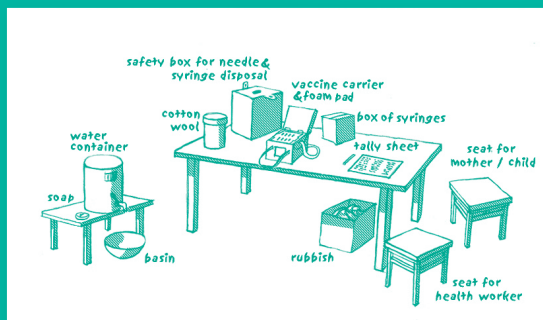


# Training for mid-level managers (MLM)

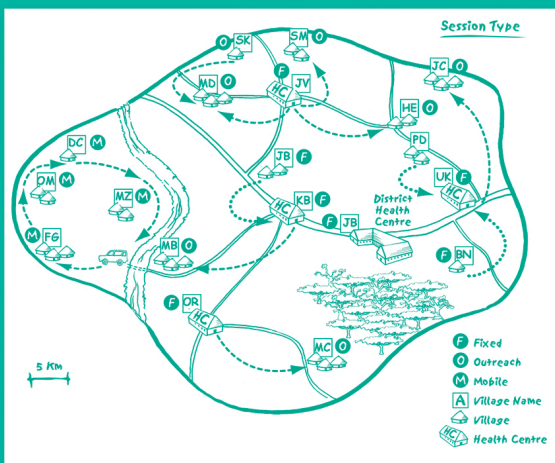
## 3. Immunization safety



*Vaccine safety and quality*

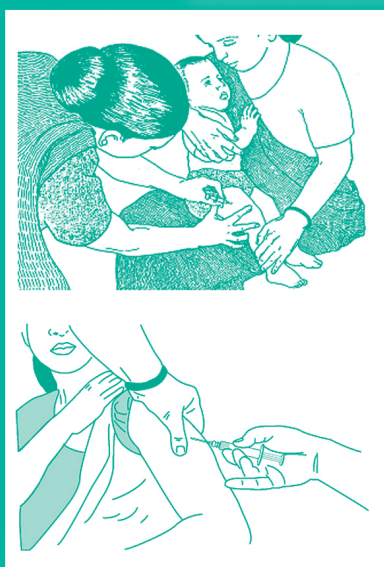
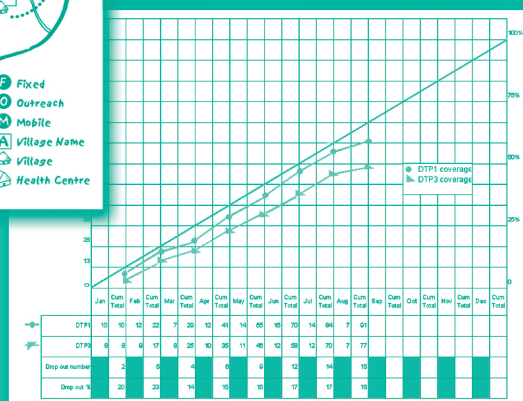
*Safe injections and waste disposal*

*Immunization safety surveillance*



### The vaccine vial monitor says...

- ✓ The inner square is lighter than the outer circle. If the expiry date has not passed, USE the vaccine.
- ✓ At a later time the inner square is still lighter than the outer circle. If the expiry date has not passed, USE the vaccine.
- ✗ Discard point: the colour of the inner square matches that of the outer circle. DO NOT use the vaccine.
- ✗ Beyond the discard point: the inner square is darker than the outer circle. DO NOT use the vaccine.





# Training for mid-level managers (MLM)

## Module 3 : Immunization safety

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## Introduction to the series

This new series of modules on immunization training for mid-level managers replaces the version published in 1991. As there have been many changes in immunization since that time, these modules have been designed to provide immunization managers with up-to-date technical information and explain how to recognize management and technical problems and to take corrective action and how to make the best use of resources.

More and more new, life-saving vaccines are becoming available, yet the introduction of a new vaccine does not necessarily require a separate plan and separate training. This new series for mid-level managers integrates training for new vaccine introduction into each subject addressed by the modules. In this way, introduction of new vaccines is put into its day-to-day context as part of the comprehensive range of activities required to improve immunization systems.

In the context of these modules, mid-level managers are assumed to work in secondary administrative levels, such as a province; however, the modules can also be used at national level. For district managers (third administrative level), a publication on 'immunization in practice'<sup>1</sup> is widely available. As it contains a large amount of technical detail, it is also recommended for mid-level managers courses.

In writing these modules, the authors tried to include essential topics for mid-level managers, while keeping the modules brief and easy to use. They are intended to complement other published materials and guidelines, some of which are referred to in the text. Many more documents are available on the CD-ROM which accompanies this series. Each module is organized in a series of steps, in which technical information is followed by learning activities. Some knowledge and experience are needed to complete the learning activities, but even new readers should be imaginative and constructive in making responses. Facilitators should also be aware that the responses depend on the national context. Thus, there are no absolutely right or wrong answers, and the series does not set down new 'policies' or 'rules'. The authors hope that the readers of these modules will find them informative, easy to read and an enjoyable learning experience.

### **Modules in the mid-level managers series**

Module 1 : Cold chain, vaccines and safe-injection equipment management

Module 2 : Partnering with communities

Module 3 : Immunization safety

Module 4 : Supportive supervision

Module 5 : Monitoring the immunization system

Module 6 : Making a comprehensive annual national immunization plan and budget

Module 7 : The EPI coverage survey

Module 8 : Making disease surveillance work

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<sup>1</sup> *Immunization in practice: A practical guide for health staff*. Geneva, World Health Organization, 2004

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## Acknowledgments

This new series of modules on immunization training for mid-level managers is the result of team work between a large number of partners including the Centers for Disease Control and Prevention (CDC), IMMUNIZATIONbasics, Program for Appropriate Technology in Health (PATH), United Nations Children's Fund (UNICEF), United States Agency for International Development (USAID) and the World Health Organization (WHO). The authors are especially grateful to the consultants from the University of South Australia who have made a major contribution to the development of the modules.

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## Abbreviations & acronyms

AD	auto-disable (syringe)
AEFI	adverse events following immunization
AIDS	acquired immunodeficiency syndrome
BCG	bacille Calmette-Guérin (vaccine)
CDC	Centers for Disease Control & Prevention
DT	diphtheria-tetanus toxoids (vaccine)
DTP	diphtheria-tetanus-pertussis (vaccine)
EPI	Expanded Programme on Immunization
HBV	hepatitis B virus
HepB	hepatitis B (vaccine)
HHE	hypotonic hyporesponsive episode
Hib	<i>Haemophilus influenzae</i> type b
HIV	human immunodeficiency virus
IFRC	International Federation of Red Cross and Red Crescent Societies
IIP	<i>Immunization in practice</i>
MDVP	multi-dose vial policy
MMR	mumps, measles, rubella (vaccine)
OPV	oral polio vaccine
PATH	Program for Appropriate Technology in Health (USA)
PPE	personal protective equipment
SOP	standard operating procedure
Td	tetanus-diphtheria toxoids
TT	tetanus toxoid
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VAPP	vaccine-associated paralytic poliomyelitis
VVM	vaccine vial monitor
WHO	World Health Organization

# Introduction to Module 3

## Purpose of this module

*Every day thousands of injections of vaccine are given in your area. As a mid-level manager you should be confident that all your health workers follow all the principles of immunization safety. What happens when a serious adverse event occurs? Can you manage an initial response in your area well enough to ensure that the immunization service is not disrupted?*

*This module describes how to ensure every vaccination is given safely, how to manage waste materials, and how to monitor the service sufficiently to be alert and responsive to any serious adverse event should it occur.*

Immunization safety is a wide subject area, ranging from vaccine manufacturing and regulation to the point of use of vaccine at immunization sessions, and includes the disposal of used equipment. This module is aimed at the mid-level manager who is concerned with managing day-to-day implementation of the immunization service. There are many other issues of immunization safety, including vaccine quality, that are not within the area of control of the mid-level manager; for these issues there are many other written materials and guidelines available.

Immunization safety is greatly dependent upon proper cold-chain and safe-injection supply management; these subjects are addressed in detail in *Module 1: Cold chain, vaccines and safe-injection equipment management*. Annex 1 provides common questions related to immunization safety.

Above all, a safe immunization service will ensure the trust and full participation of the community.

Adherence to immunization safety principles:

- reduces the risk of disease transmission by injections;
- reduces the risk of preventable adverse reactions;
- reduces the impact of real vaccine reactions through proper case management;
- ensures the effectiveness of vaccines.

This module comprises three topics:

**Vaccine safety and quality** > **Safe injections and waste disposal** > **Immunization safety surveillance**

# 1. Vaccine safety and quality

## 1.1 Safe cold-chain practices

Vaccines are sensitive to heat and freezing, so 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. The cold chain consists of a series of storage and transport links, all designed to keep vaccines within an acceptable temperature range until they reach the user.

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

- has reduced effectiveness in protecting against disease;
- can result in higher rates of local reactions.

All programme managers should attach high priority to the maintenance of the cold chain including the main equipment (refrigerators, freezers, cold boxes, backup generators) and cold rooms. Storekeepers and repair technicians should receive proper training to manage this important component of the Expanded Programme on Immunization (EPI). Several indicators are available to detect if the vaccines have been frozen or have been exposed to heat.

## 1.2 Reconstitution and proper use of diluents

In the past, tragedies related to reconstitution of freeze-dried vaccines with insulin, muscle relaxant and other inappropriate solutions have occurred. Managers should ensure that such products are not stored in the vaccine refrigerators or cold boxes. To avoid this confusion, WHO now encourages vaccines and diluents to be distributed together.

The diluent supplied with a vaccine is part of the licensed product and is specifically designed for the needs of that vaccine with respect to volume, pH level and chemical properties.

Table 3.1 outlines the recommendations for safe use of diluents.

Table 3.1 : Safe use of diluents

- Careful stock control and accurate records are vital to monitor that the correct diluent is always kept and distributed with each vaccine type and batch.
- In order to avoid confusion during reconstitution, diluents should be supplied, transported and distributed together with the vaccine types to which they correspond.
- Only use the diluents supplied and packaged by the manufacturer with the vaccine.
- Vaccines and diluents must be clearly labelled and identified.
- Health workers must always read the labels to be sure that they have the diluent provided by the manufacturer for that specific vaccine and vial. If the label is missing or cannot be read, the product should not be used.
- Diluents must be cooled to between +2°C and +8°C before reconstitution.
- Draw up all the diluent in the vial and then reconstitute the vaccine to make sure the correct number of doses per vial is obtained.
- Diluents should be handled with the same care as vaccines. Health workers should be trained to know the proper way to reconstitute each of the vaccines they are using.
- Discard reconstituted vaccines within six hours of reconstitution.
- Diluents must not be frozen.
- Diluents from other vaccines or from other manufacturers must NOT be used.
- Sterile water for injection must NOT be used as a vaccine diluent.
- Inside the refrigerator, proper grouping and marking of medical products should be done.
- Do not leave the reconstitution needle in the vial; this leaves the vial open to contamination.
- Do not reconstitute vaccine until the person needing the vaccine injection is present.

### Ten critical steps to reconstitute vaccines safely

1. Read the label on the diluent to make 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 vaccine vial monitor (VVM) to make sure that it is not at, or beyond the discard point.
4. Cool the diluent to between +2°C and +8°C, preferably a day prior to its use.
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.

6. Discard the used reconstitution syringe and needle into a safety box without recapping.
7. Do not leave the reconstitution needle in the vaccine vial.
8. After reconstitution, insert the vial in the foam pad of a vaccine carrier. Never allow the vial to become immersed in water.
9. Discard all reconstituted vaccine at the end of the session, or within six hours, whichever comes first.
10. Use a new auto-disable (AD) 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.

### Special note on Hib vaccines

DTP or DTP-Hib is used for reconstitution of DTP-Hib or DTP-HepB-Hib respectively. Do not mix Hib vaccine with DTP or DTP-HepB unless they are packaged together or intended to be administered together as pentavalent vaccine.

## 1.3 Safe use of opened multi-dose vials of vaccine in subsequent immunization sessions

As part of a policy to reduce vaccine wastage, WHO has developed guidelines on how to continue using vials of certain vaccines (not all vaccines), once they have been opened.

The revised multi-dose vial policy (Table 3.2) applies only to OPV, DTP, TT, DT, Td, hepatitis B and liquid formulation of Hib vaccines that:

- meet WHO requirements for potency and temperature stability;
- are packaged according to International Standards Organization (ISO) standards;
- contain an appropriate concentration of preservative such as thiomersal (for injectable vaccines only).

Note that all vaccines supplied through UNICEF meet these requirements.

It is good practice to write the date of opening on vials to which the multi-dose vial policy applies, and which will be kept for use for subsequent sessions.

Table 3.2: Multi-dose vial policy (MDVP) revised in 2000

Multi-dose vials of OPV, DTP, TT, DT, Td, hepatitis B and liquid formulations of Hib vaccines 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 four weeks**, *provided that all the following conditions are met*.

1. The expiry date has not passed.
2. The vaccines are stored under appropriate cold-chain conditions (+2°C to +8°C).
3. The vaccine vial septum has not been submerged in water.
4. Aseptic technique has been used to withdraw all doses.
5. The VVM, if attached, has not reached the discard point.

**Note:** The revised policy does not change the recommended procedures for handling vaccines that must be reconstituted; for example bacille Calmette-Guérin (BCG) vaccine, measles, yellow fever and some formulations of Hib vaccines. Once a vial of any of these vaccines is reconstituted, it must be **discarded at the end of each immunization session or at the end of six hours, whichever comes first**.

Table 3.3: Examples of some vaccines to which the multi-dose vial policy applies. (Note: This is not an exhaustive list)

1. DT vaccine, adsorbed.
2. dT.
3. Td vaccine for adults, adsorbed.
4. TT vaccine, adsorbed.
5. DTP vaccine, adsorbed.
6. DTP-Hib vaccine, liquid.
7. DTP-HepB vaccine.
8. HepB vaccine.
9. Hib vaccine, liquid.
10. Oral polio vaccine.

Table 3.4: Examples of some vaccines to which the multi-dose vial policy **does not** apply (not an exhaustive list)

**Use within six hours of reconstitution or by the end of the immunization session, whichever comes first, and then discard.**

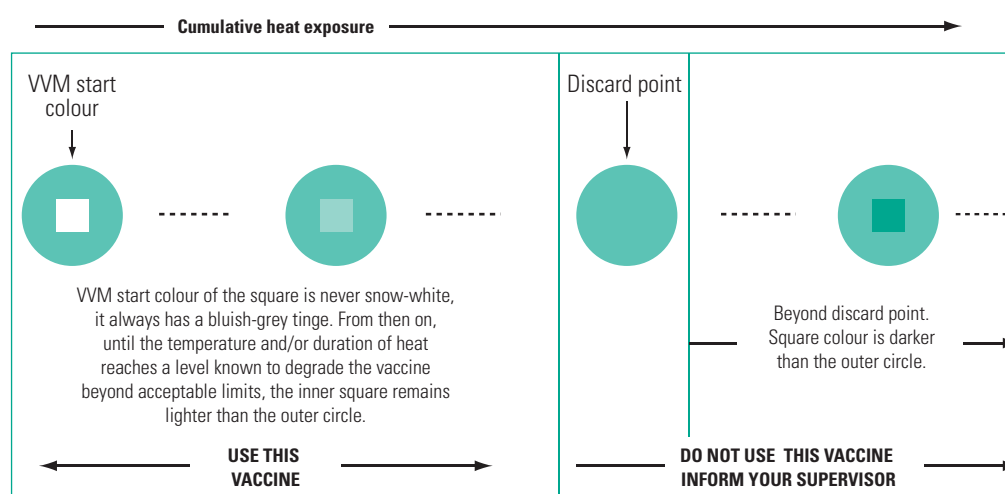
1. BCG vaccine.
2. DTP+Hib vaccine, lyophilized.
3. DTP-HepB+Hib vaccine, liquid + lyophilized.
4. Hib vaccine, lyophilized.
5. Yellow fever vaccine.
6. Meningitis vaccine A&C.
7. Measles vaccine.
8. MMR vaccine.

## 1.4 Check if vaccines are safe to use

Before you use any vaccine you must observe the following rules:

1. Check the labels of the vaccine and diluent. If the label is not attached, discard the vial or diluent.
2. Check the expiry date. If the expiry date has already passed, you must discard vials and diluents.
3. Check the vaccine vial monitor (VVM). If it indicates that the vaccine has passed the discard point, you must discard it immediately.

Figure 1 : How to read a VVM



4. If the device indicates exposure to sub-zero temperatures, or if you suspect that a freeze-sensitive vaccine (DTP, DT, TT, Td, HepB, DTP-HepB, liquid Hib and DTP-HepB+Hib vaccine) has been frozen, you should perform the shake test (see *Module 1: Cold chain, vaccines and safe-injection equipment management* for details).
5. For **each** vaccine used, health workers must know the:
  - i. age at which each dose should be given;
  - ii. number of doses required and minimum intervals between doses;
  - iii. correct dosage.

## 1.5 Reasons for delaying or withholding vaccines (contraindications)

Health workers should use every opportunity to immunize eligible infants and adults, unless the infant or adult has a health condition that does not permit vaccination. Sometimes there are reasons why a specific vaccine should NEVER be administered (also called an absolute contraindication) and sometimes the health worker should delay giving the vaccine for a short time (also called a

temporary contraindication). These different types of reasons for delaying or withholding a vaccine are listed in Table 3.5. Health workers must know about the correct reasons for withholding immunization. The incorrect reasons for withholding a vaccine are called « false contraindications » and these are listed in Table 3.6.



**Key point:** Delaying immunization because of false reasons (false contraindications) results in a missed opportunity to fully immunize an infant or adult.

**Table 3.5: Reasons why specific vaccines should NEVER be administered and reasons why vaccines may be DELAYED for a short time**

Reasons for NEVER administering a specific vaccine (also called absolute contraindications).

If the infant or person has:

- symptomatic (showing symptoms) or **documented** human immunodeficiency virus (HIV) infection — do NOT immunize with BCG;
- symptomatic (showing symptoms) HIV infection — do NOT immunize with yellow fever vaccines;
- a history of a severe adverse event following a dose of a specific vaccine (anaphylactic reaction or severe shock) — do NOT give follow-up doses of that particular vaccine, but provide the infant or adult with other vaccines.

Reasons for delaying administering a specific vaccine (also called temporary contraindications).

The following vaccines should not be administered until the specific condition is no longer present.

- On theoretical grounds, measles and yellow fever vaccines are not recommended during pregnancy.
- Do not give measles vaccine to persons with a history of an anaphylactic reaction to neomycin, gelatin or other components.
- Yellow fever vaccine is contraindicated for persons with severe allergy to egg.
- Measles and yellow fever vaccines are contraindicated in persons who are severely immunocompromised as a result of congenital disease, HIV infection, advanced leukaemia or lymphoma, serious malignant disease, or treatment with high-dose steroids, alkylating agents or antimetabolites, or in persons who are receiving immunosuppressive therapeutic radiation.

Table 3.6 : Conditions which ARE NOT contraindications to immunization

The incorrect reasons for withholding a vaccine are called « false contraindications ». The list below of conditions comprises some examples of « false contraindications ». If an infant or adult presents with any of these, they should be vaccinated.

- Minor illnesses such as upper respiratory infections, or diarrhoea with fever < 38.5°C.
- Allergy, asthma, or other atopic manifestations such as hay fever or 'snuffles'.
- Prematurity; low-birth-weight infant.
- Malnutrition.
- Infant being breastfed.
- Family history of convulsions.
- Treatment with antibiotics, low-dose corticosteroids or locally acting (e.g. topical or inhaled) steroids.
- Dermatoses, eczema or localized skin infection.
- Chronic diseases of the heart, lung, kidney and liver.
- Stable neurological conditions, such as cerebral palsy and Down syndrome.
- History of jaundice after birth.

None of the above list is a true reason for withholding vaccination. If an infant or adult has any of these health issues they should be vaccinated.



## 2. Safe injections and waste disposal

### Introduction

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.

It is well known that giving injections using non-sterile procedures can cause abscesses and transmit life-threatening infectious diseases, including hepatitis B, hepatitis C, and HIV/AIDS in recipients, health workers and the community. While the main goal of immunization is to prevent illness and death, the overriding concern of any public-health intervention must be *primum non nocere* (« first do no harm »).



**Key point:** Unsafe injections can:

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

### 2.1 Selecting safe injection equipment

In a joint statement, WHO-UNICEF-UNFPA-IFRC urged that by the end of 2003 all countries should use only auto-disable (AD) syringes for immunization.

WHO no longer recommends the use of standard plastic disposable injection equipment and sterilizable syringes and needles for immunization, with the exception of reconstitution syringes used for reconstitution of freeze-dried vaccines. Until AD syringes for reconstitution become widely available, standard disposable equipment should be used for reconstitution of vaccines.

All sterilizable injection equipment should be phased out of immunization programmes because there is a high risk of disease transmission associated with their use.

WHO recommends that only the following types of single-use syringes are safe to use for the administration of injectable vaccines: auto-disable syringes and prefilled auto-disable syringes.

Auto-disable syringes are recommended for administering vaccines in routine immunization and mass campaigns. There are many types of AD syringe, and these are widely available at a similar cost to plastic disposable syringes.

Main characteristics of AD syringes are that they:

- are designed to ensure a single use only;
- have a pre-set volume limit;
- have a fixed needle of an appropriate gauge for immunization;
- are automatically rendered unusable after they have delivered a full dose;
- are available as 0.5 ml and 0.05 ml units, while other sizes are available for reconstitution purposes.
- once the vaccine is administered by the syringe, it is impossible to refill by drawing back the plunger forcibly or by applying back pressures to the needle of the syringe.

For further details on the use of AD syringes and prefilled auto-disable syringes see *Immunization in practice: A practical guide for health staff*, Module 4.<sup>1</sup>



### Learning activity 3.1: Using AD syringes

Practice using AD syringes.

List possible difficulties in handling the material.

Discuss possible problems and solutions; for example what to do if:

- there are not enough ADs to vaccinate all the children at the session;
- after expelling air from the syringe there is no longer 0.5 ml of vaccine remaining.

## 2.2 Safe injection practices

Vaccines must be administered using safe injection practices and safe injection equipment. To avoid harm to the recipient and to health workers, the following safe injection practices should be implemented.

1. Use a new sterile AD syringe and needle for every injection.
2. Use a new sterile syringe and needle each time a lyophilized vaccine is reconstituted.
3. Discard an AD syringe that has touched any non-sterile surface (e.g. hands, environment surfaces) before injection.
4. Prepare the injection materials on a designated surface (table or tray) that is clean, and where blood and body fluid contamination is unlikely.
5. Protect fingers with a small gauze pad before opening glass ampoules.

<sup>1</sup> *Immunization in practice: A practical guide for health staff*. Geneva, World Health Organization, 2004

6. For multi-dose vials, always pierce the septum with a sterile needle. Never leave a needle in place in the stopper of the vial.
7. WHO considers it is not necessary to disinfect the skin before and after an injection. If disinfections are practiced, use a clean single-use swab, maintain the product-specific recommended contact time, and do not use cotton balls stored wet in a multi-use container.
8. Never re-cap the AD syringe, but dispose of it immediately into the safety box after use.

### 2.2.1 Using safety boxes

Sharps, and more 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; needle-stick injuries can easily occur and carry a high potential for infection, including hepatitis B and hepatitis C, human immunodeficiency virus (HIV) and sepsis.

To prevent risk of infection to the community and to health workers, the safe disposal of used needles and syringes is a critical component of any immunization programme. Without recapping, vaccinators should place needles and syringes in safety boxes immediately after administering vaccines.

Different safety boxes are assembled in different ways, but appropriate instructions are always printed on each box. Make certain that there is a correctly assembled safety box in the area where injections will be given. The safety boxes should be within immediate reach of your work station so that you can dispose of the used syringe promptly after giving the injection.

*Many needle-stick injuries happen after the injection, but before the syringe is placed in a safety box.*

If providing immunizations away from the clinic (during an outreach session, for example), be sure to take the safety box, even if the box already has some used syringes in it.

Keep an extra, empty safety box nearby at all times, in case the box you are using fills up.

## 2.3 Estimating correct amounts of safe injection and waste-disposal equipment

In addition to receiving the correct type of safe injection and waste-disposal equipment, health workers also need to have sufficient supplies. Managers should plan the ordering and distribution of injection and waste-disposal equipment.

Safe injection equipment should always be bundled with vaccines (see *Module 1: Cold chain, vaccines and safe-injection equipment management*).

When a new vaccine is introduced, the requirement of safe injection equipment will need to be revised. Module 1 shows how to make calculations of vaccine and safe injection equipment based upon the presentation and schedule of each vaccine.



**Key point:** All immunization centres and mobile teams should receive sufficient supplies of safe injection equipment and safety boxes on a timely basis.

## 2.4 Positioning children for injections

Unexpected motion at the time of injection can lead to accidental needle-stick injuries. To prevent this, position the child securely before giving the injection. Adults may tuck the child's legs between theirs 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 tell him/her when you are about to give them an injection.*



### Learning activity 3.2

Review this picture and list what is wrong with the positioning.



## 2.5 Making an immunization waste-disposal plan

Management of waste from campaigns and routine injection requires appropriate local solutions. The first step is to review the amount of waste to be discarded.

Estimate the quantities of AD and other syringes to be disposed of, by health facility, per year and per month.

Using a map of the area, mark the quantities of waste per month according to each health facility.

Decide which health facilities can be reached monthly for waste collection and central disposal, and which need to dispose of waste on-site.

Indicate alternatives to waste collection for those facilities that are not suitable for collection and central disposal.

Checklist of actions.

1. Inventory (list and map) all health-care facilities in the district including mobile sites, health-posts, primary health-care centres and district hospitals.
2. For each health-care facility, record access and logistical constraints for the whole year (taking into account seasonal variations).
3. Estimate the categories and the quantities of sharps generated (disposable syringes, lancets, etc.).
4. Review waste handling and treatment and disposal practices, and identify facilities with dangerous practices which require urgent action to rectify.

The map and data can be used to quantify waste generated in each facility, to be processed at a chosen site. Such a map would show the facilities generating waste, the approximate quantities generated per month, and the sites that have the capacity to dispose of waste (infrastructure, staff, transport).

**Table 3.7: Sample immunization waste disposal plan**

District of:					Date:			Completed by:	
Health-care setting					Logistics			Proposed action	
Name	Type	Annual target population	Monthly target	Final disposal site	Distance (km)	Road condition	Safety boxes per month		
Maki	HC	1200	100	District office	20	Good	1	Collect monthly	

## 2.6 Handling and disposal options when syringes and needles are not separated

### 2.6.1 Collecting syringes with needles attached

#### WHO–UNICEF safety boxes

These puncture-proof boxes are specifically designed to receive syringes with the needles attached. 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. Should not be reused.



#### Locally available puncture-resistant cardboard boxes, plastic bottles

In the case of supply shortages of standard safety boxes in small health-care facilities, alternative solutions can be implemented to store used syringes, 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 are not appropriate for this.



## 2.6.2 Puncture-proof box management

**On-site incineration and burial** (an option for small facilities that cannot transport to a centralized facility).

### On-site burial in a protected or concrete pit

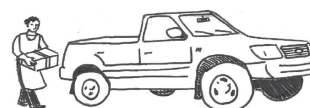
Safety boxes may be burned and buried on premises in a controlled manner. A fence should restrict access to the pit. In unstable soils, the sides of the pit should be lined with brick or concrete to prevent collapse. A 10–15 cm layer of earth should be placed on each layer of waste, and the pit should be filled with soil or concrete when the contents reach 50 cm 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.



### Off-site treatment at a centralized facility.

#### Collection of safety boxes for off-site treatment

Safety boxes can be collected on a regular basis (by vehicle or even by bicycle) and sent to a centralized treatment facility for autoclaving or correctly controlled incineration.



#### Autoclaving or microwaving

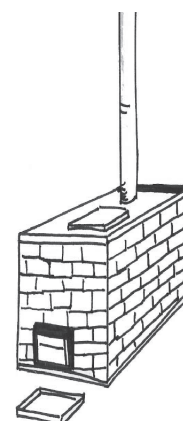
After collection, syringes may be sterilized in an autoclave (saturated steaming at high temperatures), the use of which is restricted to waste treatment.



#### High temperature incineration (850°C)

High temperature incinerators are now available at low cost and are thus affordable for medium-sized health-care facilities. The temperature must be at least 850°C to ensure minimal emission of toxic gases.

Design and operating procedures, and distance from populated areas should be carefully respected. For this purpose, only well-trained staff should operate the incinerator. Proper operation procedures must be followed to ensure the high temperatures necessary.



**Good practices on waste management**

- Waste segregated into infectious and non-infectious waste.
- All syringes or needles collected in a puncture- and leak-proof container (with colour coding or bearing a biohazards sign/symbol). Alternatively, needles are removed immediately by means of a needle remover, and disposed of on-site.
- Non-sharp infectious wastes are collected in bags (with colour coding, or bearing a biohazards sign/symbol).
- Infectious waste bags and sharp containers are stored in a secure place prior to transportation for treatment/disposal.
- Availability and use of Personal Protective Equipment (PPE), and facilities for handwashing for all persons handling waste.
- Immunization of staff against Hepatitis B virus (HBV).
- Regular supervision and correction of problems.

**Learning activity 3.3: Waste management**

Using the information in this module and Table 3.7 discuss which waste-disposal systems and techniques you would advise under the following circumstances.

- A health facility that has a catchment area with a total population of 5000 people.
- A district health centre with a catchment area of 200 000 people.
- A provincial hospital that provides in-patient immunization services in addition to all its other services.
- A district in the process of conducting a measles immunization campaign.

## 2.7 Supervision and monitoring

EPI managers are responsible for the implementation of safe injection practices and waste-disposal policies in their area to ensure vaccinators and the community are not exposed to the risk of blood-borne diseases caused by unsafe injections and incorrect disposal of injection equipment. As part of this accountability, they may be required to provide higher-level supervisors with evidence that they have implemented the practices required by their national policies and guidelines.

During supervisory visits :

- ensure that national guidelines and standard operating procedures (SOP) for injection safety, infection control and waste disposal are available in written form in all health facilities ;
- when implementing safe practice for injections and disposal of used equipment in the work place, organize meetings with health personnel and discuss their experiences ;
- identify any problems or challenges, try to solve them together and communicate those solutions to all staff.

Health workers should understand that they must inform their supervisors when it is not possible to follow the procedures.

In some countries and provinces, Immunization Safety Officers are appointed by national authorities to ensure that effective coordination, monitoring, and supervision of safe injection and waste-disposal practices are implemented at provincial and district levels. These officers are given the responsibility to ensure that managers and other responsible staff correctly implement a safe injection policy.



## 3. Adverse Events Following Immunization (AEFI) surveillance

### 3.1 Definition of 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:

1. detecting, monitoring and responding to adverse events following immunization (AEFI);
2. implementing appropriate and immediate action to correct any unsafe practices detected through the AEFI surveillance system, in order to lessen the negative impact on the health of individuals and the reputation of the immunization programme.

### 3.2 Types of AEFI

An effective immunization safety surveillance system must be able to find and differentiate between the various types of AEFI (Table 3.8) in order to prevent their occurrence, or reduce their impact.

Table 3.8: Five main types of AEFI

1. Vaccine reaction	Event caused or precipitated by the inherent properties of the vaccine (active component or one of the other components e.g. adjuvant, preservative, stabilizer) when given correctly.
2. Programme errors	Event caused by an error in vaccine preparation, handling, or administration.
3. Coincidental	Event that happens after immunization but is not caused by the vaccine. This is due to a chance temporal association.
4. Injection reaction	Event arising from anxiety about, or pain from, the injection itself rather than the vaccine.
5. Unknown	The cause of the event cannot be determined.

#### 3.2.1 Vaccine reactions

Vaccine reactions are classified as:

- common minor reactions (Table 3.9)
- rare, more serious reactions (Table 3.10).

Most vaccine reactions are minor, and include mild side-effects, such as local reactions (pain, swelling and/or redness), fever and systemic symptoms (e.g. vomiting, diarrhoea, malaise), which can result as part of the normal immune response to the vaccine. Some of the non-antigenic vaccine components (e.g. adjuvants, stabilizers or preservatives) can cause some of these reactions.

**Table 3.9: Common minor vaccine reactions**

Vaccine	Local reaction (pain, swelling, redness)	Fever (greater than 38 °C)	Irritability, malaise and non-specific symptoms
BCG	Common	–	–
Hib	5%–15%	2%–10%	–
Hepatitis B	Adults up to 15% Children up to 5%	1%–6%	–
Measles/MMR	Up to 10%	5%–15%	Up to 5% (rash)
Oral polio (OPV)	–	Less than 1%	Less than 1% <sup>a</sup>
Tetanus/DT/Td	Up to 10% <sup>b</sup>	Up to 10%	Up to 25%
Pertussis (DTP – whole cell) <sup>c</sup>	Up to 50%	Up to 50%	Up to 60%

<sup>a</sup> Diarrhoea, headache, and/or muscle pains.  
<sup>b</sup> Rate of local reactions likely to increase with booster doses, up to 50% to 85%.  
<sup>c</sup> With whole cell pertussis vaccine. Acellular pertussis vaccine rates are lower.

**Table 3.10: Rare serious vaccine reactions, onset interval and rates**

Vaccine	Reaction	Onset interval	Rate per million doses
BCG	Suppurative adenitis BCG osteitis Disseminated BCG-itis	2–6 months up to several years 1–12 months	100–1000 –
Hib	None known	–	–
Hepatitis B	Anaphylaxis	0–1 hour	1–2
Measles/MMR <sup>a</sup>	Febrile seizures Thrombocytopenia (low platelets) Anaphylaxis	5–12 days 60 days 0–1 hour	330 30 1
Oral polio (OPV)	Vaccine associated paralytic poliomyelitis (VAPP)	4–30 days	Up to 0.4 <sup>b</sup>
Tetanus	Brachial neuritis Anaphylaxis Sterile abscess	2–28 days 0–1 hour 1–6 weeks	5–10 1–6 6–10
DTP	Persistent (>3 hours) inconsolable screaming Seizures Hypotonic hyporesponsive episode (HHE) Anaphylaxis/shock	0–48 hours 0–3 days 0–24 hours 0–1 hour	1000–60 000 600 <sup>c</sup> 30–990 1–6
Japanese encephalitis	Serious allergic reaction Neurological event	0–2 weeks 0–2 weeks	10–1000 1–2.3
Yellow fever	Allergic reaction/anaphylaxis	0–1 hour	5–20

<sup>a</sup> Reactions (except anaphylaxis) do not occur if already immune (~ 90% of those receiving a second dose); children over six years are unlikely to have febrile seizures.  
<sup>b</sup> VAPP risk is higher for first dose (12 per 1.4–3.4 million doses) compared to 1 per 5.9 million for subsequent doses, and 1 per 6.7 million doses for subsequent contacts.  
<sup>c</sup> Seizures are mostly febrile in origin, and rate depends on past history, family history and age, with a much lower risk in infants under the age of four months.



### Learning activity 3.4: Using data on reported vaccine reactions

You are reviewing all the AEFI reports that have been reported for the past six months. During this reporting period there has been:

- a measles vaccination campaign with 2 million doses of vaccine administered to children between nine months and five years of age;
- during the routine immunization sessions and outreach sessions 1.5 million doses of DTP, OPV, HepB have been administered, and 250 000 doses of tetanus vaccine have been administered to pregnant and/or childbearing age women.

After the data have been entered into the computer database and analysed, you note the following results.

There was one report of anaphylaxis occurring 30 minutes after administration of measles vaccine.

There were 10 cases of febrile seizures within seven days of DTP administration.

There was one case of a death reported to be associated with hepatitis B vaccine, but the death occurred one month after the vaccine was administered.

1. Do the reports of anaphylaxis, febrile seizures, severe local abscess and fever, occur at an expected rate per administered doses for that AEFI and that vaccine?
2. Do any of these cases require further investigation? If investigation is required, what action will you take to solve the problems you find?
3. What feedback will you provide to the health workers about these findings?

### 3.2.2 Programme errors and AEFI

The view that vaccines are the most common cause of AEFI is incorrect. On the contrary, incorrect immunization practices that can be prevented are more often the cause (see Table 3.11). Careful epidemiological investigation of an AEFI is needed to pinpoint the cause and to correct these malpractices.

Table 3.11 : Examples of incorrect immunization practices and associated AEFI

Incorrect practices	Possible severe reactions following immunization
Non-sterile injection <ul style="list-style-type: none"> <li>• Reuse of disposable syringe or needle</li> <li>• Improperly sterilized syringe or needle</li> <li>• Contaminated vaccine or diluent</li> </ul>	<ul style="list-style-type: none"> <li>• Infection such as local abscess at injection site, sepsis, toxic shock syndrome, or death</li> <li>• Blood-borne infection transmitted, such as hepatitis, HIV</li> </ul>
Reconstitution error <ul style="list-style-type: none"> <li>• Inadequate shaking of vaccine</li> <li>• Reconstitution with incorrect diluent</li> <li>• Drug substituted for vaccine or diluent</li> <li>• Reuse of reconstituted vaccine at subsequent session</li> </ul>	<ul style="list-style-type: none"> <li>• Local abscess</li> <li>• Vaccine ineffective</li> <li>• Negative effect of drug, e.g. insulin, oxytocine, muscle relaxants</li> <li>• Death</li> </ul>
Injection at incorrect site <ul style="list-style-type: none"> <li>• BCG given subcutaneously</li> <li>• DTP/DT/TT too superficial</li> <li>• Injection into buttocks</li> </ul>	<ul style="list-style-type: none"> <li>• Local reaction or abscess</li> <li>• Local reaction or abscess</li> <li>• Sciatic nerve damage</li> </ul>
Vaccine transportation/storage incorrect <ul style="list-style-type: none"> <li>• VVM changed colour</li> <li>• Clumping of adsorbed vaccine</li> </ul>	<ul style="list-style-type: none"> <li>• Local reaction from frozen vaccine</li> <li>• Vaccine ineffective<sup>a</sup></li> </ul>
Contraindications ignored	Avoidable severe reaction

<sup>a</sup> Vaccine being ineffective is an 'effect', it is not strictly an adverse event.

### 3.2.3 Coincidental AEFI

Vaccines are normally scheduled early in life, when infections and other illnesses are common and underlying congenital or neurological conditions may be present. Consequently, many events including deaths are falsely attributed to vaccines (rather than a chance association).

Coincidental events are unrelated to the immunization but medical officers should be encouraged to ensure the proper diagnostic workup and management of the AEFI cases even when not related to the vaccination.

Parents or the community may blame the vaccine, especially if the child was previously healthy. These cases still require investigation to allay public fears and to maintain credibility. Responding to a community's concerns about immunization safety is important in maintaining confidence in the immunization programme.

An event is more likely to be coincidental if a similar event affected others in the same age group around the same time, although they did not receive the suspect vaccine(s). There may also be evidence showing that the event is not related to immunization.

### 3.2.4 Injection reactions

Individuals and groups of individuals can react before and after an injection of any kind. This reaction, unrelated to the content of the vaccine, can include hyperventilation resulting in light-headedness, dizziness, tingling around the mouth and in the hands, vomiting, breath-holding, fainting (relatively common), and convulsions.

Some individuals may be needle-phobic, aggravating such reactions. In a group situation, mass hysteria is possible, especially if a patient is seen to faint or have some other reaction. Clear explanations about the immunization, and calm, confident delivery, will decrease the level of anxiety about the injections, and thus reduce the likelihood of an occurrence.

## 3.3 Establishment and maintenance of an effective AEFI monitoring system

Mid-level managers have a responsibility for maintaining the immunization safety surveillance system. This system should be part of any existing system of reporting information (e.g. immunization coverage reports, disease incidence reports, and adverse reaction reports).

The following policies and standard operating procedures will ensure that effective safety surveillance is maintained.

- Specific roles and responsibilities for the staff to follow.
- Case definitions of each AEFI that are consistent with national standards.
- Clear guidelines for reporting and investigating AEFI up to the next level (data management rules).
- Standard forms for reporting and investigating.
- Standard forms for line listings.
- An AEFI database for comprehensive analysis (from the lowest practicable level in the system up to national level).

### 3.3.1 Detecting and reporting AEFI

Whenever AEFI are detected, they must be reported on a timely basis so that the cause can be identified.

Peripheral health workers may not report AEFI for one or more of the following reasons.

1. Not considering the event as related to immunization.
2. Not knowing about the reporting system and process.
3. Fear that the report will lead to personal consequences.
4. Guilt about having caused harm and being responsible for the event.
5. Uncertainty about reporting an event when not confident about the diagnosis.

A manager can overcome these reporting barriers by:

- increasing awareness of the importance of reporting;
- teaching staff how to report AEFI;
- encouraging staff to report, even in situations of uncertainty;
- emphasizing that investigations are about finding problems with the system, and not blaming individuals;
- giving positive feedback to health workers for reporting AEFI.

*(a) Which AEFI to report*

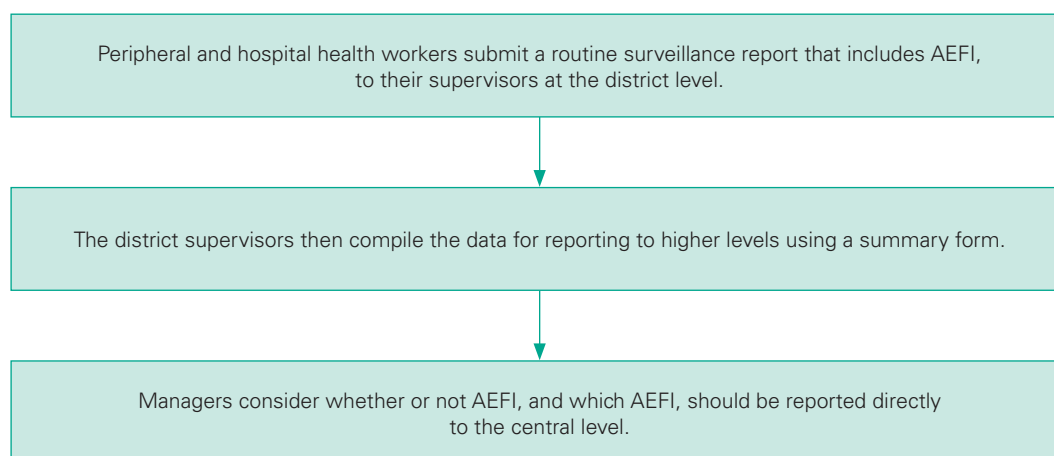
Managers should ensure that their staff monitor and report an agreed list of adverse events. Health workers should know to monitor and report at least the following AEFI.

1. All injection site abscesses.
2. All cases of BCG lymphadenitis.
3. All deaths that are believed by health workers, or the public, to be related to immunization.
4. All cases requiring hospitalizations that are believed by health workers, or the public, to be related to immunization.
5. Other severe or unusual medical incidents that are believed by health workers, or the public, to be related to immunization.

The above five categories of AEFI are sometimes called 'trigger' events because their presence should stimulate or trigger a response from a manager to take action.

*(b) How and what to report*

In most systems the following steps are used to report AEFI.



There should be national guidelines for each country on what and how to report, and each manager will need to contact their supervisor to obtain their country's guidelines. Reports should be made on a standard AEFI Report Form.

At a minimum, the AEFI report needs to include :

- a description of the event including date and time of onset of AEFI ;
- timing of the event in relation to immunization ;
- vaccine(s) given including batch number ;
- patient's identifying details including address and family member contact.

Additional items, such as patient information (age, ethnicity, gender), vaccine information (manufacturer, lot number), and administration information (date of immunization, site and route of injection) could be included.

*(c) When to report*

So that investigations can begin as soon as possible, the reportable AEFI should be reported upward within 24 hours of detection by a health worker, and/or a manager's receiving a relevant report. This timely report allows for :

- quick identification of any programme errors that might be present ;
- implementation of early corrective strategies before other people are exposed to the same error ;
- members of the community seeing that their health and concerns are taken seriously.

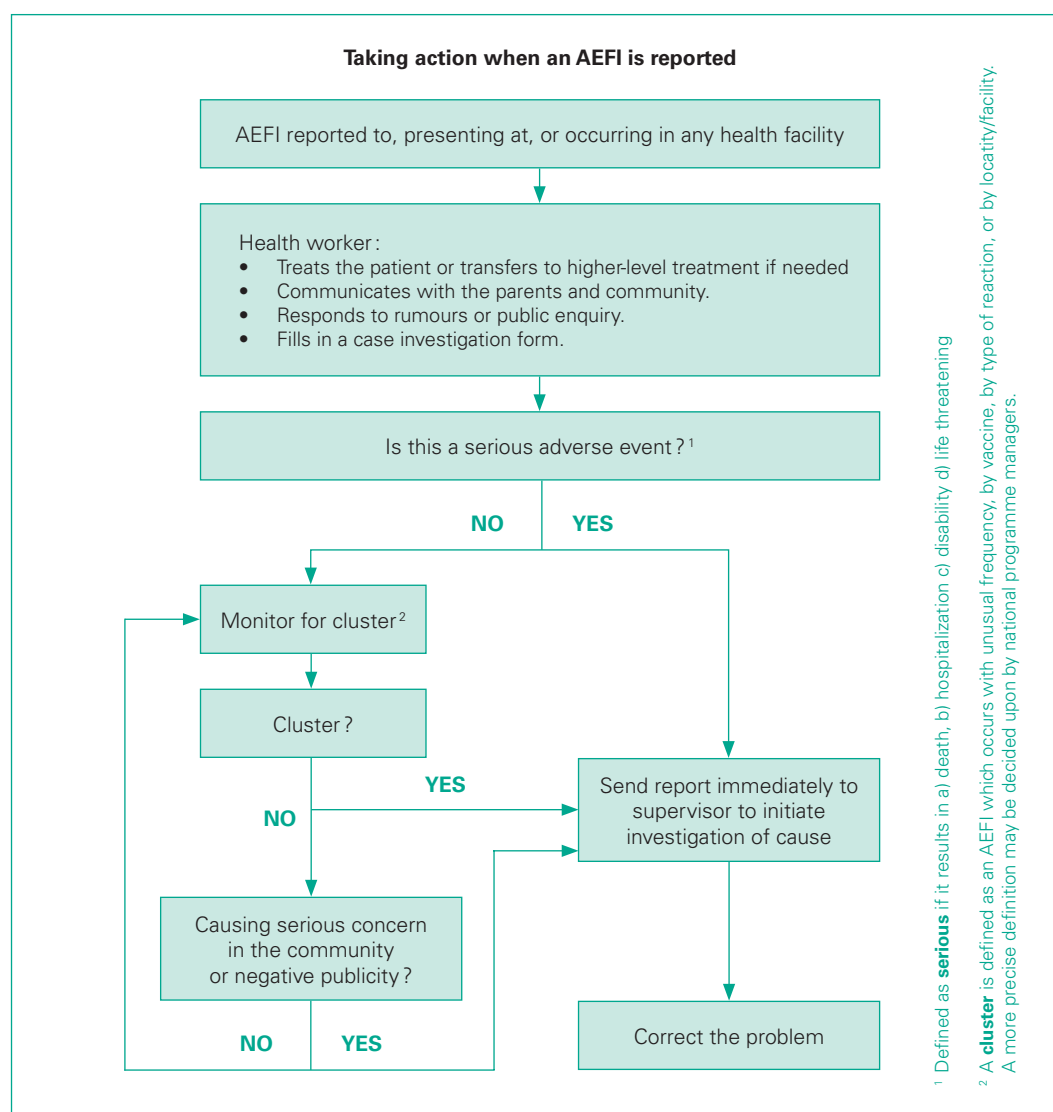


### Learning activity 3.5: Reporting AEFI

- List the AEFI you are required to report in your country's surveillance system.
- Compare your list with the list in section (a) above. Is there a difference? Explain why.
- To whom and where are AEFI to be notified in your area of responsibility?
- List the actions that are taken on receipt of a report for each of the AEFI on your list.

### 3.3.2 Taking action in response to AEFI reports

The following flow chart shows what action should be taken when an AEFI is reported at a health facility.



A manager's main actions in response to AEFI reports are to :

- ensure all relevant AEFI reports are obtained from health workers ;
- review these reports and compare them with the national list of reportable AEFI (to filter the data) ;
- send those reports that are required by national guidelines to the next level.

Depending on the cause of the AEFI, other actions a manager may take to reduce the risk from AEFI are to ensure to :

- maintain a safe and effective vaccine logistics system, including a functioning cold chain, adequate supplies of safe injection equipment, and proper waste disposal ;
- train health workers in properly identifying, responding to and reporting AEFI ;
- develop and practice effective communication and promotion strategies for health workers and the community about AEFI reporting.



**Learning activity 3.6: AEFI and communicating with the community. Be prepared to quickly respond to rumours and public enquiries.**

An infant has died five days after receiving his first dose of DTP in a rural health centre. The centre serves a community with a total population of 50 000 people. Since the death of this infant, many parents have refused to have their children immunized. A full investigation revealed no error of administration or problem with the vaccine.

1. What type of AEFI are you dealing with here ?
2. What strategies would you implement to convince the community that vaccination is safe and necessary, despite the recent infant death ?



## Annex 1 : Common questions on immunization safety

1. Name the five criteria for the multi-dose vial policy.
2. Name four things that a health worker must check before filling a syringe from a vial.
3. Name three advantages of the auto-disable (AD) syringe.
4. What should you do with discarded vaccine vials ?
5. Name three correct ways of disposing of full safety boxes.
6. Which variables should be in the vaccine stock-record book ?
7. Describe how to do the shake test.
8. How do you keep opened vaccine vials cold during a session ?
9. What are some common mistakes that lead health workers to use the wrong diluents to reconstitute vaccines ?
10. Give two indicators for monitoring immunization safety at the district level.
11. Give two absolute contraindications for immunization with a specific vaccine.
12. Name two types of AEFI that you have recent experience of. What action did you take ?

### Case-studies

1. In the morning a health worker sets out to do an outreach session: all vaccines have VVM at Stage 1 and there are four ice packs in the vaccine carrier. By the afternoon, the health worker notices that the ice packs have melted, but there are several more infants to be immunized — what should he/she do ?
2. What issues should be taken into account when implementing « earliest expiry first out » policy for vaccine handling ?
3. You are in the middle of an outreach session; you open your vaccine carrier and find that several vials (both opened and unopened) are submerged in water. What should you do ?
4. You realize that the refrigerator is packed full and does not have space for diluents. The refrigerator contains items other than vaccines, such as insulin and other medications that need to be kept cool. What should you do ?
5. On 22 September 2007, a health worker opens a DTP vial which has VVM stage 1 when you notice that the expiry date on this batch of vials is 20 September 2007. What would you do ?



The World Health Organization has provided technical support to its Member States in the field of vaccine-preventable diseases since 1975. The office carrying out this function at WHO headquarters is the Department of Immunization, Vaccines and Biologicals (IVB).

IVB's mission is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases. The Department covers a range of activities including research and development, standard-setting, vaccine regulation and quality, vaccine supply and immunization financing, and immunization system strengthening.

These activities are carried out by three technical units: the Initiative for Vaccine Research; the Quality, Safety and Standards team; and the Expanded Programme on Immunization.

The Initiative for Vaccine Research guides, facilitates and provides a vision for worldwide vaccine and immunization technology research and development efforts. It focuses on current and emerging diseases of global public health importance, including pandemic influenza. Its main activities cover: i) research and development of key candidate vaccines; ii) implementation research to promote evidence-based decision-making on the early introduction of new vaccines; and iii) promotion of the development, evaluation and future availability of HIV, tuberculosis and malaria vaccines.

The Quality, Safety and Standards team focuses on supporting the use of vaccines, other biological products and immunization-related equipment that meet current international norms and standards of quality and safety. Activities cover: i) setting norms and standards and establishing reference preparation materials; ii) ensuring the use of quality vaccines and immunization equipment through prequalification activities and strengthening national regulatory authorities; and iii) monitoring, assessing and responding to immunization safety issues of global concern.

The Expanded Programme on Immunization focuses on maximizing access to high quality immunization services, accelerating disease control and linking to other health interventions that can be delivered during immunization contacts. Activities cover: i) immunization systems strengthening, including expansion of immunization services beyond the infant age group; ii) accelerated control of measles and maternal and neonatal tetanus; iii) introduction of new and underutilized vaccines; iv) vaccine supply and immunization financing; and v) disease surveillance and immunization coverage monitoring for tracking global progress.

The Director's Office directs the work of these units through oversight of immunization programme policy, planning, coordination and management. It also mobilizes resources and carries out communication, advocacy and media-related work.

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