#### National Center for Immunization and Respiratory Diseases



### EPIDEMIOLOGY **EVENTION** OF PREVENTABLE **Vaccine Storage and Handling** DISEASES 🤝 14TH EDITION **Pink Book Web-on-Demand Series** July 18, 2024 Liz Velazquez, RN, BSN, COHN-S Nurse Educator Immunization Services Division



- Describe the fundamental principles of the immune response.
- Describe immunization best practices.
- Describe an emerging immunization issue.
- For each vaccine-preventable disease, identify those for whom routine immunization is recommended.
- For each vaccine-preventable disease, describe characteristics of the vaccine used to prevent the disease.
- Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.

### **Continuing Education Information**

- To claim continuing education (CE) for this course, please follow the steps below by July 1, 2026.
- Search and register for course WD4810-071824 in CDC TRAIN.
- Pass the post-assessment at 80%.
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- If you have any questions, contact CDC TRAIN at <u>train@cdc.gov</u> or CE Coordinator, Melissa Barnett, at <u>MBarnett2@cdc.gov</u>

### **Disclosure Statements**

- In compliance with continuing education requirements, all planners and presenters must disclose all financial relationships, in any amount, with ineligible companies during the previous 24 months as well as any use of unlabeled product(s) or products under investigational use.
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### **Disclosure Statements**

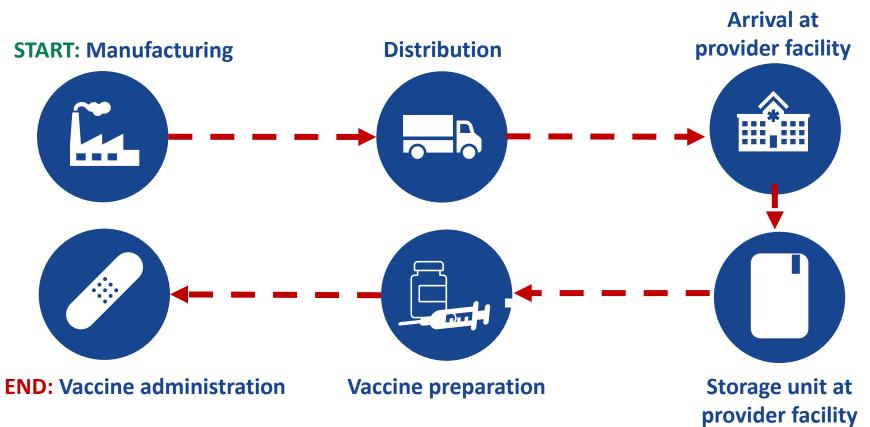
The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention. Vaccine Storage and Handling Overview

### **Impact of Improper Vaccine Storage and Handling**

- Improper vaccine storage and handling can result in:
  - Vaccines that are not viable
  - Unnecessary revaccination
  - Cost to facility, staff, and patients
  - Diminished trust in your practice and staff...and in vaccinations

### **Vaccine Cold Chain**

### Vaccine Cold Chain



Pinkbook | Vaccine Storage and Handling | CDC

### Why does cold chain matter?

- Vaccine potency reduced with improper storage:
  - Overexposure to heat
  - Freezing temperatures
  - Exposure to light
- Once potency is lost, it cannot be restored.

### What Is Needed to Maintain a Cold Chain?

- You, well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management and procedures





## **Staff and Training**

### **Vaccine Coordinator Recommendations**

#### Primary coordinator

- Responsible for ensuring all vaccines are stored and handled properly
- Expert on routine and emergency standard operating procedures (SOPs)

#### Alternate coordinator

- Expert that can assist primary and fulfill duties in their absence
- All other staff
  - May be trained to complete duties



### **Primary and Alternate Vaccine Coordinator Duties**

- Order vaccines
- Oversee proper receipt and storage of vaccine deliveries
- Maintain vaccine inventory information
- Organize and monitor vaccines within storage units
- Rotate stock and remove expired vaccine from storage units
- Set up temperature monitoring devices
- Check and record minimum/ maximum temperatures daily

- Respond to temperature excursions (out-of-range temperatures) and equipment failures
- Oversee proper vaccine transport (when necessary)
- Oversee emergency preparations
- Create and update storage and handling SOPs

### **Storage and Handling SOPs**

• Facilities should develop and maintain clearly written, detailed, and up-to-date storage and handling SOPs for three major areas:



### **Staff Training**

- Complete training:
  - As part of employee orientation
  - Annually as a refresher
  - When new vaccines are added
  - When recommendations are updated

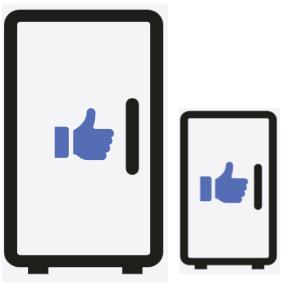


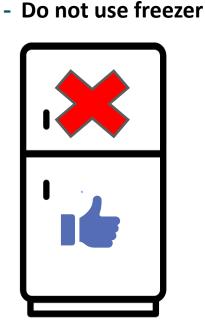
# Vaccine Storage and Temperature Monitoring Equipment

### **Equipment: Vaccine Storage Units (1)**

Preferred: Purpose-built or pharmaceutical-grade units

- Large, compact, or combo





Acceptable alternative:

Household-grade units

! Never use a dorm-style unit!!



### **Equipment: Vaccine Storage Units (2)**



#### **Ultra-cold freezer**

Between -90°C and -60°C (-130°F and -76°F)



**Standard freezer** 

Between -50°C and -15°C (-58°F and +5°F)



Refrigerator Between 2°C and 8°C (36°F and 46°F)

### **Equipment: Temperature Monitoring Devices (TMDs)**



- **Recommended** A digital data logger (DDL) with these features:
  - A detachable buffered probe
  - Able to measure minimum and maximum temperatures
  - Uncertainty of +/-0.5°C (+/-1°F)
- Other features
  - Alarm
  - Low battery indicator
  - At least 30-minute reading rate

### **Certificate of Calibration**

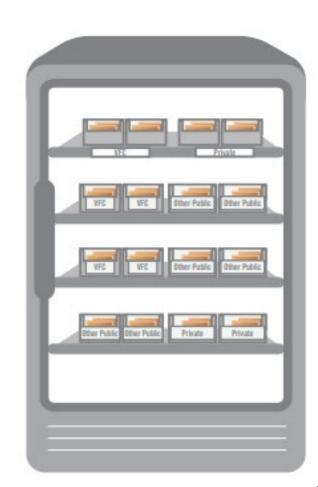
- DDLs must be calibrated every two to three years, or per the manufacturer's suggested timeline.
- Certificate should include:
  - Model/device name or number
  - Serial number
  - Date of calibration
  - Confirmation that the instrument passed testing
  - Recommended uncertainty of +/-0.5°C (+/-1°F) or less





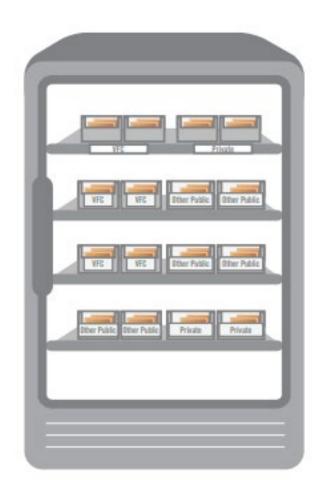
### **Storage Unit Best Practices (1)**

- Store in the original packaging with lids closed in separate containers.
- Place earliest expiration dates in the front.
- Label shelves and vaccine containers.
  - Vaccine Label Examples (cdc.gov)
- Store vaccines with similar names or packaging on separate shelves or storage units.
- Avoid danger zones.
- Use water bottles appropriately.
- Only store vaccines, diluents, and water bottles.



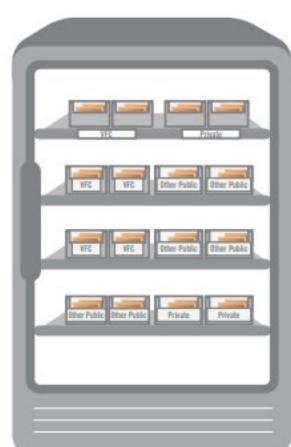
### **Storage Unit Best Practices (2)**

- Store in the original packaging with lids closed in separate containers.
  - Allow 2 to 3 inches between vaccine containers and the storage unit walls.
  - Store diluent with the corresponding refrigerated vaccine, whenever possible.
- Place earliest expiration dates in the front.



### **Storage Unit Best Practices (3)**

- Store in the original packaging with lids closed in separate containers.
- Place earliest expiration dates in the front.
- Label shelves and vaccine containers.
  - Vaccine Label Examples (cdc.gov)
- Store vaccines with similar names or packaging on separate shelves or storage units.
- Avoid danger zones.
- Use water bottles appropriately.
- Only store vaccines, diluents, and water bottles.



### **Storage Unit Best Practices (4)**

- Store in the original packaging with lids closed in separate containers.
- Place earliest expiration dates in the front.
- Label shelves and vaccine containers.
  - Vaccine Label Examples (cdc.gov)
- Store vaccines with similar names or packaging on separate shelves or storage units.
- Avoid danger zones.
- Use water bottles appropriately.
- Store only vaccines, diluents, and water bottles.

#### **How to Store Vaccines**

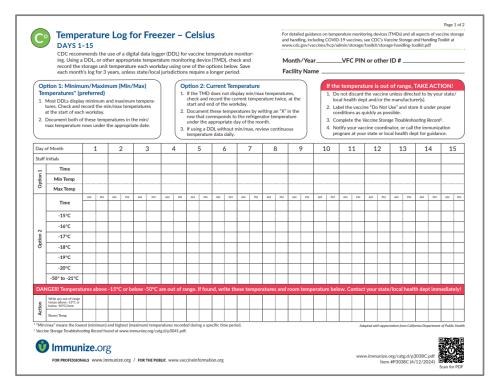




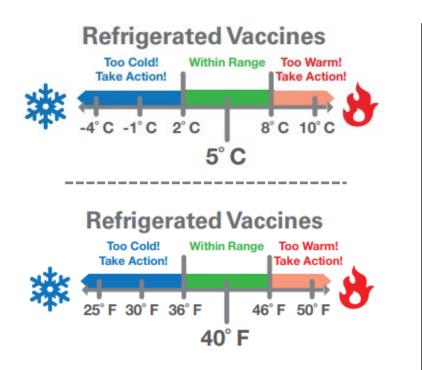
# Vaccine Temperature Management

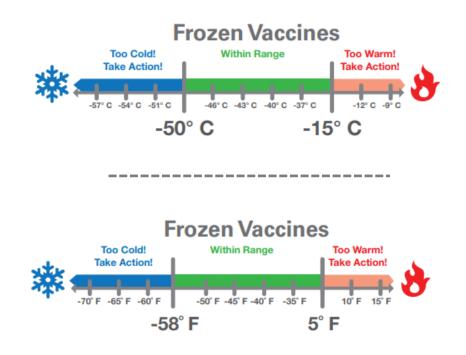
### **Monitoring Storage Unit Temperatures**

- Preferred: Check and record minimum and maximum temperatures once each workday, preferably in the morning.
  - If your TMD displays current temperature only, check and record temperatures two times a day, at the start and end of the workday.



### **Recommended Storage Unit Temperature Ranges**





### **Temperature Excursion**

- Any reading outside the recommended ranges in the package insert
- Requires immediate action
- Manufacturers determine viability
- Refer to the Storage and Handling Toolkit for detailed guidance



### **Temperature Excursion Recommendations**

- 1. Notify the primary/alternate vaccine coordinator or supervisor immediately.
- 2. Notify staff by labeling exposed vaccines "DO NOT USE" and storing at appropriate temperatures; **do not discard exposed vaccines**.
- 3. Document the event.
- 4. Implement your facility SOPs to adjust unit temperature to the appropriate range.
- 5. Contact your immunization program and/or vaccine manufacturer(s) for further guidance.
- 6. Complete documentation of the event, including actions taken and results.



#### Fill in the blanks.

Read and record the \_\_\_\_\_ and

\_\_\_\_\_ temperatures of the

vaccine storage unit \_\_\_\_\_ each

day.





Fill in the blanks.

# Read and record the <u>minimum</u> and <u>maximum</u> temperatures of the vaccine storage unit <u>once</u> each day.

### **Vaccine Inventory Management**

### **Unpacking Vaccine Deliveries**

# Maintain cold chain by immediately checking and storing vaccines upon arrival:

- 1. Unpack
- 2. Examine order and document:
  - Damage
  - Receipt of order
  - Expiration dates
  - Temperature on monitoring device or cold chain monitor (CCM)
- 3. Immediately store at the recommended temperature.
- 4. Follow temperature excursion guidance if CCM temperature is out of range.

### **Inventory Recommendations**

- Use a stock record to account for every vaccine dose from delivery to use.
- Rotate stock so that vaccines that expire first are used first.
  - Rotate stock weekly and when there are deliveries.
  - Remove expired stock and handle per policy.
- Avoid overstocking vaccine supply.
  - Check stock and anticipate upcoming patient needs (flu season, back to school, community event, etc.).

# Vaccine Disposal

- Unused, unopened, expired, or compromised vaccine may be returned for credit.
  - Open or broken vials and activated manufacturer-prefilled syringes usually cannot be returned.
- Most empty vaccine vials do not require a special disposal procedure.
- Medical waste disposal requirements vary from state to state.



# **Vaccine Preparation**

#### **Vaccine Preparation Best Practices**

- Prepare vaccines in a designated area, free from distractions.
- Prepare vaccines only when you are ready to administer them.
  - Activate manufacturer-filled syringes (MFSs) syringes just before administration.
- Only administer vaccines you have prepared.



#### **Pre-Drawing Vaccines**

- Best practice: Use manufacturer-filled syringes whenever possible.
  - Pre-drawing vaccine doses is not recommended.
    - General-use syringes are designed for immediate administration, not storage.
    - Increased risk for vaccination errors if syringes are not appropriately labeled or administered by another person
    - Vaccine wastage occurs when too many doses are pre-drawn or stored improperly.

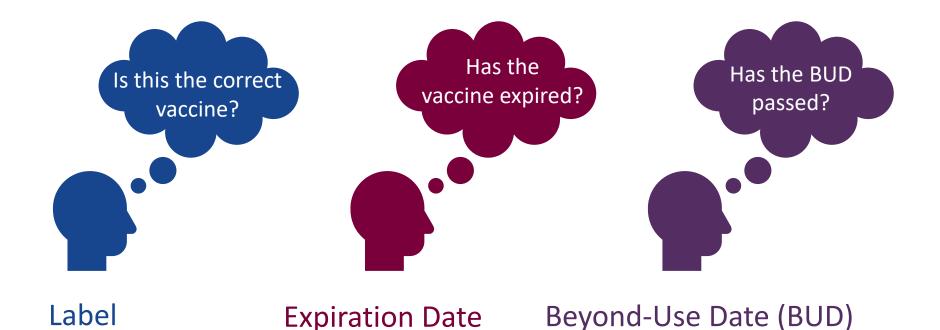


#### **Pre-Drawn Vaccine Recommendations for Large Events**

- 1. Set up a separate administration station for each vaccine type.
- 2. Draw up vaccines only when you are ready for administration.
- 3. Label each pre-drawn syringe with:
  - the vaccine name and dosage,
  - the beyond-use date and time,
  - lot number,
  - the preparer's initials, and
  - any other pertinent information, such as age range

- 4. Draw up no more than one multidose vial (MDV) or 10 doses at one time.
- 5. Monitor patient flow to avoid drawing up unnecessary doses.
- Store pre-drawn vaccines at the manufacturer-recommended temperatures.
- Discard any remaining vaccine in predrawn syringes at the end of the workday.

#### **Triple-Check Before Vaccine Preparation**





# **Expiration Date**

## **Expiration Date**



- The expiration date is the final day that the vaccine can be administered.
- Determined by the manufacturer
- Marked on the vaccine vial and original packaging
- All vaccine products have an expiration date, including diluents.
- Never administer vaccines after the expiration date.

#### Where to Find the Expiration Date



Month, day, and year of expiration

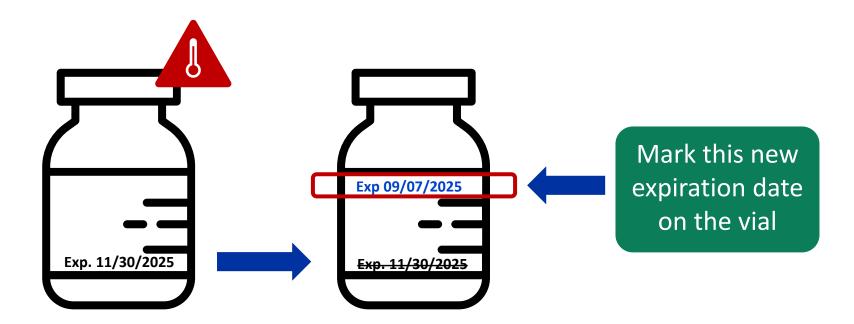


Month and year of expiration

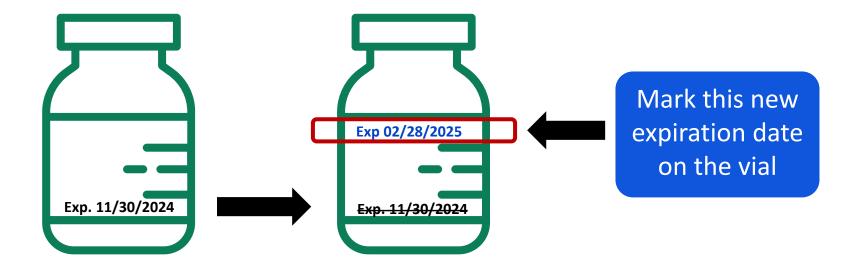


QR Code, website, or phone number

## **Expiration Date Changes: Shortened Expiration**



### **Expiration Date Changes: Extended Expiration**





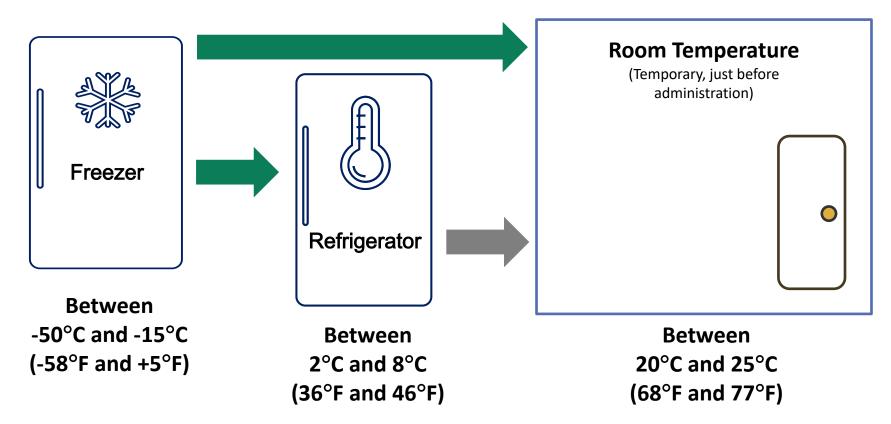
# **Beyond-Use Date/Time**

### What is a Beyond-Use Date (BUD)?

- Date/time generated when a product is transitioned between storage states or altered for patient use
- Varies by product and type of transition
- Calculated by the provider using manufacturer's guidance
- Replaces but does not extend the expiration; always use the earlier date
- Only some vaccines have a BUD.
- Never administer vaccines after the BUD.



## **BUD and Transition Between Temperatures**



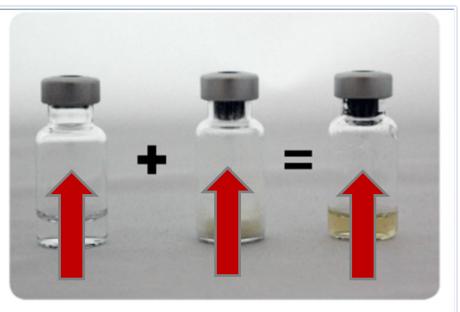
### **BUD and Vaccine in a Multidose Vial**

- Some multidose vials (MDVs) have a specified time frame they should be used after the vial is first punctured.
  - The BUD can vary from hours to days.
- Some MDVs have a specific maximum number of doses that can be withdrawn or punctures to the vial stopper.
  - Discard the vial after reaching the maximum number of doses or punctures.



#### **Reconstituted Vaccines**

- Once mixed with diluent, vaccines have a beyond-use time.
- The beyond-use time can vary from minutes to hours.
- Carefully check the package insert to determine the beyonduse time.
  - Immunize.org has a resource on how to use vaccines with diluents.



Diluent + lyophilized powder = Reconstituted vaccine

#### How is the BUD Calculated?



Day 0: First puncture



Day 28: Mark this BUD on vial



Fill in the blanks.

The

determines

the expiration date and the

calculates

the BUD.





Fill in the blanks.

The **manufacturer** determines the expiration date and the **health care provider** calculates the BUD.

# **Vaccine Transport and Handling**

### **Transport Situations**

- Off-site clinics
- Satellite facilities
- Relocation of stock
- Emergencies



## **Transport Systems**

Container Description	Emergency Transport	Transport to Off-site Clinic or Satellite Facility or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System	Yes	No
Manufacturer's Original Shipping Container	Yes (last resort)	Νο
Food/Beverage Coolers	No	No

#### **Transport Best Practices**

- Include emergency transport guidance in storage and handling SOPs.
- Avoid sunlight and extremes of temperatures.
- Transport only the amount of vaccine needed for the workday.
- Transport diluents with their corresponding vaccines.
- The total time for transport alone or transport plus clinic day is a maximum of 8 hours.
- Promptly move vaccines into storage unit upon arrival.

# **Temperature Monitoring During Transport**

- For any type of transport:
  - Record min/max temps at the beginning of transport and the destination storage unit.
  - Place buffered probe with vaccines.
  - Keep DDL display on top of transport system.
  - Keep the container closed.



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#### Temperature Log

when Transporting Vaccine at Refrigerated Temperatures

#### When transporting refrigerated vaccines, use:

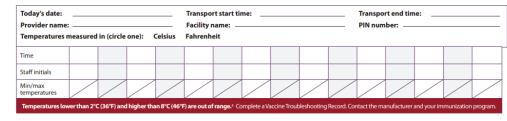
- A portable refrigerator or vaccine storage container qualified to maintain temperatures between 2°C and 8°C (36°F and 46°F).
- A digital data logger (DDL) with a thermal buffer and external temperature display (preferred). Place the probe as close as possible to the vaccine.
- This temperature log to document temperatures and how long the vaccine is in the portable storage container.

#### Temperature monitoring and transport time frames

- Most DDLs display minimum/maximum (min/max) temperatures.\*
- Record the time and min/max temperatures:
- \* At the start of transport
- \* Every time the portable storage container is opened
- When transport is completed
- The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.<sup>±</sup>
- Beyond-use date/time (BUD), if applicable, are included in transport time. For example, if the vaccine may be stored at refrigerated temperature for 120 hours, transport is included in this time frame.

#### If the temperature is out of range, TAKE ACTION!

- 1. Do NOT discard the vaccine.
- 2. Label the vaccine "Do Not Use."
- 3. Complete the Vaccine Troubleshooting Record.
- Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.



After packing the vaccine, open the portable storage container only when necessary.

- If using a company or personal vehicle, transport vaccines inside the passenger compartment (not in the trunk or bed of a truck, which may be too hot or too cold).
- Avoid leaving the portable storage container in direct sunlight or unattended.
- If needed, transport diluents with their corresponding vaccines to ensure there are equal amounts of vaccines and diluents. Follow the manufacturer's guidance for specific temperature requirements for diluents.
- Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's Vaccine Storage and Handling Toolkit for additional guidance.
- Refer to CDC's Vaccine Storage and Handling Toolkit for additional guidance when transporting vaccines.

\* If the DDL does not measure min/max temperatures, check and record temperatures hourly. \* Follow the manufacturer's guidance if it differs from this time frame.

<u>Pinkbook | Vaccine Storage and Handling | CDC</u> Temperature Log when Transporting Vaccine at Refrigerated Temperatures

#### **Emergency Backup Plan**

- Suspend vaccination activities if emergency can be anticipated.
- Establish an agreement with an alternative storage facility.
  - Even if you have an on-site generator
- Transfer vaccine to backup storage units.



# **Emergency Transport Options**

- Keep storage units and containers closed and monitor temperatures.
- Use one of the following transport systems:
  - Qualified containers and pack-outs
  - Portable vaccine unit (if power source available)
  - <u>Packing Vaccines for Transport</u> <u>during Emergencies</u>

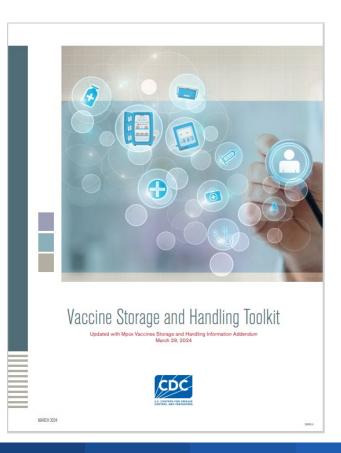




# **Clinical Resources**

# Vaccine Storage and Handling Toolkit

- Primary source for vaccine storage and handling recommendations:
  - Most current recommendations
  - Updated annually to reflect changes in guidance
  - Contains additional resources



### **CDC Resources for Staff Education**

- Multiple storage and handling resources available through CDC website, including:
  - <u>You Calls You Call the Shots: Vaccine</u> <u>Storage and Handling Module</u>
  - <u>Packing Vaccines for Transport</u> <u>during Emergencies</u>
  - Vaccine Storage Temperature Logs
  - Storage and Handling best practice fact sheets

CDC Healthcar	e Providers / Professionals		
Healthcare Professionals / Providers Home	Vaccine Storage and Handling Resources		
Clinical Resources +	Print		
Administration Tools –			
Vaccine Storage & Handling	Recommendations and Guidelines		
Storage and Handling Resources	At a Glance		
Storage and Handling Toolkit	Proper vaccine storage and handling practices play a very important role in protecting		
You Call The Shots: Vaccine Storage and Handling	individuals and communities from vaccine-preventable diseases. Vaccine quality is the shared responsibility of everyone, from the time vaccine is manufactured until it is administered.		
Vaccine Administration +	internal la constanti de		
Vaccines for Children (VFC) +			
VIS			
Reminder Systems and Strategies	Resources on Proper Vaccine Storage and Handling		
Patient Education +	COVID-19 Vaccine Storage Temperature Logs:		
Immunization Training	<u>Refrigerator Storage Temperature Log (Celsius)</u>		
	<u>Refrigerator Storage Temperature Log (Fahrenheit)</u> Ultra-Cold Vaccine Storage Temperature Log (Celsius)		
Vaccine-Preventable Diseases	Ultra-Cold Vaccine Storage Temperature Log (Fahrenheit)		
	<ul> <li>Safe and Proper Sharps Disposal During the COVID-19 Mass Vaccination Campaign</li> </ul>		
Related Links	This fact sheet reinforces how you can protect yourself from needlestick injuries while administering COVID-19 vaccines or while helping at vaccination sites.		
Vaccines & Immunizations	<ul> <li>These storage and handling fact sheets illustrate best practices for both refrigerated and frozen vaccines. Written in plain language, they include assessments to reinforce key points. While they are CDC-developed and branded fact sheets, each contains an area where you can insert your agency's logo.</li> <li>These protocols are approximately the storage of a second storage of the storage.</li> </ul>		
	<ul> <li>Temperature Monitoring Best Practices for Refrigerated Vaccines [2 pages] (Feb 2018) Fahrenheit (F).          [Celsius (C).         </li> </ul>		
	Temperature Monitoring Best Practices for Frozen Vaccines [2 pages] (Feb 2018)     Fahrenheit (E) [10] [Celsius (C) [10]		
	<ul> <li>Storage Best Practices for Refrigerated Vaccines [2 pages] (Feb 2018) Fahrenheit (E)</li> <li>[2] Celsius (C)</li> </ul>		

Storage Best Practices for Frozen Vaccines [2 pages] (Dec 2020)
 Fahrenheit (F) 
 Celsius (C)

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#### **Email us your immunization questions:**



#### **Thank You From Atlanta!**

For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



