

Using an IIS to Achieve Compliance with Vaccines for Children Program Storage and Handling Requirements

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Outline

- Background
 - Citywide Immunization Registry (CIR)
 - New York City (NYC) Vaccines for Children (VFC) Program
 - Changes in Center for Disease Control and Prevention (CDC) VFC Policy
 - NYC VFC Program Objectives
- Implementation Strategies
 - Vaccine Inventory Management (VIM) System
 - Changes in NYC VFC Policy
- Methods of Achieving Storage and Handling Compliance
- Results
- Conclusions
- Next steps

Citywide Immunization Registry

- The Immunization Information System (IIS) for New York City (NYC)
 - Began citywide in 1997
 - Contains > 7 million patient records
 - > 104 million immunizations
 - Mandatory reporting of immunizations for children <19 years
 - Reporting for adults ≥19 years requires consent

NYC VFC Program

- >1,370 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
- 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
 - Vaccine orders may be reduced if CIR reporting is low

Office of the Inspector General Audit

- Purpose was to evaluate CDC's oversight of the VFC Program
- Conducted by federal auditors in 2011
- Examined provider practices to ensure VFC vaccine accountability and proper vaccine storage and handling
 - Visited 45 provider sites in the 5 largest VFC programs (4 states, 1 city)
 - Installed Digital Data Logger(DDL) thermometers to monitor storage unit temperatures
- Findings released in 2012
 - Storage and Handling issues identified
 - Demonstrated temperature excursions not picked up by twice daily monitoring

Audit Response: PPHF Grant

- Prevention and Public Health Fund (PPHF) Grant awarded to NYC VFC in 2012
 - Improve temperature monitoring and storage and handling practices
 - Improve vaccine management and accountability
 - Increasing provider training on vaccine storage and handling
 - Developing and distributing job aids and toolkits
 - Piloting DDL thermometers at VFC provider sites

Audit Response: NYC Pilot Project Overview

- Began in August 2013 - November 2015
 - Purchased a variety of DDL thermometers to distribute to providers
 - Installed 199 DDL thermometers at provider sites
 - Created project protocols, manuals, guides
 - Increased staff and providers knowledge on DDLs
- Continued promoting usage of DDL thermometers in 2016 and 2017
 - Distributed and installed an additional 200 devices

Changes in CDC VFC Policy as of January 1, 2018

- Required use of stand alone or biological/ pharmaceutical grade refrigerators and freezers
- Mandated use of digital data logger (DDL) thermometers with the following features
 - Detachable probe (buffered with glycol, glass beads, sand or Teflon)
 - Current, minimum and maximum temperature display
 - Alarm for out of range temperatures
 - Programmable logging interval at least every 30 minutes
 - Certificate of calibration testing (done every one to two years)

NYC VFC Program Objectives

- Bring all enrolled NYC VFC providers into compliance with CDC storage and thermometer requirements by the end of 2018
- Minimize provider concerns regarding new requirements
- Leverage NYC's CIR VIM system to better capture and monitor provider compliance progression

Implementation Strategies







Vaccine Inventory Management (VIM) System

- In June 2017, NYC Bureau of Immunization released the CIR's VIM system for all VFC providers
 - Built on existing Online Ordering Tool
 - Enables lot-level vaccine management
 - Including new reports to help track and manage inventory
 - Contains fields for vaccine storage and thermometer information
 - Captures timely storage information entered by providers including type of unit and thermometer details
 - Important since VFC site visits are conducted every other year

Changes in NYC VFC Policy as of January 12, 2018

- DDL summary report upload in VIM required during vaccine ordering process
 - Must upload for each storage unit reported in VIM
 - Must be in accordance with vaccine ordering tier (monthly, bi-monthly, or quarterly) or should cover the time period since last order
 - Example:
 - Site is on a bi-monthly ordering tier
 - The site's last order was placed on August 1st
 - Next order date is October 1st
 - Uploaded DDL report must contain readings from August 1st to October 1st

VIM: Collecting Storage Unit Data

STAND-ALONE UNITS	
REFRIGERATOR UNITS	FREEZER UNITS
<div><input type="checkbox"/></div> <div></div> <div><p>The typical storage capacity of a single unit is 16.7 ft³. The storage capacity of your unit(s) may be different.</p></div> <div>Regular Stand-Alone Refrigerator</div> <div>Add/Edit</div>	<div><input type="checkbox"/></div> <div></div> <div><p>The typical storage capacity of a single unit is 15.0 ft³. The storage capacity of your unit(s) may be different.</p></div> <div>Regular Stand-Alone Chest Freezer</div> <div>Add/Edit</div>
<div><input type="checkbox"/></div> <div></div> <div><p>The typical storage capacity of a single unit is 19.7 ft³. The storage capacity of your unit(s) may be different.</p></div> <div>Stand-alone Pharmaceutical-Grade Refrigerator</div> <div>Add/Edit</div>	<div><input type="checkbox"/></div> <div></div> <div><p>The typical storage capacity of a single unit is 3.9 ft³. The storage capacity of your unit(s) may be different.</p></div> <div>Stand-alone Pharmaceutical-Grade Freezer</div> <div>Add/Edit</div>
<div><input type="checkbox"/></div> <div></div> <div><p>The typical storage capacity of a single unit is 25.0 ft³. The storage capacity of your unit(s) may be different.</p></div> <div>Commercial Stand-Alone Refrigerator</div> <div>Add/Edit</div>	<div><input type="checkbox"/></div> <div></div> <div><p>The typical storage capacity of a single unit is 5.0 ft³. The storage capacity of your unit(s) may be different.</p></div> <div>Stand-Alone Freezer</div> <div>Add/Edit</div>

CIR Online Registry VIM Screen

Vaccine Storage Unit Editor

Storage Unit Information

X

Add Unit

Stand-alone Pharmaceutical-Grade Refrigerator 1

Remove Unit



Unit name: VFC UNIT (Ex: Room 1, Basement, North, Unit A, Unit B, etc)

Section of Unit Used*

Refrigerator Only

Estimated
Refrigerator
Capacity (ft³)*

19.7

Estimated
Freezer
Capacity (ft³)*

0

Storage Unit Brand*

Helmer

Storage Unit
Model Number

478587588

Auto
Defrost?
(Freezer
Only)

☐ Yes ☐ No

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)

Is this a Continuous
Data Logger*

☒ Yes ☐ No

Thermometer
Brand*

Dickson One

Thermometer
Model Number

TWE 1485258

Calibration
Expiration Date*

12/31/2019

Does this thermometer have a
buffered probe?*

☒ Yes ☐ No

Cancel

Save

VIM DDL Summary Report Upload Screen

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

Unit Name	Estimated Storage	Storage Used for VFC Vaccine	DDL Summary Report Upload
Fridge Unit 1 Continuous DDL: Y Calibration Exp. Date: 07/19/2019	9.7 ft ³	* 100% ▼	Choose File No file chosen
Regular Stand-Alone Chest Freezer 1 Continuous DDL: Y Calibration Exp. Date: 01/16/2019	15.0 ft ³	* 100% ▼	Choose File No file chosen
VFC Fridge Unit 2 Continuous DDL: Y Calibration Exp. Date: 12/31/2019	19.7 ft ³	* (select) ▼	Choose File No file chosen

* Required

Storage and Thermometer Compliance

- Tracked VFC provider compliance using storage and thermometer data entered in VIM
 - Measured compliance weekly
 - Measured number of excursions captured at time of order
 - Monitored thermometer calibration expiration monthly
- Used several methods to conduct targeted provider outreach based on VIM data
- Linked storage and thermometer data reported in VIM to internal application, Provider Profile
 - Integrates VFC and CIR data
 - Contains provider historical information
 - Allows VFC provider compliance management by staff

PROVIDER PROFILE

CIR INFORMATION

Facility: **9009X01**
Name: Citywide Immunization Registry
Address: 42-09 28 STREET
Queens, NY 11101
Create Date: 08/03/2009 CIR Status: ACTIVE
Group:

VFC INFORMATION

Pin: **VFCCIR**
Name: CITY IMMUNIZATION REGISTRY
Address: 2 GOTHAM
LONG ISLAND CITY, NY 11101
Phone: (347) 396-2400
VFC Re-Enrollment: **YES** VFC Status: **SUSPENDED** VFC Provider: **YES**

[DAR](#) [Vaccine Orders](#) [VFC](#) [CIR](#) [VMU](#) [Flu](#) [PQA](#) [HL7](#) [HepB](#) [Matching](#) [Storage](#) [Hotline](#) [Password](#) [Logout](#)

[By Month](#) [By Vaccine](#) [Online Registry](#) [Online Users](#) [Contacts](#) [Orders](#) [Pin Notes](#) [Fac Notes](#) [Grp Notes](#) [HL7 Notes](#)

Month Year	(1) VFC Eligible	(2) CHP B	(3) Underinsured (Non-FQHCs)	(4) VFC Not Eligible	(5) VFC Unknown	(1+2+3+4+5) Total Reported	(1+2+3) VFC, ChpB, Underinsured	VFC, ChpB, Underinsured over Distrib
Jun 18	0	0	0	0	0	0	0	0%
Jul 18	0	0	0	0	0	0	0	0%
Aug 18	3	0	0	0	0	3	3	0%
Sep 18	2	0	0	0	0	2	2	0%
Oct 18	0	0	0	0	0	0	0	0%
Nov 18	0	0	0	0	0	0	0	0%
Dec 18	0	0	0	0	0	0	0	0%
Jan 19	2	0	0	0	0	2	2	0%
Feb 19	1	0	0	0	2	3	1	0%
Mar 19	0	0	0	0	0	0	0	0%
Apr 19	0	0	0	0	1	1	0	0%
May 19	0	0	0	0	0	0	0	0%
Jun 19								

Search

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[Doses Distributed by VFC](#)

[Reporting Method - Last 30 days](#)

[Facility Classification](#)

[UTD - 4:3:1:4:3:1:4 19-35 mos](#)

Vaccine Storage Management Details

Recorder has been downloaded 7/10/2019 1:16:32 PM (UTC -05:00, daylight time)

[DAR](#) [Vaccine Orders](#) [VFC](#) [CIR](#) [VMU](#) [Flu](#) [PQA](#) [HL7](#) [HepB](#) [Matching](#) [Storage](#) [Hotline](#) [Password](#)

FACILITY LOOKUP

FACILITY CODE: VFC PIN: FACILITY NAME:

FACILITY CODE: FACILITY NAME:
PHONE NO.: FACILITY ADDRESS:
EMAIL: VFC PROVIDER: **YES** VFC RE-ENROLLMENT: **YES** VFC STA:

Vaccine Storage Details

Storage Unit Details

Unit ID: **6358**
Unit Name: **STAND ALONE FREEZER**
Refrigerator Type Name: **Stand-Alone Freezer**
Section used: **FREEZER**
Manufacturer: **Igloo**
Unit Number: **1**
Model:
Auto Defrost (Freezer Only):
Estimated Refrigerator Capacity (ft³): **0**
Estimated Freezer Capacity(ft³): **1**
Create ID: **gachonu1**
Create Date: **2017-08-24**
Last Mod ID: **gachonu1**
Last Mod Date: **2018-06-06**

Thermometer Details

Storage Unit ID: **6358**
Continuous DDL: **Y**
Section: **FREEZER**
Manufacturer: **control solution**
Model: **VFC400**
Buffered Probe: **Y**
Dual Probe: **Y**
Calibration Exp. Date: **2020-04-13**
Create ID: **gachonu1**
Create Date: **2017-08-24**
Last Mod ID: **gachonu1**
Last Mod Date: **2018-06-06**

Alarm Status Recorder Info

Low ☒ OK High ☒ OK
Serial #: 7862908875 Model: VFC400-3 Battery: OK Trip #: 7
User ID:

Recorder Configuration

Start type: Push button start Temperature alarms
Start delay: None Lower: 36.0 °F after 2 Consecutive
Interval: 10 Minutes Upper: 46.0 °F after 2 Consecutive
Alarm indicator: Enabled lower & upper

Recorded Data

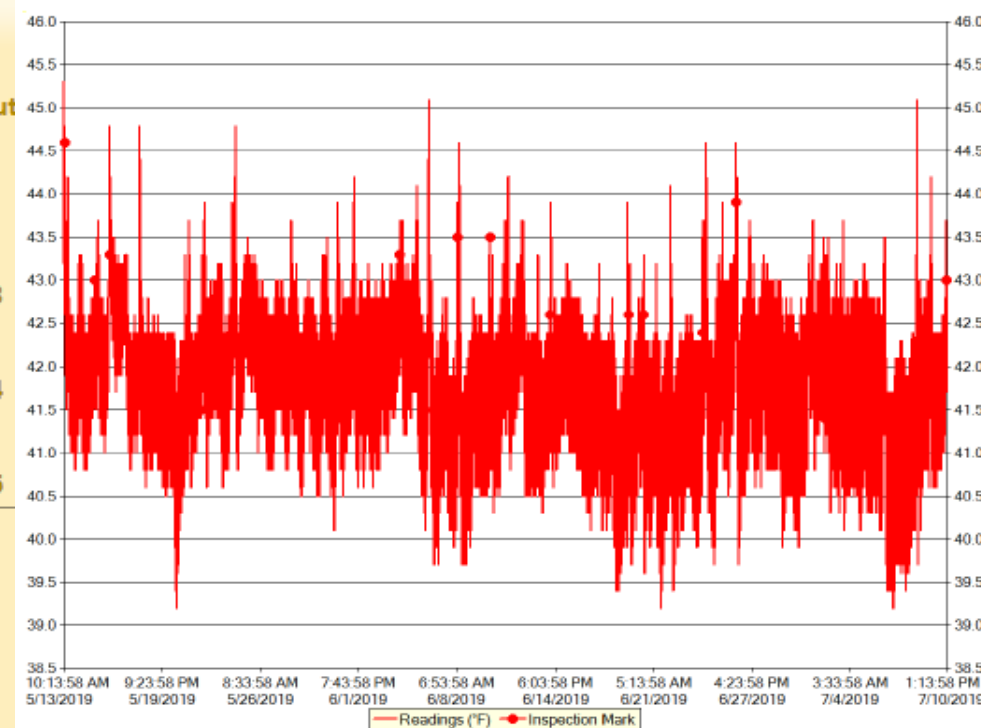
First reading: 5/13/2019 10:13:58 AM Temperature statistics
Last reading: 7/10/2019 1:13:58 PM Lowest: 39.2 °F
Elapsed Time: 58 Days, 3 Hours @ 5/20/2019 8:53:58 PM
Total readings: 8371 Highest: 45.3 °F
First evaluated: 5/13/2019 10:13:58 AM @ 5/13/2019 10:13:58 AM
Last evaluated: 7/10/2019 1:13:58 PM Average reading: 41.8 °F
Evaluated Time: 58 Days, 3 Hours Standard Deviation (S): 0.9 °F
Evaluated Readings: 8371 MKT (delta H: 83.144): 41.80 °F

Low Alarm

Triggered: (none)
Time below: (none)
Occurrences: 0
°F - Minutes below: 0.00

High Alarm

Triggered: (none)
Time above: (none)
Occurrences: 0
°F - Minutes above: 0.00



Temperature Excursion Monitoring

- If DDL summary report submitted contains an excursion that has not yet been reported, VFC staff follow-up via email
 - Provider is required to contact vaccine manufacturers
 - Provider must submit a ***Temperature Excursion Incident Report***
 - Order ID
 - Vaccine viability as per manufacturer
 - Length of excursion
 - Number of doses and types of vaccine affected
 - Reason for excursion

TEMPERATURE EXCURSION INCIDENT REPORT

NEW YORK CITY DEPARTMENT OF HEALTH & MENTAL HYGIENE: VACCINES FOR CHILDREN (VFC) PROGRAM
347-396-2404 (Phone) • 347-396-2559 (Fax) • nycimmunize@health.nyc.gov

In the event of any VFC temperature excursions, please complete this form and file it with the relevant temperature logs. Make sure to file any documents from the manufacturer as well. This report must be readily available if requested by the VFC Program.

VFC Provider Site: ABC Pediatrics VFC PIN #: 15999

Name: John Doe Phone #: 718-888-8888 Email: johndoe@health.nyc.gov

Date of Occurrence: July 1 to July 5 Time of Occurrence: 10 AM Order ID: 131313

IMMEDIATE ACTION TAKEN

1.	Was the Physician In-Charge, Vaccine Coordinator or Back-up Vaccine Coordinator notified of excursion? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
2.	What was the temperature inside the affected storage unit(s) at the time the problem was discovered (Include Min & Max temperatures as well)? *Please note that any temperature reading outside the recommended ranges (Refrigerator – between 36°F [2°C] & 46°F [8°C]; Freezer – between -58°F [-50°C] & +5°F [-15°C]) is considered a temperature excursion. <input checked="" type="checkbox"/> Refrigerator Excursion Temperature <u>24°F</u> Min Temperature <u>38°F</u> Max Temperature <u>42°F</u> <input checked="" type="checkbox"/> Freezer Excursion Temperature <u>74°F</u> Min Temperature <u>2°F</u> Max Temperature <u>5°F</u>
3.	How long were the vaccines exposed to inappropriate storage temperatures? Please record the total amount of time or cumulative time outside of range. <u>5 days for both Freezer and Fridge</u>
4.	What was the room temperature surrounding the affected unit at the time of the excursion? <u>64°F</u>
5.	Were water bottles in refrigerator & frozen coolant packs in freezer at the time of the event? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
6.	Was an inventory of the vaccines within the affected storage unit conducted? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
7.	Were the vaccines in the affected storage unit quarantined within the unit and labeled “DO NOT USE” pending manufacturer’s input? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <i>*If your vaccine storage unit(s) cannot be reset to maintain the appropriate storage conditions, follow the EMERGENCY PLAN as described within the VFC Vaccine Management Plan.</i>
8.	Has the vaccine manufacturer been contacted for further guidance? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

CAUSE OF EXCURSION:

- ☐ Power Outage Unit(s) not plugged in or not turned on
- ☒ Prolonged opening of refrigerator /freezer door
- ☐ Temperature Monitoring device moved/misplaced
- ☐ Unit’s temperature control knob setting is incorrect
- ☐ Poor air circulation inside and outside the unit(s)
- ☒ Operational problems with the storage unit(s)
- ☐ Other _____

Type & Brand Name of Storage Unit Affected by Excursion:

- | | |
|--|---|
| <input type="checkbox"/> Small Stand-Alone Refrigerator | <input checked="" type="checkbox"/> Pharmaceutical Grade (Stand-Alone Refrigerator) |
| <input type="checkbox"/> Small Stand-Alone Chest Freezer | <input type="checkbox"/> Pharmaceutical Grade (Combined Refrigerator & Freezer) |
| <input type="checkbox"/> Stand-Alone Freezer | <input type="checkbox"/> Small Household Refrigerator & Freezer (Refrigerator Only) |
| <input type="checkbox"/> Regular Stand-Alone Refrigerator | <input type="checkbox"/> Regular Household Refrigerator & Freezer (Refrigerator Only) |
| <input type="checkbox"/> Regular Stand-Alone Chest Freezer | <input type="checkbox"/> Large Household Refrigerator & Freezer (Refrigerator Only) |
| <input checked="" type="checkbox"/> Pharmaceutical Grade (Stand-Alone Freezer) | |

Storage Unit Brand Name: Helmer Scientific Model/Serial #: Fridge - HMZ3092 & Freezer -HMZ3093

Thermometer Brand Name: VFC 400- Log Tag Model/Serial #: Fridge- 1789468 & Freezer- 1789467



TEMPERATURE EXCURSION INCIDENT REPORT

NEW YORK CITY DEPARTMENT OF HEALTH & MENTAL HYGIENE: VACCINES FOR CHILDREN (VFC) PROGRAM
347-396-2404 (Phone) • 347-396-2559 (Fax) • nycimmunize@health.nyc.gov

Description of problem and actions taken:

The thermostat of the refrigerator was adjusted by a staff member since it was not holding stable temperatures. The freezer door was left open after vaccine retrieval. Our office was closed for one week and this excursion was not addressed right away. We contacted all vaccine manufacturers. Spoiled doses were reported to the City Wide Immunization registry (CIR) and returned to McKesson. All supporting documents from the manufacturers are attached.

A Provider Quality Assurance (PQA) visit may occur when vaccines are not viable.

BASED ON MANUFACTURER'S RESPONSE:

<input type="checkbox"/> Quality of VFC vaccines has not been compromised and may continue to be used.	[CONTINUE TO MANUFACTURER CASE NUMBER(S) SECTION /SIGN FORM ON PAGE 3]
<input checked="" type="checkbox"/> VFC vaccines are not approved for further use and should be identified as “spoiled”.	
Manufacturer Case Number(s):	
MSD <u>00837581</u>	PMC <u>1-1489853</u>
SKB _____	SEQ _____
Wyeth _____	

*PLEASE ATTACH COPIES OF ALL DOCUMENTS FROM THE MANUFACTURER STATING THE VIABILITY STATUS OF ALL VACCINES.
*DO NOT DISCARD VACCINES UNLESS DIRECTED BY THE MANUFACTURER(S).

Pediatric Influenza Vaccines, Manufacturer & Lot Number(s) affected due to temperature excursion:

Vaccine (Manufacturer) Place an 'X' in box next to spoiled vaccines	Vaccine Type	Lot Number(s)	Lot Expiration Date	New Expiration Date (if applicable)	Number of Doses
<input type="checkbox"/> Afluria® (SEQ)	Flu				
<input type="checkbox"/> Afluria® (NP) (SEQ)	Flu				
<input type="checkbox"/> Fluarix® (PF) (SKB)	Flu				
<input type="checkbox"/> FluMist®(NP) Quad (SKB)	Flu				
<input type="checkbox"/> Fluvirin® (SEQ)	Flu				
<input type="checkbox"/> Fluvirin®(PF) (SEQ)	Flu				
<input type="checkbox"/> Fluzone® (PMC)	Flu				
<input checked="" type="checkbox"/> Fluzone®(NP) (PMC)	Flu	<u>U5912CC</u>	<u>06/30/20</u>	<u>6/30/19</u>	<u>200</u>
<input type="checkbox"/> Fluzone® Ped Dose (NP)(PMC)	Flu				

Please note, manufacturers may provide new expiration dates for vaccines when exposed to temperatures outside of the recommended range.

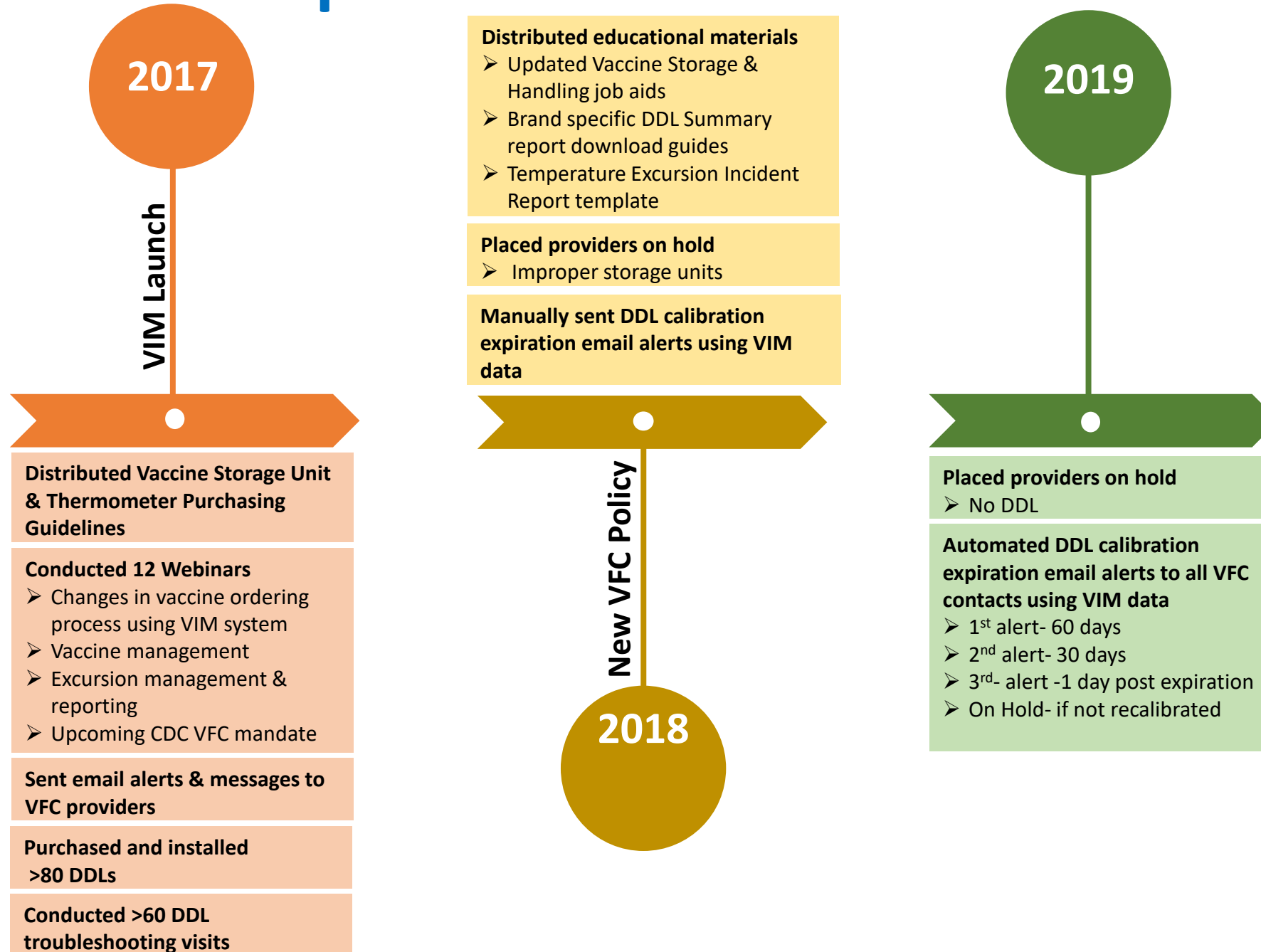
(NP) = No Preservative, (PF) = Preservative Free, & Quad = Quadrivalent

Manufacturer Codes: MSD=Merck and Co., Inc., PMC= Sanofi Pasteur, SEQ= Seqirus, SKB=GlaxoSmithKline



Methods of Achieving Storage and Handling Compliance

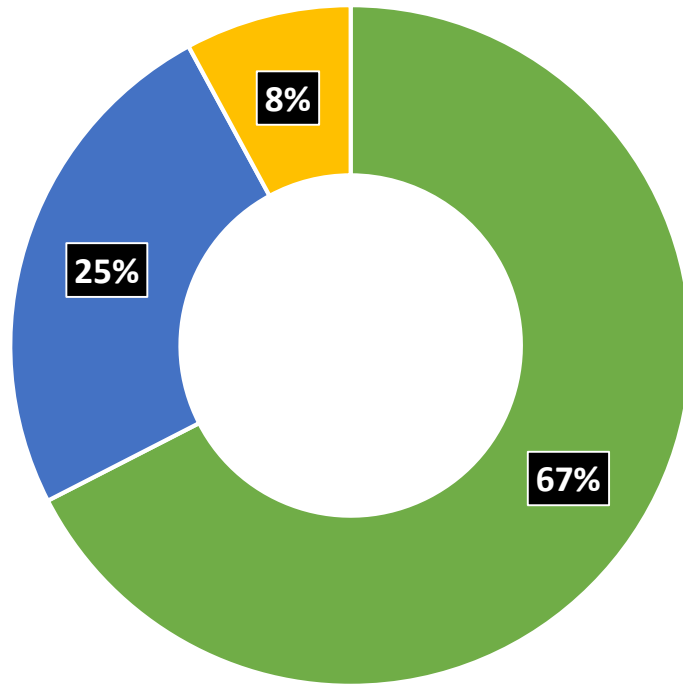
Compliance Activities Timeline



Results

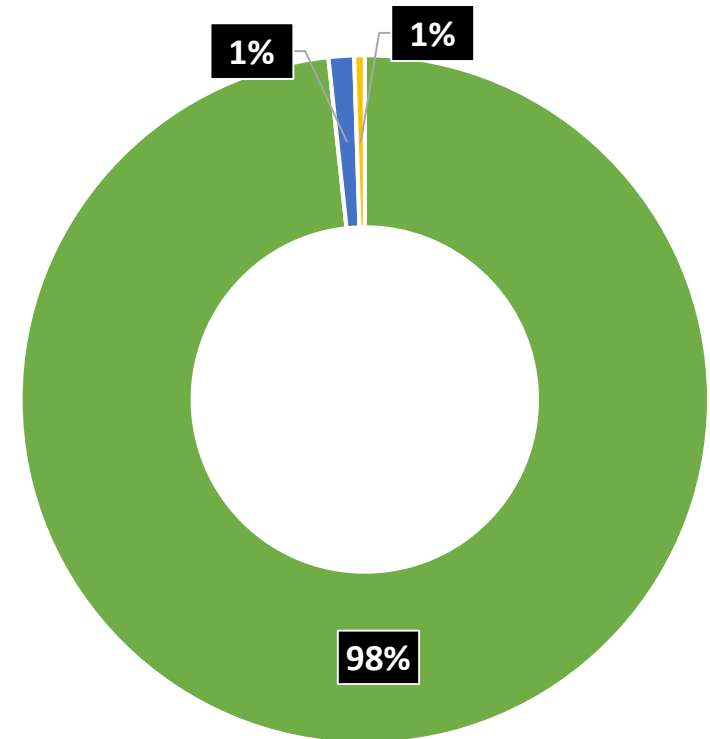
Storage Unit Compliance

September 14, 2017



VFC Sites= 1,088

June 28, 2019

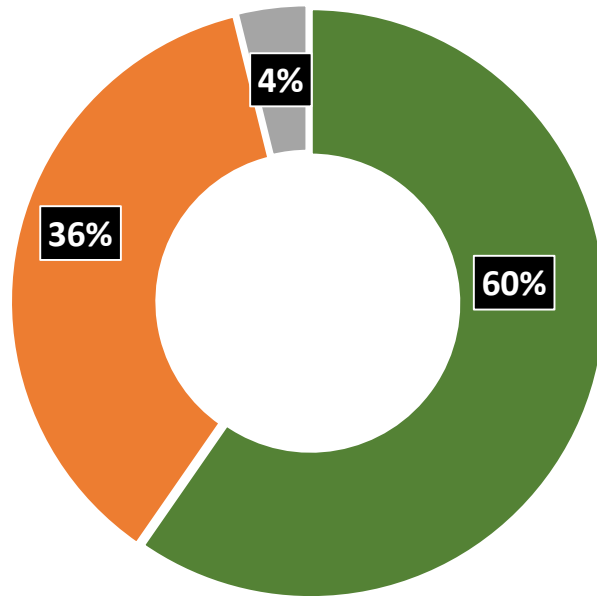


VFC Sites= 1,420

Compliant Units Non-Compliant Units One or More Unit is Compliant

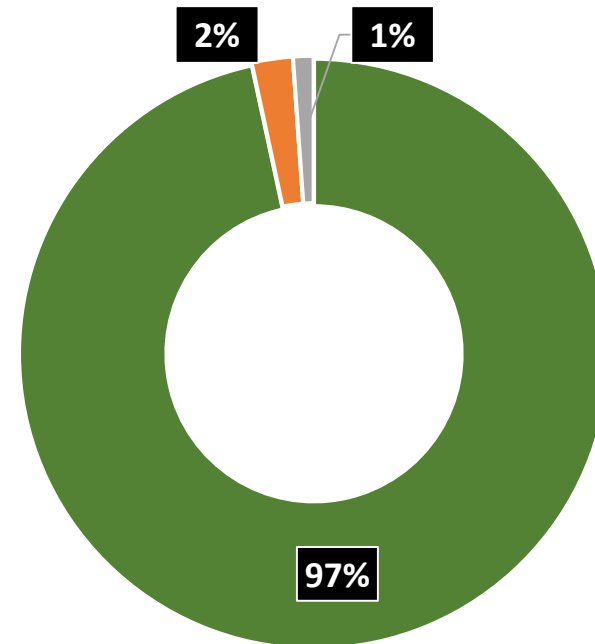
DDL Thermometer Compliance

September 14, 2017



VFC Sites= 1,088

June 28, 2019



VFC Sites= 1,420

■ DDL Thermometers ■ Non-DDL Thermometers ■ One or More Thermometer is a DDL

Vaccine Provider Holds: Non-Compliance

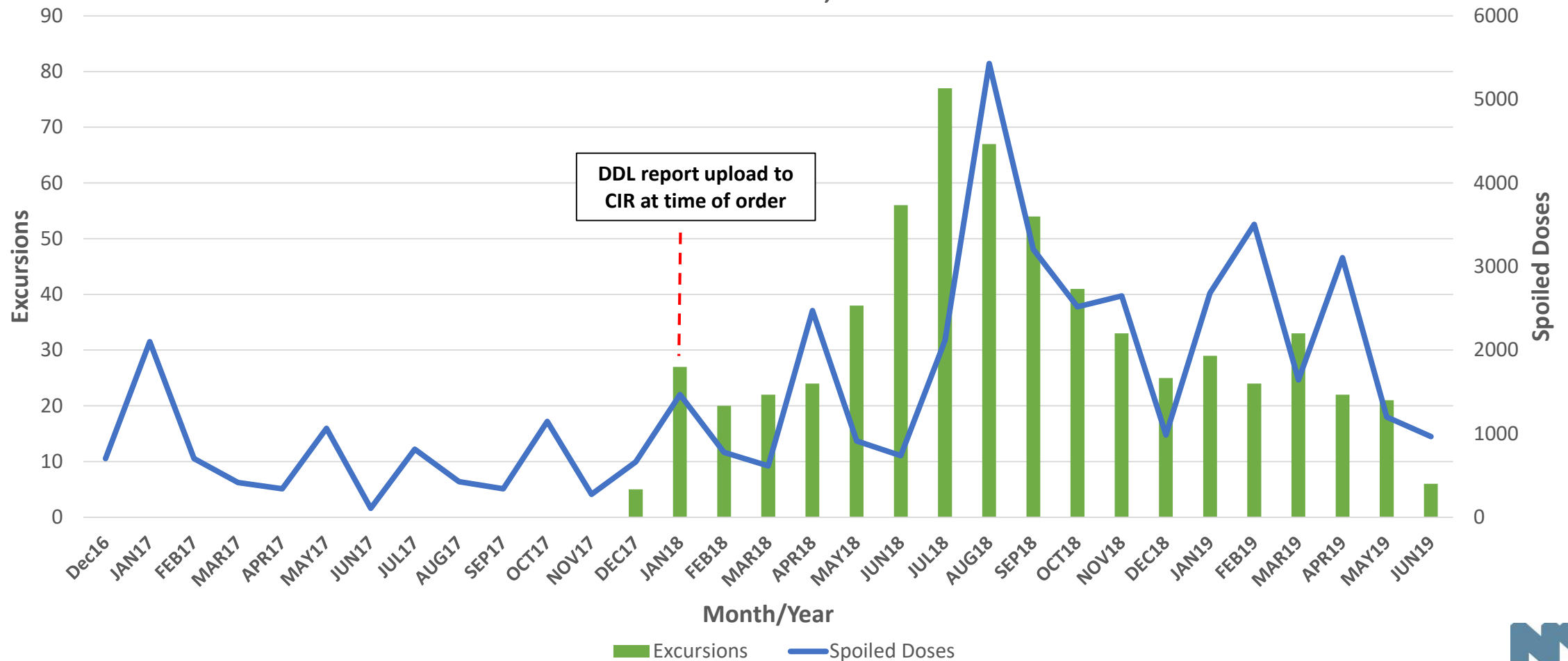
Hold Type	Hold Date	Providers on Hold	% of VFC Providers	Current Provider Holds (as of 7/17/19)	% of VFC Providers
Improper Storage Units	Feb-2018	276	20%	22	2%

Hold Type	Hold Date	Providers on Hold	% of VFC Providers	Current Provider Holds (as of 7/17/19)	% of VFC Providers
No DDLs	Feb-2019	95	7%	2	.1%

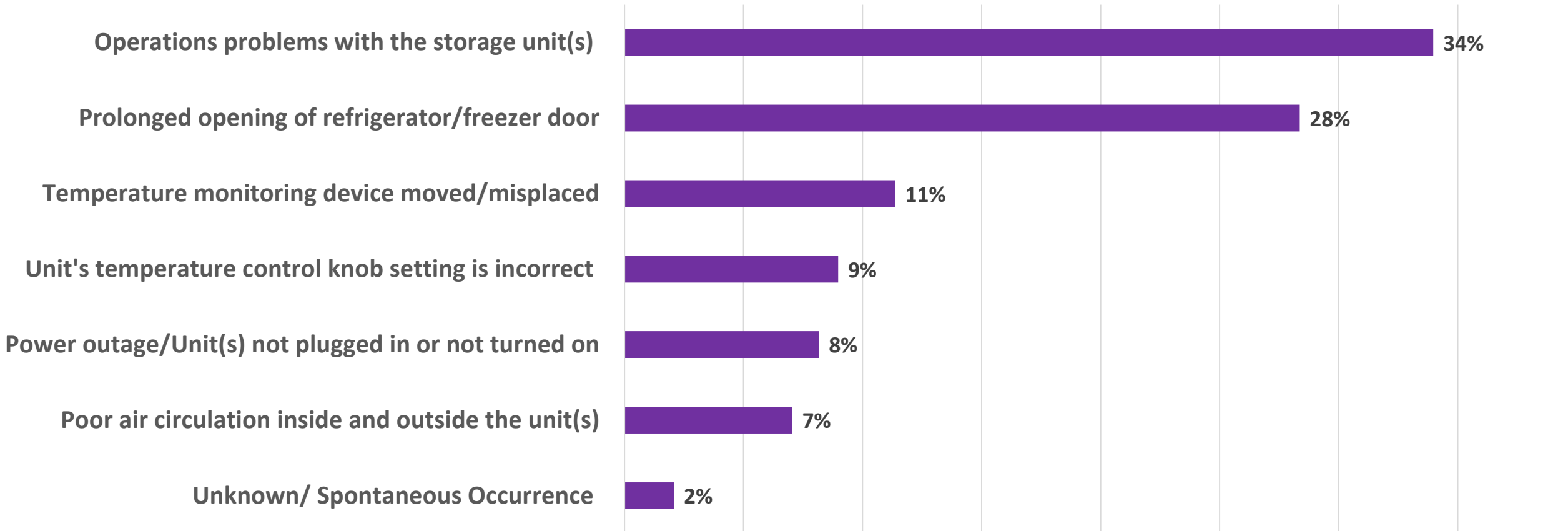
Excursions & Spoiled Doses Identified December 1, 2016 – June 30, 2019

Excursions = 624

Doses = 46,087



Reported Excursion Reasons



DDL Calibration Expiration Monitoring

- 410 sites received an email between December 19, 2018 and June 30, 2019
 - As of July 7, 2019, 386 (94%) sites recalibrated/updated their DDL calibration after receiving an email notification
 - 24 (6%) sites were placed on vaccine ordering hold for not recalibrating

Conclusion

- Capturing storage unit and DDL thermometer data in VIM
 - Enabled NYC to bring nearly 100% of VFC providers into compliance with CDC and NYC storage and handling requirements
- Requiring submission of DDL summary reports with orders
 - Captured excursions that may not have been identified
 - Excursion reporting is no longer at the provider's discretion or at time of VFC compliance visit
- Notification of DDL thermometer calibration expiration
 - Helped providers take prompt action prior to expiration
 - 94% recalibrated/updated DDL after notification was sent out

Next Steps

- Continue to monitor compliance with CDC and NYC requirements
- Educate providers on best practices of monitoring vaccines to decrease the occurrence of excursions
 - Focus on vaccine stability during the summer months
- Create electronic version of Temperature Excursion Incident Report
- Identify barriers providers encounter when recalibrating thermometers

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Bureau of Immunization
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