NEW JERSEY VACCINES FOR CHILDREN (VFC) NEWSLETTER

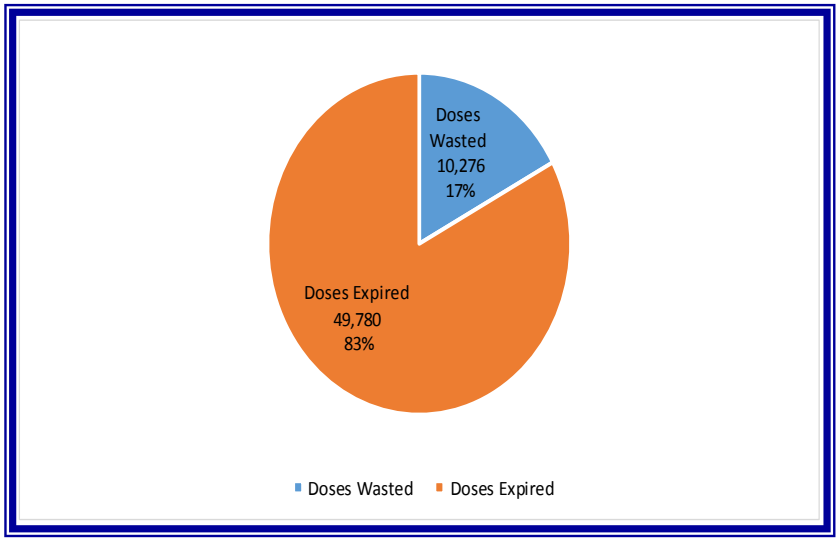
SPRING 2017

2016 VACCINE WASTE AND EXPIRATION

Immunization programs are among the most cost-effective ways to prevent disease. The success of these programs depends heavily upon the high immunization coverage of the target group and vaccine inventory management, including proper storage and handling of vaccine. Failure to adhere to recommended specifications for vaccine storage and handling can reduce their potency, thus resulting in an inadequate immune response and inadequate protection against vaccine preventable diseases.

In 2016, New Jersey Vaccines for Children (NJ VFC) and 317-Funded Adult (317) providers reported a total of 60,056 doses of wasted and expired vaccine—valued at $2,018,714. This represents a 12 percent decrease of expired and wasted doses compared to 2015. Approximately 7,500 fewer doses of vaccines were permitted to expire in the last year. However, continued vigilance is needed to further reduce vaccine expiration and waste.

Doses of Wasted and Expired Vaccine
VFC and 317 Programs, 2016



EXPIRATION IS THE MAIN CAUSE OF VACCINE LOSS

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2016 VACCINE WASTE AND EXPIRATION

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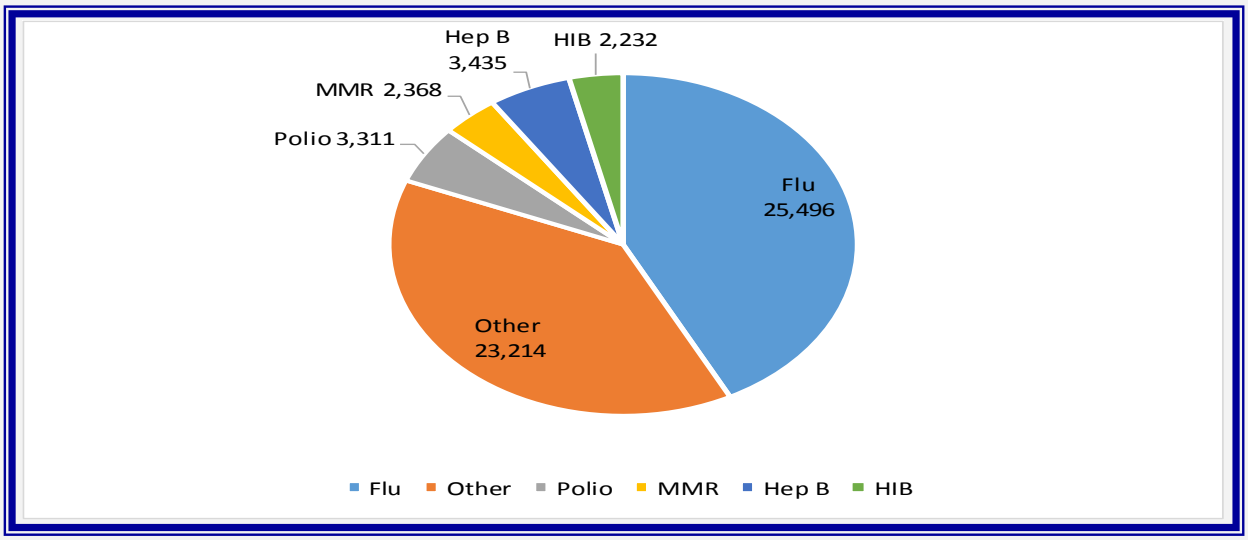
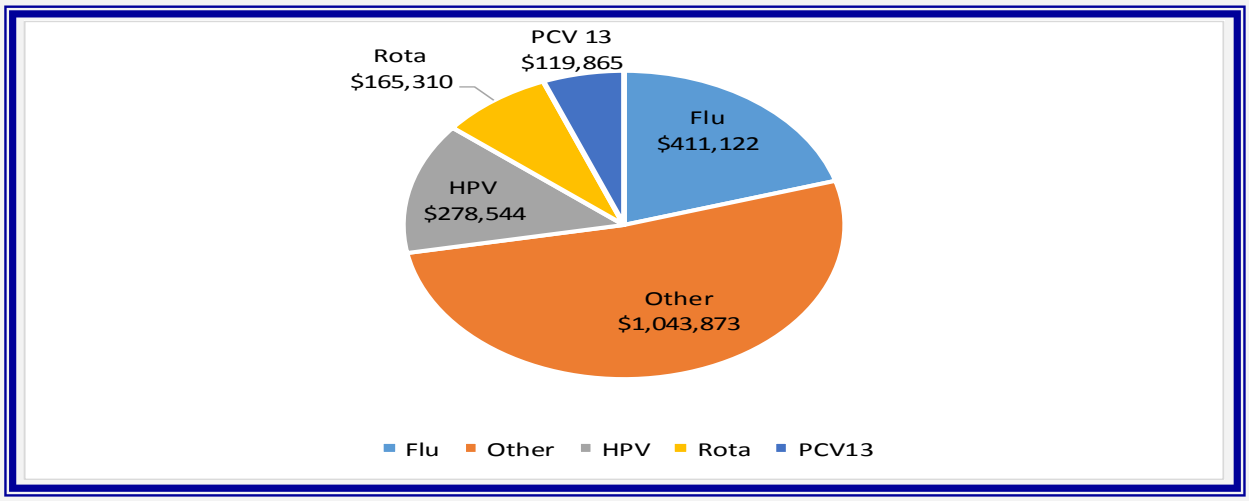
Practices should continuously implement and monitor strategies to reduce the risk of expiration or vaccine loss due to storage and handling issues. CDC recommends that providers only order and stock enough vaccine to meet patient needs. Storing a larger volume than your office needs increases the risk of wasting vaccines due to expiration or exposure to temperature excursions (e.g., due to mechanical failure of a storage unit). It is important to check expiration dates on vaccines and diluents at least once a week, and immediately remove expired vaccines and diluents from the storage units to avoid inadvertently administering them. Arrange stock in the storage unit so that for each vaccine type, doses with the earliest expiration dates are placed in front of those with later expiration dates. Always contact VFC customer service before transferring or taking vaccine out of your office. Contact VFC customer service when vaccine is three months from the expiration date so we can identify other offices where it may be transferred.

Doses of Wasted and Expired Vaccine by Type VFC and 317 Programs, 2016



Cost of Wasted and Expired Vaccines by Type VFC and 317 Programs 2016



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2016 VACCINE WASTE AND EXPIRATION

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There are some offices that report zero doses of wasted and expired vaccine. All federally funded, nonviable vaccine must be reported to the NJ VFC Program on a regular basis. Each unused dose of vaccine must be reported on the Vaccine Return Voucher (IMM-39) and then removed from online inventory.

As a provider responsible for federally funded vaccines, you and your staff should continuously monitor vaccine storage and handling practices to prevent vaccine waste and expiration. Vaccines must be kept at the temperatures recommended by the vaccine manufacturers at all times in order to observe their effectiveness. Providers should review their current vaccine storage and handling policies and ensure that all current and new office staff are aware of the correct protocols. Staff should also review the vaccine relocation plan which would be used in the event of power failures, refrigerator malfunctions, and natural disasters. It is critical to ensure all policies and plans are current and updated at least annually. For further information, please visit the Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit.

EXPLANATION OF VACCINE RETURN VOUCHER (IMM-39) CODES

The IMM-39 form is used to report all expired, wasted, or transferred vaccines to NJ VFC and/or 317 Programs. The IMM-39 has a drop-down arrow where a code must be selected.
The choices are the following:

- **W**-Wasted/Spoiled
- **E**-Expired
- **T**-Transfer

When "W" for waste and spoilage is selected, one of the following comments must be selected:

- **Failure to store properly upon receipt**—the vaccine shipment was received but not opened and stored appropriately upon receipt.
- **Mechanical failure of storage unit**—the storage unit broke down and the vaccines were exposed to out-of-range temperatures.
- **Natural disaster**—an environmental event such as a flood, fire, earthquake, tornado or hurricane. The natural disaster may have caused the storage unit to malfunction or disconnect from the power source.
- **Power outage**—loss of electricity to the storage unit (not due to a natural disaster).
- **Recall**—an official request to return vaccine made by the vaccine manufacturer or a regulatory agency.
- **Storage unit too cold**—temperatures in the storage unit were below the recommended range to store vaccine.
- **Storage unit too warm**—temperatures in the storage unit were above the recommended range to store vaccine.

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EXPLANATION OF VACCINE RETURN VOUCHER (IMM-39) CODES

(Continued from page 3)

- **Vaccine spoiled in transit**—the vaccines were not in good condition when the shipment was received. The vaccines were exposed to out-of-range temperatures during the shipping process.
- **Compromised or broken vial***—sterility is compromised or the vial is cracked.
- **Vaccine drawn into a syringe but not administered***—vaccine was prepared to be administered, but was not given in a timely manner, possibly due to parent refusal.
  ***NOTE**: Pre-drawing vaccine prior to a patient's arrival in your office is not permitted. This waste reason is designed for instances when patients may initially agree to receive a vaccine but then reconsider after counseling.*
- **Vaccine in open vial but doses not administered***—a multi-dose vial from which all doses were not used prior to the vaccine being spoiled.
- **Misplaced vaccine***—vaccine received from the VFC or 317 Program but for which you cannot account. This waste reason should rarely be used as it is the provider's responsibility to account for all doses shipped to your facility.

***Theses waste reasons may generate a waste return label but the vaccine cannot be returned to McKesson for excise tax credit. Vaccines that are wasted for these reasons should be disposed of according to your office policy.**

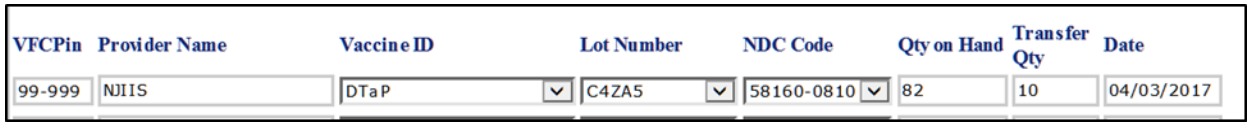
All expired and spoiled vaccine must be returned to McKesson within six months of the date of expiration or spoilage, using the waste return label generated by the IMM-39. Vaccine returned to McKesson ensures that the vaccine will be properly disposed of and credit for the excise tax will be returned to the NJ VFC Program. McKesson will accept vaccines that are more than six months past expiration; however, the excise tax will not be credited to the program.

After the IMM-39 is submitted, wasted, spoiled, expired, and transferred vaccine must then be removed from your online inventory in the New Jersey Immunization Information System (NJIIS). The process to remove vaccine from inventory is called *adding a transaction.*

Vaccine Transfer

To transfer vaccine from your inventory and add it to the PIN accepting the transfer:

- Sign into NJIIS and select *Inventory Management*, then *Vaccine Transfer*
- Choose the funding source of the vaccine: VFC Pediatric or Adult/317
- Enter the PIN *to where the vaccine is being transferred* and enter/select the other vaccine information, then save.



VFCPin	Provider Name	Vaccine ID	Lot Number	NDC Code	Qty on Hand	Transfer Qty	Date
99-999	NJIIS	DTaP	C4ZA5	58160-0810	82	10	04/03/2017

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EXPLANATION OF VACCINE RETURN VOUCHER (IMM-39) CODES

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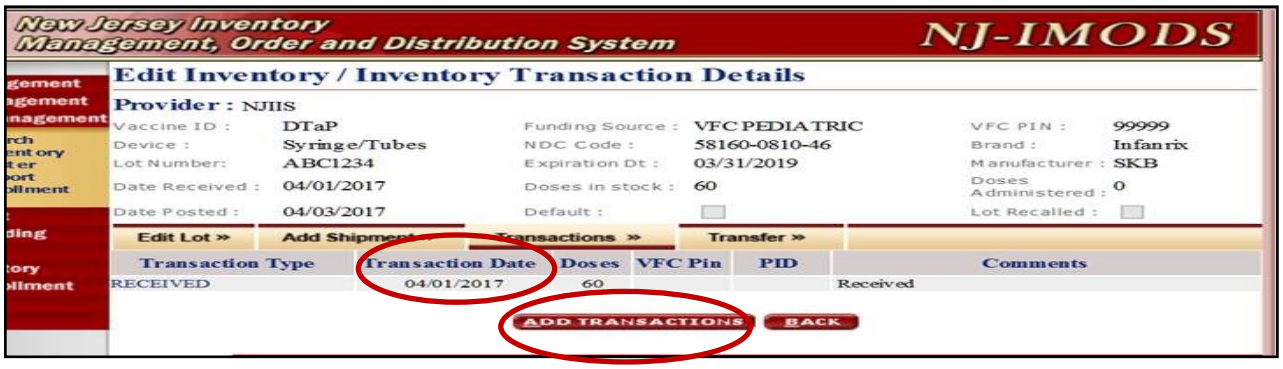
Wasted/Expired Vaccine

To remove wasted and expired vaccine from inventory:

- Sign into NJIIS and select *Inventory Management*
- In the left-hand column, click on the vaccine ID

DTaP	ABC1234	58160-0810-46	Infanrix	04/01/2017	60	0	60	VFC PEDIATRIC	03/31/2019

- Click on *Transactions*
- Click on *Add Transactions*



On the *Transactions* page, enter the number of doses to be returned or that were properly disposed of, add the date the transaction occurred and enter the same comment used on the IMM-39.

NOTE: ADDING TRANSACTIONS TO INVENTORY IS DONE *WHEN THE TRANSACTION OCCURRED.* ADDING TRANSACTIONS TO ADJUST REFRIGERATOR INVENTORY TO MATCH ONLINE INVENTORY IS FRAUDULENT AND WOULD REQUIRE REIMBURSEMENT TO THE PROGRAM.

TRANSPORTING FROZEN VACCINES

The CDC and Merck, the manufacturer, do not recommend transporting frozen vaccines after they are received. Only transport frozen vaccines in an emergency. A portable freezer is preferable for transporting frozen vaccines to maintain the recommended storage temperatures. If a portable freezer is not available, dry ice should not be used. Contact Merck after frozen vaccines are moved to obtain viability information, then contact the VFC program with the outcome.

For information regarding stability under conditions other than those recommended, call the Merck Vaccine Customer Center, 877-VAX-MERCK (877-829-6372).

COMING SOON: DIGITAL DATA LOGGERS REQUIREMENT

As of January 1, 2018, CDC will require all providers to use continuous temperature monitoring devices (data loggers) to monitor VFC/317 vaccines during routine onsite storage of vaccine, transport of vaccine, mass vaccination clinics, and as a required back-up thermometer. Consider purchasing a dual-probe data logger as the back-up thermometer so both refrigerator and freezer temperatures can be monitored if your primary thermometer(s) cannot be used.

Remember to check the date and time settings on your data logger quarterly to ensure they are correct. Sometimes the settings may be reset during a power outage. Also, don't forget to adjust the time on your data logger when daylight savings time starts and ends.

Review the data from your data logger at least weekly. If at anytime you note an out-of-range minimum/maximum daily temperature, **ACT IMMEDIATELY!** Quarantine the vaccine and call the VFC Program.

MONITORING MINIMUM AND MAXIMUM STORAGE TEMPERATURES

Maintaining proper storage temperatures is essential to ensure the viability of vaccines. Checking the minimum (MIN) and maximum (MAX) temperatures daily can help you to determine whether vaccines are stored within the recommended ranges. The MIN temperature setting shows the coldest temperature in the storage unit *since the memory was last cleared*. The MAX temperature setting shows the warmest temperature *since the memory was last cleared*. MIN/MAX temperatures are important because they will tell you if temperatures went out of range since they were last checked.

Act immediately when out-of-range min/max temperatures are recorded. Determine why temperatures went out of– range and correct the issue, if possible. Initiate your Vaccine Management Policy to get vaccine into a storage unit that maintains in-range temperatures, and then quarantine vaccines that have been exposed to out-of-range temperatures.

Quarantining vaccine is done by separating vaccine exposed to out-of-range temperatures and labelling them, "**DO NOT USE**". The Vaccine Storage Troubleshooting Record may be used as a guide to obtain viability information or follow section VII of your Vaccine Management Policy template:

WHAT INFORMATION DO I NEED TO DETERMINE VACCINE VIABILITY?

1. What circumstances occurred to question vaccine viability?
2. Which VFC or 317 vaccines were involved? Please include:
    - Brand name
    - Number of doses
    - Lot number
    - Manufacturer
    - Expiration date
3. What was the maximum and/or minimum temperature observed?
4. How long was the vaccine exposed (hours/minutes) to the above temperature? Data logger files can be downloaded for detailed time and temperature information.

MONITORING MINIMUM AND MAXIMUM STORAGE TEMPERATURES

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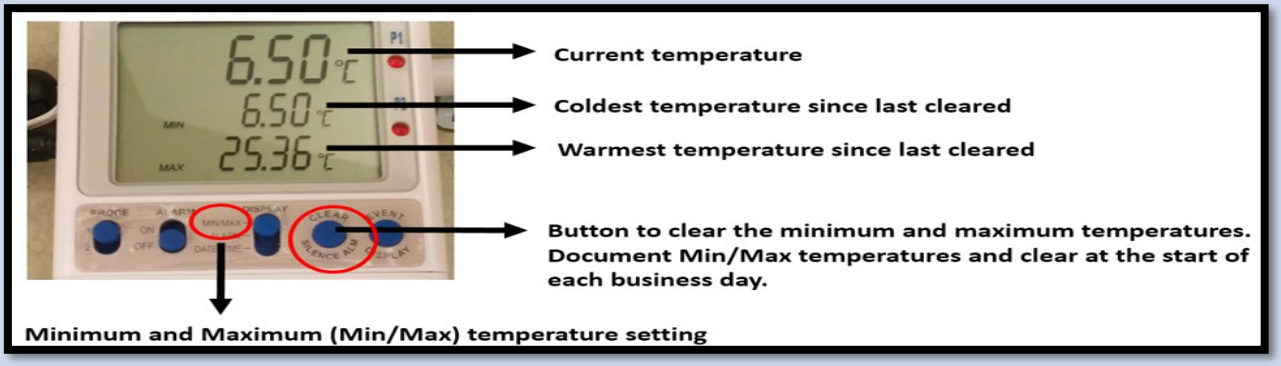


It is the provider's responsibility to contact the vaccine manufacturers to determine if vaccines exposed to out-of-range temperatures are viable. Document phone calls to manufacturers in detail. Obtain viability documentation in writing from the manufacturer.

Refrigerator temperatures between 36°F to 46°F (2°C to 8°C) are within the recommended range. Temperatures below 36°F and above 46°F are out-of-range.

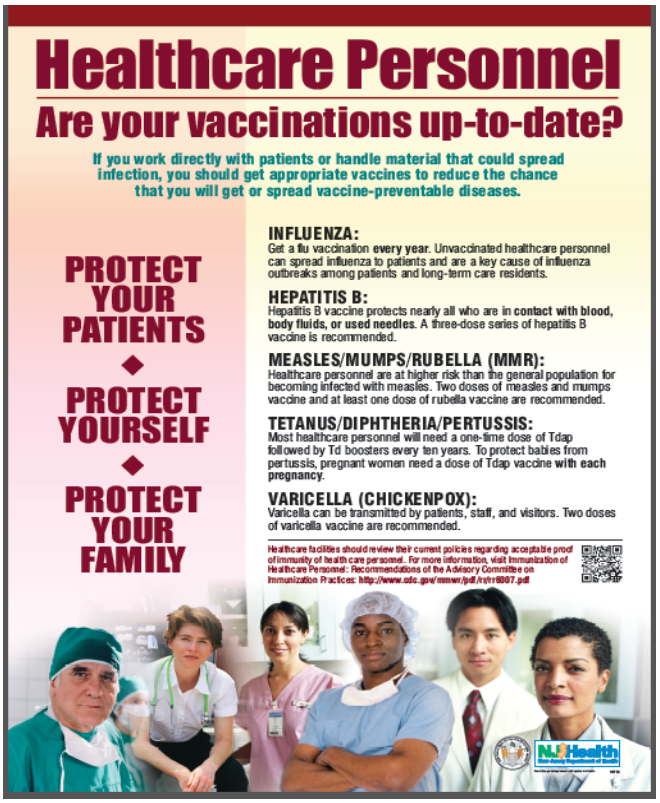
Freezer temperatures of 5°F (-15°C) are within the recommended range. Temperatures above 5°F (-15°C) or below −58°F (−50°C) are out-of-range

WHEN IN DOUBT, STORE VACCINE AT THE RECOMMENED TEMPERATURE AND KEEP VACCINE QUARANTINED UNTIL VIABILITY INFORMATION IS OBTAINED.
Contact the VFC Program for assistance; Contact us online or call: 609-826-4862.

FREE PROVIDER RESOURCES AVAILABLE

The NJ Vaccine Preventable Disease Program (VPDP) has free materials available to use in your practice. One of these materials is a poster promoting vaccination of healthcare personnel. Healthcare personnel are at risk for exposure to serious, and sometimes deadly, diseases. If you work directly with patients or handle material that could spread infection, you should get appropriate vaccines to reduce the chance that you will get or spread vaccine-preventable diseases. Protect yourself, your patients, and your family members by making sure you are up-to-date with all recommended vaccines.

Please visit the VPDP website to find our provider and patient resources. If you are interested in getting copies of specific educational materials, contact the VPDP at 609-826-4861.



RESPONDING TO PARENT QUESTIONS ABOUT HPV VACCINE DOSING SCHEDULES

In October 2016, CDC updated HPV vaccination recommendations regarding dosing schedules. CDC now recommends 2 doses of HPV vaccine for people starting the vaccination series before the 15th birthday. Three doses of HPV vaccine are recommended for people starting the vaccination series on or after the 15th birthday and for people with certain immunocompromising conditions.

CDC continues to recommend routine vaccination for girls and boys at age 11 or 12 years. The vaccination series can be started at 9 years of age. CDC also recommends vaccination through age 26 years for females and through age 21 years for males. Males age 22–26 years may be vaccinated.

In an effort to address questions and concerns from parents, the CDC created a resource titled, Clinician FAQ: CDC Recommendations for HPV Vaccine 2-Dose Schedules. For your convenience, the content of this document is listed below.

What is the recommended 2-dose HPV vaccination schedule?
For girls and boys starting the vaccination series before the 15th birthday, the recommended schedule is 2 doses of HPV vaccine. The second dose should be given 6–12 months after the first dose (0, 6–12 month schedule).

Answering parents' questions: *We now recommend 2 doses of HPV vaccine for your son or daughter, instead of 3, if your child starts the series before their 15th birthday. I still recommend your child start the vaccination series by age 11 or 12 years for best protection against HPV. He or she will need a second dose 6-12 months after the first dose.*

Who should still receive a 3-dose schedule?
CDC continues to recommend a 3-dose schedule for persons starting the HPV vaccination series on or after the 15th birthday, and for persons with certain immunocompromising conditions. The second dose should be given 1–2 months after the first dose, and the third dose should be given 6 months after the first dose (0, 1–2, 6 month schedule).

Answering parents' questions: *If your child starts the series after his or her 15th birthday or has certain health problems that weaken his or her immune system, he or she will still need the 3-dose series. We will give the second dose 1–2 months after the first, and the last dose 6 months after the first dose.*

Why did CDC make the recommendation change to a 2-dose schedule?
Over the past year, CDC and the Advisory Committee on Immunization Practices (ACIP) have been reviewing data on 2-dose schedules, including results from studies of HPV vaccines that compared the antibody responses after 2 doses and 3 doses. These studies showed that the antibody response after 2 doses given at least 6 months apart to 9–14 year-olds was as good or better than the antibody response after 3 doses given to older adolescents and young adults, the age group in which efficacy was demonstrated in clinical trials.

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RESPONDING TO PARENT QUESTIONS ABOUT HPV VACCINE DOSING SCHEDULES

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Answering parents' questions: *CDC and ACIP (a group of experts that make vaccine recommendations) have been reviewing data on 2-dose HPV vaccination schedules for several months. The evidence showed that 2 doses of HPV vaccine given at least 6 months apart in younger adolescents were as good or better than 3 doses. These updated recommendations are an example of using the latest available evidence to provide your child with the best possible protection against serious diseases.*
Answering parents' questions: *Since your child received his/her first dose of the HPV vaccine before he/she was 15 years old, we'll only need to give 1 more dose.*

Why is the 2-dose schedule change recommended only for girls and boys age 9–14 years?
ACIP makes recommendations based on the best available scientific evidence. Immunogenicity studies have shown that 2 doses of HPV vaccine given to 9–14 year-olds at least 6 months apart were as good, or better, than 3 doses given to older adolescents and young adults. Studies have not been done to show this in adolescents age 15 years or older.

Answering parents' questions: *The data we currently have from scientific studies (clinical trials) showed that 2 doses of HPV vaccine given at least 6 months apart were as good or better than 3 doses in children 9–14 years of age. Older adolescents haven't been studied in the same way, so we don't have information available for that age group. For that reason, the recommendation for number of doses has not been changed for older adolescents.*

What is the recommendation for persons with immunocompromising conditions?
CDC recommends 3 doses of HPV vaccine (0, 1–2, 6 months) for immunocompromised people age 9 through 26 years. People whose immune responses might be lower, for example due to HIV infection, cancer, autoimmune disease, or taking immunosuppressant medications, should receive 3 doses to make sure they get the most benefit. However, children with asthma, diabetes, and other conditions that would not suppress immune response to HPV vaccination can receive a 2-dose schedule.

Answering parents' questions: *Even though CDC has recommended just 2 doses of HPV for kids under 15 years, we'll need to give your child 3 doses because he/she has a health problem that weakens his or her immune system.*

If a HPV vaccine series was started with quadrivalent HPV vaccine or bivalent HPV vaccine and will be completed with 9-valent HPV vaccine, what are the intervals for the remaining doses in a 3-dose or 2-dose series?
If the first dose of any vaccine was given before the 15th birthday, vaccination should be completed according to a 2-dose schedule. In a 2-dose series, the second dose is recommended 6–12 months after the first dose (0, 6–12month schedule).
If the first dose of any vaccine was given on or after the 15th birthday, vaccination should be completed according to a 3-dose schedule. In a 3-dose series, the second dose is recommended 1–2 months after the first dose, and the third dose is recommended 6 months after the first dose (0, 1–2, 6 month schedule. If a vaccination schedule is interrupted, vaccine doses do not need to be repeated.

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RESPONDING TO PARENT QUESTIONS ABOUT HPV VACCINE DOSING SCHEDULES

(Continued from page 9)

If a girl or boy received 2 doses of HPV vaccine less than 5 months apart, do they need a third HPV vaccine dose?
Yes. In a 2-dose schedule of HPV vaccine, the recommended interval is 6–12 months, and the minimum interval is 5 months between the first and second dose. If the second dose is given earlier than 5 months, a third dose should be administered.

Answering parents' questions: *The recommended schedule is 2 doses given 6 to 12 months apart. The minimum amount of time between those doses is 5 months. Because your child received 2 doses less than 5 months apart, we'll need to give your child a third dose.*

If someone is age 15 years or older and started the vaccination series at age 11 but only received 1 dose, how many more doses do they need?
This person needs 1 more dose to complete a 2-dose series, which is recommended because the vaccination was started before turning 15 years old. In a 2-dose series, the second dose is recommended 6–12 months after the first dose. In this case, the first dose was given several years ago, so the second dose can be given right away.

Is the 9-valent HPV vaccine approved by FDA for use as a 2-dose schedule?
Yes, in October 2016, FDA approved a 2-dose schedule (0, 6–12 months) of 9-valent HPV vaccine for use in girls and boys age 9–14 years in the United States.

What HPV vaccines are currently available in the United States?
Three HPV vaccines are licensed for use in the United States: 9-valent HPV vaccine, quadrivalent HPV vaccine, and bivalent HPV vaccine. However, after the end of 2016, only 9-valent HPV vaccine will be sold in the United States.

POINTS TO REMEMBER

- Please ensure you are in compliance with the ordering, accountability, and quality assurance requirements of the NJ VFC and 317 Programs. Both Primary and Back-up Vaccine Coordinators must work in the
  office and have access to Inventory Management, Order and Distribution System (IMODS) and NJIIS for that office.
- Follow the recommended immunization schedules as established by the ACIP and NJ state immunization requirements.
- Screen for age and eligibility at each immunization visit. Insurance coverage for vaccines must be verified prior to administration of vaccine. Providers must be able to demonstrate proper screening procedures and provide associated documentation during their NJ VFC compliance visit.
- Maintain records of all children immunized with VFC and/or 317 vaccines
  by accurately entering all information, including doses administered, into the NJIIS.
- Provide vaccine information statements in accordance with the National Vaccine Injury Compensation Act (42 U.S.C. §300aa-26).