



# Vaccine Storage and Handling

## **Pink Book Web-on-Demand Series** **August 2, 2022**

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# Learning Objectives

- Describe the Advisory Committee on Immunization Practices General Best Practice Guidelines on Immunization.
- 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.
- Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

# Continuing Education Information

- CE credit, go to: <https://tceols.cdc.gov/>
- Search course number: **WD4564-080222**
- CE credit expires: **July 1, 2024**
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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.**

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**Overview**

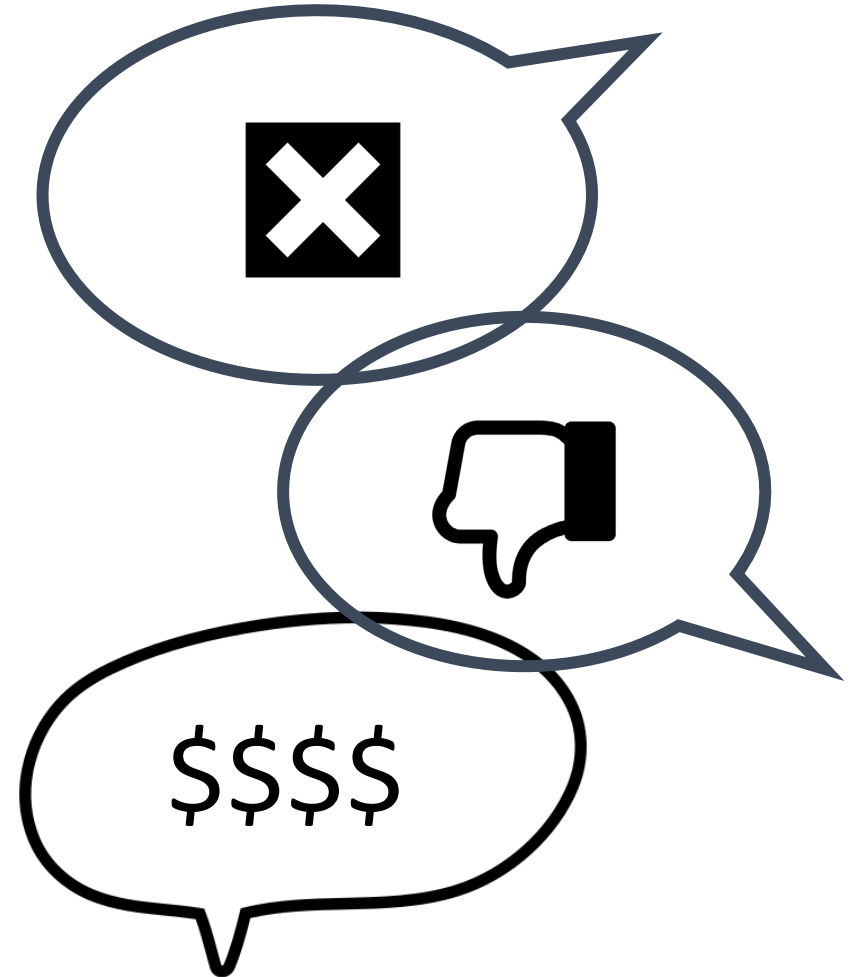
# What Do You Think?

- **Why does vaccine storage and handling matter? Improper storage and handling can:**
  - A. Affect how well vaccines work.
  - B. Erode patient's confidence in a practice or staff
  - C. Increase costs-staff time, replacement products, etc.
  - D. All the above



# What Do You Think? Answer!

- Why does vaccine storage and handling matter?
  - A. Improper storage and handling can affect how well vaccines work.
  - B. Improper storage and handling can erode patient's confidence in a practice or personnel
  - C. Improper storage can increase costs-staff time, replacement products, etc.
  - D. All the above**





# Vaccine Storage Best Practices

- **Facilities should develop and maintain clearly written, detailed, and up-to-date storage and handling standard operating procedures for three major areas:**
  - Routine storage and handling – information for vaccine inventory management.
  - Emergency vaccine storage, handling, and transport – steps to be taken when circumstances might compromise vaccine storage condition.
  - General information – contact information for vaccine manufacturers, equipment service providers, and staff training requirements.

# Staff Training

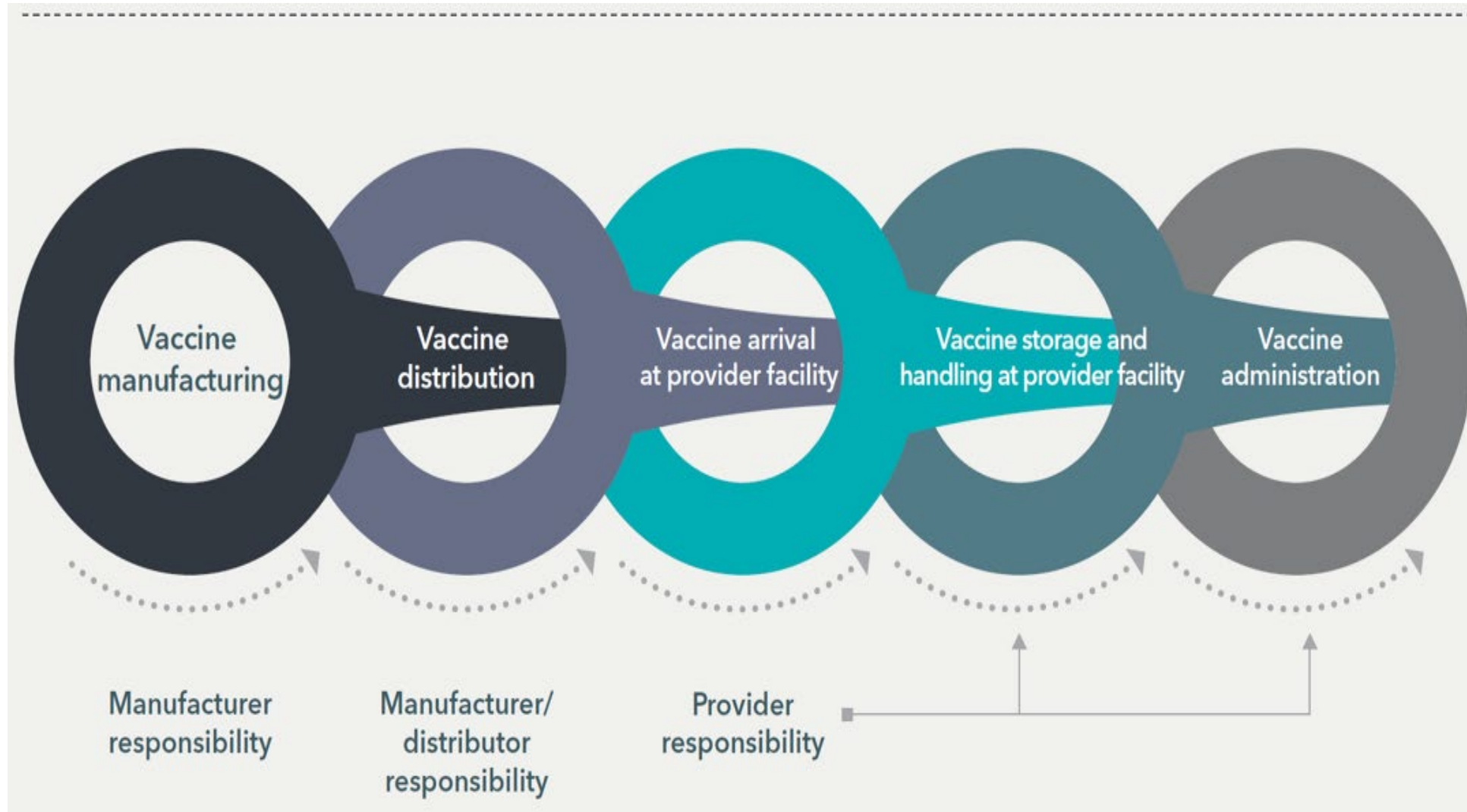
- **Complete training:**
  - As part of employee orientation
  - Annually
  - When recommendations change
  - When new vaccines are added



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**Vaccine  
Cold Chain**

# Vaccine Cold Chain



# Primary and Alternate Coordinator Duties

## ■ Primary coordinator

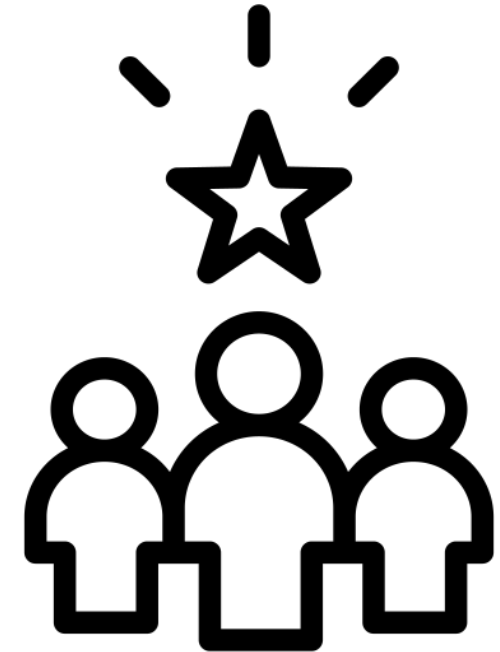
- Responsible for ensuring all vaccines are stored and handled properly
- Expert on routine and emergency SOPs
- Review and update SOPs annually

## ■ Alternate coordinator

- Expert that can assist primary and fulfill duties in their absence

## ■ All other staff

- May delegate duties to trained staff

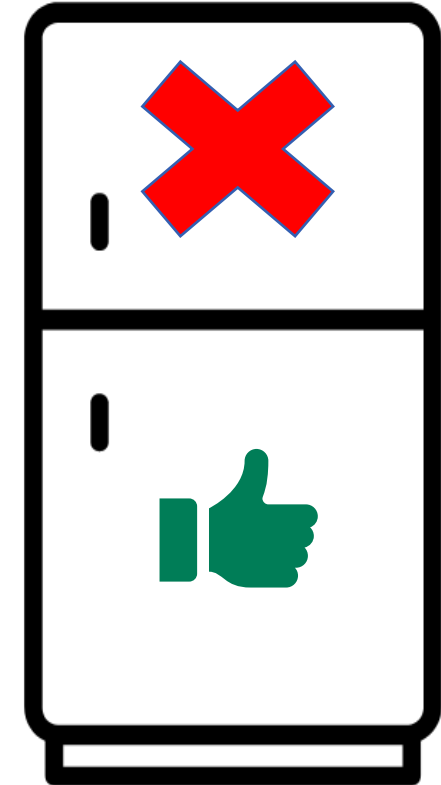
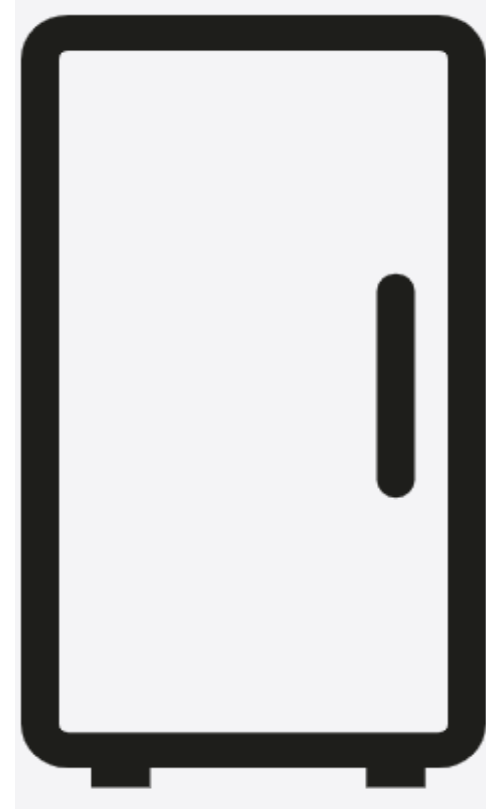


3

**Storage  
Equipment**

# Equipment: Vaccine Storage Units

- Purpose-built or pharmaceutical-grade (large or compact)
- Household-grade
  - Do not use freezer



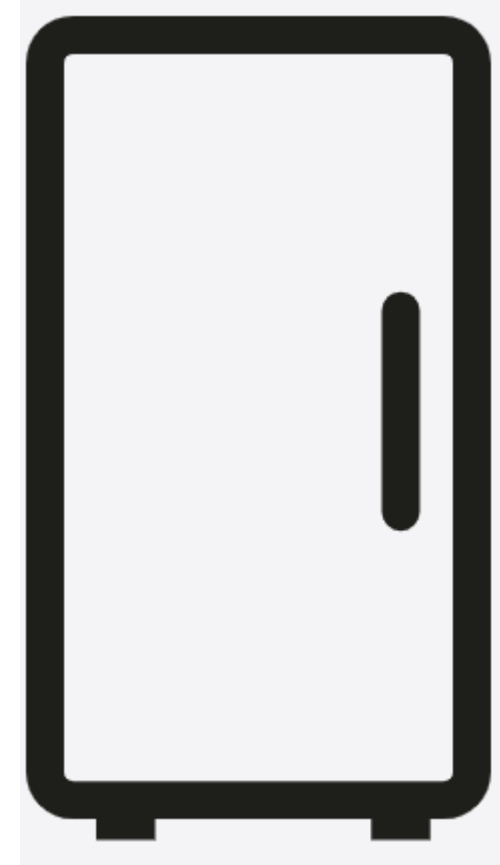
# Equipment: Vaccine Storage Units



**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)

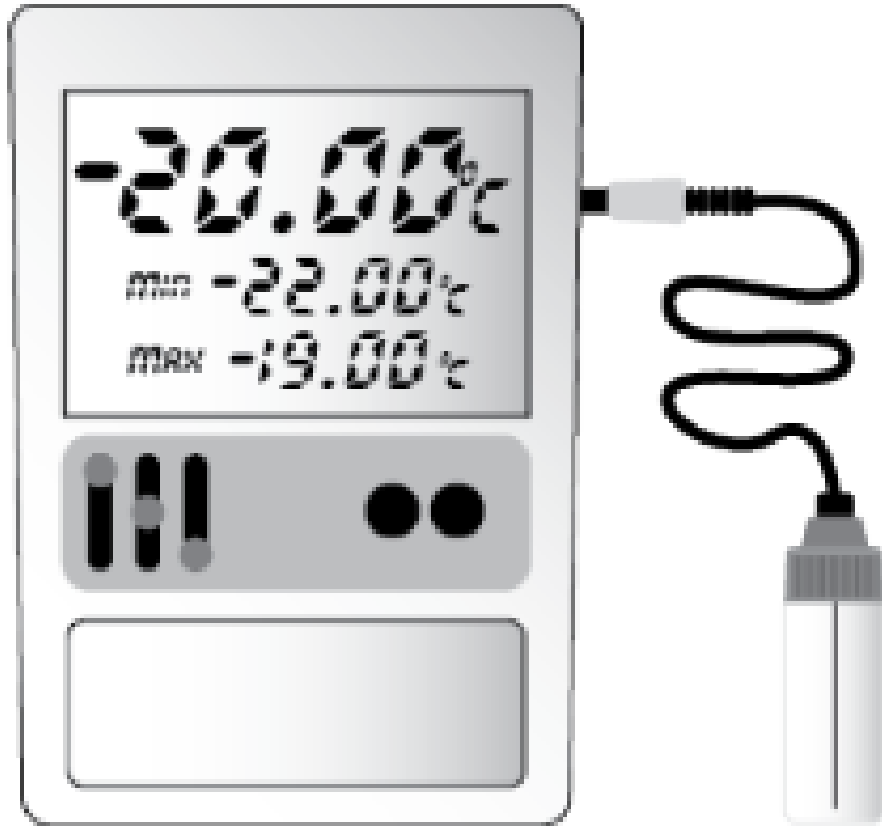


# Organization

- Store in the original packaging
- Label vaccine containers
- Avoid danger zones
- Use water bottles appropriately



# 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  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ )
- **Other features**
  - Alarm
  - Low battery indicator
  - 30-minute reading rate

# Certificate of Calibration

- **Should include:**

- Model/device name or number
- Serial number
- Date of calibration
- Confirmation that the instrument passed testing
- Recommended uncertainty of  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ) or less



# Monitoring Storage Unit Temperatures

- Preferred: Check and record min/max temperature at the start of each workday.
- If the device does not display min/max:
  - Check and record current temperature 2 times, at the start and end of the workday.

**F** **Temperature Log for Freezer – Fahrenheit**  
DAYS 1–15

For information on storage and handling of COVID-19 vaccines, see the **COVID-19 Vaccine Addendum** in CDC's updated **Vaccine Storage and Handling Toolkit** at [www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html).

Month/Year \_\_\_\_\_ VFC PIN or other ID # \_\_\_\_\_ Page 1 of 2  
Facility Name \_\_\_\_\_

**Monitor temperatures closely!**

- Write your initials below in "Staff Initials," and note the time in "Exact Time."
- If using a temperature monitoring device (TMD; digital data logger recommended) that records min/max temps (i.e., the highest and lowest temps recorded in a specific time period), document current and min/max over each workday, preferably in the morning. If using TMD that does not record min/max temps, document current temps twice, at beginning and end of each workday.
- Put an "X" in the row that corresponds to the freezer's temperature.
- If any out-of-range temp observed, see instructions to the right.
- After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

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

- Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
- Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
- Document the action taken on the attached "Vaccine Storage Troubleshooting Record."

| Day of Month                                  | 1     | 2     | 3     | 4     | 5     | 6     | 7     | 8     | 9     | 10    | 11    | 12    | 13    | 14    | 15    |
|---|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Staff Initials                                |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
| Exact Time                                    | AM PM | AM PM | AM PM | AM PM | AM PM | AM PM | AM PM | AM PM | AM PM | AM PM | AM PM | AM PM | AM PM | AM PM | AM PM |
| Min/Max Temp in Unit (since previous reading) |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |

**Danger!** Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!

|      |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| 5°F  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4°F  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 3°F  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2°F  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1°F  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 0°F  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| -1°F |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| -2°F |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| -3°F |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| -4°F |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| -5°F |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**ACCEPTABLE TEMPERATURES**

**ACTION** Write any out-of-range temps (above 5°F or below -5°F) here.  
Room Temperature \_\_\_\_\_

If you have a vaccine storage issue, contact your state or local health department for guidance and help.

IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org

**COVID-19 Vaccine**  
Temperature Log for Refrigerator Vaccine Storage (Celsius) Days 1–15

For information on storage and handling of COVID-19 vaccines, see the **COVID-19 Vaccine Addendum** in CDC's updated **Vaccine Storage and Handling Toolkit** at [www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html).

Month/Year \_\_\_\_\_ VFC PIN or other ID # \_\_\_\_\_ Page 1 of 2  
Facility Name \_\_\_\_\_

**Store COVID-19 vaccines between 2°C and 8°C. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See CDC's Vaccine Storage and Handling Toolkit, COVID-19 Addendum, for additional information.**

**Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)**

- Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
- Document these temperatures in the min/max temperature row under the appropriate date.

**Option 2: Current Temperature**

- If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
- Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
- Review the continuous DDL temperature data daily.

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

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

| Day of the month     | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|----------------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|
| Time                 |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |
| Staff Initials       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |
| Min/max temperatures |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |

**Temperatures lower than 2°C and higher than 8°C are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.**

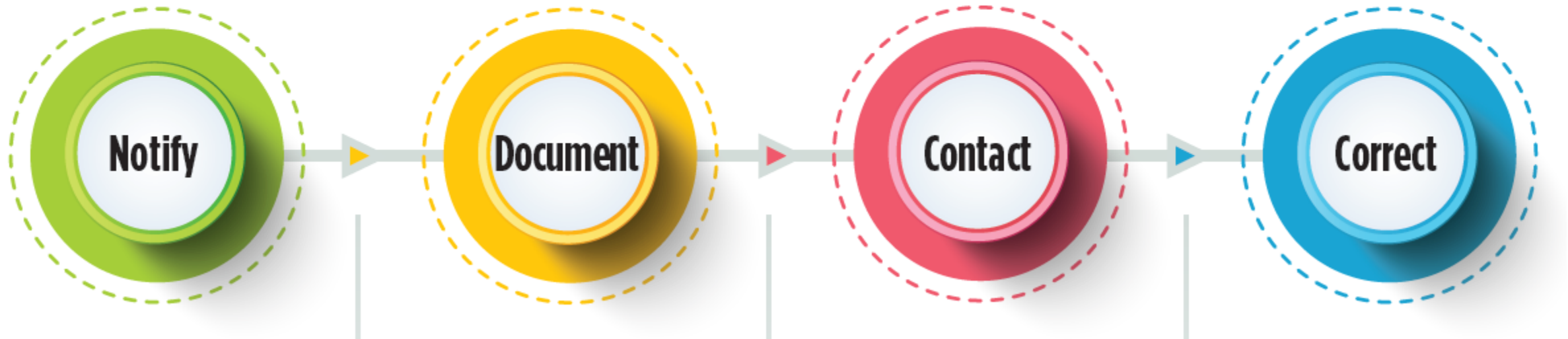
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|----------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Time           | AM | PM | AM | PM | AM | PM | AM | PM | AM | PM | AM | PM | AM | PM | AM | PM | AM | PM | AM | PM |
| Staff Initials |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 2°C            |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 3°C            |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 4°C            |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 5°C            |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 6°C            |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 7°C            |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 8°C            |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

For additional information, see the vaccine manufacturer's product information. Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log.

# Temperature Excursion

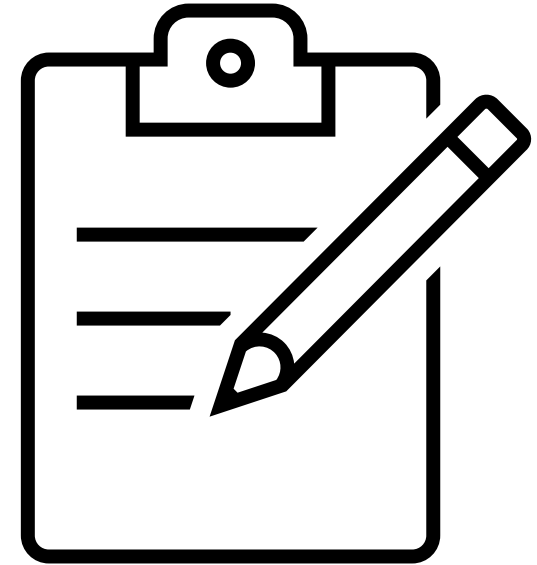
## Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



# What Do You Think?

- Fill in the blank
- Read and record the \_\_\_\_\_ and \_\_\_\_\_ temperatures of the vaccine storage unit \_\_\_\_\_ each day.



# What Do You Think? Answers!

Read and record the minimum and maximum  
temperatures of the vaccine storage unit once each day.

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**Vaccine  
Inventory  
Management**



# Vaccine Delivery

- **Maintain cold chain; immediately check and store vaccines upon arrival:**
  - Unpack
  - Examine and document:
    - Damage
    - Receipt of order
    - Temperature monitoring device or cold chain monitor
    - Expiration dates
  - **Immediately store at recommended temperature.**
  - **Notify manufacturer or others as appropriate if any issues.**

# Vaccine Inventory and Stock Records

## ■ Stock record

- Delivery date
- Name or initials of person who unpacked delivery
- Manufacturer
- Lot number and expiration date
- Number of doses
- Delivery cold chain monitor reading
- Number of doses used and balance

# Other Inventory Issues

- **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 (return, discard, etc.).
- **Avoid overstocking of vaccine supply:**
  - Check stock and anticipate upcoming patient needs (i.e., flu season, back to school, community event, etc.).

# Vaccine Disposal

- **Expired or compromised vaccine**
- **Open or broken vials and manufacturer prefilled syringes**
- **Empty vaccine vials**
- **Medical waste disposal**

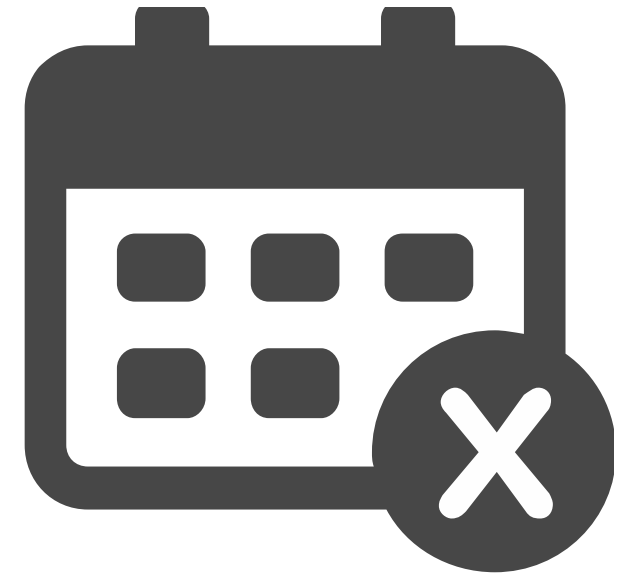
**Vaccine  
Inventory  
Management**



**Expiration  
Date**

# Expiration Date

- All products have an expiration date
- The expiration date is the final day that the vaccine can be administered
- Determined by the manufacturer
- Guarantee of full potency and safety



# Where to Find the Expiration Date



Month, day, and year of expiration



Month and year of manufacture

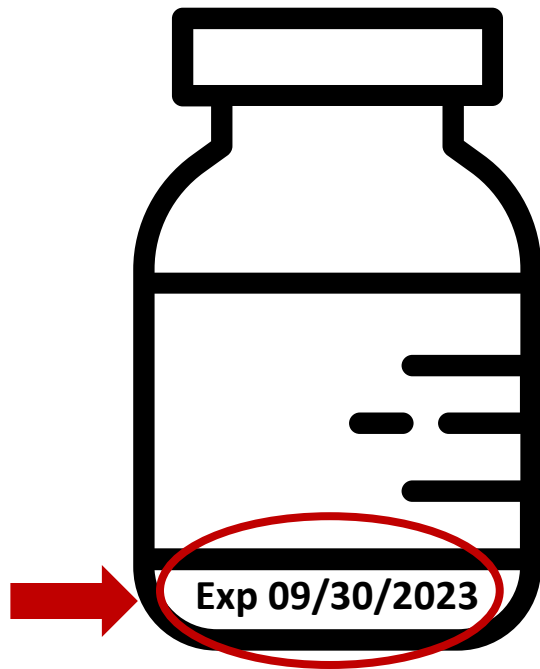


QR Code, website, or phone number



Month and year of expiration

# Where to Find the Expiration Date



Month, day, and year of expiration



Month and year of expiration



QR Code, website, or phone number



Month and year of manufacture



# Where to Find the Expiration Date



Month, day, and year of expiration



Month and year of manufacture



QR Code, website, or phone number



Month and year of expiration

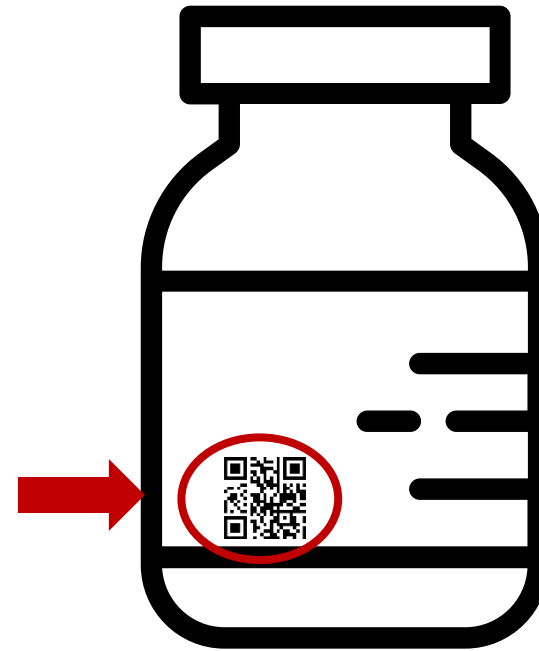
# Where to Find the Expiration Date



Month, day, and year of expiration



Month and year of expiration



QR Code, website, or phone number



Month and year of manufacture

# Where to Find the Expiration Date



Month, day, and year of expiration



Month and year of manufacture



QR Code, website, or phone number



Month and year of expiration

# What Do You Think?

- **The manufacture date is on the vial. How should the expiration date be determined?**
  - A. Specific to the vaccine; follow the manufacturer's guidance.
  - B. 12 months after the manufacture date.
  - C. Refer to the Food and Drug Administration expiration date page.
  - D. None of the above.

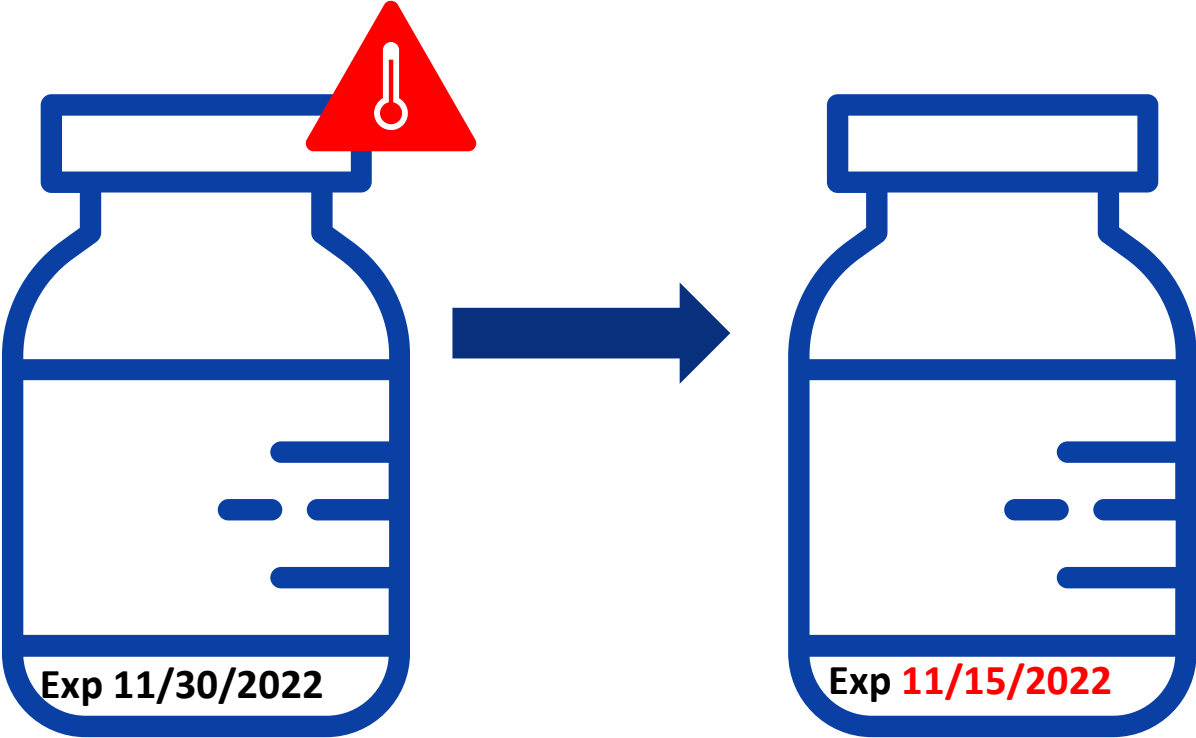


# What Do You Think? Answer!

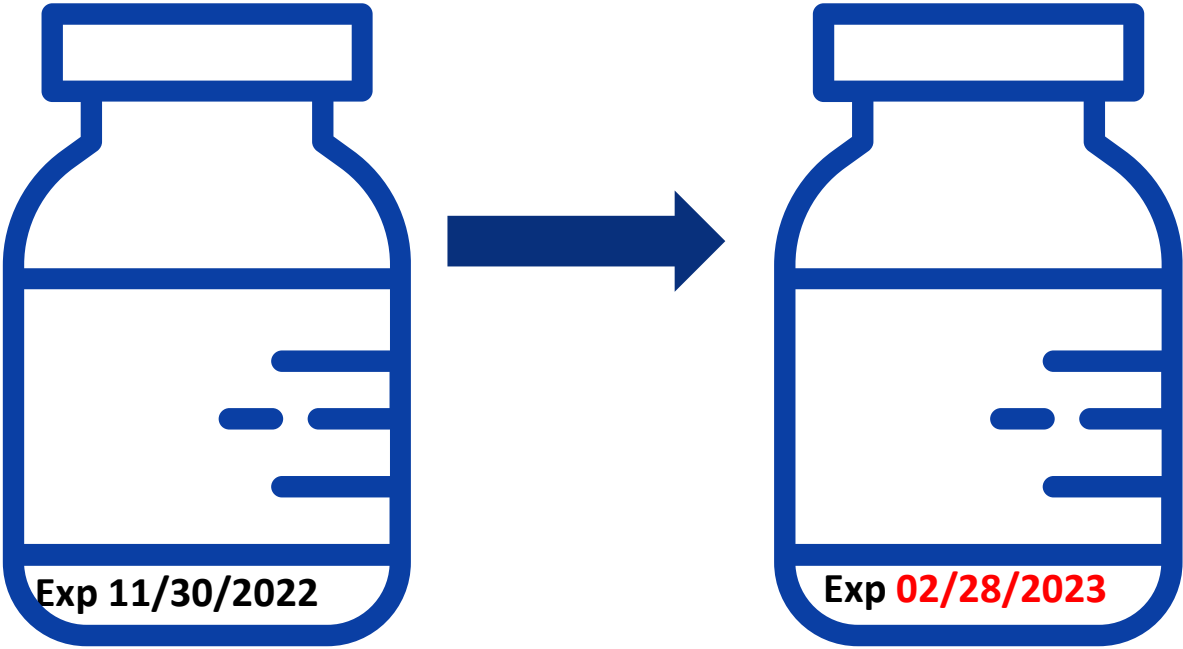
- The manufacture date is on the vial. How should the expiration date be determined?
  - A. Specific to the vaccine; follow the manufacturer's guidance.**
  - B. 12 months after the manufacture date.
  - C. Look up on the Food and Drug Administration expiration date page.
  - D. None of the above.



# Expiration Date Changes: Shortened Expiration



# Expiration Date Changes: Extended Expiration



**Vaccine  
Inventory  
Management**



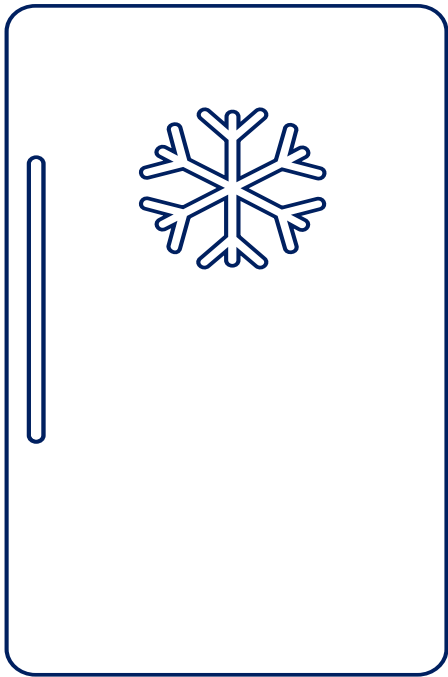
**Beyond-Use  
Date/Time**



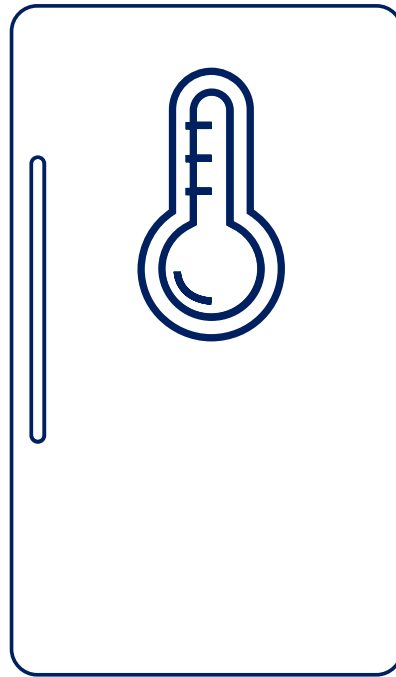
# What is a Beyond-Use Date/Time (BUD)?

- **Date/time generated when a product is transitioned between storage states or altered for patient use**
- **Set by the provider**
- **Replaces but does not extend the expiration; always use the earlier date**
- **Only some vaccines have a BUD**

# BUD and Transition Between Storage States



Freezer



Refrigerator

  
Never use vaccine  
after the  
beyond-use  
date/time!

# How is the BUD Calculated?

- **The designated timeframe is not the same and varies from product to product.**
- **Specific information regarding the BUD and how it is calculated can be found in the vaccine's package insert or Emergency Use Authorization (EUA) Fact Sheet.**

# How is the BUD Calculated?

| December 2022 |    |    |    |    |    |    |
|---------------|----|----|----|----|----|----|
|               |    |    |    | 1  | 2  | 3  |
| 4             | 5  | 6  | 7  | 8  | 9  | 10 |
| 11            | 12 | 13 | 14 | 15 | 16 | 17 |
| 18            | 19 | 20 | 21 | 22 | 23 | 24 |
| 25            | 26 | 27 | 28 | 29 | 30 | 31 |

Day 0: Punctured vial

| January 2023 |    |    |    |    |    |    |
|--------------|----|----|----|----|----|----|
| 1            | 2  | 3  | 4  | 5  | 6  | 7  |
| 8            | 9  | 10 | 11 | 12 | 13 | 14 |
| 15           | 16 | 17 | 18 | 19 | 20 | 21 |
| 22           | 23 | 24 | 25 | 26 | 27 | 28 |
| 29           | 30 | 31 |    |    |    |    |

Day 28: From puncture

# What Do You Think?

- Fill in the blanks below to identify who determines the expiration date and BUD:
- The \_\_\_\_\_ determines the expiration date and the \_\_\_\_\_ determines the BUD.

# What Do You Think? Answers!

- Fill in the blanks below to identify who determines the expiration date and BUD:

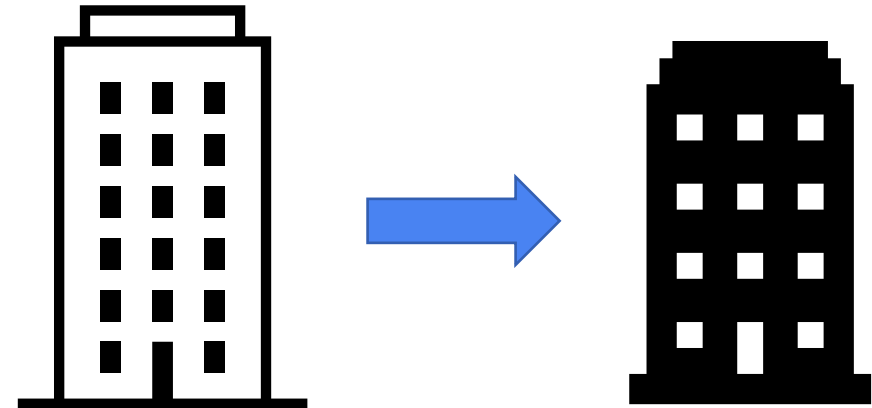
The manufacturer determines the expiration date and the health care provider determines the BUD.

# 5

## **Emergency Vaccine Storage and Handling**

# Emergency Backup Equipment

- **Alternative storage facility**
  - Even if generator is on site
- **Additional storage unit(s)**
  - In use or for emergency use
- **Backup generator**
  - May prevent need for transport
- **Backup battery power source**





# Alternative Facility Inaccessible

- **Keep storage units and containers closed.**
- **Use TMDs**
- **Use one of the following containers:**
  - Qualified containers and pack-outs
  - Portable vaccine unit (if power source available)
  - *Packing Vaccines for Transport during Emergencies* system

# Power Outage

- **Record room temperature**
- **Record min/max storage unit temperatures:**
  - As soon as the power goes out AND during the outage
- **Avoid temperature excursions:**
  - Shift to transport plan or use alternative containers.
- **If temp reading can only be obtained by opening door and there is no alternative facility, wait until power is restored.**
  - Record room and unit temperatures (min/max, if available) and length of time power was off.
  - Follow procedures for temperature excursion, if one occurred.

6

**Vaccine  
Transport**

# Transport Situations

- **Off-site or satellite facilities**
- **Emergencies**

# Transport Systems

## Transport System Recommendations

|   | Emergency Transport    | Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock |
|---|------------------------|---|
| Portable Vaccine Refrigerator or Freezer                              | Yes                    | Yes   |
| Qualified Container and Packout                                       | Yes                    | Yes   |
| <a href="#">Conditioned Water Bottle Transport System<sup>†</sup></a> | Yes                    | No  |
| Manufacturer's Original Shipping Container                            | Yes (last resort only) | No  |
| Food/Beverage Coolers   | No                     | No  |

# Transport Planning

## ■ Protocols

- Identify trained staff
- Vehicles
- Inventory
- Documentation

## ■ Emergencies

- Contact emergency vaccine storage facility
- Suspend operations prior to emergency

## ■ Considerations

- Company or personal vehicle
- Use passenger compartment
- Avoid sunlight
- Monitor vaccine temperature
- Move vaccines into storage unit upon arrival

# Temperature Monitoring during Transport

- **For any type of transport:**

- Use a temperature monitoring device (DDL preferred).
- Place buffered probe with vaccines.
- Keep display on top.

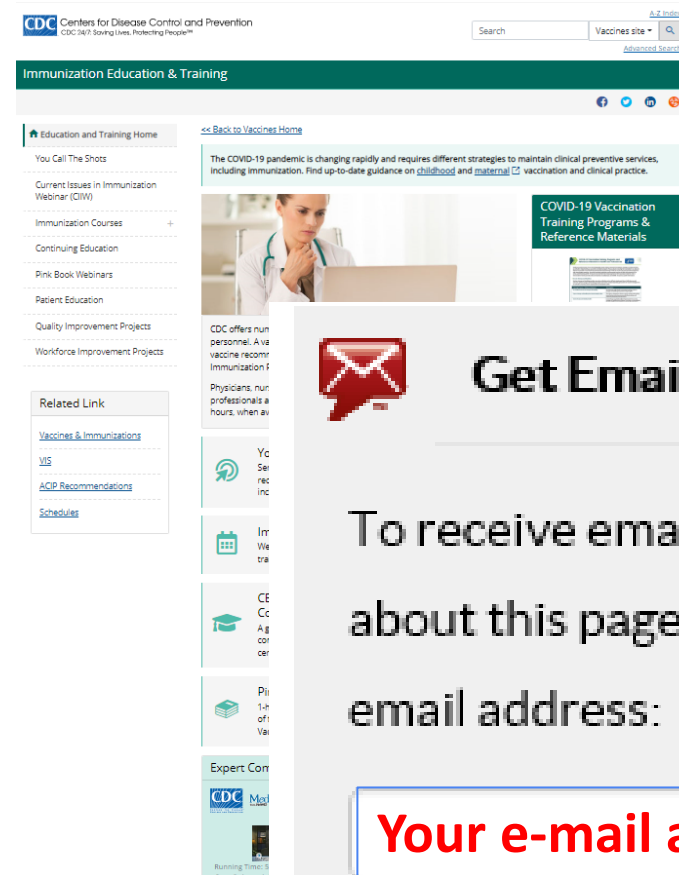
7

**Clinical  
Resources**



# CDC Resources for Staff Education

- Multiple education products available free through the CDC website including:
  - *You Call the Shots* self-study modules
    - Vaccine Storage and Handling and others
  - Pink Book webinar series
  - Current Issues in Immunization webinars
  - Continuing education available for all
- Sign up for e-mail updates



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# Vaccine Storage and Handling Toolkit

- **Primary source for CDC storage and handling recommendations**
  - Most current recommendations
  - Other materials updated based on toolkit contents



Vaccine Storage and Handling Toolkit



January 2019

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# Continuing Education Information

- CE credit, go to: <https://tceols.cdc.gov/>
- Search course number: **WD4564-080222**
- CE credit expires: **July 1, 2024**
- CE instructions are available on the **Pink Book Web-on-Demand Series** web page
- Questions and additional help with the online CE system, e-mail [CE@cdc.gov](mailto:CE@cdc.gov)

Training and Continuing Education Online (TCEO)



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# E-mail Your Immunization Questions to Us

- [NIPINFO@cdc.gov](mailto:NIPINFO@cdc.gov)



# Thank You From Atlanta!

