Vaccine Storage and Handling

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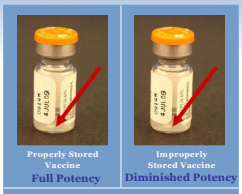
Outline

- Storage & Handling Policies & Procedures
- Temperature Excursions
- VFC Program Requirements
- VFC Program Updates
- Q&A Session

STORAGE AND HANDLING POLICIES AND PROCEDURES

Why is Storage and Handling Important?

- Vaccines are very fragile and can lose potency with exposure to excessive heat or cold – leading to potentially severe public health implications
- Cold chain failure could cost providers thousands of dollars, and/or cause them to have to revaccinate
- Vaccines can be exposed to out of range temperatures yet look normal - visual inspections are unreliable



Properly Stored Vaccine
Full Potency

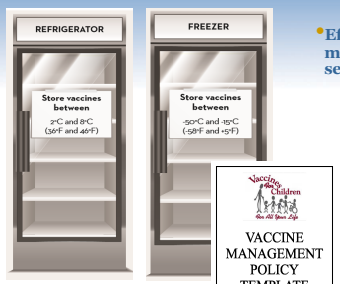
Improperly Stored Vaccine
Diminished Potency

Visual inspection of vaccines is an unreliable method of assuring potency

Cold Chain

- The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition
- The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor, delivery to the provider facility, storage of vaccines by the provider, and ends with the administration of vaccines to the patient
- Vaccine potency is reduced every time there is a break in the cold chain and a vaccine is exposed to improper conditions

Cold Chain Management



VACCINE MANAGEMENT POLICY TEMPLATE

- Effective cold chain management relies on several elements
  - A vaccine management policy that adheres to proper storage and handling procedures
  - Well-trained staff
  - Reliable cold storage and temperature monitoring equipment

Vaccine Storage Equipment

Pharmaceutical Grade → Household / Commercial Grade (Standalone) → Household / Commercial Grade (Combination)* → Dormitory / Bar Style Combination Unit

Under the counter

Full-sized

The CDC does not recommend using the freezer compartment of a combination commercial unit

Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances

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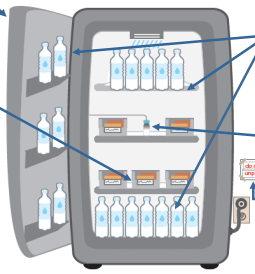
Vaccine Cold Storage Preparation and Organization

Obtain 5 Days of In-range Temps Prior to Storing Vaccines

- Mark the front of unit 'NOT FOR FOOD OR BEVERAGE' and post temperature log sheet
- Keep vaccines in original packaging
- Organize vaccines by name in ventilated storage bins
- Label bins with the vaccine name
- Separate look-alike, sound-alike drug names
- Separate publicly-funded vaccines from privately purchased ones



- Do not store ice packs in the refrigerator or freezer
- Label water bottles 'DO NOT DRINK' and place them on the top shelf, along the floor, and in the door racks
- Bonus: Frozen, conditioned water bottles can be used in emergency transport containers in the event of a unit malfunction
- Temperature probe should be located on the center shelf
- Mark outlet(s) 'DO NOT UNPLUG' and circuit breakers "DO NOT STOP POWER TO CIRCUIT BREAKER"
- Extensions cords and surge protectors create multiple points of failure and should be avoided

Improper Vaccine Placement

Proper Vaccine Storage

Vaccine Rotations

- All providers are REQUIRED to rotate vaccine stock weekly
- Always place vaccines with shorter expiration dates in front of those with longer expiration dates
- Notify New Jersey VFC at least three months in advance if you have vaccines that you will not use before they expire

Cold Storage Unit Lock

Digital Data Logger (DDL)

DDLs MUST be NIST certified and calibrated with the following functionality:

- Detachable, buffered probe that best reflects vaccine temperatures
- Alarm for out-of-range temperatures
- Low battery indicator
- Current, minimum (Min), and maximum (Max) temperature display
- Uncertainty of +/-0.5°C (+/-1°F)
- User programmable logging interval (30 minute interval at minimum)

PROVIDERS ARE ALSO REQUIRED TO HAVE AT LEAST ONE ADDITIONAL DDL AS A BACK-UP THERMOMETER

Temperature Monitoring and Min/Max

Staff must be well trained to use the DDL and must:

- Ensure that the probe is placed correctly within the vaccine storage unit
- Ensure that the alarms are set correctly
- Ensure the device is set to record the temperatures at least every 30 minutes
- Understand the display features:
  - Current temperature
  - Min temperature
  - Max temperature
- Download the DDL data at least weekly, whenever the alarm sounds, and whenever there is an out-of-range Min/Max temperature

MIN/MAX MUST BE RESET AT THE START OF BUSINESS EACH DAY UNLESS DEVICE HAS AN AUTOMATIC RESET

Temperature Documentation

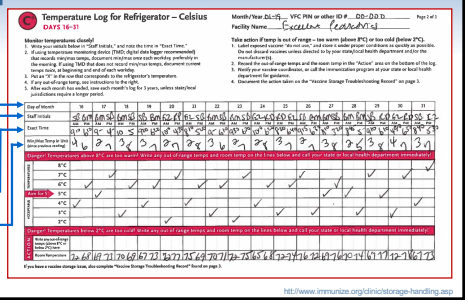
CDC recommends that providers:

- Check and record storage unit Min/Max temperatures at the start of each workday
  - The Min/Max temperatures recorded should be those obtained since the last workday when the Min/Max temperatures were reset. If you have a manual Min/Max reset, be sure to reset the device after recording the temperature!
- Check the current temperature each time vaccines are accessed
- Place temperature monitoring log sheet on each storage unit door (or nearby), and record the following information
  - Min/Max temperatures
  - Date
  - Time
  - Name or initials of person who checked and recorded temperatures
  - Any actions taken if a temperature excursion occurred
- Review storage unit temperature readings and review downloaded DDL files weekly to look for any trends

MAINTAIN TEMPERATUE DOCUMENTAION AT LEAST 3 YEARS

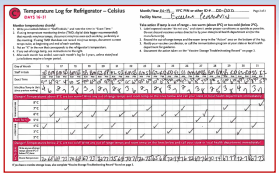
Temperature Documentation: Paper Log

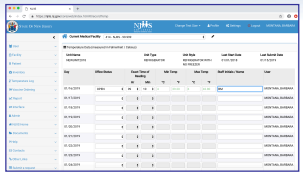
- Date
- Name or initials of person who checked and recorded temperatures
- Exact time
- Min/Max temperatures



http://www.immunize.org/clinic/storage-handling.asp

Temperature Documentation: New Jersey Immunization Information System (NJIIS)





VFC PROVIDERS MUST ENTER MIN/MAX TEMPERATURES INTO NJIIS

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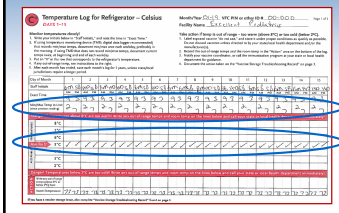
Temperature Monitoring Errors



- Be sure that the information recorded on the temperature logs (paper and NJIIS) is accurate
- Prolonged periods of time with identical information should be questioned
  - Is Min/Max being cleared each day?
  - Is the alarm setting being recorded instead of Min/Max?
  - Has the person been trained?
  - Is the importance of accurate information stressed by leadership?

THE PHYSICIAN WHO SIGNS THE VFC PROVIDER AGREEMENT IS RESPONSIBLE FOR ENSURING THAT VACCINES ARE STORED APPROPRIATELY

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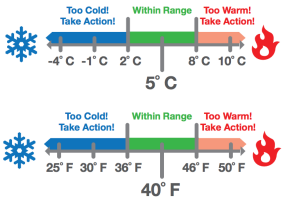
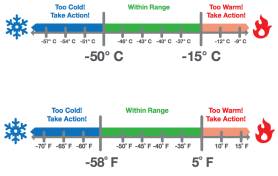
TEMPERATURE EXCURSIONS

Appropriate Temperature Ranges

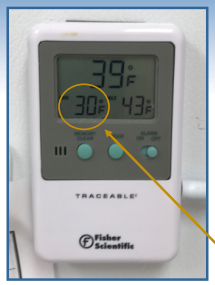
Refrigerator Temperatures



Freezer Temperatures



Temperature Excursions



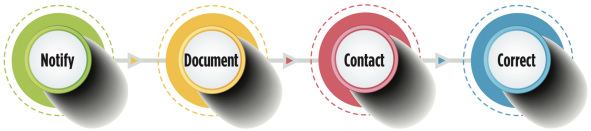
What is a temperature excursion?

- Any temperatures that fall outside of the CDC and vaccine manufacturers' recommended ranges are considered temperature excursions
- Temperature excursions require IMMEDIATE ACTION
- In general, manufacturers analyze information about the magnitude of the temperature excursion, total amount of time temperatures were out of range, and information about each vaccine exposed to determine vaccine viability

MINIMUM TEMPERATURE OUT OF RANGE

Temperature Excursion Response

FOLLOW THESE STEPS WHENEVER THERE IS A TEMPERATURE EXCURSION



Excursion Response: Notification

- Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor
- Quarantine the vaccines and notify staff by labeling the exposed vaccines, "DO NOT USE." Place them in a separate container apart from other vaccines in the storage unit. This will ensure that vaccines will not be administered until instructed by the VFC Program
- Do not discard these vaccines

Excursion Response: Documentation

Document details of the temperature excursion:

- Date and time
- Storage unit temperature (including Min/Max during the time of the event)
- Room temperature, if available
- Name of the person completing the report
- General description of the event (i.e., what happened)
- Downloaded DDL file to determine the length of time vaccines may have been exposed to out-of-range temperatures
- Inventory of affected vaccines including lot numbers and expiration dates
- List of items in the unit other than vaccines (including water bottles)
- Any problems with the storage unit and/or affected vaccines before the event (previous excursions)
- Other relevant information

Excursion Response: Calculating Single Event

Fridge	Freezer	Time	Date
6.61	-15.5	3:00	4/16/18
6.12	-16.31	2:30	4/16/18
5.47	-17.17	2:00	4/16/18
4.6	-18.1	1:30	4/16/18
3.3	-19.2	1:00	4/16/18
1.19	-20.52	0:30	4/16/18
-0.02	-20.62	0:00	4/16/18
1.69	-18.97	23:30	4/15/18
4.87	-16.37	23:00	4/15/18
6.53	-15.8	22:30	4/15/18
5.97	-16.61	22:00	4/15/18
5.24	-17.52	21:30	4/15/18

2 hours out of range

Lowest temp -0.02°C

OUT-OF-RANGE TIME = TIME FROM LAST IN-RANGE TEMPERATURE TO NEXT IN-RANGE TEMPERATURE

Excursion Response: Rounding

Fridge	Freezer	Time	Date
6.61	-15.5	3:00	4/16/18
6.12	-16.31	2:30	4/16/18
5.47	-17.17	2:00	4/16/18
4.6	-18.1	1:30	4/16/18
3.3	-19.2	1:00	4/16/18
1.19	-20.52	0:30	4/16/18
-0.02	-20.62	0:00	4/16/18
[illegible]	-18.97	23:30	4/15/18
4.87	-16.37	23:00	4/15/18
6.53	-15.8	22:30	4/15/18
5.97	-16.61	22:00	4/15/18
5.24	-17.52	21:30	4/15/18

1.5 hours out of range

Lowest temp -0.02°C

MANUFACTURERS MAY ASK TEMPERATURES TO BE ROUNDED TO THE NEAREST WHOLE NUMBER

1.69°C WOULD ROUND UP TO 2.00°C AND BE CONSIDERED IN RANGE

Excursion Response: Calculating Multiple Events

6.5 hours out of range

Lowest temp -1.33°C

BE SURE TO CALCULATE THE TOTAL TIME OUT OF RANGE IF THERE ARE MULTIPLE EXCURSIONS

2 hours

2 hours

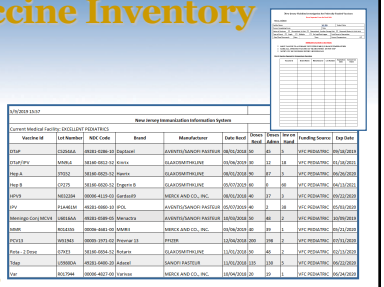
2.5 hours

Fridge	Freezer	Time	Date
2.81	-19.43	0:00	3/5/18
0.53	-20.75	23:30	3/4/18
-1.33	-20.84	23:00	3/4/18
0.09	-19.22	22:30	3/4/18
3.21	-16.39	22:00	3/4/18
6.41	-15.01	21:30	3/4/18
6	-15.67	21:00	3/4/18
5.49	-16.5	20:30	3/4/18
4.83	-17.45	20:00	3/4/18
3.91	-18.47	19:30	3/4/18
2.48	-19.65	19:00	3/4/18
-0.05	-21.01	18:30	3/4/18
-1.02	-20.49	18:00	3/4/18
0.59	-18.69	17:30	3/4/18
4.44	-15.51	17:00	3/4/18
6.28	-15.1	16:30	3/4/18
5.82	-15.9	16:00	3/4/18
5.24	-16.77	15:30	3/4/18
4.47	-17.75	15:00	3/4/18
3.39	-18.85	14:30	3/4/18
1.52	-20.11	14:00	3/4/18
-1.31	-21.2	13:30	3/4/18
-0.56	-19.81	13:00	3/4/18
1.54	-17.54	12:30	3/4/18
6.29	-15.02	12:00	3/4/18

Excursion Response: Vaccine Inventory

- Be sure to do a complete inventory of the vaccines in your storage unit at the time the excursion is identified
- Physically count the affected vaccines

PROVIDERS CAN USE THE INVENTORY LISTING FROM NJIIS AS A GUIDE BUT SHOULD REPORT AND ADDRESS ANY DISCREPANCIES



Vaccine Id	Lot Number	NDC Code	Brand	Manufacturer	Date Rec'd	Doses Rec'd	Doses Admin	Wst on Hand	Funding Source	Exp Date
DTaP	C126AA1	49281-0286-10	Daptacel	AVENTIS/SANOFI PASTEUR	08/01/2018	50	45	5	VFC PEDIATRIC	09/18/2021
DTaP/IPV	M4ALA	58160-0912-52	Kinrix	GLAXOSMITHKLINE	05/08/2018	30	12	18	VFC PEDIATRIC	01/18/2021
Hep A	37032	58160-0820-52	Havrix	GLAXOSMITHKLINE	08/01/2018	90	87	3	VFC PEDIATRIC	09/26/2020
Hep B	J2J25	58160-0820-52	Engerix-B	GLAXOSMITHKLINE	05/07/2018	60	9	48	VFC PEDIATRIC	04/11/2021
HPV9	N022204	00006-4119-03	Gardasil9	MERCK AND CO., INC.	08/01/2018	40	37	3	VFC PEDIATRIC	09/22/2020
IPV	F1A4011K	49281-0580-10	POL	AVENTIS/SANOFI PASTEUR	05/07/2018	40	3	18	VFC PEDIATRIC	01/01/2020
Meningo Conj MCV4	U6018AA	49281-0589-05	Menactra	AVENTIS/SANOFI PASTEUR	10/03/2018	50	48	2	VFC PEDIATRIC	10/09/2019
MMR	R014331	00006-4681-00	MMRII	MERCK AND CO., INC.	01/08/2018	80	35	1	VFC PEDIATRIC	05/21/2020
PCV13	W91965	00005-1971-02	Prevnar 13	PFIZER	11/08/2018	200	198	2	VFC PEDIATRIC	07/31/2020
Rota - 2 Dose	J1923	58160-0954-52	Rotarix	GLAXOSMITHKLINE	11/01/2018	50	45	2	VFC PEDIATRIC	02/13/2020
Tdap	U9989AA	49281-0495-10	Adacel	SANOFI PASTEUR	11/01/2018	155	138	3	VFC PEDIATRIC	09/22/2020
Var	R017344	00006-4827-00	Varivax	MERCK AND CO., INC.	10/04/2018	20	19	1	VFC PEDIATRIC	09/24/2020

Excursion Response: Contact

- Call the vaccine manufacturers to assess the viability of the vaccines that were exposed to the temperature excursion
- Be prepared to report all the information that you documented
- Be sure to get written documentation from the manufacturers

VFC PROVIDERS MUST NOTIFY THE VFC PROGRAM OF AN EXCURSION WITHIN 1 BUSINESS DAY

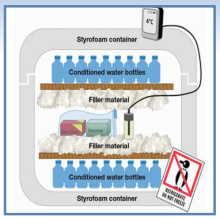
Excursion Response: Correct

- If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause
- Check the basics, including
  - Power supply
  - Unit door(s)
  - Thermostat settings
- Refer to your storage unit manufacturers' instructions and the CDC's Vaccines Storage and Handling Toolkit
- Adjust thermostat in the storage unit to ensure temperatures return to an acceptable range. If this is not possible, immediately move the vaccines to a storage unit that can maintain acceptable temperatures
- If you believe the storage unit has failed and cannot maintain the acceptable temperatures, institute emergency procedures to relocate vaccines. Never allow vaccines to remain in a non-functioning unit

BE SURE TO TRANSPORT VACCINES WITH A DDL. YOU MUST BE ABLE TO DOCUMENT THAT THE COLD CHAIN WAS MAINTAINED

Emergency Vaccine Transport

- Keep DDL with vaccines at all times
- DDL must be placed in each vaccine transport container when vaccines are being transported to another site
  - Be sure to have enough DDLs to monitor vaccine transport in an emergency
- Packing essentials for emergency vaccine transport
  - Hard-sided cooler or Styrofoam vaccine shipping container
  - Conditioned frozen water bottles
  - Insulating filler material (2 layers of each)
  - Corrugated cardboard
  - Digital Data Logger



Temperature Excursion Resolution

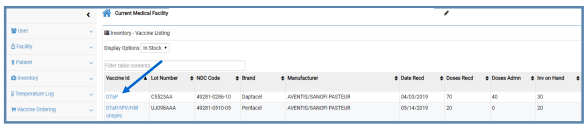
After obtaining all the manufacturers' viability determinations for the vaccines in quarantine within your storage unit:

- Wait for a final determination from the VFC Program before using or disposing of any VFC vaccine that was exposed to out-of-range temperatures
- Remove non-viable vaccines from the vaccine storage unit and label them "DO NOT USE"
- Tag all viable vaccines so that cumulative time out-of-range can be calculated should the vaccines be exposed to temperature excursions in the future

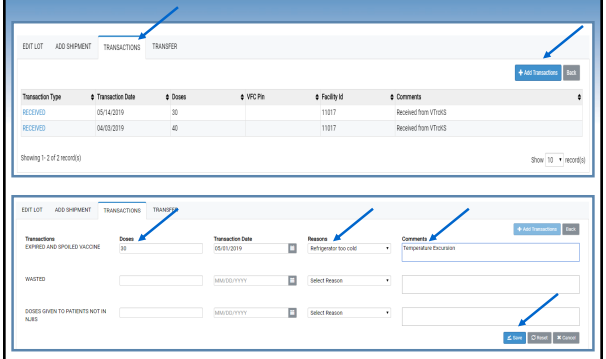
Reporting Waste

Vaccines are wasted if they are spoiled as a result of a temperature excursion, expired, broken, or drawn up but never administered

- Wasted vaccines must be reported to the VFC Program via a transaction in the NJIIS Inventory within 6 months



Reporting Waste Continued



Preventing Temperature Excursions

- Develop a culture where vaccine storage and handling is a priority
- Be sure everyone in the office understands the importance of vaccine storage and handling
- Be sure that all staff are well trained and that they have ample time/support to perform duties
- Invest in appropriate equipment – vaccine storage units and DDLs
- Record Min/Max temperatures daily, check current temperature whenever accessing unit, download DDL files weekly – assess temperatures for trends
- Optimize processes to minimize potential for temperature excursions
  - Do not keep the door of a vaccine storage unit open for long periods during stocking and inventory checks

MANY TEMPERATURE EXCURSIONS CAN BE PREVENTED BY BEING PROACTIVE!

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VFC PROGRAM REQUIREMENTS

NJ Health New Jersey Department of Health

VFC Program Eligibility

Eligible patients are children 0 through 18 years of age who:

- Are American Indian or Alaskan Native (AI/AN)
- Are enrolled in Medicaid or Medicaid Managed Care (Plan A only); or
- Do not have any health insurance; or
- Are underinsured, which means that their insurance
  - Doesn't cover ACIP-recommended vaccines
  - Doesn't cover certain ACIP-recommended vaccines. The patient would be eligible to receive only those vaccines not covered by insurance

NOTE: Underinsured children must be seen at a Federally Qualified Health Center (FQHC) to receive their immunizations. Eligibility for the VFC Program as "underinsured" is a rare situation with the implementation of the Affordable Care Act (ACA)

VFC Program Eligibility: Medicaid as Secondary

Situations occur where children may have private health insurance AND Medicaid as secondary insurance

- Providers may administer VFC vaccines to the patient and treat the patient as VFC-eligible
- Providers must select and document the eligibility category that will require the least amount of out-of-pocket expenses to the parent/guardian for the child to receive the necessary immunizations

317 Program Eligibility

Eligible patients are those who:

- Are 19 years of age and older with no insurance coverage for the ACIP-recommended vaccines needed
  - If the adult has private insurance, Medicare, or Medicaid, check if the insurance pays for a portion of the vaccine. If the insurance pays any portion of the vaccine costs, the adult is not eligible to receive vaccine under the 317 program
- Are privately-insured individuals of any age seeking vaccines during public health response activities including:
  - Outbreak response
  - Post-exposure prophylaxis
  - Disaster relief efforts

Please note: Prior approval from the 317 program must be obtained before program vaccines are used in public health response activities

Eligibility Screening and Documentation

- Eligibility must be verified before each immunization visit
- Documentation of eligibility must include:
  - Patient's eligibility category
    - Example: no insurance or Plan A
  - Date eligibility was checked

Recommendations from the Advisory Committee for Immunization Practices

- VFC and 317 providers must offer all Advisory Committee for Immunization Practices (ACIP) recommended vaccines to their patient population
- Providers are required to follow the appropriate ACIP-recommended immunization schedules

http://www.cdc.gov/vaccines/hcp/acip-recs/

Annual Re-enrollment

- Must submit each year using the online form
- Communication from the New Jersey VFC program will be sent indicating the need and timeframe to re-enroll
- Failure to re-enroll by the specified deadline will result in suspension from the program
- Continued failure to re-enroll may also result in the removal of VFC vaccines from your office

Vaccine Ordering Minimum Requirements

- Every provider who receives federally-funded vaccines must place a core vaccine order at least once every 365 days
  - Flu vaccine is not considered core vaccine and therefore flu-only orders do not satisfy the minimum ordering requirements
- If you fail to order vaccines each year, your office will become inactive. Your office will not be allowed to order any vaccines until key staff are retrained on New Jersey VFC policies and procedures and a new enrollment site visit has been successful completed

Vaccine Information Statement (VIS)

- What is a VIS?
  - A VIS is a document, produced by CDC, that informs vaccine recipients - or their parents or legal representatives - about the benefits and risks of a vaccine they are receiving
- Distribution of VIS is required by law
  - All vaccine providers, public and private, are required by the National Vaccine Childhood Injury Act (NCVIA - 42 U.S.C. § 300aa-26[2 pages]) to give the appropriate VIS to the patient (or parent or legal representative) prior to every dose of specific vaccines
- The appropriate VIS must be given prior to the vaccination, prior to each dose of a multi-dose series, and regardless of the age of the recipient

For more information visit
http://www.cdc.gov/vaccines/hcp/vis/

Vaccine Administration Documentation

By federal law, each vaccination record within a medical chart must contain ALL the below elements:

- Address of clinic where vaccine was administered
- Name of vaccine administered
- Date vaccine was administered
- Date VIS was given
- Publication date of VIS
- Name of vaccine manufacturer
- Lot number
- Name and title of person who administered the vaccine

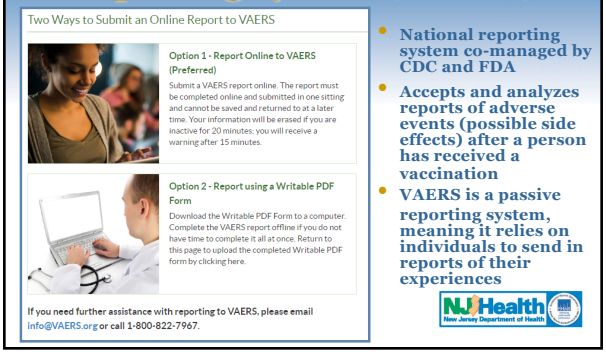
Reimbursement

- VFC & 317 providers are NOT allowed to charge patients for federally-funded vaccine
- Administration fee
  - Medicaid, Medicaid Managed Care, and Family Plan A patients: contact your Medicaid/Managed Care representative for current reimbursement schedules
  - Uninsured and underinsured patients: Providers may charge patients up to $24.23 per vaccine (regardless of number of antigens)
  - Physicians are NOT permitted to withhold VFC/317 vaccines due to the patient's inability to pay the administrative fee
- If a provider gives a VFC/317 patient one of their private vaccines they will not be reimbursed. It is the provider's responsibility to ensure proper stock for VFC/317 patients

Record Retention

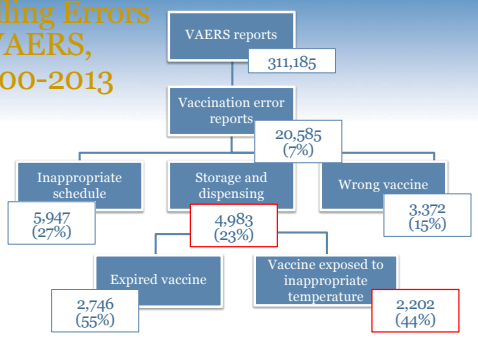
- Office must maintain ALL VFC records for a minimum of 3 years
- All active patients, must have an up-to-date vaccine administration record in their medical chart

Vaccination Adverse Event Reporting System (VAERS)



- National reporting system co-managed by CDC and FDA
- Accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination
- VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences

Storage and Handling Errors VAERS, 2000-2013



Staffing Needs for VFC/317 Providers

- Medical Director
- Vaccine Coordinators
  - Primary and Back-up
  - Must have completed NJIIS trainings:
    - Fundamentals
    - Vaccine Ordering and Management
  - Must complete annual education training
- Any changes in key staff must be reported to the New Jersey VFC Program immediately using:
  - IMM-36* (VFC) IMM-25* (317) [Change of Medical Director]
  - IMM-48 [Change of Coordinators]

When Will the VFC Program Visit?

- Compliance Visit - scheduled visit every 18-24 months to review all VFC Program requirements
  - A 20 Chart Follow-Up Visit may be required if provider does not show compliance during visit
- Storage and Handling Visit - unannounced visit focused on the safe handling and storage of vaccines
- Enrollment Visit - initial visit for a new or returning VFC site
- Educational Visit - visit centered around specific needs of a provider
- AFIX/IQIP Visit- quality improvement visit focused on improving a provider's best practices

It is the goal of VFC to see each provider at least once a year through one of the above listed visits

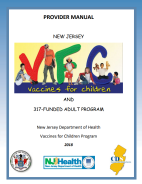
NEW JERSEY
VFC PROGRAM UPDATES

2018-2019 VFC Program Updates

- Temperature Excursion Taskforce
- Release of VFC and 317 Provider Manual
- Support of VPD outbreaks/clusters
- 2019 Re-enrollment process

New Requirements 2020 and Beyond

Resources



https://njiis.nj.gov/ecpc/web/index.html#/home

https://www.cdc.gov/vaccines/ed/youcalltheshots.html

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

https://www.nj.gov/health/phtd/documents/pdf/vfc_provider_manual.pdf

NJ Vaccines for Children Program
Email: VFC@doh.nj.gov
Telephone: 609-826-4862
Fax: 609-826-4868

Questions?