

Using an IIS to Monitor Vaccine Storage Compliance

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Outline

- Background
 - Citywide Immunization Registry (CIR)
 - New York City (NYC) Vaccines for Children (VFC) Program
 - COVID-19 and Mpox Vaccine Responses
- Online Storage Module
- Results
- Conclusions
- Next steps

Background

Citywide Immunization Registry

- The Immunization Information System (IIS) for New York City (NYC)
 - Began citywide in 1997
 - Contains > 14.4 million patient records
 - > 160 million immunizations
 - Mandatory reporting of immunizations for children <19 years
 - Reporting for adults ≥19 years requires consent

NYC's VFC Vaccination Program

- >1,340 enrolled VFC providers
 - 74% of children in NYC ages 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
 - VIM requires the upload of digital data logger summary reports prior to vaccine ordering
 - Basic module to collect vaccine storage and thermometer details released in 2015

NYC's COVID-19 Vaccination Program

- NYC was the epicenter of the COVID-19 pandemic in early 2020
- As of April 2023, NYC
 - Enrolled >3,500 providers across the COVID-19 vaccination program
 - Distributed >16,000,000 COVID doses
- Newly enrolled providers included community vaccinators and adult providers
 - Many were unfamiliar with vaccine storage recommendations and best practices
- New enrollment visits to ensure compliance could not be conducted due to the large influx of sites

NYC's Mpox Vaccination Program

- NYC launched a comprehensive Mpox vaccination program in 2022 in response to the Mpox outbreak
- As of April 2023, NYC
 - Enrolled >100 providers into the Mpox vaccination program
 - Distributed >6,000 Mpox doses
- Many of the enrolled Mpox providers were previously enrolled in either the VFC or COVID-19 vaccination programs

Challenges

- Enrollment of new providers into NYC's COVID-19 vaccination programs created challenges because many providers were not knowledgeable about vaccine storage and handling requirements
- Vaccines for Children (VFC) compliance site visits were initially suspended during the COVID-19 pandemic leading to decreased oversight for this provider group
- All providers needed to adjust to new vaccine products and workflows
 - New storage requirements for Pfizer
 - Moving vaccine from one type of storage to another with the need to document and track Beyond Use Date

Solution: Online Storage Module

- Monitor storage and thermometer compliance across three vaccination programs
- Enhance collection of vaccine storage unit and thermometer details for **all** providers receiving federally funded vaccines by enabling an image upload feature to the existing storage module in CIR
- Increase transparency and oversight of vaccine storage conditions
- Provide guidance and education regarding proper storage and temperature monitoring
- Leverage NYC's CIR VIM system to better monitor provider storage and handling compliance
 - Link vaccine distribution to storage compliance

Using the Online Storage Module to Monitor Compliance

Online Storage Module Timeline

2020

- **CDC COVID-19 Vaccination Provider Agreement released November 2020**
 - NYC created the Vaccine Provider Agreement System (VPAS) outside of its registry to conduct massive enrollment of COVID providers and gather vaccine shipping, storage and contact information
 - COVID-19 vaccine distribution & administration began December 2020
- **VFC compliance site visits suspended**
 - Decrease in oversight

2021

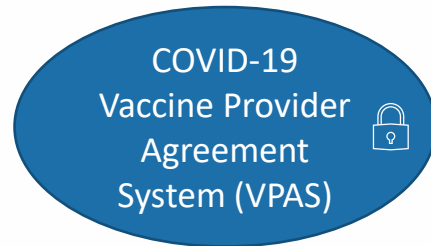
- **CDC COVID-19 Vaccination Program compliance site visits started**
 - Noncompliant storage such as dorms style units and portable units were discovered at multiple sites
 - Improper storage of vaccines in freezer section of household combination units
 - Usage of non-digital data logger thermometers to monitor vaccine temperatures
 - Discovered food in units, overcrowded units and ice build-up in freezer units

2022

- **Mpox outbreak investigation began in NYC in May 2022**
- **Deployed new module in CIR to collect vaccine storage unit and thermometer details in June 2022**
- **Mpox Vaccination Program Provider Agreement released and enrollment began in August 2022**
 - Providers enrolling in the Mpox vaccination program who were not in VFC and/or COVID program needed vaccine storage guidance and monitoring

Storage Module Workflow Overview

**COVID-19
Providers**



- Storage Unit details added to agreement was prepopulated in CIR

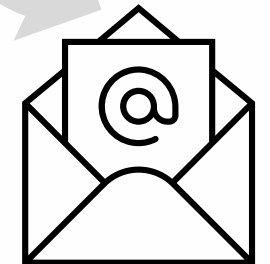
**VFC
Providers**

- Storage & Thermometer details already in CIR
- Provider can add or edit current details

**Mpox
Providers**



- Storage and DDL details including images were reviewed by staff for approval or rejection



- Automated approval or rejection sent to provider



Online Storage Module

The screenshot displays the Online Storage Module interface. It features two columns of storage unit information and a central area for adding new units.

Storage Unit 1	Storage Unit 3
Unit Label/Location: -	Unit Label/Location: Medication Room
Status: Incomplete	Status: Pending
Unit Brand: accuvax	Unit Brand: Panasonic
Type: Stand-alone Pharmaceutical-Grade Re...	Type: Stand-alone Pharmaceutical-Grade Re...
Thermometer Information	
Thermometer Brand:	Thermometer Brand: Dickson One
Status: Incomplete	Status: Pending
Calibration Expiration: 06/15/2022	Calibration Expiration: 01/24/2024
Edit Delete	Edit Delete

Central area: [+ Add Storage Unit](#)

Bottom right: [Skip And Continue](#) →

- The storage units outlined in **red** and marked **Incomplete** prompted COVID providers to update the storage module before placing **their next** COVID vaccine order
- VFC providers with previous storage unit & thermometer information were identified and **pre-approved** in the storage module
- The **Edit** hyperlink allowed for reviewing and updating the current storage unit and thermometer details on the form that appears
- Required details include type, brand, model, calibration expiration date and clear images of storage and thermometer equipment
- **Note:** To bypass this screen, COVID providers were able to **skip and continue** once but were prompted to enter storage details during their next vaccine order

Storage Unit Selection Screens

Select one of the tabs below to choose the type of storage unit:

FREEZER UNIT

REFRIGERATOR UNIT

COMBINED REFRIGERATOR & FREEZER UNIT

Small Household Refrigerator & Freezer



The typical storage capacity of a single unit is 6 ft³ (refrigerated) and 2 ft³ (frozen). The storage capacity of your unit(s) may be different.

Use of the freezer compartment of this unit is not allowed for vaccine storage.

Regular Household Refrigerator & Freezer



The typical storage capacity of a single unit is 12 ft³ (refrigerated) and 3 ft³ (frozen). The storage capacity of your unit(s) may be different.

Use of the freezer compartment of this unit is not allowed for vaccine storage.

Large Household Refrigerator & Freezer



The typical storage capacity of a single unit is 15 ft³ (refrigerated) and 5 ft³ (frozen). The storage capacity of your unit(s) may be different.

Use of the freezer compartment of this unit is not allowed for vaccine storage.

Pharmaceutical-Grade Refrigerator and Freezer



The typical storage capacity of a single unit is 6 ft³ (refrigerated) and 1.4 ft³ (frozen). The storage capacity of your unit(s) may be different.

Cancel

Adding Storage and Thermometer Information

Storage Unit Details

Pending

Unit Label/Location*
(Ex: Room 1, Basement, West, Unit A, etc.)

Unit Brand* *i*

Unit Model* *i*

Storage Type* *i*

Stand-alone Pharmaceutical-Grade Refrigerator | v

Estimated Refrigerator Capacity (ft³)* *i*

19.7

Unit Image* *i*
(Storage unit pictures must have the door open and the inside of the unit should be clearly visible. **Photos or images retrieved online or from websites are not acceptable.**)

Upload Image

Thermometer Information

Pending

Thermometer Brand* *i*

Thermometer Model* *i*

Does this thermometer have a buffered probe?* *i*

Yes No

Digital Data Logger Thermometer Image* *i*

Upload Image

Thermometer Calibration Expiration Date* *i*

mm/dd/yyyy

Do you have at least one back-up Continuous Digital Data Logger thermometer with a current and valid certificate of calibration testing? * *i*

Yes No

Image file format examples: .pdf, .jpeg, .png, .tiff, .gif

Back **Cancel** **Save**

Review of Storage Unit & Thermometer Details

- Storage details added to the CIR by providers were routed to our internal application Provider Profile via a module worklist for manual review
- The module streamlined the review process for staff by
 - Providing all of the data in a comprehensive view
 - Highlighting storage and thermometer updates needing review
 - Generating automated email notifications to providers regarding the approval/rejection status, including the reason(s) for rejection

Pending Approval List

[DAR](#) [Vaccine Orders](#) [VFC](#) [Monkeypox](#) [VMU](#) [Flu](#) [COVID-19 Vac Orders](#) [PQA](#) [HL7](#) [HepB](#) [Matching](#) [Storage](#) [Hotline](#) [Logout](#)

[FILTERS](#) [EXPORT](#)

Pin	Facility Code	Facility Name	Address	City	VFC Provider?	Storage Type	Submitted Date & Time	
VFC CIR	9009X01	IMMUNIZATION REGISTRY	42-09 28 th STREET	BROOKLYN	✓	Stand-Alone Freezer	04/03/2023, 04:58:54 PM	Details
VFC PQA	9033X01	DOHMH PEDIATRICS	42-09 28 th STREET	NEW YORK	✓	Small Stand-Alone Refrigerator	04/03/2023, 04:14:49 PM	Details
VFC CIR	9009X01	IMMUNIZATION REGISTRY	42-09 28 th STREET	NEW YORK	✓	Stand-alone Pharmaceutical-Grade Freezer	04/03/2023, 04:12:19 PM	Details
VFC PQA	9033X01	DOHMH PEDIATRICS	42-09 28 th STREET	NEW YORK	✓	Regular Stand-Alone Refrigerator	04/03/2023, 04:10:18 PM	Details
VFC CIR	9009X01	IMMUNIZATION REGISTRY	42-09 28 th STREET	BROOKLYN	✓	Stand-Alone Freezer	04/03/2023, 03:17:53 PM	Details
VFC PQA	9033X01	DOHMH PEDIATRICS	42-09 28 th STREET	BROOKLYN	✓	Small Stand-Alone Refrigerator	04/03/2023, 02:50:43 PM	Details
VFC CIR	9009X01	DOHMH PEDIATRICS	42-09 28 th STREET	BRONX	✓	Stand-alone Pharmaceutical-Grade Refrigerator	04/03/2023, 12:47:44 PM	Details

Vaccine Storage Management Details

🏠 DAR Vaccine Orders ▾ VFC ▾ Monkeypox ▾ VMU ▾ Flu ▾ COVID-19 Vac Orders ▾ PQA ▾ HL7 ▾ HepB ▾ Matching ▾ Storage ▾ Hotline ✖ Logout

FACILITY LOOKUP

FACILITY CODE: 9009X01

VFC PIN:

FACILITY NAME:

FACILITY ADDRESS:

Search

Reset

FACILITY CODE: 9009X01

FACILITY NAME: CITYWIDE IMMUNIZATION REGISTRY

VFC PIN: VFCCIR

PHONE NO.: (347) 396-2400

FACILITY ADDRESS: 42-09 28 STREET 5TH FLOOR QUEENS NY 11101

FAX: (555) 555-5555

EMAIL: TBURTON@HEALTH.NYC.GOV

VFC PROVIDER: YES

VFC RE-ENROLLMENT: YES

VFC STATUS: ACTIVE

2 Storage Units

Regular Stand-Alone Refrigerator

Label/Location: pharmacy

Brand: insignia

Model: NS-UZ17WH0

Unit Status: Pending

Thermometer Status: Pending

Storage Unit Details (New)



Type

Regular Stand-Alone Refrigerator

Label/Location

pharmacy

Brand

insignia

Model

NS-UZ17WH0

Estimated Refrigerator Capacity (Ft³)

17

Last Modified

hfarhoud2

04/03/2023, 10:58:03 AM

Approve Storage Unit?

Yes

No

Reason

Select or TYPE rejection reason

Duplicated images cannot be submitted

Freezer section of household unit cannot be used

Freezer unit needs to be defrosted. Defrost and reupload image

Incorrect file type

Incorrect image submitted

Incorrect unit brand

Incorrect unit model

Incorrect unit type

Online images are not accepted

Refrigerator Thermometer Details (New)



Brand

berlinger

Calibration Expiration Date

10/31/2024

Approve Refrigerator Thermometer?

Yes

No

Buffered Probe?

Yes

Last Modified

hfarhoud2

04/03/2023, 10:58:03 AM

DDL Summary Report

Order ID	Upload Date	Log File Uploaded
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Non-Compliant Storage Unit Images Submitted



Household unit
freezer section used



Ice build-up: Freezer
needs to be defrosted



Dorm-style unit



Overcrowded unit

Non-Compliant Storage Unit Images Submitted (2)



Food in unit



Vials exposed to light

Non-compliant DDL Thermometer Images Submitted



Thermometer temperature indicator used during vaccine shipments



Food monitoring thermometer



Min/Max Temperature Thermometer



Out of range freezer temperature displayed on thermometer

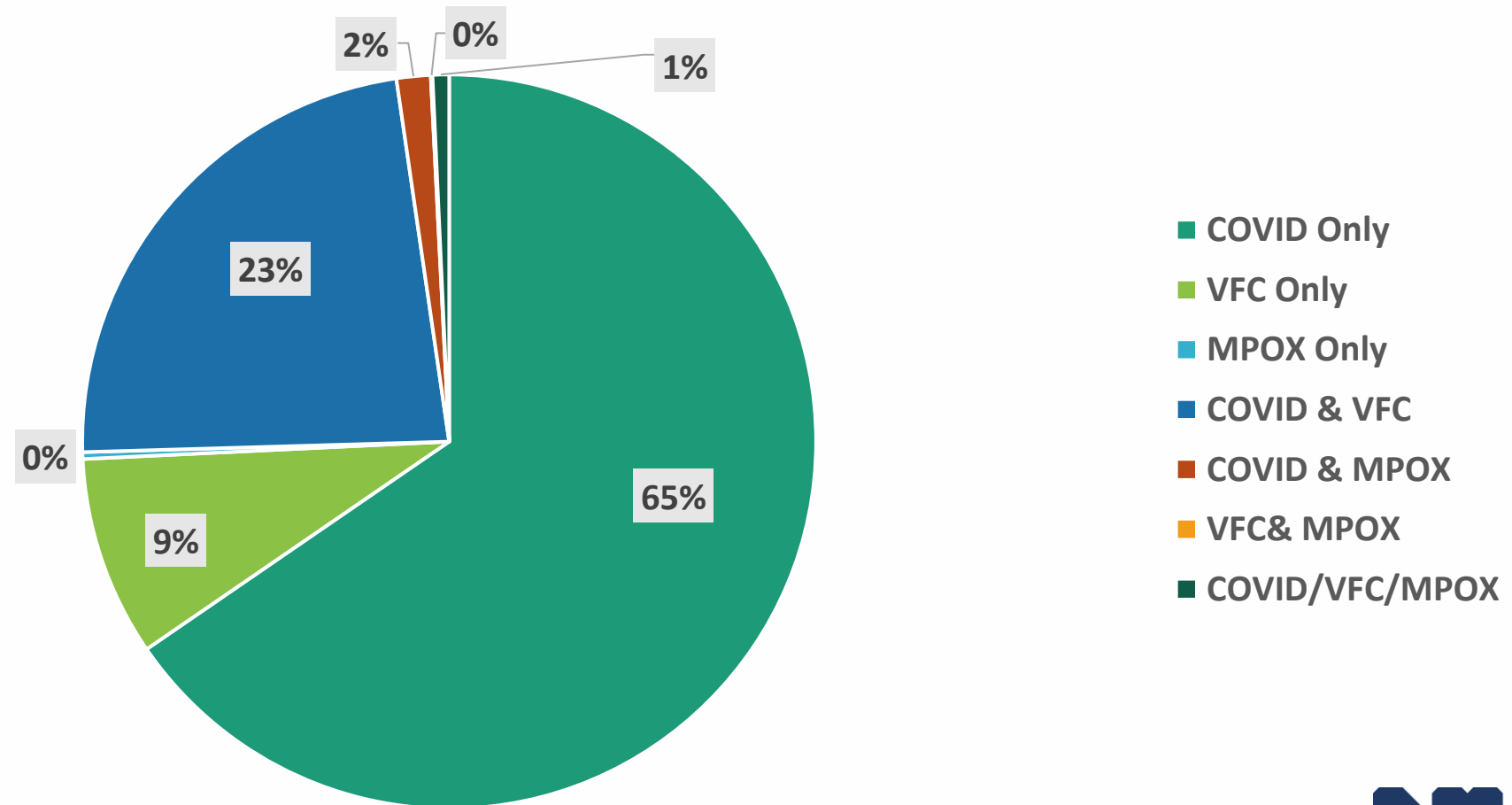
Rejected Storage & DDL Thermometer Outreach

- Vaccine ordering was suspended for providers whose DDLs or storage unit rejection reasons were dorm-style refrigerators, storing vaccines inappropriately, using non-digital data logger thermometers, or expired calibration certificate
- These providers were also referred for a storage compliance site visit or outreach to provide education

Results

NYC's Vaccination Program Enrollment

Providers Enrolled by Vaccination Program with Access to the Storage Module
As of April 11, 2023
N=3,995

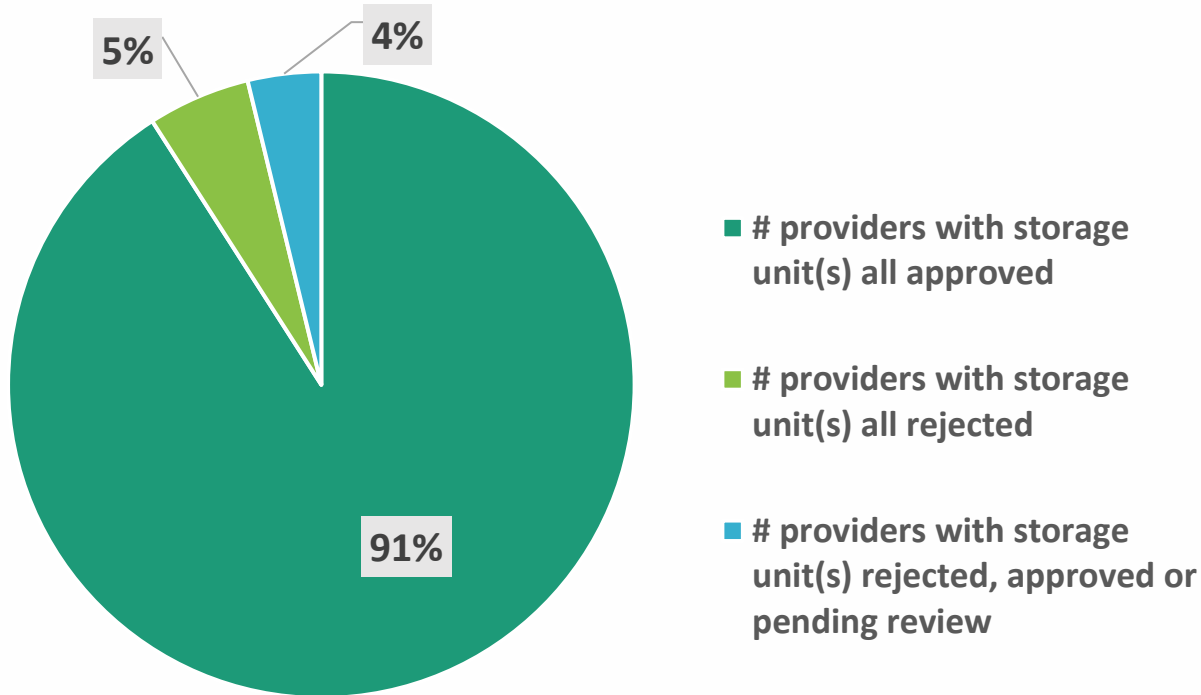


Storage & DDL Thermometer Module Access

Provider Storage Compliance Status

April 11, 2023

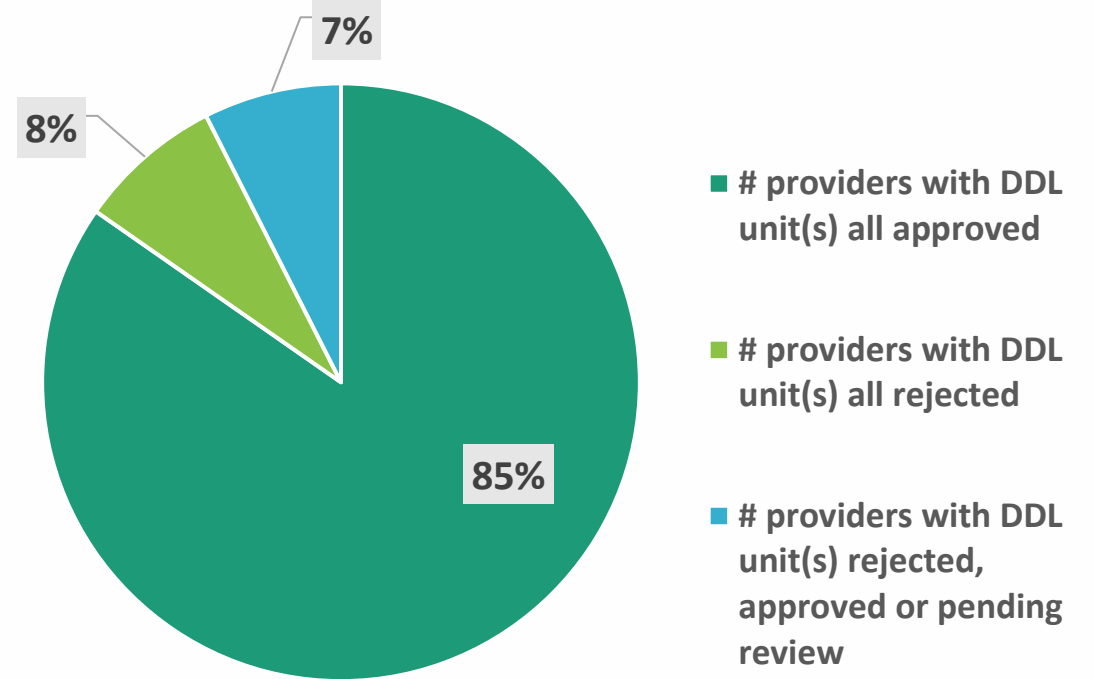
N=1,796



Provider DDL Thermometer Compliance Status

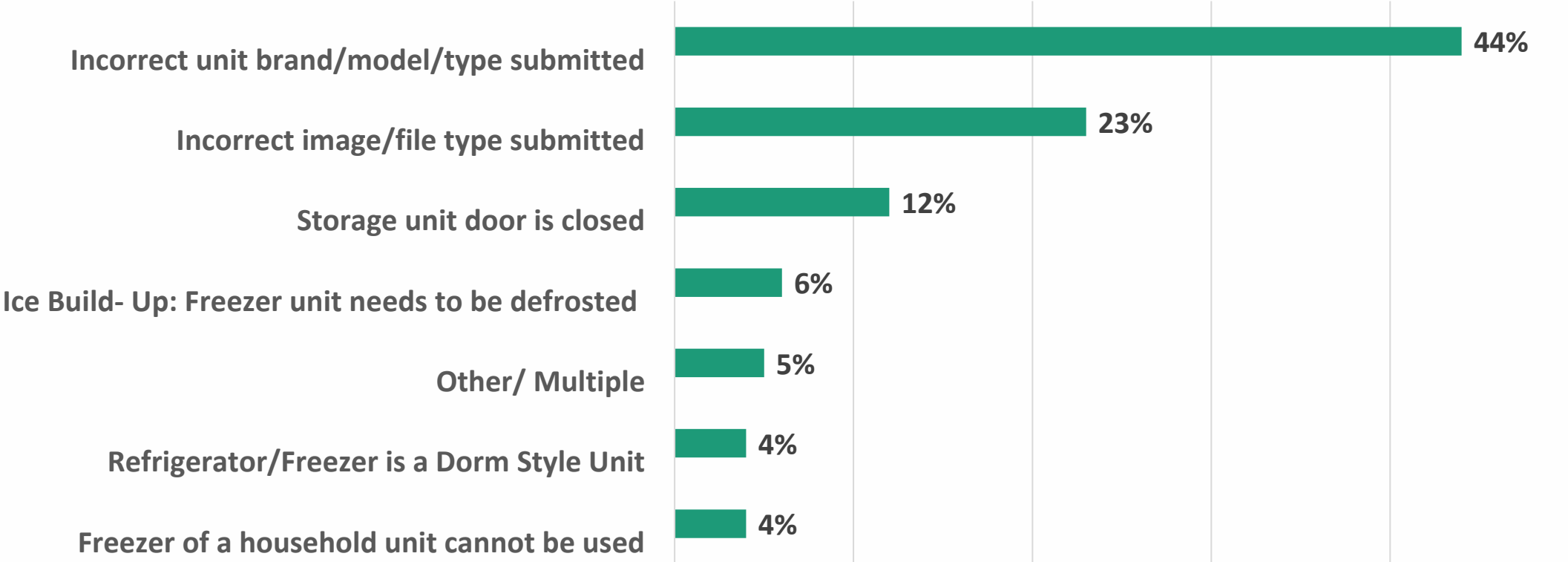
April 11, 2023

N=1,796



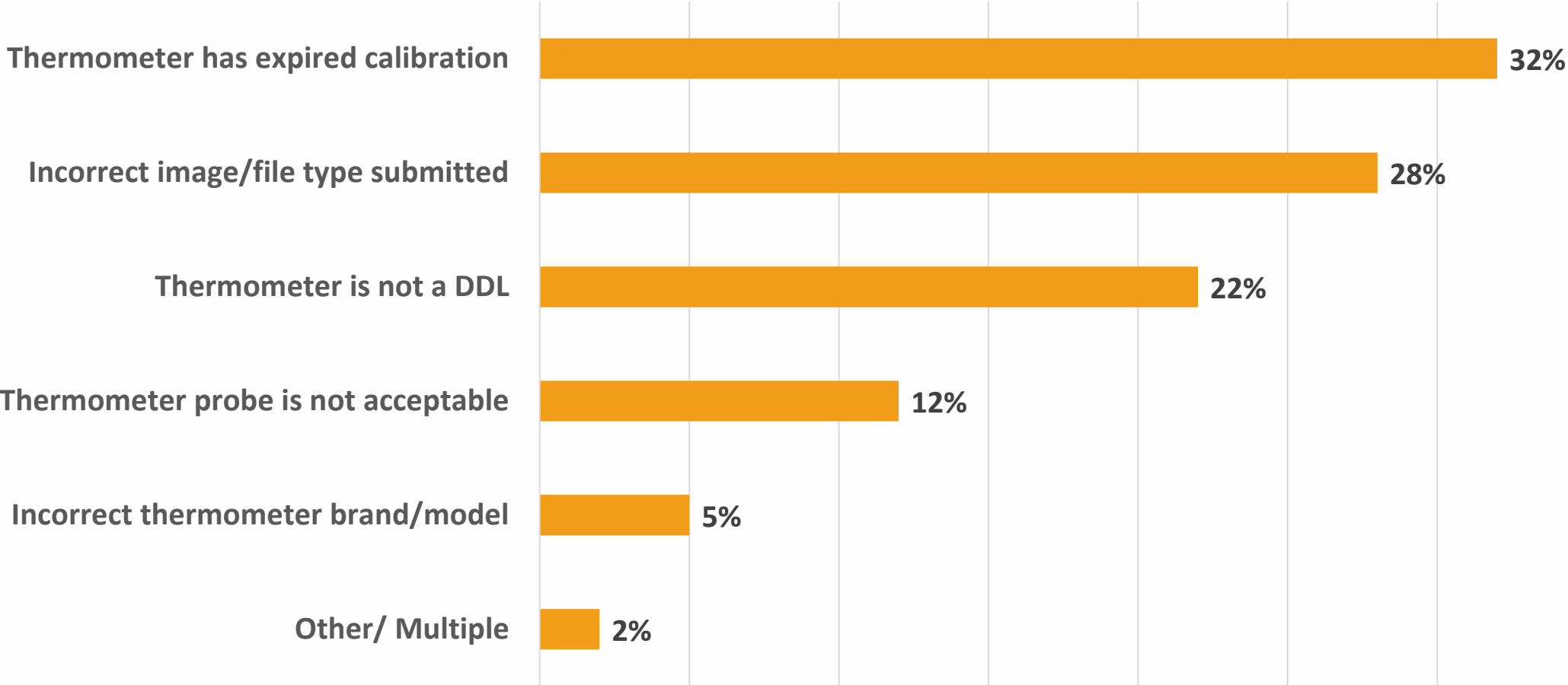
Common Storage Rejection Reasons

June 2022 - April 2023



Common Thermometer Rejection Reasons

June 2022 - April 2023



Provider Referrals

- Providers referred for follow-up if one or more errors were made:
 - DDL not properly installed
 - Provider is using a dorm-style unit
 - Food in the storage unit
 - Provider using the freezer of a household combination unit
 - Vaccines stored out of boxes, exposed to light
 - New unit: VFC visit needed
 - Provider does not have a DDL
 - Overcrowded unit
 - Provider storing Pfizer COVID-19 in a regular freezer (improper storage)
 - Provider is using a portable unit for long term storage
 - Vaccines stored in crisper drawer of the refrigerator
- Providers referred for follow-up were not prevented from ordering vaccines unless a clear threat to vaccine viability was found

Conclusion

- The implementation of this enhanced online storage module allowed for
 - Efficient and effective assessment of vaccine storage conditions
 - Identification of key compliance issues and-timely follow-ups
 - Increased site visit staff awareness of potential storage and handling compliance issues
- With the impending commercialization of COVID vaccines, collecting this information for all providers across each vaccination program will give us a head start when recruiting providers into the VFC program
 - Staff can review storage information for COVID providers enrolling in VFC via this module prior to conducting a site visit

Next Steps

- Continue to monitor compliance with CDC and NYC requirements
- Educate providers on best practices of monitoring vaccines
- Identify barriers to storage and thermometer compliance
- Incorporate the online storage tool into a quality assurance project for adult immunization programs

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