



2016 VFC (Vaccines for Children) Fall Workshop

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Live Webinar
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Topics to be Covered

- Vaccine Storage and Handling
- Transporting Vaccine
- Vaccine Ordering and Returns
- VFC Program Requirements
- Upcoming Requirements for 2017-2018
- Vaccine Updates
- Immunization Champion



Vaccine Storage and Handling



Vaccine Equipment - Refrigerator

- Stand-alone household refrigerators are recommended but do have some disadvantages
- NIST* testing showed household stand-alone refrigerators had possible front-to-back temperature variability
 - when the door was frequently opened - 2.5°C
 - during when the door was kept closed - 1°C

*NIST-National Institute of Standards and Technology



Vaccine Equipment – Refrigerator (cont.)

- Vials in the front of a tray registered warmer temperatures than those in the middle, and vials in the back of a tray registered colder temperatures than those in the middle
- Providers may continue to use these units, but they should be aware of front-to-back temperature variability



Cycling can cause temperature increases in refrigerators

- Temperature increases were greater in household combination units and stand-alone refrigerators than in pharmaceutical-grade refrigerators
- In a refrigerator that is working properly, the defrost cycle may cause a measurable temperature increase, but should not routinely cause temperature excursions



Cycling (cont.)

- Study results are consistent with manufacturer indications that storage units should cycle no more than 2–3 times a day (units that are older or located in a busy clinic with frequent opening and closing of the door may cycle more often)



Vaccine Equipment - Freezer

- Use a separate stand-alone freezer to store frozen vaccines that require storage temperatures between -58°F and $+5^{\circ}\text{F}$ (-50°C and -15°C).
- If your stand-alone freezer needs defrosting, defrost it regularly to maintain temperature stability.
- Best practice is using an auto defrost freezer



Temperatures in Freezers

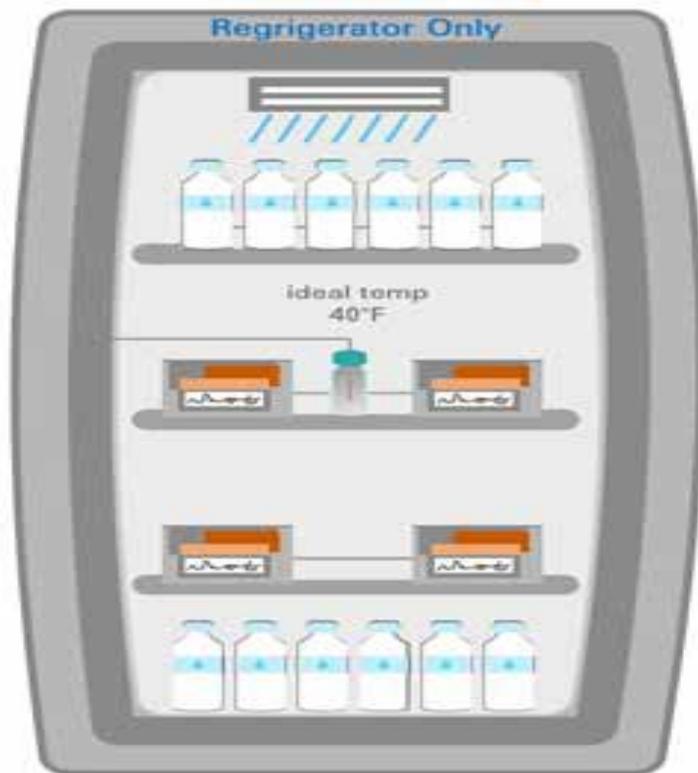
- Factory settings or midpoint temperature settings assure appropriate frozen storage temperatures. In studies, no temperature excursions above -15°C ($+5^{\circ}\text{F}$) occurred when at these settings
- Ultra-low temperature laboratory freezers should not be used for frozen vaccine storage, they can achieve temperatures lower than -50°C (-58°F). Household chest, household under-counter, pharmaceutical/ purpose built laboratory under-counter freezers did not reach temperatures below -50°C (-58°F)



Water Bottles Do Help!

- In study results, use of water bottles in stand-alone refrigerators reduced the impact of the defrost cycle by 1°C to 2°C, depending on the location of the probe
- In study results, use of water bottles eliminated excursions above 8°C caused by frequent opening and closing of the storage unit door

Water Bottles



Water bottles help to:

- stabilize temperatures
- minimize effects of frequent door open/closing
- prevent inappropriate vaccine placement when placed in risky storage areas



Water Bottles (cont.)

- Water bottles are recommended even in pharmaceutical storage units per CDC
- Be careful not to cover airflow vents in the unit
- NIST studies do show that during a power outage, pharmaceutical units with glass doors did lose temperature quickly
- Best practice is to use bottles wherever space allows



Storing Frozen Vaccine

- Frozen vaccine should be stored in plastic trays on racks or shelves in original packaging
- Although no temperature excursions occurred, in studies, vaccine placed directly on the freezer floor registered more temperature fluctuations than vaccine stored in a tray on a wire shelf



2016 CDC Vaccine Storage and Handling Toolkit

- Released June 2016
- Six months before CDC has all materials updated (temperature charts, etc.)
- Should implement immediately—will be required by January 1, 2017



2016 CDC Vaccine Storage and Handling Toolkit

- There is no change to the freezer temperature range
- Changes/adjustment in refrigerator temperature range:
 - Fahrenheit was 35°- 46°F and is now 36°- 46°F
 - Should try to maintain at 40°F
 - Celsius range remains unchanged



2016 Storage and Handling Toolkit (cont.)

- If temperature is at 35°F, is it considered an excursion? No, as long as the manufacturer states the range begins at 35°F
- A complete Q&A will be posted on the Immunization Program Website



Temperature Excursion

If you have a temperature excursion, the following steps must be taken:

- Remove vaccine from the unit not working and put in another working unit. Mark “do not use” on the vaccine
- Contact each manufacturer to discuss the viability of the vaccine
- If viable, put vaccine back in unit and document the incident
- If non-viable, the vaccine must be returned to McKesson following the return protocol



Thermometers

- Must have a valid Certificate of Calibration that matches each thermometer you have in the unit on site
- Order a new thermometer a couple of months before the old expires
- Discard old Certificate of Calibration and keep the new one in a secure location
- Before purchasing a new thermometer, request a copy of the certificate of calibration to assure it meets the requirements



Transporting Vaccine

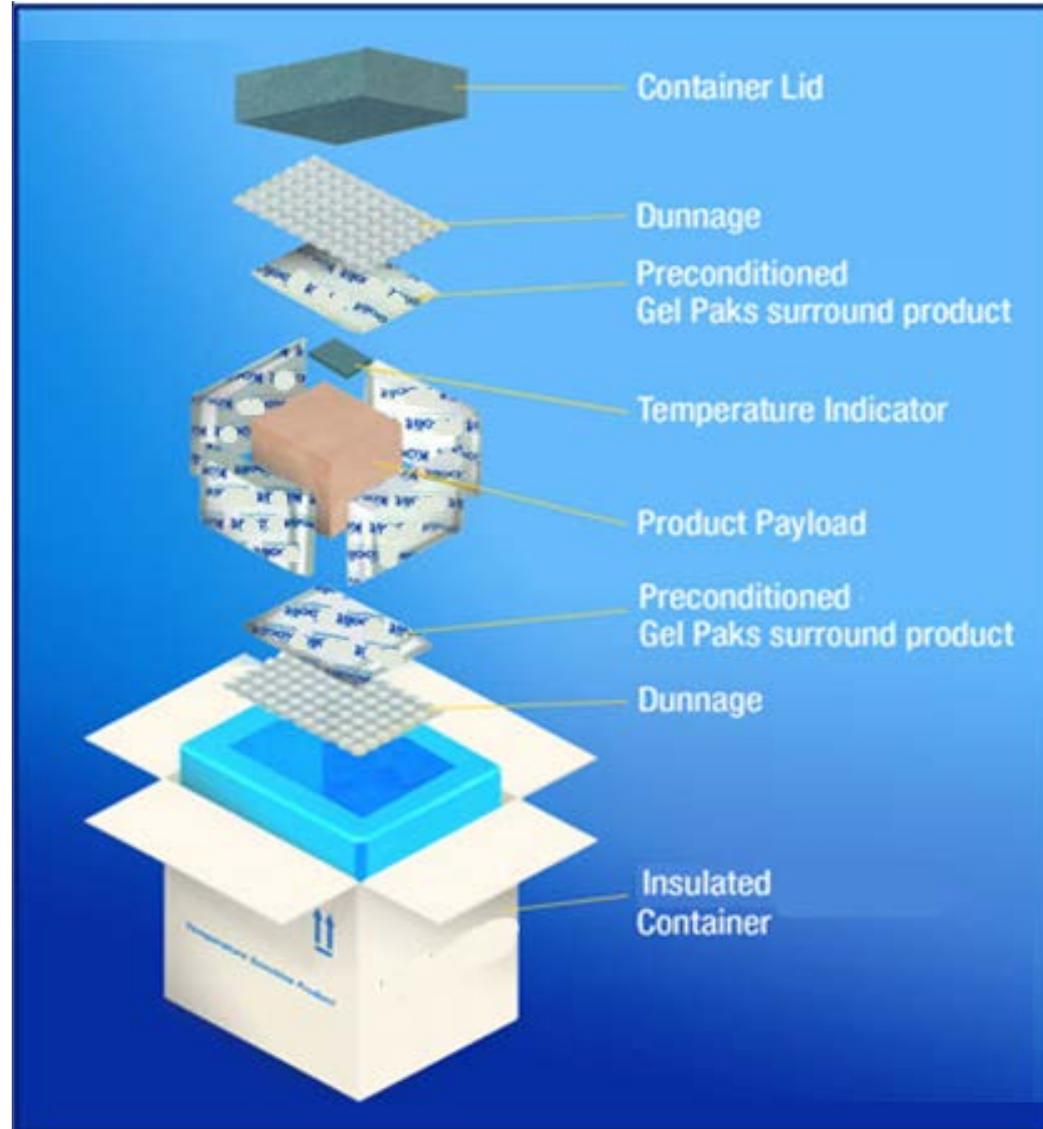


Guidance for Vaccine Transport - Containers

- Recommended Containers:
 - Hard-sided coolers
 - Styrofoam coolers/vaccine shipping boxes (a minimum of 2" walls)
 - Any pre-qualified cold chain transport container
 - **DO NOT USE soft-sided collapsible coolers**
 - Poorly insulated containers resulting in significant temperature gradients
- Should have containers that are large enough to move the provider's entire stock



Example of a qualified pack out



CDC does not endorse the use of any Manufacturer or Brand for Qualified Containers and pack outs



Transporting Vaccine (cont.)

- If you are moving your office, plan your move ahead of time!
- Your vaccine needs to go to an alternate location during the move
- Refrigerators that are moved should be plugged in and monitored for three days before vaccine is returned to the unit



Vaccine Ordering and Returns



Ordering Vaccine

- All providers should only order enough vaccine for a 4-5 week supply
- All inventory must be verified and updated before you place your order
- Orders will be denied if your inventory has not been adjusted or it appears you will have too much vaccine on hand
- Point of Contact for vaccine orders:
 - Lynette Hanson, Lynette.hanson@wi.gov
 - 608-267-5148



Accepting Orders and Transfers

- It is a requirement that every provider accept transfers that occur in WIR
- Subsequent orders will be denied if ordered transfers are not being accepted in WIR upon receipt of vaccine from McKesson



Ordering Vaccine - Holidays

- Last date to place an order in 2016 will be Friday, December 9, 2016
- Orders will be uploaded to McKesson and may be delivered before the end of the year.
- Normal processing of orders will resume the week of January 2, 2017



Vaccine Returns

- All vaccines must be returned to McKesson (includes multi-dose vials that are not open)
- McKesson return form must be completed
- Label will come via email or mail (keep WIR contact up-to-date so email can be used)
- If label is not received within 10 days after receipt of VTrckS* Return Number, contact the person who sent it to you



Returns (cont.)

- Resending return forms causes duplicate returns to be processed
- After 30 days of assigning a VTrckS Return Number, McKesson will not allow any state to request a new label. The return will have to be cancelled and reentered



Returns (cont.)

- Once you have submitted your return to the Immunization Program, **you cannot add or remove any other vaccine to that return.** The numbers must be the same.
- Adding additional product causes additional work for all. In April, there were 80 corrections that had to be made.



Returns (cont.)

- Value of vaccines returned between 8/1/2015 and 7/31/2016 is \$2.9 million (this includes all vaccines)
- Influenza vaccine alone was approx. \$2.2 million (expired)



- Reason for Return and doses returned:
 - Expired Vaccine: 149,828 Doses
 - Mechanical Failure: 9,062 Doses
 - Natural Disaster: 538 Doses
 - Refrigerator too Warm: 201 Doses
 - Failure to Store Upon Receipt: 174 Doses
 - Total Returned: 160,399 Doses



VFC Program Requirements



Wisconsin VFC Requirements (not all inclusive)

- Vaccines must be kept in their original packaging (or in amber bags or baggies with NDC#, Lot # and Expiration Date clearly marked outside)
- Temperatures must be recorded twice a day
- Minimum/maximum temperatures must be recorded and initialed



WI VFC Requirements (cont.)

- All vaccine orders must be placed via the WIR
- All vaccines administered must be entered into the WIR (either through direct entry or data exchange)
- VFC eligibility must be recorded at the dose level, not just the client level



WI VFC Requirements (cont.)

Required to screen and document for VFC eligibility at each visit: (must meet one)

- < 19 years old
- No insurance
- Medicaid eligible
- American Indian or Alaska Native (AI/AN)*
- Underinsured** (does not include high deductible or high copay)
- * No proof needed. If patient states they are AI/AN, they are VFC eligible
- ** Only at a FQHC or RHC



Re-enrollment 2016

- Annual re-enrollment is required for the program.
- Re-enrollment was in May/June
- Portal now closed
- Sites that did not re-enroll have been suspended
- To continue in the VFC Program, suspended sites would need to enroll again



Vaccine Restitution Policy

Vaccine Restitution Policy (Wastage)

- Dose-for-dose replacement of vaccines that are lost due to negligence (i.e., left vaccine on the counter, didn't plug refrigerator in, etc.)
- Expired vaccine is excluded (unless a pattern of over ordering occurs, you may then be responsible)
- Will be sent in September through the mail
- Must be signed and returned by every provider or you may be suspended until it is signed



Continuous Electronic Temperature Monitoring

Electronic Continuous Temperature Monitoring
(piloting with 20+ providers)

- Letters going on to providers who have expressed interest in off site monitoring
- Agreement to be signed
- Followup with sites to determine how it is working
- After 6 months of testing other providers can apply



Minimum Requirements

- Provider must have specific protocols and systems for:
 - Training staff on proper use and interpretation of data
 - Training staff on proper actions needed when temp excursions occur
 - Must be able to provide historical data upon request from the VFC Program
 - Manually monitor temps when monitoring system is not working
 - Test alarm functions at least 2x/year and document



Equipment Requirements

- The monitoring system must meet all of the following:
 - Continuously assess and records temp readings
 - Probes must have current and valid Cert of Calibration. Cert must be kept on-site at each location.
 - Temp probes, encased in buffered material are kept in the center of the unit
 - System is alarmed and alarm is set for appropriate temp ranges



Equipment (cont)

- Documentation of temperature monitoring can be provided in readable and interpretable printed form upon request
 - System must record current temp, time, date and staff name or initials twice daily
 - If system cannot log this information then temperature log must be maintained with the above information
 - Recorded data must be kept for a minimum of three years
- *Recommendation that system records at a minimum of one reading per hour. Many systems record more frequently



New Email List

- The VFC Program is going to be using a new email listserv called GovDelivery
- Add or remove yourself or others
- Users can manage their own accounts
- Important to keep it up-to-date as important information is sent out periodically from the VFC Program
- More information to be coming soon



Upcoming Requirements for 2017-2018



Requirements for 2017

- Annual workshop attendance/viewing will be required for all providers
- For 2016, if a site visit has been scheduled, you are exempt
- In 2017, if you have a site visit, you will still be required to attend the workshop or view a recorded webinar



Requirements for 2017

- Updated Vaccine Management Plan is available and must be signed, dated, and posted
- Must post an Emergency Response Plan

Both of these are required to be posted where everyone can see or knows where to find in the event of an emergency



Requirement for 2018 Digital Data Loggers

- 2012 – Initial CDC provider recommendations
 - Use of digital data loggers with a probe in liquid
 - Separate stand-alone units were recommended
- 2018 – Initial CDC provider requirement: All VFC providers will be required to use a digital data logger, which is an electronic device with a buffered probe used for continuously monitoring and recording temperatures



Data Logger Requirements

CDC has released the following statement:

“**All** VFC providers storing federal vaccine must use a continuous temperature monitoring device with an active temperature display, with continuous monitoring and recording capabilities where the data can be routinely downloaded, and a detachable, buffered probe.”



Data Loggers (cont.)

Data logger features include:

- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperatures
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings
- User programmable logging interval (or reading rate)



Data Loggers (cont.)

- Providers will continue to be required to perform twice-a-day assessment and recording of temperatures. However, the details on meeting this requirement will be updated with the deployment of the requirement in 2018
- VFC Program will make available a list of data loggers and contacts. This is not an endorsement for one product over the other



Vaccine Updates



2016-17 Influenza Season

- FluMist® is not available this year
- State supplied prebooked FluMist® will be automatically converted to an injectable prefilled syringe product:
 - GSK .5 Prefilled Syringe
 - Sanofi .5 Prefilled Syringe
 - Seqirus .5 Prefilled Syringe



New Vaccine - 2016

Flucelvax – Manufactured by Seqirus

- Quadrivalent Product
- Produced using cell culture technology
- Uses cells rather than eggs
- Preservative free
- Latex free
- 4 years and above
- Side effects similar to other influenza vaccines



Flucelvax-Efficacy

- 7 international clinical trials
- 11,404 participants
- 83.8% prevention of influenza caused by viruses matched to those in the vaccine trial
- 69.5% prevention of all influenza viruses



Vaccine Availability

- HPV9 (HPV4 is no longer available)
- Bexsero-Novartis - MenB
- Trumenba-Pfizer - MenB
- MenHibrix-GSK -MenB+Hib



Vaccine Updates

- Pentacel continues to be in short supply through 2016
- Single antigen products are available



Vaccine Presentations

Effective October 1, 2016

- Will continue to have choice of vaccines
- Currently many vaccines available in both syringe and vial
- Beginning October 1, 2016, certain presentations for some vaccines will not be available



Presentations (cont.)

| Vaccine Type | Current Presentation | As of October 1 |
|-----------------------------|----------------------|-----------------|
| Infanrix | Vial/Syringe | Syringe Only |
| Kinrix | Vial/Syringe | Syringe Only |
| Hep A-Ped/Havrix | Vial/Syringe | Syringe Only |
| Twinrix | Vial/Syringe | Vial Only |
| Hep B-Ped/Engerix | Syringe | Syringe Only |
| Hep B-Ped/Recombivax | Vial/Syringe | Vial Only |



Immunization Champions

- Annually, one Champion from each state is honored and it is announced during National Infant Immunization Week (which is typically in April of each year)
- A champion shows skills in leadership, collaboration, innovation, and is an advocate for immunizations.
- <http://www.cdc.gov/vaccines/events/niiw/champions/index.html>

WI Immunization Champion 2016



- Joyce Osieczanek, Medical Assistant, Aurora Health Care, Sheboygan, WI



Joyce Osieczanek

- Immunization Coordinator for Aurora Health Care, Sheboygan
- Develops and implements policies and guidelines that help Aurora be more efficient and effective in immunization services
- Educates pediatricians, nurses, and other medical professionals in her area
- Assisted in establishing the Sheboygan County Immunization Coalition
- Go to the website to see her complete biography



How to Be Considered

- Either be nominated by another or self nominate
- Submit nomination form directly to the Wisconsin Immunization Program
- Include a picture of the nominee
- Can submit any time during the year for consideration for the next year



Errors

- Continue to receive monthly temperature chart submission. This requirement was rescinded in 2013.
- Many sites are still not screening properly for VFC eligibility.
- All required documentation of federally required information is still not being documented.
- If unsure, please contact your Regional Advisor or the Immunization Program at 608-266-1506.



To Receive Credit for Attending

- Next week you will be required to go back into TRAIN and complete an assessment on this training
- Upon successful completion of the assessment you will be sent a certificate via TRAIN
- Instructions will come next week via email on how to complete the assessment and receive the certificate



- Upon completion of the assessment you will receive a certificate. You should print this out and keep with your other VFC documents.



Department of Health Services



THANK YOU!