Vaccine Storage and Handling

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Topics

- Vaccine Storage and Handling Requirements
  - Storage Units
  - Temperature Monitoring and Recording Requirements
  - Data Loggers
  - Vaccine Management Plans
  - Keys to Vaccine Storage and Handling
- Vaccine Storage and Handling Related Vaccine Loss

Source:
2022 TVFC and ASN Operations Manual
2022 TVFC and ASN Provider Manual

Vaccine Adventures

It’s Time for another ADVENTURE!

Storage and Handling Requirements

Storage Units

DSHS Recommends the following types of units for vaccine storage (listed in preferential order):

1. Pharmaceutical grade/purpose-built
2. Stand-alone, single purpose fridge and stand-alone, single-purpose freezer
3. Combination household unit
   - A strong recommendation must be given for staff to obtain a stand alone freezer where they can store the frozen vaccine separately.
   - Separate data loggers for each compartment

Dorm-style units and small combination refrigerator and freezer units with a single external door are <u>NEVER PERMITTED.</u>

2022 TVFC and ASN Operations Manual Pg. 64-65
2022 TVFC and ASN Providers Manual Pg. 44-45

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Storage Units

- Storage units must be large enough to hold the year's largest inventory without crowding.
  - i.e. - Back to School Season and Flu Season
- **FOOD** and/or **DRINKS** are not allowed to be stored in the same unit as TVFC/ASN vaccines.
- If other biologics need to be stored in the same unit as TVFC/ASN vaccines, then they should be stored below the vaccines to avoid contamination.
- TVFC/ASN-enrolled providers are required to have appropriate equipment that can store vaccine and maintain proper conditions.

2022 TVFC and ASN Providers Manual Pg. 44, 50
2022 TVFC and ASN Operations Manual Pg. 65, 68

Storage Units

DSHS prohibits the use of the following cooling materials in units storing TVFC/ASN vaccine:

- **Gel packs (thawed or frozen)**
- **Ice packs**
- **Coolant packs from vaccine shipments**
- **Any other coolant material that is not allowed by CDC or the TVFC/ASN Program**

2022 TVFC and ASN Operations Manual Pg. 68
2022 TVFC and ASN Providers Manual Pg. 46

Water Bottles

It is <u>required</u> that all TVFC/ASN-enrolled providers ensure that:

- Each refrigerator and freezer must contain a sufficient number of water bottles to help maintain proper storage temperature.
- Water bottles are labeled “Do Not Drink”
- Water bottles are placed appropriately in the unit:
  - Top Shelf
  - Unit door
  - Floor
  - In place of fruit/vegetable crisper drawers
  - Near the vent
  - Along the walls

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2022 TVFC and ASN Provider Manual Pg. 45-48

Water Bottles

Water bottles should NOT be used in pharmaceutical/purpose-built units only if the manufacturer indicates that water bottles negatively affect the functionality of the unit.

2022 TVFC and ASN Operations Manual Pg. 68
2022 TVFC and ASN Providers Manual Pg. 46

Vaccine Storage

All TVFC/ASN vaccines are required to be stored in the central area of the refrigerator and/or freezer shelves.

TVFC/ASN vaccines are NOT allowed to be stored in:

- Fruit/Vegetable bins
- Meat Drawers
- The top shelf of the refrigerator
- The floor of the refrigerator
- The door of the refrigerator or freezer

Vaccines must be stored and/or stacked to allow cold air to circulate freely.
i.e. - Leave 2-3 inches between all vaccine and the refrigerator walls.

2022 TVFC and ASN Provider Manual Pg. 46-49

Vaccine Storage

Additional Requirements:

- Vaccine with diluent must be kept together in the same box (if they come together). If they do not, whenever possible, store diluent with the corresponding refrigerated vaccine.
- Place vaccines with the earliest expiration dates in front of those with later expiration dates.
- Always store vaccines in their original packaging with lids closed.
- Never store loose vials or manufacturer-filled syringes outside of their packaging.

2022 TVFC and ASN Provider Manual Pg. 47-49

Vaccine Storage

- Attach labels to shelves and containers to clearly identify where each type of vaccine and diluent is stored.
- Store vaccines with similar packaging or names, or with both pediatric and adult formulations on separate shelves.
- Clearly label the formulation “pediatric” or “adult”.
- Clearly label and store privately purchased vaccine on different shelves from TVFC/ASN vaccine.
- Do not pack a storage unit too tightly as this restricts air circulation and impacts vaccine temperature.

2022 TVFC and ASN Provider Manual Pg. 47-49

Vaccine Storage

For TVFC/ASN vaccine stored in an auto-dispensing or door-less purpose-built unit, it may be required to remove the vaccine from the original packaging. This original packaging **must** be kept and readily accessible in the event the vaccine must be transported outside of the unit.

2022 TVFC and ASN Operations Manual Pg. 65
2022 TVFC and ASN Provider Manual Pg. 47, 49

Storage Unit Power Supply

DSHS prohibits the use of the following for units storing TVFC/ASN vaccine:

- **Surge Protectors**
- **Outlets with built-in circuit switches (ground fault interrupt receptacles)**
- **Power outlets that can be activated by a wall switch**
- **Multi-outlet power strip**
- **Extension Cords**

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2022 TVFC and ASN Provider Manula Pg. 59

Storage Unit Power Supply

To ensure that the power supply for vaccine storage units is protected, TVFC/ASN-enrolled providers are <u>required</u> to:

- Plug unit(s) directly into a wall outlet.
- Plug only one unit into an outlet.
- Post a “Do Not Unplug” sign on or near all electrical outlets where units are plugged in.
- Post a “Do Not Disconnect” sign on or near each circuit breaker.
- Use plug guards on all units that store TVFC/ASN vaccines. (May be ordered from DSHS)

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2022 TVFC and ASN Provider Manual Pg. 58-59

Storage Unit Temperatures

Refrigerator

- The refrigerator compartment must maintain temperatures between **36°F** and **46°F** (**2°C** and **8°C**) for vaccine viability.
- The refrigerator temperature should be set at the recommended temperature of **40°F** (**4°C**).

Freezer

- The freezer compartment must maintain temperatures between **-58°F** and **+5°F** (**-50°C** and **-15°C**) for vaccine viability.

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2022 TVFC and ASN Provider Manual Pg. 45

Storage Unit Temperatures

Prior to using a new or newly repaired storage unit TVFC/ASN-enrolled providers are required to:

- Document twice daily refrigerator and/or freezer temperature recordings on a temperature recording form (stock no. EC-105) for 7 operational days, using a certified and calibrated data logger.
- Record the minimum/maximum temperatures once daily, at the beginning of each business day, to ensure temperatures are within appropriate ranges.
- These recordings must be submitted to the RE for review and approval, before a vaccine order is approved.

2022 TVFC and ASN Provider Manual Pg. 49-50

Temperature Recording

It is <u>mandatory</u> for TVFC/ASN providers to meet and maintain temperature recording requirements to ensure temperatures are within appropriate ranges.

- It is required to check, record, and initial all refrigerator and freezer unit temperatures, twice daily each day the site is open.
- It is required to record the minimum/maximum temperatures for each unit, once daily, at the beginning of each business day.
- Minimum and maximum temperature readings must be reset from the day before at the end of each business day (if the device requires this function).

2022 TVFC and ASN Provider Manual Pg. 50-51
2022 TVFC and ASN Operations Manual Pg. 80

Vaccine Adventures

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Temperature Recording

Temperature Recording Forms

- Temperatures must be recorded manually on temperature recording forms, using a data logger.
  - **Do NOT round up or down, record only the numbers left of the decimal point.**
  - **Do NOT convert from Celsius to Fahrenheit or Fahrenheit to Celsius.**
- Must be posted on each TVFC/ASN vaccine storage unit door or nearby in a readily accessible and visible location.
- Must be maintained for at least 5 years and be easily available.
- Temperature recording forms must still be completed and submitted to the RE if an auto-dispensing unit is being utilized.

2022 TVFC and ASN Provider Manual Pg. 50-51

Temperature Excursions

If an out-of-range temperature excursion is observed, the information must be documented, and the following actions must be taken immediately:

1. Place vaccines in a vaccine quarantine bag.
2. Store vaccines in a unit where they can be kept under appropriate conditions.
3. Generate a report from the data logger for discussion with the vaccine manufacturer.
4. Contact the vaccine manufacturer that is listed on the box to obtain documentation for the viability of the vaccine.
5. Contact the RE to report the manufacturer's vaccine viability determination, submit the manufacturer's determination letter(s) or online validity results and complete the Vaccine Storage Troubleshooting Record, page 3 of the Temperature Recording Form (stock no. C-105).

2022 TVFC and ASN Provider Manual Pg. 51

Temperature Excursions

RESOURCES

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.

Notify

- Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor.
- Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.

Document

- Document details of the temperature excursion:
  - Date and time
  - Storage unit temperature (including minimum/maximum temperatures during the time of the event, if available)
  - Room temperature, if available
  - Name of the person completing the report
  - General description of the event (i.e., what happened)
  - If using a digital data logger (DDL), determine

Contact

- Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).
- Be prepared to provide the immunization program or manufacturer with documentation and DDL data so they can offer you the best guidance.

Contact manufacturer

Correct

- If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.
- Check the basics, including:
  - Power supply
  - Unit door(s)
  - Thermostat settings
- If the excursion was the result of a temperature fluctuation,

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Data Loggers

Refrigerators and freezers that store TVFC/ASN vaccines are <u>required</u> to contain a centrally located data logger with a current certificate of calibration :

- The recording interval must be set to at least every 30 minutes.
- All TVFC/ASN sites must have at least one backup data logger with a valid and current certificate of calibration.
- The backup data logger is recommended to have a **<u>different</u>** calibration retesting date than the data logger in use.
- Data logger data should be downloaded at least once per week

2022 TVFC and ASN Operations Manual Pg. 65-66
2022 TVFC and ASN Provider Manual Pg. 53, 56

Data Logger Capabilities

<u>Required</u> data logger capabilities:

- An active temperature display that can be easily read by all staff from the outside of the unit, without having to open the door.
  - The data logger must have functionality that does not require a computer password to access the temperature display.
  - The display must remain active for temperature readings (i.e., must not have sleep mode turned on).
- The display must show the current temperature, as well as minimum and maximum temperatures
- Low battery indicator

2022 TVFC and ASN Provider Manual Pg. 53-54

Data Logger Capabilities

- Alarm for out-of-range temperatures
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings (device will not rewrite over old data and stops recording when memory is full)
- User-programmable logging interval (or reading rate) at a maximum time interval of every 30 minutes.

2022 TVFC and ASN Provider Manual Pg. 53-54

Data Logger Capabilities

- Detachable probe
- Probes should be placed in buffered material:
  - A vial filled with liquid (glycol, ethanol, glycerin)
  - A vial filled with loose media (sand, glass beads)
  - A solid block of material (Teflon®, aluminum)
- Using probes in buffered material ensures the temperature being documented is an accurate representation of the temperate of the vaccine in the vial rather than the air temperature of the storage unit.

2022 TVFC and ASN Provider Manual Pg. 54

Data Loggers

The data logger probe must be placed:

- As close to the vaccine as possible
- In the center of the unit
- Away from walls, ceilings, cooling vents, doors, floor and back of the unit.

The data logger probe must not be placed:

- Suspended from wire shelves in the unit
- Suspended by tape or other means attached to the inside ceiling of the unit.

2022 TVFC and ASN Provider Manual Pg. 55

Data Loggers

In pharmaceutical or purpose-built units, the data logger probe should be placed in a central location; however, some units have data logger probes that are fixed to the wall. These units data loggers are accepted due to manufacturer guidelines showing that the units maintain more consistent temperatures throughout the unit.

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Data Logger Certificate of Calibration

TVFC/ASN-enrolled clinic sites are required to have a calibrated data logger in each unit that stores TVFC/ASN vaccine that is either:

- International Laboratory Accreditation Cooperation (ILAC) laboratory accredited or
- Has a valid and up-to-date certificate issued by an ILAC laboratory.

A valid certificate of calibration must be readily available and posted on or near the refrigerator and/or freezer unit(s).

2022 TVFC and ASN Provider Manual Pg. 55

Data Logger Certificate of Calibration

All certificates of calibration are <u>required</u> to contain:

- Model number
- Serial number
- Date of calibration
- Measurement results that indicates the unit passed the test and the documented uncertainty is within suitable limits (+/-1F +/-0.5C) and
- A statement indicating that it meets International Organization for Standardization/International Electronic Commission (ISO/IEC) 17025 standards.

2022 TVFC and ASN Provider Manual Pg. 55-56

Data Logger Certificate of Calibration

Refrigerators and freezers manufactured with built-in temperature monitoring capabilities are required to also have a certificate of calibration. The thermostat must be adjustable as needed to maintain proper temperature. These units must meet all TVFC/ASN data logger requirements.

2022 TVFC and ASN Provider Manual Pg. 56

Data Loggers

DSHS prohibits the use of the following temperature monitoring devices:

- **Thermometers including alcohol or mercury thermometers, even if placed in fluid-filled bio-safe liquid vial**
- **Bi-metal stem temperature monitoring devices**
- **Food temperature monitoring devices**
- **Household mercury temperature monitoring devices**
- **Chart recorders**
- **Infrared temperature monitoring devices**
- **Temperature monitoring devices that are not calibrated**

2022 TVFC and ASN Operations Manual Pg. 66-67
2022 TVFC and ASN Provider Manual Pg. 54-55

Room Temperature Thermometers

A room thermometer is required to record the room temperature when a temperature excursion occurs in a vaccine storage unit.

This is important for making vaccine viability determinations, if necessary.

2022 TVFC and ASN Providers Manual Pg. 56

Vaccine Adventures

It's Time for another ADVENTURE!

Vaccine Depots

Definition:

A site that accepts vaccine and then re-sends (fills) orders to others.

Vaccine depots are <u>not</u> allowed in the TVFC/ASN Programs!

Vaccine Management Plan

All TVFC/ASN enrolled sites are <u>required</u> to have a current routine and emergency vaccine management plan:

- Must be reviewed and signed at least annually or more frequently if staff or other changes occur and staff should confirm that the back-up site is still able to function as their emergency site.
- Must be posted on or near the storage unit so that it's easily accessible
- Must include:
  - Names and phone numbers of emergency contacts
  - Plan regarding how to move and transport vaccine
  - Address of alternate location for vaccine storage

2022 TVFC and ASN Operations Manual Pg. 70-71
2022 TVFC and ASN Providers Manual Pg. 60-62

Emergency Vaccine Transfers

Staff must be prepared to collect and provide the following information when transporting vaccine to the alternate location:

- Document the time of the emergency/power outage and the amount of time the vaccine was exposed to inappropriate temperatures.
- Document the temperature of the refrigerator/freezer before removing any vaccine for transport.
- Indicate which containers are being used, what packing materials will be used and how the vaccine will be packed for transportation.
- Take inventory of the vaccine, documenting the number of doses of each vaccine and the expiration dates.

2022 TVFC and ASN Providers Manual Pg. 62-63

Packing for Emergency Vaccine Transport

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

1 Gather the Supplies

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.

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 +/-1°F (+/-0.5°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 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.**

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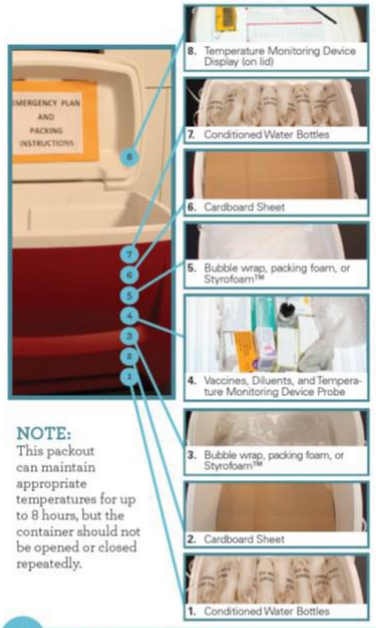
Visit www.cdc.gov/vaccines/SandH for more information, or your state health department.

Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles

- 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.



Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.

Insulating material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

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.

Insulating 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).

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

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

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.
Storage – Transfer boxes of vaccines quickly to storage refrigerator.
Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

2022 TVFC and ASN Providers Manual Pg. 69-70

Vaccine Adventures

It's Time for another ADVENTURE!

Vaccine Adventures

Know Your Neighbors!

It's Time for another ADVENTURE!

Keys to Vaccine Storage and Handling

Vaccine viability depends on the knowledge and habits of the clinic staff.

All staff who handle TVFC/ASN vaccine must be trained on proper storage and handling of vaccine.

2022 TVFC and ASN Operations Manual Pg. 64

Keys to Vaccine Storage and Handling

Vaccine Manufacturing

Manufacturer Responsibility

Vaccine Distribution

Manufacturer & Distributor Responsibility

Vaccine Arrival at Provider Facility

Vaccine Storage and Handling at Provider Facility

Vaccine Administration

Provider Responsibility

Knowledge Check

Find 10 things that are wrong with vaccine storage in this fridge

Knowledge Check

Find 10 things that are wrong with vaccine storage in this fridge

1. Vaccine stored in door
2. Beverage in fridge
3. Vaccines not in bins
4. Vaccine too close to vent
5. Food in fridge
6. Vaccine stored in bins
7. Missing water bottles
8. No plug guard
9. No “Do Not Unplug Sign”
10. No Data Logger

Knowledge Check

Question

One of the most common reasons that refrigerators are out of temperature range is:

A. Power outage

B. The thermometer is broken

C. Staff doesn't shut the refrigerator door

D. The refrigerator thermostat is not working properly

Knowledge Check

Answer

One of the most common reasons that refrigerators are out of temperature range is:

A. Power outage

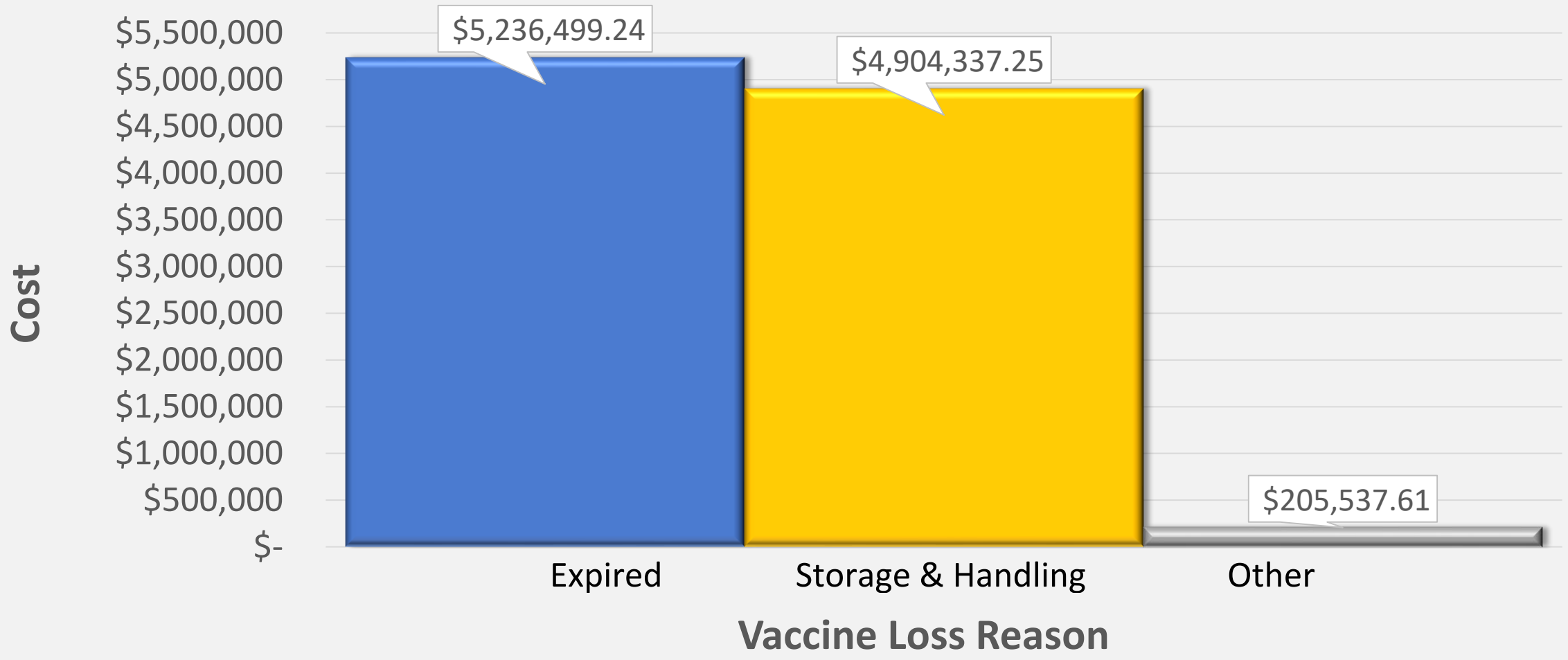
B. The thermometer is broken

C. Staff doesn't shut the refrigerator door

D. The refrigerator thermostat is not working properly

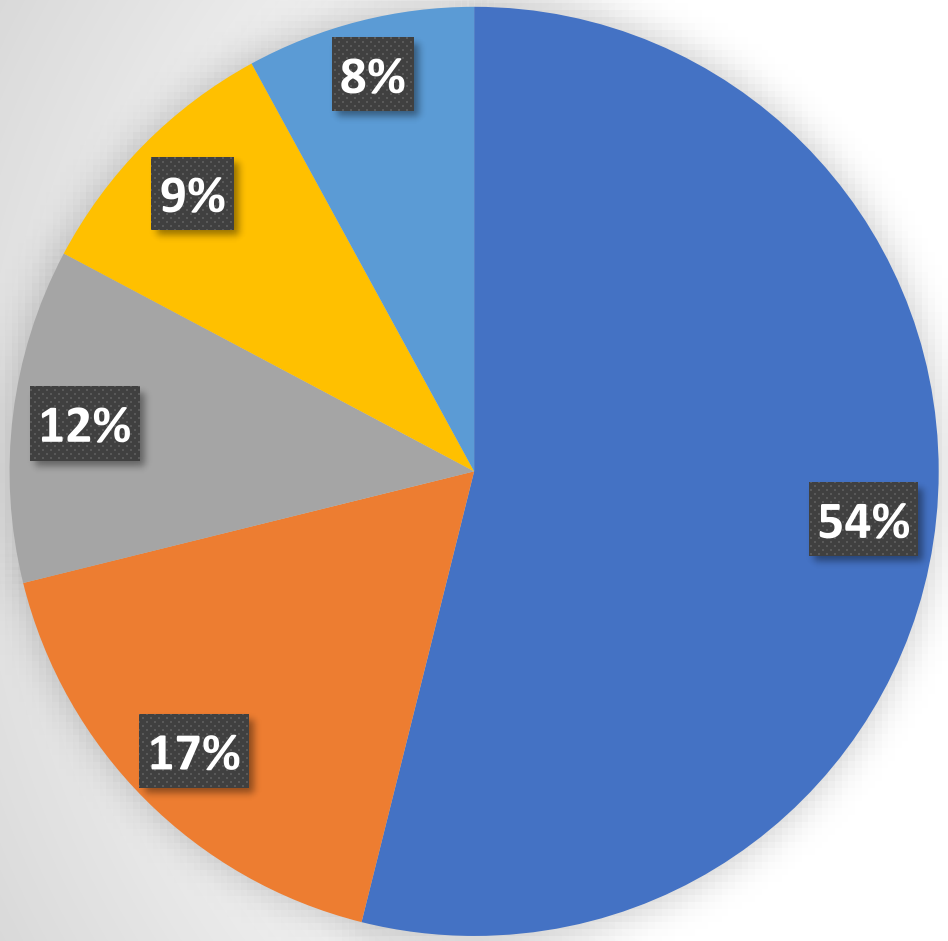
Storage and Handling Related Vaccine Loss

Cost of Vaccine Loss Statewide



Note: Data set represents time period of July 2020 to June 2021. Flu-related loss is not included.

Vaccine Loss Due to Storage & Handling



- Natural disaster/Power outage
- Unit temperature too warm or too cold
- Vaccine spoiled in transit
- Mechanical failure (refrigerator/freezer)
- Failure to store or handle properly

Note: Data set represents time period of July 2020 to June 2021.

Thank you!

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Questions?

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