Kansas Department of Health and Environment
Division of Public Health

Vaccine Management Best Practices

Kayla Burton & Gail Pickering | June 2023

What does vaccine management entail...?

Vaccine Storage

- Storage unit
- Storage unit placement
- Temperature Monitoring Device (TMD)
- Monitoring vaccine temperature and equipment
- Power supply
- Regular maintenance

Vaccine Inventory

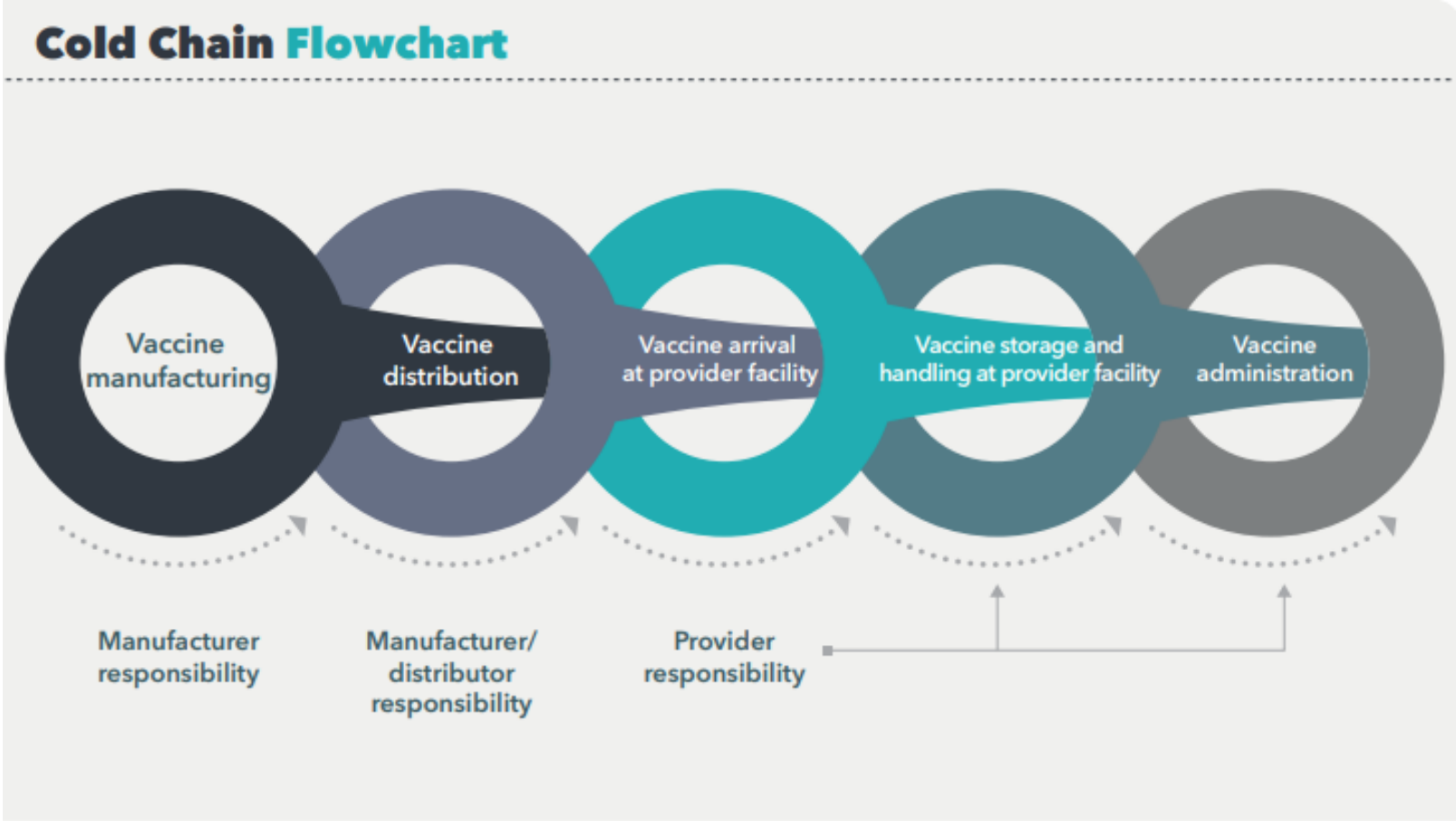
- Vaccine counting
- Ordering
- Delivery
- Unpacking
- Stock rotation
- Organization

  - Expiration dates
  - BUD dates
  - Vaccine returns and waste

Why is vaccine storage so important?

- Ensures efficacy of the vaccines
- Prevents the need for revaccination which increases confidence in vaccines and staff
- Limits significant financial loss due to wasted vaccine
- Improper storage and handling of vaccines can decrease the potency resulting in inadequate immune responses in patients and poor protection against disease

When does the storage best practice begin?



Begins with the vaccine manufacturer and does not end until the vaccine is administered

Source: cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

What type of storage unit is best to use to store vaccines?

A. Dormitory style
B. Upright
C. Stand alone
D. Freezer/Refrigerator combo with two doors to separate freezer and fridge
E. Pharmaceutical Grade

What type of storage unit is allowed to store vaccines?

Two Door Style Home Units

Publicly funded vaccine **requirement**: The refrigerator is approved to hold vaccines, (providing it holds steady temperatures), but **NOT** the freezer.

Regular Maintenance of Your Storage Units

- Check the power supply of the storage unit
- Make sure “do not unplug” and “do not adjust” signs are posted where staff can see
- Check and clean coils of the storage unit per manufacturer guidance
- Check seals and door hinges
- Defrost freezer as ice builds up
- Wipe down the interior shelves to discourage bacteria and fungus growth
- Check backup generators quarterly and have generator serviced annually

cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Temperature Monitoring Device (TMD)

Publicly funded vaccine must be monitored with a digital data logger (DDL) as the temperature monitoring device (TMD).

A DDL is very accurate and can report detailed information on all temperatures recorded at past and present intervals, it also shows how long a unit has been running outside of the required temperature range (possible temperature excursion).

Why use a Digital Data Logger (DDL)?

- A buffered temperature probe measures actual vaccine temperatures accurately.
- Temperatures can be downloaded from a DDL to a computer or retrieved from a website.
- Reports can be downloaded and saved.
- They are required to have a current certificate of calibration.

A Three Step Best Practice for Dailiy Temperature Monitoring

MIN/MAX

Must check min/max twice daily. Once the clinic opens and one hour prior to closing.

SET

Press the set button after you review the min/max temps. This will time stamp your DDL report.

WHAT'S THE TEMP NOW?

Check the current temp of the storage unit everytime you access vaccines in the fridge. Must document twice daily.

NO MORE THAN 3 DAYS CAN PASS WITHOUT MANUALLY CHECKING AND RECORDING TEMPS

Storage Unit Temperatures in Celsius

Refrigerator	2° C to 8° C
Freezer	-50° C to -15° C
Ultra Cold	-90° C to -60° C

Conditioned Water Bottles

- Place water bottles on the top shelf and the floor of the unit and place bottles in the door racks.
- Putting water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure.
- Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance

Manual Temperature Review and Documentation

If you have a storage unit or device that uses continuous monitoring, you still need to visualize your temperatures.

Technology is not infallible

Monitoring Devices

What devices are available to receive alerts on your cell phone if there is a change in temperature?

- Temp Stick
- SensorPush Wireless Thermometer & Hygrometer
- MarCell Cellular Monitoring System
- Sensaphone
- Stanley
- Sonicu

Vaccine Inventory

Scheduling and receiving vaccines

- Maintain the cold chain
- Unpack as soon as possible
- Use a stock record to account document vaccine inventory
- Tally sheets can help with reconciliation at the end of each month

Designate a vaccine coordinator

- In charge of rotating diluent and vaccine stock at least once a week, to make sure vaccines that expire the soonest will be used first
- Removing expired vaccines from the fridge/freezer and remove them from the inventory in WebIZ

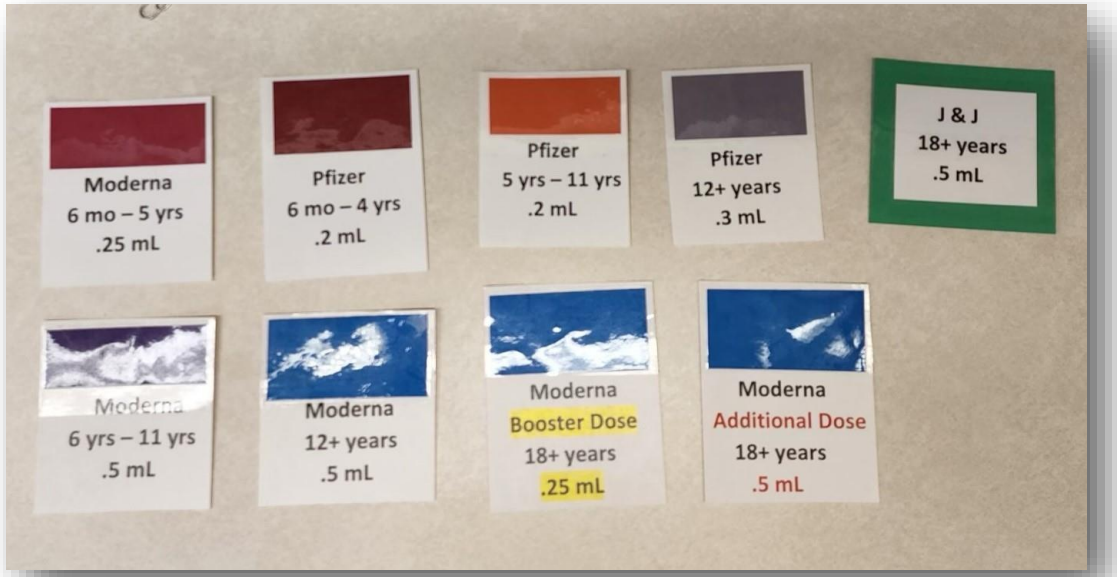
Organization and Storage of Vaccine

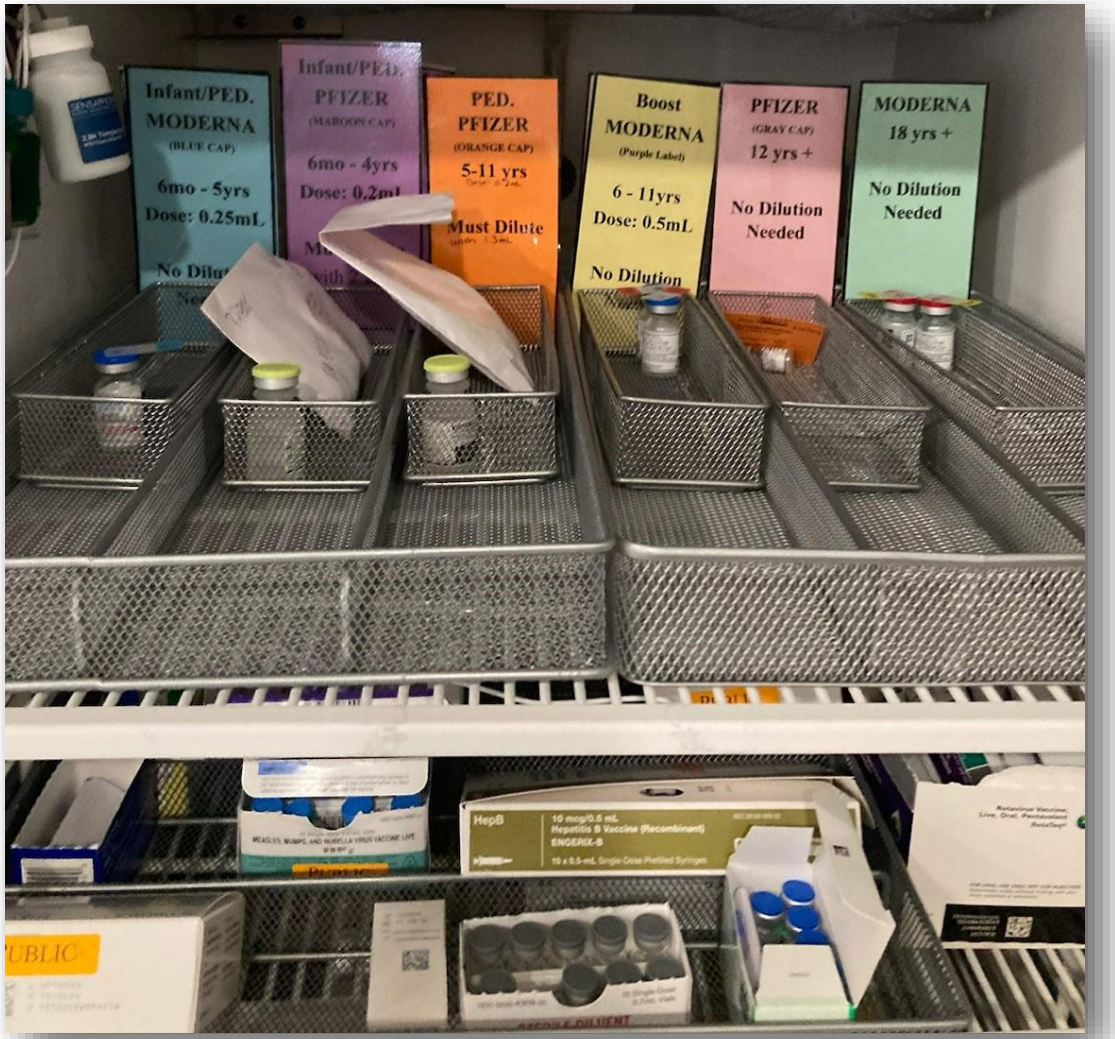
1. **Original Packaging -** Store vaccine in its original packaging. In their upright positions. Protected from light.
2. **Positioning** - Vaccines and diluents should be placed 2-3 inches away from the unit walls, ceiling, floor and door.
3. **Labeling** - Label shelves and containers to clearly identify where each type of vaccine is stored.
4. **Similar Packaging -** Keep pediatric vaccines and adult vaccines separated in their group and on different shelves.

Organization and Storage of Vaccine

5. **Avoid overcrowding -** Air flow is vital to maintain the temperature. Do not store in the door, in refrigerator drawers or under the cooling vents.
6. **One and only -** Only vaccines, diluent and conditioned water bottles should be in the refrigerator.
7. **Row by row -** Arrange vaccines and diluents in rows and allow space in between for air flow.
8. **Expiration dates -** Place those vaccines that will expire first in front.

Best Practice Examples





Best Practice Examples

Best Practice Examples

2022–2023 Influenza Season Vaccine Label Examples

Healthcare professionals can easily confuse different influenza vaccines within the storage unit. Labeling the area or container where vaccines are stored can help staff quickly locate and choose the correct vaccine—perhaps preventing a vaccine administration error. Depending on how vaccines are organized within storage units, labels can be placed on vaccine storage containers or bins, or directly attached to shelving where the vaccines are placed. Other helpful strategies to identify the correct vaccine include col
additional information such
and Prevention (CDC) alsc
temperature range, and to
https://www.cdc.gov/vaccir

The following labels are ex
based on manufacturer pa
Immunization Practices (A
https://www.cdc.gov/mmwr
recommendations to ensur

Vaccine Label Examples

Staff can easily become confused about vaccines within the storage unit because there are so many brands and formulations available. Labeling the area where vaccines are stored can help staff quickly locate and choose the correct vaccine—perhaps preventing a vaccine administration error. Depending on how vaccines are organized within the storage unit, labels can be placed on containers or bins or directly attached to shelves where vaccines are placed. Other helpful strategies to prevent vaccine administration errors include color-coding labels (e.g., one color for pediatric and another for adult vaccines) and providing additional information such as age indications or other information unique to the vaccine.

In addition, some vaccines must be reconstituted before administration. These vaccines have two components—a lyophilized vaccine and a diluent that must be mixed together. **The lyophilized vaccine should only be reconstituted or mixed using the diluent supplied by the manufacturer**. Consider posting reminders or labeling vaccines to remind staff to reconstitute certain vaccines prior to administration.

The following labels are examples that may be used to help organize vaccines. Labels are based on recommendations from the Advisory Committee on Immunization Practices (ACIP) and may include indications different from those of the Food and Drug Administration. The Centers for Disease Control and Prevention (CDC) also recommends vaccines be stored in the original packaging to protect the contents from light, to help maintain the recommended temperature range, and to help prevent administration errors.

Note: Some vaccine preparations are being transitioned from vials and prefilled syringes that contain latex (natural rubber) to vials and prefilled syringes that are not made with natural rubber latex. Read the package insert that accompanies the product to check for the presence of natural rubber or latex.

National Center for Immunization and Respiratory Diseases
Immunization Services Division

Updated 4/25/2022

Haemophilus influenzae type b-Containing Vaccines

Hib (ActHIB)

Ages: 6 weeks through 4 years
Use for: Any dose in the series
Route: Intramuscular (IM) injection

Reconstitute Hib powder ONLY with manufacturer-supplied 0.4% sodium chloride diluent

Beyond Use Time: If not used immediately after reconstitution, store at 2°C to 8°C (36°F to 46°F) and discard if not used within 24 hours. Shake well prior to administration.

Hib (PedvaxHIB)

Ages: 6 weeks through 4 years
Use for: Any dose in the series
Route: Intramuscular (IM) injection

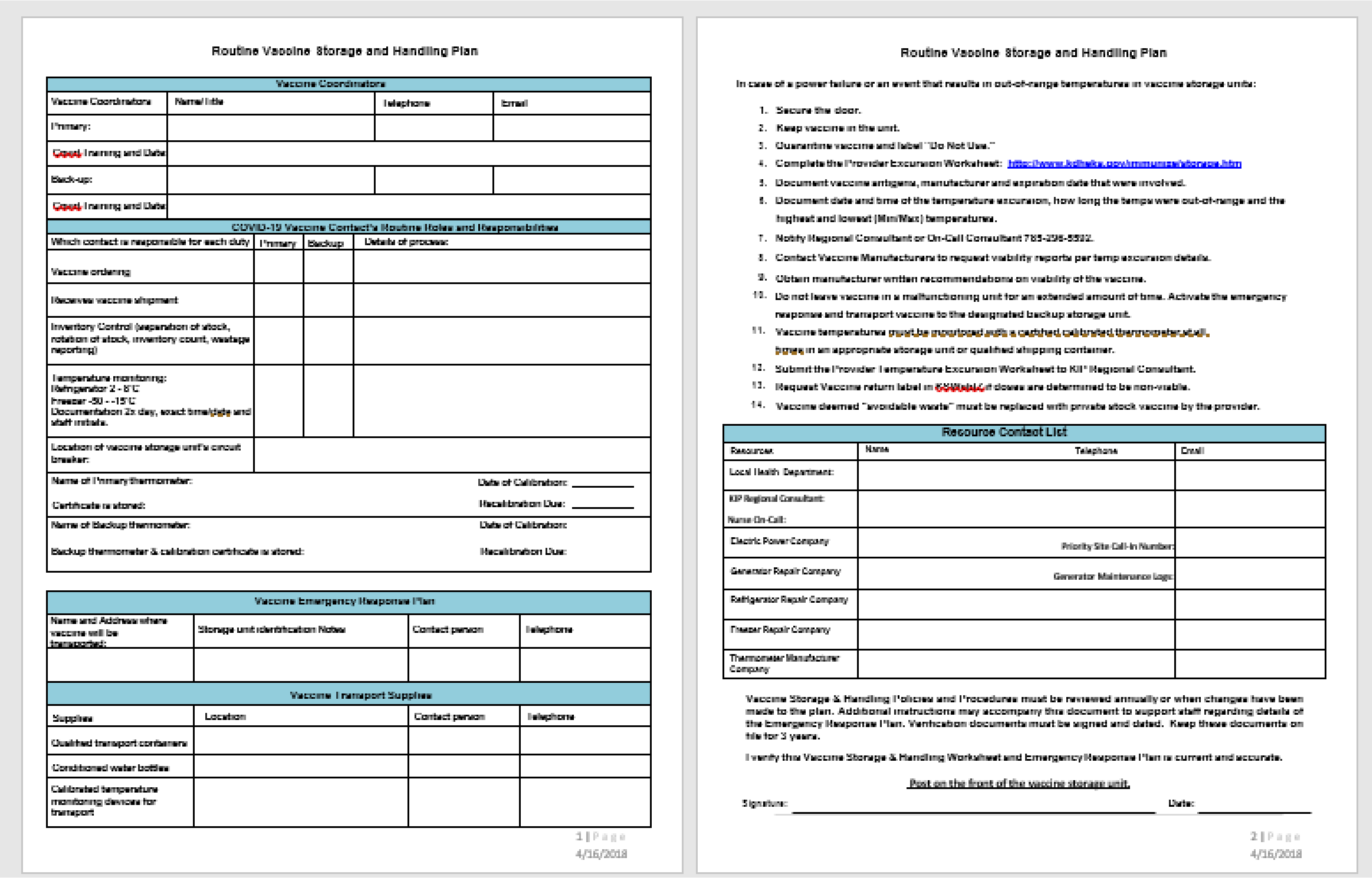
Hib (Hiberix)

Ages: 6 weeks through 4 years
Use for: Any dose in the series
Route: Intramuscular (IM) injection

Reconstitute Hib powder ONLY with manufacturer-supplied 0.9% sodium chloride diluent

Beyond Use Time: If not used immediately after reconstitution, store at 2°C to 8°C (36°F to 46°F) and discard if not used within 24 hours. Shake well prior to administration.

Vaccine Storage and Handling Plan



Routine Vaccine Storage and Handling Plan

Vaccine Coordinators			
Vaccine Coordinators	Name/Title	Telephone	Email
Primary:			
Cert. Training and Date			
Back-up:			
Cert. Training and Date			

COVID-19 Vaccine Contact's Routine Roles and Responsibilities			
Which contact is responsible for each duty	Primary	Backup	Details of process:
Vaccine ordering			
Receives vaccine shipment			
Inventory Control (separation of stock, rotation of stock, inventory count, wastage reporting)			
Temperature monitoring: Refrigerator 2 - 8°C Freezer -50 - -15°C Documentation 2x day, exact time/date and staff initials.			
Location of vaccine storage unit's circuit breaker:			
Name of Primary thermometer:			Date of Calibration:
Certificate is stored:			Recalibration Due:
Name of Backup thermometer:			Date of Calibration:
Backup thermometer & calibration certificate is stored:			Recalibration Due:

Vaccine Emergency Response Plan			
Name and Address where vaccine will be transported:	Storage unit identification Notes	Contact person	Telephone

Vaccine Transport Supplies			
Supplies	Location	Contact person	Telephone
Qualified transport containers			
Conditioned water bottles			
Calibrated temperature monitoring devices for transport			

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Routine Vaccine Storage and Handling Plan

In case of a power failure or an event that results in out-of-range temperatures in vaccine storage units:

1. Secure the door.
2. Keep vaccine in the unit.
3. Quarantine vaccine and label "Do Not Use."
4. Complete the Provider Excursion Worksheet: http://www.kdheks.gov/immunize/storage.htm
5. Document vaccine antigens, manufacturer and expiration date that were involved.
6. Document date and time of the temperature excursion, how long the temps were out-of-range and the highest and lowest (Min/Max) temperatures.
7. Notify Regional Consultant or On-Call Consultant 785-296-5592.
8. Contact Vaccine Manufacturers to request viability reports per temp excursion details.
9. Obtain manufacturer written recommendations on viability of the vaccine.
10. Do not leave vaccine in a malfunctioning unit for an extended amount of time. Activate the emergency response and transport vaccine to the designated backup storage unit.
11. Vaccine temperatures must be monitored with a certified calibrated thermometer at all times in an appropriate storage unit or qualified shipping container.
12. Submit the Provider Temperature Excursion Worksheet to KIP Regional Consultant.
13. Request Vaccine return label in KSWebIZ if doses are determined to be non-viable.
14. Vaccine deemed "avoidable waste" must be replaced with private stock vaccine by the provider.

Resource Contact List			
Resources	Name	Telephone	Email
Local Health Department:			
KIP Regional Consultant: Nurse On-Call:			
Electric Power Company	Priority Site Call-In Number:		
Generator Repair Company	Generator Maintenance Logs:		
Refrigerator Repair Company			
Freezer Repair Company			
Thermometer Manufacturer Company			

Vaccine Storage & Handling Policies and Procedures must be reviewed annually or when changes have been made to the plan. Additional instructions may accompany this document to support staff regarding details of the Emergency Response Plan. Verification documents must be signed and dated. Keep these documents on file for 3 years.

I verify this Vaccine Storage & Handling Worksheet and Emergency Response Plan is current and accurate.

Post on the front of the vaccine storage unit.

Signature: ______________________ Date: ____________

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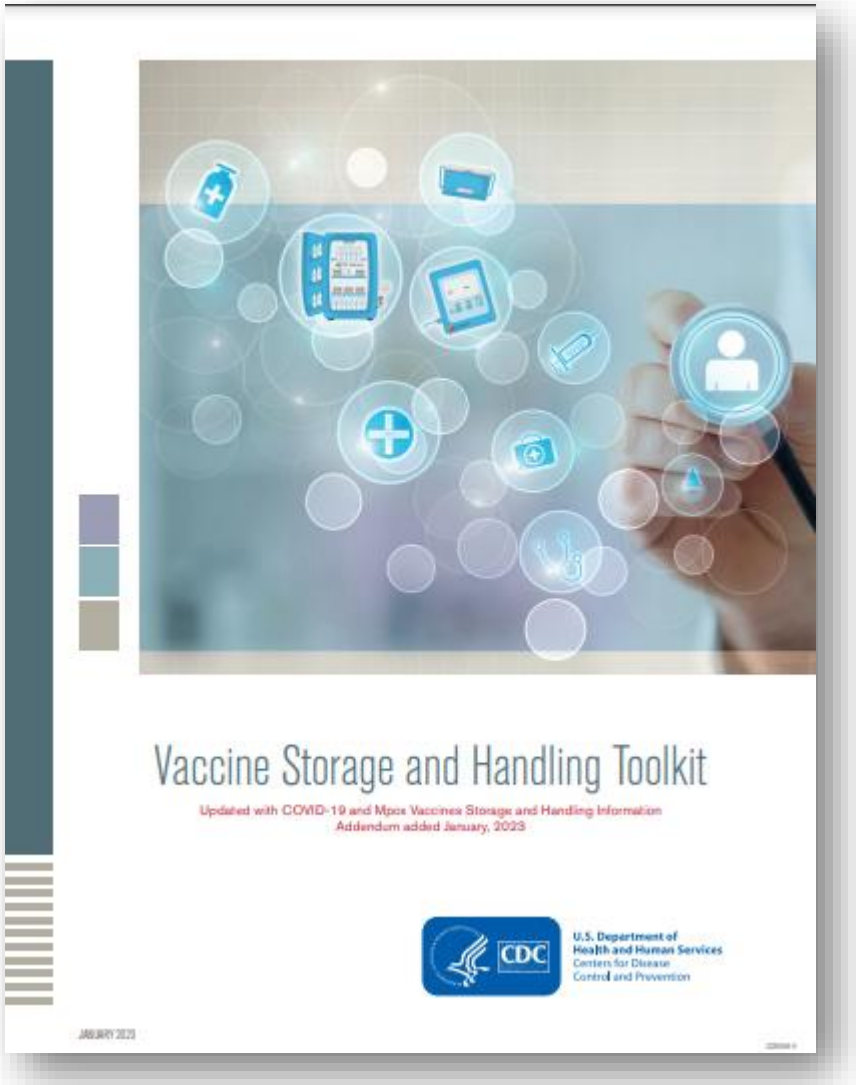
Imperative to Vaccine Management Best Practices is to have a detailed Vaccine Storage and Handling Plan

- Vaccine Coordinators contact information
- Coordinators roles and responsibilities
- Vaccine emergency response plan
- Vaccine transport supplies
- Resource contact list

Vaccine Storage and Handling Toolkit

UPDATED
JANUARY 2023



Resources

CDC STORAGE AND HANDLING TOOLKIT
cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

CDC VACCINE STORAGE AND HANDLING RESOURCES.
cdc.gov/vaccines/hcp/admin/storage/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Frecs%2Fstorage%2Fdefault.htm

Patricia Beckenhaupt, RN, MS, MPH, CDC Public Health Analyst. VACCINE STORAGE AND HANDLING. February 19, 2015.

Handout. Immunize.org (formerly Immunization Action Coalition (IAC). CHECKLIST FOR SAFE VACCINE STORAGE AND HANDLING.

National Institute of Standards and Technology. RELIABLE VACCINE STORAGE.
nist.gov/programs-projects/reliable-vaccine-storage

Vaccine Management Best Practices

Thank you/Questions

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