

Module

Reconstituting Vaccines Safely

3

Reconstitution affects both the safety and the effectiveness of vaccines. This module reviews the procedures involved in the safe reconstitution of vaccines.

Objectives:

After completing this module, participants will be able to:

- explain the importance of using the specific diluent when reconstituting vaccines;
- describe the safe procedures for reconstituting vaccines;
- describe major safety concerns related to reconstituted vaccines.

Time:

1 hour

Key topics:

- Discarding reconstituted vaccine after 6 hours
- Using the correct diluent with each vaccine

Trainer's aids:

- Practical Exercise (page 38)
- VVM Cards (pages 39-42)
- Small poster of reconstituted vaccine vial (page 43)
- Quiz (pages 45-47)

Trainer preparation:

- Review lecture notes.
- Photocopy the “Freeze-dried Vaccines” poster (page 43) and place on the wall during session.
- Prepare the VVM Cards (pages 39-42) for use in Practical Exercise (page 38).

Reconstituting Vaccines Safely

Correct reconstitution of vaccines is critical to safe injection practices. Safe and effective use of reconstituted vaccines requires storage of vaccines and diluents at appropriate temperatures, mixing of vaccines only with specific diluents, the ability to identify contaminated vaccines, and the knowledge of when to discard vaccines. Review these issues in Module 3 carefully, because incorrect use of reconstituted vaccines can be fatal.

Reconstituting Vaccines Correctly

Errors in reconstituting vaccines commonly occur when:

- vial labels are missing, making correct identification of the vial impossible;
- health workers believe that diluents are interchangeable;
- diluents for different vaccines are mixed together in the refrigerator; and
- medication is stored in the same refrigerator where a busy health worker can mistakenly choose the wrong vial.

These errors are dangerous and must be avoided.

Use ONLY diluent recommended by the manufacturer to reconstitute vaccine.

It is important to reconstitute vaccine using only the diluent provided by the manufacturer for each specific vaccine. Diluents are not interchangeable.

Using the wrong diluent, substituting normal saline, or using sterile water makes the vaccine ineffective and less able to provide protection against disease. Deaths have resulted when vaccines were incorrectly mixed with medications other than diluents specifically approved for use with specific vaccines by the manufacturer.

Even if the diluent's main ingredient is sterile normal saline or water, other vials of sterile normal saline or water can never serve as substitutes: use the diluent provided by the manufacturer for the specific vaccine.

Vaccines Need Specific Diluents

A partial list of vaccines that need specific diluents includes:

- BCG vaccines
- Measles-containing vaccines
- Freeze-dried *Haemophilus influenza* type b (Hib) vaccines
- Yellow fever vaccines

Trainer's Note

- Show poster (page 43).

Reconstituted vaccines should be kept cool, and away from sunlight.

Keeping reconstituted vaccines **between 2° to 8°C** helps to maintain their potency. Place them in slits made in a foam piece that sits in the top of the vaccine carrier. This also keeps the vial out of direct sunlight.

Discard reconstituted vaccines after 6 hours.

BCG vaccines, measles-containing vaccines, yellow fever vaccines, and freeze-dried Hib vaccines do not have preservatives that limit the growth of microorganisms. As a result, microorganisms that enter the vial during reconstitution can multiply rapidly. **Reconstituted vaccines must be discarded 6 hours after reconstitution.** Deaths have resulted when children received injections of reconstituted vaccines that were not discarded after 6 hours.

If possible, store only vaccines in the refrigerator with other vaccines.

Vaccines accidentally reconstituted with other medications such as insulin or anesthetics have resulted in deaths. It is safer to keep vaccines and diluents separate from other medication vials to avoid confusion and mistakes.

Do not reconstitute vaccine until the person needing the vaccine injection is present.

Remember that reconstituted vaccines are sensitive, must be kept cool after reconstitution, and must be discarded after 6 hours. For these reasons, the vaccine should not be reconstituted until the person needing the immunization is present.

Use a new syringe and needle to reconstitute each vial of vaccine. After mixing the diluent and vaccine, discard the syringe and needle.

Follow the steps below to safely reconstitute vaccines:

1. Read the label on the diluent to be sure that it is the diluent provided by the manufacturer for that specific vaccine and vial size.
2. Check to make sure the expiry date has not passed.
3. Cool the diluent to 2-8°C prior to use to avoid heating the vaccine.
4. Draw the entire contents of the diluent vial into the mixing syringe.
5. Empty the entire contents of diluent into the vaccine vial.
6. Discard the used mixing syringe and needle.
7. Do not leave the mixing needle in the vial; this is a common mistake that leaves the vial open to contamination.
8. Roll the vial between your fingers to mix the contents until all of the vaccine powder has dissolved. If necessary, note the date and time the vial was mixed.
9. Keep the reconstituted vaccine cool by placing the vaccine inside slits cut in the top of a foam pad that has been cut to fit a vaccine carrier. WHO recommends this technique to keep vaccine cold and protected from sunlight. Other techniques for keeping the vaccine cold—such as placing the vial inside a cup of ice—can damage or remove the vaccine vial label.
10. **Discard all reconstituted vaccine 6 hours after reconstitution.**
11. Withdraw the vaccine from the vial using the same needle and syringe that will be used to inject the vaccine.

Trainer's Note

- Review Key Points of Module 3.
- Conduct Practical Exercise: “Selecting Vaccines from the Vaccine Carrier” (page 38).
- Conduct Quiz (pages 45-47).

Key Points

- Using the wrong diluent or another medication to reconstitute a vaccine can make the vaccine ineffective or dangerous.
- Use ONLY the diluent approved by the manufacturer to reconstitute the specific type of freeze-dried vaccine.
- Do not reconstitute the vaccine until the person needing a particular vaccine is present.
- Discard reconstituted vaccines within 6 hours of reconstitution.
- Use a sterile syringe and needle to mix each vial of freeze-dried vaccine.
- Do not leave a needle in the top of the vial.
- Use the same syringe and needle to draw up the dose and to inject.

Practical Exercise

Selecting Vaccines from the Vaccine Carrier

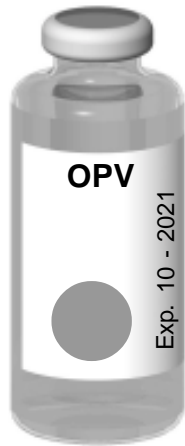
1. Show the participants the VVM cards on pages 39-42.
2. Read the following scenario to the participants: “Assume you are an immunizer taking vials out of a vaccine carrier at the beginning of a campaign. The vials were taken from the refrigerator and placed in the vaccine carrier an hour earlier. Assume reconstituted vaccines were mixed the day before. Assume no vials have been opened today.”
3. Ask the participants to identify the vials they would USE, and the vials they would NOT USE. Participants should explain why they would not use the vials.
4. Offer the participants the following hints:

The vial is not usable if it:

- has expired or has no label;
 - **is contaminated** (for example, if there are leaks or cracks in the vial; **OR** there is a change in appearance or floating particles; **OR** the top of the opened vial has been submerged in water; **OR** the top of the vial is pierced with a used needle or a sterile needle on a used syringe; **OR** reconstituted vaccine has been opened for more than 6 hours after reconstitution);
 - was exposed to excessive heat, as indicated by the VVM.
5. The answers are printed on the back of each illustration. Review the correct answers with the group.

VVM Cards

Unopened



1



2

Opened



3

Unopened



4


Answer:
DISCARD

Because:

- No label on vial.

2

Unopened Vial of OPV




Answer:
DISCARD

Because:

- The VVM has reached the discard point.

1

Unopened Vial of OPV



Answer:
DISCARD

Because:

- The VVM is beyond the discard point.

4

Opened Vial of Vaccine Diluent

Answer:
DISCARD

Because:

- The entire volume of the diluent vial should have been mixed to ensure correct vaccine concentration. Diluents usually do not contain preservatives and should be mixed immediately upon opening.

3

VVM Cards

Reconstituted



5

Unopened



6

Unopened



7

Unopened



8

Unopened Vial of Measles Vaccine

Answer:
USE

6

Reconstituted Vial of Measles Vaccine

Answer:
DISCARD

Because:

- Reconstituted vaccines should be used as soon as possible after mixing and discarded within 6 hours.

5

Unopened Vial of Yellow Fever Vaccine

Answer:
USE

8

Unopened Vial of Measles Vaccine

Answer:
DISCARD

Because:

- The VVM is beyond the discard point.

7

DANGER

BCG, Measles, Yellow Fever,
and freeze-dried Hib Vaccine



Must be discarded 6 hours
after reconstitution

Adapted from poster CCPS/21, (4031) Freeze-dried Vaccine, World Health Organization (WHO)

Notes:

Quiz

Quiz Questions

1. What are some common mistakes that lead health workers to use the wrong diluent to reconstitute vaccines?
2. Why is it important to reconstitute vaccine using the diluent prepared by the manufacturer for their specific vaccine?
3. When should reconstituted vaccines be discarded?
4. Name the vaccines that must be discarded within 6 hours of reconstitution.
 - A. BCG vaccines
 - B. Freeze-dried Hib vaccines
 - C. Yellow fever vaccines
 - D. Measles-containing vaccines
 - E. All of the above
5. What may happen if reconstituted vaccines are stored longer than 6 hours after reconstitution?
6. What are some major safety concerns related to reconstituted vaccines?

Trainer's Note

Use this oral quiz to stimulate classroom discussion. After the discussion for each question, repeat the correct answer. At the end of the quiz, review this module's Key Points again.

Quiz Answers

1. What are some common mistakes that lead health workers to use the wrong diluent to reconstitute vaccines?

- *Saving vials with missing labels, making correct identification of vial contents impossible.*
- *Storing diluents for different vaccines mixed together in the refrigerator.*
- *Believing that diluents are interchangeable.*
- *Storing other medications in the refrigerator where a busy health worker can mistakenly choose them.*

2. Why is it important to reconstitute vaccine using the diluent prepared by the manufacturer for their specific vaccine?

Manufacturers specifically prepare and test each vaccine diluent for the particular formulation of each vaccine. Using other substances may make the vaccine ineffective and thus, may provide less protection against disease.

3. When should reconstituted vaccines be discarded?

WHO recommends that reconstituted BCG vaccines, measles-containing vaccines, yellow fever vaccines, and freeze-dried Hib vaccines be discarded within 6 hours of reconstitution.

4. Name the vaccines that must be discarded within 6 hours of reconstitution.

E. *All of the above*

5. What may happen if reconstituted vaccines are stored longer than 6 hours after reconstitution?

Because freeze-dried vaccines do not have preservatives that limit the growth of microorganisms, microorganisms that enter the vial during reconstitution can multiply. Reconstituted vaccine saved longer than 6 hours after mixing may have high numbers of bacteria so must be considered contaminated and discarded immediately. Deaths have resulted from toxic shock when children received injections of reconstituted vaccines that had been mixed for longer than 6 hours.

6. What are some major safety concerns related to reconstituted vaccines?

- *Reconstituted vaccines should be used within 6 hours of reconstitution. After 6 hours, discard them.*
- *Vaccines accidentally reconstituted using insulin and anesthetics stored in the same refrigerator have resulted in death.*
- *Using a diluent intended for another vaccine or medication to reconstitute vaccine will probably render the vaccine ineffective. When reconstituting vaccines, use **ONLY** the diluent recommended by the manufacturer for that particular vaccine.*
- *Reconstituted vaccines should be kept cool (stored between 2° to 8°C) once reconstituted. This helps maintain the efficacy of the vaccine and helps slow the growth of organisms inside the vial.*

Notes: