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Vaccine reconstitution and administration

Vaccines are produced in two different forms: as a liquid, which is ready to administer, or as a freeze-dried powder that must be mixed with a liquid – a process known as 'reconstitution' – before it can be used. Reconstitution of freeze-dried vaccine must be carried out using a sterile syringe and needle for each vial of diluent. The process of reconstitution requires careful attention and use of the **correct diluent** for each type and batch of vaccine in order to ensure adequate potency, safety and sterility of the resulting mixture.

The reconstitution process

Reconstitution of freeze-dried vaccine **must** be carried out using **only** the specific diluent provided by the manufacturer for each type and batch of vaccine. Diluents are specifically designed for the needs of each vaccine, and therefore, are **not interchangeable**. Diluents may appear to be simple water, but in fact usually contain a variety of chemicals and additives. These may include :

- stabilizers to improve heat stability of the vaccine;
- bactericides to maintain sterility after reconstitution;
- chemicals to assist in dissolving the vaccine into a liquid;
- buffers to ensure the correct acidic balance of the mixture.

Special attention should be paid when opening diluent ampoules and freeze-dried vaccine vials to avoid any loss of either the liquid diluent or the freeze-dried powder. Reconstitution should be carried out away from direct sunlight to protect the vaccine from exposure to harmful ultraviolet light. Although vaccines which are sensitive to light are usually supplied in dark brown glass vials, they must still be protected from exposure to sunlight during reconstitution and during subsequent use.

To reconstitute, draw the diluent into a sterile syringe and inject it into the vaccine vial. Use the **whole amount** of diluent provided for reconstitution to obtain the correct number of doses and the proper concentration of vaccine in the vial. Agitate the vial gently to ensure proper mixing of the liquid diluent and the dry powder, continuing this process until all powder has dissolved. After reconstitution, the vaccine vial should be kept in the foam pad of a vaccine carrier or wrapped in dark paper or foil and kept in the cold chain during use. The syringe and needle used for reconstitution should be immediately dropped into a safety box or a safe container without recapping. Do **not** leave the needle used for reconstitution in the rubber stopper of the vaccine vial. This would provide an open path for pathogens to enter the vial and thus expose the vaccine to serious risk of contamination.

A new sterile syringe and needle must be used to draw the necessary dose for each immunization injection. Remember, all reconstituted vials must be discarded at the end of the immunization session or within 6 hours, whichever occurs first. Do **not** keep such vials for use in subsequent sessions.

Unlike many multi-dose liquid vaccines, reconstituted vaccines do NOT contain a preservative, and thus become an ideal environment for growing dangerous organisms. This is why the maximum period for using a reconstituted vial is one immunization session, or within 6 hours, whichever occurs first. Remember also to avoid any risk of introducing contamination, the reconstituted vial should never be allowed to become wet or submerged in water. Therefore, if kept in a vaccine carrier during the immunization session, **always** insert the vial in a slit in the foam pad of the carrier, and do not allow it to come into contact with any water which may collect in the bottom of the vaccine carrier.

For freeze-dried vaccines, [Vaccine Vial Monitors](#) (VVM) are placed on a part of the vial that will be removed during the reconstitution process such as on the metal cap for a vial, or the neck of an ampoule. VVMs must be checked before reconstitution to ensure that the vaccine has not been exposed to excessive heat, but after reconstitution, the part where the VVM is located will have been

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removed. Therefore, VVMs cannot and should not be referred to after reconstitution, as they are no longer applicable.

Ten critical steps to reconstitute vaccines safely:

1. Read the label on the diluent to be sure that it is the correct diluent provided by the manufacturer for that specific vaccine and vial size.
2. Check the expiry date to make sure that it has not passed.
3. Check the status of the VVM to make sure that it is not at or beyond the discard point. Discard the VVM during reconstitution.
4. Cool the diluent to below +8°C, preferably a day prior to its use.
5. Draw the entire content of the diluent into a new sterile mixing syringe and empty the entire contents of the diluent into the vaccine vial.
6. Discard the used mixing syringe and needle into a safety box without recapping.
7. Do not leave the mixing needle in the vaccine vial.
8. After reconstitution, wrap the vaccine vial in dark paper or foil or insert in a foam pad of a vaccine carrier. **Never** allow the vial to become wet or immersed in water.
9. **Discard all reconstituted vaccine at the end of the session, or within 6 hours, whichever comes first.**
10. Use a new sterile syringe and needle to withdraw each dose of the vaccine and use the same needle and syringe for injecting the vaccine. After giving the injection, drop the used syringe and needle into the safety box without recapping.

Resource documents

[Proper handling and reconstitution of vaccines avoids programme errors. V&B update December 2000 \(ENG 320KB in pdf\)](#)

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