



**Department  
of Health**

**NYS Vaccines for Children (VFC) Program  
Training Series  
16: Vaccine Preparation**

New York State Department of Health  
Bureau of Immunization

Hello and welcome.

This training is intended to provide guidance to NYS Vaccines for Children (VFC) providers on preparing vaccine for administration.

## Equipment Selection

- Use a new, separate needle and syringe for each injection
- Check needle/syringe expiration date
- Never administer vaccines to more than one patient with same needle/syringe
- Keep varying needle lengths in supply based on patient population
- Needle selection should be based on:
  - Prescribed route
  - Size of individual
  - Injection technique
- 22-25 fine gauge needle usually appropriate for vaccines



Image obtained from the Centers for Disease Control and Prevention (CDC) [Vaccine Storage and Handling Toolkit](#)



In terms of equipment selection, always use a new, separate needle and syringe for each injection.

Some syringes and needles are packaged with an expiration date so be sure to consider this when selecting and ordering injection supplies.

Never administer vaccines from the same syringe to more than one patient, even if the needle is changed.

Each VFC provider should keep a supply of varying lengths of needles and syringes that are appropriate for the patient population they serve.

Needle selection should be determined by: the prescribed route, the size of the individual being vaccinated and the injection technique. A 22-25 fine gauge needle can usually be used for administering vaccines.

Additional information and training on needle selection, administration routes and injection techniques can be found in separate clinical trainings on vaccine administration. Visit the Resources slide at the end of this training for links to

those trainings.

## Inspect Vaccine Prior to Use

1. Check expiration date on vaccine and diluent vials
  - Use through last day of the month indicated on the expiration date
    - Ex 1: If expiration is 6/2017 – good through 6/30/2017 (do not use on or after 7/1/2017)
    - Ex 2: If expiration is 6/15/2017 – good until 6/15/2017 (do not use on or after 6/16/2017)
  - Never administer expired vaccines
    - If expired vaccine is administered accidentally, contact the VFC Program right away (1-800-543-7468)
  - Some vaccines may have Beyond Use Dates (BUDS)
    - Indicated from date/time vial is opened or reconstituted
  - Refer to separate document [Monitoring Expiration Dates](#) for more information
2. Check vaccine and diluent vials for damage or contamination
  - If suspected, do not use and contact vaccine manufacturer for guidance



The expiration date on each diluent and vaccine vial should always be checked before preparing vaccine for administration. Vaccine can be used through the last day of the month indicated on the expiration date unless otherwise stated.

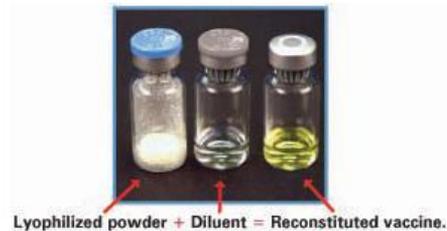
Never administer expired vaccines. If expired vaccine is administered accidentally, contact the NYS VFC Program right away at 1-800-543-7468.

Some vaccines must be used prior to the expiration date that is printed on the label. This is referred to as the Beyond-Use Date or BUD. Vaccines with a beyond use date usually have a shorter expiration date that begins after the time the vial is opened or reconstituted. A separate document is available which gives detailed information on Monitoring Expiration Dates. Visit the Resource slide at the end of this training for a link.

Vaccine and diluent vials should also be closely checked for damage or contamination prior to use. If damage or contamination is suspected, do not use the vaccine and contact the vaccine manufacturer for guidance.

## Reconstitution with Diluents

- Lyophilized (freeze-dried) vaccines that come in powder or pellet form
  - Must be mixed with a liquid (diluent) before administration
  - Process known as “reconstitution”
- Diluents
  - Use only specific diluent for each vaccine
  - Vary in volume and composition
  - Some contain antigen for specific vaccine (e.g., DTaP-IPV)
  - **Not interchangeable** unless specified by manufacturer
- NEVER use a stock vial of sterile water or normal saline to reconstitute vaccines
- NEVER administer vaccine reconstituted with the wrong diluent
  - Contact the NYS VFC program for guidance 1-800-543-7468



Source: Centers for Disease Control and Prevention



Some vaccines are supplied in a lyophilized (freeze-dried) form that requires reconstitution with a liquid diluent. This freeze dried form can come in powder or pellet form and must be mixed with a diluent, prior to administration. This process is known as reconstitution.

Each diluent is specific to the corresponding vaccine and can vary in attributes such as volume, sterility, pH, and chemical balance. Some diluents contain antigen for a specific vaccine.

Vaccines and diluents are not interchangeable unless specified by the manufacturer.

If vaccine must be reconstituted, use only the diluent supplied for that vaccine. NEVER use a stock vial of sterile water or normal saline to reconstitute vaccines. NEVER administer vaccine reconstituted with the wrong diluent. If the vaccine is administered accidentally, contact the NYS VFC program for guidance regarding revaccination.

# Steps for Reconstitution

*Reconstitute according to manufacturer's guidelines just prior to administration*

1. Use only the manufacturer-supplied diluent for each vaccine
2. Inject diluent into vaccine vial and agitate vial to thoroughly mix vaccine
3. Inspect vaccine for discoloration or cloudiness
  - 1. If discoloration or cloudiness is present, contact manufacturer**
4. Use all of the diluent supplied for a single dose
5. Draw up all of the vaccine once thoroughly reconstituted
6. See job aids for additional information:
  1. <http://www.eziz.org/assets/docs/IMM-897.pdf>
  2. <http://www.immunize.org/catg.d/p3040.pdf>



This slide outlines the steps for reconstituting vaccine with a diluent.

Reconstitute vaccine according to manufacturer's guidelines just before administration.

Use ONLY the manufacturers supplied diluent for that vaccine.

Inject all the diluent into the vaccine vial and agitate the vial to ensure thorough mixing. Consult the specific instructions provided in the product information.

After reconstitution, inspect the vaccine for discoloration or cloudiness. If it appears cloudy or discolored, do not continue use the vaccine, and contact the manufacturer for guidance.

Use all of the diluent supplied for a single dose and then draw up all of the vaccine after it is thoroughly reconstituted.

Unless a needle gets contaminated or damaged, it's not necessary to change needles between drawing vaccine from the vial and administering the vaccine.

Follow the links on this slide for job aids related to reconstitution and using diluents.

## Filling Syringes

- Agitate vial to mix vaccine thoroughly into a uniform suspension before withdrawing vaccine
- Inspect vaccine for discoloration or particles that can't re-suspended
  - If problems are noted, don't administer the vaccine
- Follow standard medication preparation guidelines to draw up doses
- Don't draw up doses until just before administering
- Cap on vaccine vial functions as dust cover
  - Once removed, cleanse exposed rubber stopper with a sterile alcohol wipe
  - For multi-dose vials, cleanse the rubber stopper between each dose drawn
- Never combine vaccine into a single syringe or transfer vaccine from one syringe to another



Image obtained from the California Department of Public Health <http://epiz.org/assets/docs/IMM-897.pdf>



Agitate the vaccine vial to mix vaccine thoroughly and obtain uniform suspension prior to withdrawing vaccine. Inspect vaccine for discoloration or particles that can't be re-suspended.

If problems are noted, the vaccine should not be administered.

Follow standard medication preparation guidelines when drawing a dose of vaccine into a syringe

Do not draw the vaccine dose into a syringe until it is to be administered.

The cap on a vaccine vial functions as dust cover.

Once removed, cleanse the exposed rubber stopper with a sterile alcohol wipe.

For multi-dose vials, cleanse the rubber stopper each time prior to withdrawing a dose.

Never combine vaccine into a single syringe or transfer vaccine from one

syringe to another.

# Single Dose Vials

- One-time use (do not contain preservative)
- Never use for more than one patient
- Do not remove cap from a single-dose vial until ready to use
- Always check the vial before removing the cap to assure the correct vaccine has been selected
- Unused single-dose vials without a protective cap should be discarded at the end of the workday and reported as waste in NYSIIS
  - not possible to determine if the rubber seal has been punctured



Image obtained from the CDC's Storage and Handling Toolkit



Single-dose vials are designed for one-time use only as they do not contain a bacteriostatic agent to preserve the vaccine after opening.

Single dose vials should never be used for more than one patient.

Do not open a single-dose vial until the vial is ready to use. Once the protective cap has been removed, as shown in the photo on this slide, the vaccine should be used because it is not possible to tell if the rubber seal has been entered or punctured by a needle.

Check the vial label before removing the cap on the vial to ensure that the correct vaccine has been selected.

Unused single-dose vials without a protective cap should be discarded at the end of the workday and reported as waste in the New York State Immunization Information System (NYSIIS).

## Multi-dose Vials

- Can be entered more than once; contain a bacteriostatic (preservative) agent
  - Use a new needle/syringe each time
  - **Keep open multi-dose vials away from patient treatment area to prevent contamination**
  - **Indicate a tally mark on outside of vial to indicate when a dose has been withdrawn**
- Can be used until expiration date printed on the vial unless:
  1. Contaminated or compromised
  2. Beyond Use Date (or BUD) is noted in package insert
    - BUD is date/time after which a vaccine should not be used
      - Occurs prior to expiration date
      - Label with: Date vaccine was first opened, Initials and Beyond Use Date (BUD)



Image obtained from the CDC's Single Dose and Multi-dose Vial Infographic



Multi-dose vials can be used more than once to draw up multiple doses because they DO contain a bacteriostatic (or preservative) agent. But you still need to use a new needle or syringe each time vaccine is drawn from a multi dose vial.

Multi-dose vials that will be used for more than one patient should not be kept or accessed in the immediate patient treatment area to prevent inadvertent contamination. For the same reason, any multi-dose vial brought into the immediate patient treatment area should be discarded after use.

You should indicate that you have withdrawn a dose by making a tally mark on the outside of the multi-dose vial. This is a good way to tell how many doses are left.

Multi-dose vials can be used until the expiration date printed on the vial unless they have been contaminated, compromised, or there is a “beyond use date” in the package insert. The Beyond Use Date is the date or time after which a vaccine should not be used. Beyond Use Dates always occur prior to the expiration date printed on the vial by the manufacturer, never after. When handling multi-dose vials with BUDs, calculate the BUD using the time interval

found in the vaccine's package insert. Label the vaccine with the date the vaccine was opened, the correct beyond use date and time, and your initials.

## Manufacturer-Filled Syringes

- Prepared and sealed by manufacturer
- Once activated (syringe cap removed or needle attached) sterile seal is broken
- Vaccine must be used or discarded by end of workday and reported as waste in NYSIIS



Source: Centers for Disease Control and Prevention, Pink Book Webinar Series, Vaccine Storage and Handling and Administration



Manufacturer-filled syringes are prepared and sealed under sterile conditions by the manufacturer.

Once a manufacturer-filled syringe is activated (i.e., syringe cap removed or needle attached), the sterile seal is broken.

The vaccine should then be used or discarded by the end of the workday and reported as waste in NYSIIS.

# IPOL

- Does not have a Beyond Use Date (BUD)
- Can be used after opening until expiration date printed on the vial or package
  - Unless contaminated or stored inappropriately
- 28-day Joint Commission Multi-Dose vial rule does not apply to vaccine



Image obtained from <http://www.webmd.com>



## **IPOL is a multi-dose vial and it does not have a beyond use date.**

As mentioned previously, multi-dose vials are good until the expiration date printed on the vial or package unless they have been contaminated or compromised.

There has been confusion about whether a Joint Commission Multi-dose Vials standard applies to open multi-dose vials of vaccine, like IPOL. **It does not. This 28 day rule regarding open multi-dose vials does not apply to vaccine. Visit the resources section of this training for a link which confirms this information.**

## Don't Pre-Draw Vaccines!

- Once vaccines are inside syringes, it can be difficult to tell them apart
  - Leads to administration errors
- Pre-drawn vaccines that are not used need to be discarded, leading to unnecessary vaccine waste
- Bacterial growth and contamination of pre-drawn syringes can occur (in syringes without bacteriostatic agents)
- Vaccine can interact with polymers in plastic syringes
  - Vaccine potency can be reduced



The Centers for Disease Control and Prevention or CDC recommends that providers draw up vaccines only at the time of administration and that providers do not pre-draw vaccines.

Once vaccines are inside syringes, it is difficult to tell them apart. This can lead to administration errors.

Pre-drawn vaccines that are not used must be discarded by the end of the workday, this leads to unnecessary and avoidable vaccine waste.

Most syringes are designed for immediate administration, not for storage. Bacterial contamination and growth can occur in syringes with pre-drawn vaccine that does not contain bacteriostatic agents.

Also, vaccine components may interact with polymers in plastic syringes over time, which can potentially reduce vaccine potency making the vaccine ineffective.

## Immunization Clinics

- Pre-drawing vaccines in advance of clinics is not recommended
- **Best practice:** use manufacturer-filled syringes for large immunization clinics instead
- If vaccines must be pre-drawn:
  - Have separate administration stations for each vaccine type
  - Don't draw up vaccines before arriving at clinic site
  - Don't draw up more than 1 multi-dose vial or 10 doses at once
  - Monitor patient flow closely
  - Vaccinators should administer the doses they have pre-drawn
  - Discard remaining pre-drawn syringes when the clinic ends



Vaccine manufacturers do not recommend that vaccines be pre-drawn in advance of vaccination clinics. This is due to many reasons but one reason is that no data exists on the stability of vaccines stored in syringes that have been filled by providers.

As an alternative to pre-drawing vaccines, CDC recommends using manufacturer-filled syringes for large immunization clinics.

However, if vaccine must be pre-drawn use the following guidance:

- If more than one vaccine type is to be administered, separate administration stations should be set up for each vaccine type to prevent medication errors.
- Vaccines should NOT be drawn up prior to arriving at clinic site. Drawing up doses of vaccine hours or even days before a clinic is NOT acceptable.
- At clinic site, no more than 1 multi-dose vial or 10 doses should be drawn up at one time by each vaccinator.
- Patient flow should be monitored to avoid drawing up unnecessary doses.
- Vaccinators should administer whichever doses they have pre-drawn.

- At end of workday, any remaining vaccine in pre-drawn syringes should be discarded.

## Vaccine Preparation Dos and Don'ts

### DO:

- Use new needles/syringes for each injection
- Base needle size on route, technique & patient
- Check expiration dates on all products
- Check vaccine for damage or contamination
- Always sterilize rubber vial stopper before withdrawing a dose
- Mix reconstituted vaccine by agitating vial
- Use single-dose vials and prefilled syringes for single-dose administration
- Draw up vaccine only when ready to administer
- Administer dose as soon as possible after filling

### DON'T:

- Reuse syringes/needles
- Use expired, damaged, discolored, or contaminated vaccine
- Use sterile water or saline for reconstitution.
- Use reconstituted vaccine if any precipitate
- Combine different vaccines
- Transfer vaccine between syringes
- Combine partial doses
- Pre-draw vaccine
- Use vaccine drawn up by someone else



Now we will summarize some of the dos and don'ts of vaccine preparation.

- Use a separate needle and syringe for each vaccine injection. Base needle selection on the prescribed route of the vaccine, the size of the individual and the injection technique being used.
- DON'T reuse syringes or needles.
- Check the expiration dates on needles and syringes as some are packaged with an expiration date.
- Inspect vaccine and diluent vials for damage or contamination and always check expiration and beyond use dates.
- The cap on top of a vaccine vial functions as a dust cover. Once removed, clean the exposed rubber stopper with a pre-packaged sterile alcohol wipe.
- Never administer expired, damaged, discolored or contaminated vaccine or diluent.
- If reconstitution is needed, do not use sterile water or saline, use the manufacturer supplied diluent.
- Agitate the vial to mix the reconstituted vaccine thoroughly and obtain a uniform suspension prior to withdrawing each dose.
- Inspect the vaccine visually for discoloration, precipitation or if it cannot be re-suspended prior to administration. If problems are noted (e.g., discoloration or cloudiness), do not administer the vaccine.
- Use single-dose vials and manufacturer-filled syringes appropriately, as single-dose administration. Discard single-dose vials with dust covers removed and/or activated

- manufacturer filled syringes at the end of the workday.
- DON'T combine multiple vaccines into one syringe. Vaccines should never be combined in a single syringe except when specifically approved by the Federal Drug Administration or FDA and packaged for that specific purpose. Most combination vaccines will be combined by the manufacturer.
  - DON'T transfer vaccine from one syringe to another.
  - Partial doses from separate vials should not be combined to obtain a full dose. Both of these practices increase the risk of contamination.
  - The Centers for Disease Control and Prevention (CDC) recommends that providers draw up vaccines only at the time of administration and administer doses as soon as possible after filling.
  - DON'T administer a vaccine that someone else has prepared and drawn up. If vaccine is drawn up by one person and administered by a different person, the person administering vaccine cannot be sure about what is in the syringe and its sterility.

## Resources

### **Centers for Disease Control and Prevention (CDC)**

*Vaccine Administration, Epidemiology and Prevention of Vaccine-Preventable Diseases*

*The Pink Book: Course Textbook – 13<sup>th</sup> Edition (2015)*

<http://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html>

*Vaccine Storage and Handling Toolkit*

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

*Vaccine Storage Labels*

<http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf>

### **The Joint Commission**

*Standards FAQ – Multi-dose Vials – Vaccine 28 day rule*

[https://www.jointcommission.org/standards\\_information/jcfaqdetails.aspx?StandardsFAQId=1079&StandardsFAQChapterId=10&ProgramId=0&ChapterId=0&IsFeatured=False&IsNew=False&Keyword=](https://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQId=1079&StandardsFAQChapterId=10&ProgramId=0&ChapterId=0&IsFeatured=False&IsNew=False&Keyword=)

### **New York State Vaccines for Children (VFC) Program**

*Monitoring Expiration Dates Handout*

[http://www.health.ny.gov/prevention/immunization/vaccines\\_for\\_children/docs/monitoring\\_expiration\\_dates.pdf](http://www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/monitoring_expiration_dates.pdf)

### **Immunization Action Coalition (IAC)**

*Vaccines with Diluents, How to Use Them*

<http://www.immunize.org/catg.d/p3040.pdf>

*Web-based Education and Resources on Administering Vaccine*

<http://www.immunize.org/clinic/administering-vaccines.asp>

### **California VFC Program, EZIZ**

*Preparing Vaccines*

<http://eziz.org/resources/vaccine-admin-job-aids/>



Here is a listing of available resources.

## Additional Training for NYS VFC Providers

**Next: NYS VFC Program Training Series #17: Vaccine Transport**



There are a number of additional trainings available.

The next and final training in this series is #17, Vaccine Transport.