

Vaccine Storage and Handling Toolkit

National Center for Immunization and Respiratory Diseases

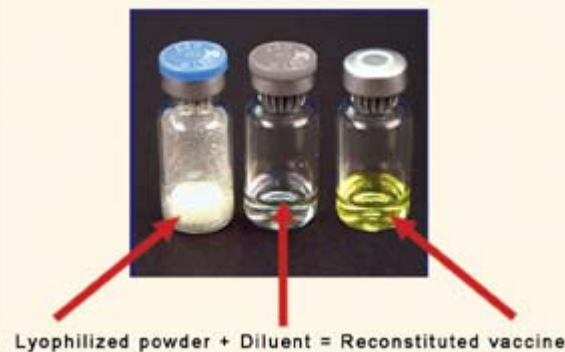
Vaccine Preparation and Disposal

Preparation for Vaccine Administration

Reconstitution

Definitions

Vaccines that come as lyophilized (freeze-dried) powders must be mixed with a liquid (called a diluent) in a process known as "reconstitution" before they can be administered.



Diluents

Diluents vary in their volume. The volume of diluent provided depends on whether a single-dose or multidose vial of vaccine is to be reconstituted. Diluents also vary in their ingredients. Some consist of sterile water only, but others may contain a variety of other substances that can be used to dissolve the lyophilized vaccine into a liquid, stabilize the reconstituted vaccine,

Use only the specific diluent provided by the manufacturer for each type of vaccine to ensure adequate potency and safety of the resulting mixture.

and/or maintain the sterility of the reconstituted vaccine. Diluents are specifically designed to meet the volume, pH (acid/alkaline balance), and chemical needs of each vaccine so that optimal immune responses can be achieved. Diluents are **not interchangeable**,

unless specified by the manufacturer (e.g., the diluent for MMR, MMRV, varicella, and zoster vaccine). Therefore, use only the specific diluent provided by the manufacturer for each type of vaccine to ensure adequate potency and safety of the resulting mixture. Do not use diluents from other manufacturers.

Instructions for Reconstitution

Refer to the package inserts for instructions on reconstituting specific vaccines.

In general, certain steps should be followed when reconstituting vaccines:

1. Reconstitute vaccine immediately prior to use.
2. Do not allow vaccines to sit out and warm up during the reconstitution process. Limit the time live virus vaccines are exposed to light.
3. Check the diluent label to be sure that the vial contains the correct diluent provided by the manufacturer for that specific vaccine.
4. Check the diluent label to be sure that the vial contains the correct volume of diluent for reconstitution so that the proper number of doses per vaccine vial is obtained.
5. Check the labels on both the diluent vial and the lyophilized (freeze-dried) vaccine vial to make sure they have not expired. Do not administer expired vaccine (see [Expiration Dates](#) in the Vaccine Inventory Management section for details). Do not use expired diluent.
6. Remove the protective caps from the diluent and lyophilized vaccine vials and wipe the stoppers with an alcohol swab.
7. Select a disposable syringe and a needle of the proper length for the vaccine and route of administration. For single-dose reconstituted vials, the needle used for drawing up the diluent is the same needle you will use for vaccine administration. There is no need to change the needle in this case. Only change the needle if it has been damaged or contaminated during the reconstitution and drawing up process. For multidose reconstituted vials, do not use the same needle and syringe to administer multiple vaccine doses. Use a new needle and syringe for each dose of reconstituted vaccine administered.
8. Insert the needle into the diluent vial and withdraw the entire contents.
9. Inject all the diluent into the lyophilized vaccine vial and agitate or rotate the vial to ensure thorough mixing (follow the specific instructions given in the package inserts).
10. Observe the reconstituted vaccine for color and appearance and verify that the appearance matches the description in the package insert. If the lyophilized vaccine cannot be resuspended or if the reconstituted vaccine does not look as it should (e.g., discoloration, extraneous particulate matter), mark the vial as "DO NOT USE" and return it to proper storage conditions. Contact the vaccine manufacturer and the state health department immunization program for further guidance (see [Handling Inappropriate Vaccine Storage Conditions \[Light and Temperature\]](#) in the Storage Troubleshooting section for details). Get another diluent vial and another lyophilized vaccine vial and begin the reconstitution process again.
11. For multidose vials, record the date and time of reconstitution on the vaccine vial. For single-dose vials, record the date and time of reconstitution on the vaccine vial if it is not administered immediately after reconstitution.
12. For single-dose vials, withdraw the entire contents of the reconstituted vaccine into the syringe. For multidose vials, withdraw the appropriate volume of vaccine into the syringe. Recheck the vial contents, expiration date, and doctor's order before administering the vaccine.
13. Administer the vaccine soon after reconstitution to minimize loss of potency. The expiration date and time after reconstitution varies by vaccine. See [Expiration of Reconstituted Vaccine](#) in this section for details.

14. After giving the injection to the patient, do not recap the needle. Discard the used needle and syringe using medical waste disposal procedures (see [Disposal of Vaccine and Diluent](#) in this section for details).

Expiration of Reconstituted Vaccine

Once lyophilized (freeze-dried) vaccines have been reconstituted, their shelf lives are limited and they must be stored under appropriate temperature and light conditions.

Reconstituted vaccine must be used within a specified time or else be discarded.

Reconstituted vaccine must be used within a specified time or else be discarded. Contact the vaccine supplier, which may be the vaccine manufacturer or the state health

department immunization program, for specific policies regarding the disposition of expired vaccine. If the expired vaccine is publicly purchased vaccine, contact your state health department immunization program for instructions on returning expired vaccine for excise tax credit.

The life of each reconstituted vaccine varies from product to product. Consult the product package insert for the most up-to-date information about expiration dates and times following reconstitution. Unused reconstituted vaccines kept beyond these limits should **not** be administered. The best way to avoid such waste is to reconstitute and draw up vaccines immediately before administration.

Shelf Lives of Reconstituted Vaccines

Vaccine	Expiration After Reconstitution
Varicella vaccine	30 minutes (protect from light)
TriHIBit [®] vaccine (DTaP/Hib)	30 minutes
Menomune [®] (single-dose vials)	30 minutes
MMRV vaccine	30 minutes (protect from light)
Zoster vaccine	30 minutes (protect from light)
MMR vaccine	8 hours (protect from light)
ActHIB [®] vaccine (Hib)	24 hours
Menomune [®] (multidose vials)	35 days

Dating Vaccine

Mark each opened multidose vial with the **date** it was first opened. Mark reconstituted vaccine with the **date and time** it was reconstituted. Dating these vials is important for two reasons. First, some vaccines expire within a certain time after opening or after reconstitution. This may not correspond to the expiration date printed on the vial by the manufacturer. For example, multidose vials of meningococcal vaccine should be discarded if not used within 35 days after reconstitution, even if the expiration date printed on the vial by the manufacturer has not passed. Second, dating opened or reconstituted vials helps manage vaccine inventory by identifying vials that should be used first.



Mark each opened multidose vial with the date it was first opened.
 Mark each reconstituted vaccine with the date and time it was reconstituted.

Whenever possible, use all the vaccine in one multidose vial before opening another vial. Similarly, use all the reconstituted vaccine in one vial before reconstituting another vial. This policy helps to reduce vaccine waste.

Use of Multidose Vials Versus Single-Dose Vials

Multidose vaccine vials contain bacteriostatic agents that prevent the growth of bacteria. Once opened, they can be used until their dates of expiration, unless they become contaminated. All multidose vials must be stored under appropriate temperature and light conditions at all times before and after they have been opened. Single-dose vials are meant for one-time use only.

Once the protective caps have been removed from single-dose vials, it may not be possible to determine if the rubber seals have been punctured. Therefore, do not open single-dose vials until you are

Single-dose vials are meant for one-time use only.

ready to use them. To avoid needless wastage of vaccine, **always** check the vial before removing the cap to make sure you have the correct vaccine type, and remove the cap only when you are ready to draw up and administer the vaccine. Single-dose vials must be stored under appropriate temperature and light conditions at all times before and after they have been opened. Contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for specific policies regarding the disposition of opened unused single-dose vials. If these vials are publicly purchased vaccine, contact the state health department immunization program for instructions on returning opened unused single-dose vials for excise tax credit.

Prefilling Syringes

Recommendation

The National Center for Immunization and Respiratory Diseases (NCIRD) strongly recommends that providers draw vaccine only at the time of administration.

The National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention strongly recommends that providers draw vaccine only at the time of administration to ensure that the cold chain is maintained and that vaccine is not inappropriately exposed to light. **Do not** predraw doses before they are needed.

Problems Associated with Prefilling Syringes

NCIRD strongly discourages prefilling syringes and has identified the following problems associated with this practice:

- Once vaccine is inside the syringe, it is difficult to tell which vaccine is which; this may lead to **administration errors**.
- Prefilling syringes leads to **vaccine wastage** and increases the risk of vaccine **storage under inappropriate conditions**.
- Most syringes are designed for immediate administration and not for vaccine storage. **Bacterial contamination and growth** can occur in syringes you prefill with vaccines that do not contain bacteriostatic agents, such as the vaccines supplied in single-dose vials.
- No stability data are available for vaccines stored in plastic syringes. Vaccine components may interact with the plastic syringe components with time and thereby **reduce vaccine potency**.

- Finally, prefilling syringes is a violation of medication administration guidelines, which state that an individual should only administer medications he or she has prepared and drawn up. This is a **quality control and patient safety problem** because if you do not draw up the vaccine yourself you cannot be sure of the composition and sterility of the dose you are administering.



Prefilling syringes is generally discouraged.

Influenza Clinics and Prefilling Syringes

The vaccine manufacturers do not recommend that influenza vaccine be predrawn in advance of a large influenza vaccination clinic because there are no data on the stability of vaccine stored in syringes filled by providers. NCIRD also strongly discourages this practice for the reasons noted in the previous section.

Although predrawing vaccine is generally discouraged, **a limited amount** of vaccine may be predrawn in a mass immunization setting **if** the following procedures are followed:

- Only one vaccine type may be administered at the clinic. If more than one vaccine type is to be administered, separate vaccine administration stations must be set up for each vaccine type to prevent medication errors.
- Vaccine should not be drawn up in advance of arriving at the clinic site. Because of the lack of data on the stability of vaccine stored in plastic syringes, the practice of drawing up quantities of vaccine hours or even days before a clinic is **not acceptable**.
- Vaccine should be transported to the clinic site in the manufacturer-supplied packaging.
- Inactivated influenza vaccine must be maintained at 35° to 46°F (2° to 8°C), either inside a refrigerator or inside a properly chilled vaccine transport container. If the vaccine is stored in a transport container, an insulating barrier—such as crumpled paper or bubble wrap—must be placed between the vaccine and the refrigerated/frozen packs. An insulated barrier includes air pockets to help protect the vaccine from exposure to freezing temperatures. A single layer of towel over ice is not adequate protection (contact your state health department immunization program for details and see [Maintaining the Cold Chain During Transport](#) in the Resources section for general guidelines).
- Upon arrival at the clinic site, each healthcare worker (HCW) may draw up a **small**

quantity of vaccine to meet the initial needs of the clinic—no more than 1 vial or 10 doses, whichever is greater. This will limit the amount of time the vaccine is held in the syringe before administration and reduce vaccine wastage.

- During the clinic, HCWs should alternate activities. One may stop vaccinating and fill additional syringes as needed; when this HCW resumes vaccinating, the other HCW may stop and draw up additional vaccine as needed. This minimally slows the patient flow, limits the amount of vaccine drawn up at any one time, and conforms to good medication administration practices, in which each HCW administers the vaccine he or she drew up.
- Patient flow should be monitored to avoid drawing up unnecessary doses.
- At the end of the clinic day, any remaining vaccine in syringes should be discarded. Vaccine that has been drawn up and not administered may not be used on subsequent days.

Manufacturer-Supplied Prefilled Glass Syringes



Manufacturer-supplied prefilled glass syringes.

Manufacturer-filled glass syringes are available for a variety of vaccines. NCIRD does not have a preference for specific vaccine brands or product presentations; either vials or manufacturer-filled syringes (when available) are acceptable for use, depending on the preferences of your practice. Manufacturer-filled syringes are an alternative to prefilling syringes yourself. These syringes are prepared under sterile conditions that meet standards for proper handling and

storage, and they are individually labeled. They have been specially designed by the manufacturers and thoroughly tested to assure vaccine potency and sterility over prolonged storage times. As long as they are stored under appropriate conditions (temperature and light), they may be kept and used until their dates of expiration unless they become contaminated. When manufacturer-filled glass syringes are not supplied with needles, the needles should be attached just before administration. If a needle is attached to a sealed manufacturer prefilled syringe, the syringe should be used or discarded at the end of the clinic day because the sterile seal has been broken. This does not apply to prefilled syringes prepared by the manufacturer with the needle already attached.

Disposal of Vaccine and Diluent

Unused vaccine and diluent doses may be returnable under certain circumstances. Contact the vaccine supplier, which may be the vaccine manufacturer or the state immunization program, for specific policies regarding the disposition of unopened vials, expired vials,

Contact the state health department for details about medical waste disposal procedures in your area.

unused doses, doses drawn but not administered, and potentially compromised vaccine due to inappropriate storage conditions. If these vials or doses are publicly purchased, contact the state health department immunization program for instructions on returning doses for excise tax credit.

The state health department immunization program and the manufacturer may advise you to discard the vials or syringes. This should be done using medical waste disposal

procedures. Contact the state health department for details about medical waste disposal procedures in your area. In general, vaccine and diluent vials, used needles, and used syringes (that may or may not contain vaccine) may be dropped into a sharps container and autoclaved, or disposed of following the procedures for all other biohazard materials. In places where medical waste is buried, soaking the medical waste in a 1:10 dilution of bleach for at least 10 minutes before disposal is advised.



Sharps container.

Centers for Disease Control and Prevention

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