



NATIONAL IMMUNIZATION PROGRAM
MANUAL OF OPERATIONS

BOOKLET 5

CHAPTER 6
Injection Safety

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INJECTION SAFETY

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Injection Safety

A. Rationale

Clients deserve quality immunization services. An essential component is safety everytime vaccines are administered. Immunization safety reduces the risk of disease transmission by injection; reduces the risk of preventable adverse reactions and the impact of real vaccine reactions through proper case management; and, ensures the effectiveness of the immunization. By adhering to immunization safety standards and protocols, clients will be assured and satisfied and continue to trust, use and participate in immunization services from the health facility. These are expected to help increase immunization coverage in the catchment area.

B. Objectives

Chapter 6 covers the overall guidelines on how to ensure safety in every immunization provided. After reading this Chapter, it is hoped that we will be able to:

1. Describe the principles and guidelines to be observed for immunization safety;
2. Identify key support systems to be put in place to ensure safety; and
3. Outline the steps in managing and responding to AEFI cases.

C. Scope and Coverage

Chapter 6 discusses the following topics:

- Components of vaccine safety and quality: safe use of opened multi-dose vials of vaccine for subsequent immunization sessions;
- Guidelines on safe injections and proper disposal of vaccine wastes;
- Adverse events following immunization and how to establish and maintain a monitoring and reporting system for such events; and,
- Common questions related to immunization safety.

In summary, this Chapter is comprised of three major topics:



D. Setting Up An immunization Session

D.1 Safe Cold Chain Practices

Vaccines are sensitive to heat and freezing, so they must be kept at the correct temperature from the time they are manufactured until they are used in order to preserve their quality.

The system used for keeping and distributing vaccines in good condition is called the **cold chain**. This consists of a series of storage and transport links, all designed to keep vaccines within an acceptable temperature range until they reach the user. The cold chain is a system of transporting vaccines within the recommended temperature range: (+2 °C to +8 °C for refrigerator, -15 °C to – 25 °C for freezer).

A vaccine that has deteriorated due to unsafe cold-chain practices:

- Has reduced effectiveness in protecting against disease; and
- Can result in higher rates of local reactions

As program managers or health care providers, we should place high priority on maintaining the cold chain, including the equipment (refrigerators, freezers, cold boxes, backup generators) and cold rooms in the health facility. Cold chain technicians must receive proper training to manage this important component of the Immunization Program. Several indicators are available to detect if the vaccines have been frozen or have been exposed to heat. Procedures on the proper management of cold chain are discussed in the separate Cold Chain Management Manual.

D.2 Reconstitution and Proper Use of Diluent

1. Safe Use of Diluents

- 1.1. Careful stock control and accurate records are basic to monitor that the correct diluents are always kept and distributed with each vaccine type and batch. To avoid confusion during reconstitution, it is necessary to supply, transport and distribute diluents together with the vaccine types to which they correspond.
- 1.2. Only use diluents supplied and packaged by the manufacturer with the vaccine. Do NOT use diluents from other vaccines or from other manufacturers. Do NOT use sterile water for injection as vaccine diluents.
- 1.3. Clearly label and identify vaccines and diluents. Inside the refrigerator, group and mark properly the different vaccines with those expiring first in front. Cool the diluents between +2°C to +8°C, preferably a day prior to use. Do NOT freeze diluents.
- 1.4. Always read the label to make sure that it is the correct diluent provided by the manufacturer for that specific vaccine and vial size. If the label is missing or cannot be read, do NOT use the product.
- 1.5. Draw the entire contents of the diluent into a new sterile reconstitution syringe and empty the entire contents of the diluent into the vaccine vial. Reconstitute the vaccine to make sure the correct number of doses per vial is obtained.

- 1.6. After reconstitution, insert the vial in the foam pad of the vaccine carrier. NEVER immerse the vial in water.
- 1.7. Do not leave the reconstitution needle in the vial. This leaves the vial open to contamination. Discard without recapping the used reconstitution syringe and needle into a safety box.
- 1.8. Discard all reconstituted vaccine at the end of the session, or within six hours, whichever comes first.
- 1.9. Do not reconstitute vaccine until it is ready to be used. Handle diluents with the same care as vaccines. Review and practice the proper way to reconstitute each of the vaccines being used.

2. Safe Use of Opened Multi-Dose Vials of Vaccine in Subsequent Immunization Sessions

All opened WHO-prequalified multi-dose vials of vaccines should be discarded at the end of the immunization session, or within six hours of opening, whichever comes first, UNLESS the vaccine meets all four of the criteria listed below. If the vaccine meets the four criteria, the opened vial can be kept and used for up to 28 days after opening. The criteria are:

- 2.1. The vaccine is currently prequalified by WHO.
- 2.2. The vaccine is approved for use up to 28 days after opening, as determined by WHO.
- 2.3. The vaccine is not past its expiration date.
- 2.4. The vaccine vial has been, and will continue to be, stored at WHO at manufacturer-recommended temperatures. In addition, the vaccine vial monitor- if one is attached- is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.
 - a. It is good practice to write down the date of opening of vials to which the multi-dose vial policy applies. Also note which will be kept for use for subsequent sessions.
 - b. Other examples of vaccines to which the multi-dose vial policy applies are:
 - OPV / IPV
 - DPT, Hep B, PENTAVALENT
 - Td
 - Hep B (Monovalent)
 - c. Examples of vaccines to which multi-dose vial policy does not apply:
 - BCG vaccine
 - MR vaccine
 - MMR vaccine
 - JE vaccine

- d. For vaccines without VVM, excess unopened vaccines not used during an immunization session shall be marked with a check mark (✓) before storage to the refrigerator. The mark shall indicate that the vaccine vial was taken out from the refrigerator. This vial shall be for use first in the next immunization session.

Multi-Dose Vial Policy

1. Multi-dose vials of OPV, PENTA, Td and Hepatitis B from which one or more doses of vaccine have been removed during an immunization session, may be used in subsequent immunization sessions for up to a maximum of 28 days, provided that all the following conditions are met.
 - The expiry date has not passed.
 - The vaccines are stored under appropriate cold-chain conditions (+2°C to +8°C)
 - The vaccine vial septum has not been submerged in water.
 - Aseptic technique has been used to withdraw all doses.
 - The VVM, if attached, has not reached the discard point.
2. **Note:** The revised policy does not change the recommended procedures for handling vaccines that must be reconstituted. For example, for BCG and MMR vaccines: once a vial is reconstituted, it must be discarded at the end of each immunization session or at the end of six hours, whichever comes first.

3. Check if Vaccines are Safe to Use

Observe the following rules:

- 3.1. Check the vaccine and diluent labels. If the label is not attached, discard the vaccine or diluent.
- 3.2. Check the expiry date. If the item is expired, discard it.
- 3.3. Check the vaccine vial monitor (VVM). If it indicates that the vaccine has passed the discard point, discard it immediately.
- 3.4. If the temperature monitoring device indicates exposure to sub-zero temperatures, or if you suspect that a freeze-sensitive vaccine (PENTA, Td and Hep B vaccine) has been frozen, perform the shake test. For the detailed procedure, refer to the Cold Chain Manual.
- 3.5. For each vaccine used, health workers must know the following:
 - age of client at which each dose should be given;
 - number of doses required and minimum intervals between doses; and,
 - correct dosage

FIGURE 14.
How to Read the VVM

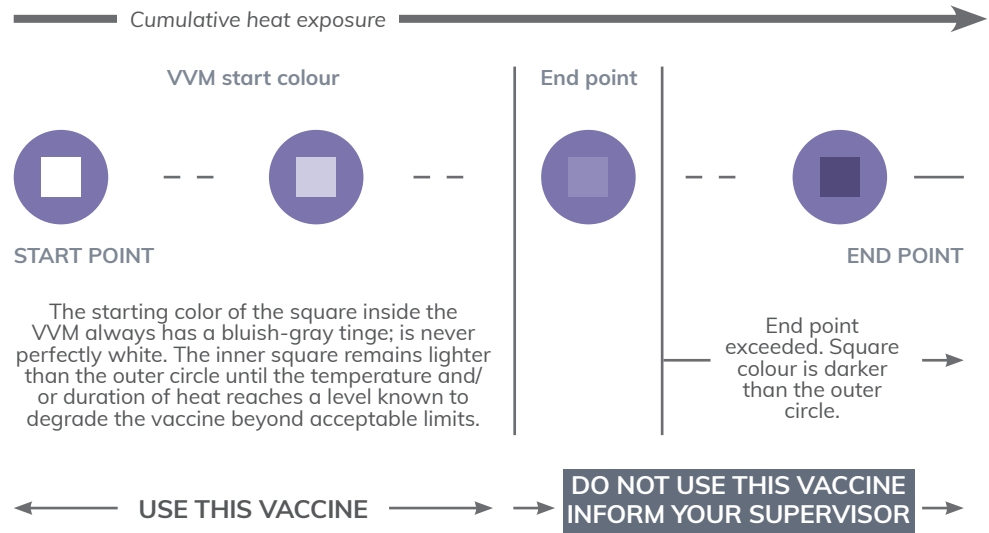


FIGURE 15.
How to Perform
Shake Test

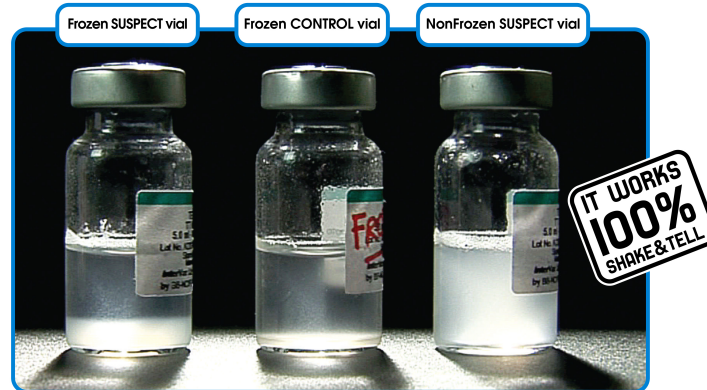
SHAKE TEST

Shake the vial vigorously for 10 seconds and place them on a flat surface

- 1 Select one vial from each type and batch of SUSPECT vaccine as CONTROL. Freeze the control vials until they are solid frozen and label them **FROZEN**.
- 2 Allow **FROZEN** control vials to thaw completely.
- 3 Shake **FROZEN** control and SUSPECT vials from the same batch in one hand for 10-15 seconds.
- 4 Observe **FROZEN** control and SUSPECT vials side-by-side to compare their sedimentation rates.

The SUSPECT vial sediments similar or faster than the FROZEN vial. This is a FAIL test. Vaccine must be discarded.

The SUSPECT vial sediments slower than the FROZEN vial. This is a PASS test. Vaccine can be used.



D.3 Safe Injections

Injection safety is the safe handling of all injection equipment; routine monitoring of the availability and use of safe injection equipment; and, correct disposal of contaminated injection equipment.

1. Observe Safe Injection Practices

Administer vaccines using safe injection practices and equipment. To avoid harm to both the client or recipient and the health worker, the following safe injection practices must be observed and carried out:

- 1.1. Inspect the packaging very carefully. Discard the needle or syringe if the package has been punctured, torn or damaged in any way.
- 1.2. Use a new sterile AD syringe and needle for every injection.
- 1.3. Use a new sterile syringe and needle each time a lyophilized or freeze-dried vaccine is reconstituted.
- 1.4. Do not touch any part of the needle. Discard any AD syringe that has touched any non-sterile surface (such as hands or other surfaces) before injection.
- 1.5. Prepare the injection materials on a clean, designated surface (table or tray), where blood and body fluid contamination is unlikely. Prepare each dose immediately before administering. Do NOT prepare several syringes in advance.
- 1.6. Never recap the AD syringe. Dispose of it immediately after use into the safety box.
- 1.7. Protect the fingers with a small gauze pad before opening glass ampules.
- 1.8. For multi-dose vials, always pierce the septum with a sterile needle. Never leave a needle stuck in the stopper of the vial.
- 1.9. In cleaning, use cotton balls wet with sterile water. There is no need to use alcohol.
- 1.10. Follow product-specific instructions for use, storage and handling of vaccines.
- 1.11. Hold the child firmly. Anticipate and prevent sudden movement during and after injecting the vaccine.

Important Things to Remember

Unsafe Injection can:

- harm the recipient
- expose the health worker to avoidable risk
- result in contaminated wastes that are a danger to the community

2. Select Safe Injection Equipment

2.1. Types of Injection Equipment

TABLE 12.
Different Equipment Used to Administer Injectable Vaccines

Equipment	Remarks
Auto-disable (AD) syringes	Equipment of choice
Prefilled AD injection devices	Available for some antigens only
Reusable syringes and needles	Not recommended
Single use disposable (non AD) syringes and needles	Use for mixing purposes only

Main Characteristics of AD syringes:

- Designed as self-locking syringes for single use
- Sterilized and sealed by the manufacturer
- Automatically rendered unusable after they delivering a full dose
- Available in 0.5 ml and 0.05 ml units and impossible to refill by drawing back the plunger forcibly or by applying back pressure to the needle of the syringe



2.2. Prevent needlestick injuries and infections

a. Minimize handling of needles and syringes

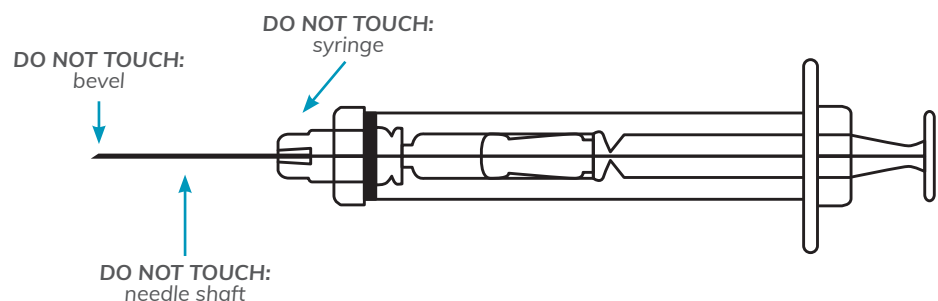
- Place a safety box close to the person doing vaccinations so used syringes and needles can be disposed of immediately.
- Avoid recapping the needle. If recapping is necessary (for example, if the injection is delayed because the child is agitated), use a single-handed scoop technique.
- Do NOT manually remove the used needle from the syringe.
- Do NOT carry used syringes and needles around the immunization area or work site.
- When ready to inject: draw up the vaccine, inject, and place the syringe in the safety box, Do NOT put the syringe down between steps.
- Seal securely and dispose of the safety box when it is three-quarters full.
- Do NOT manually sort needles and syringes.

b. Handle syringes and needles safely

Needlestick injuries may occur:

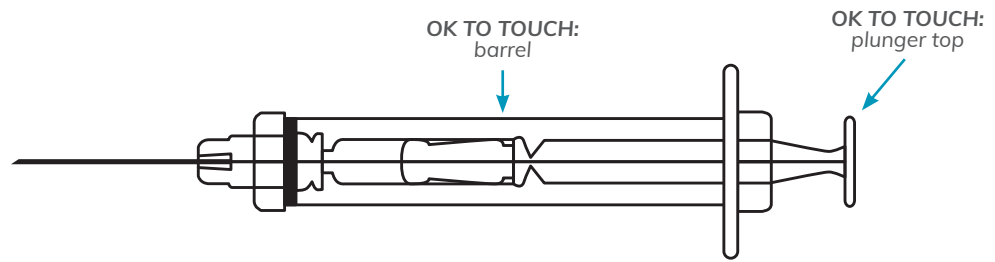
- When health workers recap needles or walk around while carrying used syringes and needles;
- If clients, especially children, are not positioned securely while being injected;
- If unsafe disposal procedures leave people or animals exposed to used syringes and needles.

FIGURE 16.
Parts of a Syringe and
Needle That Must Not Be
Touched



IMPORTANT: If you touch any of these parts, discard the syringe and needle and get new sterile ones.

FIGURE 17.
Parts of a Syringe and
Needle That May Be
Touched



You may touch the barrel and the plunger top.

c. Position children correctly for injections

Unexpected motion at the time of injection can lead to accidental needlestick injuries. To prevent this, position the child securely before giving the injection.

- Have the adult sit and place the child on her / his lap. Make sure one of the adult's arms is behind the child's back, and one of the child's arms wraps around the adult's side.
- The adult may tuck the child's legs between her/his own to secure them, or hold the child's legs. The adult should also hold the child's free arm.
- Health workers cannot hold the child because they need both hands for the injection.
- Even though the child is securely positioned, always warn the adult when you are giving the injection.

**For all patients- If
a needlestick injury
happens:**

- Reassure clients and carers.
- Consider referral to Infectious Disease out-patient clinic.
- If unavailable at time of discharge from department, follow-up hepatitis B serology. Arrange for booster vaccination if required.

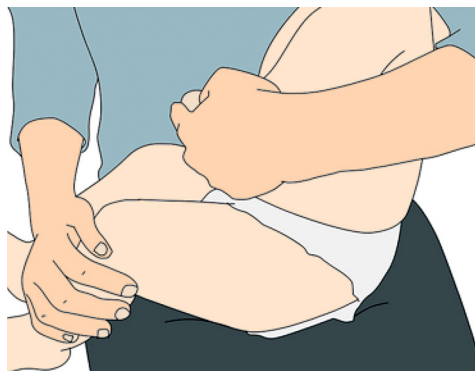
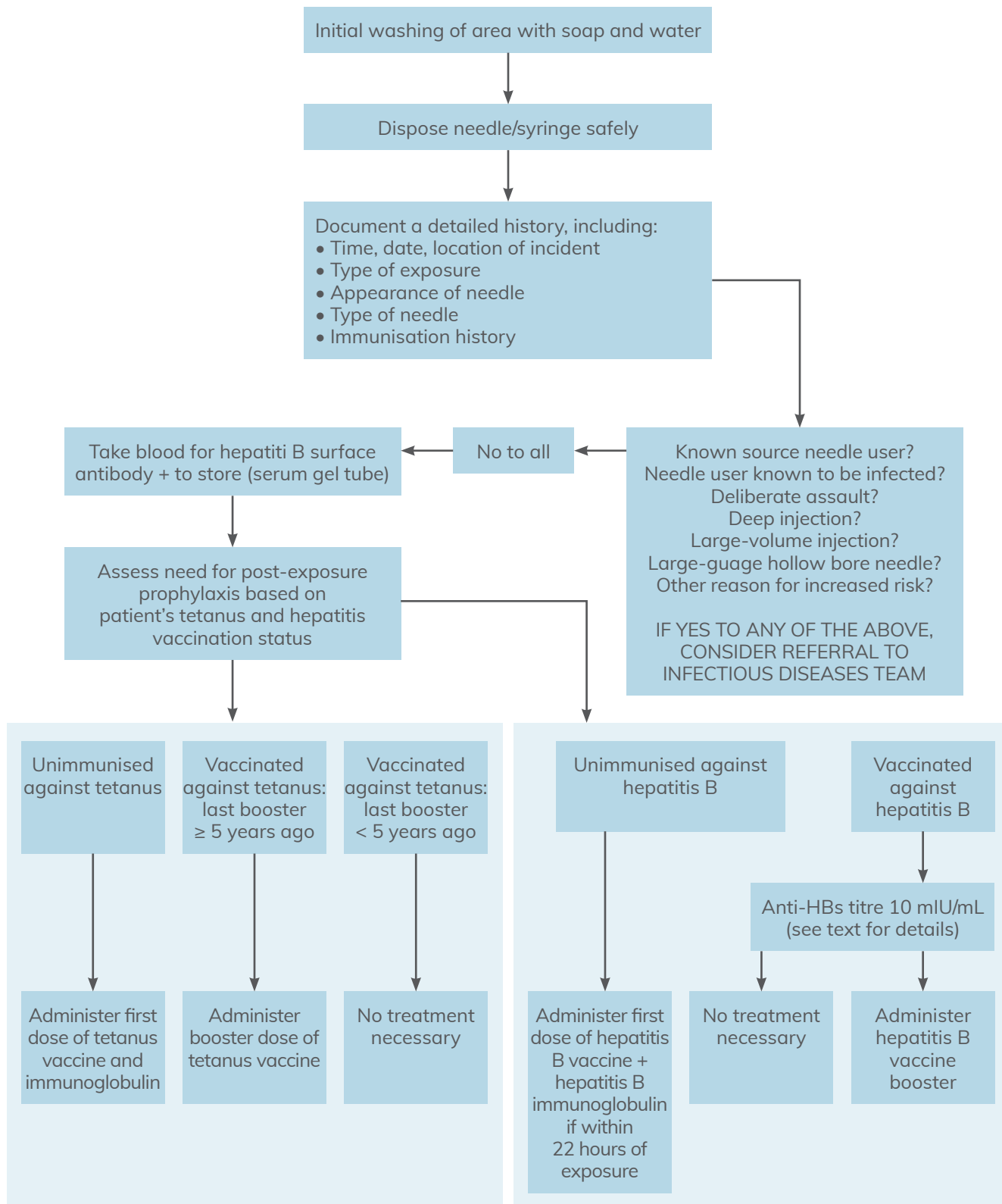


FIGURE 18.
Correct Position for Child Receiving injection

2.3. Management of Accidental Needlestick Injury

If accidental needlestick happens, the health worker should perform the following:

Needlestick Injury Protocol



Source: Clinical Practice Guidelines: Emergency Department Management of Community-Acquired Needlestick Injury

D.4 Dispose of Used Syringes and Needles

Sharps, specifically needles, are considered the most hazardous category of health care waste for health-care workers and the community at large if they are not properly handled and disposed of. These can cause serious health and environmental problems. Unsafe disposal can spread the very same diseases that we are working to prevent.

1. Use Safety Boxes

To prevent risk of infection of service providers and the community at large, safe disposal of used needles and syringes is a critical component of any immunization program. Injection equipment should be discarded immediately after use.

1.1. Proper Use of Safety Boxes

Without recapping, place needles and syringes in safety boxes immediately after administering vaccines

- a. Place all used injection equipment except reusable syringes and needles in a safety box immediately after use. These containers are waterproof and tamper-proof and needles cannot easily pierce them.
- b. Safety boxes require proper assembly before use. Different safety boxes are assembled in different ways. Appropriate instructions are printed on each box. Make sure there is a correctly assembled safety box in the area where injections will be given. How to assemble the safety box is shown below.

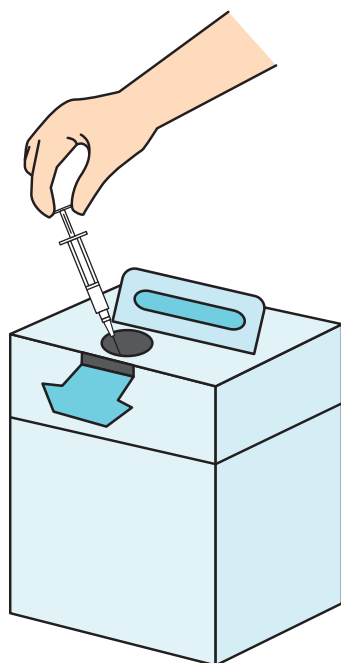


FIGURE 19.
Safety Box

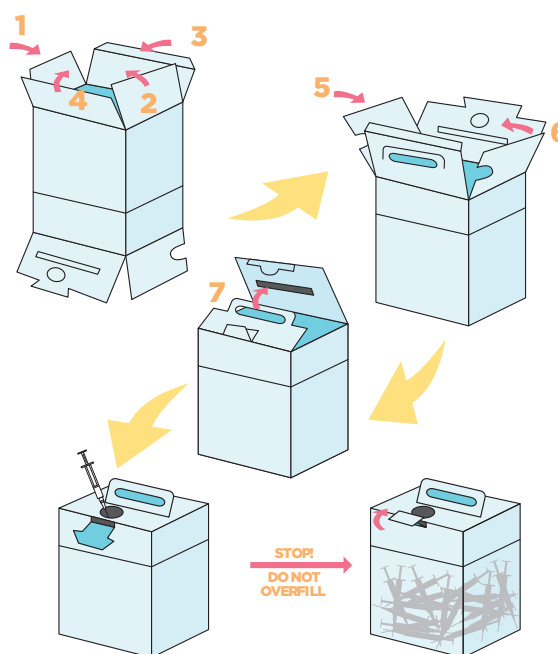


FIGURE 20.
Safety Box Assembly and Use

2. Dispose of sharps waste and injection equipment

- a. Destroy all injection equipment. Use auto-disable or disposable mixing syringes and needles once. Destroy them after use.
- b. NEVER dump used syringes and needles in open areas where people might step on them or children might find and play with them. Do NOT dispose of syringes and needles along with other kinds of waste.
- c. Place the safety box within reach of the health worker. After each injection, immediately place the syringe and needle in the safety box or sharps container.
- d. Do NOT recap the needle.
- e. If you are using needle removers or needle cutters, safely separate the used needle and syringe immediately after each injection.
 - After removing the needle with a device, immediately place the syringe in the safety box.
 - Place the needle in a separate safe container.
 - When the needle container is full, close it and dispose of it by burying it in a protected sharps pit.
- f. Following the immunization session or when the safety box is three-quarters full, close the container.
- g. Do NOT transfer used syringes and needles from safety boxes to other containers.
- h. A five litre safety box can hold about 100 syringes and needles. When these are already three quarters full, destroy them AS CLOSE AS POSSIBLE to the immunization session site, and AS SOON AFTER the session as is practical.
- i. Find a safe place to bury or burn the box.

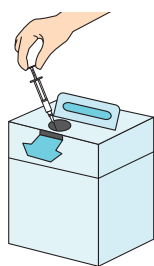
Caution

Never put the following materials in a safety box. Discard them with other medical waste:

- Empty vials;
- Discarded vaccine vials;
- Cotton pads;
- Compressors;
- Dressing material;
- IV bags or extension tubes;
- Latex gloves; or
- Any kind of plastic materials or waste products.

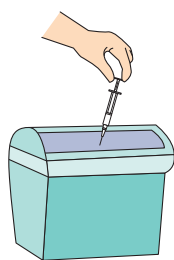
3. How to Handle and Dispose of Syringes and Needles that are not Separated

Collect syringes with needles attached and dispose of them in:



Standard safety boxes

These puncture-proof boxes are specifically designed to receive syringes with the needles attached. These should not be reused. Different safety boxes have different nominal capacities.



Puncture-resistant plastic safety boxes

These are more expensive and might be more difficult to find for small and medium health-care facilities in some areas. Capacity: 100 syringes. These should not be reused.



Locally available puncture-resistant cardboard boxes, plastic bottles

In cases of supply shortages of standard safety boxes in small health-care facilities, alternative solutions can be implemented, such as puncture- and leak-proof boxes, or thick plastic containers. These should be labelled as containing hazardous sharps waste. Open boxes, bleach bottles and thin plastic containers should NOT be used.

4. Dispose of the filled safety boxes

Three methods are commonly used to destroy filled safety boxes or to keep them away from people. Any selected method of waste disposal must comply with national and subnational environmental regulations and with specific Department of Health instructions for your health center.

4.1. Encapsulation

A specially made safety pit is an option to dispose of loose used syringes and needles. A safety pit is usually two meters deep and one meter in diameter so that it can be lined with a locally made concrete pipe. The pit has a concrete lid with a capped metal pipe set in it. Used syringes and needles are dropped through the metal pipe and into the pit.

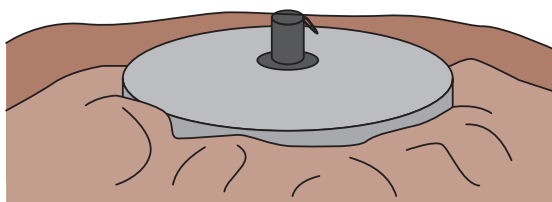


FIGURE 21a.
Safety Pit

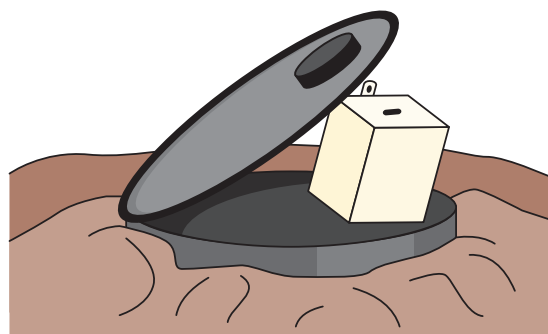


FIGURE 21b.
Safety Pit Using Oil Drum

4.2. Burial in a disposal pit

Used injection equipment may also be buried in a disposal pit. Choose the site carefully and dig a pit large and deep enough for bulky boxes. If contaminated AD syringes are somehow removed from the box and are carried into streams or fields, people may step on them or children may play with them.

- a. Choose a site where people will not dig or build latrines in the future.
- b. Fence off and clear the area.
- c. Dig the pit at least two meters deep. Make sure that the material will be removed from the pit, for example, during the rainy season.
- d. Take the filled safety boxes to the pit site just before burying. Do not open or empty the boxes.
- e. Place the filled safety boxes in the pit.
- f. Cover the boxes with at least 30 cm (at least 12 inches) of soil. If possible, cover the site with concrete when the pit is full.
- g. Make sure a qualified and trained staff member supervises the process. Do NOT leave this vital task to untrained people.

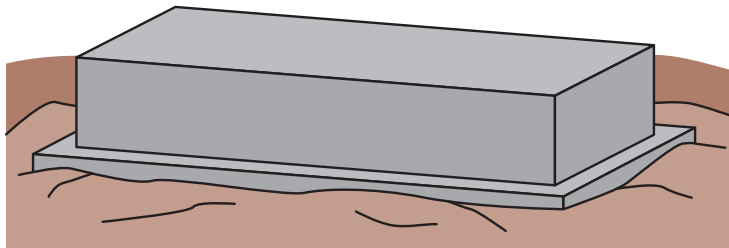


FIGURE 22.
Disposal Pit

4.3. Puncture-proof box management

On-site burial is an option for small facilities that cannot transport medical waste to a centralized facility).

Safety boxes may be buried on premises in a controlled manner. The pit should be fenced to restrict access. In unstable soils, the sides of the pit should be lined with brick or concrete to prevent collapse. A 10-15 cm (four to six inches) layer of earth should be placed on each layer of waste, and the pit should be filled with soil or concrete when the contents reach 50 cm (20 inches) of the surface of the hole. Once closed, the site should be marked to prevent any future digging. Open dumping of boxed or bagged waste should be PROHIBITED.

5. Supervise and Monitor the Disposal

As managers or health providers, we are responsible for implementation of safe injection procedures and waste-disposal policies to ensure no one is exposed to the risk of blood-borne diseases caused by unsafe injections and incorrect disposal of injection equipment.

As managers during supervisory visits, we must:

Ensure that national guidelines and standard operating procedures (SOP) for injection safety, infection control and waste disposal are practiced in all health facilities;

As health workers, we are:

Required to provide our supervisors with evidence of carrying out the procedures required by national policies and guidelines.

Good Practices on Waste Management

- Waste MUST be segregated into infectious and non-infectious waste.
- All syringes or needles are collected into puncture-and-leak-proof containers (color coded or bearing a biohazards sign / symbol). Alternatively, needles are removed immediately by means of a needle remover and disposed of onsite.
- Non-sharp infectious wastes are collected in bags (color coded, or bearing a biohazards sign / symbol).
- Infectious waste bags and sharp containers are stored in a secure place prior to transport for treatment / disposal.
- Personal Protective Equipment (PPE) and facilities for hand washing must be available and used for all persons handling waste.
- There must be regular supervision and correction of problems.

E. Adverse Events Following Immunization (AEFI) Surveillance

An adverse event following immunization (AEFI) is defined as a medical event or incident that takes place after an immunization, but is not necessarily caused by immunization. AEFI surveillance includes:

- Detecting, monitoring and responding to adverse events following immunization (AEFI)
- Taking appropriate and immediate action to address safety issues detected through the AEFI surveillance system to lessen the negative impact on the health of individuals and the reputation of the immunization program.

1. Types of AEFI

An effective immunization safety surveillance system is able to detect and differentiate between various types of AEFI to prevent their occurrence or reduce their impact.

TABLE 13.
Five Types of AEFI

Types of AEFI	Description
1. Vaccine product-related reaction	Caused or triggered by a one or more inherent properties of the vaccine
2. Vaccine quality defect-related reaction/devices	Caused or triggered by one or more quality defects of the vaccine, including its administration device as provided by the manufacturer.
3. Immunization error-related reaction	Caused by inappropriate vaccine handling, prescribing or administration; by its nature preventable.
4. Immunization anxiety-related reaction	Arising from anxiety about the immunization.
5. Coincidental event	Caused by something other than the vaccine, immunization error or immunization anxiety.

2. AEFI Investigation

Investigating an AEFI is the primary responsibility of City / Provincial level program staff, depending on their capacity to carry out AEFI case investigations. Where the LGU so requires, the Regional level staff shall provide technical assistance.

The DOH NIP strongly recommends that AEFI investigation be conducted by a team composed of duly authorized representatives from the Epidemiology and Surveillance Unit (ESU), Regional Food and Drug Regulation Officer (FDRO), EPI Coordinator and Health Promotion Officer.

Initial response and complete investigation shall be conducted within 48 hours upon reporting of a serious AEFI. The AEFI Case Investigation Form (CIF) shall be used in the investigation of cases. The completed CIF for serious AEFIs, other severe and unusual events occurring within four weeks after immunization and clusters of minor AEFIs shall be submitted within 48 hours or after completion of the investigation to the RESU for initial causality assessment.

During investigation, each investigating team shall have the following roles:

- a. ESU – will primarily conduct epidemiologic investigation
- b. EPI – assist in AEFI investigation, document immunization practices including cold chain management
- c. FDA /FDRO – assist in AEFI investigation, document registration of distributed vaccines including specific vaccine lot and batch number
- d. Health Promotion Officer – conduct risk communication

3. AEFI Reporting

After completing primary AEFI investigation, a report form shall be sent to the Regional Epidemiology and Surveillance Unit. At the same time, the DOH Epidemiology Bureau shall be immediately informed about the serious AEFI case.

- Higher AEFI authorities at the Municipal, City and Province levels shall be immediately notified about any death, severe AEFI or unusual medical incident.
- The AEFI reporting form should be duly filled up by the EPI nurse / Provincial EPI manager. The attending doctor should enter the clinical details, sign and dispatch the form.

For detailed explanation about AEFI, please refer to the *Manual of Procedure for Surveillance and Response to AEFI*.

Regarding the specific policy for AEFI and specific roles at each level of administration, refer to DOH Administrative Order 2010-0017 and 2010-0017-A

