

# New Jersey Vaccines for Children (VFC) Newsletter

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#### 2019 - 2020 Influenza Season

All persons ≥ 6 months of age should get the flu shot each year! Children 6 months through 8 years should receive 2 doses of flu vaccine during their first season of vaccination at least 4 weeks apart.

As per N.J.A.C. 8:57-4.19, children 6-59 months of age attending any licensed preschool or child care facility shall receive at least one dose of the flu vaccine annually before December 31.





For more information about immunization requirements, please visit

https://www.nj.gov/health/cd/imm\_requirements/

#### VFC and 317 Flu Vaccines Available 2019 - 2020

Pediatric

- FluMist (AstraZeneca)
- Sprayer; 10 pack
- Fluarix Quadrivalent (GSK)
- 0.5mL, single dose syringe, 10 pack
- FluLaval Quadrivalent (GSK)
- 0.5mL single dose syringe, 10 pack
- Fluzone Quadrivalent (Sanofi)
- 0.5mL, single dose syringe, 10 pack

- Adult
- FluLaval Quadrivalent (GSK) 0.5 mL, single dose syringe, 10 pack
- Flucelvax Quadrivalent (Sequiris) 0.5mL, single dose syringe, 10 pack

• Flucelvax Quadrivalent (Sequiris) 0.5mL, single dose syringe, 10 pack

#### Flu vaccine ordering is open!

Don't delay vaccination to procure a specific brand if an alternative is readily available!

# **Understanding vaccine loss**

Vaccine loss is a general term for vaccines that can no longer be administered to patients. There are three categories of vaccine loss:

Expired, Spoiled, and Wasted VACCINE LOSS IS COSTLY!



# Vaccine Expiration Date: 8/15/06 Note Use through August 15, 2006. Do NOT use on or after August 16, 2006



#### **Wasted Vaccine**

**Expired Vaccine** 

#### **Options in NJIIS**

- Vaccines with broken vial or syringe
  - Example: Vial dropped and cracked
- Lost or unaccounted for vaccines
  - This option should only be used after receiving approval from VFC Program Management
- Open vial but all doses not administered
  - Example: Seven doses of 10 dose vial of IPOL deemed non-viable due to temperature excursion

#### **Spoiled Vaccine**

#### **Options in NJIIS**

- Failure to store properly upon receipt
  - Example: Vaccine delivered to office but left on counter for days
- Mechanical failure
  - Example: Storage unit compressor stopped working
- Natural disaster/power outage
  - o Example: Power outage due to storm
- Recall
  - Example: Vaccine recalled by manufacturer or FDA
- Refrigerator too cold/too warm
  - Example: Unit experiences temperature excursion not due to power outage, natural disaster, or mechanical failure
- Vaccine spoiled in transit
  - Example: Vaccines exposed to out-ofrange temperatures during transport
- Spoiled Other

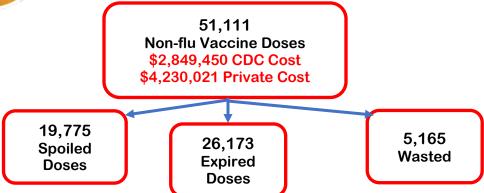
Expired and Spoiled vaccines in their original syringes or vials should be returned to McKesson within 6 months. The VFC Program receives Federal Excise Tax Credit for the returned vaccine. The VFC Program is not credited with the cost of the vaccine.

#### DO NOT RETURN WASTED VACCINE!

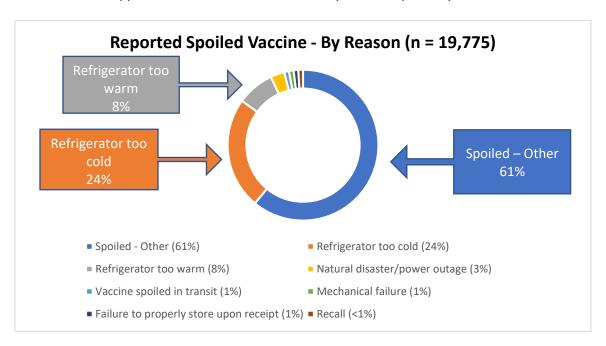
Broken vials and syringes, partially used multidose vials, etc. must be disposed of in accordance with office policy and applicable laws.



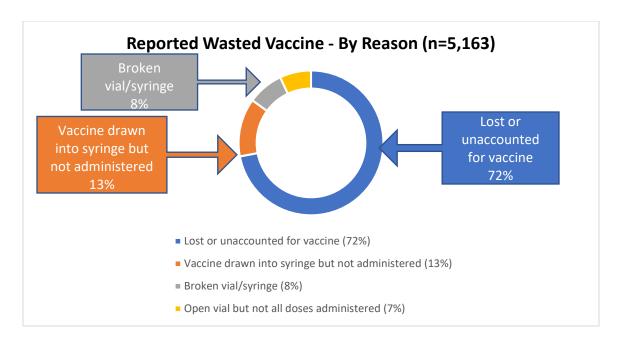
# 2018 VFC and 317 Vaccine Loss



In 2018, providers reported in NJIIS that a total of 51,111 doses of non-influenza vaccines were expired, spoiled, and wasted. Specifically, 19,775 doses were reported to be spoiled, 26,173 were reported to be expired, and 5,165 were reported to be wasted. The approximate CDC cost of these lost vaccines is \$2,849,450; the approximate cost of these vaccines if purchased privately would be \$4,230,021.

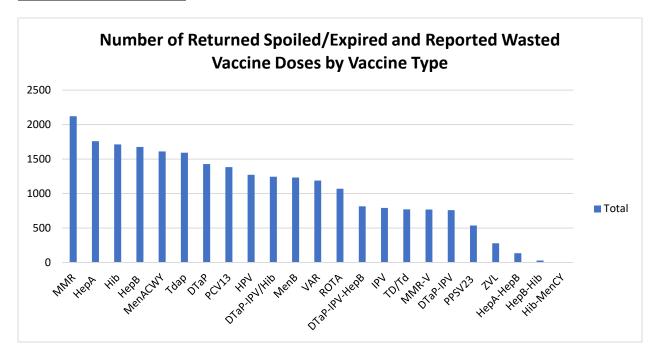


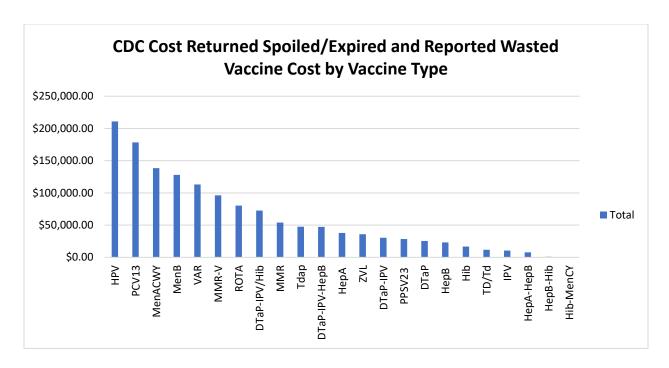
Of the 19,775 doses reported to be spoiled, providers indicated "Spoiled – other" as the reason for 12,043 doses (61%), "Refrigerator too cold" for 4,818 doses (24%), and "Refrigerator too warm" for 1,659 doses (8%). Other reasons cited included "Natural disaster/power outage" for 537 doses (3%), "Vaccine spoiled in transit" for 291 doses (1%), "Mechanical failure" for 197 doses (1%), "Failure to properly store upon receipt for 197 (1%), and "Recall" for 10 (<1%).



Of the 5,163 doses reported to be wasted, providers indicated "Lost or unaccounted for vaccine" for 3,693 doses (72%), "Vaccine drawn into syringe but not administered" for 653 doses (13%), "Broken vial/syringe" for 427 doses (8%), and "Open vial but not all doses administered for 390 doses (7%).

While 45,948 doses were reported to be expired and spoiled, only 19,007 doses (11,172 expired and 7,835 spoiled) were received by McKesson for a refund of the Federal Excise Tax Credit to the VFC Program. This means that 26,941 doses (59%) of expired and spoiled vaccines have not been accounted for by providers.





Among the 24,170 vaccines received by McKesson as spoiled/expired and reported as wasted (19,007 spoiled/expired and 5,163 wasted) are the following: DTaP, DTaP-IPV, DTaP-IPV-HepB, DTaP-IPV/Hib, HepA, HepB, HepB-Hib, Hib, Hib-MenCY, HPV, IPV, MenACWY, MenB, MMR, MMRV, PCV13, PPSV23, Rota, TD/Td, Tdap, VAR, ZVL. The total CDC cost for these 24,170 lost vaccines is estimated to be \$1,395,263. MMR accounted for the greatest number of lost doses (2,121) with an estimated CDC cost of \$54,069, followed by HepA (1,759 lost doses) with an estimated CDC cost of \$37,766. HPV accounted for the greatest financial loss with an estimated CDC cost of \$211,101 for 1,272 doses, followed by PCV13 with an estimated CDC cost of \$178,341 for 1,383 doses.

In addition, providers reported a loss of 24,987 influenza vaccines (21,683 expired, 1,807 spoiled, 1,497 wasted). Only 9,636 doses (41%) of these reported expired and spoiled vaccines were received by McKesson.

Providers must be able to account for all doses of vaccine received and must minimize vaccine loss.

All reported doses of expired and spoiled vaccine must be returned to McKesson.

DO NOT RETURN WASTED VACCINE! Broken vials and syringes, partially used multidose vials, etc. must be disposed of in accordance with office policy and applicable laws.

Providers may be held responsible for replacing lost vaccines on a dose-for-dose basis.



### Prevent vaccine loss!

Well-trained staff and an involved Medical Director are the keys to successful vaccine management!



Sound vaccine management practices can help prevent vaccine loss! Some tips for success are below:

Ensure you accurately assess and report your eligible population in NJIIS

Ensure your NJIIS on-line inventory is up-to-date

Promptly report all doses of vaccine administered in NJIIS

Rotate stock weekly and whenever a new shipment arrives - place vaccines with shorter expiration dates in front

Notify NJ VFC Program at least 3 months prior to vaccine expiration date if you will not use the vaccine. VFC will provide a list of providers that might be able to accept a transfer.

Maintain your vaccines at the appropriate temperatures at all times including during tranport

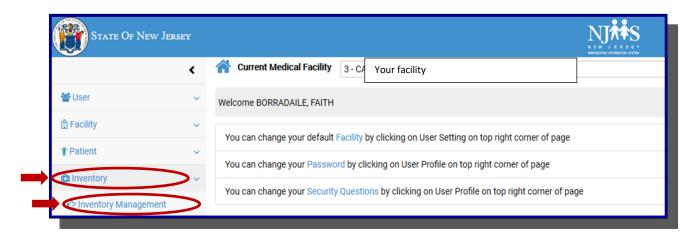
Never prepare vaccines prior to assessing the patient and ensuring that the vaccines will be administered

# A guide to reporting vaccine loss

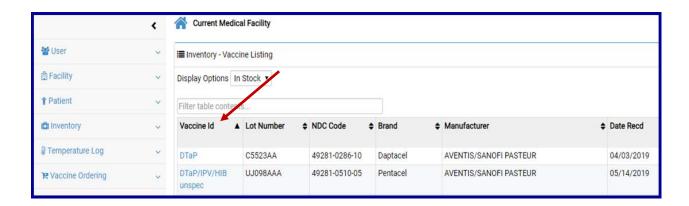
All **Expired**, **Spoiled**, and **Wasted** VFC and 317 vaccines must be reported to the NJ VFC Program. In order to report vaccine loss, you must use the transaction feature within NJIIS. Please be sure to follow these steps:

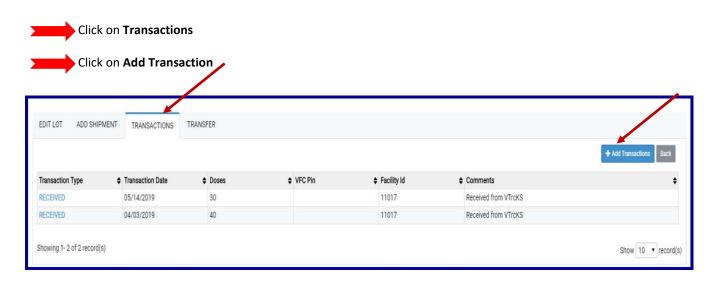
Log into NJIIS and go to Inventory

Click on the Inventory Management drop-down menu

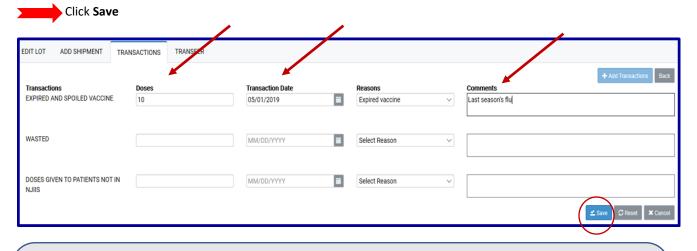


## Click on Vaccine Id





Enter the appropriate number of doses lost next to "EXPIRED AND SPOILED" OR "WASTED," as appropriate based on the type of vaccine loss. Then select the appropriate reason from the dropdown menu. Add an additional comment to further describe the reason for the vaccine loss such as "Last season's flu," "temperature excursion," "Parent refused after preparation," etc.



- A UPS shipping label will automatically be generated within 1 2 weeks of report of "Expired and Spoiled" vaccines. Labels are not generated for reports of "Waste." "Waste" including broken vials and syringes, partially used multidose vials, etc. must be disposed of in accordance with office policy and applicable laws.
- The UPS return label will be emailed to the email address listed for the Primary Coordinator in NJIIS
- Print the return shipping label from the "Retrieve Your Shipping Label" link in the email and secure it to the box of lost vaccines to be returned
- Labels will expire if not used within 30 days

Transacting out vaccine doses from inventory for the sole purpose of making your physical inventory match your NJIIS online inventory is considered fraud and may result in removal from the VFC Program!

For more information on reporting vaccine loss or transacting doses, take the Vaccine Ordering and Management Webinar. Information is available through the NJIIS website at <a href="https://njiis.nj.gov/core/web/index.html#/training">https://njiis.nj.gov/core/web/index.html#/training</a>

# CDC Policy Change: Billing administration fee



Wednesday, Jan 1st 2020

#### Effective January 1, 2020

Providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child may issue only a single bill to the patient within 90 days of vaccine administration.

- The policy does not apply to vaccine administration fees billed to Medicaid for children who meet the Medicaid eligibility criteria for the VFC program
- This policy is also applicable for un/underinsured 317-eligible patients
- Unpaid administration fees may not be sent to collections, and the provider may not refuse to vaccinate an eligible patient who has unpaid vaccine administration fees

# **Training opportunities**

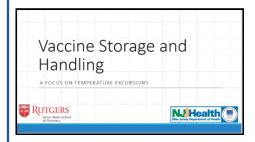
#### (S)HOT TOPICS: A FOCUS ON FUNDAMENTALS

The Vaccine Preventable Disease Program and Rutgers School of Public Health Workforce Development hosted the 2019 New Jersey Immunization Conference on May 29, 2019. If you missed the conference, you can still view the plenary speakers **JoEllen Wolicki** and **Sean Trimble** by visiting

http://rutgerstraining.sph.rutgers.edu/immunization2019/recordings.html

WD4246 Avoiding Errors in Vaccine
Storage and Handling
JoEllen Wolicki, BSN, RN, Nurse
Educator
NCIRD

WD4247 **Developing Vaccine Storage and Handling Recommendations**Sean Trimble, MPH, MT (ASCP), Public
Health Advisor
NCIRD



# VACCINE STORAGE AND HANDLING: A FOCUS ON TEMPERATURE EXCURSIONS

The NJ VFC Program has developed many resources to support providers in following vaccine storage and handling best practices. The Program recently collaborated with Rutgers' Ernest Mario School of Pharmacy to create the webinar, Vaccine Storage and Handling: A Focus on Temperature Excursions. This webinar reviews best practices in vaccine storage and handling and includes information on responding to temperature excursions. The webinar is available at <a href="https://njiis.nj.gov/core/web/index.html#vfcDocs">https://njiis.nj.gov/core/web/index.html#vfcDocs</a>. Continuing education credits will be available for this activity.

# Responding to temperature excursions

Staff must be able to recognize and respond to temperature excursions when they occur – even when they occur outside of normal business hours. If you use a digital data logger (DDL) with advanced features, you can be notified about temperature excursions should they occur when you are not at the office. Responding to temperature excursions when they occur minimizes vaccine loss. Staff should also be well-trained in the prevention of temperature excursions!



- Notify the primary or back-up vaccine coordinator immediately
- Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.

Document details of excursion including:

- Date and time
- Download DDL to determine length of time of excursion and minimum/maximum temperatures
- Inventory vaccines and compare to NJIIS inventory
- Complete the New Jersey Vaccine Viability Investigation Form for Federally Funded Vaccines (VIFFV)





- Contact the VFC Program within 1 business day at 609-826-4862 or VFC@doh.nj.gov
- Contact vaccine manufacturers to obtain written viability statements
- Email signed VIFFV, viability statements, and DDL files in .csv, .xlx, or.txt format to VFC@doh.nj.gov
- Don't dispose of vaccines until directed to do so by the VFC Program

- If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause
- Check the basics power supply, unit doors, thermostat settings
- If you believe the unit has failed, implement your emergency plan. Do not allow vaccines to remain in a non-functioning unit. Always use a DDL when transporting vaccines!



- When directed by the VFC Program, remove non-viable vaccines from the storage unit and label them, "DO NOT USE."
- Depending on the circumstances, providers may be required to replace non-viable vaccines on a dose-for-dose basis
- Tag all viable vaccines in the unit so that cumulative time out-of-range can be calculated should the vaccines be exposed to future temperature excursions
- If patients were administered non-viable vaccines, providers are responsible for notifying, counseling, and revaccinating patients, as appropriate at the provider's expense

# All about Digital Data Loggers (DDL)

Since January 1, 2018, the CDC requires that providers monitor VFC vaccine storage unit temperatures using DDLs. The DDL must remain with the vaccines at all times including during transport. Every office must also have a back-up DDL that is readily available in case the primary unit fails. A DDL is a great tool to help limit vaccine loss by helping to precisely determine the specifics of a temperature excursion. However, the tool is only as good as the users.

The primary and back-up vaccine coordinators and all staff who are involved with vaccine storage and handling must be trained to use the DDL(s) at the office. The staff should set the alarms so that they are alerted whenever the temperatures go out-of-



range. Staff must understand how to read the minimum and maximum (min/max) temperatures daily and how to clear the min/max – some devices automatically reset the min/max every 24 hours. Staff must also be able to download the DDL files at least weekly and whenever an out-of-range temperatures is noted and must be comfortable interpreting the reports. Staff should check to see if and when batteries need to be changed and most importantly, when the device is due for recalibration.

The manufacturers of DDLs have training materials. Staff must have the time to review all the training materials – often times, manufacturers have materials in a variety of formats including written materials and videos. It is ultimately the Medical Director's responsibility to make sure everyone in the office is trained in vaccine storage and handling including the use of the DDL.

Each DDL must have a current, valid Certificate of Calibration Testing or Report of Calibration. The back-up DDL should have a different calibration retesting date to avoid requiring all DDLs to be sent out for recalibration at the same time. If the back-up DDL has the same calibration date, providers must have the unit retested prior to the expiration, thereby ensuring that a calibrated DDL is available for required temperature monitoring at all times.

If you have questions about your specific DDL model or you have having trouble with the unit, you should directly reach out to the DDL manufacturer's customer service for assistance.

The VFC Program continues to offer providers DDLs through its **DDL Loan Program** (while supplies last). If you are interested in acquiring one of the DDLs below at no cost, please contact us at 609-826-4861 or VFC@doh.nj.gov.

VFC Digital Data Logger Loan Program Options					
Digital Data Logger Type	Refrigerator/ Freezer	Number of Probes	Alert/Alarm Type	Recalibration	Set-up
Berlinger Fridge-tag 3	Refrigerator Only	1	Local and remote text messages (remote feature available with prepaid subscription)	Due 2 years from calibration date (Lithium battery will run out in 3 years and cannot be replaced – Provider will need to purchase a replacement DDL)	Contact Berlinger for set-up at (508) 927-1634
LogTag Utred 30-WiFi	Refrigerator or Freezer	1	Local and remote text messages (remote feature available with prepaid subscription)	Due 2 years from calibration date	Contact LogTag for set-up at (866) 402-8282 ext. 1#
Control Company Traceable Excursion-Trac	Refrigerator and Freezer	2	Local only	Due 2 years from calibration date	VFC Representative will set-up Call Control Company for post set-up support (281) 482-1714