

EVOLUTION OF STORAGE & HANDLING CHANGES

- OIG Report
 - Poor storage and handling practices among sampled states
 - Required CDC implement changes to storage & handling requirements
- NIST studies of storage units
 - Combination units vs Stand-alone storage units
- New technology for temperature monitoring
 - Digital Data Loggers

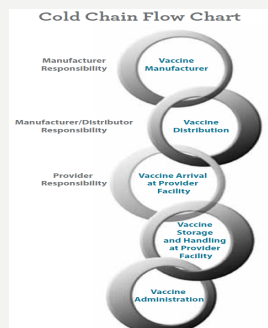
STORAGE AND HANDLING POLICIES AND PROCEDURES

WHAT IS A “COLD CHAIN”?

The system used to keep and distribute vaccines in good condition

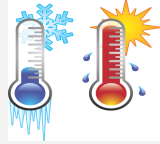
- Transport and Storage
- Trained Personnel
- Efficient Management Procedures

Excess heat or cold adversely affects the cold chain, increasing the risk that a patient will not be protected against a vaccine-preventable disease.



TEMPERATURE MONITORING

Maintain the refrigerator at **36° to 46°F**, or **2 to 8°C**
(Aim for 40° F or 4°C)



Maintain the freezer at **5°F to -58°F**, or
-15°C to -50°C
(Aim for below 0° F or -18°C)

DIGITAL DATA LOGGER (DDL) REQUIRED AS OF JANUARY 1, 2018

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



1. Detachable probe that best reflects vaccine temperature
2. Alarm for out-of-range temperatures
3. Current, minimum, and maximum display
4. Low battery indicator
5. Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$)
6. Memory storage of at least 4,000 readings
7. User programmable logging interval (30 min interval at minimum)
8. An active temperature display that can be easily read from outside of the unit.

Providers are also required to have at least one additional DDL as a back-up thermometer.

DDL PROBE PLACEMENT

- DDL probes should be placed in the center of the unit – away from coils, walls, floors and cooling vents/fans – to get the most accurate reading.
- When temperatures seem to be out-of-range, check the placement first.

DOCUMENTING TEMPERATURES

- New temperature documentation requirements as of January 1, 2018
- All temperature logs must include:
VFC PIN, date and time of reading, initials of individual who took each reading, and the minimum and maximum temperature displayed on your DDL.
- Documentation options
 - Use enhanced temperature log in NJIIS daily
 - Suggestion: print copy every 2 weeks
 - OR
 - Record temperatures on paper temp log
 - All temperature logs must be kept on storage unit door or nearby in readily accessible and visible location.
 - Paper temperature logs should be kept for 3 years
 - **LOGS MUST NOT BE REMOVED FROM OFFICE**

For paper temperature log templates visit

www.immunize.org

UNDERSTANDING MIN/MAX



**MUST BE RESET AT
THE START OF
BUSINESS EACH DAY**

Minimum/maximum temperature readings, shows the warmest and coldest temperatures reached in a unit since last reset.

REVIEW DDL DATA REGULARLY

Download and review DDL data

- At least weekly
- Any time an alarm sounds
- When current, min or max temperatures are noted to be out of range



REPORTING TEMPERATURE EXCURSIONS

What is a temperature excursion?

Any temperatures that fall outside of the CDC and vaccine manufacturer recommended ranges are considered temperature excursions.

What should I do in the event of a temperature excursion?

1. Quarantine the vaccines which means bagging & labeling "DO NOT USE". This will ensure that vaccines will not be administered until instructed by the VFC Program.
2. Adjust the thermostat in the storage unit to ensure that the temperatures return within an acceptable range. If this is not possible, immediately move the vaccines to a storage unit that can maintain acceptable temperatures.
3. Call or email the VFC Program and report the temperature excursion within one business day.
4. Call the vaccine manufacturers to assess the viability of the vaccines that were exposed to the temperature excursion.

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ADJUSTING STORAGE UNIT TEMPERATURES

- Turn thermostat knob slowly, making small adjustments toward a warmer or colder setting as necessary.
- Allow temperature inside unit to stabilize for 30 minutes then recheck temperature.
- Adjust thermostat again as necessary. Aim to stabilize refrigerator temperature around 40°F (5°C). Aim to stabilize freezer temperature below 0°F (-18°C).
- Recheck temperature every 30 minutes until stable.
 - Consider placing additional water bottles in refrigerator or ice packs in freezer to increase temperature stability

TEMPERATURE MONITORING: NEW STORAGE UNITS

- Allow 5 business days of temperature readings to make sure temperatures are within appropriate ranges before using units to store vaccines.
- If temperatures fail to stabilize, consider placing additional water bottles to increase temperature stability.
- It may take **2 to 7** days to stabilize the temperature between 36°F and 46°F (2°C and 8°C) in a newly installed or repaired refrigerator. Likewise, it may take **2 to 3** days to stabilize the temperature between -58°F and +5°F (-50°C and -15°C) in a newly installed or repaired freezer.
- Report all new units to the VFC Program. You must obtain approval before transferring vaccines into a new unit.

TEMPERATURE MONITORING EXERCISE

VACCINE PLACEMENT

Vaccine should never be placed...

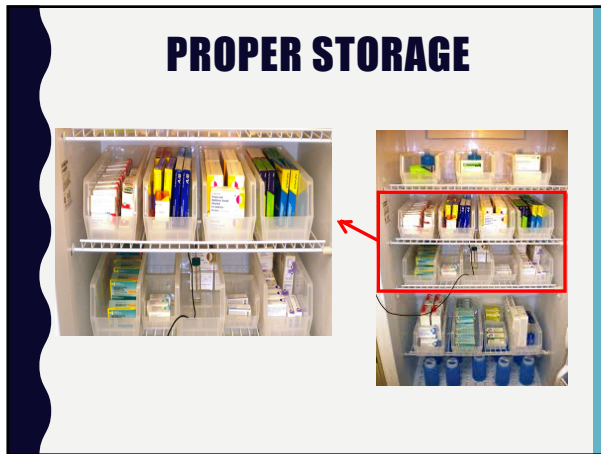
In poor circulation areas

- Vegetable or crisper bins
- Shipping box
- Over packed units
- Storage bags

In extreme or unstable temperatures situations

- Outside of acceptable temperature ranges
- On floor of units
- Near unit Coils
- Outside of Original Packaging
- In unit door shelves
- In unit with food/drink





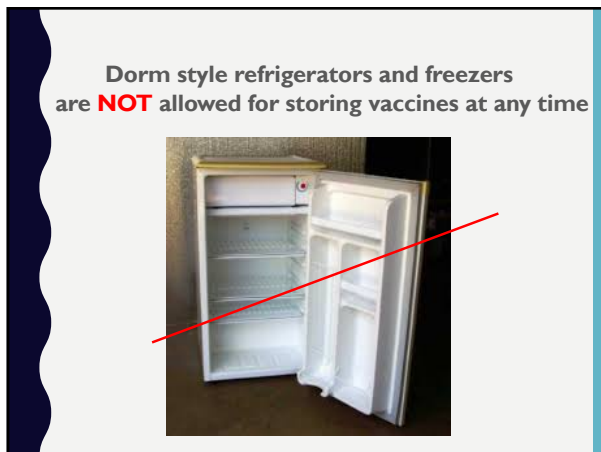
APPROVED STORAGE UNITS

- Refrigerator and freezer must have externally separate, sealed doors.
- Household-style units are not recommended
- Pharmaceutical grade and stand-alone storage units are preferred
- Make sure your your unit has enough room for your stock without overcrowding.

Household-style

Pharmaceutical-grade

Stand-alone





TRANSPORTING VACCINES

VACCINE SHOULD NOT BE ROUTINELY TRANSPORTED

- Vaccine may only be transported in insulated containers with ice packs and DDL
- Never place vaccine in trunk
- Never leave vaccine in car when it is parked, especially in extreme cold or hot temps
- Refrigerated vaccines should not be placed directly on cold packs
- Frozen vaccines may sit directly on ice packs
- Diluents may travel at room temperature or with refrigerated vaccines (if transporting Diluents with refrigerated vaccines, refrigerate diluents in advance so that it does not raise the temperature of refrigerated vaccines)
- Vaccines should never be transported with dry ice

PACKING VACCINES FOR TRANSPORT

1. Conditioned Water Bottles

2. Cardboard Sheet

3. Bubble wrap, packing foam, or Styrofoam™

4. Vaccines, Diluents, and Temperature Monitoring Device Probe


5. Bubble wrap, packing foam, or Styrofoam™

6. Cardboard Sheet

7. Conditioned Water Bottles

8. Temperature Monitoring Device Display (on lid)

NO MORE FROZEN ICE PACKS... USE WATER BOTTLES



Conditioned frozen water bottles


- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes.)

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WASTE PREVENTION

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 it expires



PREVENTATIVE MEASURES

Refrigerator/Freezer Lock



PREVENTIVE MEASURES

- NIST calibrated DDL with audible alarm
- No unit should be plugged into a surge protector - all storage units must be plugged directly into outlet.
- Place DO NOT UNPLUG signs on outlets and circuit panels

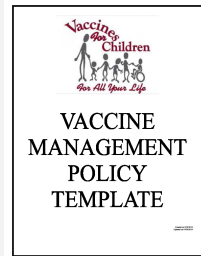


INADEQUATE DOOR SEALS

- Door seals should be checked regularly
- Seals for units usually start around \$45 and can be found at local hardware stores
- To check seals:
 1. Place paper strip against the cabinet of the unit
 2. Close the door
 3. Pull the paper strip...if it moves easily or falls away by itself, the door and the seals may need to be adjusted

VACCINE MANAGEMENT PLAN

- Should be posted on the front of the refrigerator.
- Must include the following information:
 - Designated responsible vaccine coordinator and backup
 - Alternate storage facility
 - Electrical company contact information
 - Refrigerator/ freezer repair company contact information
 - Information about staff training
- Must be signed and updated annually



REPORTING WASTE

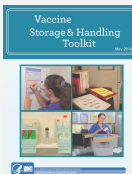
MUST BE DONE WITHIN 6 MONTHS OF WASTE/EXPIRATION

- Only unopened vials or pre-filled syringes should be returned.
- Opened vials or syringes must be disposed,
- But **all waste must be reported.**

Waste return labels should be automatically generated within 6 weeks of report

For an additional resource regarding storage and handling, please go to:

<http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>





PROGRAM ELIGIBILITY

VFC Program

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.

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PROGRAM ELIGIBILITY

317 Program

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

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.

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/>

RECORD RETENTION

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

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 VFC or 317 vaccine.
- Administration fee
 - Medicaid, Medicaid Managed Care, and FamilyPlan 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

VACCINE INFORMATION STATEMENT (VIS)

- What is a VIS?
 - AVIS 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/>

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]
**these forms are found on our website under new enrollment packages.*
 - 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
- **New Enrollment Visit**- initial visit for a new or returning VFC site
- **Educational Visit**- visit centered around specific needs of a provider
- **AFIX 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 VFC PROGRAM UPDATES

- Updated VFC functionality in NJIIS 2.0
- DDL requirement
- Temperature documentation changes
- Release of VFC and 317 Provider Manual

NEW REQUIREMENTS 2019 AND BEYOND



VFC CONTACT INFORMATION

CALL:
609-826-4862

OR

EMAIL:
VFC@doh.nj.gov

