Federal Democratic Republic of Ethiopia
Ministry of Health

Immunization

Distance Learning Module for the Health Extension Programme

HEAT
Health Education and Training
HEAT in Africa

unicef
unite for children

The Open University

AMREF
Better Health for Africa

Federal Democratic Republic of Ethiopia
Ministry of Health

The Ethiopian Federal Ministry of Health (FMOH) and the Regional Health Bureaus (RHBs) have developed this innovative Blended Learning Programme in partnership with the HEAT Team from The Open University UK and a range of medical experts and health science specialists within Ethiopia. Together, we are producing 13 Modules to upgrade the theoretical knowledge of the country's 33,000 rural Health Extension Workers to that of Health Extension Practitioners, and to train new entrants to the service. Every student learning from these Modules is supported by a Tutor and a series of Practical Training Mentors who deliver the parallel Practical Skills Training Programme. This blended approach to workplace learning ensures that students achieve all the required theoretical and practical competencies while they continue to provide health services for their communities.

These Blended Learning Modules cover the full range of health promotion, disease prevention, basic management and essential treatment protocols to improve and protect the health of rural communities in Ethiopia. A strong focus is on enabling Ethiopia to meet the Millennium Development Goals to reduce maternal mortality by three-quarters and under-5 child mortality by two-thirds by the year 2015. The Modules cover antenatal care, labour and delivery, postnatal care, the integrated management of newborn and childhood illness, communicable diseases (including HIV/AIDS, malaria, TB, leprosy and other common infectious diseases), family planning, adolescent and youth reproductive health, nutrition and food safety, hygiene and environmental health, non-communicable diseases, health education and community mobilisation, and health planning and professional ethics.

In time, all the Modules will be accessible from the Ethiopian Federal Ministry of Health website at **www.moh.gov.et**; online versions will also be available to download from the HEAT (Health Education and Training) website at **www.open.ac.uk/africa/heat** as open educational resources, free to other countries across Africa and anywhere in the world to download and adapt for their own training programmes.

Dr Kesetebirhan Admasu

State Minister of Health

Ethiopian Federal Ministry of Health

Acknowledgements

Immunization is one of the 13 Blended Learning Modules for the Ethiopian Health Extension Programme. Together with the practical skills training sessions that accompany each of the supported self-study texts, this programme will upgrade the Health Extension Workers who complete the curriculum to Health Extension Practitioners at Level-IV of the Ethiopian Occupational Standards. The upgrading programme is sponsored by the Ethiopian Federal Ministry of Health (FMOH) and the Regional Health Bureaus (RHBs). The FMOH gratefully acknowledges the receipt of funding for this programme from the Ethiopian Office of UNICEF (the United Nations Children's Emergency Fund), The Open University UK, the Alan and Nesta Ferguson Foundation Trust UK, and AMREF (the African Medical and Research Foundation).

Immunization was produced by a team of Ethiopian experts, who were trained and supported by experts in blended learning pedagogy from the HEAT (Health Education and Training) Team for Africa at The Open University UK. The contributors of original material are:

- Dr Kalid Asrat, FMOH, Ethiopia
- Dr Amha Mekasha (Module Academic Coordinator) Addis Ababa University
- Dr Gavin Grant, WHO/Ethiopia EPI
- Dr Basiro Davey, The Open University
- Dr Janet Haresnape, The Open University

The Academic Editors of *Immunization* are Dr Basiro Davey, Deputy Director (Ethiopia), HEAT Team at The Open University UK, and Dr Janet Haresnape, in the Department of Life Sciences at The Open University UK. The other members of the HEAT Team are:

- Lesley-Anne Long, HEAT Programme Director
- Alison Robinson, HEAT Programme Coordinator
- Dawn Partner, HEAT Senior Production Assistant
- Jessica Aumann, HEAT Programme Assistant
- Ali Wyllie, HEAT Lead eLearning Adviser

We acknowledge the vital contributions of the Programme Coordinators within Ethiopia:

- Ato Mohammed Hussein Abeseko, UNICEF Ethiopia and the Federal Ministry of Health
- Ato Tedla Mulatu, AMREF Ethiopia

The cover design for *Immunization* is by Chris Hough, Learning and Teaching Solutions, The Open University UK. The cover photographs are with acknowledgement to hdptcar (large image). This file is licensed under the Creative Commons Attribution Licence http://creativecommons.org/licenses/by/2.0. Julien Harnels (small image). This file is licensed under the Creative Commons Attribution-Share Alike Licence http://creativecommons.org/licenses/by-sa/2.0

We particularly wish to acknowledge our use in this Module of extracts and illustrations from the World Health Organization's series *Immunization in Practice: A practical resource guide for health workers* in its various editions (1998, 2001, 2004, 2009), particularly Module 2 'The vaccines', Module 3 'The cold chain', Module 4 'Ensuring safe injections', Module 5 'Planning immunization sessions to reach every infant', Module 6 'Holding an immunization session', and Module 7 'Monitoring and using your data'.

The opinions expressed in this Module are those of the authors and do not necessarily reflect the views of any of the donor organisations whose generous support made the production of *Immunization* possible.

Contents

Introduction to the *Immunization* Module

Many serious communicable diseases are easily preventable by immunization. The World Health Organization estimates that it saves between two to three million lives every year — the majority in regions with low incomes, under-developed infrastructure and large rural populations. Immunization (vaccination) can make an enormous difference to the health of individuals, communities, and nations like Ethiopia. The vaccine-preventable diseases included in the National Expanded Programme on Immunization (EPI) in Ethiopia are tuberculosis, poliomyelitis, diphtheria, pertussis (whooping cough), tetanus, measles, pneumonia and meningitis due to *Haemophilus influenzae* type b, pneumonia due to *pneumococcal* bacteria, diarrhoeal disease due to rotavirus infection, and hepatitis B disease. An efficient and thorough immunization programme, in which the vaccines are stored and administered correctly, can prevent these diseases and hence save many lives — particularly of young children.

In this Module, you will learn how immunization can lead to the development of immunity and is therefore able to protect individuals from many life-threatening communicable diseases. You will also learn the correct route of administration for each vaccine, and about the rare contraindications that mean you should not vaccinate a particular child. Immunization is only effective if vaccine management is good, and if vaccines are administered safely, so we will tell you how to reduce the risk of adverse effects following immunization (AEFIs), and what to do if they occur. Vaccines must be kept at the correct temperature right from the time they leave the factory until the time they are injected into a person, or they lose their potency. How to maintain vaccines at the correct temperature is explained in the study session on the cold chain. We will teach you how to predict your community's requirements for each vaccine, so that you can order enough doses and minimise wastage. Another important aspect you will learn is how to dispose safely of potentially hazardous waste materials, such as needles and syringes, after your immunization sessions.

Immunization campaigns are only successful if they are managed well, and if the community understands their significance. The importance of communication with parents and community leaders about the benefits of immunizing infants aged under one year and women of childbearing age (15 to 49 years) is emphasised throughout this Module. You will also learn about the effective organisation of immunization activities at your Health Post, in outreach sites, and in mobile teams. The ability to deliver improved immunization coverage rates and reduced levels of dropout from immunization programmes also requires excellent record-keeping, and thorough monitoring and evaluation of the outcomes of your activities.

The ten study sessions in this Module contain clear guidelines on how to conduct all these important activities. Through these methods, Ethiopia has already had much success in reducing vaccine-preventable diseases. For example, the number of reported cases of measles was over 10,000 per year in 1980; although the total estimated population has more than doubled since then, the number of reported cases of measles was less than 1,200 in 2009. There have also been huge reductions in the reported cases of polio and neonatal tetanus since immunization against these diseases was introduced. Successes such as these are due to the rapid increase in the immunization coverage rate among target populations.

Much of the credit for successful immunization campaigns is due to the activities of health professionals like you. This is why you have such a big part to play in protecting women and children from vaccine-preventable diseases in your community. We hope that this Module will help you in this effort.

Study Session 1
Immunity, Vaccines and the Expanded Programme on Immunization

Introduction

In the *Communicable Diseases* Module, Part 1, Study Sessions 3 and 4, you learned that some diseases are preventable by immunization with vaccines. Many different types of vaccines are available, and these can be enormously successful in preventing some of the major communicable diseases particularly those that affect children if they are used correctly. This Module teaches you about the concepts and procedures required to deliver an effective immunization service in your community. In this first study session, you will learn about how the immune system protects us from infection, the general principles underlying immunization, the types of immunity and the types of vaccines available.

We will also explain the main features of the Expanded Programme on Immunization (EPI) in Ethiopia, and what you as a Health Extension Practitioner can do to help to make it successful. Immunization benefits the whole country because it has the following general outcomes:

- It prevents millions of people dying needlessly each year.
- It has led to some diseases being eradicated from the world altogether, for example smallpox, and others are targets for elimination, e.g. polio and neonatal tetanus.
- It promotes health and optimal growth and development in children.
- It releases resources for other health interventions.
- It is an investment for a healthy population and a stronger economy.

Learning Outcomes for Study Session 1

When you have studied this session, you should be able to:

1.1 Define and use correctly all of the key words printed in **bold**. (SAQs 1.1, 1.2 and 1.3)

1.2 Describe how the human immune system protects the body from infection, and distinguish between the main types of immunity. (SAQs 1.1, 1.2 and 1.3)

1.3 Describe the main general types of vaccines and what they contain. (SAQ 1.3)

1.4 Describe the main features of the Expanded Programme on Immunization (EPI) and how Health Extension Practitioners can help to achieve its strategies. (SAQ 1.4)

1.1 Immunity and the immune system

Immunity is a state in which the body has sufficient defences to be able to resist the development of communicable diseases caused by **infectious agents**. The main types of infectious agents are bacteria, viruses, fungi,

protozoa and parasites. They are also often referred to as **pathogens**, which means 'disease-causing organisms'. We will use both terms in this Module.

■ Which of the following are infectious agents: the hepatitis B virus, polio virus, *Mycobacterium tuberculosis*, *Neisseria gonorrhoeae*, *Candida albicans*, *Giardia intestinalis*, and *Plasmodium falciparum*?

□ All of these are infectious agents. The list includes two viruses (causing hepatitis and polio), two bacteria (causing tuberculosis and gonorrhoea), a fungus (*Candida* causes oral and genital thrush), one protozoan (*Giardia* causes diarrhoea), and one parasite (*Plasmodium* causes malaria).

The **immune system** is the name given to the network of cells, proteins, tissues and organs within the body (Figure 1.1), which act together to protect us against infectious agents. In addition to the structures shown in Figure 1.1, the cells of the immune system also circulate in the blood and some of them migrate through the tissues. These cells are usually known as **white blood cells**, which is a confusing name because they are found throughout the body – not just in the blood. Wherever an infectious agent gets into the body, it will soon be detected and attacked by the immune system.

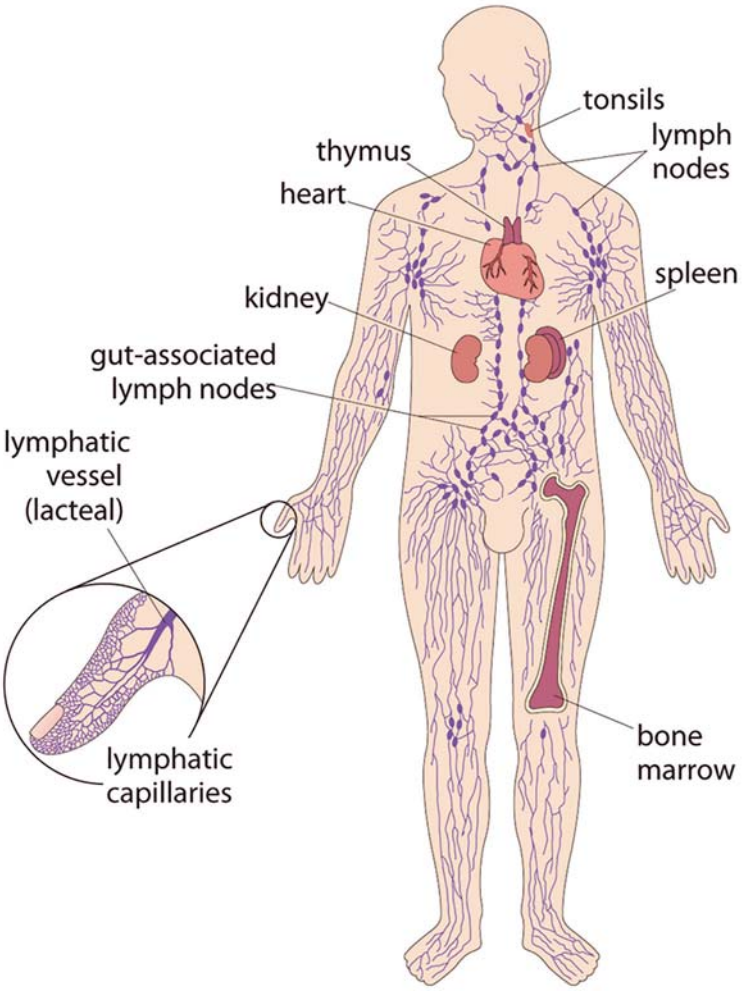


Figure 1.1 The sites in the body (in addition to the blood) where the cells and molecules of the human immune system are concentrated. (Source: The Open University, *SXR376 Preparatory Reading*, Figure 1.2)

The immune system of a healthy and well-nourished adult may be able to fight an infection and stop the disease from developing, or reduce it to mild symptoms. But in very young or elderly persons, or people who are malnourished or in bad health – particularly if they already have HIV, TB or malaria – the immune system is not strong enough to protect them from a new infection. They can become very ill and even die without medical treatment.

- In addition to the immune system, can you think of other ways in which the human body protects itself from infectious agents?

- Intact skin covering our bodies acts as a barrier preventing entry of infectious agents. You may have also thought of the hairs and mucus inside the nose, which trap bacteria from the air. Coughing and sneezing, vomiting and diarrhoea rids the body of large numbers of infectious agents, but also spreads them to other people.

1.1.1 How does the immune system protect us from infection?

In this section, you will learn about the different ways in which people can acquire immunity (become immune) to infectious agents. Immunity may be non-specific or specific.

Non-specific immunity

Non-specific immunity (also known as *innate immunity* — 'innate' means 'already formed at birth') includes protection from infectious agents by mechanical barriers, such as intact skin or the mucus membranes lining the inside of our nose, mouth, lungs, reproductive system and gut. It also includes the actions of some kinds of white blood cells that can engulf ('eat') or kill a wide range of infectious agents, without distinguishing between them.

Specific immunity

In this study session, we will focus on **specific immunity**, which is the type generated by immunization. Specific immunity is produced when the immune system reacts specifically against one particular type of infectious agent in ways that we will now describe.

When bacteria, viruses or other pathogens get into the body, they are identified as 'foreign' by special white blood cells in the immune system, known as *helper T lymphocytes* or **helper T cells** (Figure 1.2 overleaf). Infectious agents are recognised as foreign because they have unique proteins — called **antigens** — on their surfaces, which the helper T cells can detect. Each type of infectious agent has its own unique antigens, so the person's immune system can tell which type of infectious agent has got into the body, and direct an attack specifically against that pathogen. Some infectious agents release antigens into the body fluids of the organism and the helper T cells detect these too. Thus, a simple definition of an antigen is any substance that is foreign to the organism that is exposed to it, and which the organism's immune system can detect specifically and attack.

You learned about the family of white blood cells called lymphocytes (pronounced 'lim-foh-sites') in the study sessions on HIV/AIDS in Part 3 of the *Communicable Diseases* Module.

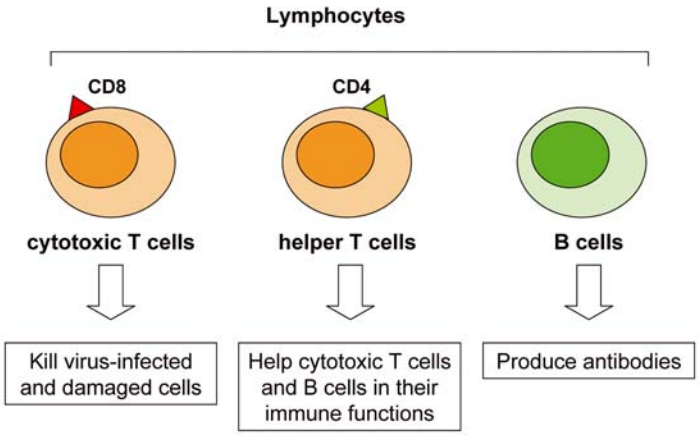


Figure 1.2 Three types of lymphocytes involved in the immune response against infectious agents in the human body. (Diagram: Dr Ignacio Romero)

The surface molecules labelled CD8 and CD4 are unique 'markers' of these cells

The helper T cells activate ('help') the rest of the immune system to attack the specific infectious agents they have detected in our bodies. In particular, they help two other types of lymphocytes shown in Figure 1.2. The *cytotoxic T cells* kill our own cells which have become damaged or infected by viruses.

The *B lymphocytes* or **B cells** make special proteins called *antibodies* in response to infectious agents getting into the body. **Antibodies** are proteins made by B cells, which circulate in the blood or body fluids and attach to the antigens in (or released by) infectious agents. Infectious agents that have antibodies attached to them are neutralised, or destroyed, by the person's immune system.

The helper T cells also cause the production of long-lived **memory cells**, which circulate in the body for years, sometimes for the person's whole life. These cells 'remember' that they have met the infectious agent in the past — either during an infection, or through immunization — and they direct a rapid and effective immune attack against it if it ever gets into the body again.

1.1.2 What is immunization?

'Vaccination' refers simply to the administration of a vaccine, whereas 'immunization' means that the person developed immunity as a result of being vaccinated (or immunized).

The principle in **immunization** is to introduce a harmless preparation of the antigens from an infectious agent into the body of a person, who becomes immune to the infectious agent as a result. The harmless preparation of antigens is called a **vaccine** (pronounced 'vax-een'). It is made from killed or weakened viruses or bacteria, or antigens extracted from the infectious agents. Immunization should happen *before* the person develops a vaccine-preventable infection, so vaccines are usually given to babies and young children, either by injection or swallowing liquid drops. However, you should note that there are many communicable diseases that *cannot* be immunized against at the present time, because a suitable vaccine does not yet exist.

- Can you think of two very important communicable diseases which do not yet have a vaccine?

- You may have thought of malaria and HIV/AIDS.

1.2 Types of specific immunity

Specific immunity can be naturally or artificially acquired, in both cases through either 'active' or 'passive' mechanisms. In this section, we will briefly distinguish between these four types of specific immunity.

1.2.1 Naturally acquired immunity

Naturally acquired immunity occurs 'naturally' without any intervention from a health professional. The difference between the 'active' and the 'passive' forms depends on whether the immune person makes the antibodies themselves (actively), or gets them from someone else (passively).

Naturally acquired active immunity

Naturally acquired active immunity occurs after an infection activates the person's immune system. For example, non-immunized children who develop measles and recover from the illness, get better because they have made an effective immune response against the measles virus. As a result, they acquire protection from measles for the rest of their lives (i.e. they are *immune* to measles). They have *naturally acquired* active immunity because the protection developed naturally in their bodies, without a vaccine being given. The immunity is *active* because the children produced their own antibodies and memory cells, which *specifically* attack any invading measles viruses they meet in the future.

Naturally acquired passive immunity

Naturally acquired passive immunity occurs when a mother gives her own antibodies to her baby, transferring them from her blood to the fetal blood across the placenta, or giving them to the baby in her breastmilk. The immunity created by these **maternal antibodies** is *naturally acquired* from the mother (without any medical intervention). During the first few months of a baby's life, until the mother stops breastfeeding, her antibodies provide *passive* protection to the baby against infectious agents that the mother has encountered during her own life. The term 'passive' is used because the baby didn't produce the antibodies itself. The active production of antibodies by the immune system of the baby takes several years to develop properly.

Information about fetal, maternal and placental circulation is given in Box 5.2 in Study Session 5 of the *Antenatal Care* Module.

Do you know that the tetanus vaccine given to a mother during antenatal care will also protect the newborn infant from tetanus for the first few weeks or months of its life? This is because the maternal antibodies against tetanus bacteria cross the placenta and get into the fetus.

1.2.2 Artificially acquired immunity

In **artificially acquired immunity** the person must be artificially and intentionally exposed to foreign antigens (actively), or given someone else's antibodies (passively), in order to generate a protective immune response.

Artificially acquired active immunity

Artificially acquired active immunity is protection produced by intentional exposure of a person to antigens in a vaccine, so as to produce an active and lasting immune response. The antigens in the vaccine stimulate the immune system to produce antibodies and memory cells which are *specifically*

directed against the antigens in the vaccine. After the immunization, if the living infectious agents with the *same* antigens that were in the vaccine get into the person's body, the correct antibodies are already present and they bind to the infectious agents. The memory cells generate a rapid immune response from the rest of the immune system, and the infectious agents are quickly attacked and destroyed, often before symptoms of the disease can develop.

Vaccine doses

Some vaccines are given as a single dose, but others are given as a course of three doses at intervals of a few weeks. Some vaccines also require a 'booster dose' five to ten years after the original immunization. This is necessary to increase the immune response and ensure an adequate level of protection.

Once established, the protection provided by immunization usually lasts for several years, or even for life. This makes immunization a highly effective method of giving long-lasting immunity.

Artificially acquired passive immunity

Artificially acquired passive immunity is protection acquired by giving a person an injection or transfusion of antibodies made by someone else. These antibodies neutralise the infectious agents in the usual way, but the protection lasts only a few weeks because the antibodies gradually break down and are not replaced. In artificial passive immunization there is no involvement of the person's own immune system.

1.2.3 Summary of types of specific immunity

Table 1.1 gives a summary of the four different types of specific immunity, with examples to illustrate each of them.

Table 1.1 Summary of different types of specific immunity.

Type of specific immunity		**Example of how immunity might be acquired**
Naturally acquired immunity	Active	Infection
	Passive	Maternal antibodies crossing the placenta, or in breastmilk
Artificially acquired immunity	Active	Intentional exposure to antigens in a vaccine
	Passive	Injection or transfusion of someone else's antibodies

- ■ You give a polio vaccination containing polio antigens to a baby girl. What type of immunity will the child develop? Explain your answer.

- □ The child will develop artificially acquired active immunity. She was deliberately exposed to polio antigens in the vaccine, so her immunity is artificially acquired. She produced her own antibodies and memory cells directed against the polio antigens, so her immunity is active.

1.2.4 Herd immunity

Herd immunity refers to the level of resistance against a specific communicable disease in the community as a whole. When a high proportion of a community is immune to a particular disease that spreads from person to person (e.g. measles), the infectious agents causing that disease find it difficult to infect any non-immune (susceptible) people. This could result in the infection 'dying out' in that community, because there are not enough infected people to act as a reservoir for the infectious agents. A high level of herd immunity benefits everyone, because it makes it more difficult for a particular infection to spread from person to person through that community.

- Suggest two ways in which the level of herd immunity can increase in a community.

- If a vaccine exists, immunization of a large proportion of community members is the best way to increase their herd immunity. If there is no vaccine, but a large proportion have suffered from a particular infection in the past and recovered from it, herd immunity increases because many people have naturally acquired active immunity (Figure 1.3).

Note that herd immunity is not relevant in communicable diseases where the main reservoir of infectious agents is the environment (e.g. tetanus), or in other animals (e.g. rabies). Susceptible people can still be exposed to these infectious agents, even if herd immunity is very high, because they do not usually spread from person to person.

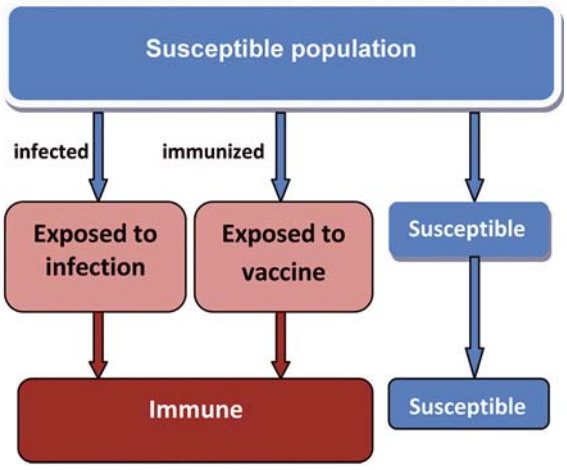


Figure 1.3 Herd immunity can increase in a community through exposure to infection or to a vaccine. (Diagram: Basiro Davey)

The aim of a comprehensive immunization programme is to raise the level of herd immunity so that almost everyone in the population is immune. The **immunization coverage rate** is the proportion of the population that has been immunized. An immunization coverage rate of over 80% can produce effective herd immunity for some communicable diseases. However, some infectious agents, such as the measles virus, are so easily spread from infected to susceptible people that they require much higher immunization coverage rates — close to 100% — in order to produce effective herd immunity.

1.3 Types of vaccines

Let's now move on to look at the various types of vaccine. You might have been immunized by injection yourself, or seen children being given immunization by oral drops. What are the differences between these vaccines, and what do they contain?

Vaccines are made from weakened or killed bacteria or viruses, or extracts taken from them, which are intended to produce immunity against a disease. At present, there are no vaccines in the EPI in Ethiopia to prevent infections by fungi, protozoa, parasites or many other important bacterial and viral diseases — but researchers are trying to develop new vaccines, particularly against malaria and HIV. You will learn about the main **antibacterial vaccines** (which protect against bacterial infections) in Study Session 2 and the main **antiviral vaccines** (which protect against infections by viruses) in Study Session 3. Here we describe the five general types of vaccine and how they are made safe to use in the human body. They are:

- live-attenuated vaccines
- inactivated vaccines
- sub-unit vaccines
- recombinant vaccines
- conjugate vaccines.

1.3.1 Live-attenuated vaccines

Live-attenuated vaccines are prepared from viruses or bacteria that are whole, active and able to cause infection, but they have been weakened in the laboratory. The term 'attenuated' (pronounced 'at-ten-you-ay-ted') means 'made weak', so the infectious agents in the vaccine should cause no disease at all.

Measles vaccine and oral polio vaccine (OPV) are live-attenuated antiviral vaccines. Bacillus of Calmette and Guerin (BCG) is a live attenuated antibacterial vaccine (named after its French inventors) that protects infants and young children against severe forms of tuberculosis (TB).

Live-attenuated vaccines generally activate the immune system very effectively, because they cause a similar reaction in the body as if to a natural infection. For example, a single dose of measles vaccine produces lifelong protection against measles because it is highly **immunogenic**, i.e. it has a very high ability to produce immunity.

If a mild fever and small rashes appear in a child you have vaccinated against measles, tell the mother not to worry. Reassure her that her child will be protected against the more serious measles disease.

However, live-attenuated vaccines can sometimes produce a weakened disease pattern in a small proportion of vaccinated children. For example, measles vaccines can induce fever and an occasional rash, but this is very unusual and is nothing to worry about. The live-attenuated oral polio vaccine (OPV) can very rarely cause a type of paralysis, but on average this happens in only one child in every 1–10 million vaccinated children.

1.3.2 Inactivated vaccines

The pentavalent vaccine used in the EPI in Ethiopia contains five vaccines and is sometimes referred to as DPT-HepB-Hib vaccine. The letters refer to diphtheria-pertussis-tetanus-hepatitis B-*Haemophilus influenzae* type b.

Whole-cell **inactivated vaccines** are produced by first growing viruses or bacteria in the laboratory and then inactivating (killing) them with heat or chemicals. Because they are not alive, they cannot cause the disease. The pertussis component of the pentavalent vaccine used in the EPI in Ethiopia is an example. The whole-cell inactivated version of this vaccine contains the *Bordetella pertussis* bacteria, which cause whooping cough, but they have been killed so that they are no longer harmful.

- Even though they cannot cause infection in the immunized person, the infectious agents in an inactivated vaccine are still immunogenic. What does this mean?

- They are still capable of causing a strong immune reaction in the immunized person, which usually protects him or her from that particular infection in the future.

1.3.3 Sub-unit vaccines

Sub-unit vaccines are made from parts of infectious agents, or certain chemicals produced by bacteria. Because the vaccine does not contain whole organisms, they cannot cause disease in immunized people. The diphtheria and tetanus components of the pentavalent vaccine are of the sub-unit type. Diphtheria and tetanus bacteria each produce special **toxins** — harmful chemicals that cause the symptoms of these diseases. The pentavalent vaccine contains diphtheria and tetanus **toxoids** — modified versions of the bacterial toxins, which have been developed in a laboratory. The toxoids don't cause disease symptoms, but they do stimulate a protective immune response in vaccinated people. A sub-unit version of the pertussis vaccine now exists and is increasingly being used instead of the older whole-cell inactivated version.

1.3.4 Recombinant vaccines

Recombinant vaccines are produced by inserting genetic material from a disease-causing organism into a harmless cell, which then makes lots of copies of the antigens of the infectious agent. The antigens are then purified and used as a vaccine. An example is hepatitis B vaccine (the HepB component of the pentavalent vaccine used in Ethiopia).

1.3.5 Conjugate vaccines

A **conjugate vaccine** is made by conjugating (joining together by chemical bonds) an antigen from an infectious agent and a large 'carrier' protein. The combination makes the antigen more immunogenic than it would be on its own. An example is the *Haemophilus influenzae* type b (Hib) vaccine included in the pentavalent vaccine in Ethiopia.

Now we turn our attention to how these vaccines are used in Ethiopia.

1.4 The Expanded Programme on Immunization

The **Expanded Programme on Immunization** (**EPI**) began in 1974 when the World Health Assembly pledged to ensure that all children in all countries receive life-saving vaccines. Each year, immunization now prevents more than 2.5 million deaths among children worldwide. An additional 2 million lives could be saved if available vaccines reached every child.

Ethiopia started the EPI in 1980 to reduce mortality and morbidity from vaccine-preventable diseases among children and mothers. The immunization coverage rate has been increasing since that time, but not as fast as the original target. The Ethiopian Federal Ministry of Health (FMOH) has prepared a plan to increase the immunization coverage rate to 80% of the population in 90% of the *woredas* (districts) in the country. Health Extension Practitioners like you can play a major part in the success of this plan.

1.4.1 Vaccine-preventable diseases in the EPI in Ethiopia

The vaccine-preventable diseases included in the EPI in Ethiopia are:

- tuberculosis (TB)
- poliomyelitis (polio)
- diphtheria
- pertussis (whooping cough)
- tetanus
- measles
- pneumonia and meningitis caused by *Haemophilus influenzae* type b bacteria
- liver disease caused by hepatitis B viruses
- pneumonia and other infections caused by *Streptococcus pneumoniae* bacteria
- diarrhoeal diseases caused by rotaviruses (joining the EPI soon).

In order to achieve the EPI objectives, the FMOH has outlined five strategies that are applicable throughout the country (see Box 1.1). Next we will examine each of them in turn and consider what you can do to progress these strategies.

Box 1.1 EPI strategies

- Increase and sustain high immunization coverage rates
- Increase the quality of immunization services
- Reduce missed vaccination opportunities and trace defaulters
- Improve public awareness and community participation in immunization programmes
- Ensure prompt reporting and improved control of vaccine-preventable diseases.

1.4.2 Increase and sustain high immunization coverage rates

The key to increasing and sustaining *high immunization coverage rates* is to increase the *accessibility* of immunization services, particularly by opening more vaccination delivery sites at times when mothers can bring their infants. As you know, many children are not immunized because they live far away from health facilities. These children could be given the opportunity to be vaccinated through establishing outreach services, supported by mobilisation teams going from house-to-house identifying children (and mothers) who need vaccinations.

You might also have seen health workers giving immunizations in your community in well-publicised campaigns that encourage parents to bring children to the *kebele* office or the Health Post for vaccination. The progress achieved by the Health Extension Workers at one Health Post can be seen in Figure 1.4. Planning and managing your routine immunization activities are described in detail in Study Session 8, and communication for an effective immunization service is in Study Session 9.

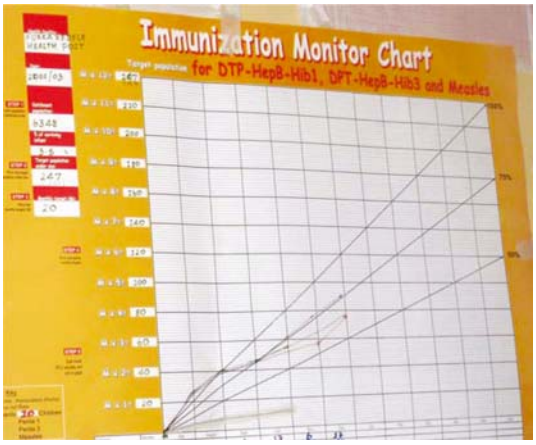


Figure 1.4 Increasing immunization coverage rates achieved in one year at Fura Health Post in the Southern Nations, Nationalities and Peoples Region (SNNPR) of Ethiopia. (Photo: Janet Haresnape)

1.4.3 Increase the quality of immunization services

A successful immunization service has to be of *high quality*. This means that you must use safe injection practices, and all the required vaccines and other supplies must be available in good condition, and on a regular and timely basis. Poor quality vaccines will not prevent illness. Therefore, to improve the EPI, you need to keep the vaccines at the proper temperature, take good care of the injection equipment and ensure reliable vaccine stock control.

In Study Sessions 5–10, you will learn how to introduce and use quality assurance methods to improve the efficiency and quality of the immunization service at your Health Post

You also need to have good interpersonal communication, supportive supervision and skilled manpower to plan and conduct an effective immunization programme. By increasing your skills as a Health Extension Practitioner, you can play an important role in immunizing all the children in your area. Reaching every child should be your goal.

1.4.4 Reduce missed vaccination opportunities and trace defaulters

It is common in Ethiopia to see many children and mothers who have been to a health facility, but have not been immunized. Thus, another important strategy is to *reduce missed opportunities and trace defaulters.*

Reasons for missed immunizations

It is important that you check whether or not children and mothers are immunized *whenever* they come into contact with the health service. If they have missed the opportunity of being immunized during their earlier visits, then you should immunize them. You will learn how to give immunizations in Study Session 4.

Sometimes some children are not given the vaccine at the right time because they have a **contraindication** — a medical reason for *not* giving the vaccine either temporarily or permanently, such as a serious illness or high-grade fever (38.5ºC or above). Contraindications are described in Study Sessions 2, 3 and 7. However, very few children have genuine reasons for not vaccinating them at all. Immunization should not be missed if the child has a mild illness.

Tracing defaulters

Have you come across children who started the immunization programme, but have not completed the schedule? These children are still at risk of vaccine-preventable diseases. It is therefore essential to keep a proper registration system of vaccinations, and to establish a community network for tracing **defaulters** — i.e. people who fail to complete a course of immunization or treatment. You will learn about EPI registration and defaulter tracing in Study Session 8 and a system for identifying them in Study Session 10.

1.4.5 Improve public awareness and community participation in immunization programmes

In the EPI, you are expected to improve public awareness through intensive, regular social mobilisation and health education campaigns, in order to:

- maximise participation of community members in EPI activities
- increase public demands for immunization and the vitamin A supplements that are routinely given to infants during the immunization programme.

The techniques for involving the whole community are described in the Module on *Health Education*, *Advocacy and Community Mobilisation*.

It is very important to involve the whole community, including political and religious leaders, through seminars, public meetings and direct contacts. You should aim to work with and fully utilise women's groups, youth associations and *idirs* (self-help associations at village level), so that they support and help to promote the immunization service (see Study Session 9).

1.4.6 Ensure prompt reporting and improved control of vaccine-preventable diseases

Reporting formats for immediately reportable and weekly reportable cases of priority diseases are in Study Session 41 of the *Communicable Diseases* Module, Part 4.

It is a key part of your role to identify cases of vaccine-preventable diseases, such as measles, polio, neonatal tetanus and bacterial pneumonia and meningitis, and report them to your supervising Health Centre, who will report to the District (*woreda*) Health Office. Control of these diseases is largely the result of effective immunization campaigns achieving high immunization coverage rates, and the isolation and treatment of people who are infected, to reduce the risk of infection spreading into the susceptible population.

1.5 Your role in achieving the goals of the EPI

Your role as a Health Extension Practitioner is to lead the following activities, based on the national EPI recommendations:

- Take every opportunity to identify and immunize all eligible children.
- Ensure all eligible children attending the Health Post are immunized according to the recommended schedules.
- Make immunization services routinely available at convenient times for mothers, ideally every day.
- Involve the community in the schedule for outreach immunization sessions, so that you cover the target population within the target period.

There are five key operations that you need to undertake to run an EPI service efficiently and effectively, which are summarised in Box 1.2. You will learn about these key operations in detail in later study sessions in this Module.

Box 1.2 Five key operations for an effective immunization service

1. Service delivery: involves strategies and activities in giving safe and timely vaccinations.
2. Logistics: includes delivery of vaccines and necessary equipment to the site of use, transport, management of the 'cold chain' and safe waste disposal.
3. Vaccine supply and quality: includes forecasting of vaccine needs, procurement, monitoring of vaccine usage rates and vaccine safety.
4. Disease surveillance: involves monitoring of disease incidence, record keeping and reporting (see the *Communicable Diseases* Module, Study Sessions 39 to 41).
5. Advocacy and communication: consists of social mobilisation, advocacy, community education on immunization and vaccination programme promotion.

The diagram on the left of Figure 1.5 summarises the five operational components listed in Box 1.2, and the diagram on the right reminds you that in order to achieve them there must also be:

- sustainable financing
- management
- strengthening human and institutional resources.

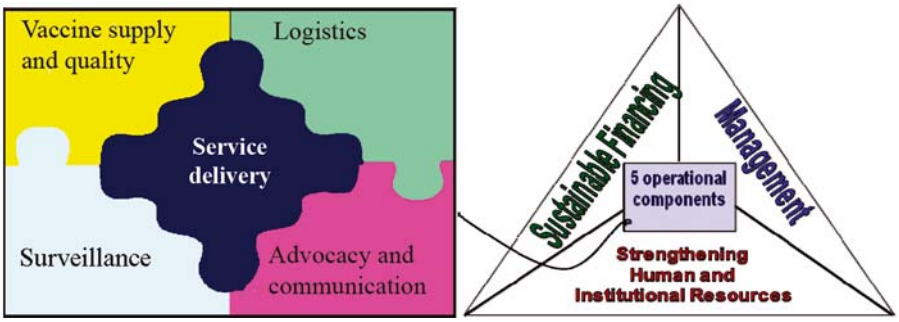


Figure 1.5 (left) The five key immunization operations, and (right) the three additional requirements for achieving an effective immunization service.

In the next two study sessions, you will learn the details of the antibacterial and antiviral vaccines used in the EPI in Ethiopia.

Summary of Study Session 1

In Study Session 1, you have learned that:

1 Immunization is beneficial and effective in the prevention of disease, death and disability from vaccine-preventable diseases. Worldwide, more than 2.5 million childhood deaths are prevented by immunization each year.

2 The vaccine activates the immune system to produce antibodies and memory cells, which identify and attack infectious agents used in making the vaccine if the live organisms get into the body in the future.

3 Immunity is the state of being resistant to a particular infection; it can be naturally or artificially acquired, either as active or passive immunity.

4 Immunization of over 80% of the population gives protection to the susceptible population in a community through herd immunity to vaccine-preventable diseases that are transmitted from person to person.

5 Vaccines can be prepared as live-attenuated or killed (inactivated) vaccines, or as sub-unit, recombinant or conjugate vaccines.

6 The vaccine-preventable diseases targeted in the Expanded Programme on Immunization (EPI) in Ethiopia are: tuberculosis (TB), poliomyelitis (polio), diphtheria, pertussis (whooping cough), tetanus, measles, pneumonia and meningitis caused by *Haemophilus influenzae* type b bacteria; pneumonia and other infections caused by *Streptococcus pneumoniae* bacteria; and hepatitis B diseases of the liver and diarrhoeal disease caused by rotaviruses.

7 To achieve the objectives of the EPI, you have an important role in implementing the national strategies to increase and sustain high immunization coverage, increase the quality of the immunization service, reduce missed vaccinations and trace defaulters, improve public awareness

and community participation in immunization programmes, and ensure prompt reporting and improved control of vaccine-preventable diseases.

8 Immunization activities consist of five key operational components: service delivery, logistics, vaccine supply and quality, disease surveillance, advocacy and communication. In addition, sustainable financing, effective management and strong human and institutional resources are also required.

Self-Assessment Questions for Study Session 1

Now that you have completed this study session, you can assess how well you have achieved its Learning Outcomes by answering these questions. Write your answers in your Study Diary and discuss them with your Tutor at the next Study Support Meeting. You can check your answers with the Notes on the Self-Assessment Questions at the end of this Module.

SAQ 1.1 (tests Learning Outcomes 1.1 and 1.2)

When the immunization coverage rate is high, the herd immunity of a community is increased. Explain what this means and how everyone in the community benefits from it — including people who are not immune — in the case of a disease like measles, which is transmitted from person to person.

SAQ 1.2 (tests Learning Outcomes 1.1 and 1.2)

You see a breastfed baby who appears to be immune to measles, even though he has not been vaccinated. His older brother has measles, but the baby has not developed the illness. How can this happen, and what is this type of immunity called?

SAQ 1.3 (tests Learning Outcomes 1.1, 1.2 and 1.3)

(a) What type of vaccine is the diphtheria component of the pentavalent vaccine?

(b) Explain how immunization with the pentavalent vaccine gives protection from diphtheria.

(c) What is this type of immunity called?

SAQ 1.4 (tests Learning Outcome 1.4)

The EPI was started many years ago, but it did not reach its original target of increasing the immunization coverage rate by 10% every year. The EPI has drawn up strategies to improve the immunization service in Ethiopia. How can you help to implement these strategies?

Study Session 2 Antibacterial Vaccines

Introduction

You learned about the main vaccine-preventable bacterial diseases in Study Session 3 of the *Communicable Diseases* Module, Part 1.

The most effective way of reducing the major vaccine-preventable diseases is to maintain a high level of immunization in the whole population, using the routine Expanded Programme on Immunization (EPI) vaccines. In this study session, you will learn about the antibacterial vaccines that are approved for routine use in Ethiopia for preventing some common bacterial diseases, and the storage, dosages and schedules for immunization with these vaccines.

This study session will also help you to give clear information about vaccination to the people in your community, including the importance of giving the vaccines as scheduled to their children – even though it makes them cry for a short time (Figure 2.1). Reassure parents about the low risk of adverse events following immunization (AEFIs) and how to manage vaccine reactions if they occur.

Figure 2.1 Immunization saves millions of children's lives. (Photo: AMREF Ethiopia/ Demissew Bizuwork)

As you learned in Study Session 1, **contraindication** — in the context of immunization — means a medical reason for *not* giving the vaccine, either temporarily or permanently. Note that children with a mild illness should still be immunized at the scheduled time. Contraindications, such as a **high-grade fever** (38.5°C or above), mean you should refer the child to a health centre and wait until they recover before giving the missed vaccine dose. Specific contraindications for each vaccine are given in the sections that follow.

Learning Outcomes for Study Session 2

When you have studied this session, you should be able to:

2.1 Define and use correctly all of the key words printed in **bold**. (SAQs 2.1 and 2.5)

2.2 Describe the antibacterial vaccines included in the Expanded Programme on Immunization (EPI) in Ethiopia. (SAQs 2.1, 2.2 and 2.4)

2.3 Describe the storage, dosages and schedules of the antibacterial EPI vaccines. (SAQs 2.1 and 2.2)

2.4 Describe the possible adverse events following immunization with the antibacterial EPI vaccines and how you manage them at Health Post level. (SAQs 2.3 and 2.4)

2.5 Describe the contraindications that mean you should not immunize a child with one of the antibacterial EPI vaccines. (SAQs 2.3 and 2.5)

2.1 BCG vaccine

2.1.1 What is BCG?

Tuberculosis diagnosis and treatment is fully described in Study Sessions 13 to 17 in the *Communicable Diseases* Module, Part 2.

You have already learned about the different types of vaccines in Study Session 1. **BCG** is a *live-attenuated* antibacterial vaccine that protects against severe forms of tuberculosis in infants and young children. **Tuberculosis** (**TB**) is a disease caused by the bacterium *Mycobacterium tuberculosis*. It

usually attacks the lungs, but can also affect other parts of the body, including the bones, joints and brain. The letters, B, C and G stand for Bacillus of Calmette and Guerin.

Bacillus describes the rod shape of the tuberculosis bacteria; Calmette and Guerin are the names of the people who developed the vaccine.

■ What does a **live-attenuated antibacterial vaccine** mean?

□ Bacteria in the vaccine are alive, but they have been weakened (attenuated) in the laboratory so that they cannot cause the disease.

2.1.2 Effectiveness of BCG vaccine

The **effectiveness** of a vaccine means its capability to protect vaccinated people from the disease that immunization aims to prevent. In the case of BCG vaccine, the effectiveness is highly variable — protection from TB ranges from 0–80% of those who are vaccinated. This means that some vaccinated individuals may not be protected against TB at all, and up to 80% of the others will receive some protection. The strongest reason for vaccinating with BCG is that it protects young children against developing the more serious forms of tuberculosis, such as TB meningitis (affecting the brain), TB in both lungs and extra-pulmonary TB (affecting other organs).

2.1.3 BCG vaccine storage, dosage and immunization schedule

BCG vaccine is a freeze-dried powder, supplied in small glass bottles called *ampoules*. Vaccines that come as powders must be mixed with a liquid called a **diluent**. This process is known as **reconstitution**, which means thoroughly mixing the powder with the diluent to activate the vaccine before it can be administered. Before use, you must reconstitute BCG vaccine powder with the appropriate diluent supplied for this purpose, using a mixing syringe to mix the diluent with the powder in the ampoule. You will learn how to do this in Study Session 4.

BCG storage

BCG vaccine can be also affected and damaged by heat and light, so it should be stored between +2°C and +8°C. The vaccine powder may be frozen for long-term storage, but the diluent and the reconstituted vaccine must never be frozen. Since BCG vaccine is easily destroyed by sunlight, the vials containing the vaccine powder are mostly made from black or brown glass. Some other vaccines which are supplied as powders can stay in good condition for a long time in a refrigerator and are not spoiled as long as they remain dry. But BCG vaccine can be spoiled and lose its strength in a very short time. Also, since other harmful bacteria can grow in the reconstituted BCG vaccine, it should be used within six hours of mixing the powder with the diluent. If there is any leftover reconstituted BCG vaccine, it should be thrown away in the correct medical waste container at the end of the immunization session.

BCG dosage and schedule

The recommended injection dose for newborns and infants under one year is 0.05 ml, containing 0.05 mg of BCG vaccine powder which has been reconstituted with 0.05 ml of the specific diluent supplied with the vaccine.

For children aged over one year, the dose is twice this amount — 0.1 ml containing 0.1 mg of BCG vaccine powder.

How to give an intradermal injection and other vaccination routes are described in detail in Study Session 4 of this Module.

BCG vaccine is given at birth or as soon as possible thereafter. The vaccine is given **intradermally** (into the top layer of the skin) in the *right* upper arm in Ethiopia. This is so the injection site can be inspected later.

Table 2.1 summarises the characteristics of the BCG vaccine. The only reason for *not* giving the BCG vaccine is if the newborn has symptoms of HIV-disease, which may include a high-grade fever. You will learn more about routes of administration and cold storage of all the common vaccines, including BCG, in Study Sessions 4 and 6 of this Module.

Table 2.1 Summary of BCG vaccine characteristics.

Category	**Description**
Type of vaccine	Live-attenuated antibacterial vaccine
Number of doses	One
Schedule	At birth, or as soon as possible after birth. If not given at birth, it is better to give within the first three months, when the infant is at greatest risk of developing the most severe forms of TB, such as TB meningitis. Immunization is generally ineffective at older ages.
Booster (additional dose)	None
Contraindications	Babies or infants showing symptoms of HIV infection
Adverse events	Study Session 7 discusses AEFIs, adverse events following immunization, more generally. Mild normal reaction (swelling, small sore). Rarely, severe reaction, e.g. local abscess, or swelling of glands (lymph nodes)
Special precautions	Correct intradermal administration is essential. A special syringe and needle is used for the administration of BCG vaccine (described in Study Session 4)
Dosage	BCG vaccine is given in the *right* arm in Ethiopia, but in the left arm in some other countries. Infants aged under one year, give 0.05 mg of BCG vaccine powder reconstituted in 0.05 ml of diluent; over one year, give 0.1 mg in 0.1 ml of diluent
Injection site	Outer upper right arm or shoulder. Routes of administration are described in Study Session 4
Injection type	Intradermal (into the top layer of skin). Types of injection are described in Study Session 4
Storage	Store between +2°C and +8°C. BCG vaccine powder may be frozen for long-term storage, but the diluent and reconstituted vaccine must never be frozen. Discard any reconstituted vaccine after no more than six hours. Vaccine storage is described in Study Session 6

2.1.4 Adverse events following BCG immunization and how to treat them

Adverse events may occasionally occur after immunization, in addition to the desired protective effect. They can include swelling and tenderness at the injection site. For BCG immunization, the *normal reaction* is a small raised swelling, which immediately appears at the injection site (Figure 2.2). This usually disappears within 30 minutes.

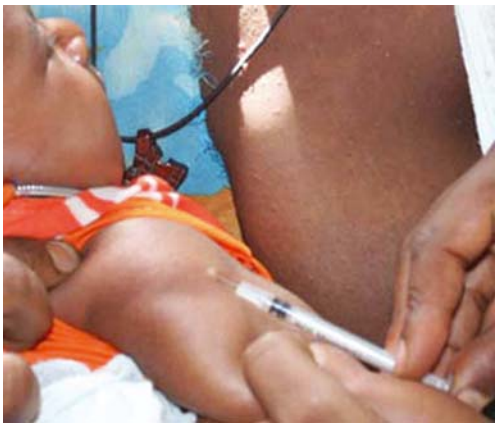


Figure 2.2 A small raised swelling can be seen at the site of an intradermal BCG injection. (Photo: AMREF Ethiopia/Demissew Bizuwork)

After approximately two weeks, a small red sore normally develops at the injection site, which is about 10 mm in diameter (the size of the unsharpened end of a pencil). The sore remains for about another two weeks and then heals, leaving a small scar about 5 mm across (Figure 2.3). This is a sign that the child has been effectively immunized. If there is no scar at the injection site six weeks after a BCG immunization, the injection must be repeated. If there is still no skin reaction to the second injection, the child should be referred to a higher-level health facility.

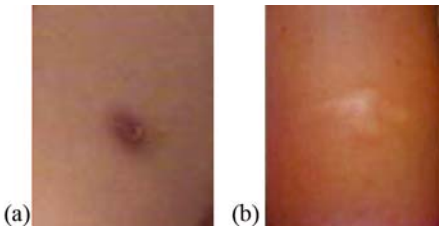


Figure 2.3 (a) The small sore at the injection site is a sign that the child has been effectively immunized with BCG vaccine. (b) A healed BCG vaccination scar on the arm of an adult. (Photos: supplied by Dr Kalid Asrat and Dr Basiro Davey)

Occasionally, there is an *abnormal adverse event* following BCG immunization, such as swelling of glands in the armpit, or rarely the formation of an abscess at the injection site (Figure 2.4).

An **abscess** is a collection of pus and inflamed tissue at the site of bacterial infection. It can be due to bacterial causes other than BCG.

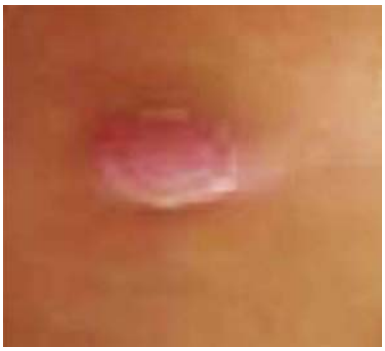


Figure 2.4 An abscess is a rare adverse event following BCG immunization. This one is about 1.5 cm in diameter, but they can be larger. (Photo: supplied by Dr Kalid Asrat)

Abnormal adverse events following BCG vaccination may occur because:

- an unsterile needle or syringe was used
- too much vaccine was injected
- the vaccine was injected too deeply under the skin, instead of into its top layer.

Table 2.2 summarises the adverse events that may occur following BCG immunization and how you can treat them at Health Post level.

Table 2.2 Adverse events following BCG immunization and their management.

Adverse events	**Management**	**Comments**
Small sore at the site of injection after two weeks, which may last two weeks	Keep dry and clean (do not put any ointment on the sore or give the child any medicine)	Will heal naturally to leave a small scar
Swollen glands (lymph nodes) in the armpit	Surgical or drug treatment may occasionally be required at a health centre	Refer the child to a health centre
Abscess at the injection site	Amoxicillin syrup is an antibiotic preparation used to treat bacterial infections, which is available at Health Post level. Amoxicillin syrup orally three times daily.	Refer the child *urgently* to the next higher health facility

2.1.5 Who should not get BCG vaccine?

The only contraindications for BCG immunization are symptoms of HIV infection. These include chronic lung infection, tuberculosis, persistent diarrhoea and other serious symptoms of HIV-related diseases, as described in the *Communicable Diseases* Module, Part 3.

2.2 Pentavalent vaccine

2.2.1 What is pentavalent vaccine?

A vaccine that contains five different antigens in one combined preparation is called a **pentavalent vaccine** ('penta' comes from the Greek word for five). You do not need to remember these details, but the pentavalent vaccine in common use in Ethiopia is a combination of one *inactivated* whole-cell vaccine (against pertussis bacteria), two *sub-unit* vaccines (the diphtheria and tetanus toxoids), one *conjugate* vaccine (against *Haemophilus influenza* type b bacteria) and one *recombinant* vaccine (against hepatitis B virus). Thus, the pentavalent vaccine used in Ethiopia in the EPI combines five different vaccines in one injection to protect against four bacterial diseases: diphtheria, tetanus, pertussis and *Haemophilus influenzae* type b (often abbreviated to Hib), and one viral disease caused by hepatitis B viruses. It is a fully liquid vaccine, which comes in a single dose vial.

Sometimes you will see the pentavalent vaccine used in Ethiopia described as DPT-HepB-Hib vaccine. This is the term used in the *IMNCI* Module in this curriculum.

- What is an **inactivated antibacterial vaccine**?

- It consists of bacteria that have been killed so that they cannot cause the disease.

- What is a **toxoid**?

- It is a modified version of the toxin (harmful protein) produced by certain bacteria, including those causing diphtheria and tetanus. The toxoid is used in vaccines to immunize against the disease.

2.2.2 The anti-bacterial components of pentavalent vaccine

Three of the antibacterial components in the pentavalent vaccine used routinely in the EPI in Ethiopia are known as DPT (diphtheria-pertussis-tetanus), referring to the three bacterial diseases they prevent. In Ethiopia, DPT is only given in the pentavalent vaccine, but some other countries give DPT as a separate injection. The fourth antibacterial component of the Ethiopian pentavalent vaccine is called Hib, which stands for *Haemophilus influenzae* type b. These four components are described below.

Diphtheria toxoid

Diphtheria toxoid is a sub-unit antibacterial vaccine, made from the modified toxin (poison) produced by the bacteria *Corynebacterium diphtheriae*. The vaccine protects against diphtheria, a serious bacterial infection causing a sore throat, high fever and serious complications which can be fatal. It has become rare in Ethiopia and most other countries where infants are routinely vaccinated against it.

Pertussis vaccine

Pertussis vaccine is an inactivated antibacterial vaccine, which contains killed whole bacterial cells. It protects against pertussis (also known as whooping cough), a highly contagious, acute respiratory infection caused by the bacteria *Bordetella pertussis*.

Tetanus toxoid (TT)

Tetanus toxoid (TT) is a sub-unit antibacterial vaccine, made from the modified toxin produced by the bacteria *Clostridium tetani*. Tetanus is a disease that is acquired through exposure to the spores of these bacteria, which are universally present in the soil. TT vaccine is also given on its own as a 'booster' to women of childbearing age, and we will say more about this in Section 2.4.

Haemophilus influenzae type b (Hib)

Hib vaccine is a conjugate antibacterial vaccine, which protects against pneumonia and meningitis caused by the bacteria *Haemophilus influenzae* type b. These bacteria are the most common cause of bacterial meningitis in children under five years of age in countries where Hib vaccine is not routinely given to all infants. **Meningitis** refers to severe infection of the membranes surrounding the brain and spinal cord, which can rapidly lead to high fever, paralysis and death. *Haemophilus influenzae* type b bacteria are also the second most common cause of bacterial pneumonia in children. (In Section 2.3 you will learn about the vaccine that protects against *Streptococcus pneumoniae*, the most common cause of bacterial pneumonia in children.) **Pneumonia** is a severe infection in the lungs, which causes the air sacs to fill with fluid and pus; this makes breathing painful and difficult, and reduces the oxygen getting into the body. Note that Hib vaccine only protects against diseases caused by type b *Haemophilus influenzae* bacteria (there are other types), and it does not prevent pneumonia or meningitis caused by other infectious agents.

The fifth component of the pentavalent vaccine used in the EPI in Ethiopia protects against the viruses that cause hepatitis B liver disease; we will describe it in Study Session 3, together with the other antiviral vaccines in the Ethiopian EPI.

2.2.3 Storage, dosage and schedule of pentavalent vaccine

Pentavalent vaccine comes in single-dose glass bottles called *vials*, which should be stored at between +2°C and +8°C. It should never be frozen, or allowed to become warmer than +8°C, as this will destroy its effectiveness.

If it is allowed to stand for a long time, fine particles settle to the bottom of the vial leaving a cloudy liquid above them. This is normal. Shake the vial to mix the vaccine with the liquid before using it.

Three doses of 0.5 ml each are given intramuscularly (IM, into the muscle) of the upper outer part of the *left* thigh, before injecting pneumococcal vaccine (PCV10) in the *right* thigh (see Section 2.3.1). The injections are given to infants at the age of 6, 10 and 14 weeks. If an infant misses a scheduled dose, give it as soon as possible and complete the series of three doses — there is no need to start the series of doses over again. Pentavalent vaccine is usually not given after 6 years of age because there is an increased risk of adverse reactions in older children.

The characteristics of immunization with pentavalent vaccine are summarised in Table 2.3.

Table 2.3 Summary of pentavalent immunization characteristics in the Ethiopian EPI.

Category	Description
Type of vaccine	Five different antigens combined, including one inactivated whole-cell vaccine, two sub-unit vaccines (toxoids), one conjugate vaccine and one recombinant vaccine
Number of doses	Three (referred to as Penta1, Penta2 and Penta3)
Schedule	At 6, 10 and 14 weeks of age
Booster (additional doses)	None in males; boosters of tetanus toxoid vaccine are given to women of childbearing age
Contraindications	Severe allergic reaction or encephalopathy to a previous pentavalent immunization (see Section 2.2.5)
Adverse events	Mild local reactions are common (see Section 2.2.5); rarely, injection-site abscess
Special precautions	Usually not given after six years of age because of the increased risk of serious adverse reactions
Dosage	0.5 ml
Injection site	Upper outer left thigh. Injection sites are described in Study Session 4
Injection type	Intramuscular (IM). Types of injection are described in Study Session 4
Storage	Store between +2°C and +8°C. Never freeze. Storage of vaccines is described in Study Session 6

2.2.4 Effectiveness of pentavalent vaccine

On average, 78–95% of individuals who have received three vaccine doses will normally be protected against all five diseases covered by the pentavalent vaccine. This means that in every 100 people who receive three doses, on average, between 78–95 of these individuals will be protected against all five diseases.

2.2.5 Adverse events following pentavalent immunization and how to treat them

The possible adverse events following immunization with pentavalent vaccine are generally mild: serious reactions are very rare (see Section 2.2.6). The mild reactions are:

- *Soreness.* Some children may develop mild soreness, redness, or swelling at the injection site, but this will go away within 1–3 days.
- *Fever.* Some children may develop a mild fever (a temperature of around 37.3°C to 38.4°C, measured with a thermometer in the child's armpit, is termed a **low-grade fever**). It should disappear within a day. Fever that begins more than 24 hours after a pentavalent injection is unlikely to be a reaction to the vaccine and should be investigated.
- *Crying* for more than three hours, mostly because of pain, occurs in up to 1% of infants.

A serious but rare adverse event is an *abscess*, which may develop a week or more after immunization (Figure 2.5), usually because an unsterile needle or syringe was used, or the vaccine was not correctly injected into the muscle. The management of these adverse events at Health Post level is summarised in Table 2.4.

Table 2.4 Management of adverse events following immunization with pentavalent vaccine at Health Post level.

Adverse event	Management	Comments
Low-grade fever (37.3°C to 38.4°C)	Paracetamol syrup, 5 ml as required, up to a maximum of four doses	Will usually disappear within a day
Pain and soreness at the injection site	Paracetamol as above; warm compress (a warm cloth or another warm material) applied under pressure to the sore area of skin and held in place for some time	Will usually disappear within a day
Abscess at the injection site	Amoxicillin syrup orally three times daily	Refer the child *urgently* to the next higher health facility

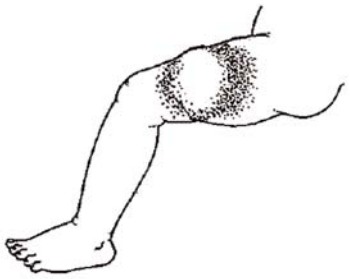


Figure 2.5 An abscess caused by an unsterile needle or syringe, or incorrectly administered pentavalent vaccination. (Source: WHO, 1998, *Immunization in Practice*, Module 2, *EPI Vaccines*, Figure 2-C, p.8)

2.2.6 Who should not get pentavalent vaccine?

Do not give another dose of the pentavalent vaccine if a child develops any of these severe reactions to the first dose:

- **Severe allergic reaction** (doctors call it *anaphylaxis*), which includes severe rash, breathing difficulty, signs of shock, weak and rapid pulse, dizziness or fainting.
- **Encephalopathy**, **(**Enchephalopathy is pronounced 'en-seff-ah-lopp-ah-thee') which is a disease of the brain that presents with coma, decreased level of consciousness and/or prolonged convulsions, occuring within seven days of a pentavalent vaccination, and where the symptoms are not due to another identifiable cause.

A child who develops a severe reaction to the first vaccination should be referred to a higher level health facility immediately.

2.3 Pneumococcal vaccine (PCV10)

Next we describe a new antibacterial vaccine that is being introduced into the routine EPI in Ethiopia.

Pneumococcal infections are described in the *Communicable Diseases* Module, Part 4, Study Session 35.

Pneumococcal vaccines (PCVs) protect against pneumonia and other pneumococcal infections caused by *Streptococcus pneumoniae* bacteria. These bacteria can attack different parts of the body, causing serious infections in the lungs (pneumonia), the inner ear (acute otitis media), the bloodstream (bacteraemia), and the membranes covering the brain and spinal cord (meningitis). The WHO estimates that up to one million children die of pneumococcal infections every year, mainly in sub-Saharan Africa and South East Asia. In Ethiopia, pneumonia is the leading cause of death among children under five years, accounting for 28% of all deaths in this age group.

The *Streptococcus pneumoniae* bacteria exist in many different 'strains'. Several different conjugate pneumococcal vaccines have been developed to give protection against different subsets of these strains. The vaccine that is being introduced in Ethiopia as part of the EPI is called **PCV10**, also known by its brand name *Synflorix*. PCV10 is highly effective at preventing

infections caused by the strains of *Streptococcus pneumoniae* bacteria included in the vaccine preparation.

2.3.1 Storage, dosage and schedule of PCV10

PCV10 is a freeze-sensitive vaccine, which must be stored in the refrigerator between +2°C to +8°C. You should keep the vials on the same shelf of the refrigerator as the vials of pentavalent vaccine because they are given to infants at the same immunization session. The liquid PCV10 does not contain any preservative, so once you have opened a vial, any unused vaccine should be discarded after six hours and not returned to the refrigerator.

The vaccination schedule for PCV10 (*Synflorix*) is the same as for the pentavalent vaccine: three doses are given at 6, 10 and 14 weeks of age by intramuscular (IM) injection into the *right* outer upper thigh muscle (the opposite thigh to the pentavalent vaccine). The dosage for each vaccination with PCV10 is 0.5 ml. The vaccine is a liquid that comes in two-dose vials.

Any child who presents to a health facility for vaccination who is aged less than one year old is eligible to receive PCV10 vaccine if they missed the primary series of doses at 6, 10 and 14 weeks. Children should receive all three doses of PCV10 by their first birthday, but if a child starts their first dose of PCV10 at the age of 11 months, they should complete the remaining two doses at intervals of four weeks. Table 2.5 shows the schedule for PCV10 immunizations for children who have already started the series of pentavalent vaccine doses.

Table 2.5 PCV10 vaccination schedule for children who have received 0 or 1-3 pentavalent vaccine doses. (FMOH, June 2011, *Introduction of Pneumococcal Conjugate Vaccine in Ethiopia: A Reference Handbook for Health Extension Workers*, p.8)

Vaccination status if infant aged less than one year at time of PCV10 introduction	**At first contact**	**Subsequent contact – after 4 weeks**	**Subsequent contact – after 4 more weeks**
Never received any Penta	Penta1 + PCV1	Penta2 + PCV2	Penta3 + PCV3
Already received Penta1	Penta2 + PCV1	Penta3 + PCV2	PCV3
Already received Penta2	Penta3 + PCV1	PCV2	PCV3
Already received Penta3	PCV1	PCV2	PCV3

2.3.2 Adverse events and contraindications of PCV10

Refer all cases of severe vaccine reactions urgently.

Mild local reactions (redness, pain and slight swelling at the injection site) and/or mild fever and irritability of the child may occur in one-third to one-half of the infants vaccinated with PCV10, but these reactions usually disappear within 24 hours. Manage these mild reactions as described earlier in Table 2.4 for pentavalent vaccine. Rare severe reactions to the vaccine include convulsions, severe allergic reaction (anaphylaxis), swollen lymph glands and encephalitis.

The contraindications for PCV10 are the same as for pentavalent vaccine: do not give PCV10 to an infant who comes to you with a high-grade fever, or who developed a severe vaccine reaction after a previous dose. However, you should vaccinate infants with PCV10 if they only have a mild illness, such as a common cold or low-grade fever.

2.4 Tetanus toxoid (TT) vaccine

2.4.1 What is tetanus toxoid vaccine?

The same tetanus toxoid (TT) vaccine that is given to infants in the pentavalent vaccine is also given on its own, as a single vaccine, to women of childbearing age (Figure 2.6). The vaccine is a cloudy liquid, and the powder can settle to the bottom of the vial if it is left to stand for a long time. Shake the vial to mix the vaccine powder and liquid before use.

Figure 2.6 These women are of childbearing age and should be immunized with TT vaccine to protect them and their babies from tetanus. (Photo: AMREF Ethiopia)

■ From your reading of Study Session 1, how do you think immunizing women against tetanus also prevents tetanus in their newborn babies?

□ Neonatal tetanus is a major cause of death in newborns; it is described in detail in Study Session 3 of the *Communicable Diseases* Module, Part 1. The antibodies that form in the mother's body in response to the vaccine pass across the placenta and get into the fetus; they give 'passive' protection against tetanus to the baby during the birth and for the first few months of life.

2.4.2 Schedule, dosage, storage and effectiveness of TT vaccine

If given as a separate vaccine to pregnant and non-pregnant women of childbearing age, at least two doses of 0.5 ml of TT vaccine are given intramuscularly (IM) into the upper arm (Figure 2.7 on the next page); but for maximum long-lasting protection throughout the childbearing years women should receive more than two doses (TT2+), and the ideal is to give five doses. It should be stored at between +2°C and +8°C and never frozen. Table 2.6 summarises the characteristics of TT vaccine; the periods of protection after each dose are given in Table 2.7.

Figure 2.7 Make sure all pregnant women are immunized against tetanus.

Table 2.6 Summary of tetanus toxoid (TT) vaccine characteristics in women.

Category	Description
Type of vaccine	Toxoid (sub-unit vaccine)

Number of doses	Women: at least two doses – ideally five (see Table 2.7)
Schedule	Women: first dose at first contact during childbearing years, or as early as possible in pregnancy (then see Table 2.7)
Booster	Every 10 years during childbearing years
Contraindications	Severe allergic reaction to a previous dose, or encephalopathy
Adverse events	Paracetamol can be given to treat mild reactions, but avoid giving any medication to pregnant women. Mild reactions, e.g. low-grade fever, soreness, redness and pain at the injection site: usually disappears after 1–3 days.
Dosage	0.5 ml
Injection site	Women: outer upper arm
Injection type	Intramuscular (IM)
Storage	Store between +2°C and +8°C. Never freeze

Table 2.7 Duration of protection in women following 1–5 doses of TT vaccine.

Dose (0.5ml)	**When given**	**Duration of protection**
TT1	At first contact with women of childbearing age, or as early as possible in the pregnancy	No protection
TT2	At least 4 weeks after TT1	3 years
TT3	At least 6 months after TT2	5 years
TT4	At least 1 year after TT3	10 years
TT5	At least 1 year after TT4	All childbearing years

2.4.3 Adverse events and contraindications of TT vaccine

The possible adverse events following immunization of women with TT vaccine are usually mild: low-grade fever, and soreness/pain at the injection site (see Table 2.6 above), which can be treated with paracetamol in women who are not already pregnant. Women of child-bearing age who developed a severe allergic reaction or encephalopathy to a previous dose of TT vaccine should not be given TT again.

2.5 Meningococcal vaccines

Finally, we refer to the **meningococcal vaccines** which are in common use in some countries. Although not yet routinely available in the EPI in Ethiopia, these vaccines are used to control outbreaks of meningitis caused by the *Neisseria meningitides* bacteria, which occur in at least six different types. Types A, B, C, Y, W135 and X cause most cases of meningococcal meningitis. *Quadrivalent* vaccines (containing the antigens of four of these types) are available in the USA, and a vaccine specifically designed for Africa is being used in the countries with the highest burden of meningococcal meningitis.

2.6 In conclusion

Table 2.8 summarises the antibacterial vaccines in the Expanded Programme on Immunization (EPI) in Ethiopia. In Study Session 3, we will turn our attention to the antiviral vaccines in the EPI.

Table 2.8 Summary of antibacterial vaccines in the current EPI in Ethiopia.

Vaccine	Protects against	Doses/when	Route
BCG	Tuberculosis	One: at or soon after birth	Intradermal, outer upper right arm
Pentavalent vaccine	Diphtheria, pertussis, tetanus, Hib disease and hepatitis B	Three: at 6, 10 and 14 weeks	Intramuscular, outer upper left thigh
TT	Tetanus	At least two: ideally three to five in women of childbearing age	Intramuscular, outer upper arm
PCV10	Pneumonia caused by some *Streptococcus pneumoniae* strains	Three: at 6, 10 and 14 weeks	Intramuscular, outer upper right thigh

Summary of Study Session 2

In Study Session 2, you have learned that:

1 The most effective way to protect people from the common vaccine-preventable diseases is to maintain a high level of immunization with the vaccines in the routine Expanded Programme on Immunization (EPI).

2 The common EPI antibacterial vaccines used in Ethiopia are: BCG, which protects children against the most serious effects of tuberculosis (TB); a pentavalent vaccine, which protects against diphtheria, pertussis, tetanus, cases of meningitis and pneumonia caused by *Haemophilus influenzae* type b, and hepatitis B liver disease; and PCV10, which protects against pneumonia and some other infections caused by specific strains of *Streptococcus pneumoniae* bacteria.

3 At least two doses of TT vaccine (and ideally five) should also be given to pregnant women and women of childbearing age to protect them and their newborns from tetanus.

4 A meningococcal vaccine is available to control outbreaks of meningitis caused by *Neisseria meningitides* bacteria; it is not a routine EPI vaccine.

5 To guarantee long-term protection, all doses of the routine antibacterial vaccines in the EPI should be given. A child who misses a vaccination should be given the missed dose as soon as possible and complete any remaining doses at the scheduled time.

6 The EPI antibacterial vaccines are very effective and safe for infants, and TT vaccine is safe for women of childbearing age and during pregnancy. Adverse events following immunization are usually mild, e.g. low-grade fever and soreness at the injection site, which can easily be managed; serious adverse events are extremely rare.

7 Infants with minor illnesses may be immunized safely. But if they are suffering from a high fever (38.5°C or above), they should be referred to a health centre; delay the immunization until after they recover. Other contraindications are HIV disease, severe allergic reaction or encephalopathy following a previous dose of a vaccine.

Self-Assessment Questions (SAQs) for Study Session 2

Now that you have completed this study session, you can assess how well you have achieved its Learning Outcomes by answering these questions. Write your answers in your Study Diary and discuss them with your Tutor at the next Study Support Meeting. You can check your answers with the Notes on the Self-Assessment Questions at the end of this Module.

SAQ 2.1 (tests Learning Outcomes 2.1, 2.2 and 2.3)

Which of the following statements is *false*? In each case, say what is incorrect.

A All the antibacterial vaccines in the EPI in Ethiopia are injected intramuscularly in the outer upper arm.

B All of the antibacterial EPI vaccines will lose their effectiveness if they become frozen.

C If five doses of TT vaccine are given to a woman of childbearing age at the correct intervals, she will receive the fifth dose at least 2 years and 7 months after the first dose.

D Most infants who are immunized with three doses of pentavalent vaccine at the correct intervals will be protected against diphtheria, pertussis and tetanus.

E BCG vaccine is supplied as a powder which has to be mixed with a special diluent to activate the vaccine before use.

F If a vial of pentavalent vaccine has a deposit like fine sand at the bottom, you should throw it away.

SAQ 2.2 (tests Learning Outcomes 2.2 and 2.3)

Read Case Study 2.1 and then answer the question that follows it.

Case Study 2.1 Birke's story

Birke is two months' pregnant with her first baby. She is at the antenatal clinic and hears Nurse Ayele telling a group of women about neonatal tetanus, a disease that causes death in newborn babies. Nurse Ayele talks about the injection that women can get to protect themselves and their babies. Birke asks for the injection.

'I am sorry,' says Nurse Ayele, 'I can't give you tetanus toxoid now. It's too early in your pregnancy and it might harm the baby.'

Birke is surprised. She says: 'My friend told me that the health workers in Dembi Health Post give these injections to every woman the first time she goes to the antenatal care clinic, even if she is only one month pregnant. They say it is not dangerous.'

- Who is following the correct procedure: Nurse Ayele or the health workers in Dembi Health Post?

SAQ 2.3 (tests Learning Outcomes 2.4 and 2.5)

Complete Table 2.9 by filling in the management of the adverse events listed.

Table 2.9 Adverse events following immunization with antibacterial vaccines and their management at Health Post level.

Adverse event	**Managment**
Low-grade fever	
Soreness at the injection site	
Abscess at the injection site	
Swollen lymph glands	
Severe allergic reaction (rash, breathing difficulty, rapid pulse, dizziness or fainting)	
Coma and/or convulsions	

SAQ 2.4 (tests Learning Outcomes 2.2 and 2.4)

The mother of a 10-day-old infant visited your Health Post. She told you that her baby has a small sore on her right upper arm following a vaccination given immediately after the birth. What would you tell the mother?

SAQ 2.5 (tests Learning Outcomes 2.1 and 2.5)

What should you do if an infant is brought to you for routine EPI immunization at 14 weeks and you find that he or she has a temperature of 39°C? Is this a contraindication for vaccination?

Study Session 3 Antiviral Vaccines

Introduction

In this study session, you will learn about the antiviral vaccines that are in common use for preventing viral diseases in most developing countries, including Ethiopia, and the recommended dosages and schedules for immunization with these vaccines. There are many other antiviral vaccines available in the world that are not widely used in developing countries, so we will concentrate here on the common antiviral vaccines available for the Expanded Programme on Immunization (EPI) in Ethiopia. These are hepatitis B (HepB) vaccine, oral polio vaccine (OPV) and measles vaccine. You will also be reminded about the need to give vitamin A supplements at the same time as the measles vaccine, and to children who present to you with measles. Then we describe one of the newer antiviral vaccines against rotavirus, which is being added to the EPI. Finally, we mention yellow fever vaccine, which is not in the EPI but may be required for travel abroad.

Studying this session will enable you to give clear information to the people in your community about the value of immunizing their children with these vaccines, which prevent long-term disability and save many millions of lives. You will be able to tell parents that these vaccines are very safe, and any adverse events following immunization are almost always very mild and easily treated. We will also describe the contraindications that mean you should not immunize a child, either temporarily or permanently.

To guarantee long-term protection, all doses of the antiviral EPI vaccines should be given. If a child misses the scheduled date for an immunization, he or she should be given the missed dose as soon as possible. There is no need to re-start the immunization schedule.

Learning Outcomes for Study Session 3

When you have studied this session, you should be able to:

3.1 Define and use correctly all of the key words printed in **bold**. (SAQ 3.1)

3.2 Describe the common antiviral vaccines available in the Expanded Programme on Immunization (EPI) in Ethiopia, and the new rotavirus vaccine that will become available soon. (SAQ 3.2)

3.3 Describe the storage, dosages and schedules of the common antiviral EPI vaccines, and the dosage of vitamin A given routinely with measles vaccine or to children with measles. (SAQs 3.2, 3.3 and 3.4)

3.4 Describe the possible adverse events following immunization with the antiviral EPI vaccines and how you manage them at Health Post level. (SAQ 3.3)

3.5 Describe the contraindications for the antiviral EPI vaccines. (SAQ 3.5)

3.1 Hepatitis B vaccine (HepB)

3.1.1 What is HepB vaccine?

Hepatitis B diseases are discussed in Study Session 4 of the *Communicable Diseases* Module, Part 1.

Hepatitis B (HepB) vaccine protects against the hepatitis B diseases, which affect the liver and are caused by hepatitis B viruses. If a child is infected with hepatitis B viruses, liver disease may develop many years later in adult life. In Ethiopia, HepB vaccine is routinely given to infants as one of the five vaccines combined in the pentavalent vaccine (which also protects against diphtheria, pertussis, tetanus and *Haemophilus influenzae* type b). The four antibacterial vaccines in the pentavalent vaccine used in Ethiopia were described in Study Session 2.

■ HepB vaccine is a recombinant vaccine. What does this mean?

□ A **recombinant vaccine** is produced by inserting genetic material from a disease-causing infectious agent into harmless cells in the laboratory. The cells with the new genes begin to manufacture the unique antigens that identify the infectious agent. These antigens are then purified and used in the vaccine.

HepB vaccine is also available on its own as a single vaccine, which may be given to healthworkers as a 'booster' to increase their protection against infection by bloodborne hepatitis B viruses from patients. The vaccination schedule in adults is not the same as the schedule you already know for infants, who receive HepB vaccine as part of the pentavalent vaccine in the Ethiopian EPI.

■ How many doses and at what ages should infants receive pentavalent vaccine containing HepB vaccine? What is the route of administration?

□ They should receive three doses of pentavalent vaccine at the age of 6, 10 and 14 weeks, as you learned in Study Session 2. The route of administration is by intramuscular injection into the left outer upper thigh muscle.

The HepB component of the pentavalent vaccine is very safe and effective: up to 95% of infants who receive all three doses of pentavalent vaccine are protected against hepatitis B virus infection. The contraindications are the same as already described for pentavalent vaccine: infants with a high-grade fever should not be vaccinated until they recover. An infant who develops a severe allergic reaction, swollen lymph glands or encephalopathy to a previous dose of pentavalent vaccine should not be given another dose.

■ Do you remember the storage conditions for pentavalent vaccine containing HepB vaccine and the four antibacterial vaccines?

□ The vaccine vials should be stored in a refrigerator at between +2°C and +8°C, and never frozen.

3.2 Oral polio vaccine (OPV)

3.2.1 What is OPV?

You will learn more about the oral administration of vaccines in Study Session 4.

Oral polio vaccine (OPV) is made from live-attenuated polioviruses (note that 'poliovirus' is all one word). OPV is a light red or light yellow liquid supplied in vials that either have droppers as caps, or they come with separate glass droppers. The vaccine is given by putting two drops into the child's mouth (Figure 3.1).

Poliomyelitis is described in Study Session 4 of the *Communicable Diseases* Module, Part 1. It has been eliminated by vaccination in many countries and the WHO aims to eradicate it from the world.

OPV gives protection against the three types of polioviruses (types 1, 2 and 3) that cause **poliomyelitis** (polio) — a crippling disease of the brain and spinal cord.

- What is the crippling effect of polio called? And what does this mean?

- It is called **acute flaccid paralysis** (**AFP**), which is the sudden onset of severe weakening or loss of muscle tone in the legs, arms or hands.

Figure 3.1 A child receiving oral polio vaccine drops. (Photo: UNICEF Ethiopia/ Indrias Getachew)

Note that the vaccine used for routine immunizations in the EPI is not the only type of OPV available. Other types may be issued to control outbreaks of polio if they occur, but are not used for routine protection of infants; these vaccines should be returned to the central store after the supplementary immunization campaign.

3.2.2 Storage, dosage, schedule and effectiveness of OPV

Store OPV between +2°C and +8°C; but it may be frozen for long-term storage.

Four doses are given, each of two drops. OPV should be given at birth, 6 weeks, 10 weeks and 14 weeks of age. The interval between all doses must be at least four weeks. The birth dose is known as OPV0; the subsequent doses are referred to as OPV1 (at 6 weeks), OPV2 (at 10 weeks), and OPV3 (at 14 weeks).

You should not give OPV0 (the birth dose) to an infant who is more than 14 days old. If this dose has not been given by 14 days, miss this dose and wait until the child is six weeks old, and then give OPV1. You should also give the first doses of the other routine EPI vaccines, including PCV10, at six weeks. The remaining doses should be given as scheduled at 10 and 14 weeks.

If a child spits out the vaccine drops, or vomits immediately after a dose of OPV, it is quite safe to repeat the dose. You should still give the scheduled dose even if a child has diarrhoea at the time; give OPV as usual, but administer an extra (fifth) dose at least four weeks after he or she has received the final dose in the schedule. Ninety-nine per cent of those who are vaccinated with four doses of OPV are protected from polio for life, but during campaigns children are often given additional boosters of OPV to ensure high herd immunity.

3.2.3 Contraindications of OPV and adverse events

OPV is a very safe vaccine and there is no contraindication to prevent giving it. Serious adverse reactions to OPV are very rare: acute flaccid paralysis has been reported in approximately one child in every 1–10 million children who have been vaccinated with OPV. Table 3.1 summarises what you should know about OPV.

Table 3.1 Summary of oral polio vaccine (OPV) immunization characteristics.

Category	Description
Type of vaccine	Live-attenuated antiviral vaccine
Number of doses	Four (referred to as OPV0, OPV1, OPV2 and OPV3), plus campaign doses
Schedule	At birth, 6, 10 and 14 weeks
Additional dose	If the child spits or vomits after OPV, repeat the dose immediately; if the child has diarrhoea, give a fifth dose at least 4 weeks after the scheduled fourth dose
Contraindications	None
Adverse events	Very rarely AFP; refer immediately to a health centre
Special precautions	None
Dosage	2 drops
Administration route	Into the mouth (oral)
Storage	Store between +2°C and +8°C (may be frozen for long-term storage)

- What should you do if a baby vomits immediately after being given the oral polio vaccine?

- You should repeat the dose immediately; it is quite safe to give the baby an extra dose of OPV.

3.3 Measles vaccine

3.3.1 What is measles vaccine?

Measles is discussed in Study Session 4 of the *Communicable Diseases* Module, Part 1.

Measles vaccine is made from live-attenuated virus and is supplied as a powder that has to be reconstituted with (dissolved in) the special diluent provided to use with it. You will learn about vaccine reconstitution in detail in Study Session 4.

Measles is a highly infectious disease caused by a virus that weakens the immune system, leaving children susceptible to other dangerous childhood infections. The common signs and symptoms of measles are a red skin rash, runny nose and conjunctivitis (Figure 3.2).

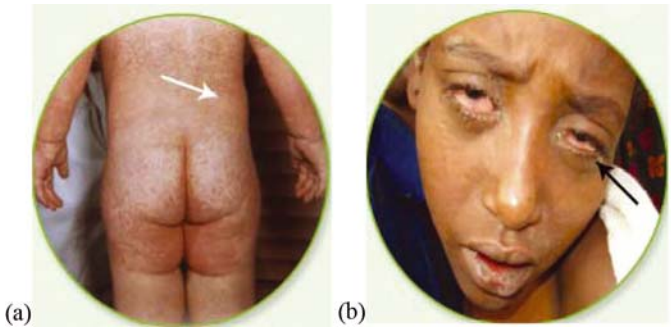


Figure 3.2 (a) Measles rash covering the whole body of a child; (b) Conjunctivitis (red, watery eyes) caused by measles. (Photos: WHO and Ethiopian Federal Ministry of Health, 2005, *Case Definition of Measles*)

■ Measles vaccine is a live-attenuated vaccine. What does this mean?

□ You learnt about different types of vaccine in Study Session 1, Section 1.3.

It means it has been made from measles viruses that have been weakened in the laboratory so that they cannot cause the disease. But they are still *immunogenic*, which means they activate the immune system of the vaccinated person to produce immunity against measles viruses if encountered in the future.

3.3.2 Storage, dosage and schedule of measles vaccine

The vials containing the dry measles vaccine powder can be frozen for long-term storage, but after reconstitution with the correct diluent, measles vaccine should be kept at between +2°C and +8°C, and never frozen. Any remaining reconstituted vaccine must be thrown away after six hours, or at the end of the immunization session, whichever comes first.

One dose of 0.5 ml of measles vaccine is injected **subcutaneously** (into the fatty layer below the skin and above the muscle) in the outer upper arm as soon as possible after nine months of age. Waiting this long is advisable because the maternal antibodies against measles that are transferred to the unborn baby before birth last longer in the blood of the baby than other antibodies. As a result, immunization with measles vaccine is often not effective before nine months of age. The aim in the EPI in Ethiopia is to give measles vaccine to all children at nine months of age. To achieve high-level population immunity, a second dose is ideally given after 12 months of age during supplementary immunization activities.

■ What are antibodies and how can maternal antibodies help in combating measles?

□ You learnt about antibodies in Study Session 1.

Antibodies are specialized proteins that circulate in the blood and other body fluids. They are produced by B cells in the immune system. They identify foreign antigens, such as those found on infectious agents (e.g. the measles virus), and neutralise them so they are unable to cause disease. Maternal antibodies are those produced by the mother when she is vaccinated, which are transmitted passively to the fetus across the placenta, or to her baby in her breastmilk. Maternal antibodies directed against measles viruses will protect the infant from measles in the first few months of his or her life.

In special situations, for instance in measles outbreaks, in emergencies such as in refugee camps with high measles transmission, or among HIV-infected children, an ‘early’ extra dose of measles vaccine may be given at six months. If a child has received measles vaccine before nine months of age, a second dose should be administered at nine months, or as soon as possible afterwards. All children should ideally receive a supplementary dose of measles vaccine after 12 months of age as part of measles elimination campaigns.

3.3.3 Effectiveness of measles vaccine

Measles vaccine is highly effective at preventing measles; 85% of infants who are immunized at 9 months are protected from measles for the rest of their lives; vaccine efficacy rises to 95% after a second dose after 12 months of age. In the year 2000 there were an estimated 750,000 deaths from measles worldwide. By 2008, vaccination campaigns had succeeded in reducing this number by 75%. The World Health Organization (WHO) estimated that in 2008 around 83% of the world's children were receiving one dose of measles vaccine by their first birthday.

3.3.4 Contraindications for measles vaccine, adverse events and how to manage them

Children who develop a severe allergic reaction should be referred immediately to a health centre, and should not be given measles vaccine again.

In around 20% of children, a mild fever lasting one to three days may occur approximately one week after immunization. A few children (less than 5%) develop a mild rash. Injection-site abscess or severe allergic reactions including rash, breathing difficulty and fainting occur very rarely. Table 3.2 gives a summary of the possible adverse events following measles vaccination and how to manage them.

Table 3.2 Management of adverse events following immunization with measles vaccine.

Adverse event	Management	Comments
Low-grade fever Slight rash	Give paracetamol syrup (5 ml) up to 4 doses	Usually lasts 1 to 3 days
Abscess at injection site	Amoxicillin syrup orally three times daily	Refer urgently to a higher health facility
Severe rash, breathing difficulty, loss of consciousness	Do not give measles vaccine again	Refer the child to a health centre immediately

Table 3.3 summarises what you should know about measles vaccine.

Table 3.3 Summary of measles vaccine immunization characteristics.

Category	Description
Type of vaccine	Live-attenuated antiviral vaccine
Number of doses	One in routine EPI schedule, plus one in supplementary campaigns
Schedule	At 9 months in the EPI; after 12 months in campaigns
Additional early dose	At 6 months in some circumstances (see Section 3.3.2)
Contraindications	Severe allergic reaction to previous dose
Adverse events	Fever, rash and (rarely) severe allergic reaction or abscess (see Section 3.3.4)
Special precautions	None
Dosage	0.5 ml
Injection site	Outer upper arm
Injection type	Subcutaneous
Storage	Store between +2°C and +8°C (Note: the vaccine powder may be frozen for long-term storage, but not the diluent or the reconstituted vaccine)

3.3.5 Vitamin A supplements and measles prevention

It is important to know that in countries such as Ethiopia where vitamin A deficiency frequently occurs among children, vitamin A should be given routinely every six months. If a child has not previously received a vitamin A supplement, it should be given at the same time as the measles vaccine. This is because measles increases the risk of blindness due to vitamin A deficiency. Signs of vitamin A deficiency are white spots on the sclera (white part of the eye) and clouding of the cornea (the thin tissue covering the black centre of the eye and the coloured parts around it). In severe cases, blindness results.

Vitamin A is supplied in capsules of 100,000 IU (international units, which is the standard measurement for vitamin doses). Each capsule has a nipple at one end. The drops are given by cutting across the middle of the nipple with scissors and immediately squeezing the drops into the child's mouth (Figure 3.3). Vitamin A drops are also given in Child Health Days to ensure the dose is repeated every six months, until the child reaches five years.

Do not put the vitamin A capsule into the child's mouth, or allow the child to swallow the capsule.

Figure 3.3 A child receiving vitamin A drops at a scheduled immunization clinic where he will also receive measles vaccine. (Photo: UNICEF Ethiopia/Indrias Getachew)

The routine dose of vitamin A for a child aged 6–11 months is the drops from one capsule (100,000 IU); the drops from two capsules (200,000 IU) are given to children aged 12–59 months at regular intervals, every six months. This ensures that all children are fully protected from the harmful effects of vitamin A deficiency.

Vitamin A for children with measles

What should you do if you see a child who has already developed measles? Do not give vitamin A drops if the child has received a dose within the last month. But if a child with measles has not recently received a vitamin A supplement, give the vitamin A treatment dosages summarised in Table 3.4 on the next page. *The second dose should be given 24 hours after the first dose.*

Table 3.4 Vitamin A treatment dosages for children with measles in different age-groups.

Age	Immediately on diagnosis	After 24 hours	Follow-up
Infants less than 6 months old	50,000 IU	50,000 IU	Third dose given two to four weeks later if there are still signs of vitamin A deficiency
Infants aged 6–11 months	100,000 IU	100,000 IU	
Children aged 12 months and over	200,000 IU	200,000 IU	

3.4 Rotavirus vaccine

Rotavirus vaccine is one of the new antiviral vaccines that should soon become available as part of the routine EPI in Ethiopia. Rotaviruses are the leading cause of severe diarrhoeal disease and dehydration among children in many developed and developing countries. The WHO estimates that 20% of child deaths under five years from diarrhoeal diseases worldwide are due to rotavirus infection — most of them in countries like Ethiopia. Globally, more than 125 million cases and up to 610,000 deaths annually are due to rotavirus diarrhoea.

3.4.1 Dosage and schedule of rotavirus vaccine (Rotarix™)

Two new live-attenuated rotavirus vaccines have been licensed for use in routine immunization programmes. They are both given orally to infants as drops into the mouth. The vaccine chosen for the EPI in Ethiopia is known by its brand name **Rotarix™**. It is a liquid suspension vaccine, supplied in single-dose 'squeeze-tube' vials.

Rotarix™ is given in two oral doses, each of 1.5 ml, at the following time intervals:

- First dose at 6 weeks of age, but no later than 12 weeks
- Second dose at least 4 weeks after the first dose
- The two-dose schedule should be completed by 16 weeks, but no later than by 24 weeks of age.

Note that the ideal schedule is to give the first dose of Rotarix™ to all infants at 6 weeks of age at the same time as giving Penta1 and OPV1, and give the second dose at 10 weeks at the same time as Penta2 and OPV2.

3.4.2 Storage and effectiveness of Rotarix™

Rotarix™ is a freeze-sensitive vaccine that must be stored in the refrigerator at a temperature of between +2°C to +8°C. It is a very safe vaccine, which provides 90–100% protection from severe rotavirus disease to fully immunized infants, and 74–85% protection against rotavirus diarrhoea of any severity.

You will receive instructions on the contraindications for giving rotavirus vaccine, and the management of possible adverse events following immunization, when Rotarix™ is introduced into the EPI in Ethiopia.

3.5 Yellow fever vaccine

Finally, we will briefly mention an antiviral vaccine that is not part of the routine EPI in Ethiopia, but is given in certain circumstances. **Yellow fever vaccine** is a live-attenuated antiviral vaccine, supplied as a powder which must be reconstituted with the appropriate diluent before use. It is not included in the national EPI in Ethiopia because the risk is very low, but it is given to people who want to travel abroad to countries like Kenya and Uganda where yellow fever is endemic. Some countries (like the USA and South Africa) require a current yellow fever vaccination certificate as a condition of entry from Ethiopia. **Yellow fever** is a viral vector-borne disease, transmitted by certain species of mosquitoes when they take a blood meal. Infection can result in a high fever, nausea and internal bleeding leading to shock, and in extreme cases, death.

■ Yellow fever vaccine is a live-attenuated vaccine. Which other antiviral vaccines of this type have you already learnt about in this study session?

□ Measles vaccine and OPV are also live-attenuated vaccines.

Mild reactions to yellow fever vaccine occur occasionally and include headache, muscle pain or low-grade fever.

3.6 In conclusion

Table 3.5 summarises the current and forthcoming antiviral EPI vaccines in Ethiopia**.**

Table 3.5 Summary of antiviral vaccines in the EPI in Ethiopia.

Vaccine	Protects against	Doses/when	Route
HepB	Hepatitis B	Three: at 6, 10 and 14 weeks, in the pentavalent vaccine	Intramuscular, upper outer left thigh
OPV	Poliomyelitis	Four: at birth, then at 6, 10 and 14 weeks (additional campaign doses may be given)	Oral (drops into the mouth)
Measles	Measles	One: at 9 months, or as soon as possible thereafter (plus one additional campaign dose)	Subcutaneous, outer upper arm
Rotavirus	Rotavirus diarrhoea	Two: at 6 and 10 weeks (but first dose no later than 12 weeks, second dose no later than 24 weeks, with an interval of at least 4 weeks between doses)	Oral (drops into the mouth)

Summary of Study Session 3

In Study Session 3, you have learned that:

1 The common antiviral vaccines in the EPI in Ethiopia are hepatitis B (HepB) vaccine, which is given in the pentavalent vaccine, oral polio vaccine (OPV) and measles vaccine. A rotavirus vaccine (Rotarix^{TM}) to protect against diarrhoea and dehydration caused by rotaviruses will become part of the EPI soon.

2 To guarantee long-term protection, all recommended doses of the antiviral vaccines should be given. If a child misses the scheduled date for an immunization, the child should be given the missed dose as soon as possible. There is no need to restart the immunization schedule.

3 The antiviral EPI vaccines are very effective and safe for children, and any adverse events following immunization are usually mild and easily managed; serious adverse events are extremely rare.

4 There are no contraindications to prevent giving the oral polio vaccine; if a child vomits a dose, give a replacement dose immediately; if the child has diarrhoea at the time of vaccination, give a fifth dose at least 4 weeks after the scheduled fourth dose.

5 Contraindications for the other antiviral vaccines are high-grade fever, or a severe allergic reaction or encephalopathy following a previous dose.

6 Vitamin A drops should be routinely given at the same time as measles vaccine, or if a child presents with measles, to reduce the risk of eye damage which can be serious enough to cause blindness.

7 Yellow fever vaccine is not part of the EPI in Ethiopia, but may be required by travellers going abroad to certain countries.

Self-Assessment Questions (SAQs) for Study Session 3

Now that you have completed this study session you can assess how well you have achieved its Learning Outcomes by answering the following questions. Some of the question test the Learning Outcomes for Study Session 2, as well as those for Study Session 3. Write your answers in your Study Diary and discuss them with your Tutor at the next Study Support Meeting. You can check your answers with the notes on the Self-Assessment Questions at the end of this Module.

SAQ 3.1 (tests Learning Outcomes 2.1, 2.2, 3.1 and 3.2)

Classify each of the following vaccines as either antibacterial or antiviral (or both) by putting crosses in the appropriate columns of Table 3.6. Write the name of the diseases or conditions that each vaccine prevents in the last column of the table.

Table 3.6 Antibacterial and antiviral vaccine characteristics.

Vaccine	Antibacterial	Antiviral	Protects against
BCG vaccine			
Measles vaccine			
Pentavalent vaccine			
Yellow fever vaccine			
Pneumococcal vaccine (PCV10)			
OPV			
TT vaccine			
Meningococcal vaccine			
Rotavirus vaccine			

SAQ 3.2 (tests Learning Outcome 3.3)

Summarise the dosage, route of administration and schedule for each of the current antiviral EPI vaccines used in Ethiopia by completing Table 3.7.

Table 3.7 Summary of dosage, route and schedule for antiviral EPI vaccines.

Vaccine	Dosage and route	Schedule
HepB (as part of pentavalent vaccine)		
OPV		
Measles		

SAQ 3.3 (tests Learning Outcome 3.4)

Complete Table 3.8 to indicate the possible adverse events following immunization with OPV and measles vaccines, and their management at Health Post level.

Table 3.8 Adverse events following OPV and measles immunization, and their management.

Vaccine	Adverse events	Management
OPV		
Measles		

SAQ 3.4 (tests Learning Outcomes 2.3 and 3.3)

What immunizations (if any) should the following children be given? Assume that rotavirus vaccine has *not* yet been introduced.

(a) A newborn baby.
(b) A ten-month-old child who has had BCG, OPV3, PCV3 and Penta3.
(c) An eight-month-old child who has had BCG, OPV3, PCV3 and Penta3.
(d) A six-week-old child who has had BCG and OPV0.

SAQ 3.5 (tests Learning Outcomes 2.5 and 3.5)

Fatima's grandmother brings her to your Health Post when she is ten weeks old for OPV2, PCV2 and Penta2. Three days later, Fatima becomes very ill and develops a severe allergic reaction. After a brief period of hospitalisation, she recovers fully. When Fatima is 14 weeks old, her grandmother brings her to see you at an immunization clinic. She has a mild episode of diarrhoea at the time.

(a) What vaccines (if any) should you give Fatima?
(b) What should you explain to Fatima's grandmother?

Study Session 4 Vaccine Preparation and Administration Routes of the EPI Vaccines

Introduction

In this study session you will learn how to prepare the EPI vaccines used in Ethiopia, which were described in Study Sessions 2 and 3. Some vaccines come as fully prepared liquids for injection or administering by drops into the mouth. Other vaccines comes as powders that have to be reconstituted — mixed with a special liquid (a diluent) before they can be used. We will teach you how to do this and about the safe handling of needles and syringes for injecting vaccines.

Appropriate vaccine administration and safe vaccination practices are both very important for vaccine effectiveness. The recommended site, route and dosage for each vaccine are based on research and practical experience. In the final sections of this study session you will learn about the correct routes of administration for each of the EPI vaccines, together with instructions for positioning the child or adult client. The four administration routes are:

- **Intradermal** (**ID**): the vaccine is injected into the top layers of the skin.
- **Subcutaneous** (**SC**): the vaccine is injected into the fatty tissue below the skin and above the muscle.
- **Intramuscular** (**IM**): the vaccine is injected into the muscle.
- **Oral**: the vaccine is given by drops into the mouth.

Learning Outcomes for Study Session 4

When you have studied this session, you should be able to:

4.1 Define and use correctly all of the key words printed in **bold**. (SAQs 4.1 and 4.3)

4.2 Summarise the standard precautions to minimise the risk of infection or injury when handling vaccines, diluents and injection equipment. (SAQs 4.2 and 4.3)

4.3 Describe how to reconstitute BCG and measles vaccines with the correct diluent before administration. (SAQs 4.1 and 4.3)

4.4 Describe the correct route of administration for each of the injectable EPI vaccines. (SAQs 4.1 and 4.3)

4.5 Describe the correct preparation and administration of oral polio vaccine (OPV). (SAQ 4.5)

4.1 Preparing to give injectable vaccines

In this section, you will learn about the necessary steps before administration of the injectable EPI vaccines in routine use in Ethiopia.

4.1.1 Standard procedures for giving safe injections

First, you should always follow the *standard procedures* (also known as *universal precautions*) for preventing infection and injury when you are giving an injection.

■ What **standard procedures** should you take before giving an injection?

Standard procedures are described in several parts of this curriculum, including the *Antenatal Care, Labour and Delivery Care,* and *Communicable Diseases* Modules.

□ You should:

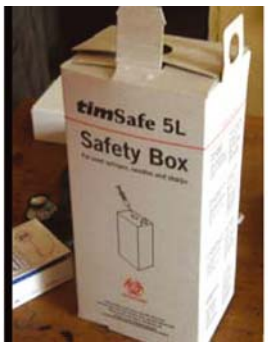


Figure 4.1 A standard safety box. (Photo: Basiro Davey)

- Wash your hands thoroughly with soap and water, and allow them to 'air dry'.
- Prepare all the equipment you need and lay it out on a clean tray that has been swabbed with antiseptic solution.
- Organise your equipment to minimise the risk of injury from needles and broken glass.
- Make sure there is a safety box nearby for the safe disposal of used syringes and needles (Figure 4.1).
- Make sure that children are securely held by someone they know and trust, in the correct position to enable you to give the injection (Figure 4.2). You cannot hold the child because you need both hands to give the injection.

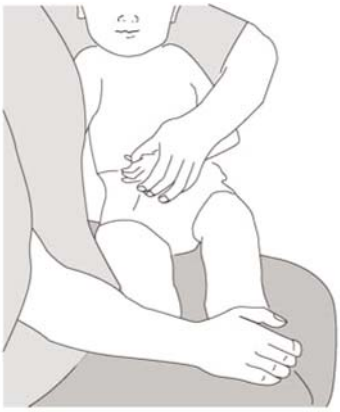


Figure 4.2 The mother or another caregiver should hold the child securely like this. (Source: WHO, 2004, *Immunization in Practice*, Manual 4, *Ensuring Safe Injections*, Figure 4-D)

- The skin at the site of the injection should be swabbed clean with an appropriate antiseptic solution. After giving the injection, press a clean cotton swab onto the site until all bleeding stops.

You will learn about these and other immunization safety issues in more detail in Study Session 7.

4.1.2 Preparing injection equipment

Careful preparation before giving an immunization is very important, and includes selection of the correct syringes and needles.

Syringe selection

A separate syringe should be used for each injection. BCG vaccine should be injected using a 0.1 ml syringe; for all other EPI vaccines, use a 1 ml syringe. Disposable syringes are supplied in sterile plastic packages and are

designed to be used once only and then put into a safety box. The safest type recommended by the World Health Organization is the **auto-disable (AD) syringe** (Figure 4.3). This has the needle already attached and a plunger mechanism that prevents the syringe from being used a second time. If the syringe and needle are supplied separately, when you remove a syringe from its package, take care not to touch the syringe adapter shown in Figure 4.4.

Figure 4.3 Auto-disable 1 ml syringes, supplied with needles already attached. (Photo: Basiro Davey)

Needle selection

The needle used should be of the appropriate diameter for the vaccine. Typically, vaccines are not very thick liquids, and therefore a fine needle size of 22–26 gauge (outer diameter) can be used. A new needle and syringe is used for each injection. Note that for vaccines that need to be reconstituted with diluent before use, you should use a separate 'mixing' syringe and needle (like those shown in Figure 4.4) for reconstitution. Use a new auto-disable (AD) syringe and needle to inject the client.

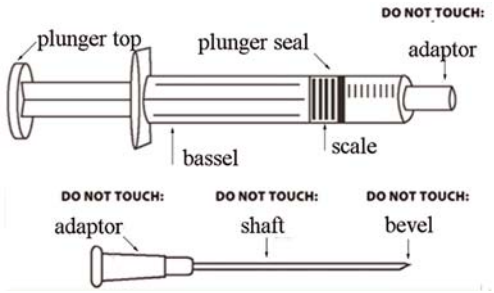


Figure 4.4 Parts of a syringe and a hollow needle, showing the areas that should not be touched. (Source: Adapted from WHO, 2004, *Immunization in Practice,* Module 4, *Ensuring Safe Injections,* Figures 4-B and 4-C)

Figure 4.4 shows the parts of a needle — *none of which should be touched.* Open the protective wrapping around the needle and remove it without touching the adaptor. The needle is inside a plastic outer case. Holding the needle by the outer case, push the needle adapter onto the syringe adapter until they 'lock' together firmly.

Vaccine reconstitution is taught in the next section. Diluents were introduced in Study Session 2.

4.1.3 Inspecting vials and ampoules of vaccines and diluents

Vaccines and diluents are supplied in either a vial or an ampoule. A **vial** is a glass bottle with a thin rubber membrane across the top, which is held in place by a metal or plastic cap (Figure 4.5a). An **ampoule** is a sealed sterile glass or plastic bottle with a thin 'neck' (Figure 4.5b). The ampoule has to be broken open at the neck before the vaccine (or diluent) can be withdrawn. Note that some injectable vaccines are supplied in single-dose vials, and some contain more than one dose. You will learn how to use multi-dose vials in Study Session 7.

Vaccines (e.g. BCG) that are sensitive to light are supplied in dark glass vials or ampoules.

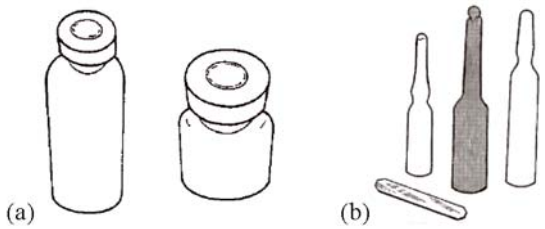


Figure 4.5 (a) Vials. (b) Ampoules, with a metal file to 'scratch and break' the neck of the ampoule. (Source: WHO, 1998, *Immunization in Practice*, Module 7, *During a Session: Preparing Vaccines*, Figures 7-M and 7-I)

Vials and ampoules should be carefully inspected for damage or contamination prior to use. The **expiry date** printed on the vial or ampoule, or the box they came in, should be checked. The expiry date gives the last day of the month that the vaccine or diluent can be used, unless otherwise stated on the package labelling. Expired vaccines and diluents should never be used. You will learn more about stock control to avoid wastage in Study Session 5.

Check the **vaccine vial monitor (VVM)**, which is a label that changes colour when the vaccine vial has been exposed to heat over a period of time. The VVM enables you to check if the vaccine has not passed the discard point due to heat exposure. It cannot tell you if the vaccine has been damaged by freezing. You will learn more about this, and other components of the 'cold chain' for preserving vaccines, in Study Session 6.

■ What is the correct temperature for storing vaccines supplied as liquids?

□ It is between +2°C and +8°C, as you learned in Study Sessions 2 and 3.

4.1.4 Reconstituting BCG and measles vaccines with diluent

Reconstitution is the process of mixing vaccines that come as powders with the diluent provided with the vaccine. This section will also explain how to open vials and ampoules. BCG and measles vaccines are the two routine EPI vaccines that require reconstitution, following the steps below:

It is very important to reconstitute a powder vaccine using *only* the diluent provided by the manufacturer *specifically* for that vaccine

1 Wash your hands and organise your equipment and work area

Wash your hands with clean water and soap and follow the standard procedures outlined in Section 4.1. Your aim is to minimise the risk of infection or injury to yourself, your clients and their caregivers.

2 Inspect the vaccine vial or ampoule

Measles vaccine powder (and most fully liquid vaccines) come in vials, but BCG vaccine powder comes in ampoules. Check that the vial or ampoule is not cracked. Check the vaccine vial monitor (VVM) and the expiry date as described above, and discard any vaccines that are no longer safe to use.

3 Tap the vial or ampoule

To make sure that all of the vaccine powder is at the bottom of the vial or ampoule, tap it with your finger.

4 Open the vaccine vial

The centre of the metal cap on a vaccine vial is pre-cut so that it can be removed easily. Lift the centre of the metal cap and bend it back, using a metal file. Some vials have plastic stoppers instead of metal caps. Flip off the stopper with your thumb. When the cap or stopper is removed, it reveals the rubber membrane on top of the vial, protecting the vaccine (Figure 4.6). How to open an ampoule of BCG vaccine is described in step 6.

Figure 4.6 (left arrow) The centre of the metal cap has been bent back and removed; (right arrow) the plastic stopper has been removed. (Source: WHO, 1998, *Immunization in Practice*, Module 8, *During a Session: Giving Immunizations*, p.4)

5 Inspect the diluent

Most diluents for reconstituting vaccines come in sealed ampoules, which you open by breaking off their pointed tops. Check that the ampoule is not cracked and that it has been chilled to between +2ºC and +8ºC before use.

Make sure that you are using the diluent the manufacturer sent with the vaccine, and that the expiry date has not passed. Each vaccine has its own diluent and must not be reconstituted with anything else. Deaths have resulted when vaccines were incorrectly mixed with liquids other than the specific diluent approved by the manufacturer for use with the vaccine.

Even if the main ingredient of the diluent is sterile normal saline or sterile water, you must *never* use normal saline or water instead of the correct diluent.

6 Open the ampoule of diluent

The process for opening an ampoule of BCG vaccine is exactly the same as for opening an ampoule of diluent.

Hold the ampoule between your thumb and middle finger, and use your index finger to support the top (Figure 4.7a on the next page). Use the metal file packed with the ampoules to scratch hard around the neck of the ampoule. Wrap the ampoule in a piece of clean cloth and gently break off the top. It breaks where you made the scratch (Figure 4.7b on the next page). If you injure your hand while doing this, discard the ampoule because the diluent may have become contaminated. Cover the wound before opening a new ampoule.

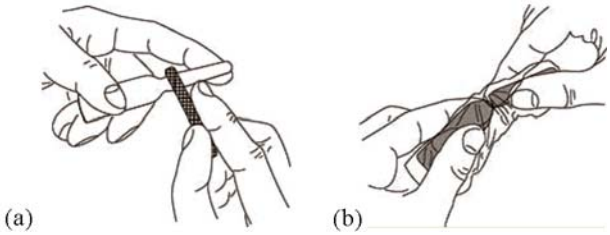


Figure 4.7 (a) Scratching and (b) breaking the neck of an ampoule. (Source: WHO, 2004, *Immunization in Practice*, Module 6, *Holding an Immunization Session*, p.16)

7 Draw diluent into the mixing syringe

Use a new disposable mixing syringe (0.1 ml for BCG and 1 ml for other vaccines) attached to an appropriate-sized needle. Hold the ampoule at an angle (as shown in Figure 4.8), and put the needle into the open top. Pull back the plunger to draw all the diluent from the ampoule into the syringe.

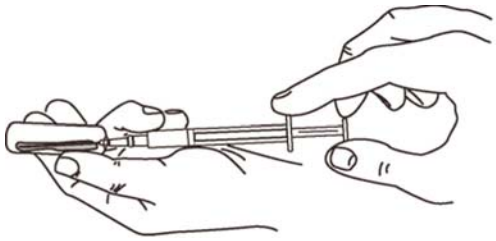


Figure 4.8 Withdrawing diluent from an ampoule. (Source: WHO, 2004, as in Figure 4.7, p.16)

8 Reconstitute the vaccine

Insert the needle of the mixing syringe through the rubber membrane on top of the vaccine vial, or (for BCG) into the open neck of the vaccine ampoule (Figure 4.9). Push the syringe plunger in with your thumb to empty the diluent into the vaccine vial or ampoule, where it begins to mix with the vaccine powder. Draw them both up slowly into the syringe and inject them back slowly into the vial or ampoule. Repeat this mixing step several times until the vaccine powder is thoroughly mixed with the diluent.

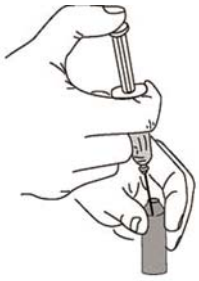


Figure 4.9 Adding diluent to a vaccine ampoule. (Source: WHO, 2004, as in Figure 4.7, p.17)

Discard the mixing syringe and needle in a safety box and use new ones for the immunization. Ideally, you should use an auto-disable (AD) syringe for the immunization.

9 Keep reconstituted vaccines cold

Place the vial or ampoule of reconstituted vaccine into the spaces in the foam pad (a piece of soft foam that fits on top of the ice-packs; Figure 4.10) to keep it cold during your immunization session. You will learn more about the use of foam pads and ice-packs in Study Session 6.

Figure 4.10 The foam pad on top of the ice-packs in a vaccine carrier. (Photo: Janet Haresnape)

10 Do not keep unused reconstituted vaccine

Unused reconstituted vaccine must be administered within the time limit stated by the manufacturer (usually six hours). Any unused vaccine should be thrown away after six hours, or at the end of the immunization session if you finish before the time limit has passed.

- Why should you throw away reconstituted vaccines after an immunization session is completed?

- Reconstituted vaccines lose their potency (strength) quickly. As you learned in Study Sessions 2 and 3, reconstituted BCG vaccine is quickly damaged by sunlight and heat, and reconstituted measles vaccine is also damaged by heat.

4.2 Routes of immunization for injectable vaccines

In this section you will learn about the routes of administration for the injectable EPI vaccines. The injection routes are either intradermal (ID), subcutaneous (SC) or intramuscular (IM). Figure 4.11 shows the correct needle position for each of these routes. In all cases, you should follow the standard procedures for reducing the risk of infection and injury (Section 4.1).

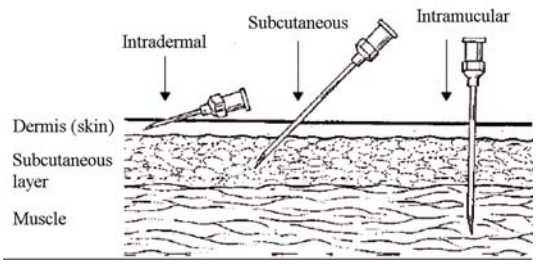


Figure 4.11 Needle positions for intradermal, subcutaneous and intramuscular injections. (Source: WHO, 2001, *Immunization in Practice,* Module 2, *EPI Vaccines,* Figure 2-G, p.21)

4.2.1 Intradermal immunization with BCG vaccine

Intradermal (**ID**) means within or between the layers of the skin (dermis). BCG vaccine is the only EPI vaccine which is given intradermally. BCG vaccine should be reconstituted with the appropriate diluent before administration, as described in Section 4.2 above.

Swab the outer surface of the child's outer upper right arm with antiseptic solution and allow it to dry. Select a sterile 0.1 ml syringe with a 26 gauge needle (Figure 4.12) and draw 0.05 ml of the reconstituted BCG vaccine into the syringe. Hold the syringe with the needle pointing upwards and tap the syringe so any air bubbles float to the top of the barrel. Gently push the plunger just enough to expel the air through the needle — you should see a tiny drop of vaccine emerging from the tip of the needle. This ensures that you do not inject air into the child's skin. Make sure the vaccine dose is exactly 0.05 ml by checking the scale on the barrel of the syringe.

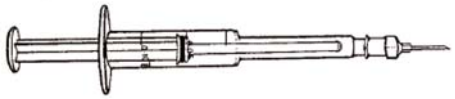


Figure 4.12 The 0.1 ml syringe and 26 gauge needle used for BCG immunizations. (Source: WHO, 1998, *Immunization in Practice*, Module 8, *During a Session: Giving Immunizations*, Figure 8-A)

Ideally you should use auto-disable (AD) syringes with needles attached.

- Why should you use a 0.1 ml syringe to inject BCG vaccine and a 1 ml syringe for all other injected EPI vaccines?

- The dose of BCG vaccine is very small – only 0.05 ml. In order to measure and inject such a small dose accurately you must use a 0.1 ml syringe. All other injected vaccines are given in doses of 0.5 ml, so you should use a 1 ml syringe.

Inject the recommended dose of 0.05 ml of reconstituted BCG vaccine into the most superficial layers of the skin (intradermally) in the upper right arm. You should insert the tip of the needle just under the skin by inserting the bevel and a little bit more of the needle into the skin, while keeping the bevel facing upwards (Figures 4.13). The syringe should be lying along the child's arm (Figure 4.14.)

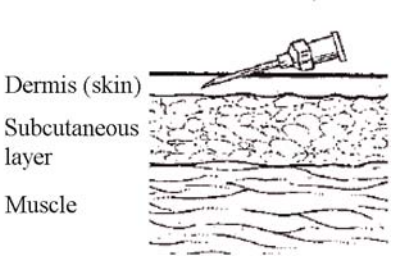


Figure 4.13 Needle position for intradermal injection of BCG vaccine. (Source: WHO, 2001, *Immunization in Practice,* Module 2, *EPI Vaccines*, Figure 2-A)

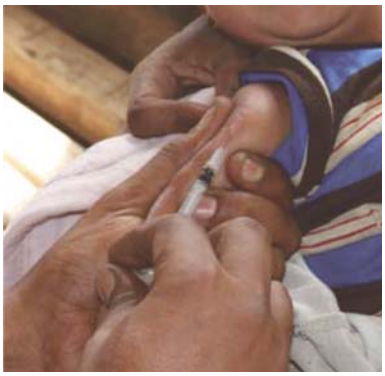


Figure 4.14 Correct position of the 0.1 ml syringe and needle for BCG immunization. (Photo: AMREF Ethiopia/Demissew Bizuwork)

The reason for injecting the vaccine in the same place (upper right arm) for each child is to make it easy to find the BCG scar subsequently. This enables you to check that the immunization has been effective. If the child does not develop a sore at the injection site, which heals to form a small scar (see Figure 2.3a in Study Session 2), the BCG vaccination should be repeated.

4.2.2 Subcutaneous immunization with measles vaccine

Where vitamin A deficiency is common among children, as in Ethiopia, vitamin A drops are given at the same time as measles vaccine, as described in Study Session 3.

Subcutaneous (**SC**) injections are given into the fatty tissue below the skin and above the muscle. Measles vaccine is the only routine EPI vaccine which is administered subcutaneously. The vaccine comes in powder form and must be reconstituted before use with the approved diluent (as described in Section 4.1.4), and used within six hours of reconstitution.

The child shown in Figure 4.15 should be held securely by a caregiver to prevent sudden movements

For the immunization, select a sterile 1 ml auto-disable (AD) syringe or a sterile syringe attached to a 23 gauge needle, and draw 0.5 ml of the reconstituted measles vaccine into the syringe. Expel any air bubbles as described above for BCG immunization (Section 4.2.1). Swab the skin of the child's outer upper arm with antiseptic solution and let it air dry. Hold the child's arm from below, and pinch the skin with your fingers and thumb (as shown in Figure 4.15 on the next page), to push up a fold of skin on top of the arm. Push the needle a little way under the pinched-up skin. The needle should go in at a sloping angle (Figure 4.16), not straight down. Inject 0.5 ml of the vaccine into the fatty subcutaneous layer below the skin, but above the muscle.

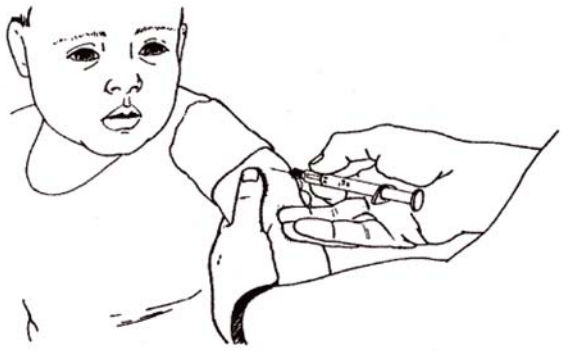


Figure 4.15 Subcutaneous injection of measles vaccine. (Source: WHO, 1998, *Immunization in Practice*, Module 8, *During a session: giving immunizations*, Figure 8-N)

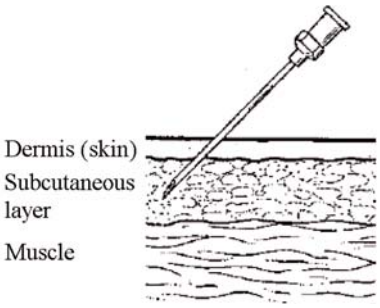


Figure 4.16 Needle position for subcutaneous injection of measles and yellow fever vaccines. (Source: WHO, 2001, as Figure 4.13, but Figure 2-B)

4.2.3 Subcutaneous immunization with yellow fever vaccine

Yellow fever vaccine is not currently used routinely in the EPI in Ethiopia, but may be required by travellers going abroad to countries where the disease is common. It is the only other vaccine, apart from measles vaccine, which is injected subcutaneously, and is also given into the outer upper arm.

4.2.4 Intramuscular immunization with all other EPI vaccines

All the other EPI vaccines in routine use in Ethiopia are injected intramuscularly. **Intramuscular** (**IM**) injections are administered into the muscle layer below the skin and subcutaneous tissue, using a 1 ml syringe with a 26 gauge needle pointing straight down into the muscle (Figure 4.17).

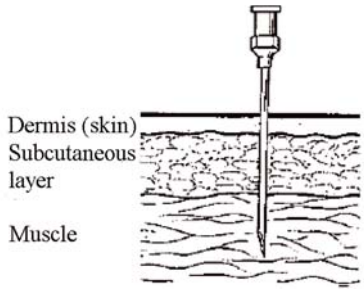


Figure 4.17 Needle position for intramuscular injections. (Source: WHO, 2001, as Figure 4.13, but Figure 2-C)

Pentavalent and pneumococcal vaccines

Pentavalent vaccine and the new pneumococcal vaccine (PCV10) are injected intramuscularly into the opposite thighs. Swab the thigh area with antiseptic solution and let it air dry, then inject 0.5 ml of vaccine as shown in Figure 4.18. Make sure the child is held securely.

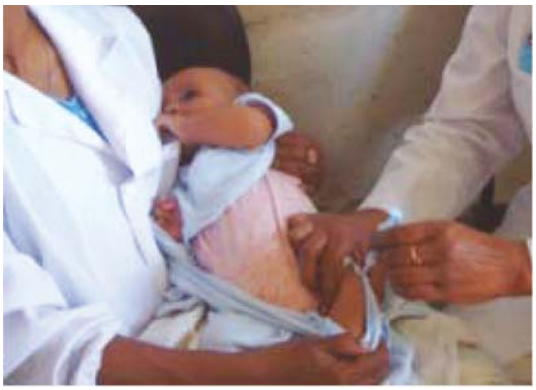


Figure 4.18 Holding a child for immunization by intramuscular injection into the outer upper thigh. (Photo: Dr Kalid Asrat)

Tetanus toxoid (TT) vaccine

Tetanus toxoid is commonly given separately on its own to pregnant women and non-pregnant women of childbearing age. Before giving TT vaccine, you should shake the vial so that any particles of vaccine that have settled to the bottom of the vial are mixed completely with the liquid. If the tetanus toxoid is not well mixed, the correct dose may not be given.

Note that pentavalent vaccine and PCV10 must be given as two *separate* injections into *opposite* thighs (pentavalent on the left and PCV10 on the right).

Inject 0.5 ml of TT vaccine intramuscularly (IM) using a sterile 1 ml syringe and a sterile 22 gauge needle into the muscle of the upper left or right arm, depending on the woman's preference (Figure 4.19). At least two doses, and ideally five doses, should be given for maximum protection of women and their newborns from tetanus.

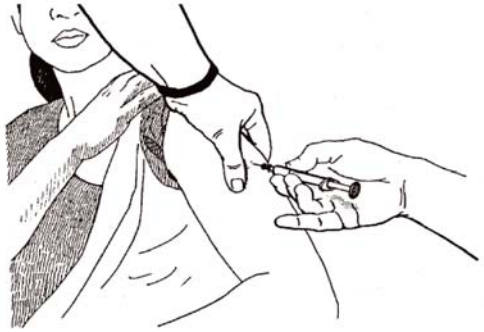


Figure 4.19 Intramuscular injection of tetanus toxoid into a woman of childbearing age. (Source: WHO, 2004, *Immunization in Practice*, Module 6, *Holding an Immunization Session*, p.22)

You learned about the effectiveness of different numbers of TT vaccine doses in Study Session 2, Table 2.7.

The shake test

Pentavalent, PCV10 and TT vaccines are all damaged by freezing. After freezing, the vaccine tends to form flakes that quickly settle at the bottom of the vial after shaking. If you suspect the vaccine has been accidentally frozen, you should check for damage by conducting a *shake test* before you use it. (You will learn how to do the shake test in Study Session 6.)

4.3 Oral administration of vaccines

The oral route of administration is used for polio vaccine (OPV) and will also be used for the rotavirus vaccine (Rotarix^{TM}) when it becomes available in the EPI in Ethiopia.

4.3.1 Oral administration of OPV

OPV is a clear red or yellow liquid vaccine that may come in either of two types of containers:

- Small plastic bottles that work like droppers – the drops are given directly from the dropper into the baby's mouth.
- Glass vials with a dropper (also made of glass) supplied in a separate plastic bag. Remove the metal or plastic cap from the vial of OPV. Then cut open the plastic bag containing the dropper and fit it onto the top of the OPV vial (Figure 4.20) before use.

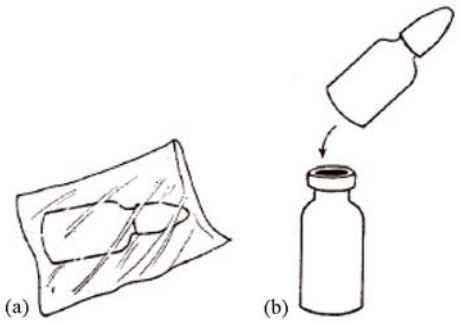


Figure 4.20 (a) Removing a dropper from its plastic bag, and (b) fitting it on top of a vial of OPV. (Source: WHO, 1998, *Immunization in Practice*, Module 8, *During a Session: Giving Immunizations*, Figure 8-E)

Ask the parent or carer to hold the child firmly with the child lying on its back. Then open the child's mouth by squeezing the cheeks gently between your fingers to make the child's lips point outward. Hold the dropper over the child's mouth at an angle of 45 degrees (Figure 4.21) and let two drops of the vaccine fall from the dropper onto the child's tongue. If the child spits out the vaccine or vomits, give another dose immediately.

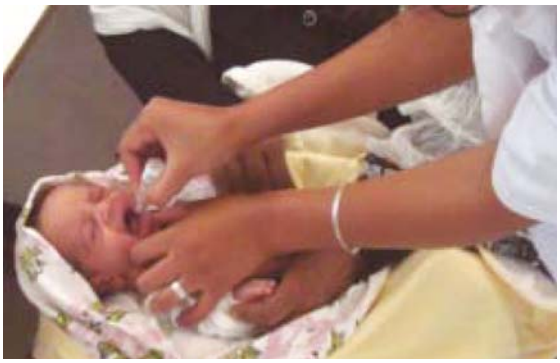


Figure 4.21 OPV drops being administered to a newborn baby. (Photo: Dr Kalid Asrat)

4.3.2 Oral rotavirus vaccine

Rotavirus vaccine is also administered orally in a similar way as described for OPV, but Rotarix™ is supplied in single-dose 'squeeze-tube' vials. Each vial contains 1.5 ml of vaccine which is squeezed slowly — drop by drop — into the infant's open mouth. You will be given more detailed instructions when the vaccine is introduced into the EPI in Ethiopia.

4.4 In conclusion

Table 4.1 summarises what you should know about the routes and sites of administration of the EPI antibacterial and antiviral vaccines.

Table 4.1 Summary of routes of administration and injection sites of the EPI vaccines.

Vaccine	**Route of administration**	**Injection site**
OPV and rotavirus vaccine (Rotarix™)	Oral	None (given by mouth)
BCG	Intradermal (ID)	Outer upper right arm
Measles	Subcutaneous (SC)	Outer upper arm
Pentavalent (DPT-HepB-Hib)	Intramuscular (IM)	Outer left upper thigh
Tetanus toxoid (TT) for women of childbearing age	Intramuscular (IM)	Outer upper arm
Pneumococcal vaccine (PCV10)	Intramuscular (IM)	Outer right upper thigh

Summary of Study Session 4

In Study Session 4, you have learned that:

1 Correct preparation before giving an immunization is very important to minimise the risk of infection or injury to yourself, your clients or their caregivers, and to maintain the effectiveness of the vaccine during transfer from the manufacturer's vial to the syringe and finally to the client.

2 Correct vaccine preparation includes using standard procedures (hand washing, skin preparation using antiseptics, etc.), selection of an appropriate syringe and needle, inspection of vials and ampoules to check the expiry date and vaccine vial monitors (VVMs) to ensure that vaccines and diluents are in good condition, vaccine reconstitution for those vaccines that require it, and keeping vaccines cold during the immunization session.

3 Always use the appropriate diluents provided specifically for the reconstitution of BCG or measles vaccines before use. Never use sterile normal saline or sterile water as a substitute for the correct diluent.

4 The injectable EPI vaccines are each given by a specific route and site: BCG vaccine is injected intradermally into the upper right arm; measles vaccine is injected subcutaneously into the upper arm; pentavalent vaccine and pneumococcal vaccine (PCV10) are injected intramuscularly into opposite upper thigh muscles; tetanus toxoid vaccine is injected intramuscularly into the woman's upper arm.

5 Oral polio vaccine (OPV) is given by two drops into the infant's mouth. Rotavirus vaccine (Rotarix™) is given as 1.5 ml of drops into the infant's mouth.

Self-Assessment Questions (SAQs) for Study Session 4

Now that you have completed Study Session 4, you can assess how well you have achieved its Learning Outcomes by answering the following questions. Some questions test your understanding of some Learning Outcomes for previous study sessions, as well as those in this one. Write your answers in your Study Diary and discuss them with your Tutor at the next Study Support Meeting. You can check your answers with the Notes on the Self-Assessment Questions at the end of this Module.

SAQ 4.1 (tests Learning Outcomes 4.1, 4.3 and 4.4)

Place a cross in the appropriate boxes in Table 4.2 to indicate the correct route of administration for each vaccine, and whether it is supplied as a liquid or if it has to be reconstituted with diluent before use.

Table 4.2 Vaccine administration and reconstitution summary.

	Route of administration				Reconstitution?	
Vaccine	**ID**	**SC**	**IM**	**Oral**	**Yes**	**No**
BCG						
Pentavalent						
Measles						
Polio (OPV)						
Pneumococcal (PCV10)						
Rotavirus (Rotarix™)						
TT (in women)						

SAQ 4.2 (tests Learning Outcomes 2.4, 3.4 and 4.2)

Read Case Study 4.1 and then answer the questions that follow it.

Case Study 4.1 Bekelech's immunization clinic

Three worried mothers have brought their sick babies to the Health Post one week after the babies received their scheduled EPI vaccines at six weeks of age. When Bekelech, the Health Extension Practitioner, checks the babies, she finds that they each have red and painful swellings on the left upper thigh and moderate fever. When they were immunized at the Health Post a week previously it had been a very busy day. Over 25 parents brought their children for immunizations, five pregnant women needed TT vaccine, and several people arrived with other health problems. Bekelech remembered that things kept going wrong that day and she had to rush to finish immunizing all the clients before nightfall.

(a) What is the swelling in the thighs of the three sick babies, and what could have caused it?
(b) What should Bekelech do about this problem?

SAQ 4.3 (tests Learning Outcomes 4.1, 4.2, 4.3 and 4.4)

Read Case Study 4.2 and then answer the question that follows it.

Case Study 4.2 Fatuma's immunization clinic

Fatuma is preparing to give BCG vaccinations to a number of babies. Before giving the vaccination, she washes her hands, checks that the expiry date on the vaccine ampoule has not passed, she taps the ampoule to make sure all the vaccine powder is at the bottom, and opens the ampoule. She inspects the diluent and uses it to reconstitute the vaccine. She places the reconstituted vaccine on a foam pad placed on top of conditioned ice-packs in a vaccine carrier, and administers it intradermally to each baby in the upper right arm.

- What two things has Fatuma forgotten to do? In each case, explain why this is important and what could happen as a result of it being forgotten.

SAQ 4.4 (tests Learning Outcome 4.5)

What is incorrect in the following statement?

- OPV is given to babies by first withdrawing the liquid vaccine into a sterile syringe, and then pushing the plunger just enough to let 2 drops of vaccine drip from the syringe into the baby's mouth.

Study Session 5 Vaccine Supply and Stock Management

Introduction

This study session deals with how to determine vaccine needs and how to keep your stock of vaccines in a reliable way, so that your immunization programme will not be interrupted as a result of shortage of supply. We also explain how to avoid wastage of vaccines by reducing the risk that the stock will pass its expiry date. The study session involves a lot of calculations using basic mathematics (addition, subtraction, multiplication and division) and using letters to represent values that you will need to measure or estimate. You are advised to apply your own data after each of the examples given here, to help you understand how the calculations apply in your setting.

Learning Outcomes for Study Session 5

When you have studied this session, you should be able to:

5.1 Define and use correctly all of the key words printed in **bold**. (SAQs 5.1, 5.3 and 5.4)

5.2 Calculate the size of the target population in your community and forecast their vaccine needs, using three different methods. (SAQs 5.1 and 5.2)

5.3 Calculate vaccine wastage rates and wastage factors and apply them to orders of vaccine stocks to minimise wastage. (SAQs 5.1 and 5.3)

5.4 Calculate the minimum and maximum quantities of vaccines required for a stated supply period and manage the critical stock level effectively. (SAQ 5.4)

5.1 Estimating vaccine needs

Vaccine management involves estimating the number of vaccine doses, diluents and injection equipment (e.g. syringes, needles) needed for a particular population over a stated supply period. In order to run an efficient and effective immunization session you need to have an adequate supply of vaccines of acceptable quality. This is essentially dependent on reliable planning and monitoring. You might have heard from mothers in the community that the health facility ran out of vaccines and their child could not be immunized. On the other hand, health facilities may have an excess stock of vaccine that has passed its expiry date and has to be thrown away. You should try to ensure that these situations do not arise in your Health Post (Figure 5.1).

Figure 5.1 Fura *kebele* Health Post, in the Southern Nations, Nationalities and Peoples Region (SNNPR) of Ethiopia, has been commended for meeting high performance targets. (Photo: Janet Haresnape)

Before we move on, remind yourself of the meaning of some key terms from previous study sessions.

■ What is the expiry date?

□ The **expiry date** is the (international calendar) date after which a vaccine, diluent or other consumable item should not be used for the purpose of immunization, because of possible loss of *potency* (vaccines; diluents) or *durability* (syringes, needles and other items).

Potency refers to the 'strength' or 'effectiveness' of a vaccine; **durability** refers to the time period that equipment such as syringes or needles remain in good condition (how long they last).

■ What is a diluent?

□ A **diluent** is a liquid used to reconstitute a freeze-dried vaccine. Each vaccine has its own diluent which should not be used to reconstitute any other vaccine.

Determining your vaccine needs accurately is important because it allows you to manage your immunization programme efficiently. Good vaccine management:

- enables you to use vaccines efficiently, and reduce wastage
- avoids shortages or excess accumulation of vaccines.

If the vaccine needs for your Health Post are not estimated correctly, and the wrong amounts are supplied by the health centre, this may result in shortage of vaccines or excess stock.

■ What is the problem if you order excess stock?

□ There is the risk that the vaccines will pass their expiry date before you need to use them, so they will be wasted.

We now consider how you can determine the vaccine needs for your Health Post. There are three methods based on:

- size of the target population for immunization
- previous vaccine consumption data
- size of the scheduled immunization sessions.

You will learn about each of these methods in the sections that follow. But you should note that vaccine requirements are likely to vary a lot from one

kebele to another; the stocks required for your immunization programme may be very different from the examples used in this study session.

5.2 Estimating vaccine needs based on the size of the target population

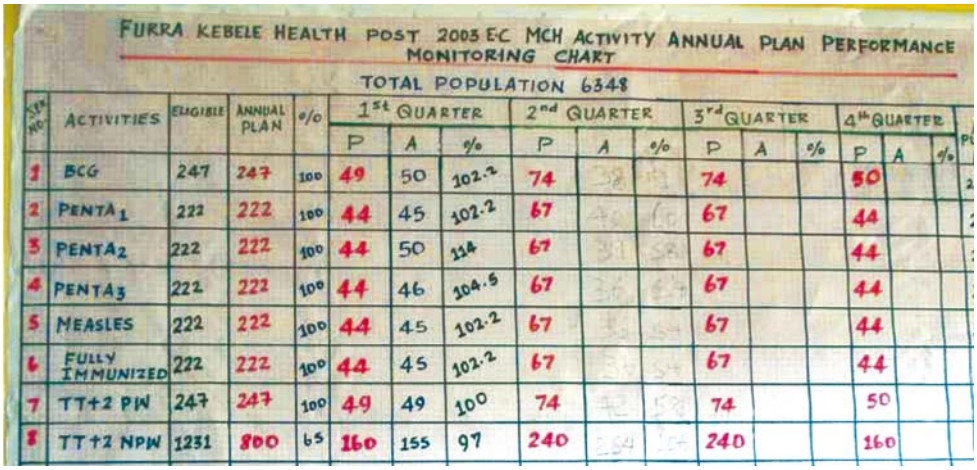
5.2.1 What is the target population?

The **target population** is the number of people who are eligible for vaccination with a particular vaccine. We use the letters 'pt' to represent the target population in calculations.

- For *tetanus toxoid (TT) vaccine* the target population is the total number of pregnant and non-pregnant **women in the childbearing age-group** (15–49 years). (Children will usually be protected from tetanus by receiving three doses of pentavalent vaccine at 6, 10 and 14 weeks of age.)
- For *BCG vaccine*, the target population is all **live births** (i.e. complete expulsion from the mother, regardless of duration of pregnancy, showing any evidence of life).
- For *all other vaccines* in the Expanded Programme on Immunization (EPI) in Ethiopia, the target population is all **surviving infants** (i.e. survive to their first birthday).

You learnt about tetanus toxoid (TT) vaccine and all the other the vaccines available in the EPI in Ethiopia in Study Sessions 2 and 3.

To calculate vaccine needs based on the target population, you need to know the *size of the target population*, the *number of doses* required according to the EPI schedule, and the *percentage immunization coverage rate* you have been given as the target in your annual activity plan (Figure 5.2).



FURRA KEBELE HEALTH POST 2003 E.C MCH ACTIVITY ANNUAL PLAN PERFORMANCE MONITORING CHART

TOTAL POPULATION 6348

S/No	ACTIVITIES	ELIGIBLE	ANNUAL PLAN	%	1st QUARTER			2nd QUARTER			3rd QUARTER			4th QUARTER		
					P	A	%	P	A	%	P	A	%	P	A	%
1	BCG	247	247	100	49	50	102.2	74			74			50		
2	PENTA1	222	222	100	44	45	102.2	67			67			44		
3	PENTA2	222	222	100	44	50	114	67			67			44		
4	PENTA3	222	222	100	44	46	104.5	67			67			44		
5	MEASLES	222	222	100	44	45	102.2	67			67			44		
6	FULLY IMMUNIZED	222	222	100	44	45	102.2	67			67			44		
7	TT+2 PW	247	247	100	49	49	100	74			74			50		
8	TT+2 NPW	1231	800	65	160	155	97	240			240			160		

Figure 5.2 Annual activity plan performance for immunizations in Fura *kebele* with a total population of 6,348 people in 2003 E.C. (Ethiopian calendar, or 2010 in the European calendar). (Photo: Janet Haresnape)

In Figure 5.2, the column headed 'eligible' gives the number in the target population for each vaccine. You can see that the health workers in this Health Post planned to immunize 100% of the eligible children and 100% of the pregnant women (TT+2 PW, pregnant women receiving more than 2 doses of TT vaccine). Columns headed P refer to 'planned' numbers for immunization, and A are the 'actual' numbers immunized — in the first quarter of the year, they exceeded their targets for all categories except

TT+2 NPW (non-pregnant women of childbearing age receiving more than 2 doses of TT).

Next, we will show you how to use data from an area similar to that of your *kebele* to calculate the target population for vaccination, so you can construct an annual activity plan for immunization like the one shown in Figure 5.2.

5.2.2 Calculating numbers in the target population

Table 5.1 shows an estimate of the target population for immunization in a *kebele* with a total population of 5,000. A figure of 4% of the Ethiopian population is usually taken to estimate the coverage required for all live births and surviving infants. You can assume that (on average) about 23% of the Ethiopian population will be women of childbearing age, of whom about 4% will be pregnant in a typical year.

Table 5.1 Estimating the target population for immunization in a *kebele* with a total population of 5,000.

Category	% of total population	Estimated number in target population
Live births	3.6	180
Surviving infants	3.4	170
Women of childbearing age (pregnant and non-pregnant)	23	1,150

You estimate the target population by multiplying the total population by the percentage in a particular category; for example in Table 5.1:

Expressing a percentage as a decimal number is easy, e.g.
90% is the same as 0.9; 23% is the same as 0.23, and 4% is the same as 0.04.

- The estimated number of women eligible for TT vaccination (Figure 5.3) is 5,000 × 23% (or 0.23) = 1,150
- The estimated number of children eligible for all other EPI vaccines is 5,000 × 4% (or 0.04) = 200, if you take the simple average of 4%. If you use the Ministry of Health indicators of live births (3.6%) and surviving infants (3.4%), the numbers will be 170 and 180 respectively.

Figure 5.3 About 23% of the Ethiopian population are women of childbearing age (pregnant and non-pregnant combined). (Photo: Ali Wyllie)

- Look back at Figure 5.2. What was the estimated target population eligible for TT immunization in Fura *kebele* in the year shown?

□ The estimated eligible population for TT vaccination was 1,478 women of childbearing age (247 pregnant and 1,231 non-pregnant) in Fura that year; this is 23% of the total population of 6,348 in the *kebele*.

5.2.3 Calculating required doses based on the immunization schedule

In addition to calculating the number of people in the target population, you also need to know the number of doses required in the EPI schedule in order to immunize everyone (total coverage). You learned about the EPI schedule in Study Sessions 2 and 3, but we repeat the key points in Table 5.2. We use the letters 'dn' to represent the number of doses in calculations.

Table 5.2 Vaccine schedule by age and number of doses.

Vaccines	**Schedule by age**	**Number of doses in schedule (dn)**
BCG	At birth	1
Pentavalent	At 6, 10 and 14 weeks	3
Polio (OPV)	At birth, 6, 10 and 14 weeks	4
PCV10	At 6, 10 and 14 weeks	3
Measles	At 9 months	1
Tetanus toxoid	On reaching childbearing age Ideally all women of childbearing age should receive five doses of tetanus toxoid.	At least 2

- If you have an estimated 200 surviving infants in your *kebele,* how many doses of pentavalent vaccine would be needed to complete the EPI schedule for all these children? Use the data on % of total population in Table 5.1.

□ The target population is 170 surviving infants, so you would need 510 doses to complete the EPI schedule for all of them, because each surviving infant should have three doses of pentavalent vaccine.

5.2.4 Immunization coverage targets

You now know how to calculate the annual vaccine needs for immunization of everyone in the target population. The EPI policy is to immunize 100% of the target population, but you may not be able to reach everyone in the target population in one year (for example, if your *kebele* includes very remote areas). Your annual action plan will include a percentage target from the *woreda* health office for the **immunization coverage rate** — the percentage of the eligible population that has been agreed as your objective for immunization with each of the EPI vaccines this year. The performance of your Health Post will be measured against this target.

If the annual target is *less* than 100% for a particular vaccine, you can estimate the number of vaccine doses you will actually need as follows. Start with the number of doses required to immunize *everyone* in the target population (i.e. total coverage), and multiply that number by the agreed (lower) percentage target for immunization coverage in your setting. We use the letters 'ic' to represent the percentage target for immunization coverage in calculations. Now look at the example in Table 5.3. (Your targets will be different.)

Table 5.3 Estimate of actual vaccine doses needed for various percentage targets for immunization coverage in an imaginary population of 5,000. (ic stands for immunization coverage target)

Vaccine	Number of doses for 100% coverage	% coverage target (ic)	Actual number of doses needed
BCG (1 dose)	200	90	180
Polio (4 doses)	800	90	720
Pentavalent (3 doses)	600	100	600
PCV10 (3 doses)	600	90	540
Measles (1 dose)	200	80	160
Tetanus toxoid (2 doses)	2,300	65	1,495

- How many doses of TT vaccine would you need to immunize the eligible women in Table 5.3 with *three* doses per woman, if you increased the percentage coverage target to 70%?

- Total 100% coverage with three doses would require 3,450 doses. If the coverage target is 70%, the actual doses required would be $3{,}450 \times 0.7 = 2{,}415$ doses.

Note that you can use the same method of calculation to estimate the number of ampoules of specific diluents required to reconstitute the freeze-dried vaccines (BCG and measles), and your requirement for injection equipment.

5.2.5 Vaccine wastage rates and wastage factors

Using calculations like the one in Table 5.3 enables you to determine the number of vaccine doses you need. However, some vaccine doses may be wasted during the year for various reasons (Box 5.1 on the next page). The **wastage rate** is the percentage of vaccine doses that are wasted. The general guideline on the amount of vaccine wastage that is considered acceptable for different types of vaccines is also shown in Box 5.1.

Box 5.1 Vaccine wastage

Some reasons for vaccine wastage:

- Some unused doses may have to be thrown away, e.g. because they have passed their expiry date or lost their labels.
- Some doses may be spoilt for one reason or another (e.g. vaccines damaged by storage at the wrong temperature).
- Some vials or ampoules may be broken during transport and handling.

Acceptable vaccine wastage rates:

- For liquid vaccines supplied in single or two-dose vials (e.g. pentavalent vaccine and PCV10), a wastage rate of 5% is acceptable.
- For OPV, a wastage rate of 10% is considered acceptable.
- For liquid vaccines supplied in multi-dose vials of 10 or more doses, a wastage rate of 15% is acceptable.
- For reconstituted vaccines, wastage rates of 50% for BCG and 25% for measles vaccine are considered acceptable.

Calculating the wastage factor

The **wastage factor** is the factor (number) that you multiply your estimated vaccine needs by, in order to allow for some doses being wasted. We use the letters 'wf' to represent the wastage factor in the following equation:

wastage factor (wf) = 100 ÷ (100 minus the % wastage rate)

where the wastage rate is the number of doses wasted, expressed as a percentage.

Note the 'brackets first' rule. In equations that include brackets around some of the numbers, you always calculate the answer to whatever is *inside* the brackets *first*, before you do anything else.

■ If the wastage rate is 30%, what is the wastage factor?

□

Wastage factor = 100 ÷ (100 – 30)
= 100 ÷ 70
= 1.43

Therefore, if 30% of the doses are wasted, the wastage factor will be 1.43.

Now you have learned how to calculate the basic values you need to estimate your vaccine needs for the target population. These values are the target population (pt), the number of doses in the schedule (dn), the immunization coverage target (ic) and the wastage factor (wf).

5.2.6 Calculating annual vaccine needs from the size of the target population

To calculate the annual vaccine needs for your immunization programme from the size of the target population, you need to multiply together the four values explained in Sections 5.2.1 to 5.2.4 of this study session. The calculation can be summarised using the equation shown below:

Annual vaccine needs = pt × dn × ic × wf

The equation uses the following values:

- target population (pt)
- number of doses in the schedule (dn)
- target immunization coverage (ic) expressed as a decimal number (not a percentage)
- wastage factor (wf) expressed as a decimal number.

■ Calculate the annual vaccine needs for pentavalent vaccine for a target population of 200 surviving infants, using the equation given above. Remember that three doses of this vaccine per child are needed for full immunization. Assume the target coverage rate is 90% and the wastage factor is 1.33 in this example.

□ The calculation is as follows:

- number of surviving infants (pt) = 200
- number of pentavalent doses in the EPI schedule (dn) = 3
- target coverage rate (ic) expressed as a decimal number = 0.9 (90%)
- wastage factor (wf) = 1.33

Annual pentavalent vaccine needs = pt × dn × ic × wf

= 200 × 3 × 0.9 × 1.33

= 178

In this example, 718 doses of pentavalent vaccine would be needed annually. Remember that the requirement in your own *kebele* may be different.

Now we turn to the second method of calculating vaccine needs.

5.3 Estimating vaccine needs on the basis of previous consumption

This method is based on the consumption of vaccines during the previous reporting period (usually the previous year). Some adjustment may be necessary if you believe that there has been any increase in the population size since the previous vaccine consumption was recorded. This method is useful for a Health Post where the stock management is good, but there is insufficient information on immunization objectives and targets for the next action plan. It is also useful when placing short-term orders.

In a *kebele* where stock management is efficient, there is likely to be good information on previous vaccine consumption. For example, you can probably see from the red bars in Figure 5.4 that 97 babies were immunized at birth with BCG in this *kebele* in 2001 (Ethiopian calendar). So this number could be used to predict the BCG vaccine requirement in the following year.

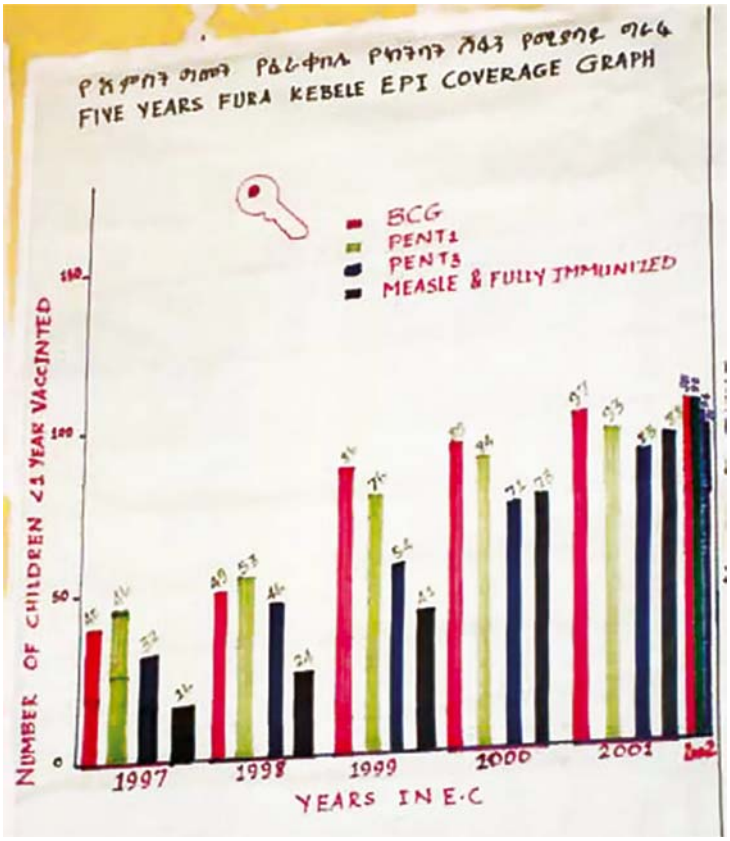


Figure 5.4 EPI coverage for infants aged under one year during a five year period at Fura *kebele*, SNNPR, Ethiopia; years are in the Ethiopian calendar (E.C.). (Photo: Janet Haresnape)

5.3.1 Calculating annual vaccine needs from previous consumption

For this calculation, we use an equation based on the stock of vaccine at the beginning and end of a particular period, the vaccines received during that period, and the vaccines lost, destroyed or thrown away during that period. The equation is given below:

Annual vaccine needs (in doses) = (i+r) – (f+l)

Remember the 'brackets first' rule; calculate the sums inside the brackets *first*, before you do anything else.

The equation includes the following numbers of doses:

- initial vaccine stock at the beginning of the period (i)
- vaccines received during the period (r)
- stock remaining at the end of the period (f)
- lost, destroyed or expired doses (l).

- Use the above equation to calculate the annual vaccine needs (in doses) for pentavalent vaccine in a particular *kebele,* in which the initial stock at the beginning of the year was 250 doses, and the quantity received during the year was 1,250 doses. At the end of the year there were 500 doses remaining in stock. The quantity lost during the year was 125 doses.

- The answer is calculated as follows:

Annual vaccine needs = (i+r) – (f+1)

= (250 + 1,250) – (500 + 125) doses

= 1,500 – 625 doses

= 750 doses

In this example, the estimated annual pentavalent vaccine need based on previous consumption is 750 doses.

- In the example given in Section 5.2.5, the estimated annual pentavalent vaccine need, based on the *size of the target population*, was 718 doses. However, the estimate based on the *previous year's consumption* (see above) was 750 doses. If both these imaginary examples had come from the same Health Post, what explanations could you suggest for the difference between the two estimates?

- Clearly the Health Post staff used *more* vaccine doses (750) in the previous year than was predicted from the size of the target population (718). There are several possible reasons for this, including:
  - There were more surviving infants in the *kebele* than the 200 estimated from calculating 4% of the total population size of 5,000.
  - The Health Post staff achieved a higher immunization coverage rate in the previous year than the 80% target they were asked to deliver.
  - They wasted more doses of vaccine than expected.

5.4 Estimating vaccine needs based on the size of immunization sessions

Now we show you how to calculate vaccine needs based on the *size of immunization sessions*. This method is appropriate if you cannot determine the rates of vaccine wastage, or vaccine stock management is not good. The equation you should use to estimate the annual vaccine needs by this method is given below:

Annual vaccine needs = posts × weeks × sessions × vials × doses, where:

- posts = number of immunization sites
- weeks = number of weeks the service is delivered during the year
- sessions = number of immunization sessions per week
- vials = number of vials opened per immunization session
- doses = number of doses per vial.

Table 5.4 shows how to calculate vaccine needs based on the size of immunization sessions in an imaginary example, using a vaccine supplied in multi-dose vials containing 10 doses per vial.

Table 5.4 Calculation of annual vaccine needs based on the size of immunization sessions.

immunization posts		weeks delivered		sessions per week		vials per session		doses per vial		total doses
1	×	48	×	2	×	1	×	10	=	960

So the vaccine needs for this particular multi-dose vaccine, based on the size and number of vaccination sessions = 960 doses per year.

■ Why do you think an estimate based on the size of the immunization sessions is likely to be *higher* than one based on previous consumption?

□ An estimate based on the size of the immunization sessions assumes that *all* of the scheduled immunization sessions will actually be held for each of the scheduled weeks in the year. But if some sessions cannot be held (for example, if there was a shortage of vaccine, or if the health worker was ill), then the actual number of vaccine doses given would be *lower* than estimated using the method illustrated in Table 5.4.

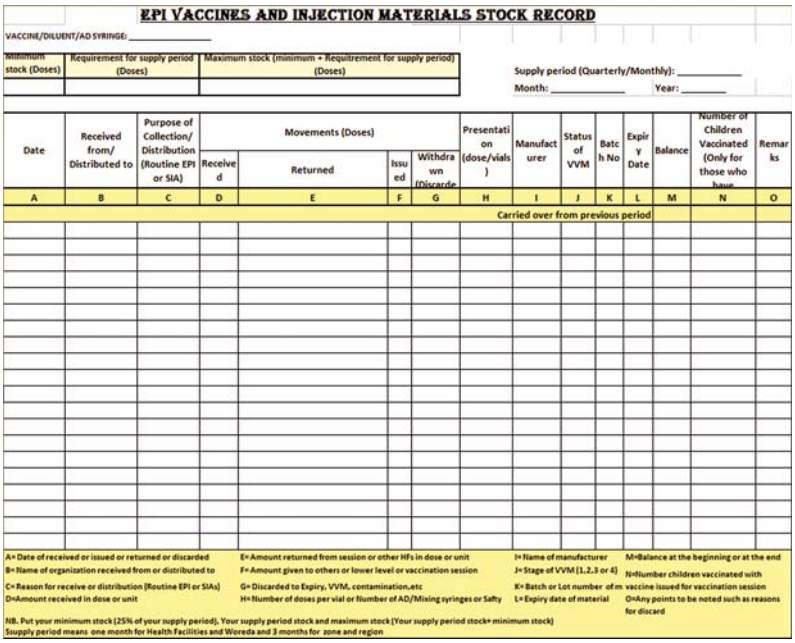
5.5 Ordering vaccines

In the previous section you learnt how to estimate vaccine needs. Vaccines are very expensive, so it is important to ensure that the ordered vaccines will be used and not spoiled. The World Health Organization (WHO) recommends that every order for vaccines should take into account the considerations in Box 5.2. There are some new terms in this box which are explained on the next page.

Box 5.2 Considerations for vaccine ordering

Health facility staff should always use an EPI Vaccine and Injection Materials Stock Record (see Figure 5.5 on the next page) to help them to:

- Avoid stock *shortages,* especially when mass immunization campaigns are planned.
- Avoid stock *excesses*, by not ordering excess stock, or exceeding the recommended storage periods.
- Avoid situations where vaccines *expire* during their storage period.
- Ensure that the other necessary stocks (e.g. diluents, syringes, needles; wick and paraffin or kerosene for refrigerators, etc.) are ordered at the same time as the vaccines.
- Organise stock using the principle of '*bundling*' for all supplies required delivering an immunization session.
- Ensure that there are adequate *cold chain* storage facilities (both in capacity and temperature; see Study Session 6).



EPI VACCINES AND INJECTION MATERIALS STOCK RECORD

VACCINE/DILUENT/AD SYRINGE: _____

Minimum stock (Doses)	Requirement for supply period (Doses)	Maximum stock (minimum + Requitrement for supply period) (Doses)

Supply period (Quarterly/Monthly): _____
Month: _____ Year: _____

Date	Received from/ Distributed to	Purpose of Collection/ Distribution (Routine EPI or SIA)	Movements (Doses)				Presentation (dose/vials)	Manufacturer	Status of VVM	Batch No	Expiry Date	Balance	Number of Children Vaccinated (Only for those who have	Remarks
			Received	Returned	Issued	Withdrawn (Discarde								
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
Carried over from previous period														

A= Date of received or issued or returned or discarded
B= Name of organization received from or distributed to
C= Reason for receive or distribution [Routine EPI or SIAs]
D=Amount received in dose or unit
E= Amount returned from session or other HFs in dose or unit
F= Amount given to others or lower level or vaccination session
G= Discarded to Expiry, VVM, contamination,etc
H= Number of doses per vial or Number of AD/Mixing syringes or Safty
I= Name of manufacturer
J= Stage of VVM (1,2,3 or 4)
K= Batch or Lot number of m
L= Expiry date of material
M=Balance at the beginning or at the end
N=Number children vaccinated with vaccine issued for vaccination session
O=Any points to be noted such as reasons for discard

NB. Put your minimum stock (25% of your supply period), Your supply period stock and maximum stock (Your supply period stock+ minimum stock)
Ssupply period means one month for Health Facilities and Woreda and 3 months for zone and region

Figure 5.5 This stock record should be kept up to date at all times to ensure that stock shortages and stock excesses are avoided.

Bundling refers to the practise of organising related stock all together in 'bundles' consisting of the correct numbers of all the items you need during an immunization session:

- good quality vaccines and diluents
- auto-disable (AD) syringes (or single-use disposable syringes and needles, if these are still used)
- safety boxes, etc.

Auto-disable (AD) syringes were mentioned in Study Session 4, and are specially modified disposable syringes with a fixed needle; an AD syringe is automatically disabled after it has been used once, because the plunger cannot be pulled back a second time. The WHO recommends that immunization programmes use AD syringes for all vaccinations, to prevent re-use of contaminated injection equipment.

The **cold chain** is fully described in Study Session 6, and refers to the network of refrigerators, cold stores, freezers, cold boxes and vaccine carriers, and their efficient organisation and maintenance, so that vaccines are kept at the right temperature at all times. This ensures that vaccines keep their potency during their transportation and storage at all stages, from leaving the factory to the point of administration to the target population.

Storage of vaccines is a major challenge. Vaccines are easily damaged during storage if the cold chain is not maintained. Therefore it is important to divide the vaccine supply into manageable periods for the purpose of ordering stocks. A Health Post will usually have a shorter supply period (four weeks) than a health centre. The next section explains how to calculate the quantities of vaccine needed for a specific supply period.

5.5.1 Calculating quantities of vaccine for a particular supply period

The vaccine needs for a specific storage or supply period (in this case, 12 months or 48 working weeks) can be calculated using the following equation:

$q_{period} = (q_{year} \div 12) \times p_{supply}$ when the supply period is given in months, or $q_{period} = (q_{year} \div 48) \times p_{supply}$ when the supply period is given in working weeks.

where:

q_{period} = vaccine needs for the period

q_{year} = annual vaccine needs

p_{supply} = supply period (in months or weeks).

You can see an example of vaccine needs calculated in weeks in the following question.

■ If the number of doses of vaccine required for one year in an imaginary *kebele* is 2,000, how many doses would be needed for a two-week period?

□ In this example, the annual vaccine needs q_{year} = 2,000 and the supply period p_{supply} is 2 weeks.

The vaccine needs for one week would be 2,000 doses ÷ 48 working weeks.

So the vaccine needs for the period (q_{period}) of 2 weeks is (2,000 ÷ 48) × 2 = 83 doses.

Therefore, 83 doses would be required for a two-week period in this example.

5.5.2 Calculating the minimum stock level

The time between the date of ordering vaccines and the date when you collect them may not be as soon as you would wish it to be. There may be an increase in vaccine demand that you want to respond to quickly, but you may find there are unexpected delays in restocking. Therefore, you should always aim to keep a minimum amount of vaccine in stock. The **minimum stock level** is the minimum number of vaccine doses that should be in the refrigerator when the next supply of vaccines is collected. Usually, the minimum stock is taken as 25% of the total vaccine needs for the supply period.

The minimum stock level can be calculated using the following equation:

$s_{mini} = q_{period} \times 25\%$ (or 0.25)

where s_{mini} is the minimum stock level and q_{period} is the vaccine needs for the period.

■ Imagine that at a particular Health Post, the number of doses of oral polio vaccine (OPV) required for a 2-week supply period is 80. If the minimum stock should be 25% of the total vaccine needs for the supply period, what should the minimum stock level be at this Health Post when the next supply of vaccine is collected from the health centre? (Remember that 25% is expressed as 0.25 in calculations.)

□ The number of doses of OPV required for 2-weeks is 80.

The percentage required as minimum stock is 25% (0.25).

So the minimum stock is 80 × 0.25 doses, or 20 doses.

This means that there should be at least 20 doses of OPV in stock at this Health Post when the next supply of vaccine is collected.

5.5.3 Calculating the maximum stock level

You have learned that vaccines are easily damaged and that they are very expensive. It is not good practice to keep an unnecessary amount of vaccine in stock. The **maximum stock level** is the maximum number of vaccine doses that should be present in the refrigerator *immediately after* a new supply has been collected from the health centre.

The maximum stock level can be calculated using the following equation:

$$s_{maxi} = q_{period} + s_{mini}$$

where s_{maxi} is the maximum stock level, q_{period} is the vaccine needs for the period, and s_{mini} is the minimum stock level.

■ Think again about the Health Post where the number of doses of OPV needed for a 2-week supply period is 80 and the minimum stock level is 20 doses. What should the maximum stock level of OPV be in this Health Post?

□ The number of OPV doses needed at this Health Post for a 2-week period is 80, and the minimum stock level is 20 doses, so the maximum stock level is (80 + 20) = 100 doses. So there should be no more than 100 doses of OPV in stock when the next supply of this vaccine is collected.

If your supplies of vaccine *exceed* your maximum stock level, it may be wise to consider returning some vials to the higher level facility.

5.5.4 Calculating the critical stock level (or 'time to order')

It is important to be aware of your vaccine stock, and to place your next order at the right time. The **critical stock level** (or 'time to order' level) is the number of vaccine doses in stock at the time when it is absolutely necessary to place a new order. 'Time to order' calculations take into account the level of vaccine consumption while waiting for the new supply. This precaution is necessary to prevent the vaccine stock from dropping below the minimum stock level before the new order can be collected. The **delivery time** is the time interval between the day the vaccines are ordered and the day that you collect them from the health centre.

The critical stock level can be calculated using the following equation:

$s_{critical} = q_{delivery} + s_{mini}$, where:

- $s_{critical}$ is the critical stock level
- $q_{delivery}$ is the number of doses needed during the delivery time, and
- s_{mini} is the minimum stock level.

$q_{delivery} = (q_{period} \times t_{delivery}) \div n$, where:

The number of doses required during the delivery time ($q_{delivery}$) can be calculated using the following equation:

- $t_{delivery}$ is the number of days between placing the order and collecting new vaccines
- n is the number of days in the supply period (i.e. the period that the health facility maintains its vaccine stocks at, or above, the minimum level).

Now attempt Activity 5.1 to calculate the critical stock level for an imaginary Health Post. You will need paper and a pen or pencil to help you make the calculations.

Activity 5.1 Calculating the critical stock level

At a particular Health Post, it often takes 2 working days for the HEW to collect her new supply of vaccines after ordering them from the health centre, which is 15 km away along difficult tracks. The number of doses of OPV she needs for a supply period of 2 weeks is 80 doses.

What is the critical stock level (or 'time to order' level) for OPV at this Health Post? Assume that the minimum stock level is 25% of the number of doses needed for the 2-week supply period (10 working days).

Write down all your calculations so that it is clear how you reached your answers. Do this before you check our answer below.

Answer

The calculation of the critical stock (or 'time to order') level can be done using the equations given above Activity 5.1. First, calculate the number of doses you will need during the delivery time ($q_{delivery}$) by using the equation:

$q_{delivery} = (q_{period} \times t_{delivery}) \div n$

In this Health Post, q_{period} is 80 doses of OPV, $t_{delivery}$ is 2 days, and the supply period is 10 working days (2 weeks) so n is 10.

$q_{delivery} = (80 \times 2) \div 10 = 16$ doses

The minimum stock level (s_{mini}) is 25% of 80 doses, which is 20 doses. The critical stock level ($s_{critical}$) is calculated using the equation:

$s_{critical} = q_{delivery} + s_{mini}$

In this Health Post, $q_{delivery}$ is 16 doses and s_{mini} is 20 doses, so:

$s_{critical} = (16 + 20) = 36$ doses.

So the staff at this Health Post should place an order for OPV when the critical stock level is reached at 36 doses.

In the next study session you will learn about keeping vaccines and diluents safe and effective by maintaining the cold chain. This is vitally important in reducing wastage, as well as maintaining the potency of the vaccines.

Summary of Study Session 5

In Study Session 5, you have learned that:

1 Vaccine management is important because vaccines are easily damaged and they are very expensive.

2 Accurate estimation of all stock requirements avoids shortages and prevents wastage from excessive orders; good vaccine stock management is essential to the smooth running of immunization sessions.

3 There are three methods of estimating annual vaccine needs, based on:

- size of the target population
- previous consumption levels
- size of immunization sessions.

4 These methods can also be applied to estimates of other immunization supplies, such as diluents and injection equipment.

5 It is essential to keep the EPI Vaccine and Injection Materials Stock Record up to date; this will help you to avoid stock shortages and stock wastage.

6 It is good practise to organise stocks of vaccines, diluents, syringes, needles and safety boxes together in bundles.

7 It is important to ensure that vaccine stocks do not fall below the recommended minimum level, or rise above the recommended maximum level, and that you order new supplies when the stock falls to the critical level.

Self-Assessment Questions (SAQs) for Study Session 5

SAQ 5.1 (tests Learning Outcomes 5.1, 5.2 and 5.3)

Imagine that you are working in a *kebele* with a total population of 5,700, and that 5% of the total population are children aged 0 to 11 months. There is only one immunization site — your Health Post. You have been given a target of 90% immunization coverage for pentavalent vaccine for the year. The wastage rate has been agreed as 5%.

- Based on the national EPI schedule for this vaccine, calculate the annual pentavalent vaccine needs, based on the size of the target population in this *kebele*.

SAQ 5.2 (tests Learning Outcomes 5.2)

Imagine that in your *kebele* you plan to deliver two sessions of immunization per week for 45 weeks of the year. Your Health Post is provided with PCV10 (Synflorix) vaccine in multi-dose vials of 2 doses per vial, and at each immunization session 5 vials are used.

- Estimate the annual PCV10 vaccine needs for the Health Post, based on the size of the immunization sessions.

SAQ 5.3 (tests Learning Outcomes 5.1 and 5.3)

If the wastage rate for oral polio vaccine (OPV) is 10%, what wastage factor would you need to use when calculating the annual OPV needs, based on the size of the target population?

SAQ 5.4 (tests Learning Outcomes 5.1 and 5.4)

(a) How much PCV10 vaccine would be required by the Health Post mentioned in SAQ 5.2 for a 2-week period?
(b) What is the minimum stock level for PCV10 vaccine for a 2-week period for this Health Post?
(c) What is the maximum stock level for PCV10 vaccine in the same period?

Study Session 6 The Cold Chain

Introduction

In this study session you will learn about the **cold chain** — the equipment and procedures that you will use to keep vaccines within the correct temperature range (between +2°C and +8°C), so that they remain in good condition. Vaccines should be stored carefully at all times, beginning at the factory where they are manufactured and at every stage until the moment they are given to children and mothers. Excess heat or cold will reduce the vaccine potency (strength), increasing the risk that recipients will not be protected against vaccine-preventable diseases.

The cold chain has three main components: equipment for vaccine transport and storage, well-trained personnel, and efficient management procedures. In this study session, and the next two sessions, you will learn how all three components are required to ensure that vaccines are transported and stored safely.

Learning Outcomes for Study Session 6

6.1 Define and use correctly all of the key words printed in **bold**. (SAQs 6.1 and 6.2)

6.2 Describe the common types of cold chain equipment and their uses in your Health Post. (SAQs 6.1, 6.2, 6.5 and 6.6)

6.3 Describe how you can monitor the effectiveness of the cold chain for vaccines at your Health Post and when you are transporting vaccines. (SAQs 6.1, 6.2, 6.5 and 6.7)

6.4 Describe how vaccines can be spoiled and how to prevent this from happening. (SAQs 6.4, 6.6 and 6.7)

6.5 Describe how to load vaccines and diluents correctly into cold chain equipment. (SAQ 6.3, 6.4 and 6.6)

6.6 Briefly describe how to maintain cold chain equipment (undertake minor repairs). (SAQs 6.5 and 6.7)

6.1 Components of the cold chain

The **cold chain** has three main components, each of which must combine to ensure safe vaccine transport and storage:

- transport and storage equipment
- trained personnel
- efficient management procedures.

This study session is about the first of these components. You can see the cold chain equipment in Figure 6.1 on the next page, together with the storage temperatures required at each storage place, from arrival in the country to the storage in your Health Post. Next we will describe the common cold chain equipment you will use when you collect vaccines from the health centre and in your practice at the Health Post and in the community.

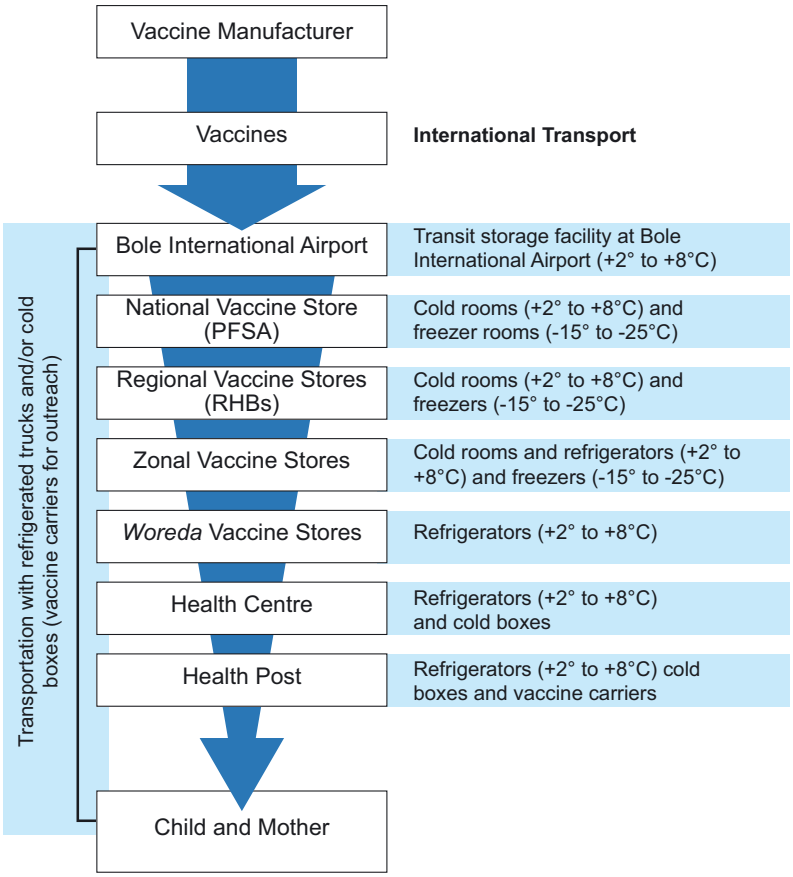


Figure 6.1 The cold chain. (Adapted from: WHO, 2004, *Immunization in Practice*, Module 3, *The Cold Chain*, Figure 3A, p.2)

6.2 Cold chain equipment in Health Posts

The common cold chain equipment used in Health Posts are refrigerators, cold boxes, vaccine carriers, ice-packs and foam pads. In this section, the correct use of each of these will be described.

6.2.1 Refrigerators

A **refrigerator** is a cooling apparatus. Health facility refrigerators may be powered by electricity, kerosene, paraffin, bottled gas or solar energy. Electric refrigerators are usually the least costly to run and the easiest to maintain, but they must have a reliable electricity supply, which is not often possible in rural Health Posts in Ethiopia. Different refrigerators have different capacities for storing vaccines and for freezing and storing ice-packs (Figure 6.2).

Figure 6.2 A Health Extension Worker with a kerosene-powered refrigerator in a rural Health Post in SNNPR, Ethiopia. This refrigerator has a freezer compartment on top, and plenty of space for the vaccines, diluents and other supplies that must be kept cold. (Photos: Janet Haresnape)

A refrigerator in a Health Post should be able to hold:

- One month's supply of vaccines and diluents in the refrigerator compartment.
- A minimum stock of one to two weeks' supply of vaccines and diluents (i.e. an additional 25% of the standard stock).
- Frozen ice-packs (strong, specially made plastic bottles containing frozen water) standing in the freezer compartment for at least 24 hours to become fully frozen.
- Unfrozen chilled ice-packs in the refrigerator compartment (Figure 6.3); they help to keep the refrigerator cold for a while if there is a power failure. You can also keep ordinary plastic bottles filled with chilled water in the refrigerator for the same purpose.

Figure 6.3 These unfrozen (chilled water) ice-packs help to keep the refrigerator cold during a power failure. They should always be stored vertically to avoid possible leaks. (Photo: Basiro Davey)

6.2.2 Cold boxes and vaccine carriers

A **cold box** is an insulated container that can be lined with 'conditioned' ice-packs to keep vaccines and diluents cold — but not frozen — during transportation of vaccine supplies from the health centre, or to outreach sites. (We will explain what 'conditioning' ice-packs means in the next section.) Cold boxes can also be used for short periods of vaccine storage (from two to seven days, depending on the manufacturer) when the refrigerator is out of order or being defrosted, or if vaccines are being transported in a vehicle for a few days by mobile immunization teams.

Do not put *frozen* ice-packs into the main refrigerator compartment! They could cause the temperature to drop too low and destroy the freeze-sensitive vaccines.

Cold boxes are quite large. At Health Post level you may instead use a smaller insulated container called a **vaccine carrier** (Figure 6.4). Vaccine carriers are also lined with conditioned ice-packs to keep vaccines and diluents cold during transportation from the collection store at the health centre, or on journeys to outreach sites, and for temporary storage during Health Post immunization sessions. They are smaller than cold boxes and are easier to carry if walking, but they do not stay cold for as long — at most 36–48 hours with the lid closed (depending on the type).

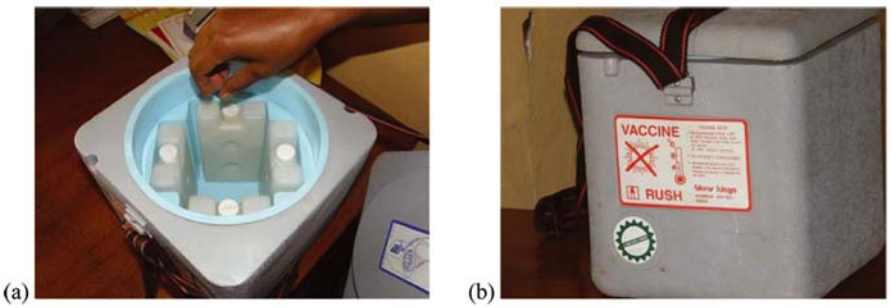


Figure 6.4 (a) A vaccine carrier lined with conditioned ice-packs. (b) This type of vaccine carrier stays cold for a maximum of 36 hours if the lid remains closed. (Photo: Basiro Davey)

6.2.3 Ice-packs

Ice-packs are flat, rectangular plastic bottles filled with water and then either kept at refrigerator temperature (Figure 6.3 on the previous page), or frozen and then conditioned for use in vaccine carriers and cold boxes (Figure 6.4a). The number of ice-packs required for a cold box or vaccine carrier varies.

Every Health Post should have a minimum of two sets of ice-packs for each of their cold boxes and vaccine carriers, one in the process of being frozen or refrigerated, and the other conditioned for use in a cold box or vaccine carrier.

Freezing ice-packs

The proper freezing and conditioning of ice-packs is essential for maintaining the potency of vaccines. To freeze ice-packs, follow the steps in Box 6.1.

Box 6.1 Freezing ice-packs

- Fill the ice-packs with water, leaving about 20% air space at the top, and put the cap on tightly.
- Hold each ice-pack upside down and squeeze it to make sure it does not leak.
- Put the ice-packs upright in the freezer compartment of the refrigerator, so that the surface of each ice-pack is touching the evaporator plate, and close the door.
- Leave ice-packs in the freezer for at least 24 hours to freeze solid. After 24 hours they should be ready to use.
- After each vaccination session put the melted ice-packs back in the freezer as soon as possible.

Keep extra unfrozen ice-packs that do not fit in the freezer in the bottom part of the main refrigerator compartment (look back at Figure 6.3). This helps the water in these chilled ice-packs to freeze relatively quickly when you put them into the freezer, and it also helps to keep this section of the refrigerator cold in case of a power failure.

Conditioned ice-packs and chilled water packs

Conditioned ice-packs have first been fully frozen, and then removed from the freezer and left at room temperature for a short time (it may take over 30 minutes if the room is cold). Allow the frozen ice-packs to sit at room temperature until the ice begins to melt and water starts to form. Check to see if each ice-pack has been conditioned properly by shaking it and listening for the sound of water moving inside. This prevents the ice-packs from freezing the vaccines inside a cold box or vaccine carrier, and damaging the freeze-sensitive vaccines.

Studies conducted in many countries on cold chain temperatures have revealed that many vaccines are damaged more severely by freezing than by heat. So it is crucial to use properly conditioned ice-packs or chilled water packs when transporting freeze-sensitive vaccines like pentavalent, PCV10 and TT. **Chilled water packs** can be made by almost filling the ice-pack containers or ordinary plastic water bottles with water and placing them in the main compartment of the refrigerator for about 24 hours. Using chilled water packs may be more efficient than using conditioned ice-packs, because it takes more electricity, gas or kerosene, and more time, to freeze ice-packs and then condition them. Also, there is a risk that if frozen ice-packs are not conditioned properly, they may expose freeze-sensitive vaccines to damage from freezing during transport in vaccine carriers or cold boxes.

6.2.4 Foam pads

A **foam pad** is a piece of soft foam that fits on top of the conditioned ice-packs in a cold box or a vaccine carrier (Figure 6.5). There are some cuts in the foam to allow vaccine vials to be inserted in the pad.

During immunization sessions, the foam pad can be used as a temporary lid to keep unopened vaccines inside the carrier cool, while providing a surface to hold and protect opened vaccine vials and keep them cool (Figure 6.6). Vaccines are protected from heat damage during an immunization session if they are inserted in the foam pad above the ice-packs in the vaccine carrier.

Figure 6.5 The foam pad in a vaccine carrier has cuts to hold vials and vaccines during an immunization session. (Photo: Janet Haresnape)

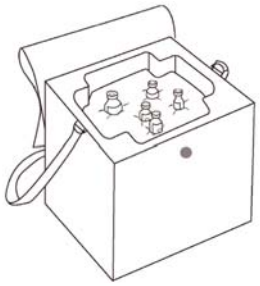


Figure 6.6 Foam pad with vaccine vials inserted. (Source: WHO, 2004, as in Figure 6.1, p.8)

6.3 Cold chain monitoring equipment in your Health Post

It is important to know about the common cold chain monitoring equipment for keeping a record of the temperature that vaccines and diluents are exposed to during transportation and storage. The items of equipment used are vaccine vial monitors, freeze indicators and thermometers.

6.3.1 Vaccine vial monitors

A **vaccine vial monitor (VVM)** is a label that changes colour when the vaccine vial or ampoule has been exposed to temperatures above 8ºC over a period of time. Before opening a vaccine container, the status of the VVM must be checked to see whether the vaccine has been damaged by heat. Manufacturers attach VVMs to vials and ampoules of most vaccines. The VVM is printed on the label or cap, or the neck of ampoules of freeze-dried vaccines (Figure 6.7). It looks like a square inside a circle. As the vaccine vial is exposed to more heat, the square becomes darker.

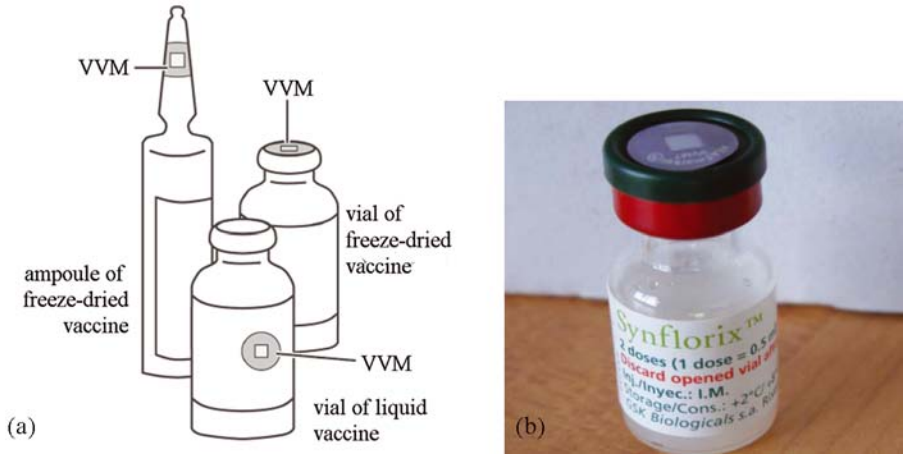


Figure 6.7 (a) Vaccine Vial Monitors (VVMs) on the neck of an ampoule, or on the label or cap of a vaccine vial (Source: WHO, 2004, as in Figure 6.1, p.10). (b) A vial of liquid PCV10 vaccine (Synflorix) with the VVM on the cap (Photo: WHO).

You should only use vaccines where the inner square in the VVM is *lighter* in colour than the outside circle (Figure 6.8, top row). Vials with VVMs in which the inner square has begun to darken, but is still lighter than the outer circle (Figure 6.8, second row), should be used *first*, i.e. *before* vials where the VVM square has not begun to darken. Vials with VVMs in which the inner square matches the colour of the outer square, or in which the inner square is darker than the outer circle, have reached or gone beyond the **discard point** and should not be used (Figure 6.8, bottom two rows).

Do not use vaccines that have reached the discard point, even if they have not passed their expiry date!

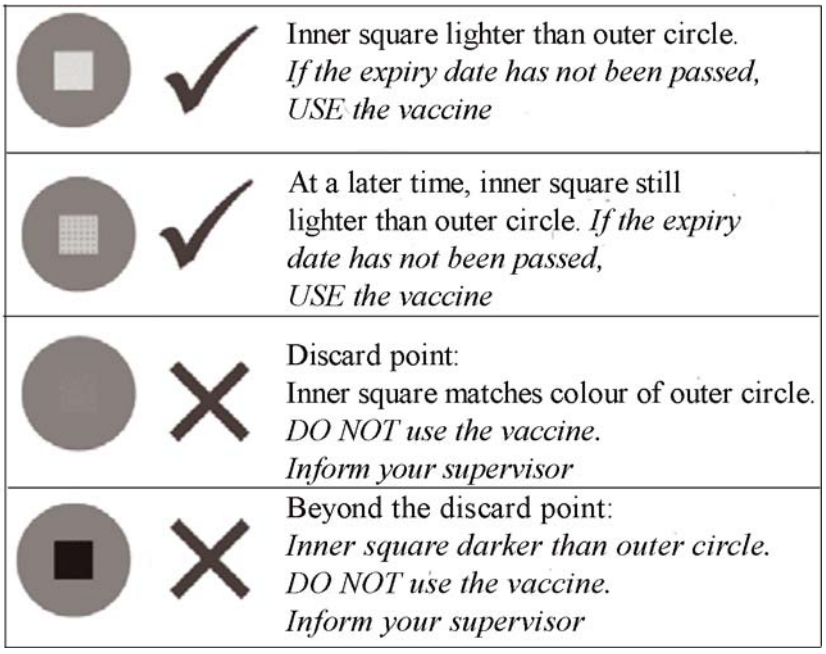


Figure 6.8 How to read a vaccine vial monitor (VVM). (Source: WHO, 2004, as in Figure 6.1, p.11)

VVMs respond to heat — but not to freezing!

VVMs respond to heat — *they do not measure exposure to freezing temperatures*. A vaccine may have been frozen and have lost its potency, but the VVM cannot tell you this. So even if the VVM indicates that the vaccine has not been exposed to heat, the vaccine may still have been frozen. Therefore, for freeze-sensitive vaccines, it is important to establish that they have not been frozen before using them. Inspect the freeze indicator, as described next.

6.3.2 Freeze indicators

Freeze indicators are devices used to monitor the exposure of vaccines to freezing. Freeze indicators are packed with batches of freeze-sensitive EPI vaccines (pentavalent, PCV10 and TT), as well as with other freeze-sensitive vaccines such as HepB, which may be used to protect healthcare workers. The most commonly used type of freeze indicator is the **freeze-tag** (Figure 6.9). This is an irreversible temperature indicator that shows if a product, such as a vaccine, has been exposed to freezing. It consists of an electronic temperature measuring circuit with a liquid crystal display (LCD). A small blinking dot of light in the corner of the display shows that the freeze-tag is functioning correctly.

Figure 6.9 Freeze-tags showing: (a) 'good status' display; (b) 'alarm status' display. (Photo: WHO)

If the freeze-tag is exposed to a temperature below 0°C (with a range between +0.3 °C and –0.3 °C) for more than 60 minutes (with a range of between 57 to 63 minutes), the display will change from the 'good status' (Figure 6.9a) to the 'alarm status' (Figure 6.9b).

Vaccines that have been exposed to freezing may have been damaged and should be checked by using the shake test, as described below.

6.3.3 The shake test

The **shake test** is how you check whether freeze-sensitive vaccines (pentavalent, PCV10, TT or HepB) have been subjected to freezing temperatures, which are likely to have damaged them. To perform the shake test, follow the steps below:

Step 1 — *Prepare a frozen control vial*: Take a vial of vaccine of the same type and batch number as the vaccine you want to test, and from the same manufacturer. Freeze the vial until the contents are solid (at least 10 hours at –10°C) and then let it thaw. This is the **frozen control vial** (the middle vial in Figure 6.10). Mark the vial clearly so that it is easily identifiable and will not be used by mistake.

Step 2 — *Choose a test vial*: Take a vial (or vials) of vaccine from the batch that you suspect has been frozen. This is the suspected **frozen test vial** (on the left in Figure 6.10).

Step 3 — *Shake the control and test vials*: Hold the frozen control vial and the suspected frozen test vial together in one hand and shake them vigorously for 10–15 seconds.

Step 4 — *Allow the vials to rest*: Leave both vials to rest by placing them on a table side by side and not moving them further. A freeze-sensitive vaccine (see the vial on the right in Figure 6.10) that has not been frozen appears as a uniformly cloudy liquid. After freezing, the vaccine tends to form flakes that quickly settle at the bottom of the vial to form a sediment when you leave it to rest after vigorous shaking. The speed at which the flakes settle is called the *sedimentation rate*. Note that some vials have large labels that conceal the vial contents. This makes it difficult to see the sedimentation process. In such cases, turn the control and test vials upside down and observe sedimentation taking place in the neck of the vials.

Step 5 — *Compare the vials*: Observe the difference in sedimentation rates in the frozen control and suspected frozen test vials for a maximum of 30 minutes. View both vials against the light to compare the sedimentation rate. If the vaccine in the suspected test vial shows a much slower sedimentation rate than the vaccine in the frozen control vial, you can conclude that the test vaccine has most probably *not been frozen* and can be used.

■ What should you conclude if the sedimentation rate is similar in the suspected test vial and the frozen control vial?

□ You should conclude that the test vial has probably been damaged by freezing and the vaccine *should not be used.*

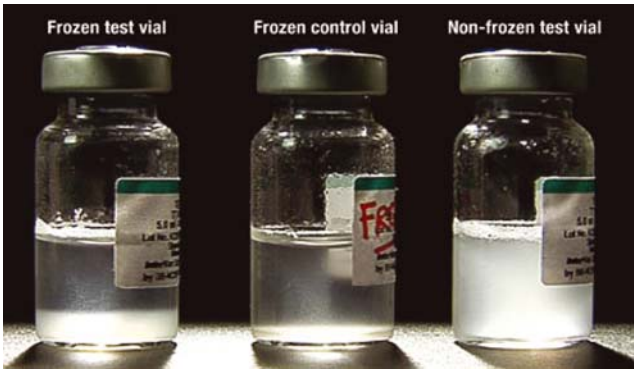


Figure 6.10 Three vials of liquid freeze-sensitive vaccine viewed with the light behind them: (left) frozen test vial in which a sediment has settled to the bottom of the vial after vigorous shaking; (centre) frozen control vial in which the sedimentation rate can be compared with the rate in a suspected frozen test vial; (right) non-frozen test vial showing the uniformly cloudy appearance of a vaccine that has not been damaged by freezing. (Photo: WHO)

The shake test should be conducted for all vaccines with the following characteristics:

- Vaccines packed in boxes that have a freeze indicator (e.g. freeze tag, see Figure 6.9), which is found to be activated.
- Refrigerator temperature records that show the temperature has fallen below +2ºC.

- Where you suspect that the vaccines may have been frozen by mistake, for example by placing too close to the freezer plate in the refrigerator, or touching frozen ice-packs.

If the vaccine fails the 'shake test' it must be discarded. There is no need to conduct a shake test if a liquid vaccine vial is already frozen solid — simply discard it. Also discard any vials that develop white lumps of sediment attached to the glass, which cannot be dispersed despite vigorous shaking. This can happen if pentavalent vaccine is exposed to freezing below 0ºC.

6.3.4 Thermometers

A **thermometer** is an instrument for monitoring the temperature of your cold chain equipment — refrigerator, cold box or vaccine carrier. It enables you to adjust the temperature to the correct range for the storage and transport of vaccines.

At a Health Post, either a dial or a stem (bulb) thermometer may be used to monitor the equipment temperature. On a dial thermometer, the needle moves around the scale, pointing to plus (+) numbers when it is warmer, and to minus (–) numbers when it is colder (Figure 6.11a). On a stem (or bulb) thermometer, coloured fluid in the bulb moves up the scale as it becomes warmer, and down the scale as it becomes colder (Figure 6.11b).

■ What temperature is showing on the thermometers in Figure 6.11? Is this a safe temperature for the storage of liquid vaccines?

□ Both thermometers are recording a temperature of +5°C. This is safe for storing liquid vaccines, which should be maintained between +2°C and +8°C.

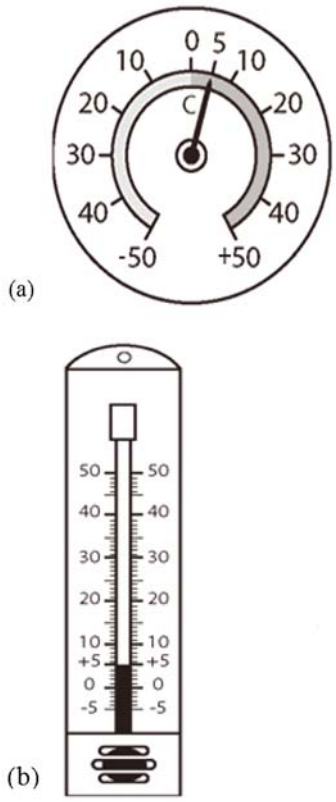


Figure 6.11
(a) Dial thermometer, and (b) stem thermometer. (Source: WHO, 2004, as in Figure 6.1, p.13)

6.4 How to load cold chain equipment

Refrigerators, cold boxes and vaccine carriers must be loaded correctly to keep the temperature of the vaccines and diluents inside within the acceptable range. All health workers in a Health Post should know how to monitor the cold chain equipment and what action to take if the temperature is too high or too low.

6.4.1 The design of vaccine refrigerators

All electric powered refrigerators have a thermostat. The **thermostat** is a device that automatically responds to temperature changes by activating switches controlling the cooling equipment to maintain the refrigerator compartments at the correct temperature. You can alter the setting of the thermostat if the temperature of the refrigerator is found to be too high or too low when you check the thermometer. Gas or kerosene refrigerators are adjusted by altering the size of the flame.

To ensure that the refrigerator is effective for storing your vaccines, there are a number of guidelines that you should follow (Box 6.2).

Box 6.2 Guidelines for storing vaccines in a refrigerator

- Do not keep opening and closing the refrigerator door, since this raises the temperature inside the refrigerator.
- Do not put vaccines on the door shelves. The temperature in this part of the refrigerator is too warm to store vaccines, and when the door is opened the door shelves are instantly exposed to room temperature.
- Discard all expired vaccines (past their expiry date), or vaccines with VVMs that have reached or are beyond their discard point, or vaccines that have been reconstituted for more than six hours.
- Do not return reconstituted vaccines (BCG, measles) or opened PCV10 vials to the refrigerator. They should be discarded at the end of the immunization session or after six hours, whichever comes soonest.
- The refrigerator should not be packed too full. Approximately half of the total space inside should be left empty to allow air to circulate around the vaccines and diluents and keep them cool.
- Vaccines, diluents and ice-packs should ideally be kept in a separate refrigerator from other items. However, if your Health Post has only one refrigerator and you need to store other heat-sensitive supplies in it, such as drugs, ointments, serum and blood samples, be sure to label them clearly and keep them on a separate shelf from the vaccines and diluents.
- Food and drinks should NEVER be stored in a vaccine refrigerator.

There are a number of different types of refrigerator. Some front-loading refrigerators have one door, with a second freezing compartment inside. Others have two separate compartments, with different doors (look back at Figure 6.2, and see the diagram in Figure 6.12).

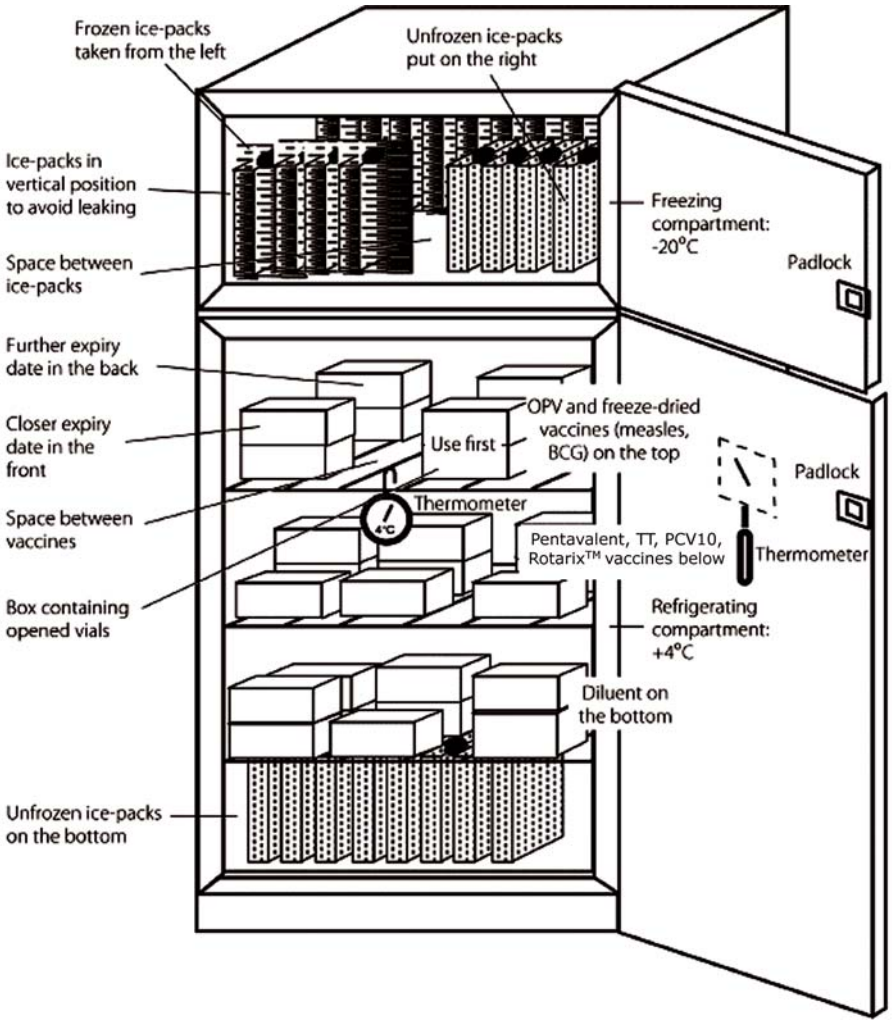


Figure 6.12 Front-loading refrigerator with separate freezing compartment on top. (Source: WHO, 2004, as Figure 6.1, p.18)

The two compartments shown in Figure 6.12 should be used as follows:

- The main compartment (the refrigerator), in which the temperature should be kept between +2ºC and +8ºC, is used for storing vaccines and diluents.
- The top compartment (the freezer) is used for freezing ice-packs. If the refrigerator is working properly, this compartment will be between –15ºC and –20ºC.

Notice the 'use first' box, for multi-dose vaccines that have been opened, or unopened vials that have been taken out for an immunization session but not used. These vials should be used before other vials.

Boxes containing vials with long expiry dates are stored at the back, and those with shorter expiry dates are at the front.

Remember that you must *not* return opened vials of PCV10 vaccine to the refrigerator; it is a liquid vaccine without preservative and once it is opened any remaining vaccine in the two-dose vial should be discarded after six hours or at the end of the immunization session, whichever comes soonest.

6.4.2 Loading a vaccine refrigerator

A vaccine refrigerator should be loaded as illustrated in Figure 6.12 and as described in Box 6.3.

Box 6.3 Guidelines for loading a vaccine refrigerator

- Freeze and store ice-packs in the freezer compartment.
- Store all the vaccines and diluents in the refrigerator compartment.
- If there is not enough space, diluents can be stored at room temperature.
- It is important to chill diluents by putting them in the refrigerator for several hours before you use them to reconstitute BCG or measles vaccines.
- Arrange the boxes of vaccine so air can move between them.
- Keep boxes of freeze-sensitive vaccines (pentavalent, PCV10, TT and HepB) away from the freezing compartment, the refrigeration plates, and the side or bottom linings of the refrigerator, where they might become frozen by accident.
- Keep melted ice-packs or ordinary plastic water bottles filled with chilled water on the bottom shelf of a front-loading refrigerator. These help to keep the temperature cool in case of a power cut.
- Store vaccines in locations appropriate to the style of refrigerator you use. For a front-loading refrigerator with the freezing compartment on the top (Figure 6.12), vaccines should be stored as follows:
  - OPV and freeze-dried vaccines (BCG and measles) on the top shelf
  - all other vaccines on the middle shelves
  - diluents on the bottom.
- Some refrigerators have ice-packs lining the freezing compartment. This type is called an ice-lined refrigerator (Figure 6.13). In this type, all the vaccines should be stored in the basket provided with the refrigerator as follows:
  - measles vaccine, BCG and OPV are stored in the bottom only
  - freeze-sensitive vaccines (pentavalent, PCV10, TT and HepB) in the top only.

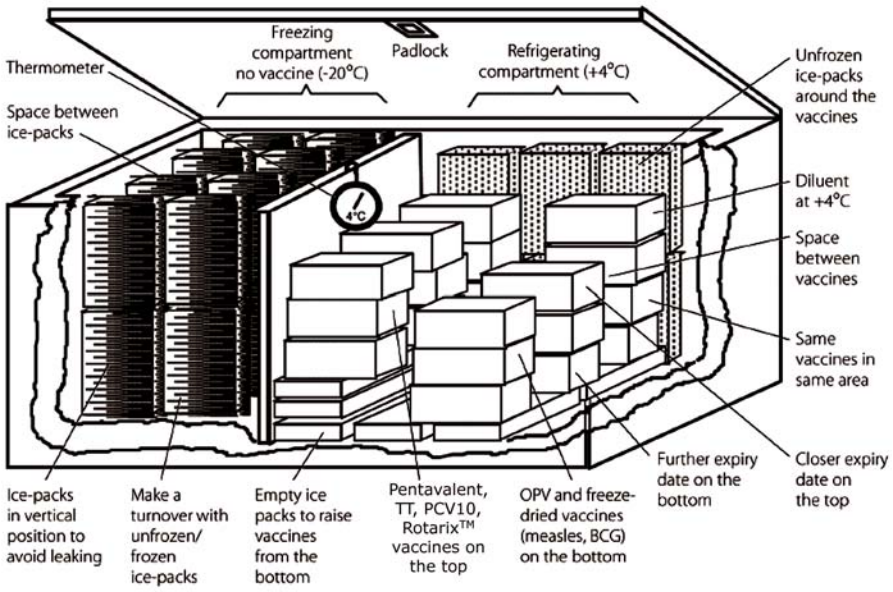


Figure 6.13 Storing vaccines in an ice-lined refrigerator. (Source: WHO, 2004, as in Figure 6.1, p.19).

6.4.3 Loading cold boxes and vaccine carriers

When you are loading vaccines into cold boxes and vaccine carriers before an immunization session, it is important to follow the steps in Box 6.4.

Box 6.4 Guidelines for loading cold boxes and vaccine carriers

- At the beginning of the day of the immunization session, take all the frozen ice-packs you need from the freezer compartment of the refrigerator and close the door.
- Allow the frozen ice-packs to sit at room temperature until the ice begins to melt and water starts to form. This is important because if the ice packs are too cold, freeze-sensitive vaccines may be damaged by freezing.
- Check to see if each ice-pack has been prepared properly by shaking it and listening for the sound of water moving around the ice inside. Ice-packs in which the ice has begun to melt are called **conditioned ice-packs**.
- Put conditioned ice-packs against each of the four sides of the cold box or vaccine carrier, and also on the bottom of the cold box. Ordinary plastic bottles of chilled water can also be used.
- Put the vaccines and diluents in the middle of the cold box or carrier.
- In vaccine carriers, place a foam pad on top of the conditioned ice-packs. In cold boxes, place conditioned ice-packs on top of the vaccines.
- Close the lid of the cold box or vaccine carrier tightly. It is then ready to be taken to the immunization session.

6.5 Maintaining the correct temperature of cold chain equipment

It is important to maintain the correct temperature in your cold chain equipment, and to adjust the temperature of your vaccine refrigerator if it is too high or too low.

- Why is it important to monitor the temperature of your vaccine refrigerator?

- All vaccines are heat-sensitive and most are freeze-sensitive. Therefore it is important to monitor the temperature of the refrigerator, so that the vaccines are prevented from becoming too warm or freezing.

6.5.1 Monitoring the temperature of your vaccine refrigerator

It is important to monitor the temperature of the main section of a refrigerator, so that you can ensure that it stays within the acceptable range for storage of vaccines.

- What is the acceptable temperature range for vaccine storage?

- It is between +2ºC and +8ºC.

To monitor the temperature of your refrigerator, you will need a thermometer and a temperature chart (see Figure 6.14), which you should tape to the outside of the refrigerator door. Then follow the steps in Box 6.5.

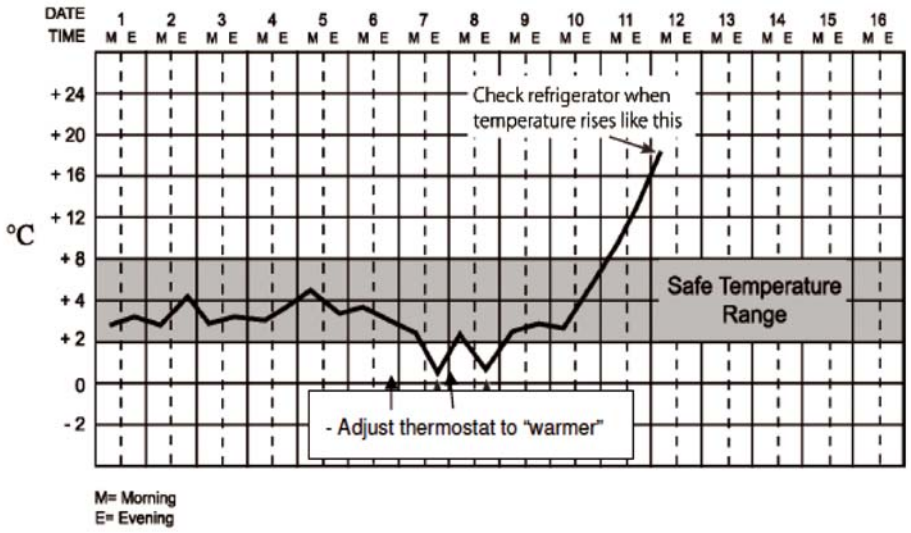


Figure 6.14 Temperature chart, showing the safe temperature range and unsafe temperatures that require adjustment of the thermostat, or checking that the refrigerator is working properly. (Source: WHO, 2004, as in Figure 6.1, p.23)

Box 6.5 Guidelines for monitoring the refrigerator temperature

- Set the refrigerator thermostat during the coldest part of the day to around +2ºC to +4ºC.
- Measure the temperature of the refrigerator first thing in the morning and before you leave the Health Post in the evening. If the temperature is between +2ºC to +8ºC, do not adjust the thermostat.
- Record the temperature at least twice every day (every morning and every evening, seven days a week) on the refrigerator temperature chart, as shown in Figure 6.14.

When a temperature monitoring chart has been completed, replace it with a new one. Keep the completed charts in a record book for future reference. Action should be taken when the temperature goes out of the safe range, as illustrated in the example in Figure 6.14.

■ According to Figure 6.14, what was the temperature of the refrigerator on the 7th day of the month: (a) in the morning, and (b) in the evening? Would any action have been required to adjust the temperature on that day, and if so, what should that action be?

□ Based on the temperature chart in Figure 6.14, you should have noticed that:

(a) In the morning of the 7th day of the month, the temperature of the refrigerator was about +2ºC, which is within the acceptable temperature range. No adjustment was needed.

(b) In the evening, the temperature had dropped to below +1ºC, which is below the acceptable range. The thermostat should have been adjusted to 'warmer', as described in the next section.

6.5.2 Adjusting the temperature of your vaccine refrigerator

The +2ºC to +8ºC safe margin may be difficult to maintain, especially for a kerosene refrigerator, so you should frequently check the condition of the vaccines. Here we give some guidelines on what to do if the temperature of your refrigerator becomes too low or too high.

Kerosene and gas refrigerators

The temperature of a kerosene or gas refrigerator is adjusted by increasing or decreasing the size of the flame. If the temperature inside the main refrigerator compartment is *too low*, you can increase the temperature by *decreasing* the flame size. A smaller flame means less cooling, so the temperature in the refrigerature will rise. If the refrigerator temperature is *too high*, you can reduce it by *increasing* the flame size. A bigger flame means more cooling, so the temperature in the refrigerature will fall. Monitor the change in temperature frequently – about every 15 minutes – after adjusting the flame, until the temperature remains steadily between +2°C to +8°C, to ensure that it does not rise too high or fall too low.

Electric refrigerators: if the temperature is too low

If the refrigerator temperature falls *too low* (below +2°C), you should take the following actions:

Thermostat dials in most refrigerators are labelled from 1 to 6, where 1 is the *warmest* and 6 is the *coldest* setting.

- Adjust the thermostat so that the arrow points to a *lower* number, e.g. if the thermostat dial was set at 5, adjust it to 4. This will make the refrigerator get *warmer*.
- Check freeze-sensitive vaccines to see whether they have been damaged by freezing. You can do this by using the shake test, which you learned about earlier (Section 6.3.3).

Electric refrigerators: if the temperature is too high

If the refrigerator temperature becomes *too high* (above +8°C), you should take the following actions:

- Make sure that the refrigerator is working. If not, check if the power supply is present.
- Check whether the door of the refrigerator or the freezing compartment closes properly. The seal may be broken, allowing warm air to leak into the refrigerator. If the seal is broken, it will need to be replaced.
- Adjust the thermostat so that the dial points to a *higher* number, e.g. if the dial was set at 3, adjust it to 4. This will make the refrigerator get *colder*.
- Check whether ice is preventing cold air in the freezing compartment from entering the refrigerator compartment. If the refrigerator is blocked with too much ice, it may be necessary to defrost it (remove the ice).

If the temperature cannot be maintained between +2ºC and +8ºC, store vaccines in another place, such as a vaccine carrier, and try to get the refrigerator repaired as soon as possible.

6.5.3 Maintaining the correct temperature in cold boxes and vaccine carriers

It is just as important to maintain the correct temperature in cold boxes and vaccine carriers as it is in your refrigerator. To do this, you should follow the steps below:

- Place an adequate number of conditioned (melting) ice-packs or chilled water bottles in the cold box or vaccine carrier.
- Always place the cold box or vaccine carrier in the shade – never in a sunny place.
- Avoid opening the lid of your cold box or vaccine carrier except when you are removing a vaccine, and close it again immediately afterwards.
- Use the foam pad above the conditioned ice-packs to hold vials during immunization sessions.

Do not adjust the thermostat to a colder setting immediately after a power cut, or just after you have put a new batch of vaccine into the refrigerator. The refrigerator could become too cold and freeze the vaccines.

If the ice-packs have completely melted

If you find that the ice-packs inside the cold box or vaccine carrier have completely melted during an immunization session, you should follow the steps below:

- Discard all vials of reconstituted vaccines (BCG and measles).
- Check the VVM status of the vaccines, and return those that can still be used to a refrigerator at the correct temperature as soon as possible.
- Place them in the 'use first' box, and use them before other vials at your next immunization session.

6.6 How to maintain cold chain equipment

In this section we give some basic guidelines on how to maintain your cold chain equipment.

6.6.1 Maintaining vaccine refrigerators

A refrigerator works well only if it is properly installed, cleaned and defrosted (ice is removed) regularly. Thick ice in the freezer compartment does not keep a refrigerator cool. Instead, it makes the refrigerator work harder and uses more electricity, gas or kerosene. You should defrost the refrigerator when ice becomes more than 0.5 cm thick, or once a month, whichever comes first.

What to do when a vaccine refrigerator is out of order

If your vaccine refrigerator stops working, protecting the vaccines is the first priority. Move them to another cold place until the refrigerator is repaired. If you think that the problem will last only a short time, you may use a cold box or vaccine carrier lined with conditioned ice-packs or chilled water bottles for temporary storage. If the breakdown is likely to last a long time, you should move the vaccines to another refrigerator as quickly as possible — for example, by transporting them in a vaccine carrier to the nearest health centre.

When you have moved your vaccines to a safe place, check the electricity, gas or kerosene supply that keeps the refrigerator cold. If it is not working because the gas or kerosene has run out (Figure 6.15), try to get a new supply delivered as soon as possible. If the breakdown is due to a mechanical problem, try to repair the refrigerator if you can. If this is not possible, report the problem to the repair technician and your supervisor at the nearby health centre. Don't forget to record the breakdown on the daily temperature recording chart.

Figure 6.15 A Health Extension Worker checks the kerosene tank of a kerosene refrigerator. (Photo: Janet Haresnape)

6.6.2 Maintaining cold boxes and vaccine carriers

- Always dry your vaccine carriers and cold boxes after use. If they are left wet with the lids closed, they will become mouldy. Mould may affect the seal of the cold boxes and vaccine carriers.
- Store your cold boxes and vaccine carriers with the lid open if possible, when they are not being used.
- Avoid placing cold boxes and vaccine carriers in the sun, as sunlight can cause cracks in their walls and the lids. If a cold box or vaccine carrier wall has a small crack you may be able to repair it with adhesive tape until you can get an undamaged one.

Summary of Study Session 6

In Study Session 6, you have learned that:

1 Vaccines should be stored carefully between +2ºC and +8ºC at all times, from the factory where they are manufactured until they are used. Excess heat or cold will reduce the vaccine potency (strength), increasing the risk that recipients will not be protected against vaccine-preventable diseases.

2 Health Posts should have a vaccine refrigerator and enough cold boxes and vaccine carriers to hold one month's supply of vaccines and diluents, and one to two week's reserve stock, to ensure that routine immunizations can continue if the refrigerator is temporarily out of working order.

3 Cold chain equipment, including refrigerators, cold boxes and vaccine carriers, must be loaded correctly to maintain the temperature of the vaccines and diluents inside. Ice-packs should be conditioned (allowed to begin to melt) before use in cold boxes and vaccine carriers.

4 Vaccines and diluents should be stored in the refrigerator compartment. If there is not enough space, diluents can be stored at room temperature, but they should be chilled to between +2ºC and +8ºC before use.

5 Freeze-sensitive vaccines (pentavalent, PCV10, TT and HepB) should be kept away from the freezing compartment, refrigeration plates, side linings or bottom linings of refrigerators, and frozen ice-packs.

6 A vaccine vial monitor (VVM) is a label that changes colour when the vaccine vial has been exposed to heat over a period of time. Before opening a vial, the status of the VVM must be checked to see whether the vaccine has been damaged by heat. Vials which have passed their discard point should be thrown away.

7 VVMs do not measure exposure to freezing temperatures. Inspect the freeze-indicator and use the shake test to make sure that freeze-sensitive vaccines have not been frozen.

8 A refrigerator works well only if it is properly installed, cleaned and defrosted (ice is removed) regularly.

Self-Assessment Questions (SAQs) for Study Session 6

Now that you have completed this study session, you can assess how well you have achieved its Learning Outcomes by answering the following questions. Write your answers in your Study Diary and discuss them with your Tutor at the next Study Support Meeting. You can check your answers with the Notes on the Self-Assessment Questions at the end of this Module.

SAQ 6.1 (tests Learning Outcomes 6.1, 6.2 and 6.3)

Which of the following statements is *false*? In each case, explain what is incorrect.

A Vaccine Vial Monitors (VVMs) measure exposure to freezing temperatures.
B It is safe to use vaccines that have reached the VVM discard point if the expiry date has not passed.
C The thermometer is an instrument for measuring the temperature in a refrigerator.
D Diluents should always be kept in the main refrigerator compartment.

SAQ 6.2 (tests Learning Outcomes 6.1, 6.2 and 6.3)

Figure 6.16 shows the VVM attached to two different vials of vaccine. Would you use the vaccines with the VVM shown below in (a) and (b)? Explain your answer.

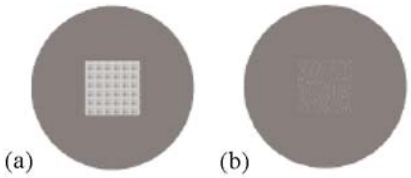


Figure 6.16 Vaccine vial monitors (VVMs) for SAQ 6.2.

SAQ 6.3 (tests Learning Outcome 6.5)

Complete Table 6.1 by putting a cross in the appropriate empty column for each vaccine to show which shelf it should be stored on in a front-loading refrigerator.

Table 6.1 Storage of vaccines in a front-loading refrigerator.

Vaccine	Top shelf	Middle shelf
Measles		
Pentavalent or DPT		
TT		
OPV		
BCG		
PCV10		

SAQ 6.4 (tests Learning Outcomes 6.4 and 6.5)

On Friday, Abeba decides to defrost and clean her refrigerator because a lot of ice has collected around the freezer compartment. She puts conditioned ice-packs in a vaccine carrier and then places the vaccines from the refrigerator in the middle. There is not enough room in the vaccine carrier for everything, so she puts the diluents on the window ledge. She thought to herself: 'The diluents will be safe here until I can put them back in the refrigerator. Diluent doesn't lose its strength as vaccine does.'

The following Monday is immunization day at the Health Post and many children come in for measles immunization. Abeba takes the measles vaccine out of the refrigerator, but at first she cannot find the diluent. Eventually she sees it on the window ledge.

(a) Can the diluent be used to reconstitute the measles vaccine?
(b) What should Abeba do before she can immunize the children?

SAQ 6.5 (tests Learning Outcomes 6.2, 6.3, 6.4 and 6.6)

Figure 6.17 shows a dial thermometer used to measure the temperature of a vaccine refrigerator. Is this temperature safe for storing vaccines? What actions should be taken?

Figure 6.17 Refrigerator dial. (Photo: Basiro Davey)

SAQ 6.6 (tests Learning Outcomes 6.2, 6.4 and 6.5)

How do you keep the following vaccines cold during an immunization session?

(a) Vaccine in opened vials that you are using.
(b) Vaccine in unopened vials.

SAQ 6.7 (tests Learning Outcomes 6.3, 6.4 and 6.6)

Look at the refrigerator temperature chart in Figure 6.14.

(a) What was the temperature on the 11th day of the month, and what actions should the Health Extension Practitioner have taken on that day?
(b) What happened on the 12th day of the month, and what actions should have been taken then?

Study Session 7 Immunization Safety

Introduction

Immunization programmes will only be successful if immunization is practised safely. In this study session, you will first be reminded about how to keep vaccines safe and give injections safely (already taught earlier in this Module). You will also learn in more detail how to identify vaccine reactions and what to do if adverse events following immunization (AEFIs) occur. Finally, we will explain about methods of safe disposal for used injection equipment, discarded vaccines, vials and ampoules, and other waste such as used cotton swabs.

Learning Outcomes for Study Session 7

When you have studied this session, you should be able to:

7.1 Define and use correctly all of the key words printed in **bold**. (SAQs 7.1, 7.2, 7.3 and 7.5)

7.2 Explain how to keep vaccines safe and maintain their quality, including the correct practices for using multi-dose vials. (SAQs 7.2, 7.3 and 7.4)

7.3 Describe how to deliver safe injections in immunization sessions, how to treat mild vaccine reactions, and how to avoid adverse events due to programme errors in your immunization service. (SAQs 7.2 and 7.4)

7.4 Identify clients with contraindications to immunization and describe the appropriate actions to take if adverse events following immunization (AEFIs) occur. (SAQs 7.3 and 7.4)

7.5 Describe the equipment and methods used for safe waste disposal during and after immunization sessions. (SAQs 7.2 and 7.5)

7.1 Importance of immunization safety

Immunization practice that is not safe affects not only the individual receiving the vaccine, but can also affect you and others in the community. Immunization injections are safe when the correct and potent vaccine is properly administered with sterile equipment that is subsequently disposed of safely.

Immunization safety includes the following components, which will be described in detail in the following sections of this study session:

- vaccine quality and safety
- injection safety
- avoiding adverse events following immunization (AEFIs)
- safe waste disposal.

The organisation of immunization sessions, good communication with parents, other caregivers, and the community, and the collection and monitoring of immunization data, are also crucial requirements for a safe and effective immunization programme. You will learn about immunization programme management in Study Session 8, communication and advocacy on immunization in Study Session 9, and techniques for monitoring your immunization programme in Study Session 10.

7.2 Vaccine quality and safety

7.2.1 Vaccine quality

Using vaccines of high quality is very important in order to protect your community against vaccine-preventable diseases. Using poor quality vaccines can have an adverse effect on the individual, and is also likely to upset the community as a whole, for example if there is an outbreak of a disease that should have been prevented by your immunization programme (Figure 7.1).

Figure 7.1 The confidence of mothers in the safety and quality of the immunization programme is crucial to its success. (Photo: Steve Evans, accessed from Wikimedia Commons)

The first check on the quality of vaccines supplied to health facilities in Ethiopia is made by a national body authorised for this purpose. Other checks follow on their condition at every stage in the transport to health facilities around the nation. However, once vaccines are in your care, you are responsible for maintaining their quality by storing them at an appropriate temperature until they are used. All vaccines are sensitive to heat, most cannot be frozen, and some are damaged by bright light; so it is crucially important to ensure that they are not exposed to heating or freezing, and are kept out of direct sunlight. Therefore, as you learned in Study Session 6, the cold chain should be maintained at all times, from the original manufacturer of the vaccine until the moment of administration to your clients.

7.2.2 Safety of the cold chain

If vaccines are spoiled by incorrect storage conditions, they will not be effective in preventing the associated disease, and they could also cause adverse reactions. This is also true for the diluents (ampoules of special liquid) used to reconstitute the freeze-dried (powder) BCG and measles vaccines before use. Each of these vaccines has its own specific diluent, which cannot be used for another vaccine. Diluents can be stored at room temperature if there is no room for them in the refrigerator, but before use they must be completely chilled to between +2°C and +8°C, so they reach the same temperature as the vaccine they are being mixed with.

- Which vaccines and diluents available for routine use in the EPI in Ethiopia should not be frozen? What action should you take if freezing occurs?

- Pentavalent vaccine, PCV10, TT and OPV should not be frozen. Also, the diluents for reconstituting BCG and measles vaccines should not be frozen. If any of these vaccines or diluents becomes frozen, they are no longer effective and should be discarded.

- Which vaccines can be frozen (under exceptional circumstances) for temporary storage?

- The only EPI vaccines in Ethiopia that can be frozen are the freeze-dried powder vaccines (BCG and measles) before reconstitution. Normally, all vaccines should be stored at between +2ºC and +8 ºC in the main (chilled) compartment of the vaccine refrigerator.

7.2.3 Multi-dose open vial policy

WHO Policy Statement, 2000, *The use of opened multi-dose vials of vaccine in subsequent immunization sessions.*

In order to reduce vaccine wastage, the Ethiopian Federal Ministry of Health (FMOH) and the World Health Organization (WHO, 2000) have developed guidelines on how to continue using vials of some types of vaccines once they have been opened, so they are not discarded unnecessarily at the end of the immunization session. These vaccines are supplied in **multi-dose vials** containing preservatives, so each vial can be used for many doses. Opened vials that are returned to the refrigerator must be labelled with the date they were opened, so you know when to discard them.

Opened vials of OPV and TT vaccines are the only EPI vaccines used in Ethiopia that can be used in subsequent immunization sessions *within four weeks* until the vaccines in the vials are fully used, provided that *all* five conditions in Box 7.1 are maintained. These conditions must be observed at every immunization session at the Health Post or at an outreach site.

Box 7.1 Conditions for using opened vials of multi-dose vaccines

Expiry dates are written in the European calendar (not the Ethiopian calendar).

- The **expiry date** has not been passed, i.e. the date after which the vaccine should not be used for immunization.
- The vaccines have been stored between +2°C and +8°C under appropriate cold chain conditions at all times.
- The vaccine vial has not been submerged in water (e.g. from leaking ice-packs in a vaccine carrier).
- The **vaccine vial monitor** (VVM), if attached, has not reached its discard point (look back at Figure 6.8 in Study Session 6).
- A new sterile needle and syringe and standard infection-control procedures have been followed to prevent contamination of vials when vaccine doses were withdrawn previously.

Standard procedures to reduce the risk of infection, contamination and injuries were taught in Study Session 4.

(Source: Adapted from WHO, 2004, *Immunization in Practice*, Module 3, *The Cold Chain*, p.16)

■ Why do you think it is important to prevent opened vials from being submerged in water?

□ The rubber membrane protecting the top of an opened vial has been pierced by needles whenever previous doses were withdrawn, so water could get into the vial if it becomes submerged.

If the conditions in Box 7.1 have been maintained, opened vials of OPV and TT vaccines may be returned to your refrigerator at a temperature between +2°C and +8°C after an immunization session. Put them in the 'use first' box to remind you that they should be used first (before unopened vials) the next time you give immunizations with these vaccines. (Look back at Figure 6.12 and note the position of the 'use first' box in the front-loaded refrigerator.)

Vaccines that should *not* be returned to the refrigerator after an immunization session are:

- opened vials of reconstituted BCG and measles vaccines
- opened vials of PCV10 vaccine (which does not contain a preservative).

These vaccines must be *discarded* 6 hours after reconstitution, or at the end of each immunization session — whichever comes first.

If a PCV10 vial is opened for one child and another is not immediately available to be vaccinated with the remaining dose in the two-dose vial, you should:

- write the time that the vial was opened on the vial so you can discard it after 6 hours if it has not been used
- ensure that the vial is kept cool in the foam pad of the vaccine carrier
- ensure that the vial is kept away from potential contamination.

Any *unopened* vials of vaccine – including unopened pentavalent vaccine, which is supplied in single-dose vials – can be returned to the refrigerator at the end of an immunization session, providing that the expiry date has not passed, storage under cold chain conditions has been maintained at all times, and the VVM has not reached the discard point.

However, if the VVM indicates that the vaccine has reached its discard point, then it should of course be thrown away and not used. Any vaccine which has passed its expiry date should also be discarded. You will learn how to do this safely later in this study session.

7.4 Injection safety

Safety in giving injections is essential for both the client and the provider. Unsafe injections can lead to the transmission of diseases such as HIV and hepatitis. Unless the waste materials of the injection process are disposed of safely, they may result in the spread of infection and cause injury.
A **safe injection** is one that:

- does not harm the recipient
- does not expose the provider to any avoidable risk
- does not result in dangerous waste.

You learned in detail about the equipment for giving safe injections in Study Session 4. Here we will remind you of the main types that may be available at your Health Post:

- Disposable, sterile, single-use syringes and needles, which are used once only and then disposed of safely. They are commonly used for mixing freeze-dried vaccines (BCG and measles) with their diluents and should never be re-used.
- Auto-disable (AD) syringes, which are the preferred type of injection equipment for administering vaccines and should replace all other injection equipment if possible. These are used once and cannot be re-used, because the plunger of the syringe cannot be pulled back again once it has been pushed forward to inject the vaccine.
- Pre-filled, single-use syringes, which already contain a single dose of the vaccine, and are made by the manufacturer in such a way that they can only be used once.

All types of injection equipment must be disposed of safely after use, as described later in this study session. But first, we remind you of the circumstances in which immunizations should *not* be given.

7.4 Contraindication to immunization

The EPI policy recommends that health workers should use every opportunity to check whether eligible children have been immunized, and to immunize them if they have not received all scheduled doses of all the EPI vaccines at the correct age. However, as you already know from Study Sessions 2 and 3, sometimes a child may be temporarily or permanently unfit to receive a specific vaccine. This is called a **contraindication to immunization**.

Minor illnesses such as upper respiratory tract infections or diarrhoea, with low-grade fever below 38.5°C, are *not* contraindications for immunizing children with EPI vaccines. Infants with a moderate or severe fever (above 38.5°C) should be considered as *temporarily* unfit for vaccination until their condition improves. A good rule to follow is that:

- if you are seeing a sick child at the Health Post and he or she is *well enough to go home*
- or you have *no reason to refer a sick child* that you have seen at home
- then the child is *well enough to be immunized*.

However, there are some **absolute contraindications** to immunization, which mean that a child should *not* be immunized (Box 7.2 on the next page). You need to be aware of these conditions, because they may seriously affect a child if he or she is immunized.

The contraindications for individual vaccines were explained in Study Sessions 2 and 3 of this Module.

Box 7.2 Absolute contraindications to immunization with EPI vaccines

- Do not give *another* dose of pentavalent or PCV10 vaccine to a child who developed convulsions or a severe allergic reaction soon after, or within three days, of receiving the previous dose. **Severe acute allergic reactions** include generalized skin itching, skin rash, difficulty in breathing, swelling of the mouth and throat, and signs of shock (low blood pressure and rapid pulse rate); the symptoms quickly get worse (this is what 'acute' means).
- Do not give *any* doses of pentavalent PCV10 vaccine to a child with recurrent convulsions, or another active neurological disease of the central nervous system (brain and spinal cord).
- Do not give BCG or PCV10 vaccines to HIV-positive infants with AIDS, or symptoms of HIV infection including chronic lung infections, tuberculosis and persistent serious diarrhoea.

■ Why do you think *symptomatic* HIV infection (with symptoms) is an absolute contraindication for BCG vaccination? Think back to what you learned about BCG vaccine in Study Session 2, and the effect of HIV on the immune system (*Communicable Diseases* Module, Part 3.)

□ BCG vaccine contains live-attenuated TB bacteria. The defence against infection in people with symptomatic HIV infection is very low, because HIV has damaged their immune system. If they are given BCG vaccine, they can develop tuberculosis.

Note that HIV-positive *asymptomatic* infants (without symptoms) should receive all EPI vaccines at the earliest age possible, according to the nationally recommended EPI schedule.

7.5 Adverse events following immunization (AEFIs)

An **adverse event following immunization (AEFI)** is the term used to describe any adverse event that takes place after immunization, which may or may *not* be caused by the immunization. There are five categories of AEFIs defined in Table 7.1 below.

Table 7.1 Categories of adverse events following immunization (AEFIs).

Adverse events	Description
Vaccine reaction	Event caused or precipitated by the vaccine when given correctly, and due to the inherent properties of the vaccine
Programme error	Event caused by an error in vaccine preparation, handling or administration
Coincidental event	Event that happens after immunization but is NOT caused by the vaccine, i.e. it is a chance association
Injection reaction	Event caused by anxiety about, or pain from, the injection itself rather than the vaccine
Unknown cause	Event for which the cause cannot be determined despite thorough investigation

7.5.1 Mild reactions to vaccines

As you already know from Study Sessions 2 and 3, most immunizations do not cause any serious health problems. Any vaccine reactions that do occur are usually mild and last only a day or two. They may include:

- swelling, soreness and redness at the injection site
- a low-grade fever, particularly after pentavalent, DPT or measles vaccination
- a slight rash, most often after measles vaccination
- some babies may display irritability (they are easily upset), or malaise (they seem low in energy and not interested in anything), particularly after pentavalent vaccination.

However, if scheduled doses of vaccines are not given because of mild reactions to a previous dose, this will lead to delayed immunization, or no immunization at all. If you allow this to happen, you will miss opportunities to protect children from vaccine-preventable diseases. Therefore, you should take every opportunity to immunize children, even if they have experienced a mild reaction previously.

Managing mild vaccine reactions

Advice on managing the common vaccine reactions should be given to parents, as well as instructions to return if there are more serious symptoms. This will help to reassure parents about immunization and prepare them for these common reactions.

Paracetamol may be needed to reduce fever. However, paracetamol should NEVER be given *before* vaccination because it reduces the effectiveness of the vaccine, i.e. the vaccine works less well in children who have taken paracetamol.

Paracetamol is useful for the common minor reactions. It eases pain and reduces fever. A feverish child can be cooled with a tepid sponge or bath, and by wearing cool clothing. Extra fluids need to be given to feverish children. For a local reaction, a cold cloth applied to the site may ease the pain.

7.5.2 Serious vaccine reactions

On rare occasions, a reaction to a particular vaccine can be serious, even so serious as to be life-threatening. When serious problems follow an immunization, rumours are likely to circulate in the community that immunization is not safe, and children may then not be brought by parents

for immunization. This will have a damaging effect on the spread of infectious diseases in the community.

■ Can you explain why a measles epidemic is likely to occur in a community if not enough children receive measles vaccine?

□

The reason is because the *herd immunity* in the population will be too low to prevent the measles viruses from spreading; it can pass from infected children to the many susceptible children who have not be immunized.

You learnt about herd immunity in Study Session 1.

Table 7.2 summarises the possible serious adverse reactions to different vaccines that you may *very rarely* encounter. For example, acute flaccid paralysis following OPV occurs about once in every 1–10 million children vaccinated.

Table 7.2 Possible onset of serious vaccine reactions.

Vaccine	Serious adverse event	Estimated period of onset (time after immunization)
BCG	Abscess (collection of pus)	1–6 weeks
	Swollen lymph nodes in the armpit	2–6 months
	Bone disease	1–12 months
Pentavalent or DPT	Severe acute allergic reaction	0–1 hour
	Continuous screaming	0–24 hours
	Brain disease, seizures (convulsions, fits)	0–3 days
	Abscess	1–6 weeks
HepB	Severe acute allergic reaction	0–1 hour
	Paralysis	1–6 weeks
Measles	Severe acute allergic reaction	0–1 hour
	Abscess	1–6 weeks
OPV	Acute flaccid paralysis	4–30 days
TT (women)	Severe acute allergic reaction	0–1 hour
	Nerve damage in the arm	2–28 days

However, most adverse events following immunization are *not* due to reactions caused by the vaccine. We will look at the other causes of AEFIs next.

7.5.3 Other causes of AEFIs

The most common causes of AEFIs are programme errors.

Programme errors

A **programme error** is the term given to an error caused by improper use of safety procedures or injection techniques. Common programme errors are summarized in Box 7.3.

Box 7.3 Incorrect immunization practices leading to possible AEFIs

- Failure to store vaccines correctly: inadequate maintenance of the cold chain at all times, leading to heat-damage or freezing of vaccines.
- Reconstitution errors: incorrect reconstitution of freeze-dried vaccines through use of the wrong diluent, the wrong amount of diluent, inadequate mixing of the vaccine powder with the diluent, or use of diluents at room temperature (they should be chilled to between +2ºC and +8ºC, the same temperature as the vaccine before mixing).
- Administration of vaccine by the wrong injection route: e.g. subcutaneous injection of BCG (it should be given intradermally), or subcutaneous or intradermal injection of pentavalent, PCV10 or TT vaccines (they should all be given intramuscularly).
- Administration of vaccine into the wrong site: e.g. giving intramuscular injections to infants in the buttocks, instead of in the outer thigh muscle; this error can lead to nerve damage.
- Administration of contaminated vaccine or diluent, or using unsterile injection equipment: this transmits infection and may cause a local abscess, or a more serious blood-borne infection such as HIV or hepatitis.
- Re-use of vaccines beyond their discard point or expiry date, or re-use of reconstituted vaccines or opened vials of PCV10 after more than 6 hours; these vaccines should be discarded and should never be returned to the refrigerator after an immunization session.
- Contraindications ignored, e.g. when a child who has had a severe reaction after a previous dose of a vaccine is immunized with the same vaccine, or a child with symptomatic HIV infection is given BCG or PCV10 vaccines.

Programme errors are mostly related to mistakes made by the health worker, which can be prevented through proper training. They may also be due to faulty equipment (e.g. a badly functioning refrigerator), or inadequate supplies of sterile injection equipment and other essential materials.

Coincidental events

An adverse event that follows an immunization may not have any association with the vaccine or the vaccination procedure – it may simply be due to coincidence. For example, a child may already be in the latent period of an infection, i.e. already infected but not yet showing any symptoms. When the symptoms appear a day or two after the immunization, the parents may conclude — incorrectly — that the vaccine has caused the infection. It is important that you investigate all AEFIs and explain to parents and the community why and how adverse events may follow an immunization simply as a chance effect.

Injection reactions

Sometimes the fear of being injected with a needle or the pain from the injection may cause a child to become very upset, perhaps even fainting or vomiting. This may also occur occasionally in women given TT vaccine. Take care to reassure the vaccinated person and any caregiver who is with them that the vaccine itself is harmless and their symptoms are due to anxiety, which will rapidly disappear.

AEFIs of unknown cause

Very rarely an adverse event occurs following immunization that cannot be attributed to any known cause, despite thorough investigation. You need to be alert to the possibility that unfounded rumours about a vaccine may start to circulate in the community. Be honest about the situation and explain that the cause is unknown but it is very unlikely to be due to the vaccine. You must report the AEFI so that the health authorities with responsibility for vaccine safety can record the event in case another similar event occurs following this vaccine, for example in another part of the country.

7.5.4 How to avoid AEFIs

In order to avoid AEFIs as much as possible, you should follow these guidelines:

- Fulfil the five requirements for using opened multi-dose vials (see Box 7.1).
- Do not vaccinate clients with absolute contraindications to immunization (see Box 7.2).
- Always reconstitute vaccines with the diluent supplied by the manufacturer. Never use another diluent.
- Discard reconstituted vaccines and PCV10 six hours after reconstitution, or at the end of the immunization session, whichever comes first.
- Do not keep other drugs in vaccine refrigerators if at all possible. If you have to keep other injectable drugs in the same refrigerator, put them on a separate shelf. AEFIs are likely to occur if you give an injection of a drug instead of the vaccine by mistake, or use a drug instead of the correct diluent.
- Prepare immunizations in a clean area where contact with blood and body fluids is unlikely.
- Use a sterile needle and syringe to prepare every injection dose immediately before administering it. Do not prepare several syringes in advance and do not re-use injection equipment.
- Do not touch the needle and never leave it in the top of the vaccine vial.
- The child should be held firmly, so that there cannot be a sudden movement during the injection.
- If you use auto-disable (AD) syringes, AEFIs due to contamination should not occur.

Do not leave the needle in the vial!

7.5.5 Detecting and responding to AEFIs

In your immunization activities, you should monitor, investigate, treat, refer and report the following AEFIs:

- all injection site abscesses
- all swelling in the armpit, particularly after BCG immunization
- all hospitalizations following immunization that occur within one month
- any other severe or unusual medical incident following immunization within one month
- all deaths that occur within one month of an immunization
- all medical events believed to be caused by immunization and about which people are concerned.

If you come across a suspected case of AEFI you should treat the affected person within your professional capacity, as described in Study Sessions 2 and 3, and refer him or her urgently to a higher health facility for further investigation and treatment. The patient should be accompanied by a responsible caregiver who has a clearly written referral note from you, explaining all relevant details.

If the AEFI is related to a known programme error, you must take immediate action to correct the cause. Liaise with the parents and community leaders to explain the cause of the AEFI, if it is known. You will learn more about communication in immunization programmes in Study Session 9.

■ A mother brings you an infant who has a large abscess on his arm. The abscess is at the site where you gave him an immunization against BCG ten days previously. What action should you take?

□ Keep the site of the abscess clean. Give amoxicillin syrup three times daily and refer the child *urgently* to a higher health facility.

All AEFIs, including those reported immediately during the month, should be counted in routine, written, monthly surveillance reports. (You will learn how to do this in Study Session 10.)

7.6 Safe waste disposal

The immunization programme should not put the community in any danger. Proper disposal of waste is an important issue and should always be planned from the very beginning. In particular, you need to plan how you will dispose of the used vials, ampoules, syringes and needles after an immunization session.

Disposal of medical waste is also taught in the *Hygiene and Environmental Health* Module, Part 2.

■ What other waste will need to be disposed of?

□ There will also be contaminated cotton swabs for cleaning the skin with alcohol or antiseptic before giving an injection, and pressed onto the injection site afterwards.

In this final section, you will learn about possible methods of disposing of waste safely. You may not have access to the best waste disposal method, so you may need to think about what innovations could be made to ensure that

you keep the environment safe for the local community. You will need to select the most appropriate disposal method and site for the particular circumstances in your area.

7.6.1 Safety boxes

In order to avoid anyone being pricked by used needles and other 'sharps' (e.g. lancets), they should always be discarded with care. Immediately after injecting a vaccine, the syringe and needle should be placed in a nearby Safety Box (Figure 7.2).

Figure 7.2 (a) Safety box in an immunization clinic. (Photo: Basiro Davey); (b) Do not overfill the safety box!

A five-litre safety box can hold about 100 needles and syringes. It is important not to wait until the safety box is completely full before disposing of it. It should be closed when it is about three-quarters full.

■ Can you explain why safety boxes should not be overfilled?

□ If the safety box is full, you could injure yourself on something sharp near the top of the box when you try to add more injection equipment.

Needle-stick injuries can transmit blood-borne infections! Do not try to recap the needle, because in doing this you could easily prick your finger.

7.6.2 Incineration and other methods of burning waste

Incineration means burning at very high temperatures under controlled conditions in an incinerator designed for this purpose. Incineration is a good way of disposing of waste, because it completely destroys needles, syringes, glass vials, and infectious agents by burning at very high temperatures. However, you may not have an incinerator (also known as a 'protected hearth') within reach of your Health Post. You could discuss the need for a proper facility for waste disposal with others in your community, such as Agricultural Extension Workers and *kebele* leaders. It might be possible to build an incinerator for you all to use (Figure 7.3).

Figure 7.3:
An incinerator used for burning healthcare waste. (Photo: Muluken Azage)

Burning in a metal drum (container burning)

If you can get a suitable container such as a metallic drum with both ends removed (Figure 7.4), you can burn your medical waste in it. The drum should be placed in a fenced area that has been cleared for this purpose. Place four bricks on the ground, with spaces between them and a metal screen or grate on top. Place the open base of the drum on the metal screen and put another screen on top. The metal screens are to allow air to flow around the burning waste so the fire gets hotter, and to reduce the amount of ash flying out of the top. Put the safety boxes and some paper, dry leaves, or small sticks into the drum, sprinkle them with a small amount of kerosene (if

available). Put paper under the drum, between the bricks, and set light to it so the flames rise through the metal screen.

When the waste has completely burned and everything has cooled, put on heavy protective gloves and carefully scrape out any tiny pieces remaining in the bottom of the drum. Put them in a box and carry it to the Health Post waste pit for burial (see below).

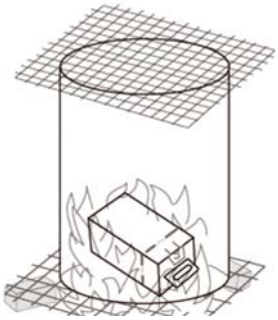


Figure 7.4 Burning a safety box in a metallic drum. (Source: WHO, 2004, *Immunization in Practice*, Module 4, *Ensuring safe injections*, Figure 4I, p.17)

Open pit burning

Open pit burning of waste is a common practice in many rural communities (Figure 7.5). The pit should be dug at least 2 metres deep in a fenced area. The waste should be placed in a closed and sealed box, such as a safety box, to be burnt. However, the problem with this method is that unburnt pieces may be blown by the wind and scattered around the pit, or the fire may go out and not destroy some of the waste. Ideally, you should watch while the waste is burning until you can see that everything in the box has been completely burnt. When the pit is three-quarters full of burnt waste, it should be covered with a deep layer of soil and (if possible) topped with concrete. It should be clearly marked so that everyone is aware that they must not dig up the contents.

Figure 7.5 Open pit burning of healthcare waste. Note the fence around the area. (Photo: Muluken Azage)

7.6.3 Burying without burning

Do not bury used injection equipment in an open cardboard box.

This method of disposing of medical waste involves digging a deep hole (known as a *sharps pit*) in a fenced area and burying the waste in the safety box, or another sealed container. If possible, the pit should be constructed with cement walls and a water-tight cover. It may be difficult to find a large enough space for repeated disposal of waste by this method. If the hole is not deep enough, the waste might become exposed when the top soil is washed away by rain or wind. Children or animals may dig up the waste unless the pit is protected by a secure fence. For these reasons, this method should be regarded as a last resort as the primary method of waste disposal. However, a pit should be constructed for burial of any small fragments remaining after waste has been burnt in an incinerator or metal container.

In the next study session we turn to other aspects of immunization programme management, in particular how you can increase the coverage rate in your catchment area.

Summary of Study Session 7

In Study Session 7, you have learned that:

1 Safe immunization is essential in order to have a successful immunization programme.

2 Immunization safety should include everyone involved: the client, the health worker and the community as a whole.

3 You should follow standard infection-control procedures, and the guidelines on vaccine preparation and the re-use of open multi-dose vials, to ensure that vaccines and immunizations are safe and effective.

4 Most vaccine reactions are mild and should not prevent the child from being immunized again. Serious adverse events following immunization (AEFIs) are rare, and are often due to programme errors by health workers. They may also be due to anxiety about the pain of an injection, or they may be coincidental events or due to unknown causes.

5 Children with a minor illness (e.g. low-grade fever, respiratory infection, diarrhoea) should still be immunized according to the routine EPI schedule. Manage their symptoms and reassure their parents.

6 Absolute contraindications to immunization are convulsions or a severe acute allergic reaction soon after a previous dose, or existing neurological disease. Infants with symptomatic HIV/AIDS should not be given BCG or PCV10 vaccines.

7 Serious AEFIs should be reported immediately. All AEFIs should be reported in monthly written surveillance reports.

8 Immunization waste must be disposed of safely to ensure that there is no danger to the community. If an incinerator or protected hearth is not available locally, safe waste disposal can be achieved by container burning or open pit burning in a protected area, or (if there is no other alternative) burial in a sharps pit protected by a fence.

Self-Assessment Questions (SAQs) for Study Session 7

Now that you have completed this study session, you can assess how well you have achieved its Learning Outcomes by answering the following questions. Write your answers in your Study Diary and discuss them with your Tutor at the next Study Support Meeting. You can check your answers with the Notes on the Self-Assessment Questions at the end of this Module.

SAQ 7.1 (tests Learning Outcomes 7.1 and 7.3)

(a) What is meant by a safe injection?

(b) Give three examples of possible programme errors in vaccine preparation or administration.

SAQ 7.2 (tests Learning Outcomes 7.1, 7.2, 7.3 and 7.5)

Which of the following actions could result in an infection being transmitted to your clients when you inject them with a vaccine? In each case, explain why or why not.

A Allowing a freeze-sensitive vaccine to become colder than +1°C for a short time.

B Allowing opened multi-dose vials of vaccine to become submerged in melted water in a vaccine carrier.

C Using auto-disable syringes for every immunization.
D Removing the cap from a disposable needle and holding it by the adaptor before you fit it onto the syringe.
E Attempting to replace the cap on a used needle before you place it in the safety box.

SAQ 7.3 (tests Learning Outcomes 7.1, 7.2 and 7.4)

Five minutes after you immunized a 6-week-old baby with her first dose of pentavalent vaccine, she became short of breath and developed a widespread rash. Her pulse became rapid and her blood pressure dropped.

(a) What is the name for this condition?
(b) What action should you take? (You will need to think back to earlier Modules in this curriculum to answer this part of the question fully.)

SAQ 7.4 (tests Learning Outcomes 7.2, 7.3 and 7.4)

Which of the following children should *not* be given an immunization and why?

(a) A healthy-looking one-week-old baby girl who you know is probably HIV-positive.
(b) A 10-week-old boy who developed a low-grade fever soon after the first pentavalent immunization, which lasted about 24 hours.
(c) A 10-week-old boy who had a convulsion soon after the first pentavalent immunization.

SAQ 7.5 (tests Learning Outcomes 7.1 and 7.5)

List one potential disadvantage of each of the following methods of disposal of a safety box containing used needles and syringes after an immunization session:

(a) An incinerator at a health centre.
(b) Burning in a metal container.
(c) Burning in an open pit.
(d) Burying without burning in a sharps pit.

Study Session 8 Immunization Programme Management

Introduction

For more details of health planning, see Study Sessions 12 to 16 of the *Health Education, Advocacy and Community Mobilisation* Module, Part 2.

This study session is on the effective management of the immunization programme in your catchment area. We will show you how to plan, implement, monitor and evaluate your immunization activities, with the overall goal of increasing the immunization coverage rate in your community and sustaining the increase over time. First, you will learn how to prepare an annual plan of the immunization programme for your Health Post and measure progress towards meeting your objectives. Then, we show you how to prepare for your actual immunization sessions, either in a fixed facility (such as your Health Post), or in outreach activities or mobile delivery teams. You have already learned how to calculate the resources you will need in Study Session 5, and you may need to refer back to those calculations as you read this study session.

Learning Outcomes for Study Session 8

When you have studied this session, you should be able to:

8.1 Define and use correctly all of the key words printed in **bold**. (SAQs 8.1, 8.2 and 8.3)

8.2 Describe the principles and concepts of planning an efficient immunization programme, and summarise the six steps in the planning process. (SAQs 8.1, 8.2 and 8.3)

8.3 List some common indicators of progress in monitoring and evaluating an immunization programme. (SAQ 8.3)

8.4 Explain how you would determine the immunization eligibility of an infant or woman who does not have an immunization record card. (SAQs 8.3 and 8.4)

8.5 Describe how to set up before an immunization session and what you should do after it has ended. (SAQs 8.4 and 8.5)

8.6 Describe how an immunization session should be managed at a fixed site, an outreach site and a mobile delivery service. (SAQ 8.5)

8.1 Planning your immunization programme

For any activity to improve the health and wellbeing of your community, you need to have a plan. It is often said that *if you fail to plan, you plan to fail*. As a Health Extension Practitioner you will be expected to develop an annual immunization action plan that can reach all the children and women in your catchment area. Thus, careful planning is an important activity that every Health Extension Practitioner must undertake.

8.1.1 Collecting basic information about the community

Before you can begin to make an effective plan for any health intervention, you must first collect some basic information about the community you serve. For example:

- The size of the total population of your *kebele,* and the size of the target population — in this case, clients for immunization.
- A map of your *kebele* showing the location of homes, health facilities and other buildings, and geographical features such as paths, ponds, rivers or forests. (Figure 8.1)

Figure 8.1 Map of a rural *kebele* around Fura Health Post in the Southern Nations, Nationalities and Peoples Region (SNNPR) of Ethiopia. (Photo: Basiro Davey)

- The distances (in kilometres, or travel time by walking) between the health centre and your Health Post, and between the Health Post and the furthest members of the community (Figure 8.2).

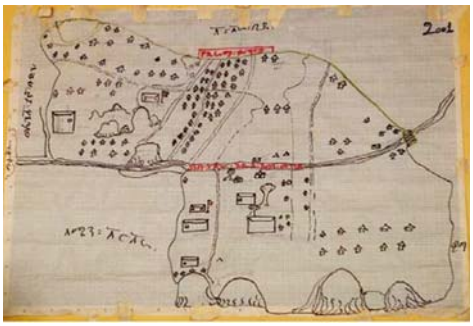


Figure 8.2 Routes that local people can take to reach the Health Post are visible in this map from a rural *kebele* near Butajira in the Oromia region of Ethiopia. (Photo: Ali Wyllie)

- Details of transport and communication networks in the area, e.g. roads, and the availability of telephone, radio or TV coverage.
- Knowledge of available energy sources in the area, e.g. electricity generators and supplies of gas, diesel or kerosene.
- The location of potential partners who could assist you, e.g. community associations, employers, private institutions, charitable organisations, etc.

Information like this will help you to anticipate possible problems that could affect your planned activities. Information such as the geography, socioeconomic situation and the health profile of the community you are working in will help you to establish the current situation and work out what problems or challenges are to be expected. If you can identify the possible problems and their causes and their effects in advance, then you may be able to work out potential solutions before the problem becomes serious.

8.1.2 Steps in the planning process

When you know a lot about your community, you can begin to make a plan of action. The planning process should follow the six steps outlined in Figure 8.3. We have briefly summarised each step in Box 8.1 on the next page, and in the rest of this section we will look at each of them in more detail.

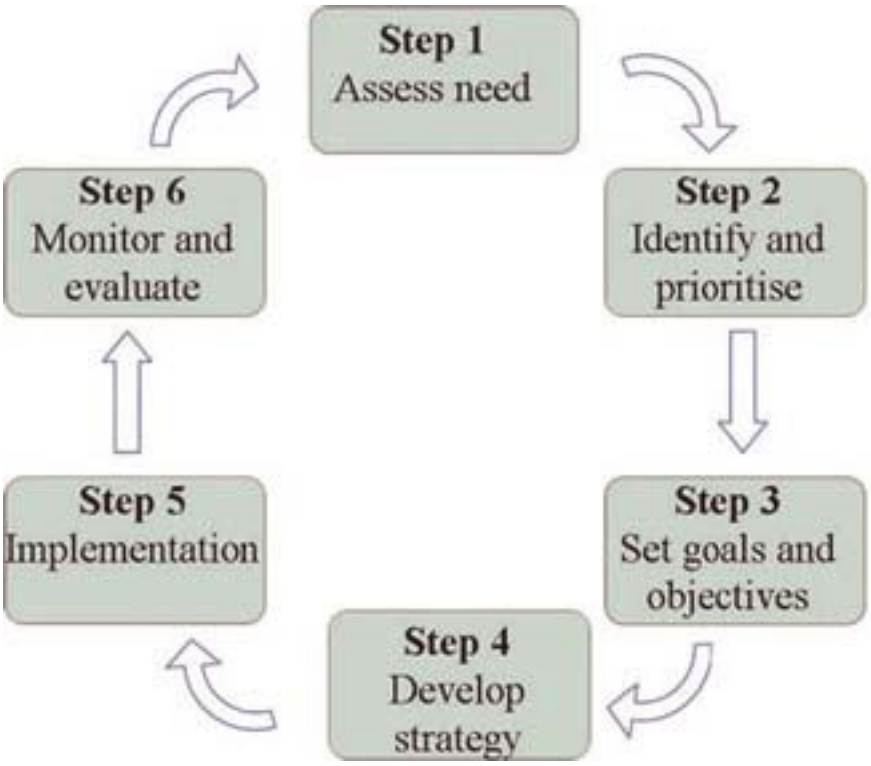


Figure 8.3 Six steps in planning health interventions. (Diagram: Henk von Stokkom)

Box 8.1 Steps in the health planning process

Step 1 *Assess need*: identify the problems and clarify the situation you want to improve.

Step 2 *Identify and prioritise*: select your priorities for action — what are the most important issues to tackle?

Step 3 *Set goals and objectives*: what is the overall goal of your activities, what are your specific objectives (targets) and in what timescale do you aim to achieve them?

Step 4 *Develop strategy*: What is your action plan? What activities, resources (people, equipment) and finances will be needed to achieve your objectives? How will you explain your action plan and gain community support for it?

Step 5 *Implementation*: How will you deliver your plan? Do you have everything you need to make it successful?

Step 6 *Monitor and evaluate*: What data will you collect and how will you evaluate the impact and outcomes of your activities? How will you measure progress towards meeting your objectives? Notice that in Figure 8.3, the results of Step 6 help you improve the next cycle of planning, beginning at Step 1.

Resource Management at Health Post level is covered in detail in the *Health Management, Ethics and Research* Module.

8.1.3 Immunization needs assessment

A **health needs assessment** is the process of identifying and understanding the health needs of your community. It includes identifying any problems and their possible causes that make it harder to meet those needs. In relation to immunization, the key questions that you need to address are:

- Has the immunization coverage rate reached the targets that were planned in the previous year? If not, what were the problems?
- If there were outbreaks of vaccine-preventable diseases in your *kebele*, what does this imply about the effectiveness of your immunization service? For example, has it been difficult for people to get to the Health Post or attend outreach events?
- Have there been many **defaulters** — clients who began a series of routine immunizations but 'dropped out' before the EPI schedule was completed? What are the possible reasons for dropouts?

■ Make a list of possible problems that might need to be addressed in your community if your goal is to increase the immunization coverage rates.

□ You may have thought of other problems in addition to those below:

- The target population is large and very widespread; people who live a long way from the Health Post find it difficult to get to immunization sessions
- The roads to the Health Post are flooded in the rainy season
- Immunization is only available on certain days; some people cannot attend on those days
- Communicating about immunization sessions is difficult; some people come on days when immunization is not available
- Vaccine supplies are sometimes not enough to immunize all the children and mothers who come
- The refrigerator is unreliable and vaccines have to be moved to the health centre for safety
- There is a high dropout rate, possibly because a child had a severe allergic reaction after an immunization last year, and negative rumours spread; some parents refused to bring children for immunization.

If you have identified problems that contribute to low immunization coverage rates in your area, discuss them with your supervisor and local health officials, and make a list of possible solutions. For example, if the problem is low immunization coverage, then the solution might be one (or more) of those listed in Box 8.2.

Box 8.2 Some ways to address low immunization coverage rates

- Improved communication with the local community about the huge benefits and very low risks of immunization
- More in-service training, updating or supportive supervision for you and other health workers, including community volunteers
- Mobilisation of additional people, equipment, finances or other resources to improve delivery of the immunization programme
- Change of immunization strategy, e.g. increased use of outreach or local immunization days
- Focus group discussions with community members to find out why immunization coverage is low
- Regular review meetings with *kebele* leaders and local health officials to assess progress
- Partnerships with other organisations (e.g. community associations, charities, private sector) to assist in delivering the programme.

Remember that some solutions may not be appropriate to your setting, or may not be feasible in your *kebele*. For example, additional in-service training may not be affordable in the short term, or there may not be a suitable local organisation willing to assist with your immunization activities.

8.1.4 Identify and prioritise problems

Prioritisation is the process of informed decision-making about what to do first, second, third and so on, when there are competing claims on human and other resources. It is impossible to solve all problems at once because there are always many resource constraints. In order to select your priority activities — in this case, with the aim of reducing vaccine-preventable diseases through delivery of an effective immunization programme — you should consider the criteria below for each of the problems you have identified:

- **magnitude of the problem** — what percentage of the population is at high risk of developing the disease, or is already affected by it?
- **severity of the problem** — how serious is the disease in question, in terms of its impact on health and the risk of death?
- **socioeconomic impact of solving the problem** — how will the social and economic circumstances of individuals, families and the community benefit if immunization coverage increases?
- **feasibility of tackling the problem** — do solutions exist, and is it realistic to increase immunization coverage with the available technical resources, personnel and organisational capabilities?
- **affordability of tackling the problem** — is the financial support adequate for an improved immunization programme?
- **acceptability to the beneficiaries** of tackling the problem in the ways suggested — does it meet community and government concerns?

■ Consider two diseases: pneumonia and the common cold. Which of these has the greatest *magnitude* and which has the greatest *severity*?

□ The number of people who suffer from a common cold is much higher than the number with pneumonia, but pneumonia is a much more serious disease than the common cold. So the *magnitude* of the problem is greater for the common cold, but the *severity* of the problem is greater for pneumonia.

A simple scoring chart, like the one in Table 8.1, can help you to rank priorities for each of the health problems identified in your needs assessment. For each problem, you decide on a score from 1 to 5 for each column, where:

1 = concern about this criterion is very low

5 = concern about this criterion is very high.

Table 8.1 A simple chart for scoring and ranking priorities for health problems.

Problem	Magnitude	Severity	Impact	Feasibility	Affordability	Acceptability	Total score	Rank
Neonatal tetanus								
Measles								

■ In the example in Table 8.1, neonatal tetanus and measles are listed as health problems that can be reduced by immunization. How would you score each of these conditions based on your knowledge of these diseases and their impact in your community?

□ We can't guess what scores you wrote in Table 8.1, because local circumstances will vary in different communities. But you should have

given a lower 'magnitude' score and a higher 'severity' score to neonatal tetanus than you did to measles. More children suffer from measles than tetanus, and measles kills a higher *number* of children than any other vaccine-preventable disease worldwide (higher magnitude). But the majority of children infected with measles recover, whereas over 70% of babies with neonatal tetanus will die (higher severity). To take another example, you may have decided that the feasibility of vaccinating children *once* against measles is greater than the feasibility of vaccinating pregnant women, and all women of childbearing age at least *twice* (preferably three to five times) with tetanus toxoid.

When you have given a score to each problem in your priority chart, you add up the scores and enter this figure in the 'Total score' column. You then assign a rank to each problem according to its total score. The highest scoring problem has a rank of 1; the next highest scoring problem has a rank of 2, etc. Conducting an assessment like this will help to clarify your thinking about which problems to tackle first. This will also enable you to explain the *reasons* for your priorities to community members, so they understand why you have prioritised certain activities.

8.1.5 Setting goals and objectives

Once you have identified problems with feasible solutions and ranked your priorities, then you must set clear objectives (or targets) for each problem in your priority list in order to make progress towards your overall goal. In this case, the goal is to increase the immunization coverage rate in your community. The **objectives** for delivering your goal must be specific and measurable, and state exactly *what* you want to achieve, *where* the activities will take place, *which* target group will be addressed and *when* the target should be achieved. For example, some possible objectives of an improved immunization programme might be:

- To reach 95% coverage of all eligible children in the catchment area with the third dose of pentavalent vaccine (Penta3) by the end of the year.
- To conduct immunization sessions at the Health Post twice every week for 48 weeks of the year.
- To update the registration of newborns in your catchment area once a month for the whole year.

■ What objective could you set for tetanus toxoid (TT) coverage?

□ You may have thought of other objectives, but one might be to increase by 20% the number of women of childbearing age who receive more than two doses of TT this year (Figure 8.4).

Figure 8.4 Immunizing all women of childbearing age with more than two doses of TT vaccine protects them and their babies. (Photo: Basiro Davey)

Notice that in all the examples above, a timescale is given for achieving the objective, and the outcome (success or failure to meet the objective) can easily be measured if accurate records are kept. Record keeping is covered in Study Session 10.

8.1.6 Developing strategies and activities in your action plan

After agreeing your objectives, the next task is to decide on the strategies and activities for achieving them. This means working out the methods you will use and the activities you will undertake, and writing a clearly stated action plan. The **action plan** should include every activity to be performed during the year, the *time* when that activity is to be done, *who* will do it, *how* that

person (or people) will do it, and what *resources* will be needed. In developing your action plan, you should ensure that your strategy and activities are relevant to resolving the identified problems, and that they are technically feasible, financially affordable and acceptable to the community.

■ What activities might you undertake in order to meet the objective of updating registration of newborns in your community every month?

□ Here are some suggestions. You may have thought of others.

- Ask about recent births in each family whenever you visit a household for any reason.
- Ask *kebele* leaders, traditional birth attendants and other influential people what recent births have occurred in each village.
- Ask each mother who visits the Health Post when she (or any other women in her family) last had a baby, and check that you have recorded the birth.

8.1.7 Estimating resource needs

You have already learnt how to estimate the size of your target population and your resource needs in Study Session 5.

Your action plan should also include an estimate of your resource needs. Resources include people, materials, time, finance and information, and these should be determined in advance for each of the planned activities. The first and most important estimate is the total size of the population and the number in the target population for your activities.

■ What is the target population for the Expanded Programme on Immunization (EPI)?

□ It is the number of children aged 0–11 months and women of childbearing age (15–49 years).

You can then determine the resources required (vaccines, diluents, infection equipment, etc.) for delivering an effective immunization programme for this target population. The next step in the action plan is to allocate people (e.g. community volunteers), materials, time and finance to each of the activities in your plan.

8.1.8 Implementing your action plan and maintaining community support

Community communication about immunization is described in more detail in Study Session 9.

Once the action plan for the year is complete, it should be communicated to all stakeholders at community level, your supervisor and the *woreda* health office. You should arrange a meeting with local government administration officials, community leaders and community volunteers to discuss your plan and gain their approval and support (Figure 8.5). Once approved, it is your responsibility to implement the plan. You have to keep all stakeholders well informed about progress during the year, so that you can agree on a solution to any problems you encounter during the implementation period.

Figure 8.5 Discuss your action plan with local officials and community leaders to ensure community support.

8.1.9 Monitoring and evaluation indicators

Monitoring and evaluation are crucially important parts of any health plan. **Monitoring** refers to the continuous observation and collection of relevant data, and **evaluation** means analysing the data to see if you are meeting your objectives. Therefore, you need to select reliable indicators of progress for each of the objectives in your action plan. Collecting and analysing data from these indicators is an essential activity during the implementation of your immunization programme.

Indicators of progress in immunization programmes

Some of the main **EPI indicators** of progress that are commonly used to monitor and evaluate immunization programmes are given below:

- **Immunization coverage rate** for each vaccine, i.e. the percentage of all eligible children who have received all doses of a vaccine under one year of age, according to the EPI schedule.
- Percentage of **fully immunized children** aged under one year, who have received all recommended doses of all vaccines (including measles vaccine at age 9 to 11 months), according to the EPI schedule (Figure 8.6).

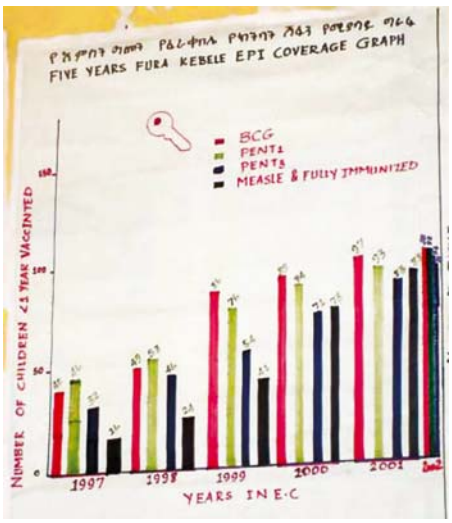


Figure 8.6 Chart showing immunization coverage rates during five years at Fura *kebele*, SNNPR, Ethiopia. The black bar to the right of each year shows the number of fully immunized children. Years are given in the Ethiopian calendar (E.C.), and correspond to 2005–2010 in the European calendar. (Photo: Basiro Davey)

- Percentage of pregnant women with **adequate TT doses**, defined as receiving any of TT3, TT4 or TT5. This indicator is often abbreviated to **TT2+** (because more than two doses of TT vaccine have been given).
- Percentage of children **protected at birth** (**PAB**) from neonatal tetanus, because their mother received a valid dose of TT2+ vaccination at least two weeks before delivery (Figure 8.7).

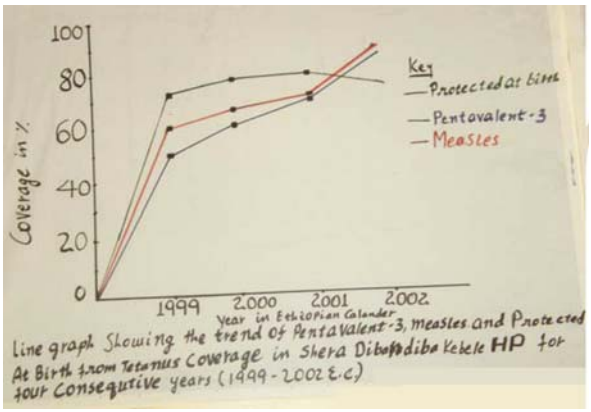


Figure 8.7 Percent of babies protected at birth from neonatal tetanus, and the pentavalent 3 and measles vaccine coverage rates in Shera Dibandibe *kebele,* Oromia region, Ethiopia. (Photo: Basiro Davey)

- **Dropout rates**: the percentage of children and mothers not completing all the scheduled EPI immunizations.
- Reported new cases in the community of:
  - neonatal tetanus
  - acute flaccid paralysis (AFP)
  - measles in children under five years of age
  - all vaccine-preventable diseases.
- Number of reports of adverse events following immunization (AEFIs).
- Vaccine wastage factors
- Reporting completeness, accuracy and timeliness.

You learned how to calculate vaccine wastage factors in Study Session 5. Monitoring and reporting procedures are taught in Study Session 10.

The collection of data on your EPI progress indicators during the year will help you to assess how well you are meeting the objectives of your action plan. You may need to revise your activities if monitoring and evaluation suggests that more needs to be done in order to achieve your objectives.

8.2 Immunization delivery at various sites

The second part of this study session describes how to implement your action plan depending on where you will be conducting the immunization session. Immunization can be delivered at various sites, each of which has some differences in terms of preparation and delivery. To increase immunization coverage, a combination of these three approaches should be used:

- **Fixed-site service** is delivered at your Health Post. Ideally, immunization should be routinely available on a daily basis, but this may not be possible in your setting. In order to increase attendance, the regular days should be fixed after discussion with community members.

- **Outreach service** involves Health Post staff and volunteers giving immunizations in the community on well-publicised dates and at well-known locations. Establishing an outreach immunization service on a regular basis, in addition to the service at your Health Post, is a key part of the approach in Ethiopia called 'Reaching Every Infant/Child'.
- **Mobile service** involves a team going to remote or hard-to-reach parts of an area and staying there for more than one day to deliver immunizations, for example to pastoral or nomadic communities.

As part of your planning procedure, you should have determined the size of the target population in your *kebele*, and made a map of your area. This will help you determine which parts of the community can best be served by fixed-site immunization, and which by an outreach or mobile delivery service. The main difference between these three ways of delivering the immunization service is the method of maintaining the cold chain. We start by considering an immunization session at your Health Post, and then briefly describe the additional requirements for an outreach or mobile delivery service.

8.2.1 Setting up an immunization session at a fixed site

First, you need to prepare the area where you can give the immunizations and record what you have done, and you need a waiting area for children and their caregivers. The workplace should be in the shade so that you can keep your vaccines away from direct sunlight. It is also important to keep yourself and your clients from direct sunshine, dust and rain. You have to keep the working area clean and quiet to make it conducive for your work. For efficient immunization, you need to avoid the workplace becoming crowded.

The example in Figure 8.8 shows the flow of people through a Health Post during an immunization session. Arrange the flow so that it can be in one direction only, to avoid clients who have already been vaccinated mixing with clients who are waiting for their turn.

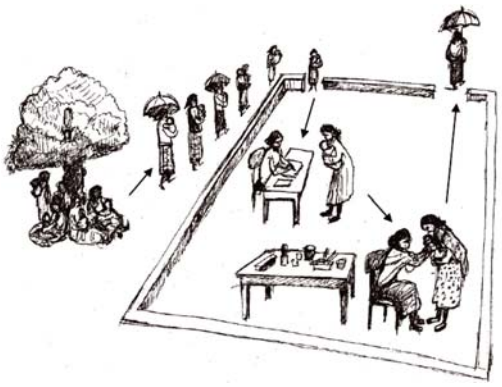


Figure 8.8 The workplace flow through a Health Post (walls and roof not shown) during an immunization session.

You need a table for registration and recording and another table to put vaccines and accessories on. Ideally, there should be enough seats for carers to sit on while waiting for their turn. While they are waiting, this area can also be used to deliver information about immunization and to check the infant immunization record cards (Figure 8.9).

Figure 8.9 Women and babies waiting for immunizations; the health worker is showing the vaccination certificate they will receive when their babies have been immunized. (Photo: UNICEF Ethiopia)

What resources do you need for a fixed-site immunization session?

Determine the number of vials you will need to take out of the refrigerator and place them in a vaccine carrier with the correct number of conditioned ice-packs. You should aim to open the refrigerator as few times as possible, preferably just once at the beginning and once at the end of the session. This is why it is important to estimate how many people you expect to come for vaccination at each session, so you can remove the right number of vaccine vials. Some multi-dose vials may have been opened and used in the previous session, so take them out of the 'use first' box and place them on the foam pad in a vaccine carrier above the conditioned ice-packs or chilled water packs.

You learned about the cold chain in Study Session 6, and about the multi-dose open vial policy in Study Session 7.

Check the quality of all vaccines and diluents as described in Study Session 6. Discard any vials or ampoules if the expiry date has passed, or if the vaccine vial monitor (VVM) has changed to the discard point, or any freeze-sensitive vaccines that have accidentally been frozen. Also discard any vaccine vial or diluent which has lost its label, because you cannot be sure what it is.

The other materials you will need for the immunization session include:

- source of water and soap for handwashing
- auto-disable (AD) syringes for immunizations and single-use disposable syringes and needles for mixing diluent with freeze-dried vaccines
- cotton swabs and antiseptic or alcohol for cleaning the skin at the injection site
- metal file to open ampoules
- stationery, including the immunization tally sheet, EPI Registration Book, pencils or pens
- new immunization cards for infants and women who have not come for immunization before
- safety boxes for syringes, needles and other sharp instruments, and another container for non-medical rubbish.

you will learn about registration and how to use the tally sheet to create your Summary Report in Study Session 10.

If the infant has any contraindications to immunization, DO NOT immunize. You learned about contraindications in Study Sessions 2, 3 and 7.

Deciding which vaccines to give an infant

Check which of the vaccines the infant has received before by looking at the information on the infant's immunization card. If the carer has forgotten or lost the card, you should look for any entry for the infant in the EPI Registration Book. You can also look for a BCG scar on the upper left arm to establish if the infant has had the BCG vaccination. If the immunization card is lost, you should issue a new one. If you cannot establish whether or not the infant has been vaccinated before, it is advisable to give all the vaccines according to the national EPI schedule — unless there are contraindications. An extra dose of vaccine does not hurt most children.

Deciding whether to give a woman a TT dose

Check the immunization card of every woman of childbearing age who attends the clinic and give her the appropriate dose according to the TT schedule. If she does not have an immunization card, ask whether she has had any previous TT vaccinations, and whether she knows how many doses she has received in the past. Give her the next dose in the series. Take into account any dose given during an earlier campaign that might have taken place in your *kebele*. If she cannot remember or does not know, you should give her a dose of TT and advise her when to come for the next one. If she is pregnant, and has not received a TT dose in the past month, immunize her with TT vaccine.

8.2.2 Recording immunizations

Record keeping is an important part of every immunization session, whether it occurs at a fixed site or during outreach or mobile services. Study Session 10 describes the records in detail, so here we will briefly mention only the main points.

The Family Folder is not only for recording immunizations, but for all vital events (e.g. births, deaths, cause of death, etc.)

Before you immunize an infant or a woman you must enter all the required information into the EPI Registration Book, the Family Folder and the Immunization Tally Sheet. You should check that the infant is the correct age for immunization, and that the infant's age on the immunization card is correct. (You will see examples of the EPI Registration Book, immunization card and tally sheet in Study Session 10.) Also, record the doses of vaccine given at each session in the Vaccine Stock Register shown in Study Session 5.

If this is the first time the infant has been brought for immunization, ask the age of the infant, and if the carer does not know the exact date of birth, try to find out the date by relating it to a historical event or national holiday, such as Easter or *Eid Al Fetir*.

The EPI Registration Book is an important record of your activity and the number of vaccine doses used. It also enables you to trace which vaccinations the infant has had if the carer fails to bring the immunization card on a future occasion. Record all vaccines and vitamin A supplements given on the tally sheet by counting the number of doses of each type of vaccine given during the session. Complete the tally sheet and the infant's immunization card.

On the immunization card you should write:

- the date for each vaccine administered or vitamin A supplement given

- the date when the next immunization is due.

You should return the card to the carer, and before she leaves the Health Post, you should explain that:

- The immunization card is an important document about the health of the infant. She should keep it in good condition and bring it with her whenever the child is brought to the Health Post *for any reason* – not just when she comes for another immunization.
- The infant should complete the full course of vaccinations. Give the carer the date when the infant should be brought back for the next dose of vaccine.
- Occasionally there are adverse reactions to the immunization, but usually these are very mild and get better quickly. Make sure the carer knows what to do if they occur, and explain that the infant should be brought back if the symptoms get worse or the reaction continues for more than a day or two.

8.2.3 Immunization delivery at an outreach site

There are very few differences between delivery of an immunization service at an outreach site, and the details already described for a fixed site such as your Health Post. The key point is that the dates, times and sites for *regular* outreach sessions should be planned carefully, with the goal of covering the target population within the target period. It is very important to work with the community in selecting the most suitable sites and the most appropriate days for outreach immunization sessions. The site should be readily accessible, such as a school or *kebele* office, or in the shade of a large tree (Figure 8.10).

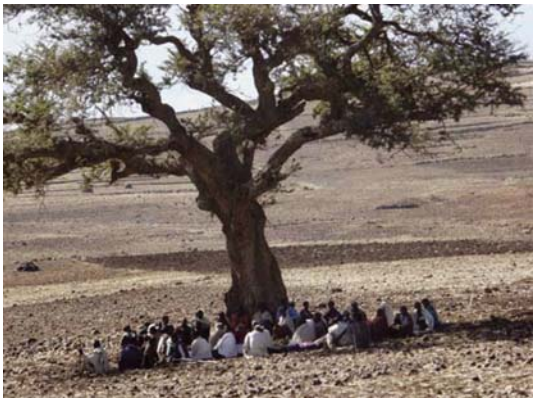


Figure 8.10 A large shady tree can be a good place for people to wait for an outreach session. (Photo: Basiro Davey)

Training, assistance and supportive supervision should be provided regularly for you and the community volunteers in outreach sites, to ensure the delivery of safe and high-quality immunization services for the local community. Monitoring and evaluation of the outreach service, with community input, is crucially important for its success. Regular meetings should be organised to discuss ways of increasing the immunization coverage locally, for example by changing the location to a more convenient site or adding new outreach sites.

Make sure that your vaccine carrier or cold box is shaded from the sun!

What resources do you need for an outreach immunization session?

Human and financial resources for outreach sessions require very careful management in order to reach every district in a sustainable manner. In addition to the resources already described for a fixed-site session, the community should help by providing chairs and tables, and local volunteers to assist you. When you arrive, inspect the site to check that it has been arranged correctly to ensure a good workflow (look back at Figure 8.8), and that all surfaces have been properly cleaned. Swab the table where the injections will be given with alcohol before you set out your equipment.

- What additional resources will you need to take to an outreach session, compared to a fixed-site session?

- You will need to pack all your equipment safely to transport it over the required distance, while maintaining the vaccines and diluents under cold chain conditions at all times. This may mean that you need a cold box, which stays cold for longer than a vaccine carrier.

When you leave the outreach site, you should collect all the safety boxes and any other waste, and take them back to your Health Post, where you can dispose of them in a safe way (see Study Session 7). Do not leave any waste at the site. You started your work in a clean area and it is important to leave the site as clean as when you began. Make sure that you thank all the community volunteers who helped you deliver a successful immunization session that day.

8.2.4 Mobile delivery

During a mobile immunization programme, it is important to plan other health intervention activities, such as malaria control and antenatal visits, at the same time.

A mobile immunization service is likely to be most appropriate for pastoral and hard-to-reach areas. The key difference with other ways of delivering immunization is that it requires a mobile team to travel from place to place, carrying all the immunization equipment and maintaining absolute cold chain conditions for several days. The organisation of a mobile team requires careful planning.

Decisions about where to conduct the immunizations should be discussed and agreed with local government officials, community leaders and other stakeholders. Once the area is identified, you should use all possible ways to get information on the eligible target population in the area, so you can estimate what resources you will need for the number of sessions planned during this trip. Make sure that news reaches every community well in advance of the dates when your mobile service will be coming, and advertise where local people should go to meet you and your team. The setting-up and delivery of each session is exactly as already described for an outreach session.

In the next study session we turn to communication about the immunization service in more detail. Good communication is essential to ensure its success, wherever immunization sessions occur.

Summary of Study Session 8

In Study Session 8, you have learned that:

1 Proper planning is a crucial step in all your immunization activities. If you do not plan properly, you are likely to fail in reaching your targets.

2 Planning consists of six steps: assessing the community's health needs, identifying and prioritising problems to be addressed, setting goals and objectives, agreeing strategies and activites in the annual action plan (including resource requirements), implementing the service, and monitoring and evaluating progress towards meeting the targets.

3 Planning should be carried out in consultation with the district health team and *kebele* leaders, agreed with all relevant stakeholders and reviewed regularly.

4 There are three types of immunization service delivery: fixed site, outreach and mobile services. Resource planning requires additional community participation at outreach or mobile delivery sites to set up the immunization workplace. The cold chain must be maintained at all times.

5 At every immunization session, all required information must be entered into the EPI Registration Book, the clients' immunization record cards, the Family Folder, the tally sheet and the Vaccine Stock Register.

6 The mother or carer of each child brought for immunization should be given a clear explanation of the importance of the immunization record card, when next to bring the child and any possible adverse events following immunization, how to treat them and what to do if a reaction is serious.

Self-Assessment Questions (SAQs) for Study Session 8

Now that you have completed this study session, you can assess how well you have achieved its Learning Outcomes by answering the following questions. Write your answers in your Study Diary and discuss them with your Tutor at the next Study Support Meeting. You can check your answers with the Notes on the Self-Assessment Questions at the end of this Module.

SAQ 8.1 (tests Learning Outcomes 8.1 and 8.2)

Rearrange the following steps in the planning process into the correct sequence and number them 1–6:

- setting goals and objectives
- assessing the community's health needs
- agreeing strategies and activities in the annual action plan, including resource requirements
- implementing the immunization service
- monitoring and evaluating progress towards meeting the targets
- identifying and prioritising problems to be addressed.

SAQ 8.2 (tests Learning Outcomes 8.1 and 8.2)

Imagine you identify a number of problems in your catchment area which you think might prevent you from implementing your immunization programme effectively. You have considered the magnitude and severity of each of the problems you have identified.

- What else should you consider in attempting to prioritise these problems?

SAQ 8.3 (tests Learning Outcomes 8.1, 8.2, 8.3 and 8.4)

Which of the following statements is *false*? In each case, explain what is incorrect.

A Community discussion and approval is essential during the development of your annual immunization action plan.
B If a mother has lost the immunization card for her child, you should send her home to find it before you agree to immunize the child.
C The percent of newborns protected at birth from neonatal tetanus is a good indicator of progress towards achieving adequate TT doses for their mothers during pregnancy.
D A fully immunized child has received all doses of all the EPI vaccines scheduled for routine immunization by the age of 14 weeks.
E Accurate entries in your EPI Registration Book during each immunization session will help you to estimate the number of doses of vaccine needed for future sessions.

SAQ 8.4 (tests Learning Outcomes 8.4 and 8.5)

After vaccinating a 6-week-old baby with BCG, OPV1, Penta1 and PCV10, you explain to the mother that she should look after her immunization card carefully, and bring it with her next time she brings her baby for immunization. You also explain the importance of completing the full course of immunizations.

- What else should you tell the mother before she leaves the Health Post?

SAQ 8.5 (tests Learning Outcomes 8.5 and 8.6)

(a) What should community volunteers prepare for an outreach immunization session before you arrive at the site?
(b) What should be provided to support the community volunteers at this site?
(c) What should you do before leaving the site at the end of the outreach session?

Study Session 9 Communication for an Effective Immunization Programme

Introduction

The *Health Education, Advocacy and Social Mobilisation* Module describes in depth the importance of communication in the health service and methods of achieving good communication. As you already know from earlier study sessions, a key part of a successful immunization programme is effective communication. Communication plays a major role in achieving the overall goal of increasing immunization coverage rates and reducing the number of infants and mothers who drop out of the programme (default) before completing all their vaccinations. This study session will deal with communication in the immunization programme in more detail.

Learning Outcomes for Study Session 9

When you have studied this session, you should be able to:

9.1 Define and use correctly all of the key words printed in **bold**. (SAQ 9.1)

9.2 Describe how you would plan and choose appropriate communication strategies to promote immunization activities and remove barriers to accessing the service. (SAQ 9.2)

9.3 Describe effective communication techniques to use with carers, members of the community and other stakeholders. (SAQs 9.1 and 9.3)

9.4 Explain how you would manage negative rumours about immunization in your community. (SAQ 9.4)

9.1 Why is communication crucial for an effective immunization programme?

Advocacy and communication form one of the five key EPI operations (Figure 9.1), which you saw first in Study Session 1. **Advocacy** refers to ways of delivering an argument effectively, so that you gain the support and commitment of policy-makers, community members and other stakeholders, and are able to 'put the case' successfully for increasing immunization coverage. **Communication** is the transmission of information from one person to another, or from a source to a destination.

Figure 9.1 The five key EPI operations.

Immunization programmes may be unsuccessful if incorrect or inadequate information is transmitted to the community. Sometimes, even though correct information may be communicated, it may be ineffective in achieving the desired outcome. It is important that you, as a Health Extension Practitioner, use terms that are readily understood when you talk to members of the community, ensuring that you appreciate local problems and show respect for local customs and culture. One way to improve communication with members of your community would be to organise a committee to look into reasons why people do not come to be vaccinated, or do not complete their vaccinations. This would help you to:

- improve relations between you as a Health Extension Practitioner and the community
- promote participatory decision-making to improve community involvement in the EPI
- support the community to develop strategies for identifying and tracing immunization defaulters
- improve the quality of the immunization service
- encourage the community to identify and report outbreaks of communicable diseases.

■ What do you hope this would achieve in the long term?

□ The hope is that this would increase immunization coverage in your *kebele* and help high immunization coverage rates to be maintained. If more infants and mothers are fully immunized, then disease and deaths from vaccine-preventable diseases will be reduced.

9.2 Planning a communication activity

A communication strategy should be included in your annual EPI action plans. There are likely to be many possible barriers to effective communication between Health Extension Practitioners like you, carers, the community and stakeholders. It is important that you identify these barriers and do your best to eliminate them. The aim is that your messages will be understood and will result in changes in behaviour, which will increase EPI coverage rates and decrease dropout rates.

The planning process involved in communication for improving immunization coverage can be summarised in a series of four steps as outlined in Figure 9.2; this is a simplified version of the six-step diagram you have already seen in Study Session 8 (Figure 8.3).

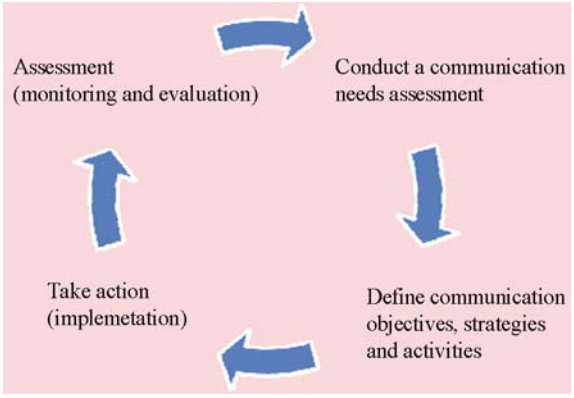


Figure 9.2 Planning process for effective communication.

9.2.1 Conduct a communication needs assessment

First, it is important to talk to people to find out about attitudes to immunization in the community, in particular whether there is opposition to it. If there is some resistance to immunization, you need to ask why this has occurred. Discussion with members of women's groups and youth groups in your *kebele* may help you to find answers to your concerns. You may be able to identify specific behaviour or attitudes that are creating a barrier to immunization in the community. Has there been an adverse incident in the past that has worried parents? Is there an opinion leader in the community who is opposed to immunization and has persuaded others to resist it? This **communication needs assessment** will help you to assess what strategies and activities to plan for this community.

9.2.2 Define communication objectives, strategies and activities

If you can identify specific barriers to immunization, you will need to decide which of these might be targeted in order to look for a solution. Which of these barriers might it be possible to remove? How might this help to increase immunization coverage and decrease dropout rates? Why are so many children not brought for immunization? Table 9.1 on the next page lists some commonly reported reasons.

Table 9.1 Top ten reasons reported by caregivers to explain why their children were not fully immunized in Ethiopia. (Source: WHO, 2006, *EPI National Survey in Ethiopia*)

Reason why child not fully immunized	**Caregivers giving this as the main reason (%)**
Unaware of need for immunization	22.8
Unaware of need to return for next dose	12.8
Vaccine not available	12.5
Mother too busy	6.3
Vaccinator absent	6.1
Place and time of immunization unknown	6.0
Immunization site too far away	5.7
Family problems and/or mother ill	5.3
Fear of adverse effects following immunization	4.0
Time of session not convenient	2.6

Stop reading for a moment and think about which of the reasons in Table 9.1 are the most likely reasons for children not being brought for immunization in your catchment area.

These are the issues that you should concentrate your communication efforts on, and that should form the basis of your communication objectives.

■ Which of the reasons listed in Table 9.1 do you think could be best addressed by improved communication? How might you hope to address these barriers to an effective immunization service?

□ Many of the reasons given in the table could be addressed by improved communication, but in particular you might have suggested:

- *Unaware of the need for immunization*: You could arrange a community meeting to explain the advantages of immunization, and the seriousness of the diseases it protects against.
- *Unaware of the need to return for the next dose*: You could ensure that all those bringing their children for immunization are clearly told when they should return and why.
- *Place and time of immunization unknown*: You can make sure there are notices clearly visible at your Health Post and in the *kebele* office announcing when and where immunization is available. You can also make every effort to remind people of these dates and places whenever you visit families, and ask your volunteers to tell everyone they visit.
- *Fear of adverse effects*: Whenever you are telling people about the advantages of immunization and the seriousness of the diseases it protects against, you could also explain that there may be mild side-effects, but that these are very rarely serious.

Setting objectives

You will recall from Study Session 8 that objectives always have to be *specific* and the outcomes must be *measurable*. A well-constructed objective identifies what will be done in order to achieve it, who will do it and where, what resources will be used, and the timescale in which the target should be achieved. You will also need to work out what resources are available in the community that can be used for the communication activities that you may wish to organise.

Having set your communication objectives, you next need to decide what activities would be the most appropriate to help you to achieve them. You should address the following questions:

- What message is it that you want to communicate?
- What media will be most suitable for communicating it?
- Will you be able to get the resources required?

Strategies and activities

There are a number of possible strategies or activities you can use to get your message across to the community. These might include a community conversation (Figure 9.3 and see Section 9.3.4 later in this study session) or a community mobilisation or advocacy programme. The work plan for conducting these activities should be realistic. You will need to think about what it is that you want to do, when you hope to do it, how many people you will need to help you and who these people might be.

Figure 9.3 A Health Extension Practitioner engaged in a community conversation. (Photo: AMREF Ethiopia)

Assessment, monitoring and evaluation

You will also need to find ways to check whether your strategy or activity is working. For example, you might have held a meeting or conducted a community conversation to explain the advantages of immunization, and the seriousness of the diseases it protects against. You hope that this might increase immunization coverage by encouraging caregivers to bring their children to the Health Post for immunization.

■ How could you evaluate whether your message was understood and whether it has made a difference to people's behaviour?

□ There are many possible ways you might try to evaluate the effectiveness of your activities. Here are some suggestions (you might have thought of others):

- You could record how many people attended the meeting or community conversation, and who they were. You could then monitor how many of these people have shown a change in behaviour. You could see if these people brought their children for immunization, or brought them more regularly than before.
- If someone who is not known to you brings their children for immunization for the first time, you could ask how they knew the immunization was available. This might help you to establish whether those who were present at the meeting or community conversation spread the message to others.

If you look back at Figure 9.1, you will see that the five key operators are connected to one another. This is because the results of your monitoring and evaluation help you to determine which strategies and activities are making progress towards achieving your objectives. This information should be fed back into your next communication analysis (Figure 9.2), so communication improves when you find out about people's attitudes and behaviour next time.

9.3 Behaviour change communication (BCC)

You will probably be aware that firmly held views do not change fast. It takes time for people to change their attitudes. The aim is to increase immunization coverage, so the goal of communication about immunization is to bring about positive behaviour change. When you deliver messages to people they may understand what you are saying and acquire knowledge about immunization, but they may not take this knowledge and apply it. They still may not bring their children for immunization. They may not actually change their behaviour.

Behaviour change communication (BCC) is a process of developing communication strategies to promote a positive change in health-related behaviours in a community, appropriate to local circumstances. This can only be done by sustained work with individuals and communities to explain the issues and implications involved and support people as they try to understand them.

9.3.1 Common methods of BCC in immunization

When you want to communicate a message, for example about the advantages of having your child immunized, you should first identify or decide who the message is intended to influence. The message to be sent to a group of school teachers, a women's group, a youth group, or a group of religious leaders is not the same, even though the aims of all these messages might be to increase immunization coverage. Their level of understanding of the issues involved is likely to be quite different. Therefore in preparing a BCC message, the first step should be to decide who you intend to address. This is your **target audience**.

■ Suppose the message you want to communicate is that there are many diseases that are serious and may lead to death, but they can be prevented by immunization; therefore, bringing babies and children for immunization from an early age is beneficial. Who would your target audience be? (Who would you want to communicate this message to?)

□ You would want to communicate this message to all mothers of babies and children (Figure 9.4), and any other caregivers in the *kebele* who are responsible for looking after babies and children.

Figure 9.4 Mothers and other caregivers are the main target audience for behaviour change communication about immunizing babies. (Photo: Basiro Davey)

Once you have identified your target audience, the next step is to think about your objective. What change in behaviour do you want your target audience to make? This could be based on the problems you have identified in your communication needs analysis. There are several strategies and activities that you can use, including advocacy, community mobilisation, community conversations and interpersonal communication — all of which are explained in detail in the *Health Education, Advocacy and Community Mobilisation* Module, Part 2. We will remind you of the main points below.

9.3.2 Advocacy

Advocacy is a process or activity that aims to influences politicians, policy-makers and opinion leaders. In the context of EPI activities, this could refer to an activity that aims to gain the support of stakeholders, community leaders and local politicians, and to encourage community acceptance of and commitment to the EPI. There are many activities and strategies that can be used in advocacy. Here are some of them:

- lobbying
- meetings
- negotiation
- project visits
- use of information and education resources.

■ Imagine that a new vaccine is being added to the routine EPI schedule, but no decision has yet been reached about when it will be available for your *kebele*. You may need to undertake some advocacy activities in order to speed up the decision to make it available locally. What do you think the most appropriate activities might be in this situation?

□ Appropriate advocacy activities might include negotiation with local political and community leaders, as well as women's and youth groups. You will need to provide them with information on the new vaccine, its safety, the diseases it can prevent and the particular needs of your community to receive its protection.

9.3.3 Community mobilisation

Community mobilisation is a process of gaining the involvement of everyone in the community for an action towards a particular goal.

■ Can you remember some of the advantages of the community mobilisation process?

□ You may not have remembered all of the advantages, but your answer should have included some of the following.

Community mobilisation:

- helps motivate the people in the community through participation and involvement of everyone in a shared goal
- builds community capacity to identify and address community needs
- helps mobilise and release local resources
- promotes long-term commitment to sustained behaviour change and hence sustainability of health improvements
- motivates communities to campaign for policy changes to respond better to their health needs
- links members of the community to the available health services
- leads to a feeling of local ownership, which ultimately leads to a more sustainable immunization programme.

In the EPI, mobilising the community is likely to enhance the programme and hence make it much more effective. In order to mobilise the community you will need to interact with your target audience members in person. You should prepare your message in a clear and simple way. You can have the interaction in community meetings, in religious places, market places, etc. Loudspeaker messages for large community meetings may be appropriate.

You may need to use written materials — for example, you could put up posters and distribute leaflets. Drama shows and local community radio broadcasts may also help your communication messages to be heard and understood.

9.3.4 Community conversation

One of the ways in which it is possible to influence behaviour is through a **community conversation** (Figure 9.5). This is a collective discussion of a particular issue, such as the causes of high dropout rate in the immunization programme, and can lead to a way of finding solutions to particular problems.

Figure 9.5 A Community conversation in progress. (Photo: Janet Haresnape)

Such a conversation will be successful when everyone is given the opportunity to be heard. Many will not participate fully in a meeting unless they feel at ease and believe their opinions will be heard. Therefore in organising a successful community conversation, you should consider the following points:

- Decide on the purpose of the conversation and advertise it widely.
- Decide who should attend or be invited.
- Prepare an agenda for the meeting.
- Decide on the date and time; make sure that everyone you want to attend is informed about when and where the meeting will take place.
- Choose a meeting place where there is little interference, so that everyone will be able to hear one another's views.
- Facilitate the conversation in an open and non-judgemental way, so everyone feels included and respected.

9.3.5 Interpersonal communication

Interpersonal communication is a term for face-to-face interaction with an individual, or a small group of people, for the exchange of information. Because it is a face-to-face interaction, the people involved have eye contact, they hear each other, and they can respond to each other's ideas. Note that interpersonal communication is a two-way process, where everyone learns from each other — including you!

Interpersonal communication is vitally important in supporting the behaviour change process. In particular it is very good for:

- Persuading and convincing individuals and target audiences about the value of the proposed behaviour change, by explaining and responding to questions and doubts about immunization.
- Addressing rumours about adverse effects of immunization.
- Addressing any personal issues the caregivers may express.
- Helping to mobilise resources from the community to enhance the immunization programme, through advocacy efforts.
- Building consensus for a concerted effort, for example to bring all eligible children for immunization.
- Explaining to caregivers about the immunization status of the child.

- Telling the caregivers about the next immunization(s) that the child will need.

Interpersonal communication skills

Here is a reminder of the important interpersonal communication skills you learned about in the *Health Education, Advocacy and Community Mobilisation* Module.

- Welcome the client warmly and offer a seat.
- Empathise with the client.
- Speak in simple terms, using easy language; give examples that the caregiver is likely to understand.
- Motivate by praising the caregiver for bringing the child for immunization and encouraging them to return for the next dose.
- Listen actively. Active listening is very different from just hearing. It is listening to another person during a conversation in a way that shows your understanding and interest. It encourages the other person to be more involved in the conversation. You can show that you are actively listening by using gestures, saying 'Aha!', or repeating what the client has said (Figure 9.6).

Figure 9.6 Active listening encourages the client to trust you and express her concerns. (Photo: Basiro Davey)

- Use appropriate visual aids. The pictures you use should be relevant to the message you want to transmit, and appropriate to the local customs.
- Summarise what has been discussed at the end of the conversation. You should check and confirm areas of agreement and disagreement.

Asking questions sensitively

It is important to give your client a chance to ask questions. This will help you to see how much she has understood and accepted what you have discussed. You can also ask her questions that enable you to assess her attitudes and the likelihood of positive behaviour change. But questioning must be done sensitively!

■ What questions might you ask a mother in one-to-one interpersonal communication if you think she may drop out of the immunization programme?

□ There are many questions you might ask, for example the ones suggested below. You may have thought of others.

- Ask specific questions such as 'Which immunizations did your child have last time? How was his health afterwards? Did you have any concerns about the vaccination?

These questions help you to establish whether the mother understands which immunizations the child has had, and which ones remain to be completed.

- Ask 'Is there anything that makes you feel unsure if you will bring your child back for the next immunization?' If she says she is unsure, gently ask about her worries and try to reassure her.

Asking about a caregiver's worries about immunization is an example of an **open question**, i.e. a question that encourages the client to answer in her own way and share her concerns with you. You should avoid asking **closed questions** where the caregiver can simply answer 'Yes' or 'No'. A closed question does not allow you to check whether the client has really understood the question, or really knows the answer.

■ Here is an example of a closed question: 'Did your child complete all her immunizations?' Change this into an open question on the same topic.

□ You could ask 'Which immunizations has your child been given, and what age was she when she got them?'

When asking questions, always give time for the client to think and answer. Let the client answer freely and do not interrupt while the client is answering.

9.4 Meeting with target audiences to promote EPI activities

In your efforts to increase immunization coverage and decrease dropout rates, you are likely to come across various interested groups of people and organisations. These may include health staff at various levels, politicians and policy-makers, community leaders, representatives from the private sector and from the NGOs (non-governmental organisations, such as UNICEF, AMREF and others), parents, and journalists. You may also particularly want to meet people from those parts of the population that have not yet been reached by the immunization programme. In this section, you will learn ways to promote immunization campaigns when you contact representatives from these target groups.

9.4.1 Meeting with community leaders

Community leaders may include *kebele* leaders, clan leaders, religious leaders, elders and school leaders, and the leaders of women's and youth groups. You should try to gather information about the community you are working in before you meet such community leaders. To increase the effectiveness of your meeting, you should identify who the relevant participants will be, decide on an agenda and what issues to discuss, and make sure that all those you want to attend the meeting are aware of the agenda, and where and when to meet. To gain the maximum benefit from the meeting, try to find out beforehand what the participants already know about immunization. It is based on this background that you can introduce the topic and build up useful discussions.

■ What issues might you want to discuss with community leaders?

□ Some possible issues are listed below. You may have thought of others:

- any concerns the leaders and families may have about immunization
- any religious or traditional beliefs about disease or immunization
- barriers that may prevent people from accessing immunization services, e.g. distance, seasonal work commitments, traditional festivals or customs, lack of money for transport, and inconvenient days, times or sites for immunization sessions
- the most appropriate times and locations for immunization sessions
- possible ways of reaching more children in the community
- whether immunization could be promoted by being mentioned regularly at religious or other gatherings.

9.4.2 Meeting with parents

One of the most effective ways to get a range of opinions in a short space of time might be to arrange small **focus groups**, with clear guidelines from you about the topic that the discussion should 'focus' on. The ideal number of participants in a focus group is between six and ten, with a facilitator who keeps the discussion focused on the agreed topic (in this case, immunization) and makes sure that everyone's views are heard. You could select particular participants, such as parents you think may be unlikely to bring their children for immunization.

You may also talk to parents one-to-one when they visit the Health Post and find out about their experiences (good and bad) with the immunization services provided. In particular, you should try to reach those parents in the community who, for one reason or another, do not visit the Health Post. Interview the mothers who do attend the Health Post first, since they are readily accessible and are often willing to talk about their experience of the services. In addition they may suggest ways of reaching those who do not use the Health Post facilities.

■ When meeting with parents, what might you want to find out?

□ There are many things you might want to find out from parents, but here are some things you may have suggested:

- what they already know about immunization
- what concerns they may have about immunization
- their traditional beliefs about disease or immunization
- any barriers to accessing existing services
- if the times and locations of immunization sessions are appropriate
- what they think about the quality of the service provided
- how they think the service could be improved.

9.4.3 Meeting with NGOs and other partners

Try to meet with any other partners or institutions who you think might be able to help improve the immunization service. Who these might be will depend on your community, but could include traditional birth attendants (TBAs), traditional healers, private health practitioners, volunteer groups and representatives of NGOs that focus on health — particularly the health of children.

9.4.4 Meetings with special groups

In your community you may be aware of some special groups who have been largely unreached by immunization services, or have chosen not to participate in them. You should try to include such people or groups in your meetings and planning process right from the start. Some examples of special groups include:

- pastoralist groups
- migrant workers
- ethnic or other minority groups
- groups in geographically remote areas, who may find it difficult to reach the site of the immunization services
- people who are injured, sick or disabled, who may find it difficult to get to where immunizations are taking place
- religious or traditional sects that refuse immunization
- refugees
- homeless families.

You should always try to ensure that your messages are concise and to-the-point, and also that they are memorable. This is particularly important in meetings with representatives from any of the special groups mentioned in this section. In the final part of this study session, we turn to some of the negative rumours about immunization that might influence people against the service in your community.

9.5 Negative rumours about immunization

Rumours about bad consequences of immunization often circulate in communities. If such **negative rumours** are not dealt with appropriately, they can cause serious problems for the effective delivery of immunization services.

■ Can you think of any rumours about immunization in your *kebele*? If so, what are they?

□ Examples of some rumours that may be circulating are that:

- vaccines are a contraceptive to control births in the population, or to limit the size of a certain ethnic group
- children are dying after receiving vaccines.

You may have come across other rumours, which could be equally damaging to the success of an immunization programme.

What can you do about negative rumours? Any negative rumours about immunization that you hear are circulating should be communicated to your supervisor as soon as possible. The following suggested actions cannot be carried out by you alone, as the local Health Extension Practitioner; you will need the full involvement of health centre officials and the district Health Office. Immediate reporting is important and advice should be sought before you take action.

With their approval, these are the steps you should take if you come across a potentially damaging rumour about immunization:

- First, try to find out what the rumour is, who was the original source of the rumour and who is spreading the rumour now. Try to establish whether there is any reason for the rumour spreading — there might be a political or religious reason, or it might simply have arisen from lack of information or incorrect information about the immunization programme.
- Once you have gathered this information, arrange a meeting with opinion leaders such as local government officials, traditional and religious leaders, community leaders and other health workers. In the meeting, begin by providing information about the immunization programme and the diseases it can prevent. Try to ensure that those present are free to ask questions and express concerns. Discuss and reach agreement on collective ways to correct the negative rumour and the wrong information about the immunization service.
- Train your community volunteers on how to give the correct information about vaccines and how to deal with the rumour.
- Distribute posters and printed materials which give correct information about immunization to the public. Such materials may be made available by your local health centre or to support regional or national campaigns.

In the final study session in this Module, we turn to a crucial aspect of your immunization programme — monitoring and evaluating the outcomes.

Summary of Study Session 9

In Study Session 9, you have learned that:

1 Barriers to accessing the immunization service include issues that can be resolved by better communication. These barriers include lack of knowledge about the need for immunization or the need to return for further doses, or about the time and location of immunization sessions; fear of adverse reactions is another barrier that good communication can overcome.

2 Immunization coverage rates can be increased and dropout rates reduced by effective advocacy and communication activities; inadequate communication with local people, in particular parents, can seriously affect the success of the immunization programme.

3 Behaviour change communication (BCC) activities should be an integral part of your planned immunization strategy; the planning process involves a communication needs assessment, the definition of communication objectives, strategies and activities, implementation, and assessment of outcomes through monitoring and evaluation.

4 You should select BCC strategies and activities appropriate to the target audience, local culture and context, such as advocacy, community mobilisation, community conversations, interpersonal communication and focus group meetings, e.g. with community leaders, parents, women's groups, youth groups, NGOs and other partners, and special groups — particularly those who have not yet been reached by the immunization service, or are reluctant to access it.

5 You should seek guidance from your supervisor and district health officials on how best to address negative rumours about immunization if they circulate in your community.

Self Assessment Questions (SAQs) for Study Session 9

Now that you have completed this study session, you can assess how well you have achieved its Learning Outcomes by answering these questions. Write your answers in your Study Diary and discuss them with your Tutor at the next Study Support Meeting. You can check your answers with the Notes on the Self-Assessment Questions at the end of this Module.

SAQ 9.1 (tests Learning Outcomes 9.1 and 9.3)

(a) What is meant by a community conversation?
(b) In what circumstances might you arrange a community conversation about your immunization programme?
(c) Who would you invite?

SAQ 9.2 (tests Learning Outcome 9.2)

Supposing you wanted to increase the low immunization coverage rate in one particular group of parents in your *kebele.* What steps would you take in the planning process to address this problem?

SAQ 9.3 (tests Learning Outcome 9.3)

Suppose that you find the main reason given for high dropout from the immunization programme is a lack of awareness of when or where immunizations take place. What measures might you take to improve the situation?

SAQ 9.4 (tests Learning Outcome 9.4)

Imagine that you discover there is a rumour circulating in your *kebele* that measles vaccination causes deafness. What would you do?

Study Session 10 Monitoring your Immunization Programme

Introduction

In this study session you will learn about how to monitor your own immunization programme. **Monitoring** is the routine ongoing collection of data and the assessment of activities, in order to enable the targets you agreed in your action plan to be compared with what you have actually achieved. Monitoring an immunization programme includes the proper use of EPI recording tools to collect reliable data, which can be evaluated to improve the planning and management of the immunization service in the future. So, in this study session, we will teach you about the main recording tools used to collect and report the data from your immunization programme, so you can monitor and evaluate your performance.

The aim of this study session is to teach you how to improve your immunization service by identifying problems and their causes, developing solutions, and incorporating these solutions as activities in your work plan. Your overall goal is to increase immunization coverage rates and reduce dropout, so that babies like the one pictured in Figure 10.1 can be protected from all the vaccine-preventable diseases covered by the EPI.

Figure 10.1 Immunization protects thousands of Ethiopian babies every year. (Photo: Sacca, accessed from Wikimedia Commons)

Learning Outcomes for Study Session 10

10.1 Define and use correctly all of the key words printed in **bold**. (SAQs 10.1 to 10.5)

10.2 Describe how to use the basic EPI recording tools: immunization cards, the EPI Registration Book and the tally sheet. (SAQ 10.1)

10.3 Explain how you calculate immunization coverage and dropout rates and use them to monitor the success of your immunization programme. (SAQs 10.2, 10.3 and 10.4)

10.4 Explain the possible causes of low immunization coverage rates, and/or high dropout rates, and suggest ways to improve these EPI indicators, including systems for tracing defaulters. (SAQs 10.3 and 10.4)

10.5 Describe how you make accurate, timely and complete immunization Summary Reports from your Health Post. (SAQ 10.5)

10.1 EPI recording tools

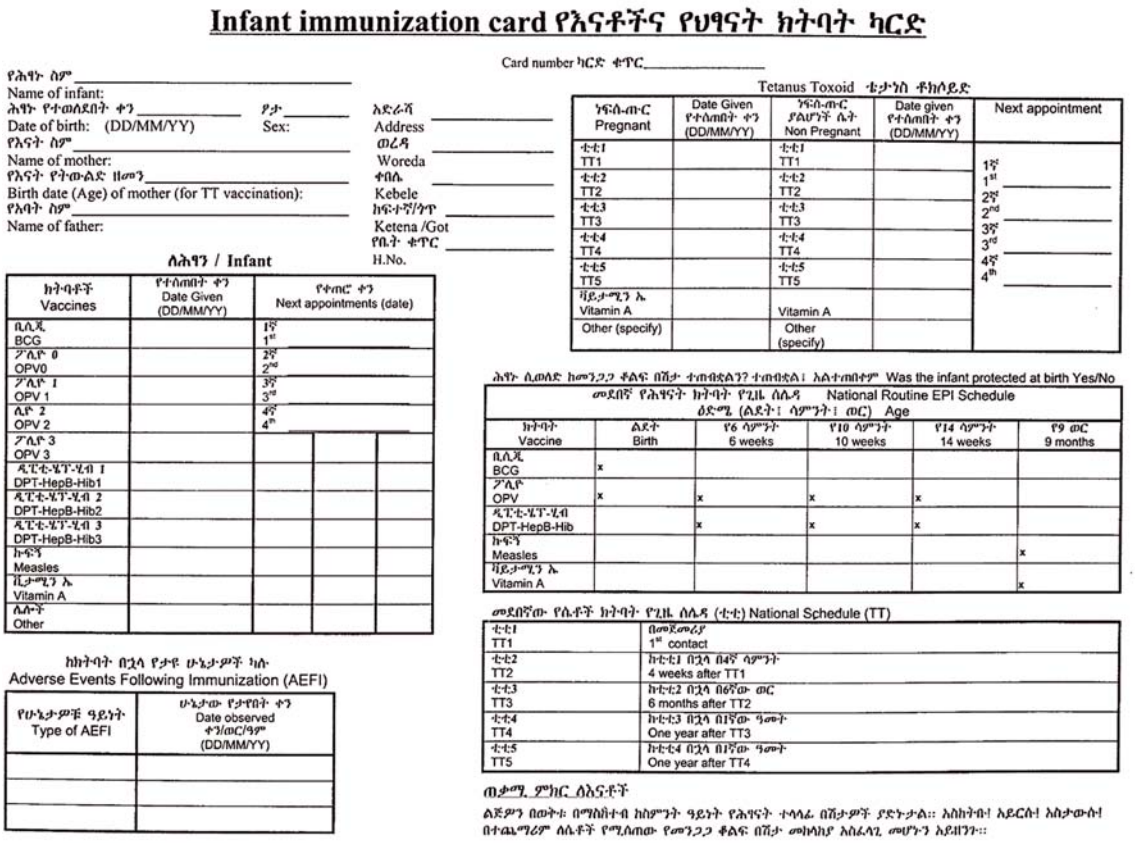
We begin by teaching you about the basic **EPI recording tools** used in immunization programmes: these are the infant immunization card, the EPI Registration Book, the tally sheet and the Summary Report Form. Already described in earlier study sessions are the Vaccine Stock Register and Family Folder, which are not covered again here.

10.1.1 Infant immunization card

The **infant immunization card** (or vaccination card) is a small card that contains relevant information about the child and his or her immunization history. It is kept by the mother or other principle caregiver of the infant. It shows:

- a unique identification number (card number)
- name of the infant
- its birth date
- its sex
- name and address of mother/parent
- date that infant was protected at birth (PAB) from neonatal tetanus
- date of each subsequent immunization and vitamin A supplement given
- date when the next immunization is due.

The cards may vary slightly, and some may show additional information, such as the age of the mother and dates of her TT immunizations (Figure 10.2).



Infant immunization card የእናቶችና የህፃናት ክትባት ካርድ

Card number ካርድ ቁጥር_____

የሕፃኑ ስም_____
Name of infant:
ሕፃኑ የተወለደበት ቀን_____ ፆታ_____
Date of birth: (DD/MM/YY) Sex:
የእናት ስም_____
Name of mother:
የእናት የትውልድ ዘመን_____
Birth date (Age) of mother (for TT vaccination):
የአባት ስም_____
Name of father:

አድራሻ _____
Address
ወረዳ _____
Woreda
ቀበሌ _____
Kebele
ክፍተኛ/ንጥ _____
Ketena /Got
የቤት ቁጥር _____
H.No.

ለሕፃን / Infant

ክትባቶች Vaccines	የተሰጠበት ቀን Date Given (DD/MM/YY)	የቀጠሮ ቀን Next appointments (date)
ቢሲጂ BCG		1ኛ 1st
ፖሊዮ 0 OPV0		2ኛ 2nd
ፖሊዮ 1 OPV 1		3ኛ 3rd
ሲዮ 2 OPV 2		4ኛ 4th
ፖሊዮ 3 OPV 3		
ዲፒቲ-ሄፕ-ሂብ 1 DPT-HepB-Hib1		
ዲፒቲ-ሄፕ-ሂብ 2 DPT-HepB-Hib2		
ዲፒቲ-ሄፕ-ሂብ 3 DPT-HepB-Hib3		
ኩፍኝ Measles		
ቪታሚን ኤ Vitamin A		
ለሎች Other		

ክትባት በኋላ የታዩ ሁኔታዎች ካሉ
Adverse Events Following Immunization (AEFI)

የሁኔታዎቹ ዓይነት Type of AEFI	ሁኔታው የታየበት ቀን Date observed ቀን/ወር/ዓም (DD/MM/YY)

Tetanus Toxoid ቴታነስ ቶክሶይድ

ነፍሰ-ጡር Pregnant	Date Given የተሰጠበት ቀን (DD/MM/YY)	ነፍሰ-ጡር ያልሆነች ሴት Non Pregnant	Date given የተሰጠበት ቀን (DD/MM/YY)	Next appointment
ቲቲ1 TT1		ቲቲ1 TT1		
ቲቲ2 TT2		ቲቲ2 TT2		
ቲቲ3 TT3		ቲቲ3 TT3		
ቲቲ4 TT4		ቲቲ4 TT4		
ቲቲ5 TT5		ቲቲ5 TT5		
ቫይታሚን ኤ Vitamin A		Vitamin A		
Other (specify)		Other (specify)		

ሕፃኑ ሲወለድ ከመንጋጋ ቆልፍ በሽታ ተጠብቂልን? ተጠብቂልን፣ አልተጠበቀም Was the infant protected at birth Yes/No

መደበኛ የሕፃናት ክትባት የጊዜ ሰሌዳ National Routine EPI Schedule
ዕድሜ (ልደት፣ ሳምንት፣ ወር) Age

ክትባት Vaccine	ልደት Birth	የ6 ሳምንት 6 weeks	የ10 ሳምንት 10 weeks	የ14 ሳምንት 14 weeks	የ9 ወር 9 months
ቢሲጂ BCG	x				
ፖሊዮ OPV	x	x	x	x	
ዲፒቲ-ሄፕ-ሂብ DPT-HepB-Hib		x	x	x	
ኩፍኝ Measles					x
ቫይታሚን ኤ Vitamin A					x

መደበኛው የሴቶች ክትባት የጊዜ ሰሌዳ (ቲቲ) National Schedule (TT)

ቲቲ1 TT1	በመጀመሪያ 1st contact
ቲቲ2 TT2	ከቲቲ1 በኋላ በ4ኛ ሳምንት 4 weeks after TT1
ቲቲ3 TT3	ከቲቲ2 በኋላ በ6ኛው ወር 6 months after TT2
ቲቲ4 TT4	ከቲቲ3 በኋላ በ1ኛው ዓመት One year after TT3
ቲቲ5 TT5	ከቲቲ4 በኋላ በ1ኛው ዓመት One year after TT4

ጠቃሚ ምክር ለእናቶች
ልጅዎን በወቅቱ በማስከተብ ከስንገት ዓይነት የሕፃናት ተላላፊ በሽታዎች ያድኑታል። አስከትበ! አይርሱ! አስታውሱ!
በተጨማሪም ለሴቶች የሚሰጠው የመንጋጋ ቆልፍ በሽታ መከላከያ አስፈላጊ መሆኑን አይዘንጉ።

Figure 10.2 Sample infant immunization card used in some parts of Ethiopia. Note that DPT-HepB-Hib vaccine is referred to as pentavalent vaccine on some cards. (Federal Ministry of Health, supplied by Dr Amha Mekasha)

We now consider how you should complete the infant immunization card. You should write down the date for each vaccine administered, or vitamin A supplement given. Include doses of TT given to the mother if she is eligible for a dose. Mark the next appointment date on the card and tell the mother when and where to return for the next dose of the vaccine. Make sure that the appointment date corresponds to a planned immunization session. Remind the mother verbally as well as by writing on the card. Always return the card to the mother or caregiver.

10.1.2 The EPI Registration Book

The EPI Registration Book (or Immunization Register) is a book for entering immunization data. It helps you keep a record of the immunization services you offer to each infant and to women of childbearing age, particularly all those who are pregnant (Figure 10.3 on the next page). Your Health Post can either have two separate EPI Registration Books, one for recording infant immunizations and another for recording TT given to women, or one book to record both. The Immunization Register can also be used like a birth register. As soon as an infant is born in the community, its name can be entered in the register even before the infant has received any immunizations. This will help you to follow up all infants in the community.

Figure 10.3 All women of childbearing age should be entered in your EPI Registration Book the first time they come to your Health Post, or outreach site. Their records should also be entered in the Family Folder. (Photo: Basiro Davey)

What information is entered in the Registration Book?

The EPI Registration Book should include the following information:

- a unique identification number (registration number)
- registration date (usually the date of the first visit)
- full name of infant
- infant's birth date
- infant's sex
- immunizations (vaccine lot number and dose) and vitamin A supplements given
- whether the infant was protected at birth (PAB) from neonatal tetanus
- additional remarks (e.g. growth monitoring).

The following information about TT doses given to women may be recorded in a separate book, or in your EPI Registration Book:

- name and address of mother
- TT immunization provided to pregnant and non-pregnant women in the target age group (15–49 years) by dose.

Using the Registration Book

You must register infants, and women in the 15–49 age group (whether they are pregnant or not), as soon as they arrive at the Health Post or outreach site. Fill in all the required information, *except* the space provided for immunizations, which should only be completed *after* the immunization has actually been given. It is important to enter a unique registration number for each infant, which is the *same* number as the one on the immunization card. This way, for the next immunization, it will be easy to locate the infant's entry in the Registration Book.

Do not create a new entry in the register each time the mother brings the infant for immunization. Ask the mother for the immunization card and look for a corresponding entry in the register. If the immunization card is not

available, ask the mother the age of her infant and details of the first immunization to help you locate the infant's entry in the Registration Book.

For every new infant who has never been immunized, create a new entry in the register and complete a new immunization card. For an infant who has come to your Health Post for the first time, but has received immunizations in another health facility, create a new entry in the register, ask for the immunization card and mark on the register the immunizations that the infant has already received.

Remember to record the vaccine dose and lot number in your Vaccine Stock Register (see Study Session 5).

10.1.3 Immunization tally sheets

Tally sheets are forms on which health workers make a mark every time they administer a dose of vaccine. These are used as the basis for monitoring and making regular summary reports of vaccine use. *Use a new tally sheet for each immunization session* (Figure 10.4). The *same* tally sheet can be used to mark vaccines given to infants, and vaccines given to pregnant and non-pregnant women in the childbearing age group.

After you have immunized an infant, record the immunization in the EPI Registration Book and on the infant's immunization card, and inform the mother which doses were given. On the tally sheet, place a mark next to the dose you have just given. Mark each vaccine dose given on the tally sheet *immediately after* giving it.

EPI REGISTRATION BOOK

Reg. No	Date	Full Name (Including Grandfather)	Sex	Date of Birth	Address		Card* no	Date Immunization**					Fully Vaccinated (✓)	GM	Remark
					Woreda	Kebele/Town		BCG Polio 0	DPT1 Polio 1	DPT2 Polio2	DPT3 Polio3	Measles			

Figure 10.4 Sample tally sheet for recording immunizations. (Source: as in Figure 10.2)

After immunizing any woman, whether she is pregnant or not, record the immunization in the EPI Registration Book and on the woman's immunization card, and mark it in the correct column of the tally sheet and the Vaccine Stock Register. If no card is available, rely on the woman's history to tally the dose. For example, if a woman says she has received three doses in the past, tally the new dose as TT4, issue a new card for the woman and mark the card with the date.

Check that the tally sheet is complete at the end of a session. Add up the number of doses of each vaccine that you have given during the session, and check that the number of doses given 'tallies' (matches) the number recorded in your EPI Registration Book. You will use this information to monitor your performance and to prepare your monthly Summary Report (described in Section 10.6) to your supervisor and the *woreda* health office. Keep the tally sheets so that your supervisor can check the data quality (accuracy of reporting).

Common mistakes during tallying

The common mistakes that can occur on tally sheets are summarized in Table 10.1.

Table 10.1 Common mistakes during tallying an immunization session.

Possible mistake	Possible problem that may occur	Correct practice
Tallying before the vaccine is administered	The child or woman may not receive the vaccine	Give the dose first, then mark on the tally sheet
Tallying at the end of a session according to the number of doses remaining in the opened vials	'Wasted' doses may be counted as being given	Tally each dose as it is given
Tallying all vaccines under one age group (including those outside the targeted age)	Inaccurate immunization coverage data	Tally separately for infants under one year and those over one year old

10.2 Monitoring EPI indicators

Sometimes you will see this statistic referred to as 'fully immunized infant' (FII).

For immunization to be effective in reducing cases of vaccine-preventable diseases and deaths, every child should be fully immunized by the age of one year. A **fully immunized child** (FIC) has received all doses of all EPI vaccines, including measles vaccine, before the age of one year. In this section, we show you the two main ways to monitor whether your immunization service has the potential to reduce the target EPI vaccine-preventable diseases. You do this by measuring the:

- immunization coverage rate for each vaccine
- dropout rates from completion of scheduled immunizations.

These are the two main **EPI indicators** that are used *internationally* to analyse the performance of EPI programmes.

10.2.1 How to measure immunization coverage rates

Immunization coverage is the percentage of eligible fully-immunized infants compared to the total number of surviving infants in the target population. The immunization coverage rate is measured by comparing the number of doses actually given and the number in the target population of surviving infants under one year of age (these are the *eligible* infants). The result is expressed as a percentage. The equation below shows you how to calculate immunization coverage rate in your *kebele*.

Immunization coverage rate (for a particular vaccine) =

number receiving all doses ÷ number in the target population x 100%, where:

- number receiving all doses is the number of surviving infants under one year of age receiving all the required doses during the previous 12 months for the selected vaccine.
- target population is the total number of eligible infants under one year of age (or total number of surviving infants) at the start of that reporting period.

■ If the total number of fully immunized infants aged under one year in a particular *kebele* was 192 during the annual reporting period, and the

total number of eligible infants in this age group was 205, what was the immunization coverage rate in that period?

□ The calculation is (192 ÷ 205) × 100% = 93.6%. In other words, in this example, 93.6% of the eligible infants were fully immunized during that reporting period.

If the number of fully immunized infants appears to be *greater* than the number in the target population, this indicates that some of the recorded information must be incorrect. The reason for this problem should be identified.

■ Can you suggest some possible reasons for this problem with the coverage data?

□ The target population data may be incorrect; there could have been more surviving infants aged under one year than the number counted. The number of fully immunized infants recorded may include some children aged over one year. Children from other areas (not counted in your target population) may have come to your Health Post for immunization.

10.2.2 How to measure dropout rates

The dropout rate is found by comparing the number of infants who start the immunization schedule with the number who complete it. Two measures of dropout rate are routinely used:

In this section, we refer to pentavalent vaccine, which is also known as DPT-HepB-Hib vaccine.

- the dropout rate between infants receiving the first dose of pentavalent vaccine (Penta1) and the third dose (Penta3)
- the dropout rate between receiving the first dose of pentavalent vaccine (Penta1) and the single dose of measles vaccine.

Pentavalent 1 to pentavalent 3 dropout rate

■ What should the interval be between receiving pentavalent 1 and pentavalent 3 vaccines?

□ The interval should be 8 weeks: pentavalent 1 is given at 6 weeks of age, and pentavalent 3 is given at 14 weeks.

If an infant fails to complete the schedule of three doses of pentavalent vaccine, it indicates that there is an **access problem** for the parents, i.e. they have difficulty in getting to (accessing) the immunization sessions for the second or third doses.

The **pentavalent 1 to pentavalent 3 dropout rate** is calculated using the following equation:

Brackets in an equation mean that you should calculate the answer to whatever is *inside* the brackets *first*.

Penta1 to Penta3 dropout rate = (Penta1 – Penta3) ÷ Penta1 × 100%, where:

- Penta1 is the number (or percentage) receiving the first pentavalent vaccine dose
- Penta3 is the number (or percentage) receiving the third dose.

■ Imagine that 156 infants received the first dose of pentavalent vaccine at your Health Post last year. The number brought back for the second dose was 140 and the number who received the third dose was 132. What was the Penta1 to Penta3 dropout rate for your Health Post last year?

□ In this example, Penta1 is 156 and Penta3 is 132.

So the Penta1 to Penta3 dropout rate in this example is:

(156 – 132) ÷ 156 × 100%, or

24 ÷ 156 × 100% = 15.4%.

Another way of analysing dropout rates is to start with the percentage of the target population that attends for pentavalent 1, and compare this with the percentage that attends for pentavalent 3. For example, imagine that 70% of the eligible infants in a *kebele* are brought to you for pentavalent 1 immunization. However, you find that only 61% of the target population complete the three-dose series of pentavalent vaccine.

■ What is the Penta1 to Penta3 dropout rate in the above example?

□ Penta1 is 70% and Penta3 is 61%.

So the Penta1 to Penta3 dropout rate = (70 – 61) ÷ 70 × 100%, or

9 ÷ 70 × 100% = 12.8%

Pentavalent 1 to measles vaccine dropout rate

There is a very long interval in the EPI schedule in Ethiopia between an infant receiving the first pentavalent immunization at six weeks old, and completing the 'fully immunized' schedule with the single dose of measles vaccine at 9 months of age (Figure 10.5). It is very important to complete all the immunizations in order to protect children from all the EPI target diseases.

Figure 10.5 All children in Ethiopia should be fully immunized according to the EPI schedule before their first birthday. (Photo: Lesley-Anne Long)

The **pentavalent 1 to measles vaccine dropout rate** is calculated using the following equation:

Penta1 to measles vaccine dropout rate =
(Penta1 – measles) ÷ Penta1 × 100%, where:

- Penta1 is the number (or percentage) of infants receiving the first pentavalent 1 dose
- measles is the number (or percentage) of infants receiving the measles vaccine.

If there is a high dropout rate between Penta1 and the measles immunization, it suggests that there is a problem for parents of *utilising* (making use of) the health services generally. A dropout rate of more than 10% indicates that the particular Health Post has a **utilisation problem** — i.e. many people are not using the services on offer.

10.2.3 Calculating the number of un-immunized infants

You should also calculate the annual number of **un-immunized infants** — i.e. eligible infants who have not completed any of the scheduled immunizations. You do this using the following equation:

number of un-immunized infants = target population – (minus) fully-immunized infants, where:

- target population is the total number of eligible infants in the target age-group for immunization (under one year)
- fully-immunized infants is the number in the target age-group who have received all doses of all the EPI vaccines.

10.3 Analysing and interpreting immunization data

After determining the immunization coverage and dropout rates, you need to analyse and interpret the data in relation to your planned targets.

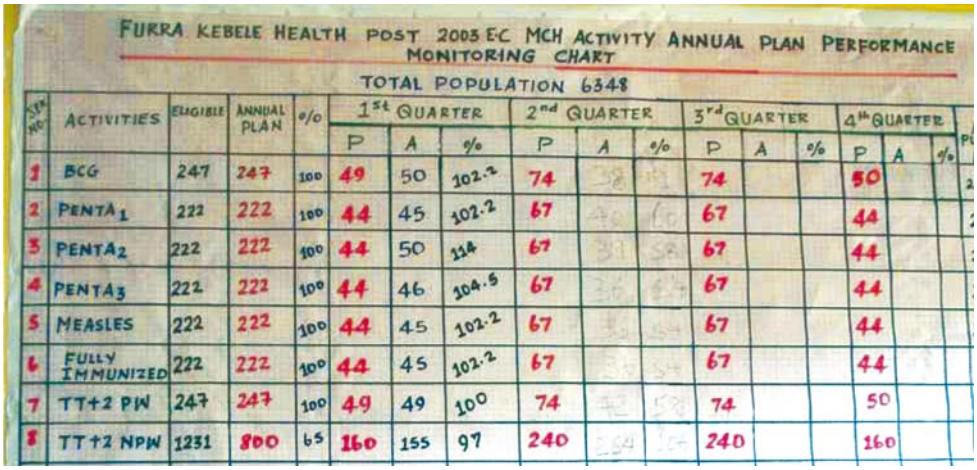
10.3.1 What data should you analyse?

You should analyse your data in terms of the categories listed in Box 10.1 for each reporting period (monthly or quarterly).

Box 10.1 Data analysis to evaluate performance of immunization programmes

- Compare the percentage immunization coverage rate with the objectives (targets) set for the immunization programme in the annual action plan.
- Compare the percentage immunization coverage rate with the equivalent data for the previous year.
- Compare the percentage immunization coverage rate of different vaccines given at the same time.
- Evaluate whether there is an access problem for the Health Post by calculating the Penta1 to Penta3 dropout rate.
- Evaluate whether there is a utilisation of health services problem for the Health Post by calculating the Penta1 to measles vaccine dropout rate; this also tells you the percentage of fully immunized children compared to the target population.
- Evaluate whether there is a problem in delivering TT+2 (more than two doses of TT vaccine) to pregnant and non-pregnant women of childbearing age.

For continuous self-monitoring at Health Post level, we suggest you use wall charts to record such indicators as actual immunization coverage rates for each quarter of the year, compared with the planned targets for that period (Figure 10.6).



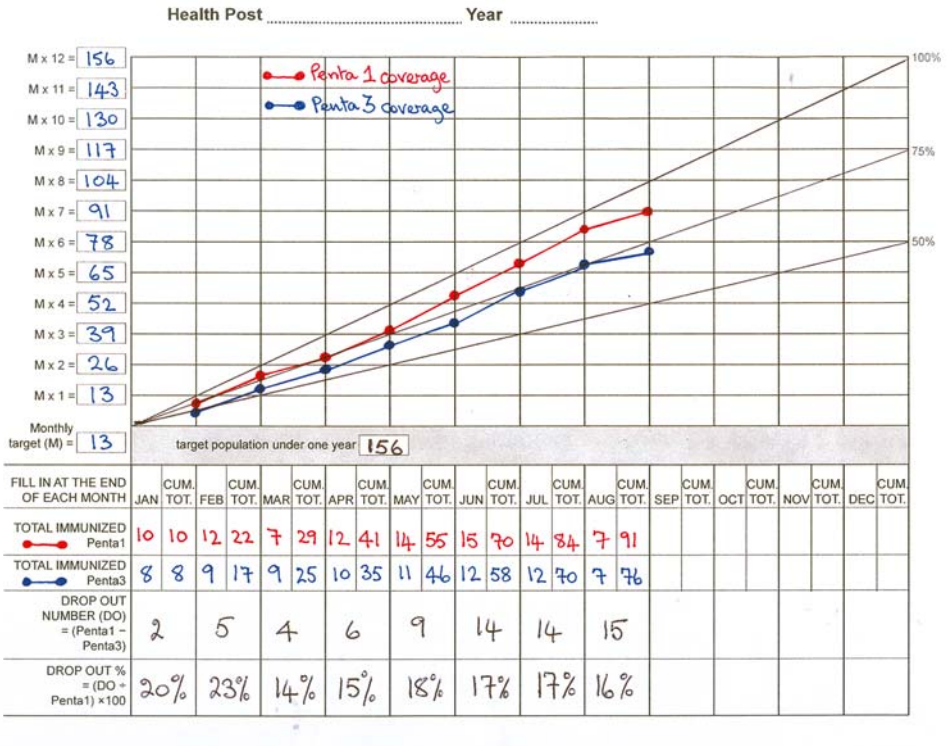
FURRA KEBELE HEALTH POST 2003 E.C MCH ACTIVITY ANNUAL PLAN PERFORMANCE MONITORING CHART

TOTAL POPULATION 6348

SER NO	ACTIVITIES	ELIGIBLE	ANNUAL PLAN	%	1st QUARTER			2nd QUARTER			3rd QUARTER			4th QUARTER		
					P	A	%	P	A	%	P	A	%	P	A	%
1	BCG	247	247	100	49	50	102.2	74			74			50		
2	PENTA1	222	222	100	44	45	102.2	67			67			44		
3	PENTA2	222	222	100	44	50	114	67			67			44		
4	PENTA3	222	222	100	44	46	104.5	67			67			44		
5	MEASLES	222	222	100	44	45	102.2	67			67			44		
6	FULLY IMMUNIZED	222	222	100	44	45	102.2	67			67			44		
7	TT+2 PW	247	247	100	49	49	100	74			74			50		
8	TT+2 NPW	1231	800	65	160	155	97	240			240			160		

Figure 10.6 Wall chart showing actual immunization coverage (number and percentage) for the first quarter of the year, and the planned targets for the remaining quarters at Fura Health Post in SNNPR. (Photo: Janet Haresnape)

Figure 10.7 illustrates how to enter data into an immunization monitoring chart, in order to assess your monthly progress in meeting a 100% immunization coverage target.



Health Post ..... Year .....

M x 12 = 156
M x 11 = 143
M x 10 = 130
M x 9 = 117
M x 8 = 104
M x 7 = 91
M x 6 = 78
M x 5 = 65
M x 4 = 52
M x 3 = 39
M x 2 = 26
M x 1 = 13
Monthly target (M) = 13

Penta 1 coverage
Penta 3 coverage
100%
75%
50%

target population under one year 156

FILL IN AT THE END OF EACH MONTH	JAN	CUM. TOT.	FEB	CUM. TOT.	MAR	CUM. TOT.	APR	CUM. TOT.	MAY	CUM. TOT.	JUN	CUM. TOT.	JUL	CUM. TOT.	AUG	CUM. TOT.	SEP	CUM. TOT.	OCT	CUM. TOT.	NOV	CUM. TOT.	DEC	CUM. TOT.
TOTAL IMMUNIZED Penta1	10	10	12	22	7	29	12	41	14	55	15	70	14	84	7	91								
TOTAL IMMUNIZED Penta3	8	8	9	17	9	25	10	35	11	46	12	58	12	70	7	76								
DROP OUT NUMBER (DO) = (Penta1 – Penta3)	2		5		4		6		9		14		14		15									
DROP OUT % = (DO ÷ Penta1) ×100	20%		23%		14%		15%		18%		17%		17%		16%									

Figure 10.7 Immunization monitoring chart with examples of data for a Health Post with a monthly target of 13 eligible infants (out of the total of 156) immunized with Penta1 and Penta3. The bottom two rows calculate the number and the percentage who dropped out between Penta1 and Penta3.

Every Health Post should display a chart like Figure 10.7 where it can be seen by all staff every day. The diagonal line from zero to the top right-hand corner (labelled 100%) shows the ideal rate of progress if every eligible infant is immunized on time.

- What is your evaluation of the progress in meeting the Penta1 and Penta3 immunization targets in the (fictional) Health Post in Figure 10.7?

- The Health Extension Practitioners have not improved their immunization coverage between January and August. Penta1 coverage has remained at about 85% of the target population, and Penta3 coverage has not exceeded 75%.

Next we discuss how to analyse immunization coverage and dropout data to shed light on what may be causing low coverage and/or high dropout.

10.3.2 Analysis of access and utilisation problems

The commonly used immunization coverage and dropout rate indicators, and what they may indicate, are summarised in Table 10.2.

Table 10.2 Immunization coverage and dropout indicators and their interpretation.

Indicator (%)	**What it may indicate**
Penta1 coverage	Availability of, access to, and initial use of immunization services by parents or caregivers
Penta3 coverage	Continuity of use by parents or caregivers
Measles coverage	Protection against a disease of major public health importance
Penta1 to Penta3 dropout	Access to the service by parents or caregivers, and quality of communication by health workers — this is an international dropout indicator
Penta1 to measles dropout	Utilisation of health services by parents or caregivers, and the perceived quality of the service in the community — this is an international dropout indicator
TT1 coverage during pregnancy	Availability of, access to, and use of immunization services by pregnant women
TT2 (TT3, TT4 or TT5 coverage) TT2+ (or TT+2 as in Figure 10.6) means the women received more than two doses of TT vaccine.	Continuity of use, client satisfaction and capability of the system to deliver a series of immunizations to women
Fully-immunized children (FIC)	Capability of the system to provide all vaccines in the childhood schedule at the appropriate age, and at the appropriate interval between doses in the first year of life; also measures public demand and perceived quality of services

Table 10.3 shows you how to assess whether low immunization coverage or high dropout rates are due to a problem of access (coming to the immunization services) or to a problem of utilisation (usage of immunization services). You should use the results of your assessment to identify and prioritise problems in your immunization programme, and work out possible solutions, as described in Section 10.4.

Table 10.3 Example of immunization problem analysis.

Observation at Health Post level	**Problems identified**
High Penta1 coverage and low dropout rate	No problem
High Penta1 coverage and high dropout rate	Utilisation problem
Low Penta1 coverage and low dropout rate	Access problem
Low Penta1 coverage and high dropout rate	Access and utilisation problems

10.4 What could be causing immunization problems?

Some possible local causes of low immunization uptake or high dropout rates are summarised in this section, which includes two new key terms (in bold).

Service organisation problems:

- Community not clearly informed of dates/times of immunization sessions at the Health Post, at outreach sites, or via mobile teams
- Immunization sessions not frequent enough, or at inconvenient sites
- Immunization session dates/times conflict with farming or family duties
- Poor vaccine quality, e.g. due to cold chain breakdown or usage after the expiry date
- Vaccine or other equipment shortages.

Staffing problems:

- Inadequate staffing levels to provide enough immunization sessions
- Inadequate training or supportive supervision for a high quality immunization service
- Health staff perceived as hostile or poor communicators by parents
- **Incorrect contraindication practices**, e.g. not immunizing children with minor illnesses, low grade fever, etc. which should not prevent them from receiving vaccines
- **Missed opportunities to immunize**, e.g. not immunizing children who visit the Health Post for another reason, unrelated to immunization.

Data collection and reporting problems:

- Incomplete or inaccurate data collection and analysis
- Failure to report monitoring data regularly
- No active follow-up of defaulters.

■ Can you suggest some possible solutions for the problems identified above?

□ You may have thought of these (and other) examples:

- Improved communication with the community (see Study Session 9)
- Better in-service training for health staff and adequate supportive supervision

- Mobilisation of additional resources, e.g. increased staffing levels, more reliable cold-chain equipment, better delivery times for vaccines and other supplies, etc.
- Apply other immunization strategies, e.g. sustainable outreach delivery, local immunization days, partnership with private and other sectors (see Study Session 8)
- Apply an effective system for tracing defaulters (see Section 10.5 below)
- Make timely, accurate reports to the higher level, so problems can be addressed collectively at the earliest opportunity.

We conclude this study session by explaining how the last two solutions in the above list should be implemented.

10.5 Systems for tracing defaulters

In this section you will learn how you trace (track) defaulters. Defaulters are those infants who started the routine EPI immunizations but failed to complete the schedule for whatever reason. If you trace defaulters regularly every month, it will make the task of follow-up much easier. You may be able to contact the mothers directly, or ask other members of the community to help you to find them. Try to ensure that every infant receives the immunizations that are overdue. There are many ways to monitor and follow-up on defaulters. Here we describe two tracking systems that can easily be used.

Using the EPI Registration Book

At the end of each month, review the EPI Registration Book to identify infants and mothers who have not received doses of vaccine at the appropriate time, according to the recommended EPI schedule.

Using reminder cards

Make **reminder cards**, which are copies of the infant's immunization cards. File them in a box behind the divider for the month when the infant's next immunization is due (Figure 10.8). Refer to these every month to identify the defaulters.

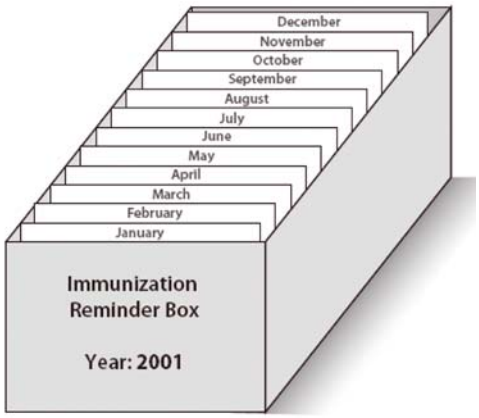


Figure 10.8 Box for storing immunization reminder cards. (Source: WHO 2001, *Immunization in Practice,* Module 7, *Monitoring and Using your Data*, Figure 7F, p.11)

10.6 Making immunization Summary Reports

The monitoring data you have collected on your immunization programme has to be organized into a **Summary Report** for transmission from the Health Post to the Health Centre that supervises you. The Health Centre collects data from all the satellite Health Posts and transmits it to the *woreda* (district) health office. The *woreda* compiles data from health facilities in the district for transmission to the higher level, and eventually to the Federal Ministry of Health. At each level the data should be analysed and used to improve the immunization programme.

10.6.1 What data should the Summary Report contain?

The Summary Report from your Health Post should include the following information:

- *Vaccinations and vitamin A supplements given to infants and women*. Data collected on the tally sheets should be organised clearly (see the sample monthly report forms shown in Appendix 10.1 and 10.2 at the end of this study session).
- *Vaccine-preventable diseases in your area*. State the number of cases of each vaccine-preventable disease and the immunization status of each case. Even if there are no cases of a disease during the reporting period, you should still provide a 'zero' report.
- *Adverse events following immunization (AEFI)*. If there have been any adverse events during the month, the details of any that are life-threatening, resulted in hospitalisation, disability (or have the potential to result in disability), or resulted in death should be reported. If there are no cases, provide a 'zero'report.
- *Vaccine usage and wastage patterns*. The usage and wastage of vaccines will vary from one session to another. However it is useful to monitor wastage and usage patterns regularly at all immunization sessions, in order to improve supply and avoid stock shortages. This can be done by recording the number of vaccine vials at the start and end of every session, and the number of vials received or wasted each month.

  Vaccine supply and stock management were described in detail in Study Session 5.
- *Any specific problems encountered during the reporting period* (e.g. stock shortages, transportation problems, cold chain failure, etc.).

10.6.2 Preparing good Summary Reports

You should ensure that the Summary Reports you prepare on your immunization service are:

- *Complete*: Ensure all the sections of the reports have been completed; no parts have been left blank and all reports due from outreach sites or mobile teams have been received.
- *Timely:* When reports are sent and received on time, there is a greater possibility of a prompt and effective response to any problems you have identified.
- *Accurate:* Before sending the reports, check the totals and all calculations to make sure that the reported figures correspond to the actual figures in the tally sheets, the EPI Registration Book and the immunization cards.

This helps you to evaluate the accuracy of your recorded data and identify and resolve any discrepancies. The district, provincial and national levels should keep track of the completeness and timeliness of reporting at your level, and remind you about any missing or late reports.

10.7 In conclusion

Now that you have completed this Module, you should be well prepared for the practical skills training that accompanies it. Be proud that you have the opportunity to improve the health of your community and save many young lives by delivering a well-managed and effective immunization service.

Summary of Study Session 10

In Study Session 10, you have learned that:

1 Monitoring of immunization programmes is very important for the planning and management of the EPI. It is the process of continuous observation and data collection, with the aim of comparing what you have achieved with your planning targets.

2 Monitoring your immunization programme includes proper use of EPI recording tools: the infant immunization cards, the EPI Registration Book (Immunization Register) and the tally sheets for each immunization session.

3 The Immunization Register helps you record the immunization services offered to each client. You must register infants and pregnant women as soon as they arrive at your Health Post or outreach site, before giving any immunizations or vitamin A supplements.

4 Tally sheets are used as the basis of your monthly or quarterly Summary Reports.

5 EPI indicators include Penta1 to Penta3 coverage, Penta1 to measles vaccine coverage, percentage of fully immunized children, percentage of women in the childbearing age-group (pregnant and non-pregnant) receiving more than two doses of TT vaccine, and protection at birth (PAB) against neonatal tetanus.

6 Estimates of whether implementation of the immunization service will (or has the potential to) reduce the target EPI diseases are obtained through measuring immunization coverage rates and dropout rates for each vaccine.

7 Pentavalent 1 coverage (and Penta1 to Penta3 dropout) is an internationally accepted measure of accessibility to the health facility; pentavalent 3 coverage (and Penta3 to measles vaccine dropout) is a measure of utilisation of health services.

8 It is important to trace defaulters by using the immunization register or reminder cards.

9 The immunization data collected should be organised into a complete, timely and accurate summary form. These reports enable you, your supervisor and the *woreda* health office to monitor the performance of your immunization service and quickly address any problems.

Self-Assessment Questions (SAQs) for Study Session 10

Now that you have completed this study session, you can assess how well you have achieved its Learning Outcomes by answering the following questions. Write your answers in your Study Diary and discuss them with your Tutor at the next Study Support Meeting. You can check your answers with the Notes on the Self-Assessment Questions at the end of this Module.

SAQ 10.1 (tests Learning Outcomes 10.1, 10.2 and 10.5)

In your Health Post, you use infant immunization cards to record immunizations given to each individual infant, and an EPI Registration Book to record the immunizations you have given.

- What *other* basic EPI recording tool should you be using and what *two* things does it enable you to do?

SAQ 10.2 (tests Learning Outcomes 10.1 and 10.3)

The percentage of children in the target population who receive the first dose of pentavalent vaccine (Penta1), and the percentage who receive measles vaccine, are commonly used EPI indicators for monitoring an immunization programme. Name *two other* EPI indicators and, in each case, explain why they are particularly useful.

SAQ 10.3 (tests Learning Outcomes 10.1, 10.3 and 10.4)

Figure 10.9 shows the percentage immunization coverage for Penta1 and Penta3 in two districts, labelled A and B. Based on the information in this figure, answer the following questions:

(a) Calculate the pentavalent dropout rate for the two districts A and B.

(b) Do the dropout rates suggest that access or utilisation is the major problem for the immunization service in each district? Explain how you reached your answer.

(c) What are the possible solutions for the problems in each district?

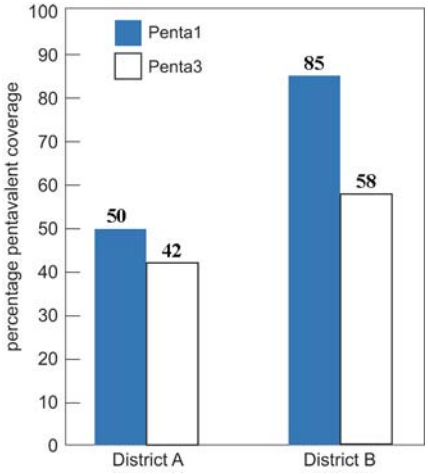


Figure 10.9 Percentage immunization coverage rates for pentavalent 1 and pentavalent 3 vaccine doses in two districts, A and B.

SAQ 10.4 (tests Learning Outcomes 10.1, 10.3 and 10.4)

In a *kebele* with a total population of 5,000, an estimated 3.6% are surviving infants under 12 months old. In September, nine infants aged under one year and two children aged between 12 and 23 months old were immunized against measles.

(a) What was the measles immunization coverage rate for infants aged under one year in September? Is it lower or higher than the estimated total population of eligible infants in that month? (You can assume that approximately the same number of babies is born alive each month.) Show how you reached your answers.
(b) List some possible reasons for the measles immunization coverage rate in this *kebele*.
(c) What actions would you take to improve the coverage with measles vaccine?

SAQ 10.5 (tests Learning Outcomes 10.1 and 10.5)

Meseret completed the Summary Report of the immunization service delivered from her Health Post for the previous month. She carefully recorded the number of doses of vaccines and vitamin A supplements given to infants and women in her catchment area during the reporting period. There were no cases of vaccine-preventable diseases and no serious adverse events following any of the immunizations, so she left this part of the report form blank. She recorded the number of vaccine vials she used during the month and the number wasted. Then she sent the report form to her supervisor.

(a) What mistake did Meseret make when she entered her data in the Summary Report?
(b) What other types of data did she forget to include in the Summary Report?

Appendix 10.1

MONTHLY EPI PLUS VACCINATION REPORTING FORM (HEALTH FACILITY LEVEL)

Region_____ **Woreda**_____ **Month** _____ **Year** _____

						VACCINATION AND VITAMIN A GIVEN TO CHILDREN																	
		Functional Sites				BCG	Measles		Pentavalent					Polio					Fully immunized		Vit A		PAB (Yes/No)
									1	2		3		0	1	2	3						
No.	EPI site	Fixed	OR	M	OR/M	0-11	0-11	12-23	0-11	0-11	12-23	0-11	12-23	0	0-11	0-11	0-11	12-23	0-11	12-23	0-11	12-23	0-11
	Total																						

PAB = Infants protected from neonatal tetanus at birth; OR = outreach site; M = mobile team delivery; OR/M = sites reporting this month

Appendix 10.2 Example of a Summary Report Form for women

Appendix 10.2

No.	EPI site	TETANUS TOXOID (TT) IMMUNIZATION AND VITAMIN A GIVEN TO WOMEN															
		Pregnant women (PW)						Non-pregnant women (NPW)						TT2+ (PW+NPW)	Vit A post-partum
		TT 1	TT 2	TT 3	TT 4	TT 5	TT2+	TT 1	TT 2	TT 3	TT 4	TT 5	TT2+		
	Total														

Notes on the Self-Assessment Questions (SAQs) for Immunization

Study Session 1

SAQ 1.1

When the immunization coverage rate is high, a large proportion of the members of a community will be immune to the disease caused by the particular infectious agent in the vaccine. This is called herd immunity. Therefore, in a disease like measles, which is transmitted from person to person, there will be a very small reservoir of infection restricted to a few infected people in the community. Transmission of infection from infected to susceptible people will very rarely occur, so the infectious agent will not be able to spread through that community and it may even 'die out'. This protects the susceptible people even though they are not immune.

SAQ 1.2

Some immunity can be acquired without vaccination. This infant has become temporarily immune to measles because he has received maternal antibodies in his mother's breastmilk (and possibly also across the placenta before he was born). This type of immunity is called *naturally acquired passive immunity* ('passive' because the antibodies protecting the baby were made by his mother, not by his own immune system).

SAQ 1.3

(a) The diphtheria component of the pentavalent vaccine is made from the toxin (poison) produced by the bacteria that cause the disease; the modified toxin is called diphtheria toxoid. This is an example of a *sub-unit vaccine*.

(b) The diphtheria toxoid in the vaccine has *antigens* in its structure which are unique to the diphtheria bacteria. Helper T cells in the immune system of the immunized person recognise these antigens as foreign. They activate other parts of the immune system to make antibodies and memory cells, which remain circulating in the body for a long time. If live diphtheria bacteria get into the body, the person's immune system is already prepared to attack them and prevent the disease from developing.

(c) This type of immunity is called *artificially acquired active immunity,* where a vaccine is used to develop active immunity against an infection ('active' because the antibodies and memory cells were made by the person's own immune system).

SAQ 1.4

There are many ways in which you can help to implement the EPI services. You may have thought of the following:

- Help to increase immunization coverage rates by using every opportunity to immunize eligible children, for example, when they are brought to the Health Post for another reason; and by making immunization routinely available at convenient times, preferably on a daily basis.
- Ensuring the community is made aware of when immunizations are available. Use any strategies you can to sustain high immunization coverage, e.g. reminders, posters, meetings, etc.
- Increase the quality of immunization services through good management, stock control and safe storage of vaccines and other supplies, and using safe injection practices and disposal of waste.
- Help to reduce missed opportunities for immunization by checking if all eligible children that you see are immunized, and tracing defaulters (children who have not completed all the vaccinations in the schedule).
- Help to improve public awareness and community participation in the immunization service by involving community leaders and groups in planning outreach sessions, so as to cover as much of the target population as possible.
- Keep an accurate register of immunizations and report any cases of vaccine-preventable diseases to the District Health Office.

Study Session 2

SAQ 2.1 (tests Learning Outcomes 2.1, 2.2 and 2.3)

A is *false.* BCG is injected *intradermally* (into the top layer of the skin). The other antibacterial vaccines in the EPI are injected intramuscularly, but only BCG and TT vaccine are injected in the upper arm. Pentavalent vaccine and PCV10 are injected in the *upper outer thigh*.

B is *false*. BCG vaccine is a powder which can be frozen before it is reconstituted with diluent. The BCG diluent and all the other antibacterial EPI vaccines will not be effective if they become frozen.

C is true. If five doses of TT vaccine are given to a woman of childbearing age at the correct intervals, she will receive the fifth dose at least 2 years and 7 months after the first dose. The intervals are TT1, then at least 4 weeks to TT2, then at least 6 months to TT3, then at least 1 year to TT4, and then at least one more year to TT5.

D is true. Between 78% and 95% of infants who are immunized with three doses of pentavalent vaccine at the correct intervals will be protected against pertussis, diphtheria and tetanus. (They will also be protected against hepatitis B and Hib diseases.)

E is true. BCG vaccine is supplied as a powder which has to be mixed with a special diluent to activate the vaccine before use.

F is *false.* If a vial of pentavalent vaccine has a deposit like fine sand at the bottom, it does not need to be thrown away; you should shake the vial to mix the vaccine with the liquid before use.

SAQ 2.2

The health workers in Dembi Health Post are correct. TT vaccine should be given to all pregnant women during their first contact with a health facility, regardless of the gestational age of their pregnancy. So Nurse Ayele should give Birke the TT immunization.

SAQ 2.3

The completed version of Table 2.9 appears below.

Table 2.9 Adverse events following immunization with antibacterial vaccines and their management at Health Post level.

Adverse event	**Management**
Low-grade fever	Paracetamol syrup, 5 ml as required, up to a maximum of four doses
Soreness at the injection site	Paracetamol (as above); warm compress applied to the affected area
Abscess at the injection site	Amoxicillin syrup orally three times daily and urgent referral to a health centre
Swollen lymph glands	Refer the child to a health centre
Severe allergic reaction (rash, breathing difficulty, rapid pulse, dizziness or fainting)	Do not give another dose of this vaccine; refer the child to a health centre immediately
Coma and/or convulsions	Do not give another dose of this vaccine; refer the child to a health centre immediately

SAQ 2.4

You should tell the mother that the sore is a result of BCG vaccination, which will protect her baby from tuberculosis. Reassure her that this is a normal reaction to the vaccine and that the small sore is a good sign that the vaccine is working effectively. Tell her the sore will heal in about two weeks and leave a small scar, which is harmless.

SAQ 2.5

This child has a high-grade fever. Give paracetamol syrup (5 ml) and refer the child to a health centre; do not vaccinate until the child recovers.

Study Session 3

SAQ 3.1

The completed version of Table 3.6 appears below.

Table 3.7 Antibacterial and antiviral vaccine characteristics.

Vaccine	Antibacterial	Antiviral	Protects against
BCG vaccine	X		Tuberculosis
Measles vaccine		X	Measles
Pentavalent vaccine	X (four components)	X (one component)	Diphtheria, pertussis, tetanus, *Haemophilus influenzae* type b meningitis and pneumonia, hepatitis B liver diseases
Yellow fever vaccine		X	Yellow fever
Pneumococcal vaccine (PCV10)	X		Pneumococcal diseases (including pneumonia)
OPV		X	Poliomyelitis
TT vaccine	X		Neonatal tetanus (and tetanus in women)
Meningococcal vaccine	X		Meningococcal meningitis
Rotavirus vaccine		X	Diarrhoea and dehydration caused by rotaviruses

SAQ 3.2

The completed version of Table 3.7 appears below.

Table 3.7 Summary of dosage, route and schedule for the antiviral EPI vaccines.

Vaccine	Dosage and route	Schedule
HepB (as part of pentavalent vaccine)	0.5 ml, three intramuscular injections	At 6, 10 and 14 weeks
OPV	2 drops, four oral doses	At birth, and 6, 10 and 14 weeks
Measles	0.5 ml, one subcutaneous injection in the EPI, plus one campaign dose	At 9 months of age in the EPI; campaign dose after 12 months

SAQ 3.3

The completed version of Table 3.8 appears below.

Table 3.8 Adverse events following OPV and measles immunization, and their management

Vaccine	Adverse events	Management
OPV	None	None required
Measles	Mild rash	None required
	Mild fever	Paracetamol syrup

SAQ 3.4

The immunizations (if any) that these individuals should receive are as follows:

(a) A newborn baby should be given BCG and OPV0.
(b) A ten-month-old child who has had BCG, OPV3, PCV3 and Penta3 should be given measles vaccine.
(c) An eight-month-old child who has had BCG, OPV3, PCV3 and Penta3 should not be given any further vaccinations until he or she is 9 months old, when measles vaccine should be given.
(d) A six-week-old child who has had BCG and OPV0 should be given OPV1, PCV1 and Penta1.

SAQ 3.5

(a) Immunize Fatima with OPV3; it is safe to give this vaccine even though she has mild diarrhoea. But do not give her PCV3 or Penta3 because she developed a severe allergic reaction three days after the earlier immunization, which may have been an adverse vaccine reaction following immunization with one of these vaccines. It is very unlikely to have been due to the previous dose of OPV.
(b) Explain to the grandmother that it is safe for Fatima to have another dose of OPV, and why you are not giving the child another dose of the other two vaccines. Tell the grandmother to come back after another four weeks; because of the diarrhoea Fatima has today, she will need an extra (fifth) dose of OPV in four weeks' time.

Study Session 4

SAQ 4.1

Table 4.2 Completed vaccine administration and reconstitution summary.

	Route of administration				Reconstitution?	
Vaccine	**ID**	**SC**	**IM**	**Oral**	**Yes**	**No**
BCG	X				X	
Pentavalent			X			X
Measles		X			X	
Polio (OPV)				X		X
Pneumococcal (PCV10)			X			X
Rotavirus (Rotarix^{TM})				X		X
TT (in women)			X			X

SAQ 4.2

(a) The red and tender swelling on the babies' left thighs is likely to be an abscess at the site where they received the pentavalent vaccine by intramuscular injection the previous week. An abscess at an injection site is usually caused by a contaminated needle or syringe, or incorrect vaccine preparation, or incorrect injection technique. The fact that Bekelech was so busy that day last week may have resulted in poor adherence to standard procedures when she immunized the babies. For example, she may have:

- used the same needle and syringe for more than one injection

- touched the needle with unclean hands before giving the injection
- placed the needle and syringe on a table top or other unclean surface
- failed to keep the vaccine cold during the long immunization session.

(b) Bekelech should:

- Treat the abscesses by giving the babies amoxicillin syrup three times daily and placing clean, warm compresses on the affected area. She should ensure that the mothers take their babies to a health centre urgently for further assessment.
- Take care in future to ensure that standard procedures are followed when giving immunizations.

SAQ 4.3

Fatuma forgot to check the VVM on the vaccine ampoule. She checked the expiry date of the vaccine, but this will not tell her if the vaccine has been exposed to heat and lost its potency. She should check the VVM and if it has passed the discard point she should discard it.

Fatuma also forgot to clean the injection site. She should clean the skin with antiseptic solution and leave it to dry before giving the vaccination. Pushing a needle through dirty skin could introduce an infection into the baby's body.

SAQ 4.4

OPV is never given to babies using a syringe as a substitute for the glass dropper supplied with the vaccine or the dropper incorporated into the vaccine vial. Using the correct dropper ensures that the correct dose of OPV is given in two drops of vaccine.

Study Session 5

SAQ 5.1

The equation for calculating the annual vaccine needs, based on the size of the target population, is:

Annual vaccine needs = pt × dn × ic × wf where:

- pt is the target population – for pentavalent vaccine this is the number of children aged 0–11 months (calculated below)
- dn is the number of doses of vaccine in the recommended schedule — this is 3 for pentavalent vaccine
- ic is the target immunization coverage rate — in this example it is 90%
- wf is the wastage factor (calculated below)

The number of children aged between 0–11 months is 5% (0.05) of the total population of 5,700, which is:

5,700 × 0.05 = 285 children in this age group (5% expressed as a decimal number is 0.05)

The wastage factor is calculated from the wastage rate of 5% using the equation:

Wastage factor (wf) = 100 ÷ (100 – % wastage rate)

So for a wastage rate of 5%:

wf = 100 ÷ (100 – 5) = 100 ÷ 95 = 1.05

Using the equation below to calculate the annual vaccine needs based on the target population size:

pt × dn × ic × wf = 285 × 3 × 0.9 × 1.05 = 808 doses

So the annual pentavalent vaccine needs, based on the size of the target population in this *kebele*, is 808 doses.

SAQ 5.2

The equation for calculating annual vaccine needs based on the size of the immunization sessions is as follows:

Annual vaccine needs = posts × weeks × sessions × vials × doses; where (for PCV10 vaccine in this example):

- posts is the number of immunization sites, which is 1
- weeks is how many weeks the immunization site operates, which is 45 in this example
- sessions is the number of sessions per week, which is 2
- vials is the number of vials used per session, which is 5
- doses is the number of doses per vial, which is 2.

So the annual vaccine needs for DPT in this example is:

1 × 45 × 2 × 5 × 2 = 900 doses.

SAQ 5.3

The wastage factor (expressed as a decimal number) is calculated from the wastage rate (expressed as a percentage), using the following equation:

Wastage factor (wf) = 100 ÷ (100 – % wastage rate)

In this example, the wastage rate for OPV has been set at 10%. So the wastage factor is:

wf = 100 ÷ (100 – 10) = 100 ÷ 90 = 1.11

Therefore, the wastage factor is 1.11.

SAQ 5.4

(a) In the example given in SAQ 5.2, there are two immunization sessions per week. Five multi-dose vials of PCV10 each containing 2 doses are used per session, so 20 doses are needed per week. Therefore the number of doses required for a 2-week supply period in this *kebele* is 40 doses.

(b) The minimum stock level is generally taken to be 25% (or 0.25) of the requirement for the supply period, which in this example is 2 weeks. The equation needed to calculate the minimum stock level for a 2-week period is:

$s_{mini} = q_{period} \times 0.25$ (25% expressed as a decimal number is 0.25)

where q_{period} is the number of doses required for the supply period, which in this example is 40 doses.

$s_{mini} = 40 \times 0.25 = 10$ doses.

So the minimum stock level for PCV10 vaccine for a 2-week period in this *kebele* is 10 doses.

(c) The maximum stock level for PCV10 for a 2-week period in this *kebele* is calculated from the following equation:

$$s_{maxi} = q_{period} + s_{mini}$$

$$s_{maxi} = 40 + 10 = 50 \text{ doses}$$

(d) So the maximum stock level for PCV10 vaccine for a 2-week period in this *kebele* is 50 doses.

Study Session 6

SAQ 6.1

A is *false*. The VVM records exposure of vaccines to heat over a period of time, but it does not record exposure to freezing temperatures.
B is *false.* Even if the expiry date has not passed, it is unsafe to use vaccines that have reached the discard point indicated by the VVM.
C is true. A thermometer measures the temperature in a refrigerator.
D is *false*. Diluents can be kept at room temperature if there is not enough space in the refrigerator, but should be chilled thoroughly before use.

SAQ 6.2

(a) The vaccine can be used because the inner square of the VVM is lighter than the outer circle. This means that the vaccine has not been damaged by excessive heat.

(b) This vaccine should not be used because the inner square of the VVM is almost as dark as the outer circle. This means that the vaccine has been damaged by excessive heat and should be discarded.

SAQ 6.3

The completed version of Table 6.1 appears below, with the correct shelf for storing each vaccine marked with a cross.

Table 6.1 Storage of vaccines in a front-loading refrigerator.

Vaccine	Top shelf	Middle shelf
Measles	**X**	
Pentavalent		**X**
TT		**X**
OPV	**X**	
BCG	**X**	
PCV10		**X**

SAQ 6.4

(a) Abeba must not reconstitute the vaccine using the diluent which has been on the window ledge for several days because it will be warm. Warm diluent damages the vaccine.

(b) Abeba should put the diluent back into the refrigerator and only use it when it is cold again (between +2ºC and +8 ºC). She should apologise to the parents and explain that they can either wait for

several hours for the diluent to reach the correct temperature, or come back for the next immunization session.

SAQ 6.5

The thermometer shows a temperature of +22°C. This is much too high a temperature for storing vaccines! They have to be stored between +2°C and +8°C. This refrigerator is not working at all and must be repaired, or the power may have been cut off. Check the gas, electricity or kerosene supply, and call your supervisor to report the problem. Move the vaccines and diluents into cold boxes and transport them quickly to the nearest health centre for cold storage.

SAQ 6.6

(a) Opened vials that you are using should be put on the foam pad that rests above the conditioned ice-packs on top of the vaccine carrier. Make sure that the vaccine carrier is in a shady place, not in sunshine.

(b) Unopened vials should be put inside the vaccine carrier with conditioned ice-packs or chilled water bottles and the lid closed until you need them.

SAQ 6.7

(a) On the morning of the 11th day of the month, the temperature of the refrigerator had risen to above +8ºC, which is above the acceptable temperature range. The refrigerator should have been checked on that day. The thermostat should have been adjusted to 'colder'. If this action was taken, and the temperature still continued to rise, the vaccines should have been moved into a vaccine carrier and attempts made to repair the refrigerator or restore the power supply (e.g. the kerosene may have run out).

(b) Figure 6.14 shows that the temperature continued to rise, and reached about +18ºC by the morning of the 12th of the month. This is much too high for safe storage of vaccines. It would be important to check the VVM on any vaccines which had remained in the refrigerator during this time, and throw away any which had reached their discard point.

Study Session 7

SAQ 7.1

(a) A safe injection is one that does not harm the client, does not expose the provider to any avoidable risk and does not result in dangerous waste.

(b) Look back at Box 7.3 for descriptions of programme errors, i.e. due to incorrect immunization practices.

SAQ 7.2

The actions that could expose your clients to infection when you immunize them are:

B Allowing opened multi-dose vials of vaccine to become submerged in melted water in a vaccine carrier. Contaminated water can infect the vaccine if it leaks into the vial through the tiny holes made by the needles used to withdraw vaccine previously.

D Removing the cap from a disposable needle and holding it by the adaptor before you fit it onto the syringe. Infection could be transferred from your hands to the needle.

Actions A, C and D do not pose in infection risk to your clients, but you should know that:

A Allowing a freeze-sensitive vaccine to become too cold will reduce its effectiveness.

C Using auto-disable syringes for all immunizations is the best way to avoid any infection risk to your clients.

E Attempting to replace the cap on a used needle poses an infection risk to you!

SAQ 7.3

(a) These are the symptoms of a severe acute allergic reaction, with signs of shock (fast pulse and low blood pressure).

(b) You should refer the child immediately to the nearest health facility – this is a potentially life-threatening reaction to the vaccine. As you should know from earlier Modules, you should keep the baby warm at all times, tell the mother to continue breastfeeding if the child will suckle and go with them if you can. If you cannot go you should send a clearly written referral note listing all the relevant details.

SAQ 7.4

(a) This HIV-positive infant is well, so she can receive the birth dose of BCG vaccine and all the routine EPI immunizations according to the normal schedule at the age of 6 weeks.

(b) Immunization with pentavalent vaccine can result in low-grade fever, which usually resolves within 24 hours. This is not a contraindication, so the child should be immunized with the second dose of pentavalent and the other routine EPI vaccines scheduled at 10 weeks.

(c) This child should not be given another pentavalent immunization. Convulsions soon after immunization are an absolute contraindication to further immunization with the same vaccine.

SAQ 7.5

The potential disadvantages of disposing of a safety box containing used needles and syringes after an immunization session, using one of the following methods, are:

(a) An incinerator at a health centre may be too far away to be a realistic method of regular waste disposal.

(b) Burning in a metal container will leave fragments of waste that must be scraped out of the drum and buried safely.

(c) Burning in an open pit may result in fragments being blown about by the wind and scattered around the pit, or not being completely burnt if the fire goes out too soon.

(d) Burying without burning in a sharps pit could result in waste being exposed by soil being washed away, or children or animals digging it up.

Study Session 8

SAQ 8.1

The six planning steps in the correct sequence are:

1 assessing the community's health needs
2 identifying and prioritising problems to be addressed
3 setting goals and objectives
4 agreeing strategies and activities in the annual action plan, including resource requirements
5 implementing the service
6 monitoring and evaluating progress towards meeting the targets.

SAQ 8.2

You should also consider the *socioeconomic impact* of reducing each problem, the *feasibility* of available solutions to each problem (are the required actions realistically deliverable, and do you have adequate resources?), and whether they are likely to be *affordable* within existing budgets. Another consideration in prioritising your activities is whether the beneficiaries in the community will find your solutions *acceptable*, and whether they meet local and government concerns.

SAQ 8.3

A is true. Community discussion and approval is essential during the development of your annual immunization action plan.
B is *false*. If a mother has lost the immunization card for her child, you should not send her home. You should question her carefully to see if she remembers what vaccines her child has received and the date of the last immunization. Check your EPI Registration Book to see if you can find an entry for her child's previous immunizations and give the next dose accordingly. If there are no available records and there are no contraindications, give the child the appropriate EPI vaccines based on its age.
C is true. The percentage of newborns protected at birth (PAB) from neonatal tetanus is a good indicator of progress towards achieving adequate TT doses for their mothers during pregnancy. The maternal antibodies developed by women who have had TT2+ within 2 weeks of delivery will protect their newborns from tetanus.
D is *false*. A fully immunized child has received all doses of all the EPI vaccines scheduled for routine immunization — including measles vaccine — by its first birthday.
E is true. Accurate entries in your EPI Registration Book during each immunization session will help you to estimate the number of doses of vaccine needed for future sessions.

SAQ 8.4

You should also tell her to bring her baby for her next dose of these vaccines in 4 weeks' time, at 10 weeks old, and explain that possible side-effects of the vaccines her baby received are mild swelling and soreness at the sites of vaccination and a slight fever, but these are nothing to worry about.

SAQ 8.5

(a) Before you arrive at an outreach site, the community volunteers should prepare the area for the immunization session by setting out a registration table and a table at which immunizations can be given, and some chairs or other places for clients to wait for their turn. The tables should be clean and the area should be tidy and well shaded, so that everyone is protected from sun and rain, and the vaccines are not exposed to heat or sunlight.

(b) Support for the community volunteers at the outreach site should be provided in the form of adequate training and supportive supervision, to enable you to deliver a safe and effective immunization service with their help.

(c) Before leaving the site at the end of the outreach session you should collect all waste and safety boxes for safe disposal back at your Health Post, and leave the area clean and tidy — just as you found it. Don't forget to thank all the volunteers!

Study Session 9

SAQ 9.1

(a) A community conversation is a process of discussion with a community group. It looks into an issue that is causing problems locally and seeks to find collective solutions to these problems.

(b) There are many situations where you might decide to arrange a community conversation about your immunization programme; for example:

- If you have large numbers of families who do not bring their children for immunization
- If you have a high dropout rate from the immunization programme in parts of your *kebele*
- If children have had serious adverse reactions after immunization
- If you believe there are negative rumours circulating in the community about immunization.

(c) The appropriate people to invite will depend on the situation:

- If you have large numbers of families who do not bring their children for immunization, you could invite representatives of those families and also any of their neighbours who do bring their children for immunization.
- If you have a high dropout rate from the immunization programme in parts of your *kebele*, you could invite parents from families whose children started their vaccinations, but did not complete them.
- If children have had serious adverse reactions after immunization, you might invite the parents of those particular children, together with other parents whose children were not adversely affected.
- If you believe there are negative rumours circulating in the community about immunization, you might invite those who you believe are being influenced by the rumours, together with community leaders and other influential people in your local community who support immunization.

SAQ 9.2

The steps you should undertake in planning your strategy are:

1 Communication needs assessment — try to find out which parents are not accessing the immunization programme and why this might be.
2 Set specific and measurable objectives — identify what barriers need to be removed in order to improve coverage rates, and what communication activities might support this goal. Establish what community resources you might have available to address the problem.
3 Plan appropriate strategies or activities, e.g. a focus group with parents, a community conversation, a meeting with opinion leaders, etc.
4 Prepare your action plan — decide when and where the communication activities will take place, who will lead them, who will be invited, how you will advertise the event and ensure the right people attend it.
5 Implement your plan.
6 Monitor and evaluate the outcomes of your communication activity — record how many people took part, and whether they changed their behaviour afterwards and brought their children for immunization.

SAQ 9.3

Lack of accurate knowledge about the immunization service could be improved by better communication. You should make sure that you communicate the times and places for the immunization sessions effectively, so that they are known to everyone. You could do this by posting notices where they will easily be seen, telling all your clients when you see them at the Health Post, or in their homes, at the market, etc., and asking your community volunteers to tell everyone they visit. You could ask community or religious leaders to announce the dates and locations of immunization sessions during their own meetings.

SAQ 9.4

If you discover such a rumour, you should do the following:

- Report the rumour and seek advice from your supervisor and health centre officials about how to deal with it.
- Collect information about the rumour — who has started it? Why do they think that measles vaccination causes deafness? Has the rumour started because of incorrect information, or is there some other reason?
- Meet with opinion leaders — give them an opportunity to ask questions, and provide clear information about the dangers of measles and how vaccination can prevent it.
- Train community volunteers to give correct information about the measles vaccine and how to deal with the rumour.
- Arrange meetings with concerned parents to communicate correct information about measles vaccination.

- Prepare posters and print materials and distribute them around your *kebele* explaining in simple local language about the benefits of measles vaccination and that it very rarely causes any bad effects.

Study Session 10

SAQ 10.1

Tally sheets should also be used to record the number of doses and the lot number of each vaccine given during each immunization session. This enables you to check that the number of doses given tallies (matches) the number recorded in your Registration Book. It also acts as a way of monitoring the number of doses given, and enables you to complete your monthly Summary Report to the higher level. You may also have mentioned your Vaccine Stock Register (see Study Session 5).

SAQ 10.2

The percentage of children in the target population who receive the third dose of pentavalent vaccine (Penta3) is particularly useful, because it indicates the continuity of use of the immunization service by parents and caregivers. A low dropout between Penta1 and Penta3 indicates that parents and caregivers are able to access the service.

The percentage of fully immunized children (FIC) is another particularly useful indicator, as it demonstrates the capability of the system to provide all the vaccines in the schedule at the appropriate times. It also gives an indication of the public demand for the service. Low dropout between Penta1 and measles immunization demonstrates satisfaction with the perceived quality of the service in the community, and also that there is not a general problem of utilisation of health services locally.

SAQ 10.3

(a) Calculation of dropout rates.

District A:

Figure 10.10 shows that 50% of infants received pentavalent 1 vaccine, and 42% completed the three-dose schedule (using pentavalent 3 coverage as the indicator). The dropout rate is calculated using the equation:

Penta1 to Penta3 dropout rate = (Penta1 – Penta3) ÷ Penta1 × 100%

The dropout rate in District A is therefore (50 – 42) ÷ 50 × 100 % = 16%.

District B:

Figure 10.10 shows that 85% of infants received pentavalent 1 vaccine, but only 58% completed the three-dose schedule (received pentavalent 3). The dropout rate in District B is therefore:

(85 – 58) ÷ 85 × 100% = 32%.

(b) In District A, the major problem is low coverage, as only 50% of children received the first pentavalent dose, which indicates an access problem for parents or caregivers. In District B, the major problem is the high dropout rate of 32%, which indicates a general problem of utilisation of health services.

c) In District A, priority should be given to raising the pentavalent 1 coverage rate, by aiming to immunize the 50% of children who have never been reached by the immunization service. In District B, the priority should be given to following up on defaulters and persuading them to complete the schedule of immunization, so the pentavalent 3 coverage rate rises from 58% to closer to the 85% who received pentavalent 1.

SAQ 10.4

(a) An estimated 3.6% of the population of 5,000 in the catchment area are under one year of age and therefore eligible for measles immunization. The total eligible population of infants in this age-group is calculated as follows:

5,000 × 0.036 (or 3.6%) = 180 infants
You would expect about 15 of these infants to have been born each month of the year (180 ÷ 12 = 15). However, only nine infants received measles vaccine during September, so the measles vaccine coverage for September was (9 ÷ 15) × 100% or 60%.

(b) The measles immunization coverage rate of only 60% is low, and indicates a problem with *utilisation* of health services for parents or caregivers.

(c) Possible actions you could take to try to reach more infants in the target age group could include:

- more house-to-house visits in remote areas (using mobile teams)
- more outreach immunization sessions
- ensuring that no opportunities are missed to immunize eligible infants with measles vaccine, e.g. if they are brought to the Health Post for another reason, or when you are visiting the family
- more effective tracing of defaulters by checking entries in the EPI Registration Book every month, and using reminder cards to tell you which infants are due for their next immunization in which month.

SAQ 10.5

(a) Meseret's mistake was leaving the Summary Report blank where she should have recorded 'zero' for cases of vaccine-preventable diseases and any serious adverse events following immunization.

(b) Meseret's Summary Report should also have included:

- the number of vaccine vials she received as new stock during the month
- any specific problems encountered during the reporting period, e.g. stock shortages, transportation problems, cold chain failures, etc.