

2020 Vaccines for Children (VFC) Vaccine Management Plan

Standard Operating Procedures (SOPs) Template

Indiana State Department of Health- Immunization Division



2020 VACCINE MANAGEMENT PLAN

OFFICE AND VACCINE COORDINATOR INFORMATION

This plan must be reviewed and updated annually (every 12 months) or when key staff change (primary/back-up coordinators and/or signatory). This plan must be dated and signed by the person responsible for the VMP content.

Office/Practice Name	
VFC PIN (6 Digits- e.g. M00L00)	
Physical Address	
Phone Number	
Fax Number	

Medical Director/Signatory	Name:
	Email:
	Contact Number:

Primary Vaccine Coordinator	Name:
	Email:
	Contact Number:

Back-Up Coordinator	Name:
	Email:
	Contact Number:

Person(s) with 24-hour access to building, in case of emergency	Name:
	Contact Number:

Reviewed on _____ by _____
Date Signature

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SIGNED PROVIDER AGREEMENT PAGE (COPY)

Place a copy of your office's signed provider agreement to receive publicly-supplied vaccine here

VACCINE COORDINATOR ROLES AND RESPONSIBILITIES

Summary

VFC providers are required to designate a primary vaccine coordinator and at least one back-up vaccine coordinator for each facility. Notify the ISDH Immunization program immediately of any changes in the medical director, primary vaccine coordinator, or back-up vaccine coordinators via the email or phone number listed below. All coordinators must be fully trained on routine and emergency standard operating procedures (SOPs) for vaccine ordering, storage, handling, transport, and inventory management.

The vaccine coordinator is responsible for overseeing all vaccine management within the facility, including:

- Developing and maintaining this Vaccine Management Plan
- Monitoring all vaccine storage and handling and vaccine administration practices in the facility, including responding to and documenting all temperature excursions and reporting them to the Indiana State Department of Health (ISDH) Staff Representative
- Overseeing vaccine ordering and notifying the ISDH Staff Representative if vaccines will expire before they are administered
- Ensuring and documenting annual vaccine management training for designated staff as well as training new staff upon hire
- Participating in and documenting completion of annual training on VFC requirements
- Storing all required documentation for three years

ISDH Staff Representative	
Contact Number	
Email	
Immunization Division Central Office Contact	800-701-0704 vaccine@isdh.in.gov (always include your VFC PIN for reference)

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More specifically, vaccine coordinators are responsible for the following:

<p>Vaccine Storage and Handling</p> <ul style="list-style-type: none"> • Ensure the vaccine cold chain is maintained at all times • Ensure refrigerator and freezer units that house VFC vaccine meet CDC requirements • Ensure storage unit digital data loggers (DDLs) and/or continuous temperature monitoring system meet CDC requirements • Oversee proper receipt and storage of all vaccine shipments, including training any office and front desk staff on storage and handling practices in the event they encounter vaccine shipments • Monitor all VFC inventory expiration dates and rotate vaccine stocks to ensure soon-to-expire vaccines are used first • Ensure VFC and privately-purchased vaccine stocks are clearly separated <ul style="list-style-type: none"> ○ have a tracking system in place to record any doses that are accidentally borrowed from VFC and ensure all VFC doses are replaced with private-purchased vaccines in a timely manner • Place “DO NOT UNPLUG” stickers by the wall outlets into which storage units that house VFC vaccine are plugged. • Circuit Breaker boxes should be clearly marked with the associated outlet and emergency contact information if the breaker box is tripped and/or there is scheduled maintenance 	<p>Vaccine Ordering and Accountability</p> <ul style="list-style-type: none"> • Submit vaccine orders via the Vaccine Ordering Management System (VOMS) in the electronic Immunization Information System (IIS) registry CHIRP (Children and Hoosiers Immunization Registry Program) • Electronically reconcile VFC vaccine inventory monthly and submit via CHIRP • Account for all wasted/expired/spoiled/borrowed vaccines in CHIRP and complete/submit all associated documentation forms to the ISDH Immunization program • Ensure all vaccine orders are received electronically in CHIRP <p>Emergency Situations</p> <ul style="list-style-type: none"> • Follow all protocols for protecting vaccines in emergency situation such as power outages, natural disasters, and equipment failure • Respond and manage all temperature excursion events • Follow all vaccine transport guidance <p>VFC Programmatic Tasks</p> <ul style="list-style-type: none"> • Participate in all program compliance site visits with an ISDH Staff Representative, which may be scheduled or unannounced • Complete and submit annual provider recertification
<p>Daily Temperature Monitoring and Recording</p> <ul style="list-style-type: none"> • Document the minimum and maximum temperatures of each storage unit at the start of each work day • Record the current storage unit temperature twice daily on ISDH temperature logs (only) • Maintain temperature monitoring devices, including a back-up device, and ensure they all have current certificates of calibration • Download DDL reports at the start of each work week and submit to your ISDH staff representative via email biweekly or at ISDH discretion. • Maintain storage equipment, including ensuring units are properly cleaned and serviced at all times 	<p>Annual Training Requirements</p> <ul style="list-style-type: none"> • Annually, primary and back-up VFC vaccine coordinators, and any staff members that have any responsibility for VFC vaccines must complete CDC’s You Call the Shots modules for Vaccine Storage and Handling and the Vaccines for Children program • Additionally, at minimum, primary and back-up coordinators must attend/complete at least additional two ISDH-coordinated educational VFC events, either in-person or virtually (CHIRP user group meetings, conference events, immunization rate increase projects)

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STAFF TRAINING AND DOCUMENTATION

The ISDH Immunization Program requires **primary and back-up vaccine coordinators** to complete the following annually:

- **CDC’s “You Call the Shots” (YCTS) Training** - Required
 - YCTS Vaccine Storage and Handling (module 10)
 - YCTS Vaccines for Children program (module 16)*
 This must be completed by any staff that will receive vaccine shipments.
It is best-practice that ALL office staff complete this training.

- Two additional educational activities:
 - Site Compliance or Storage and Handling Visit, and/or
 - ISDH or IIC coordinated education event, either in-person or virtual
 - ISDH LMS Invest Modules

All training requirements must be completed by December 31.
Certificates of completion/attendance are required. Please keep copies with this documentation sheet.

STAFF NAME	ROLE	Date Completed			
		YCTS MODULE 10	YCTS MODULE 16	EDU ACTIVITY 1	EDU ACTIVITY 2
				Event: Date:	Event: Date:
				Event: Date:	Event: Date:
				Event: Date:	Event: Date:
				Event: Date:	Event: Date:
				Event: Date:	Event: Date:
				Event: Date:	Event: Date:

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Training Documentation Overflow Sheet

STAFF NAME	ROLE	Date Completed			
		YCTS MODULE 10	YCTS MODULE 16	EDU ACTIVITY 1	EDU ACTIVITY 2
				Event: Date:	Event: Date:
				Event: Date:	Event: Date:
				Event: Date:	Event: Date:
				Event: Date:	Event: Date:
				Event: Date:	Event: Date:
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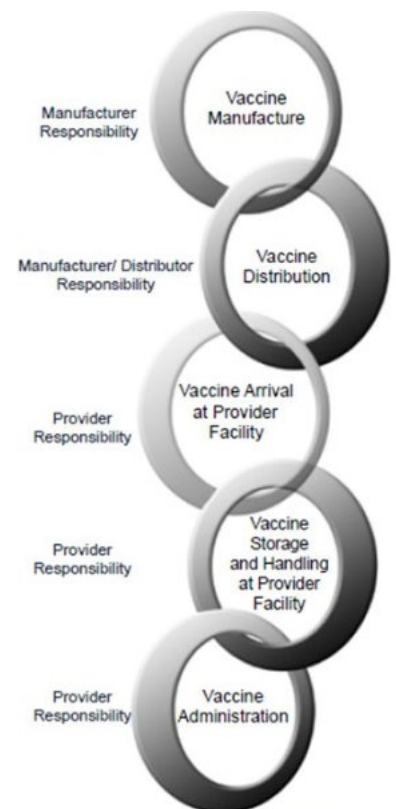
Indiana State Department of Health- Immunization Division

VACCINE STORAGE AND HANDLING PRACTICES

All vaccine storage and handling requirements and recommendations are in place to ensure the vaccine cold chain is maintained. The cold chain begins at the manufacturing plant, includes delivery to and storage at the provider facility, and ends with the administration of vaccine to the patient. Too much exposure to heat, cold, or light at any step in the cold chain can result in a loss of vaccine potency. Once potency is lost, it cannot be restored.

VFC Storage and Handling Requirements

- Stand-alone storage units that maintain correct temperatures at all times
 - Refrigerator temperature between 36°F and 46°F (2°C and 8°C); aim for 40°F
 - Freezer temperature between -58°F and +5°F (-50°C and -15°C)
 - Water bottles in storage units-against walls, in the back, on the floor- to help stabilize temperatures
 - Needs to have shelves for vaccine placement
 - NO food or drinks in the storage units
 - NO vaccine storage in the unit door, on the floor, and/or under the cooling vents of a storage unit
 - NO expired vaccine in unit
- Digital data loggers (DDLs) with continuous monitoring capabilities and a current, valid Certificate of Calibration Testing for each device, as well as at least one back-up DDL
 - Must have a glycol or other buffered solution-encased probe
 - Probe must be placed in the central area of the storage unit
 - Record DDL minimum and maximum temperatures once daily at the start of the work day
 - Download, review, and store digital reports once a week; reset DDL memory at this time
 - Record point-in-time temperature readings twice daily on standard temperature logs
- **DO NOT UNPLUG** signs by the electrical outlets into which the units are plugged
- **WARNING-EXPENSIVE VACCINE IN STORAGE** signs on the circuit breaker with emergency contact info and the fuse numbers listed; outlet breaker fuses connected to the units clearly marked inside the box



2020 Vaccines for Children (VFC) Vaccine Management Plan

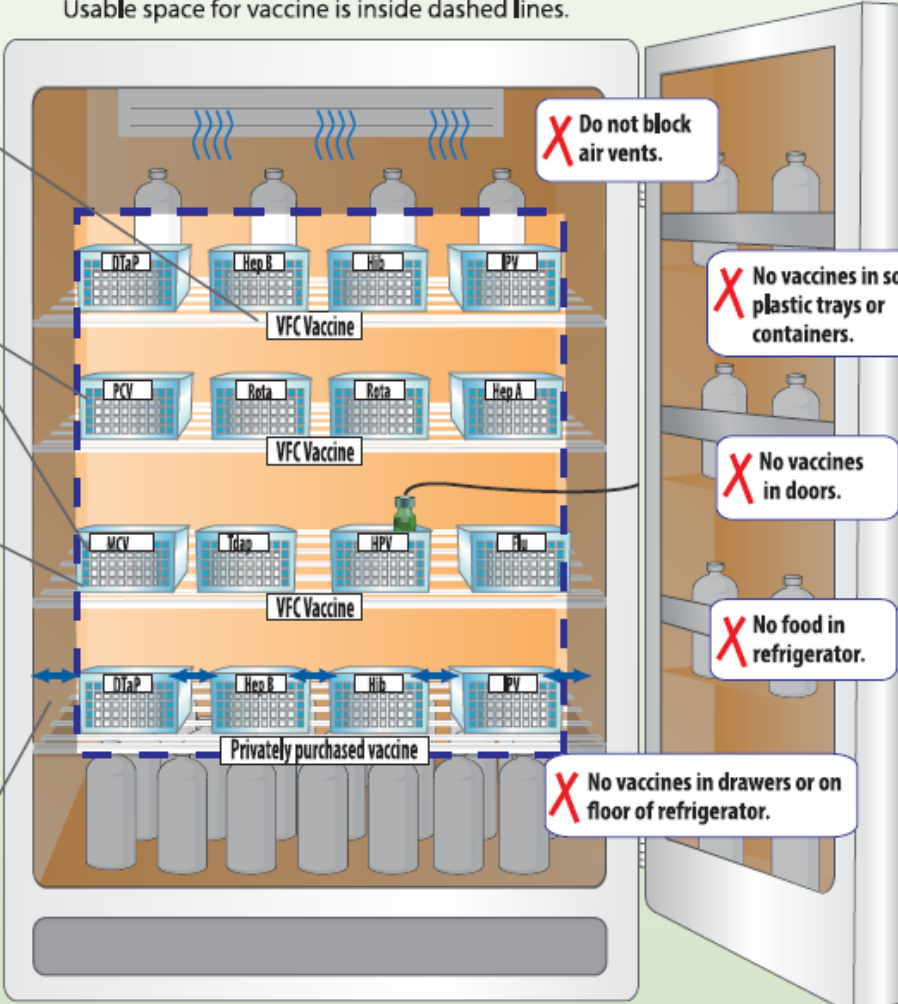
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REFRIGERATOR ROUTINE MANAGEMENT

Refrigerator-only Unit

Usable space for vaccine is inside dashed lines.



- ✓ Separate VFC vaccines from privately purchased vaccines and label them clearly.
- ✓ Group and label vaccines by pediatric, adolescent, and adult types.
- ✓ Place vaccine boxes in breathable plastic mesh baskets or directly on shelves.
- ✓ Always keep vaccines in original boxes. Do not open the box until you are ready to use vaccines.
- ✓ Keep baskets 2-3 inches from walls and other baskets.
- ✓ Store only vaccines in vaccine storage units. If storage of medications is necessary, store below vaccines.
- ✓ Store vaccines with the earliest expiration dates to the front of the shelf.
If you have vaccines that will expire within 3 months that you will not be able to use, notify Your field rep
- ✓ Keep temperatures in OK range

Do not block air vents.

No vaccines in solid plastic trays or containers.

No vaccines in doors.

No food in refrigerator.

No vaccines in drawers or on floor of refrigerator.

36.0°F 46.0°F
2.0°C 8.0°C
OK

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FREEZER ROUTINE MANAGEMENT

A carefully organized freezer helps protect vaccines and facilitates vaccine inventory management. Freeze MMR, MMRV, Varicella, and Zoster vaccines.

✓ Separate the VFC vaccine supply from privately purchased vaccine and label them clearly.

✓ Group and label vaccines by pediatric, adolescent, and adult types.

✓ Place vaccine boxes in breathable plastic mesh boxes or directly on shelves.

✓ Always keep vaccines in their original boxes. Do not open the box until you are ready to use the vaccine.

✓ Keep baskets 2-3 inches from walls and other baskets.

✓ Store vaccines with the earliest expiration dates to the front of the shelf.

If you have vaccines that will expire in 3 months that you will not be able to use, Notify your ISDH staff rep



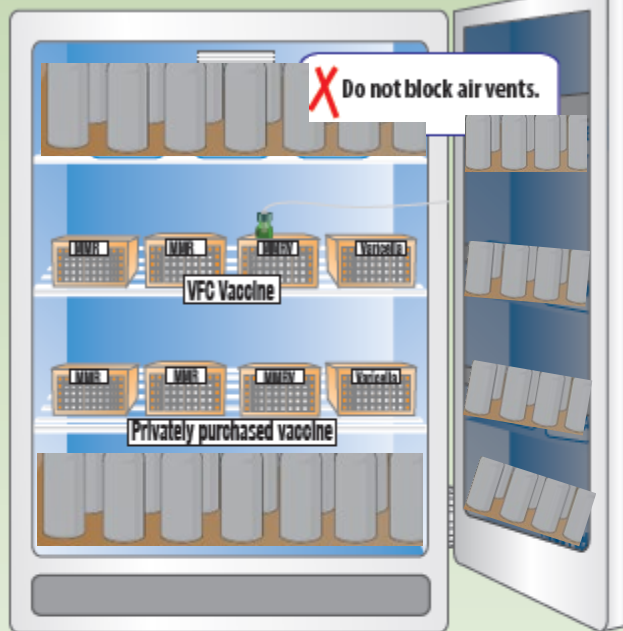
✓ Keep temperatures 5.0°F or colder.

Aim for 0.0° F or colder



Above 5°F is too warm!

Upright freezer



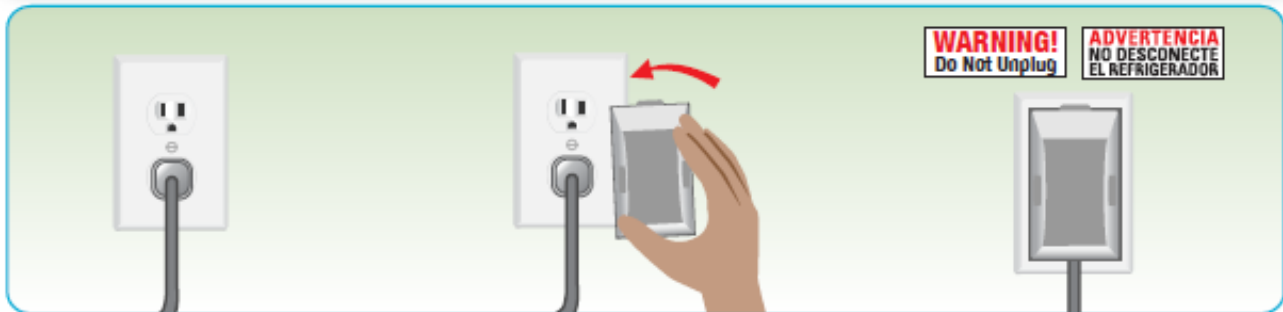
Chest freezer



POWER SUPPLY ROUTINE MANAGEMENT

Safeguard Your Power Supply

Protect plug and outlet

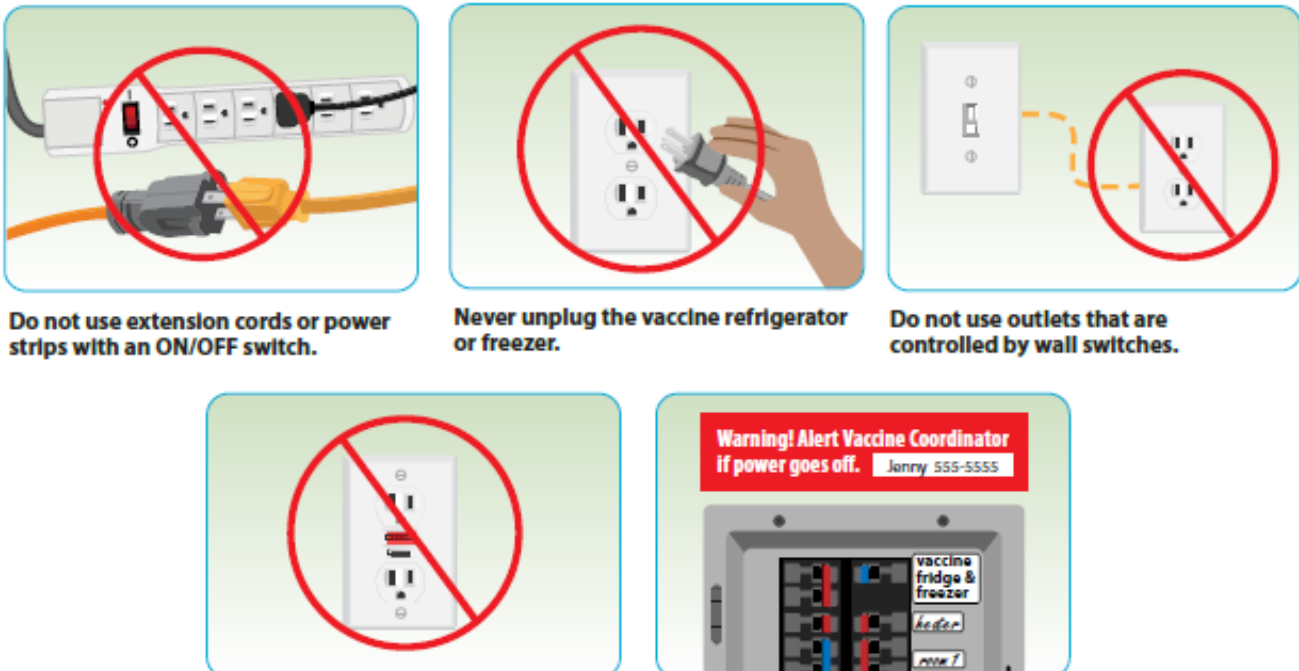


Plug in vaccine storage unit to a nearby outlet.

Secure plug with a guard/cover.

Post "Do Not Unplug" signs near outlet.

Always avoid disruption of power



Do not use extension cords or power strips with an ON/OFF switch.

Never unplug the vaccine refrigerator or freezer.

Do not use outlets that are controlled by wall switches.

Do not use outlets that have built-in circuit switches (they have red reset buttons).

Label fuses and circuit breakers. Post a sign to alert the Vaccine Coordinator any time the power goes out.

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VACCINE STORAGE UNIT/LOCATIONS AND MAINTENANCE

Maintenance/Repair
Company

Phone

Unit Type	Unit/Location ID	Brand	Model	Dates of Repair
Refrigerator				
Refrigerator				
Refrigerator				
Refrigerator				
Freezer				
Freezer				
Freezer				
Freezer				

Location of completed
temperature logs

TEMPERATURE MONITORING DEVICE LIST AND MAINTENANCE

Calibration Company/Laboratory		Contact		Phone	
Location of Certificates of Calibration					
Location of Backup Data Logger					

Digital Data Logger or Continuous Monitoring System Device Model/Serial Number	Primary?	Backup?	Calibration Expiration Date	Alarm Setting Low	Alarm Setting High

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VACCINE ORDERING PROCEDURES

- All vaccine orders are submitted through the Vaccine Ordering Management System (VOMS) in CHIRP
 - VOMS 2.0 will be launching in May of 2020. Because of this, providers will be able to order influenza through VOMS during the 2020-2021 flu season. We will discontinue the use of paper influenza order forms.

At minimum, providers should order enough vaccine for a four-week period, but no more than three months.

- *At the time of vaccine order placement:*
 - Providers must ensure contact information and delivery hours are reflective for the next three weeks to ensure accurate and prompt vaccine delivery (e.g. if your office will be closed on any day in the coming three weeks, or open for less than four (4) hours, uncheck that day as an option when placing your order)
 - Providers must submit their monthly vaccine accountability report via CHIRP
 - All vaccines administered must be entered into CHIRP prior to inventory reconciliation, via manual or Electronic Medical Record (EMR) entry
- **Non-frozen** vaccine orders typically arrive 7 to 10 days after the order has been approved in VOMS.
- **Frozen** vaccine ships directly from the manufacturer (Merck) and will arrive separately from refrigerated vaccine. Orders may arrive up to 14 days after the VOMS approval date

VACCINE RECEIVING AND DOCUMENTATION PROCEDURES

The primary and/or back-up coordinator must be immediately notified if any vaccine shipment arrives. Coordinators must immediately unpack, store, and document vaccines and diluents upon receipt.

Actions must include:

- Examining the shipping container and vaccine vials for signs of physical damage
- Comparing the contents of the container to the packing list to be sure they match
 - **If there is a discrepancy with the order, provider must immediately notify the Indiana Department of Health- Immunization Division at 1-800-701-0704.**
- Making sure lyophilized (freeze-dried) vaccines came with the correct type and quantity of diluents
- Checking both vaccine and diluent expiration dates to ensure none are expired or soon-to-expire products
- Checking the cold chain monitor (CCM) for any indication of a temperature excursion during transit
- Receiving vaccine order via CHIRP so that it populates your online inventory before staff begin using it

**WITHIN TWO HOURS OF VACCINE DELIVERY:
If any damage, excessive shipping time, cold chain breach is suspected
notify the Indiana Immunization Program at 1-800-701-0704.**

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VACCINE INVENTORY CONTROL PROCEDURES

- **Ensure proper vaccine handling and preparation practices**
 - Vaccines should be prepared immediately prior to administration
 - Reconstitute lyophilized vaccine with the diluent that came with the vaccine- nothing else
 - Always check expiration dates prior to preparing the vaccine (and its diluent)
 - A single-dose vial contains one dose and should only be used for one patient
 - A multi-dose vial is intended for ten (10) doses only and should not be punctured more than ten (10) times
 - **In the event of a “drawn but not used” vaccine:**
 - Label the vaccine with type, lot number, date/time prepared, and initials of the preparer, and place into the appropriate storage unit (refrigerator or freezer).
 - Discard any refrigerated, pre-drawn doses no later than the end of the workday
 - Varicella-containing products must be used within 30 minutes of reconstitution
- **Monitor multi-dose vial use**
 - IPV multi-dose vials can be used to their expiration date and do not have to be discarded after 28 days of opening
- **Monitor vaccine inventory expiration dates**
 - With each vaccine shipment, organize storage unit so that vaccine with the closest expiration date is placed in front to be used first
 - Conduct a patient reminder/recall for vaccine types that are soon-to-expire
 - If you have vaccine that will expire within 90 days (three months) **that your office does not anticipate using**, and you have conducted a reminder/recall, notify your ISDH staff representative to inquire about a possible transfer to another VFC provider
- **Minimize VFC vaccine borrowing**
 - VFC vaccine **cannot** be used as a replacement system for a provider’s privately-purchased vaccine inventory
 - Borrowing between inventory stocks should be rare
 - Documentation must occur when any vaccine is borrowed regardless of inventory origin (e.g. VFC to Private or Private to VFC).
 - The **Borrowing Report** is the only form of acceptable documentation and it must specify an approved reason for vaccine borrowing. The form must be submitted within 30 days of borrowing via email vaccine@isdh.in.gov or fax 317-233-3719:

Approved borrowing reasons:

- Vaccine shipment delay (public or private)
- Vaccine not useable on arrival (public or private)
- Ran out of vaccine between orders [not due to shipping delays] (public or private)
- Short dated vaccine from one stock used on a patient with the opposite eligibility (public or private)
- Accidental use of vaccine from one stock on a patient with the opposite eligibility (public or private)
 - Replacement of private dose with VFC when insurance plan did not cover vaccine (public)

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- When borrowing occurs, funding source integrity needs to be maintained both when the vaccine is originally borrowed and when stock is repaid.
- **The funding sources for borrowed and replaced doses will need to be adjusted in CHIRP**
 - Quick reference guides are located in the CHIRP Document Center
- ***Please note: 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. This one-directional borrowing exception is unique to seasonal influenza vaccine.***

VACCINE LOSS (EXPIRED/WASTED/SPOILED) MANAGEMENT PROCEDURES

All VFC providers are required to document and report all incidents of vaccine loss and wastage. When managing expired, spoiled, and wasted vaccine, providers must:

- Remove the vaccines from any storage unit that stores viable vaccines
- Label vaccines DO NOT USE
- Report and record the incident on the ISDH **Vaccine Return form**, including the vaccine type, lot number, NDC number, number of doses and reason
 - The form must be submitted within 30 days of vaccine loss via email vaccine@isdh.in.gov or fax 317-233-3719
 - All returns must be completed within six (6) months after the product expiration or waste date

Expired vaccine

- ALL expired vaccine must be returned
- Primary vaccine coordinators will receive a McKesson return label via email within thirty (30) days of Vaccine Return form submission. Ensure all contact information is current when completing the Vaccine Return form.

WHAT SHOULD NOT BE RETURNED TO MCKESSON

- Used syringes, with or without needles
- Broken vials
- Wasted products such as a syringe that was drawn up but not used
- Any multi-dose vial from which some doses have been withdrawn
- Diluent (expired or not expired)
- IG, HBIG, PPD
- Private-purchased vaccine

Discard these items according to your facility's procedures.

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VFC ELIGIBILITY AND INSURANCE

**Patients must be screened for VFC eligibility at each visit*



Eligibility for Publicly-Funded Vaccines Reference Guide for:
 Vaccines for Children (VFC) providers, Adult Vaccine Program (AVP) providers, and Electronic Medical Record (EMR) contacts

Patient Status (<19 years old)	Eligible for Public Vaccine	IIS Eligibility Category Selection	IIS Eligibility Code & Description	IIS Funding Source and Description	Billing
American Indian/Alaska Native <ul style="list-style-type: none"> Child is less than 19 years old As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603-13) 	Yes Federal (VFC) vaccine eligible	American Indian/Alaskan Native	V04 VFC eligible – American Indian/ Alaska Native	VXC1- Publicly funded vaccine stock	<ul style="list-style-type: none"> Cannot bill for cost of vaccine Can bill administration fee up to \$20.32 per vaccine dose May issue only a single bill within 90 days Cannot send to collections for unpaid administration fee
Uninsured <ul style="list-style-type: none"> Child is less than 19 years old Does not have health insurance Enrolled in a Health Care Sharing Ministry (i.e. Medi-Share, Liberty Healthshare, HealthShare Altruia, Christian Healthcare Ministries, Solidarity Healthshare) 	Yes Federal (VFC) vaccine eligible	Uninsured	V03 VFC eligible – Uninsured		<ul style="list-style-type: none"> Cannot bill for cost of vaccine Can bill administration fee up to \$20.32 per vaccine dose May issue only a single bill within 90 days Cannot send to collections for unpaid administration fee
Underinsured Child <ul style="list-style-type: none"> Child is less than 19 years old Has insurance that does not cover vaccine Served at a Federally Qualified Health Center/Rural Health Center (FQHC/RHC) or deputized Local Health Department (LHD) 	Yes Federal (VFC) vaccine eligible	Underinsured	V05 VFC eligible – Underinsured		<ul style="list-style-type: none"> Cannot bill for cost of vaccine Can bill administration fee up to \$20.32 per vaccine dose May issue only a single bill within 90 days Cannot send to collections for unpaid administration fee
<ul style="list-style-type: none"> Child is less than 19 years old Has insurance that does not cover vaccine Served at any non-FHQC or LHD VFC provider location 	Yes State (Non-VFC) vaccine eligible				<ul style="list-style-type: none"> Cannot bill for cost of vaccine Can bill administration fee up to \$20.32 per vaccine dose May issue only a single bill within 90 days Cannot send to collections for unpaid administration fee

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Eligibility for Publicly-Funded Vaccines Reference Guide for:
 Vaccines for Children (VFC) providers, Adult Vaccine Program (AVP) providers, and Electronic Medical Record (EMR) contacts

Indiana Family and Social Services (FSSA) offers a number of different programs and services under the Indiana Health Coverage Programs (IHCP). Each IHCP member is issued a number referred to as the Member ID assigned by FSSA Division of Family Resources (DFR). The type of card received depends on the IHCP program in which the member is enrolled. Providers are required to verify member eligibility on the date of service via the [Provider Healthcare Portal](#). Providers that fail to verify eligibility are at risk of claims being denied due to member ineligibility or coverage limitations.

Viewing a member ID card alone does not ensure member eligibility.

- Hoosier Health Cards are issued by FSSA DFR.
- Hoosier Care Connect members receive member ID cards from their individual Managed Care Entities (MCEs): Anthem or MHS.
- Hoosier Healthwise members receive member ID cards from their individual MCEs: Anthem, CareSource, MHS, and MDwise.

Package A (Medicaid) and C (CHIP) are NOT listed on the cards and can only be determined via the Provider Healthcare Portal.

Patient Status (<19 years old)	Eligible for Public Vaccine	IIS Eligibility Category Selection	IIS Eligibility Code & Description	IIS Funding Source and Description	Billing
<p>Medicaid</p> <ul style="list-style-type: none"> • Child is less than 19 years old • Enrolled in Traditional Medicaid • Enrolled in Hoosier CareConnect (Full Medicaid or Package A) • Enrolled in Hoosier Healthwise Package A 	Yes Federal (VFC) vaccine eligible	Medicaid	V02 VFC eligible – Medicaid	VXC1- Publicly funded vaccine stock	<ul style="list-style-type: none"> • Cannot bill for cost of vaccine • Bill according to FSSA guidelines • Vaccine administration fee reimbursement determined by FSSA- increased to \$15.00 as of January 1, 2020
<p>CHIP (new as of January 1, 2020)</p> <ul style="list-style-type: none"> • Child is less than 19 years old • Enrolled in Hoosier Healthwise Package C- Children Health Insurance Program (CHIP) 	Yes State (Non-VFC) vaccine eligible	CHIP	V22 State vaccine eligible-CHIP		<ul style="list-style-type: none"> • Cannot bill for cost of vaccine • Bill according to FSSA guidelines • Vaccine administration fee reimbursement determined by FSSA- increased to \$15.00 as of January 1, 2020

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Eligibility for Publicly-Funded Vaccines Reference Guide for:

Vaccines for Children (VFC) providers, Adult Vaccine Program (AVP) providers, and Electronic Medical Record (EMR) contacts

Patient Status (<19 years old)	Eligible for Public Vaccine	IIS Eligibility Category Selection	IIS Eligibility Code & Description	IIS Funding Source and Description	Billing
Private insurance <ul style="list-style-type: none"> Child is less than 19 years old Enrolled in private insurance plan 	No	Ineligible for VFC/Private Ins	V01 Ineligible for VFC/Private Ins	PHC70	<ul style="list-style-type: none"> Bill according to plan guidelines

Other considerations for patients that are <19 years old

Child's Insurance Status	VFC Eligible?	VFC Eligibility Category
Has private health insurance plan with Medicaid as secondary insurance	YES	Medicaid
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit AND has Medicaid as secondary insurance	YES	Medicaid
Has private health insurance that covers all vaccinations and is American Indian/Alaskan Native (AI/AN)	YES	AI/AN. However, provider should choose the eligibility category <u>most cost-effective for the child and family.</u>
Has Medicaid and is American Indian/Alaskan Native (AI/AN)	YES	Medicaid or AI/AN. Provider should use Medicaid for the administration fee because this provides the least out-of-pocket expense for the family
Has an insurance plan that does not cover all ACIP-recommended vaccines	YES	Underinsured. Child can only receive vaccines not covered by the plan.
Has health insurance covering all vaccines, but has not yet met the plan's deductible or paid for other services received at visit	NO	Insured. This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration because the plan's deductible has not been met.
Has health insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount it will cover	Depends	NO- Insured until the fixed dollar limit is met YES-Underinsured after the fixed dollar limit is reached

2020 Vaccines for Children (VFC) Vaccine Management Plan Standard Operating Procedures (SOPs) Template

Indiana State Department of Health- Immunization Division

VACCINE TRANSPORT

Required Vaccine Transportation Procedures

- **If your office is moving locations and transporting vaccines, you MUST contact your ISDH Staff representative. Relocating without notification may jeopardize VFC program enrollment status.**
- Only appropriate packing materials (see following page) may be used to safely transport and/or temporarily store vaccines
 - If an acceptable portable refrigerator or freezer unit is used, unit preparation, packing and transport must follow the unit's guidelines (i.e. AcuTemp Coolers or Fridge-Freeze units)
 - Temporary storage (i.e. during unit cleaning; offsite clinics) is possible only when acceptable portable refrigerator or freezer units are used.
- **Digital data loggers with continuous monitoring and recording capabilities must be used for all temperature monitoring during transport.**
- Vaccines must be attended at all times during transport and/or temporary storage, including temperature documentation on the **VFC Vaccine Emergency Transport Log**
 - If temperatures are not monitored during transport/temporary storage, the vaccine will be deemed wasted because there is no proof that temperatures remained within acceptable ranges, regardless of duration.
 - The responsible party will be held accountable to replace all wasted VFC doses per ISDH's Restitution policy
- Packed vaccine may never be placed in the trunk of a vehicle
- The receiving facility must immediately unpack and appropriately store vaccines into acceptable VFC vaccine storage units that are monitored using a DDL or other continuous monitoring system for which a MIN/MAX can be recorded once daily and point-in-time temperature recordings can be documented twice daily



VARICELLA-CONTAINING VACCINES

The vaccine manufacturer does not recommend transporting varicella-containing vaccines (MMR/V,VAR). If these vaccines must be transported in an emergency situation:

- They should be packed and transported in a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C).
- **Dry ice is never allowed.**
- If a portable freezer unit is not available and the vaccines cannot be packed in a unit that maintains +5°F or colder:
 - Varicella-containing vaccines may be transported and stored at refrigerator temperatures between 36°F and 46°F (2°C to 8°C).
 - Refrigerated varicella-containing vaccines must be used within 72 hours.
 - Remaining refrigerated varicella-containing vaccine must be discarded if it is not used within 72 hours. This is considered a temperature excursion and must be documented on the **Vaccine Incident Response Worksheet** and a **Vaccine Return form completed**. Refreezing varicella-containing vaccines that are stored at refrigerated temperatures is prohibited.

2020 Vaccines for Children (VFC) Vaccine Management Plan

Standard Operating Procedures (SOPs) Template

Indiana State Department of Health- Immunization Division

SUPPLIES FOR TRANSPORT

KEEP A COPY IN YOUR EMERGENCY TRANSPORT CONTAINER



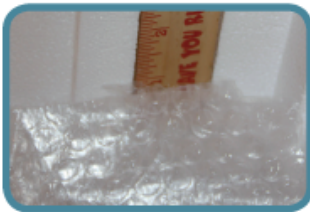
Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.



Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes).



Insulating material — You will need two of each layer

- **Insulating cushioning material** - Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** - Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



Temperature monitoring device - Digital data logger (DDL) with buffered probe. Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

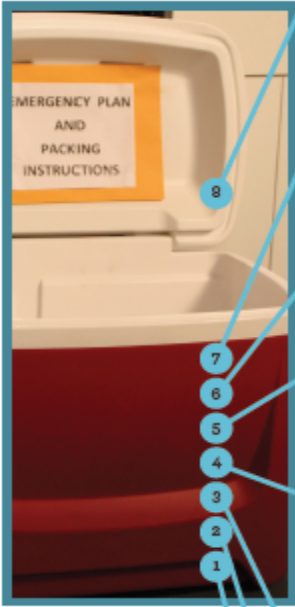
Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of Insulating cushioning material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

PACKING THE VACCINE

Conditioning frozen water bottles (this normally takes less than 5 minutes)

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice “sticks,” put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.



NOTE:
This pack-out can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

<p>8. Temperature Monitoring Device Display (on lid)</p>	<p>Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.</p>
<p>7. Conditioned Water Bottles</p>	<p>Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.</p>
<p>6. Cardboard Sheet</p>	<p>Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.</p>
<p>5. Bubble wrap, packing foam, or Styrofoam™</p>	<p>Insulating cushioning material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™</p>
<p>4. Vaccines, Diluents, and Temperature Monitoring Device Probe</p>	<p>Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe. Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading. Vaccines – Stack boxes of vaccines and diluents on top of insulating material.</p>
<p>3. Bubble wrap, packing foam, or Styrofoam™</p>	<p>Insulating cushioning material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).</p>
<p>2. Cardboard Sheet</p>	<p>Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.</p>
<p>1. Conditioned Water Bottles</p>	<p>Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.</p>

UNLOADING PACKED VACCINE

Arrive at Destination

- Before opening cooler-** Record time, temperature and all needed information on the **VFC Vaccine Emergency Transport Log**
- Storage-** quickly transfer boxes of vaccines to appropriate storage units
- Troubleshooting-** If there was a temperature excursion during transport, label all affected vaccines DO NOT USE and store at appropriate temperatures. Complete a **Vaccine Incident Response Worksheet**.

VACCINE TRANSFER PROCEDURES

Vaccine transfers involve the physical transfer of VFC vaccines and CHIRP inventory adjustments based on removal and receipt of VFC vaccines. Transfers are highly discouraged and should be rare events due to the possibilities of cold chain violations. Transfers of private-purchased vaccines are up to the discretion of the owning facility and are not subject to approval or guidance from ISDH.

As a standard practice, partially-used multi-dose vials and opened vaccine boxes should not be transferred. It is the discretion of the ISDH Staff Representative to allow transfers under 10 doses, based on need and cost efficiency.

Transfer of vaccines should only occur for the following reasons:

- Unopened vaccine is three months (90 days) or less from expiration date, AND provider will not be able to use inventory prior to expiration date
- An area outbreak has resulted in unexpected surge of walk-in patients
- VFC clinic closure/disenrollment requiring vaccine redistribution to other VFC providers
- Clinics needing to offload and transfer vaccines due to seasonal closure (such as a School Health Clinic)

If your office is moving locations and transferring vaccine, you MUST contact your ISDH Staff representative. Relocating without notification may jeopardize VFC program enrollment status.

All VFC providers MUST obtain prior approval before transferring any VFC vaccine to another VFC provider*.

- Contact your ISDH Staff Representative to issue a transfer request. Please allow up to ten (10) business days for transfer approvals. All vaccine transfers are at the discretion of ISDH staff.
- **All VFC vaccine transfers MUST follow ISDH vaccine transport procedures, including submission of a completed Vaccine Transfer form to vaccine@isdh.in.gov or fax to 317-233-3719 within 24 hours of the transfer**

***Emergency vaccine transport to another VFC provider is NOT considered a vaccine transfer and does not require advanced approval.**

OFFSITE CLINICS: VACCINE TRANSPORT, VACCINE USE, AND TEMPERATURE MONITORING PROCEDURES

Effective January 1, 2018, providers can no longer transport vaccines to/from offsite clinics in hard-side coolers or coolers available at general merchandise stores. **All offsite clinics coordinated by VFC providers that plan on using VFC vaccine for patients must obtain approval from ISDH at least two weeks prior to the event.**

Offsite Clinic Requirements:

1. All clinics must use portable vaccine refrigerators/freezers or qualified pack-out units.
2. Digital data loggers with a buffered probe and a current and valid Certificate of Calibration Testing must be placed directly with the vaccines and used to monitor vaccine temperature during transport.
3. If vaccines are transferred to a permanent storage unit at the location of the offsite clinic, the storage unit must meet the minimum storage requirements for storage of VFC vaccines and the unit must have been monitored prior to the clinic day with a digital data logger.
4. Vaccines must be monitored during the clinic using a digital data logger at least once an hour and documented on the **Offsite Clinic VFC Vaccine Temperature Monitoring Log**.
5. Within the 24 hours following completion of the off-site clinic and return of all vaccines to the permanent storage unit, the data logger must be downloaded and the report must be reviewed and sent to the respective field representative.

Use of Multi-dose vials and Diluent at Offsite Clinics

- When a multi-dose vial is used, Food and Drug Administration (FDA) regulations require that it be used only by the provider's office where it was first opened. A partially-used vial may be transported to or from off-site clinics operated by the same provider as long as the cold chain is properly maintained. *However, such a vial may not be transferred to another provider or transported across state lines.*
- Diluent should travel with its corresponding vaccine to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution
- Diluent should be transported according to its manufacturer guidelines, and should not come into direct contact with conditioned water bottles because of the potential for freezing.

Varicella-Containing Vaccines Transport to Offsite Clinics

- CDC strongly discourages transport of varicella-containing vaccines to off-site clinics, because varicella-containing vaccines (VAR, Varivax; MMRV, ProQuad; ZOS, Zostavax) are sensitive to temperature excursions.
- Providers who choose to transport these vaccines to an offsite clinic must follow the appropriate procedures:
 - Transport in a portable freezer unit that maintains temperatures between -58°F and +5°F (-50°C and -15°C)
 - The use of **dry ice is not allowed**, even for temporary storage.
 - Discard reconstituted vaccine if not used within 30 minutes.

EXCEPTION- REQUIRES APPROVAL

- Varicella-containing vaccines may be transported and stored at refrigerator temperatures at offsite clinics, between 36°F and 46°F (2°C to 8°C). This vaccine can be refrigerated for up to 72 continuous hours prior to reconstitution at the offsite clinic. **ISDH must approve the number of anticipated doses for use.**
- Varicella-containing vaccine stored at refrigerator temperatures must be discarded if it is not used within 72 hours. This is considered a temperature excursion and must be documented on the **Vaccine Incident Response Worksheet and a Vaccine Return form completed**. Refreezing varicella-containing vaccines that are stored at refrigerated temperatures is prohibited.

EMERGENCY VACCINE MANAGEMENT ACTION PLANS

Use the following guidance for emergency situations such as power outages, natural disasters, and equipment failure. This guidance also applies for any event that results in vaccine storage outside of recommended temperature range. *This includes [responding to temperature excursions identified during DDL report reviews](#) and those [caused by human error \(i.e. unit unplugged, unit door left open\)](#)*

USEFUL EMERGENCY NUMBERS

Service	Name	Phone #	E-mail
ISDH Staff Representative			
ISDH Immunization program		800-701-0704	vaccine@isdh.in.gov
Utility Company			
Building Maintenance			
Building Alarm Company			
Refrigerator/Freezer Alarm Company			
Refrigerator/Freezer Repair			
Point of Contact for Vaccine Transport			

EMERGENCY CONTACTS- In an emergency, contact the following people in the order listed:

Role/Responsibility	First & Last Name	Phone #	E-mail Address
1.			
2.			
3.			
4.			

BACK-UP POWER SOURCES AND ALTERNATIVE LOCATIONS

Does the clinic have a generator?

If so, (a) where is it located, and (b) how often does it receive testing/maintenance?

If your clinic does not have a generator, and/or your vaccine storage unit fails, it might be necessary to transport vaccines to an alternate storage location either within your building or offsite (e.g., a local hospital or another VFC provider).

Identify an alternate location(s) that has vaccine storage units and temperature monitoring devices that meet VFC Program requirements. Note: *At least one alternative location should be offsite in the event power outages affect your entire building.*

Alternate Vaccine Storage Unit/Site	Physical Address	Contact Person	Phone #	E-mail Address

Location of emergency packing supplies

CHECKLIST: BEFORE AN EMERGENCY

Proper preparation for emergency situations is essential for protecting the viability of vaccines. Use the following checklist to help ensure practices are ready for planned or unexpected situations that might impact vaccines.

Step	Description
1.	Maintain current emergency contact information for key practice staff.
2.	Maintain current contact information for alternate vaccine storage location(s), including the facility name, address, and telephone number.
3.	Be familiar with backup power sources for your office (e.g. back-up generator)
4.	Stock vaccine packing and transport supplies, including back-up digital data loggers
5.	Review (at least annually) the steps key practice staff must take to protect vaccines during all emergency situations, including how to pack and transport vaccines

CHECKLIST: SCHEDULED POWER OUTAGE

Step	Description
1.	Notify the emergency contacts listed in this emergency plan and the ISDH staff representative
2.	Contact an alternate storage facility to verify they can accept the vaccines and make a plan for transport. Update all contacts of proposed plan.
3.	Pack and transport vaccine per ISDH procedures
4.	Once power has been restored, verify storage units are functioning properly and that temperatures have stabilized within acceptable temperature ranges
5.	Notify and update emergency contacts
6.	Follow the same vaccine transport procedures and return vaccine to its original storage unit

DURING AN EMERGENCY CHECKLISTS

Select the “During an Emergency” checklist that best applies to your emergency.

Power Outage/Natural Disaster

Follow these instructions during vaccine-related emergencies in compliance with VFC Program requirements and best practices.

Step	Description		
1.	Keep calm and do not open the unit.		
2.	Place a “DO NOT OPEN” sign on vaccine storage unit(s) and leave door(s) shut to conserve cold air mass.		
3.	Notify the emergency contacts listed in this emergency plan		
4.	Note the time the outage started and storage unit temperatures at the time of power loss; continue monitoring temperatures, even if they go out of range		
5.	Assess the situation to determine the cause of the power failure and estimate the time it will take to restore power.		
6.	<table border="0"> <tr> <td style="vertical-align: top;"> A. If the outage is expected to be longer than 2 hours*: <ol style="list-style-type: none"> Contact the alternate storage facility to verify they can accept the vaccines. If vaccines will be relocated, refer to the Vaccine Transport section for instructions. If transport or relocation is not feasible (e.g., alternate location not available or travel conditions are unsafe), keep vaccine storage units closed and notify the ISDH Staff Representative </td> <td style="vertical-align: top; padding-left: 20px;"> B. If the outage is short-term and/or will be rectified in a less than 2 hours <ol style="list-style-type: none"> Keep units closed and do not allow staff to use any vaccine Do not transport or discard vaccine </td> </tr> </table>	A. If the outage is expected to be longer than 2 hours*: <ol style="list-style-type: none"> Contact the alternate storage facility to verify they can accept the vaccines. If vaccines will be relocated, refer to the Vaccine Transport section for instructions. If transport or relocation is not feasible (e.g., alternate location not available or travel conditions are unsafe), keep vaccine storage units closed and notify the ISDH Staff Representative 	B. If the outage is short-term and/or will be rectified in a less than 2 hours <ol style="list-style-type: none"> Keep units closed and do not allow staff to use any vaccine Do not transport or discard vaccine
A. If the outage is expected to be longer than 2 hours*: <ol style="list-style-type: none"> Contact the alternate storage facility to verify they can accept the vaccines. If vaccines will be relocated, refer to the Vaccine Transport section for instructions. If transport or relocation is not feasible (e.g., alternate location not available or travel conditions are unsafe), keep vaccine storage units closed and notify the ISDH Staff Representative 	B. If the outage is short-term and/or will be rectified in a less than 2 hours <ol style="list-style-type: none"> Keep units closed and do not allow staff to use any vaccine Do not transport or discard vaccine 		
7.	Monitor vaccine storage unit temperatures until power is restored		
8.	Once power has been restored, follow all steps listed in After an Emergency		

Human error (Unit unplugged/unit door left open)

Step	Description
1.	Upon hearing the alarm, identify and rectify the issue immediately (i.e. plug the unit in, shut the door)
2.	Keep calm and do not open the unit
3.	Place a “DO NOT OPEN” sign on vaccine storage unit(s) and leave door(s) shut
3.	Notify the emergency contacts listed in this emergency plan
4.	Note the time the alarm started and storage unit temperatures at the time of alarm
5.	Monitor the temperatures until they have stabilized to acceptable ranges
6.	Follow the After an Emergency Step 6 if vaccines were exposed to out-of-range temperatures
7.	Educate staff based on the identified human error issue (i.e. never unplug a vaccine storage unit)

2020 Vaccines for Children (VFC) Vaccine Management Plan

Standard Operating Procedures (SOPs) Template

Indiana State Department of Health- Immunization Division



AFTER AN EMERGENCY CHECKLISTS

Power outage/natural disaster/human error

Follow these step-by-step instructions after vaccine-related emergencies in compliance with VFC Program requirements and best practices.

Step	Description
1.	Verify storage units are functioning properly.
2.	Note the time that power was restored and/or temperatures stabilized within range, and document the storage unit temperatures (CURRENT, MIN and MAX) at that time
3.	Once vaccine storage unit temperatures have stabilized, notify the emergency contacts
4.	If vaccines were transported due to an emergency situation: <ul style="list-style-type: none"> A. Follow the same transportation procedures and transfer vaccine back to its original storage unit (Refer to the Vaccine Transport section for instructions.)
5.	If vaccines were maintained at required temperatures: <ul style="list-style-type: none"> A. Remove the “DO NOT OPEN” sign from storage unit(s) B. Notify staff that vaccines may be used
6.	If vaccines were exposed to out-of-range temperatures: <ul style="list-style-type: none"> A. Label affected vaccines “Do Not Use” and keep them in the storage unit in acceptable temperatures- DO NOT remove them from the unit or discard the vaccine B. Document and report the excursion using the Vaccine Incident Response Worksheet. Submit the completed worksheet to your ISDH Staff Representative C. <i>If vaccines are deemed spoiled by the manufacturer:</i> <ul style="list-style-type: none"> o Complete a Vaccine Return form and submit it to ISDH Immunization program via email vaccine@isdh.in.gov or fax 317-233-3719 o Adjust inventory in CHIRP o Place a vaccine order in VOMS <p style="color: red; margin-top: 10px;"><i>When calling the manufacturer, you must speak to a person and obtain a case number for your temperature excursion. If the manufacturer is closed, keep the vaccines labeled, “Do Not Use,” until you can get a case number.</i></p>

Responding to an identified temperature excursion from DDL report review

Step	Description
1.	Keep calm and do not open the unit that was affected.
2.	Place a “DO NOT OPEN” sign on vaccine storage unit(s) and leave door(s) shut
3.	Notify the emergency contacts listed in this emergency plan
4.	Note the time the excursion started and ended as well as the minimum and maximum temperatures reached during the excursion event
5.	Complete a Vaccine Incident Response Worksheet
6.	<ul style="list-style-type: none"> A. If the storage units were the contributing factor to the excursion and need to be repaired, AND the vaccine is still viable: <ul style="list-style-type: none"> B. If the storage units were the contributing factor to the excursion and need to be repaired, AND the

2020 Vaccines for Children (VFC) Vaccine Management Plan Standard Operating Procedures (SOPs) Template

Indiana State Department of Health- Immunization Division



1. Contact an alternate storage facility to verify they can accept the vaccines.
2. Refer to the [Vaccine Transport section](#) for instructions to safely relocate vaccines.
3. Then follow [After an Emergency: Storage Unit Repair/Replacement](#)

vaccine is **NOT** viable follow the [After an Emergency Step 6C](#).

Then follow [After an Emergency: Storage Unit Repair/Replacement](#)

Storage Unit Repair/Replacement

Step	Description
1.	Facilitate all storage unit repairs and or replacements. Involve your ISDH Staff Representative in any unit purchase to ensure it meets requirements.
2.	Once repairs are completed, or a new unit is installed, verify the unit is functioning properly. Record date of repair and update/add any unit information on the Vaccine Storage Unit list contained within this plan.
3.	Monitor unit temperatures using a DDL/continuous monitoring device and record all temperatures on the corresponding unit temperature log. Water bottles should be placed in the unit at this time. It make take 2 to 7 days to stabilize the temperature in a newly installed or repaired unit. Do not move vaccines back to the unit until stable temperatures have been reached and approval received from your ISDH Staff Representative.
4.	Once you have obtained the number of temperature recordings/days (up to 7 days) per your ISDH Staff Representative guidance, submit temperature logs for review. Await instruction for transport or to continue monitoring the unit.
5.	When approval is received, follow the Vaccine Transport guidelines and return vaccine to its original (or replaced, if applicable) storage unit
6.	Continue daily routine temperature monitoring

The Centers for Disease Control and Prevention (CDC) requires all Vaccines for Children (VFC) providers to develop, maintain, and implement a Vaccine Management Plan **with detailed and up-to-date standard operating procedures for routine and emergency vaccine management**. The Indiana State Department of Health (ISDH) Immunizations Division has prepared this document as a template to assist your office with this requirement. Please refer to ISDH VFC Program Policies for supplemental information and guidance.

For access to the most recent policies, documents and changes, as well as, ISDH staff directory and maps, please go to <https://www.in.gov/isdh/27938.htm>.

Signatory Page:

I have read through the current Vaccine Management Plan. I fully understand this practice's responsibilities regarding publicly-funded vaccines.

Employee Signature	Title/Position	Date