Developing Vaccine Storage and Handling Recommendations

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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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Vaccine Storage and Handling Best Practices

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 Price of Prevention: Vaccine Costs Are Souring

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:**
- Use of a Digital Data Logger with a Probe that best reflects vaccine temperature
- Active visible temperature display
- Temperature record retention
- Thermal Mass (water bottles) – help maintain stable temperatures and avoid high risk areas

### VFC Requirements with Vaccine Storage and Handling

**VFC Storage and Handling Requirements:**
- No Dormitory units
- Vaccine placement – center of unit
- Quality Data Logger with a valid certificate
- Room for complete inventory
- Protection for the power source
- Back-up Thermometer
- Record storage unit temperatures (2x a day)

### Contracted Studies - Storage and Handling

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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 throughout 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.
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

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

*NSF – Vaccine Storage JC
Preliminary Data for Door Opening Ballast Testing

[Graph showing data]

Thermal Ballast Results

[Balance scale diagram with labels: Optimal, Practical]
Bins and Trays

- 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

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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

EPS

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

- Thermogram showing the transition of water and steam phases at various temperatures.
General Steps used by Industry to Qualify Containers & Packouts

**Families of Storage Temperatures related to Transport and Shipping**

- **CRYOGENICALLY FROZEN** ≤ -180°C
- **ULTRA COLD** -60 to -80°C
- **FROZEN** 25 to -15°C
- **REFRIGERATED** 2 to 8°C
- **CONTROLLED ROOM TEMPERATURE** 15 to 25°C

**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
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/PCMs)
- Hard side or soft side
- Type of insulation used (PUR, EPS, VIP, etc.)
- Assembly (How complicated is the packout)
- Holding Temp (2-8°C, -20°C, etc.)
- Holding Time (8 hours, 24 hours, etc.)

Vaccine Transport Errors

-不要 shipping directly to the clinic location when possible
-不要 properly conditioning coolant packs or PCM
-不要 letting vaccine in direct contact with coolant packs
-不要 leaving cooler door open for long periods
-不要 repeatedly opening and closing cooler door
-不要 monitoring storage temperatures
-不用 emergency alternate storage unit plan
Emergency Vaccine Transport

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

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

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 "10+ 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

![Interest Categories](image)

CDC Vaccine Storage and Handling Resources

- Vaccine Storage & Handling webpage
  - [www.cdc.gov/vaccines/recs/storage/default.htm](http://www.cdc.gov/vaccines/recs/storage/default.htm)
- Vaccine Storage and Handling Toolkit
  - [www.cdc.gov/vaccines/recs/storage/toolkit/default.htm](http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm)
- Examples of vaccine labels
  - [www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf](http://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](http://www.cdc.gov/vaccines/ed/youcalltheshots.htm)
Thank you!

Questions?

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