Vaccine Storage and Transport

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Montana Immunization Program
2016 Regional Immunization Workshop
Webinar House Keeping

We are muting all participants upon entering the presentation.

If you would like to ask a question, please unmute your phone.

There is a chat option that allows you to type a question that can be sent to the host or the entire group.

This presentation will be posted to www.immunization.mt.gov under the VFC Training and Resource Page.

Let’s get started!!

You are sharing this monitor.
Topics

• Resources for Vaccine Storage
  Prescribing Information/Package Insert

• Vaccine Incident Reports – Behind the Scenes

• Wastage/Negligence – Year in Review

• Data Logger Program Update

• Vaccine Transport
  ◦ New Pack-out for Non-Electric Coolers
  ◦ Electric Coolers
Vaccine Storage Resources

- Montana-Specific:
  - VFC Provider Handbook
  - Data Logger Instruction Manual

- CDC Vaccine Storage and Handling Toolkit

- Professional Prescribing Information (PI)…
Professional Prescribing Information
Aka – “Package Insert”

- Required by law

- Audience – Healthcare Professionals

- Food and Drug Administration (FDA)
  - Develops Rules, Requirements, Format
  - Approves Content
  - Sends electronic updates to EHRs

- Long, complex approval process
Professional Prescribing Information
Aka – “Package Insert”

- New format in 2009 aimed at reducing med errors:
  - Standardized sections, added TOC and highlights
  - Improved clarity

- Manufacturers encouraged but not required to switch to the new format. Still variability.

- Found with product and online:
  - Manufacturer website
  - Immunization Action Coalition

- Relevance to vaccine storage?
  - Section 16
Professional Prescribing Information
New Format – Section 16

Basics:
- How supplied
- Storage temperatures
- Prohibitions

GARDASIL 9 can be administered provided total (cumulative multiple excursion) time out of refrigeration (at temperatures between 8°C and 25°C) does not exceed 72 hours. Cumulative multiple excursions between 0°C and 2°C are also permitted as long as the total time between 0°C and 2°C does not exceed 72 hours. These are not, however, recommendations for storage.

Depending on:
- New vaccine
- Updated PI format
- Updated PI information
- Vaccine presentation

Trend towards more permissive storage information in the PI.
(e.g., Gardasil)
Professional Prescribing Information

Take Home Message

• Primary resource for product-specific storage information
  But don’t get too far in the weeds!

  Refrigerated vaccines 35F – 46F
  Frozen vaccines -58F – +5F

• Find a good resource for up-to-date PI

• First stop for post-exursion information
**Vaccine Incident Reports**  
*Behind the Scenes*

- VFC providers must notify the Immunization Program of all temperature excursions involving public vaccine.  
  - We are required to know about them.  
  - We must be involved in viability determinations.  
  - Must be documented.

- Online Vaccine Incident Report (VIR)  
  - Everyone has used it!  
  - Sends notifications to IZ Program Staff  
  - Records in a database  
  - Replies and resolutions are saved in provider communication file.
Vaccine Incident Reports

Process

Submit VIR (with DL Data)

Immunization Program

Review VIR and DL Data

Consults PI, Med info, and internal guidelines

95% of VIRs

5% of VIRs

VFC Provider

Call Manufacturers

2016 Regional Immunization Workshop - L. Hutchinson
Vaccine Incident Reports
Calling Manufacturers

• Scientific/Medical Information

• What do manufacturers need?
  • Product names
  • Max/Min Temperature
  • Duration Out of Range
  • Merck requires lot numbers and expiration dates.

• What do manufacturers provide?
  • Whether they have "In-house Stability Data" to support the continued use of the vaccine based on the temperature parameters provided. You decide whether to continue using the product.
  • Manufacturer cannot “Recommend the use of any product stored outside the parameters listed on the prescribing information.” That would be an “off label” recommendation.
  • May require the information be given to a healthcare professional.
  • Case number
  • Can provider information in writing
### Vaccine Incident Reports

#### Immunization Program Response

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**Excursion Parameters**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Max Temp</th>
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<tr>
<td>Refrigerator 14 hours 15 min</td>
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**Vaccine Manufacturer Contact Information**

- GSK: 888-835-5269
- MedImmune: 877-633-4411
- Merck: 800-637-2500
- Novartis: 800-244-7668
- Sanofi Pasteur: 800-822-2453

1) GSK: Call (800)475-8222 and select option 4.
Vaccine Incident Reports
Immunization Program Response

Email and possibly a phone call followed up by an email:

- Instructions to:
  - Dispose of vaccines according to attached table
  - Fill out Wasted and Expired Form with VIR# to start process to return wasted vaccines
  - Mark vaccines that you can continue to use so they can be identified as having gone through this excursion (cumulative)
  - Log event on trouble-shooting log (cold chain certification)

- Depending on Circumstance may include:
  - Revaccination instructions
  - Trouble-shooting guidance
  - Negligence determination
  - Reimbursement request
  - Repair or replacement instructions
Temperature Excursions, Wastage, and Negligence
2015 - The Year in Review

2015 Vaccine Incident Report Data

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Data Logger Update
Time Flies When You’re Having Fun

• Five years since the start of our Data Logger Program!
  • New VFC requirement nation-wide.
  • We are way ahead of the curve.
  • Our program is serving as a model for other states.
  • Super proud and appreciative of our providers!

• New recommendation for backup data loggers:
  Store in the refrigerator. Doors and crispers are fine.

• Calibrations are due this fall:
  • We will swap out your old data loggers with freshly calibrated devices
  • Install new
  • Return old
  • Monitor for 5 days and send approval data using VIR

Watch your email for detailed instructions
Vaccine Transport

General Policy

• CDC discourages the regular transport of public vaccine and encourages direct shipment from McKesson to the end user.

• Three reasons to transport vaccine:
  • Prevent wastage due to expiration
  • Off site clinics
  • Emergencies

• Use electric coolers if possible. More info from CDC to come as they test electric coolers.

• Use a validated pack-out for non-electric coolers.
Vaccine Transport
New Validated “Pack-Out” for Non-electric Coolers

Materials

• Hard-sided cooler with ≥2 inch walls
• Frozen, conditioned plastic water bottles (2 layers)
• Cardboard (2 layers)
• 1 inch thick insulating material (2 layers)
• Data Logger with buffered probe

DO NOT USE:
• Cool packs from McKesson shipments
• Dry ice
• Soft-sided coolers
• Cold Chain Monitors
Vaccine Transport
Frozen, Conditioned Water Bottles

- Store in freezer until use.
- Will help stabilize freezer temperatures.

To condition for pack-out:
- Remove bottles from freezer.
- Soak in cold tap water until a thin film of water forms between the ice and the bottle wall, and the ice spins freely in the bottle. This takes about 3 minutes.
- Remove bottles from water and blot dry.
- Arrange conditioned bottles in cooler according to pack-out instructions.
Vaccine Transport - Pack-Out
Conditioned vs. Non-conditioned Water Bottles

**Non-Conditioned**
- In-range: 3 days 7 hours
- ≤ Freezing: 3 hours 40 minutes

**Conditioned**
- In-range: 3 days 2 hours

Table: Fahrenheit (°F)
- Max: 53.2
- Min: 38.3
- Avg: 41.4
- Std: 4.2
Vaccine Transport

Best Practices

Transport

Dos:
- Limit amount transported to only what is needed
- Develop a paper temperature log for transports
- Record time and temperature when moving vaccine to and from transport cooler
- If out-of-range temperatures occur, treat as any temperature excursion:
  - Return to monitored ref/freezer
  - DO NOT USE
  - Submit VIR with data logger data
  - Wait for our response on viability
- For electric 12V coolers – determine if your vehicle power outlet is switched (off when car is off) or unswitched (on all the time)

Don’ts:
- Carry transport coolers in the trunk of vehicles or leave coolers in vehicle for extended periods of time.

Off-Site Clinics

Dos:
- After transport, transfer vaccine to on-site ref/freezer with temperature monitoring (data logger with twice daily paper logging)

Avoid:
- Working out of the transport cooler unless it is electric and plugged in.
- If you must work out of transport cooler:
  - Use data logger and log hourly on paper
  - Have only 1 multi-dose (MDV) and 10 single-dose S/V removed for administration at a time.
Multi-Dose Vials
- Only transport opened, multi-dose vials in an emergency and only within the same organization.
- NEVER transport opened, multi-dose vials between organizations/providers or across state lines.

Frozen Vaccine (Varivax® Proquad®)
- Use an electric cooler/freezer

OR

- Transport with refrigerator vaccines
  - Put barrier between refrigerated and frozen vaccines so they aren’t touching
  - Use frozen vaccine within 72 hours
  - If not used, return to freezer and submit a VIR:
    - DO NOT USE
    - Submit VIR with data logger data (for transport cooler) and times vaccine was removed and returned to regular storage
    - Wait for our response on viability
Questions?