Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

Developing Vaccine Storage and Handling Recommendations

2019 New Jersey Immunization Conference

May 29, 2019

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- **CDC did not accept commercial support for this educational activity.**

Highlights

Developing Vaccine Storage and Handling Recommendations

I. **Vaccine Cold Chain Overview and resources**

II. **How we develop Vaccine Storage and handling recommendations and requirements**

III. **Contracted Studies**

IV. **Ongoing Studies for Vaccine Transport**

V. **Additional Studies and Looking Ahead**

Interactive Polling

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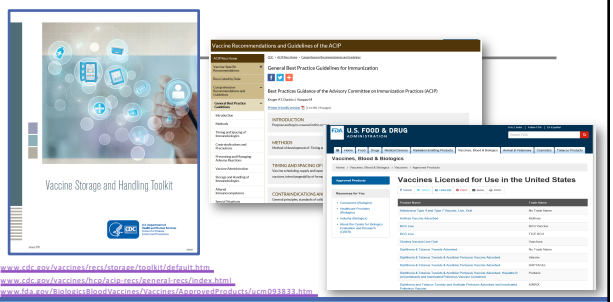
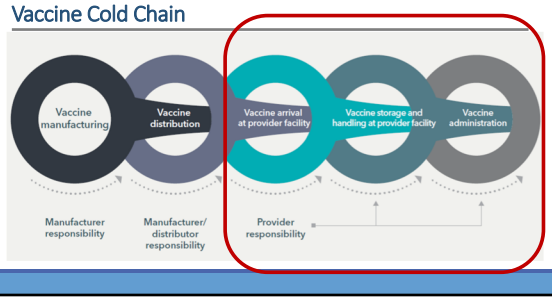
PIN: 43616

Vaccine Storage and Handling Best Practices



www.cdc.gov/vaccines/recs/storage/toolkit/default.html
www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

Vaccine Cold Chain



Vaccine Storage and Handling Cold Chain

- Vaccines must be stored properly from manufacturer to administration
- Shared responsibility among manufacturers, distributors, public health staff, and health care providers
- An effective cold chain relies on three main elements:
  - Well-trained staff
  - Reliable storage and temperature monitoring equipment
  - Accurate vaccine inventory management

Why have a good Cold Chain

- Keep from having to repeat doses
- Damage to public confidence in vaccines
- **Health of Patients** – Patients can remain unprotected from serious, vaccine-preventable diseases.

Another reason

- Vaccine can be costly and are valuable


The New York Times

HEALTH › PAYING TILL IT HURTS › Vaccines

The Price of Prevention: Vaccine Costs Are Soaring

By ELISABETH ROSENTHAL JULY 2, 2014

A Fort Knox of Vaccines

Dr. Lindsay Ivvin keeps about 10 different vaccines, worth about $34,000, in this refrigerator. This represents her current supply, which is about half the value that would be present at the start of the many season or before school starts. A few of the most expensive and common vaccines are listed.

DTaP
Diphtheria, tetanus, pertussis
40 doses at $20
TOP SHELF TOTAL $6,864

Prevnar 13
Pneumococcal disease
10 doses at $155

Menactra
Meningitis and others
20 doses at $112

MMR
Measles, mumps, rubella
23 doses at $90
2ND SHELF TOTAL $9,302

Government-Purchased Shots
Vaccines provided at no cost to doctors for children on Medicaid or who fall into certain medically underserved categories.
275 doses at $42
3RD SHELF TOTAL $11,610

FluMist
These were not used, and their value is a total loss. 50 doses at $22
4TH SHELF TOTAL $2,043

Varicella
Chickenpox. 43 doses at $94
FREEZER TOTAL $4,048

The New York Times – July 2, 2014

Article by Elisabeth Rosenthal

Photo by Ben Sklar for The New York Times

About $34,000 worth of vaccine

Storage and Handling Requirements and Recommendations

- ❑**Manufacturer Guidance and Data (Vaccine and Equipment)**
- ❑**Real world scenarios (State Programs & Providers)**
- ❑**Literature Reviews**
- ❑**Other Vaccine Storage and Handling Practices and Standards (US and International)**
- ❑**Contracted Studies**

Contracted Studies

- Variety of options available for additional research
  - – Universities
  - – Private Market
  - – Other Governmental Agencies

CDC Recommendations - Vaccine Storage and Handling

Storage and Handling Recommendations:

I. **Storage Units (Stand Alone/Pharmaceutical)**
II. **Not using the Freezer in a Household combination unit**
III. **Avoid risky storage areas**
IV. **Defrost cycles and temperature increases**
V. **Use of a Digital Data Logger with a Probe that best reflects vaccine temperature**
VI. **Active visible temperature display**
VII. **Temperature record retention**
VIII. **Thermal Mass (water bottles) – help maintain stable temperatures and avoid high risk areas**

CDC Recommendations VFC Requirements with Vaccine Storage and Handling

VFC Storage and Handling Requirements:

I. **No Dormitory units**
II. **Vaccine placement – center of unit**
III. **Quality Data Logger with a valid certificate**
IV. **Room for complete inventory**
V. **Protection for the power source**
VI. **Back-up Thermometer**
VII. **Record storage unit temperatures (2x a day)**

Contracted Studies - Storage and Handling

CDC Storage and Handling Recommendations:

I. **Storage Units (Stand Alone/Pharmaceutical)**
II. **Not using the Freezer in a Household combination unit**
III. **Avoid risky storage areas**
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V. **Use of a Digital Data Logger with a Probe that best reflects vaccine temperature**
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CDC Storage and Handling Requirements:

I. **No Dormitory units**
II. **Vaccine placement – center of unit**
III. Quality Data Logger with a valid certificate
IV. Room for complete inventory
V. Protection for the power source
VI. Back-up Thermometer
VII. Record storage unit temperatures (2x a day)

CDC/NIST Collaboration

- **Established in 2009**
- **Monitoring and maintaining the vaccine cold vaccine storage equipment and data loggers**
- **Guidance on storage equipment use**
- **Freezer use and emergency vaccine transport containers**
- **Thermal ballast and vaccine trays and bins**

CDC/NIST Collaboration

- **Combination Refrigerator (Dual-zone)**
  - Potential areas in the refrigerator section can pose a significant risk for freezing vaccine
  - *Freezer section* was unable to maintain frozen vaccine storage temperatures
  - Even with *freezer control* set to "coldest" vaccines stored inside freezer experienced thermal excursions above-15°C
  - Defrost cycle caused major thermal excursions
  - Temperature variability through out the unit.

CDC/NIST Collaboration

- **Household Standalone Refrigerator (Freezerless)**
  - **In general these units performed better than Household combination units.**
  - ***As with combination units, these also tend to have areas of temperature variability within the unit.***

CDC/NIST Collaboration

Pharmaceutical Grade Unit

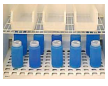
- **Pharmaceutical grade and purpose-built units performed the best**
- **Note: Pharmaceutical Grade units can be obtained as:**
  - Standalone refrigerators or Standalone Freezers
  - Combination Refrigerators and Freezer units
  - Full size or compact under/above the counter
  - May have glass doors and shelving

CDC/NIST Collaboration

- **Thermal Mass (Thermal Ballast)**
  - Additional thermal mass of water bottles acts as a temperature ballast, lessening the impact of potential temperature fluctuation
  - Tests of intermittent and continuous door opening demonstrated the value of adding water bottles to the door as a thermal ballast in the dual-zone refrigerator model.

Thermal Ballast Testing

- **Determine minimum quantity (% of unit capacity) of thermal ballast material required to deliver a measurable impact on storage temperature stability under normal operation during adverse events**



*Measurable Impact: The ability to reduce the incidence or severity of temperature excursions, as compared to a unit with no ballast

Thermal Ballast Testing Objectives

- Reduce the negative impact of defrost cycles
- Extend length of viable storage time during power outages
- Reduce the negative impact of frequent door openings

Power Outage & Cycling

Ballast Testing

Preliminary Data for Power Outage Ballast Testing

Preliminary Data for Defrost Cycles Ballast Testing

Door Opening Ballast Testing

General Door Opening Information*

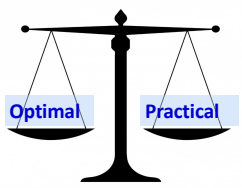
- ❑ **Average door open time: 8 seconds**
- ❑ **Average frequency: 6 openings / hour**
- ❑ **Worst-case frequency: 12 openings / hour**
- ❑ **Worst-case duration: 3 minutes**
  - Loading and/or product inventory

*NSF – Vaccine Storage JC

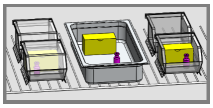
Preliminary Data for Door Opening Ballast Testing

Preliminary Data for Door Opening Ballast Testing

Thermal Ballast Results

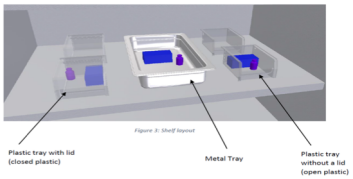


Bins and Trays



Bins and Trays Testing

- Determine suitability of different types of trays for vaccine storage
- Metal trays vs. Plastic trays
- Open trays vs. Closed (lid)



Poll Question: Bins and Trays

Which Tray Bin do you think poses the most danger to vaccines while being stored in the refrigerator?

A) Metal w/ lid

B) Metal w/o lid

C) Plastic w/ lid

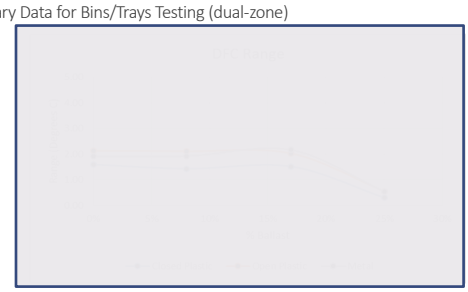
D) Plastic w/o lid

E) No difference

Vote on live.voxvote.com PIN: 43616

Preliminary Data for Bins/Trays Testing (freezerless)

Preliminary Data for Bins/Trays Testing (dual-zone)



New Challenge: Provider Transport of Vaccine

- **Vaccine manufacturers do not generally recommend or provide guidance for transport of vaccines and CDC discourages routine transport**
- **Some situations require healthcare providers to transport vaccines**
  - **Emergency transport: weather emergencies, power outages, storage equipment failures**
  - **Provider-to-provider transport: centralized office to satellite locations, transfer of soon-to-expire vaccine**
  - **Vaccine clinic transport: public vaccine clinics held in schools, community centers, reservations etc.**
- **CDC recommends the total time for transport alone or transport plus clinic workday should be a maximum of 8 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).**

Vaccine Transport Overview

Active and Passive Containers

Active Containers

No backup battery
~$650

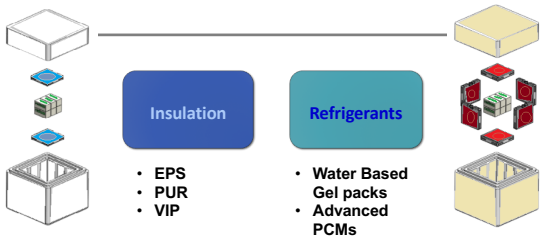
Backup battery
~$6,000

Passive Containers: Qualified Containers and Pack-outs

Qualification: Documented testing that demonstrates a high degree of assurance that a particular process or product will meet a pre-determined acceptance criteria. The criteria defines the temperature range that the product must maintain for viability (2-8°C, or -15°C).

WHY: Qualifying helps ensure that the packaging is capable of protecting the temperature sensitive products during their storage and transport.

Components for Passive Packouts



Insulation

- EPS
- PUR
- VIP

Refrigerants

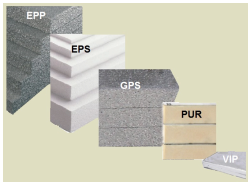
- Water Based Gel packs
- Advanced PCMs

Insulating Materials

Insulation Components

The **"R" value** of a material is its resistance to heat flow through the material.

- Soft Wood = R Value ~ 1 per inch of Thickness
- Fiberglass Batt = R Value ~ 3-4 per inch of Thickness



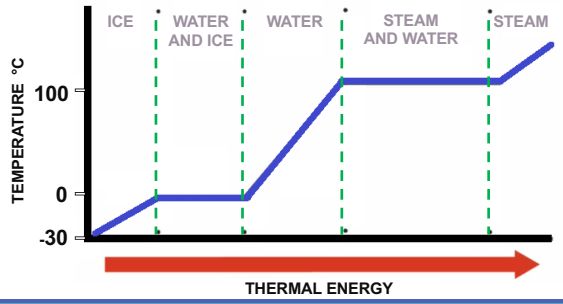
- Expanded Polypropylene (**EPP**) = R ~ 3.5
- Expanded Polystyrene (**EPS**) = R ~ 4
- Graphite Polystyrene (**GPS**) = R ~ 5
- Polyurethane (**PUR**) = R ~6 - 7
- Vacuum Insulated Panel (**VIP**) = R ~ 40

CDC Shipments

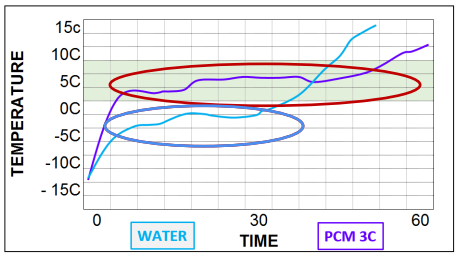
Phase Change Materials

Phase Change Material (PCM)

- **PCMs – Temperature Controlled Materials**
  - Non-water based materials that freeze and melt at or near the temperature needed (*i.e.*, vaccines).
  - PCMs come in many different types of materials and packaging, designed for many different applications
    - Gels, liquids, solids, pouches, sheets, hard sided containers



Phase Change Graph

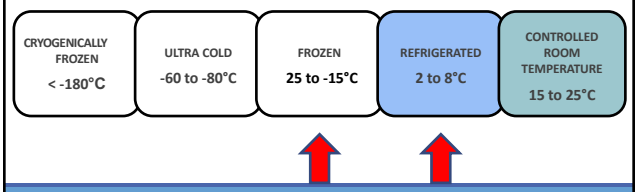


General Steps used by Industry to

Qualify

Containers & Packouts

Families of Storage Temperatures related to Transport and Shipping



Poll Question: Families of Storage Temperatures

Which temperature family is the hardest to maintain passive containers?

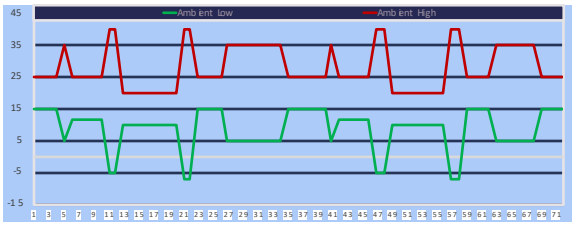
A) Ultra Cold

B) Frozen

C) Refrigerated

D) Room Temperature

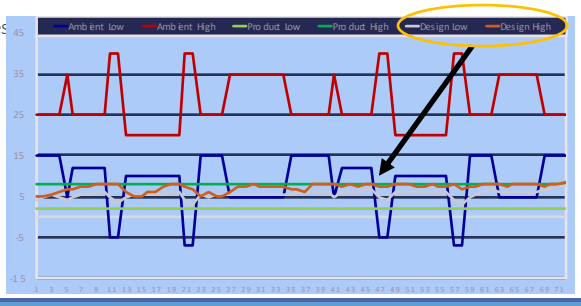
Temperature Profile

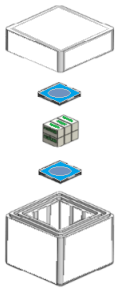


Container and Packout

- ✓ **Ambient Temperature Profile**
- ✓ **Duration**
- ✓ **Product Specification (2-8 °C)**
- ✓ **Insulation Material (Box)**
- ✓ **Refrigerant (Ice packs/PCMs)**

Des





Components

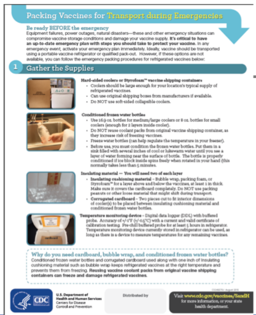
- Insulation Material (Box)
- Refrigerant (Ice packs/PCMs)

Passive Coolers – What to look for

- ❑Qualified for desired temperatures
- ❑Size – Dose capacity
- ❑Weight – (Is it designed to be carried or on wheels)
- ❑Type of Refrigerant or Cooling system (Ice Packs/PCM)
- ❑Hard side or soft side
- ❑Type of insulation used (PUR, EPS, VIP, other)
- ❑Assembly (How complicated is the packout)
- ❑Holding Temp (2-8°C, -20°C, etc.)
- ❑Holding Time (8 hours, 24 hours, etc.)

Vaccine Transport Errors

- ❑Not shipping directly to the clinic location when possible
- ❑Not properly conditioning coolant packs or PCM
- ❑Putting vaccine in direct contact with coolant packs
- ❑Leaving cooler door open for long periods
- ❑Repeatedly opening and closing cooler door
- ❑Not monitoring storage temperatures
- ❑No emergency alternate storage unit plan



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. Ideally, vaccine should be transported using a portable vaccine refrigerator or qualified pack-out. However, if these options are not available, you can follow the emergency packing procedures for refrigerated vaccines below:

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 (this normally takes less than 5 minutes.

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

Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-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 cushioning material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Distributed by

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

Emergency Vaccine Transport

- Emergency (2-8C) packout that uses common materials found in provider's offices
- Qualified for 8 hours

https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf

Frozen Vaccine Transport Measurement Objectives

- **Maintain vaccines in correct temperature range for 1h to 8h**
- **Inexpensive: minimize cost and hassle to physicians**
- **Practical and easy-to-implement**
- **Emergency transport situations: setup time and availability of materials**
- **Test commonly-used, readily-available coolers and coolant materials for suitability in a short-term, vaccine transport "packout"**
- **Determine if providers can safely transport frozen and refrigerated vaccines together**

Testing Commonly-used Transport Materials & Setups

Refrigerant materials

0 °C phase change:
- **Foam brick (4 day vaccine shipper packout)**
- **Gel pack (consumer product)**
- **Ice blanket (consumer product)**

-20 °C phase change:
- **Hard case (purpose built)**

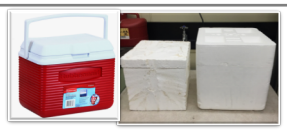
-23 °C phase change:
- **Foam brick (1 day vaccine shipper packout)**
- **Gel pack (purpose built)**

**Commercial equipment identified in this presentation does not imply recommendation or endorsement, nor does it imply that identified equipment is the best for the purpose.

Testing Commonly-used Transport Materials & Setups

Coolers

Rigid plastic cooler (food/beverage)
Styrofoam cooler (re-used vaccine delivery box)
- 2.5" thick walls
- 1.25" thick walls



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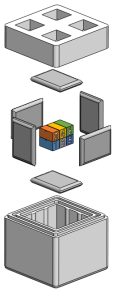
Frozen Vaccine Transport Packout using -23 °C PCM

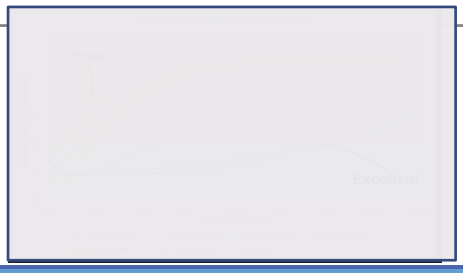
Re-used styrofoam vaccine delivery box

-23 °C phase change packs on all sides of product

All vaccines maintained below -15 °C for 17+ h



Focus on Frozen Vaccine transport
Comparison of Water-based and Purpose-Built PCMs



Cold Pack on all sides vs. top and Bottom only

cold pack only on top & bottom of vaccine load

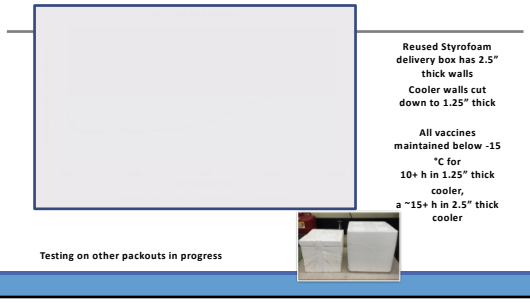
<

cold pack on all sides of vaccine load

Winner!

Plastic Food and Beverage cooler vs. Re-Used Styrofoam Vaccine Delivery box

1.25" Thick Styrofoam cooler vs. 2.5" thick Styrofoam cooler



Reused Styrofoam delivery box has 2.5" thick walls

Cooler walls cut down to 1.25" thick

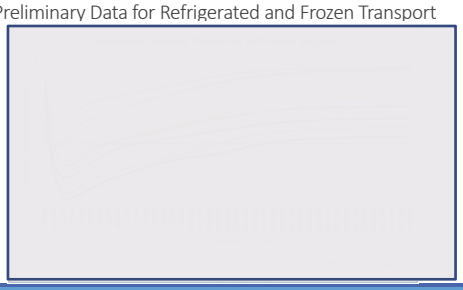
All vaccines maintained below -15 °C for 10+ h in 1.25" thick cooler, a ~15+ h in 2.5" thick cooler

Testing on other packouts in progress

Refrigerated and Frozen Transport

- Observing the impact to refrigerated vaccine when packed in the same transport container with frozen vaccine

Preliminary Data for Refrigerated and Frozen Transport



Additional Studies Underway

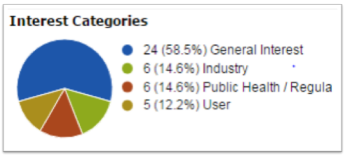
- Conducting studies on passive methods for transporting frozen vaccine 1-2 hours
- Conducting studies on passive methods for transporting refrigerated and frozen vaccine that can be opened and closed repeatedly

NSF Joint Committee on Vaccine Storage

Working to develop voluntary, consensus standards for vaccine storage units

Standard for Vaccine Storage Units

- This standard will establish minimum requirements for the materials, design, fabrication, construction, and performance of Vaccine Storage equipment.
- Units that met the standard would be identified as such



CDC Vaccine Storage and Handling Resources

- Vaccine Storage & Handling webpage
  - www.cdc.gov/vaccines/recs/storage/default.htm
- Vaccine Storage and Handling Toolkit
  - www.cdc.gov/vaccines/recs/storage/toolkit/default.htm
- Examples of vaccine labels
  - www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf
- You Call the Shots: Storage & Handling module
  - www.cdc.gov/vaccines/ed/youcalltheshots.htm

Thank you!

Questions?

Email: IZColdChain@cdc.gov