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CDC did not accept commercial support for this continuing education activity.
Achieving Compliance with Vaccines for Children Program Storage Unit and Thermometer Requirements

Melissa Mickle-Hope, MPH
Arianne Ramautar, Georgia Elysee and Amy Metroka
National Immunization Conference
Atlanta, Georgia
May 15, 2018
Outline

• Background
  o Citywide Immunization Registry (CIR)
  o New York City Vaccines for Children (VFC) Program
  o Changes in VFC Policy

• Project Description-Storage and Handling Compliance

• Results

• Conclusions

• Next Steps
Citywide Immunization Registry

• The Immunization Information System (IIS) for New York City (NYC)
  o Began citywide in 1997
  o Contains > 7 million patients
    • > 96 million immunizations
  o Mandatory reporting of immunizations for children <19 years
  o Reporting for adults ≥19 years requires consent

• Methods of reporting:
  o Non-standard batch file transfer - 4%
  o Online Registry (OLR) - 16%
  o HL7 Web service (from provider electronic health records) - 80%
NYC VFC Program

- >1,360 enrolled providers
  - 81% of all pediatric provider sites in NYC
    - 74% of children in NYC aged 0-18 years are eligible for publicly funded vaccine
    - NYC distributes > 3 million doses of VFC vaccine annually, valued at > $140 million

- All VFC vaccines are ordered through CIR’s Vaccine Inventory Management (VIM) system

- VFC vaccine distribution is linked to CIR reporting
  - Incentivizes providers to accurately report VFC vaccine usage

- Provider Quality Assurance (PQA) staff
  - Perform VFC compliance activities
  - Assessment Feedback Incentive eXchange (AFIX) visits
Vaccine Inventory Management

In June, 2017, the CIR’s Vaccine Inventory Management (VIM) system was released for all NYC VFC providers

- Built on existing Online Ordering Tool
- Automatically populated with vaccine lots shipped to providers
- Enables lot-level vaccine management
  - Including new reports to help track and manage inventory
- Inventory decremented when:
  - Administered vaccine doses are reported
  - Vaccine doses are reported as spoiled, expired or wasted
  - Manual inventory adjustments are made
- Contains fields for vaccine storage and thermometer data entry
  - Captures up-to-date storage information
  - Important since VFC site visits are conducted every other year
VIM: Accounting for VFC Vaccine Inventory

Enter your On-Hand Inventory for each lot

- Quantities in the Difference column will update accordingly
- Account for discrepancies between the CIR Expected Inventory and the On-Hand Inventory.

### Public Inventory

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Brand / Mfr</th>
<th>Lot#/ Exp.Date</th>
<th>Presentation</th>
<th>CIR Expected Inventory</th>
<th>On-Hand Inventory</th>
<th>Difference</th>
<th>Adjust Direction</th>
<th>Adjust Quantity</th>
<th>Adjustment Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hep B</td>
<td>Recombivax HB (Merck)</td>
<td>K010216 09/17/2016</td>
<td>SDV, 10-Pack</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>+</td>
<td>10</td>
<td>Select an Option</td>
</tr>
<tr>
<td>HPV</td>
<td>Gardasil (Merck)</td>
<td>K011502 04/08/2017</td>
<td>SDV, 10-Pack</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>-</td>
<td>10</td>
<td>Select an Option</td>
</tr>
<tr>
<td>MMR</td>
<td>MMR (Merck)</td>
<td>K018905 01/15/2016</td>
<td>SDV, 10-Pack</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>+</td>
<td>10</td>
<td>Select an Option</td>
</tr>
<tr>
<td>Hib</td>
<td>Pedvax Hib (Merck)</td>
<td>K023204 07/22/2017</td>
<td>SDV, 10-Pack</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>-</td>
<td>10</td>
<td>Select an Option</td>
</tr>
<tr>
<td>IPV</td>
<td>IPV (Inactivated Polio)</td>
<td>K1530-06/20/2016</td>
<td>MDV, 10-Pack</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>+</td>
<td>10</td>
<td>Select an Option</td>
</tr>
<tr>
<td>IPV</td>
<td>IPV (Inactivated Polio)</td>
<td>K1513-09/19/2016</td>
<td>MDV, 10-Pack</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>-</td>
<td>10</td>
<td>Select an Option</td>
</tr>
<tr>
<td>VAR</td>
<td>Varivax (Merck)</td>
<td>L001332 01/13/2017</td>
<td>SDV, 10-Pack</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>+</td>
<td>10</td>
<td>Select an Option</td>
</tr>
</tbody>
</table>

Adjust CIR Expected Inventory by Dose

Further reconcile before proceeding. By submitting this inventory count, you confirm that you have physically counted VFC-complete.
Changes in VFC Policy

• January 1, 2018, CDC requires:
  o Use of stand-alone or biologic/pharmaceutical-grade refrigerators and freezers
  o Use of continuous digital data logger (DDL) thermometers with a temperature probe and active temperature display

• January 12, 2018, NYC VFC program requires:
  o Upload of DDL summary reports into VIM as part of the vaccine ordering process
# VIM: Collecting Storage Unit Data

## Stand-Alone Units

<table>
<thead>
<tr>
<th>Refrigerator Units</th>
<th>Freezer Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Stand Alone Refrigerator</td>
<td>Small Stand Alone Chest Freezer</td>
</tr>
<tr>
<td>Regular Stand Alone Refrigerator</td>
<td>Regular Stand Alone Chest Freezer</td>
</tr>
<tr>
<td>Commercial Stand Alone Refrigerator</td>
<td>Stand Alone Freezer</td>
</tr>
<tr>
<td>Stand Alone Pharmaceutical Grade Refrigerator</td>
<td>Stand Alone Pharmaceutical Grade Freezer</td>
</tr>
</tbody>
</table>

- The typical storage capacity of a single unit is 9.7 ft³. The storage capacity of your unit(s) may be different.
- The typical storage capacity of a single unit is 2.9 ft³. The storage capacity of your unit(s) may be different.
- The storage capacity of your unit(s) may be different.
- The storage capacity of your unit(s) may be different.

## Combined Refrigerator & Freezer Units

<table>
<thead>
<tr>
<th>Refrigerator &amp; Freezer Units</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Household Refrigerator &amp; Freezer</td>
<td>Regular Household Refrigerator &amp; Freezer</td>
</tr>
<tr>
<td>Large Household Refrigerator &amp; Freezer</td>
<td>Pharmaceutical Grade Refrigerator and Freezer</td>
</tr>
</tbody>
</table>

- The typical storage capacity of a single unit is 8.0 ft³. The storage capacity of your unit(s) may be different.
- The typical storage capacity of a single unit is 15.0 ft³. The storage capacity of your unit(s) may be different.
- The typical storage capacity of a single unit is 29.0 ft³. The storage capacity of your unit(s) may be different.
- The typical storage capacity of a single unit is 7.4 ft³. The storage capacity of your unit(s) may be different.
VIM: Collecting Storage Unit & Thermometer Data

### Vaccine Storage Unit Editor

**Storage Unit Information**

**Pharmaceutical-Grade Refrigerator and Freezer 1**

- **Unit name:** Test Unit
- **Section of Unit Used:** Refrigerator and Freezer
- **Estimated Refrigerator Capacity (ft³):** 6
- **Estimated Freezer Capacity (ft³):** 1.4
- **Storage Unit Brand:** Test
- **Auto Defrost? (Freezer Only):** Yes

#### Thermometer Information

- **I have 1 thermometer with a dual probe in the refrigerator and freezer (entire unit used):**
- **I have 2 separate thermometers, 1 in the refrigerator and 1 in the freezer (entire unit used):**
- **I have 1 thermometer in the freezer (freezer only section used):**
- **I have 1 thermometer in the refrigerator (refrigerator only section used):**

##### Refrigerator Thermometer

- **Is this a Continuous Data Logger:** Yes
- **Thermometer Brand:** Test Brand
- **Thermometer Model Number:** XX
- **Calibration Expiration Date:** 01/01/2019
- **Does this thermometer have a buffered probe:** Yes

##### Freezer Thermometer

- **Is this a Continuous Data Logger:** Yes
- **Thermometer Brand:** Test Brand
- **Thermometer Model Number:** XX
- **Calibration Expiration Date:** 01/01/2019
- **Does this thermometer have a buffered probe:** Yes

[Image: screenshot of the Vaccine Storage Unit Editor interface]
VIM: DDL Summary Report
Upload Feature

Refrigerator/Freezer Information

Storage Capacity and Modifying Storage Units

- Please enter the storage capacity used for VFC vaccine for each unit in your practice.
- To add or remove storage units, or to edit unit information, click on the 'Modify Storage' button.

Please note: Effective January 1, 2018, Continuous Digital Data Logger (DDL) thermometers are required.

Uploading a Thermometer Summary Report

- DDL thermometer summary reports should be uploaded for each storage unit at your practice.
- Summary report dates should be in accordance with your vaccine ordering tier (monthly, bi-monthly or quarterly) or should cover the time period since your last order.
  - For example, if you have two (2) storage units and order vaccines quarterly, you must upload a DDL report for each of the units covering the previous three (3) months or the dates since your last order.
  - Temperature logs are not acceptable, only upload DDL summary reports.
- To attach your temperature summary report, click on the 'Choose File' button and select the file.

Acceptable formats: pdf, jpeg, png, .txt, .xls, .xlsx

<table>
<thead>
<tr>
<th>Unit Name</th>
<th>Estimated Storage</th>
<th>Storage Used for VFC Vaccine</th>
<th>DDL Summary Report Upload</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test329</td>
<td>9.7 ft³</td>
<td>* 100% ▼</td>
<td>Choose File</td>
</tr>
<tr>
<td>Continuous DDL: Y, Calibration Exp. Date: 12/31/2060</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular Stand-Alone Chest Freezer 1</td>
<td>15.0 ft³</td>
<td>* 100% ▼</td>
<td>Choose File</td>
</tr>
<tr>
<td>Continuous DDL: Y, Calibration Exp. Date: 12/31/2020</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Required
Temperature Excursions

• VFC staff review DDL summary reports before order is approved
• If report contains an excursion that has not been reported, VFC staff follow-up with the site
  o Provider contacts vaccine manufacturers and submits documentation as to the viability of the vaccine
  o Provider must submit a temperature excursion report
    ▪ Length of excursion
    ▪ Amount and type of vaccine affected
General Provider Outreach

• Held training webinars focusing on new CDC rules
• Installed DDLs in eligible sites
• Distributed educational materials:
  o Vaccine Storage & Thermometer Guide
  o DDL Summary Upload Guide
  o Storage & Handling Job Aids
  o DDL Summary Report Downloading Guides
Storage and Thermometer Compliance

- Used real-time storage and thermometer information entered by providers into VIM
  - Targeted providers who were out of compliance with new VFC regulations
  - Measured citywide provider compliance weekly
  - Measured spoiled doses reported as a result of DDL summary report upload
Targeted Provider Outreach Based on VIM Data

• Sent emails and made phone calls to providers with:
  o Non-compliant storage units
  o Non-compliant thermometers
  o Thermometers with expired certificates of calibration

• Conducted site visits
  o VFC contact visits
  o DDL installations
  o New storage unit inspections

• Placed providers with non-compliant units on hold
  o Sites using combined refrigerator and freezer storage units
Results
Provider Outreach

• 4 Webinars
  o 369 participants
    ▪ 318 provider sites

• DDL distribution and support
  o DDL thermometer installations, >80 in 2017
    ▪ >400 DDLs installed previously
  o DDL troubleshooting visits, >60
VFC Contacts

*CDC PEAR Data
Storage Unit Compliance

September 14, 2017
VFC Sites = 1,088
- 67% Compliant Units
- 25% Non-Compliant Units
- 8% One or More Unit is Compliant

April 27, 2018
VFC Sites = 1,334
- 91% Compliant Units
- 6% Non-Compliant Units
- 3% One or More Unit is Compliant
DDL Compliance

September 14, 2017

VFC Sites = 1,088

- DDL Thermometers: 60%
- Non-DDL Thermometers: 36%
- One or More Thermometer is a DDL: 4%

April 27, 2018

VFC Sites = 1,334

- DDL Thermometers: 81%
- Non-DDL Thermometers: 16%
- One or More Thermometer is a DDL: 3%
Unreported Spoiled Vaccine Doses Identified

<table>
<thead>
<tr>
<th>Date of Occurrence</th>
<th>Spoiled Doses Identified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov 17</td>
<td>6</td>
</tr>
<tr>
<td>Dec 17</td>
<td>449</td>
</tr>
<tr>
<td>Jan 18</td>
<td>1,769</td>
</tr>
<tr>
<td>Feb 18</td>
<td>301</td>
</tr>
<tr>
<td>Mar 18</td>
<td>427</td>
</tr>
<tr>
<td>Apr 18</td>
<td>155</td>
</tr>
</tbody>
</table>
Decrease in VFC Orders (2016-2018)

Number of Vaccine Orders

Date

2016  2017  2018

VIM Deployment 8% Decrease

New VFC Requirements 16% Decrease
VFC Ordering Survey

- Conducted phone survey in February, 2018
  - Called 223 sites due to order but hadn’t placed orders
  - Collected 113 survey responses
  - Gave immediate assistance to providers or referred them to appropriate staff for follow-up
Why Hasn’t Your Site Ordered VFC Vaccine?

- No issues and plan to place an order soon: 50%
- Inappropriate storage units: 11%
- No DDLs on site: 11%
- Sufficient vaccine inventory-no need to order: 10%
- Other: 8%
- Need help with DDL installation: 5%
- Unsure how to retrieve or upload DDL summary report: 4%
- Problem understanding the new vaccine ordering system: 3%
CIR Reporting for VFC Sites vs. Non-VFC Sites 2016-2018

The graph shows the number of immunizations reported monthly from January 2016 to December 2018 for VFC Sites (2016 VFC Sites, 2017 VFC Sites, 2018 VFC Sites) and Non-VFC Sites (2016 Non-VFC Sites, 2017 Non-VFC Sites, 2018 Non-VFC Sites). The x-axis represents the months from January to December, while the y-axis represents the number of immunizations reported.
Conclusion

• VIM storage and thermometer data enabled the tracking of provider compliance with new CDC storage and thermometer requirements
  o Targeted outreach to providers was successful
    ▪ Percentage of sites with compliant storage units increased from September 2017 to April 2018
      • 67% vs. 91%
    ▪ Percentage of sites with DDL thermometers increased from September 2017 to April 2018
      • 60% vs. 81%
  o DDL summary report upload process led to the discovery of over 3,000 doses of spoiled vaccine
  o Observed decrease in VFC vaccine orders submitted
    ▪ Continue to work with providers to address outstanding issues
Next Steps

• Monitor compliance with CDC requirements
  o Provide assistance as necessary
  o Track expired thermometer certificates of calibration

• Monitor vaccine ordering patterns

• Compare VIM data with data entered into PEAR

• Identify storage unit brands with high rates of temperature excursions
  o Encourage providers to purchase storage units that effectively hold in-range temperatures
Thank you!
Improving Vaccine Storage and Handling Compliance in New York City Pharmacies

Edward Wake
New York City Department of Health and Mental Hygiene
Bureau of Immunization
2018 National Immunization Conference
Atlanta, Georgia
May 15, 2018
Outline

• Overview of the Standing Order (SO) Program for New York City (NYC) Pharmacists
• Pharmacists’ Requirements
• Vaccine Storage and Handling (S&H) Requirements
• Quality Assurance Visit
• S&H Deficiencies Among NYC Pharmacies
• Improving S&H Compliance
• Conclusions
• Limitations
• Next Steps
New York City Department of Health and Mental Hygiene (DOHMH) issues an annual, non-patient specific SO for NYC pharmacists to vaccinate adults (≥ 18 years old)

- Began with ~55 pharmacy SOs for the 2010-11 influenza season
- In 2017-18, DOHMH issued 190 SOs for 211 independent and small-chain pharmacies
- Vaccines: flu, pneumococcal, meningococcal, zoster, tetanus and diphtheria (Td) and tetanus, diphtheria and pertussis (Tdap)
Pharmacists’ Requirements

• Attend an orientation session with Bureau of Immunization (BOI) and enter into a Cooperative Agreement (CA) with DOHMH
• Be certified to administer vaccines in New York State (NYS) and adhere to NYS professional responsibilities
• Follow vaccine administration protocols and Advisory Committee on Immunization Practice recommendations
• Report all vaccinations to the NYC Citywide Immunization Registry (CIR) according to NYS and NYC requirements
• Adhere to required S&H guidelines for vaccines
Storage and Handling Requirements

- Requirements are based on Vaccines for Children (VFC) program requirements
  - Vaccine storage units should be pharmacy grade and able to maintain a temperature of 36°-46°F (2° - 8°C)
  - A stand-alone freezer that reliably maintains a temperature between -58° and +5°F (-50° and -15°C) must be used to store Zostavax® zoster vaccine
  - Stand-alone refrigerator may be used. Combined refrigerator units must have separate exterior doors for the refrigerator and freezer components
    - No dormitory-style refrigerators
  - Refrigerator and freezer temperatures monitored with certified and calibrated thermometers that have probe extensions in buffered solution
  - Thermometers must be able to document temperature twice daily and record minimum/maximum temperatures
    - Digital data loggers (DDL) for continuous temperature monitoring are preferred.
Quality Assurance Site Visits

- Following issuance of SO:
  - All new sites and 5-10% of returning sites receive a quality assurance (QA) site visit by BOI Adult Immunization staff annually
  - Education and supporting materials provided at each visit
  - Adherence to protocols, requirements and recommendations for documentation, reporting storage and handling assessed using a standardized questionnaire
  - Onsite corrections made when feasible
  - Sites receive a letter describing strengths, deficiencies, areas for improvement
Deficiencies in S&H Compliance: 2016-17

• QA visits conducted *after SOs were issued* showed variable compliance with S&H requirements
  o Of the 43 site visits conducted during the 2016-17 season, 14 (33%) pharmacies had at least one S&H deficiency
  o QA visits to pharmacies in previous years showed similar problems with S&H deficiencies
Objective: To increase the number of pharmacies that adhered to the S&H requirements during the 2017-18 season, BOI added 2 requirements:

- All pharmacies required to provide photographic documentation of refrigerator and freezer storage units as well as thermometers *prior to receiving a standing order*
  - Pharmacists also asked if they planned to store Zostavax vaccine
- All pharmacies required to provide certificates of calibration for thermometers *prior to receiving a standing order*
QA Workflow: 2010-11 through 2016-17

Orientation

Receive signed CA/Issue SO

Site visit to selected pharmacies

Find deficiency(ies), if any

Require pharmacy to remedy deficiency(ies)
Orientation

QA Workflow: 2017-18
QA Workflow: 2017-18

Orientation → Review submitted photo documentation → → →

← ← ← ←
QA Workflow: 2017-18

Orientation → Review submitted photo documentation → Find deficiency(ies), if any
QA Workflow: 2017-18

1. Orientation
2. Review submitted photo documentation
3. Find deficiency(ies), if any
4. Require pharmacy to remedy deficiency(ies)

Reverse Flow:
1. Green
2. Purple
3. Blue
4. Red
QA Workflow: 2017-18

Orientation

Review submitted photo documentation

Find deficiency(ies), if any

Require pharmacy to remedy deficiency(ies)

Require pharmacy to remedy deficiency(ies)

Find deficiency(ies) if any

Site visit to selected pharmacies

Receive signed CA/Issue SO
2017-18 Standing Order QA Results
S&H Compliance: 2017-2018

242 Pharmacy Sites Attend Orientations

40 Exempted (Received a satisfactory QA Visit in 2016-17)

29 Opted Out (8 opted out 2017-17)

173 Pharmacy Sites Submitted Photos
S&H Compliance: 2017-2018

- Of the 173 pharmacy sites submitting photos, 31 had at least one apparent deficiency

<table>
<thead>
<tr>
<th>Deficiency</th>
<th>Number of Pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dormitory Style Refrigerator</td>
<td>7 (4%)</td>
</tr>
<tr>
<td>Noncompliant Thermometer</td>
<td>16 (9%)</td>
</tr>
<tr>
<td>Using Freezer Compartment of Combined Refrigerator*</td>
<td>13 (21%)</td>
</tr>
<tr>
<td>Using Freezer Component of Dormitory Style Refrigerator*</td>
<td>3 (5%)</td>
</tr>
</tbody>
</table>

*Only required if pharmacy planned to store Zostavax (n=61)
S&H Compliance: 2017-2018

• The thirty-one pharmacies not meeting S&H requirements contacted by BOI staff
  ○ Pharmacists complied by purchasing new equipment and providing photo documentation and/or calibration certificates, often within a few days
  ○ Some had difficulty acquiring required equipment

• Some pharmacies submitted incomplete or unclear photo documentation
  ○ BOI contacted pharmacists to send new photos; pharmacists eventually complied

• Of the 173 pharmacies submitting photos, all were ultimately compliant and received a standing order.
  ○ Some participating pharmacists expressed confusion over the process
  ○ Documentation process was labor-intensive due to limited staff power
Samples of Submitted Photos-Good
Samples of Submitted Photos-Not So Much
Just a bit outside
Of the 30 QA visits conducted during the 2017-18 season (as of May 4, 2018), there were 2 sites that had at least one S&H deficiency
- 1 had a non-compliant storage unit, e.g. dormitory style fridge
- 1 had thermometer with expired calibration certificate
Conclusions

• QA visits in 2017-18 show fewer pharmacies with S&H compliance issues compared to 2016-17 so far
  o Although only 30 of 48 sites visits have been completed for 2017-18
• All NYC pharmacies participating in the DOHMH SO program ultimately were able and willing to ensure they have compliant S&H equipment, even if there was an extra expense, but
• More sites declined to participate in 2017-18 than 2016-17 (29 vs 8, respectively)
• Process was confusing for some pharmacists
Limitations

• Documentation is self-reported

• Participation in the program was voluntary
  o Pharmacists who chose not participate may have skewed the number of 2017-18 QA visit sites with S&H deficiencies.

• This is a labor-intensive QA process
  o Record-keeping, follow-up, additional photos submissions often required
Next Steps

• Enhance the orientation and photo documentation review for next season so pharmacists are clear on submission protocol
• Continue to analyze S&H compliance after pharmacy QA visits in 2017-18 and beyond
• Compare photo submissions from 2017-18 to those in 2018-19 among returning participants for consistency and accuracy
• Develop plan for sustainability
  o Limited staffing to conduct reviews as program grows
Acknowledgements

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Thank you

Questions?

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Overview

• Assess provider reporting of temperature excursions
• Evaluate provider response to temperature excursions
• Evaluate the need for providers to submit monthly temperature logs
• Assess patient need for revaccination
• Assess provider wastage due to temperature excursions, reported and unreported
Temperature Excursion Tracking

- Providers are supposed to report vaccine excursion by phone, email or an online form.
- Tracking categories
  - Refrigerator/Freezer too warm
  - Refrigerator too cold
  - Power outage
  - Other
  - Not reported
Data Logger Temperature Log Review

- Data logger temperature logs reviewed monthly for all providers first by an Administrative Assistant for any alarms.

- The Administrative Assistant will forward any temperature logs with alarms to the VFC/AFIX Coordinator for immediate follow up.

- Reported excursions are followed up by the VFX/AFIX Coordinator at time of report from the provider as to duration of excursion, temperature, and vaccine viability.

- Excursions that are not reported (found on monthly review of data logger reports) are followed up when temperature logs are submitted as to the duration of excursion, temperature, and vaccine viability.
Temperature Excursion Requiring Reporting

- Cold temperature excursion
  - Below 36°F (2°C) for 15 continuous minutes

- Warm temperature excursion
  - Above 46°F (8°C) for 60 continuous minutes
  - Above 5°F (-15°C) for 60 continuous minutes
Reported Excursions

• 62 temperature excursions were reported from October 1, 2016 through September 30, 2017.
  • 43 total providers
    • 14 of these providers reported more than one excursion

• Total of 999 doses of wasted vaccine

• Cost of $50,402
Reported Excursion, cont.

- 35 temperature excursions were reported from October 1, 2017 through March 31, 2018.
- Total of 219 doses of wasted vaccine
- Cost of $9,002
Unreported Excursions

• 68 temperature excursions were not reported from October 1, 2016 through September 30, 2017.
  • 46 total providers had unreported excursions
    • 17 of these providers had more than one unreported excursion

• Total of 502 doses of wasted vaccine

• Cost of $19,429
Unreported Excursion, cont.

• 15 temperature excursions were not reported from October 1, 2017 through March 31, 2018.

• Total of 9 doses of wasted vaccine

• Cost $120
Revaccination

- 5 providers needed to revaccinate due to nonviable vaccine being administered from October 1, 2016 through September 30, 2017
  - 1 provider reported the excursion after the fact, the alarm was ignored
  - 4 found through monthly review

- 104 total patients

- To-date only 66 patients have been fully revaccinated (63%)

- Providers are sent a template letter to send to patients and a list of patients that were affected from the NDIIS

- The NDDoH will invalidate doses in NDIIS and monitor these patients to see that they are coming back to be reimmunized
Revaccination Cont.

• Issues identified:
  • Patients have been seen and have not received all immunizations needed
  • Patients refused to be revaccinated
  • Populations that do not seek regular medical care and move frequently
  • EMR not showing doses as invalid
Comparison on the number of temperature excursions reported and not reported in the first year of tracking

Projected totals of excursion from October 1, 2017 – September 30, 2018

- 70 reported excursions
  - 8 more reported excursions than 2017
- 60 unreported excursions
  - 38 less unreported excursions from 2017

<table>
<thead>
<tr>
<th>Time Period Assessed</th>
<th>Total of Reported and Unreported Temperature Excursions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reported</td>
</tr>
<tr>
<td>Oct. 1, 2016 - Sept. 30, 2017</td>
<td>62</td>
</tr>
<tr>
<td>Projected Oct 1, 2017 - Sept. 30, 2018</td>
<td>70</td>
</tr>
</tbody>
</table>
From October 1, 2016 through September 30, 2017 the North Dakota Immunization Program ordered 133,336 doses of vaccine

- At a cost of $6,747,633

The total of wasted vaccine due to temperature excursions was 1% of total vaccine ordered

- $69,831 total wastage in that time period

Projected total cost of wasted vaccine for October 1, 2017- September 30, 2018

- $18,004 for reported excursions
  - $32,398 less for reported excursions than 2017
- $240 for unreported excursions
  - $19,189 less for unreported excursions from 2017
Excursions Per Month in 2016-2017

Reported

Unreported
Common Reasons Reported

- Unit failure
- Power outage
- Unit door left ajar
- Room temperature
- Incorrect transporting of vaccine
- Unknown cause
Common Reasons for Unreported Excursions

- Unaware that an excursion has occurred
- Temperature probe has fallen out of the unit or moved in the unit
- Unit failure
- Unit doors left ajar
Online Reporting

• December 14, 2017 online reporting became an option for North Dakota providers.

• To-date 24 reports of excursions have been made with the online form.
  • 7 of these reports were found to be not be true excursions.

• Automatically emailed to NDDoH staff for review
What We Learned

• Monthly review will continue to be conducted due to quantity of unreported excursions

• Some providers are not acknowledging temperature excursions or reviewing their data logger temperatures

• In not reviewing data logger information providers are administering nonviable vaccine

• Nonviable vaccine being administered and the need for revaccination impacts the public trust in vaccines and provider facilities
Pros and Cons of Temperature Monitoring

Pros

• Temperature excursions were found that would not have been.

• Revaccinations did occur, but more patients would have potentially needed revaccination.

• Increased provider awareness of temperature excursions.

Cons

• Time consuming

• Even with education, some providers are still not acknowledging temperature excursions.
Contact Information

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• http://www.ndhealth.gov/immunize/