Name:

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For COVID-19 vaccine, call the manufacture.
 Helpdesk at 971-673-4832 to determine vaccine.

3. Document the event on your clinic's Vaccine

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Minir	mum Temp	4.5	3.9	4.1	3.8	3.8			3.8							
	Danger! 1	'emperatur	es above 8'	'C are too v	warm! Call	the Manu	facturer (C	OVID-19 v	accine) or	OIP Helpde	sk (all oth	er vaccine	s - 971-673	3-4832) imi	mediately!	
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oregon 3. Document the event on your clinic's Vaccine Storage Troubl immunization program

12 13 Day of Month 2 4 5 6 7 8 9 10 11 14 15 MM MM MM MM MM MM Staff Initials 10:00 10:00 10:00 10:00 10:0010:00 Exact Time 6.5 6.2 6.5 6.5 5.9 5.8 Maximum Temp 4.5 3.8 3.9 4.1 3.8 3.8 Minimum Temp Danger! Temperatures above 8°C are too warm! Call the Manufacturer (COVID-19 vaccine) or OIP Helpdesk (all other vaccines - 971-673-4832) immediately! 8°C Current Temperature 7°C 6°C 5.3 5.2 5.1 5.1 5.6 5.3 Aim for 5° 5°C 4°C 3°C

Danger! Temperatures below 2°C are too cold! Call the Manufacturer (COVID-19 vaccine) or OIP Helpdesk (all other vaccines - 971-673-4832) immediately!



Temperature Log for Refrigerator - Celsius

Days 1-15

Monitor temperatures closely!

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3. If any out-of-range temps, see instructions to the right.

Month/Year: March/20

TJ McCh

Facility Name:

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Maxir	mum Temp	4.3	4.4	4.4	4.5	4.9			7.9	7.9	7.9	7.9				
Minin	num Temp	3.8	3.8	3.8	3.7	3.7			3.6	3.6	3.6	3.6				
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 Document the event on your clinic's Vaccine Storage Troubles.

oregon immunization program

Day of Month 11 12 15 3 10 13 14 RC RC RC RC RC RC RC RC. RC Staff Initials 0830 0845 0840 0905 0755 0820 0825 0832 0820 Exact Time 4.9 4.3 4.4 4.4 4.5 7.9 7.9 7.9 7.9 Maximum Temp 3.8 3.8 3.8 3.7 3.7 3.6 3.6 3.6 3.6 Minimum Temp Danger! Temperatures above 8°C are too warm! Call the Manufacturer (COVID-19 vaccine) or OIP Helpdesk (all other vaccines - 971-673-4832) immediately! 8°C Temperature 7°C 6°C Х X X X X Х X Aim for 5° 5°C Current 4°C 3°C

Danger! Temperatures below 2°C are too cold! Call the Manufacturer (COVID-19 vaccine) or OIP Helpdesk (all other vaccines - 971-673-4832) immediately!



Temperature Log for Refrigerator - Celsius Days 1-15

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials" and note the time in "Exact Time."
- Record the maximum and minimum temperatures at the beginning of each clinic day. Max and min are the highest and lowest temps reached since the last time you checked them. Documenting the current temperature is optional.
- 3. If any out-of-range temps, see instructions to the right.
- Keep this documentation, data logger logs, and vaccine storage troubleshooting records for three years.

Month/Year: March/202

TJ McChu

Facility Name: ____

Take action if temp is out of range—too warm

Label the vaccines "Do Not Use". Store vaccines possible. Do not discard vaccines unless directe 19 vaccine) Oregon Immunization Program (all or program).

For COVID-19 vaccine, call the manufacturer. For

Helpdesk at 971-673-4832 to determine vaccine viability and next steps.

3. Document the event on your clinic's Vaccine Storage Troubleshooting Record.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials	RC	RC	RC	RC	RC			RC	RC	RC	RC				
Exact Time	0830	0845	0840	0905	0755			0820	0825	0832	0820				
Maximum Temp	4.3	4.4	4.4	4.5	10.6			5.2	5.2	4.5	4.3				
Minimum Temp	3.8	3.8	3.8	3.7	3.7			3.8	3.8	3.7	3.6				
Danger! Ter	mperature	s above 8°	C are too v	varm! Call	the Manui	facturer (C	OVID-19 v	accine) or	OIP Helpde	sk (all oth	er vaccine	s - 971-673	3-4832) imi	mediately!	
8°C															





Temperature Log for Refrigerator - Celsius Days 1-15

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials" and note the time in "Exact Time."
- Record the maximum and minimum temperatures at the beginning of each clinic day. Max and min are the highest and lowest temps reached since the last time you checked them. Documenting the current temperature is optional.
- 3. If any out-of-range temps, see instructions to the right.
- Keep this documentation, data logger logs, and vaccine storage troubleshooting records for three years.

Month/Year: N	/larcn/2024	VFC Pin:	
Facility Name:	TJ McChuckle Sho	ppe	

Take action if temp is out of range—too warm (above 8°C) or too cold (below 2°C).

- Label the vaccines "Do Not Use". Store vaccine in proper conditions as quickly as possible. Do not discard vaccines unless directed to by the manufacturer (COVID-19 vaccine) Oregon Immunization Program (all other vaccines).
- For COVID-19 vaccine, call the manufacturer. For other vaccines call the OIP Helpdesk at 971-673-4832 to determine vaccine viability and next steps.
- 3. Document the event on your clinic's Vaccine Storage Troubleshooting Record.

Day of Month	1	2	3		4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials	RC	RC	RC	RO		RC			RC	RC	RC	RC				
Exact Time	0830	0845	0840	09	05	0755			0820	0825	0832	0820				
Maximum Temp	4.3	4.4	4.4	4	5	10.6			5.2	5.2	4.5	4.3				
Minimum Temp	3.8	3.8	3.8	3.7	,	3.7			3.8	3.8	3.7	3.6				
Danger! To	emperature	s above 8°	C are too v	varm	! Call	the Manuf	acturer (C	OVID-19 v	accine) or	OIP Helpd	esk (all oth	er vaccine	s - 971-67	3-4832) imi	mediately!	
8'	°c															
										1						



Day of Month

Temperature Log for Freezer - Fahrenheit Days 1-15

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials" and note the time in "ExactTime."
- Record the maximum and minimum temperatures at the beginning of each clinic day. Max and min are the highest and lowest temps reached since the last time you checked them. Documenting the current temperature is optional.
- 3. If any out-of-range temps, see instructions to the right.
- Keep this documentation, data logger logs, and vaccine storage troubleshooting records for three years.

Month/Year: March/2024 v

acility Name: TJ McChuckle

Take action if temp is out of range—too warm (above 5°F) of

Label the vaccines "Do Not Use". Store vaccine in proper of possible. Do not discard vaccines unless directed to by the M 19 vaccine) or Oregon Immunization Program (all other vaccine).

For COVID-19 vaccine, call the manufacturer. For other valendesk at 971-673-4832 to determine vaccine viability and

3. Document the action taken on your clinic's Vaccine Storag

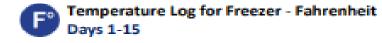


immunization

program

Day of Interior	-					-		Test .		-					
Staff Initials	BW	BW	BW	BW	BW			BW	BW					M 4	
Exact Time	0800	0917	0815	0805	0758			0840	0759						
Maximum Temp	-8	-7.1	-2.1	-3.0	5.1			5.1	5.1						
Minimum Temp	-6	8.0	-9.6	-9.5	-9.5			-9.6	-9.6						
Danger! Ter	nperatures :	above 5°F	are too wa	arm! Call ti	he Manuf	acturer (O	OVID-19 v	accine) or	OIP Helpo	lesk (all o	her vaccin	ies - 971-6	73-4832) i	immediat	ely!
5°F															
3 to 4 °F															
2 1 to 2°F															
1 to 2°F															
0 -1 to -2"F															
ല -3 to -4°F			X	X	X			X	X						
-5 to -6"F	X						,								
-7 to -8"F															
-9 to -10°F															
-11 to -12°F				_		_		_	_	_		_		_	or

Danger! Temperatures below -13°F are too cold for some COVID-19 vaccines! Call the Manufacturer (COVID-19 vaccine) or OIP Helpdesk (all other vaccines - 971-673-4832) immed



Month/Year: March/2024 VFC Pin: 000001



Facility Name: TJ McChuckle Shoppe

Monitor temperatures closely!

- 1. Write your initials below in "Staff Initials" and note the time in "ExactTime."
- Record the maximum and minimum temperatures at the beginning of each clinic day. Max and min are the highest and lowest temps reached since the last time you checked them. Documenting the current temperature is optional.
- 3. If any out-of-range temps, see instructions to the right.
- Keep this documentation, data logger logs, and vaccine storage troubleshooting records for three years.

Take action if temp is out of range—too warm (above 5°F) or too cold (below - 13°F).

- Label the vaccines "Do Not Use". Store vaccine in proper conditions as quickly as possible. Do not discard vaccines unless directed to by the Manufacturer (COVID-
- 19 vaccine) or Oregon Immunization Program (all other vaccines).
- For COVID-19 vaccine, call the manufacturer. For other vaccines call the OIP Helpdesk at 971-673-4832 to determine vaccine viability and next steps.
- 3. Document the action taken on your clinic's Vaccine Storage Troubleshooting Record.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials	BW	BW	BW	BW	BW			BW	BW						
Exact Time	0800	0917	0815	0805	0758			0840	0759						
Maximum Temp	-8	-7.1	-2.1	-3.0	5.1			5.1	5.1						
Minimum Temp	-6	8.0	-9.6	-9.5	-9.5			-9.6	-9.6						
Danger! Tem	peratures a	bove 5°F a	ire too wa	ırm! Call ti	he Manufa	cturer (C	OVID-19 v	accine) or	OIP Helpd	esk (all ot	her vaccin	es - 971-6	73-4832) i	immediate	:ly!
STF															
3 to 4 "F															
2 1 to 2°F															
1 to 2"f															
Ct. 11to .27E							:								
9 -3 to -4"F			X	X	X			x	X						
5 -5 to -6"F	X)								
-5 to -6"F															
-9 to -10°F															
-11 to -12°F															
-13 °F															



You GET A CAR!





If temperatures are out of range:

- Restrict use of the refrigerator or freezer. Place a "DO NOT USE" sign on the unit. Also, notify your clinic's primary responsible staff.
- Determine the cause and take action. The temperature excursion scenarios below give examples of how you might handle different types of excursions.
- 3. Notify the VFC Help Desk at 971-673-4VFC (4832) or vfc.help@dhsoha.state.or.us (You don't need to notify VFC if temperatures go out of range for less than half an hour or less than one degree Celsius.)
- 4. Document the incident. Include the:
 - » Length of excursion
 - » Minimum and maximum temperatures
 - » Steps taken to address the excursion, and
 - Outcome in your vaccine storage troubleshooting record, available here: http://bit.ly/ VFCProviderResources.



Vaccine Storage Troubleshooting Record (check one) Refrigerator Freezer Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

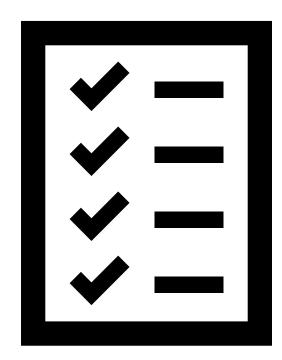
Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Tempera at the time the problem wa	as discovered	Room Temperature at the time the problem was discovered	Person Completing Report					
Date:	Temp when discovered:		Temp when discovered:	Name:					
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:				
Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.) General description (i.e., what happened?) Estimated length of time between event and last documented reading of storage temperature in acceptable range (2° to 8°C [36° to 46°F] for refrigerator; -50° to -15°C [-58° to 5°F] for freezer; -80° to -60°C [-112° to -76°F] for ultra-cold freezer (may be used for Pfizer COVID-19 vaccine). Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event.									
Action Taken (Document thorou When were the affected vaccines plocal health department and/or th Who was contacted regarding the IMPORTANT: What did you do to	placed in proper storage conditi e manufacturer[s].) incident? (For example, superv	ions? (Note: Do not discard the isor, state/local health departm	vaccine. Store exposed vaccine in proper conditio	ns and label it "do not use" until after you can	discuss with your state/				
Results What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)									











Certificates of Calibration





Vaccine/Immunization Information Sheets immuniz VIS/IISs



Should be given before every vaccination

Must be up to date

- Two different best practices:
 - Printing off from the CDC website before vaccination will help make sure they are up to date
 - If not, keep them in one place & only print off enough for a couple weeks at a time



VACCINE INFORMATION STATEMENT

Meningococcal ACWY Vaccine: What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Meningococcal ACWY vaccine can help protect against meningococcal disease caused by serogroups A, C, W, and Y. A different meningococcal vaccine is available that can help protect against serogroup B.

Meningococcal disease can cause meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, loss of limbs, nervous system problems, or severe scars from skin grafts.

Meningococcal disease is rare and has declined in the United States since the 1990s. However, it is a severe disease with a significant risk of death or lasting disabilities in people who get it.

Anyone can get meningococcal disease. Certain people are at increased risk, including:

- Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of N. meningitidis, the bacteria that cause meningococcal disease
- People at risk because of an outbreak in their community

2. Meningococcal ACWY vaccine

Adolescents need 2 doses of a meningococcal ACWY vaccine:

- First dose: 11 or 12 years of age
- · Second (booster) dose: 16 years of age

In addition to routine vaccination for adolescents, meningococcal ACWY vaccine is also recommended for certain groups of people:

- People at risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- · People with HIV
- Anyone whose spleen is damaged or has been removed, including people with sickle cell disease
- Anyone with a rare immune system condition called "complement component deficiency"
- Anyone taking a type of drug called a "complement inhibitor," such as eculizumab (also called "Soliris") or ravulizumab (also called "Ultomiris")
- Microbiologists who routinely work with isolates of N. meningitidis
- Anyone traveling to or living in a part of the world where meningococcal disease is common, such as parts of Africa
- College freshmen living in residence halls who have not been completely vaccinated with meningococcal ACWY vaccine
- U.S. military recruits







Is this VIS up to date?

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People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death. about niing a ciaim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines.

Vaccine Information Statement

Meningococcal ACWY Vaccine

42 U.S.C. § 300aa-26 8/6/2021









VIS's for all ACIP provider profile vaccines?

What about in multiple languages?

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Eligibility Coding/Miscoding

VFC providers must have working knowledge of:

- VFC eligibility categories
- Billing practices
- Documentation procedures

Staff must:

- Screen all patients for VFC eligibility
- Document specific VFC eligibility
- Document every vaccine given in ALERT IIS







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



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 or adults on OHP or other insurance	В	Private				
	OIP special projects (rarely used)	S	Special project				



Private clinic coding chart								
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	No insurance	N	VFC					
	American Indian or Alaska Native	Α	VFC					
	Underinsured	F (FQHC or RHC only)	VFC					
All ages	Privately insured children or adults on OHP or other insurance	В	Private					
	OIP special projects (rarely used)	S	Special project					



Never, except FQHC or RHC – must refer to LPHA

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	Α	VFC				
	Underinsured	F (FQHC or RHC only)	VFC				
All ages	Privately insured children or adults on OHP or other insurance	В	Private				
	OIP special projects (rarely used)	S	Special project				



Rare if ever, was used before COVID-19 commercialization

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	Α	VFC				
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All ages	Privately insured children or adults on OHP or other insurance	В	Private				
	OIP special projects (rarely used)	S	Special project				



Borrowing



- Borrowing logs
 - Must be kept for 3 years
 - Made available during the Site Visit
 - Must be filled out for each borrow

- Best Practice: Review monthly using the Ad Hoc Report in ALERT
 - Usually done on a monthly basis
 - Use it to try and catch borrows, & or coding errors



Oregon Vaccines for Children Borrowing Log

Directions for use of borrowing log:

When a provider has borrowed a vaccine from VFC stock to administer to a patient not eligible for VFC, or vice versa, the borrowing form must be COMPLETELY FILLED OUT for *each* borrowing occurrence with *each* vaccine listed on a separate row of the form. These borrowing logs must be kept as part of the VFC program records for 3 years and be made available to the VFC staff during the VFC Site Visit or upon request by the Oregon Immunization Program.

Note: Clinics cannot borrow state-supplied seasonal influenza vaccine for privately insured patients. Providers may use private stock seasonal influenza vaccine to vaccinate VFC eligible children if VFC seasonal influenza stock is not yet available. Those private stock doses used on VFC eligible children can later be replaced when VFC stock becomes available.

For each borrowed vaccine a patient receives, all of the following must be documented:

Vaccine name

Provider Name:

- Patient's name OR unique patient ID
- Patient's date of birth
- Private or VFC dose borrowed
- Date vaccine borrowed
- Reason vaccine borrowed
- Date vaccine paid back to either VFC or Private stock

Provider must sign to certify accuracy and compliance with VFC requirements.

Replacement must be made within 90 days unless clinic can justify delay.

"I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form."

Provider Signature:

Date:





Oregon Vaccines for Children Borrowing Log

Vaccine	Patient Name or ID	DOB	Stock Borrowed	Lot # (Optional)	Date Borrowed	Reason Borrowed	Date Paid Back ¹
Example: ActHib	Jane Doe	11/8/17	Private	UI181AAC	1/20/18	8	2/2/18

Reasons for Borrowing VFC Vaccine:

- Private vaccine shipment delay (vaccine order placed on time/delay in shipping)
- Private vaccine not usable on arrival (vials broken, temperature monitor out of range)
- 3. Ran out of private vaccine between orders (not due to shipping delay)
- Short-dated private dose was exchanged with VFC dose
- Accidental use of VFC dose for private patient
- Replacement of Private dose with VFC when insurance plan did not cover vaccine
- Other Explanation Required

Reasons for Borrowing Private Vaccine:

- 8. VFC vaccine shipment delay (order placed on time/delay in shipping)
- 9. VFC vaccine not usable on arrival (vials broken, temperature monitor out of range)
- 10. Ran out of VFC vaccine between orders (not due to shipping delays)
- 11. Short-dated VFC dose was exchanged for Private dose
- 12. Accidental use of Private dose for a VFC eligible patient
- 13. Other Explanation Required

Version date: 4/2018

oregon vaccines for children

¹ Replacement must be made within 90 days unless provider can justify delay.

After Site Visit



- Site Visitors will review findings
- Send an email with findings, Corrective Action Plan (CAP)
- Email will detail what needs to be completed
- Email or phone Site Visitor if you have any questions or need clarification.
- Once all follow-up, if any, is complete, the site visit will be closed out.
- See you in 18 24 months!



Asked Midjourney (text to image AI) to show me "Oregon vaccination campaign." Results given in 4 separate images.













Thank you for your help vaccinating Oregon!

Oregon Vaccine Providers Help Desk (800) 980-9431

VFC.help@odhsoha.Oregon.gov

Marie Martinez (971) 347-7275

marie.e.martinez@oha.Oregon.gov





References/Links



- ALERT Tipsheet for running an Ad Hoc List Report: <u>https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/ALERT/Documents/ALERTIISAdHocListRpt.pdf</u>
- ALERT IIS Inventory Borrowing Course on the OIP Training Portal: https://oip.csod.com/ui/lms-learning-details/app/course/b4b6799e-765d-4d1f-b318-48b4ee721d80
- ALERT Tipsheet for updating contact information (start on page 4): <u>https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/ALERT/Documents/ALERTIISUpdateContact.pdf</u>

