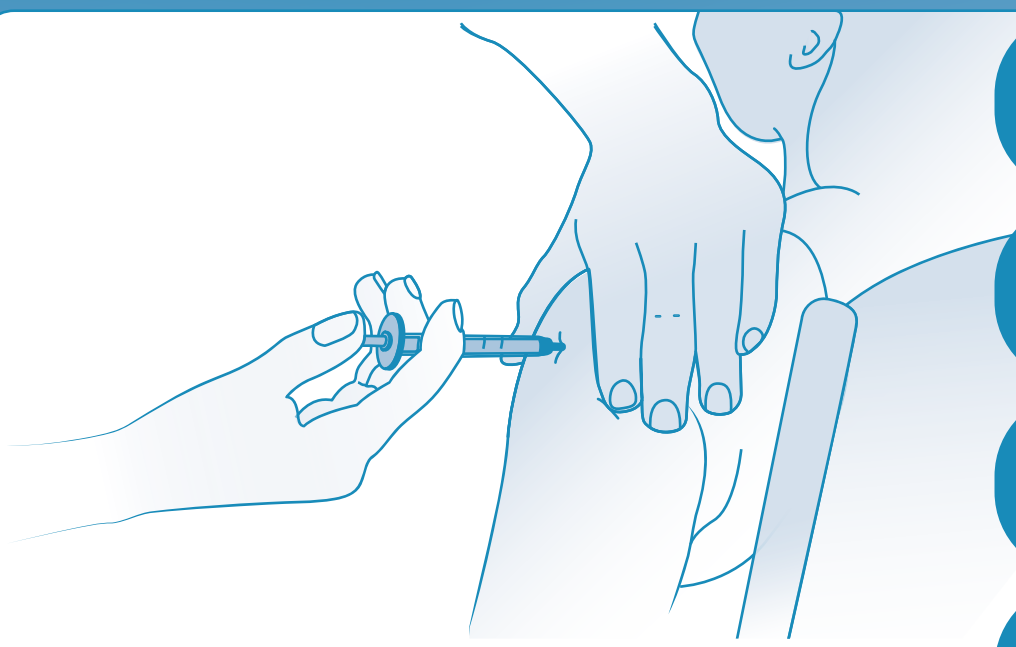
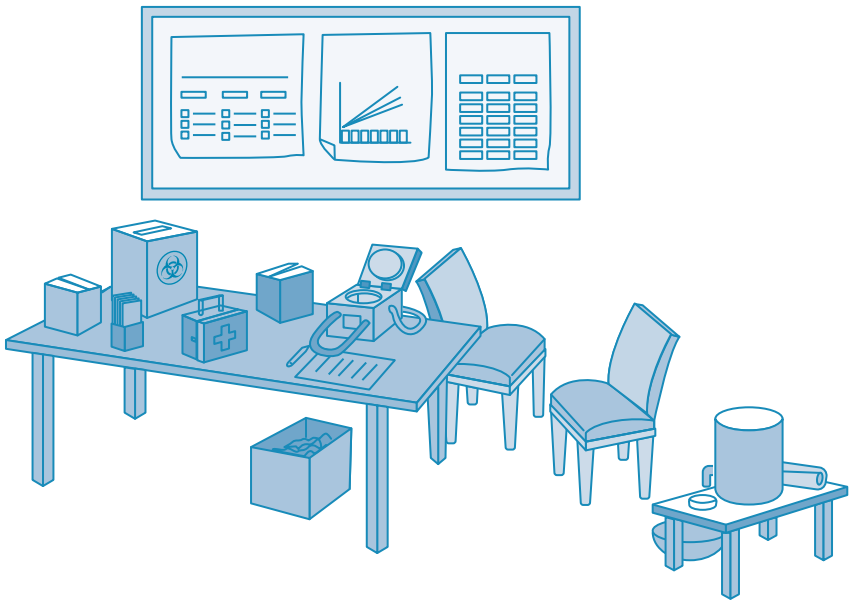
Immunization in practice

A guide for health workers





World Health Organization

Immunization in practice

A guide for health workers

World Health Organization

Immunization in practice: a guide for health workers

This publication is an updated version of the document published in 2015 under the title *Immunization in practice: a practical guide for health staff – 2015 update*, now released under a different title.

ISBN 978-92-4-011327-5 (electronic version)
ISBN 978-92-4-011328-2 (print version)

Contents

Acknowledgements

World Health Organization (WHO) gratefully acknowledges the many experts and institutions who contributed to the planning, development and review of this publication.

WHO contributors and reviewers

The following staff from the Department of Immunization, Vaccines and Biologicals, WHO spearheaded technical development and review of this publication: Maricel Castro, Jan Grevendonk, Ariel Higgins-Steele, Lisa Menning and Jun Ryan Orbina. Jhilmil Bahl along with Aleksandra Caric were responsible for the development and production of this publication.

The following WHO staff and consultants also contributed to the technical content and review of this publication.

WHO headquarters

W. Roodly Archer, Madhava Ram Balakrishnan, Rachel Belt, Carole Tevi Benissan, Adwoa Bentsi-Enchill, Cynthia Bergstrom, Diana Chang Blanc, Paul Bloem, Donald Brooks, Natasha Crowcroft, Carolina Danovaro, Shalini Desai, John Francis, Martin Friede, Marta Gacic-Dobo, Birgitte Giersing, Isaac Gobina, Alejandro Ramirez Gonzalez, Tracey S. Goodman, Santosh Gurung, Mary Hamel, Joachim Hombach, Souleymane Kone, Laura Nic Lochlainn, Sylvester Maleghemi, Paul Mallins, Melanie Marti, Patrick Michael O'Connor, Jamie Rylance, Stephanie Shendale, Heidi Soeters, Dijana Spasenoska, Christoph Steffen, Alba Vilajeliu, Annelies Wilder-Smith, Nasir Yusuf.

WHO regional and country offices

Joseph Nsiari-Muzeyi Biey, Ado Mpia Bwaka, Hilaire Dadjo, Ezekiel Dauda Danjuma, Claude Mangobo, Pamela Mitula, Harou Moussa, Charles Shey Wiysonge, WHO Regional Office for Africa; Margherita Ghiselli, Nora Lucia Rodriguez, WHO Regional Office for the Americas; Sudhir Khanal, WHO Regional Office for South-East Asia; Oleg Benes, Osman Niyazi Cakmak, Nasrin Musa Widaa, WHO Regional Office for Europe; Messeret Shibeshi, WHO Regional Office for the Eastern Mediterranean; Nyambat Batmunkh, Heeyoun Cho, Glenda Gonzales, Varja Grabovac, Chung Won Lee, Xiaojun Wang, WHO Regional Office for the Western Pacific.

Institutional contributions

Numerous technical inputs and feedback were received from the following experts:

U.S. Centers for Disease Control and Prevention, United States of America (USA): Laila Akhlaghi, Lauren Hizami, Jessica Kolis, Shibani Kulkarni, Nguyễn Công Luật, Anna Minta, Wendy Prosser, Samir Sodha, Jenny Walldorf, Kirsten Ward.

JSI, USA and JSI India PL: Laila Akhlaghi, Pritu Dhalaria, Hannah Hausi, Vicky Maiyo, Nassor Mohammed, Isaac Mugoya, Lisa Oot, Gnourfateon Palenfo, Deepak Polpakara, Wendy Prosser, Soumya Sarkar, Lora Shimp, Farishta Hannah D. Singh.

Gavi, the Vaccine Alliance (Gavi), Switzerland: Karan Sagar.

Program for Appropriate Technology in Health (PATH), USA: Steven Diesburg, Matt Morio, Joanie Robertson.

Clinton Health Access Initiative (CHAI), USA: Ashvin Ashok.

VillageReach, USA: Swetha Srinath, Mariam Zameer.

United Nations Children's Fund (UNICEF), Denmark: Marcia Attaran, Thuy Ha Bui, Innocent Dube, Sajy Elmughanni, Krista Hund, Modeste Irategeka, Ademola Itiola, Dorthe Konradsen, Bert Matthews, Gideon Olaja, Tania Zamora.

UNICEF, USA: Olamide Folorunso, Michelle Seidel, Anahitta Shirzad.

The Bill & Melinda Gates Foundation, USA: Kelly Hamblin.

Global Fund, Switzerland: Marasi Mwencha.

Consultants

Adama Sawadogo, Modibo Dicko, Gillian Mayers.

All external experts submitted to WHO a declaration of interest disclosing potential conflicts of interest that might affect, or might reasonably be perceived to affect, their objectivity and independence in relation to the subject matter of this guidance. WHO reviewed each of the declarations and concluded that none could give rise to a potential or reasonably perceived conflict of interest related to the subjects covered by the guidance.

Abbreviations and acronyms

AEFI	adverse event(s) following immunization
BCG	bacille Calmette–Guérin (tuberculosis)
COVID-19	coronavirus disease
CRS	congenital rubella syndrome
CTC	controlled temperature chain
DT	diphtheria–tetanus toxoid vaccine
dT	diphtheria–tetanus toxoid vaccine with lower concentration of diphtheria toxoid
DTP	diphtheria–tetanus–pertussis vaccine
DTP+HepB	DTP and hepatitis B vaccine
DTP+HepB+Hib	DTP, hepatitis B and *Haemophilus influenzae* type b vaccine
HBV	hepatitis B virus
Hib	*Haemophilus influenzae* type b
HIV	human immunodeficiency virus
HPV	human papillomavirus
IPV	inactivated polio vaccine
LAIV	live attenuated influenza vaccine(s)
MCV	measles-containing vaccine
MDVP	multi-dose vial policy
MenACV	monovalent meningococcal A conjugate vaccine
Men5CV	pentavalent meningococcal conjugate vaccine
MM	measles–mumps vaccine
MMR	measles–mumps–rubella vaccine
MMRV	measles–mumps–rubella–varicella vaccine
MR	measles–rubella vaccine
OCV	oral cholera vaccine
OPV	oral polio vaccine
ORS	oral rehydration solution
PCV	pneumococcal conjugate vaccine
RVV	rotavirus vaccine(s)
TB	tuberculosis
TCV	typhoid conjugate vaccine(s)
Td	tetanus–diphtheria toxoid vaccine
TT	tetanus toxoid vaccine
TTCV	tetanus toxoid–containing vaccine
USA	United States of America
VPD	vaccine-preventable disease(s)
VVM	vaccine vial monitor
WHO	World Health Organization

Introduction

Immunization in practice: a guide for health workers is a core technical resource developed to support the implementation and improvement of immunization services globally. As immunization programmes expand to address new diseases, adapt to novel vaccine technologies and respond to changing demographic and epidemiological trends, the need for clear, practical and up-to-date guidance for health workers remains critical.

Immunization in practice: a guide for health workers updates the content of two previous publications – *Immunization in practice: a practical guide for health staff* (2015 update) *(1)* and *Immunization in practice: a practical guide for health staff* (2001 update) *(2)*.

This guide reflects both longstanding immunization principles and the most recent recommendations from the World Health Organization (WHO). Reflecting the dynamic landscape of immunization, this edition incorporates newly available vaccines and expands on vital topics such as catch-up vaccination, reducing missed opportunities and integrating gender-sensitive approaches into service delivery.

Immunization in practice promotes equitable and gender-responsive strategies to ensure that all individuals, regardless of age or setting, have access to vaccines. Notably, this publication embraces the concept of life course vaccination, emphasizing that immunization is essential not only for infants and children, but also for adolescents, adults and older populations. The publication supports an inclusive approach to protecting communities across all stages of life.

The following modules have been substantially changed from the previous version (2015):

- Module 1: Diseases and vaccines
- Module 2: The vaccine cold chain
- Module 4: Microplanning for reaching every community
- Module 7: Building community support

The following modules contain minor changes to previous information:

- Module 3: Ensuring safe injections and management of immunization waste
- Module 5: Managing an immunization session
- Module 6: Monitoring and surveillance

Each module in this guide addresses a distinct aspect of immunization services – from planning and service delivery to monitoring and community engagement. The content is designed for use by health workers at the facility and district levels, with practical tools to strengthen and support their day-to-day work. This publication also supports training and capacity building and serves as a reference for supervisors and programme managers.

Development methodology

The development process of this practical guide included the review of existing WHO documents related to immunization service delivery. The development process included the following steps:

- an initial outline of the content was prepared by the lead authors;
- structured discussions were then held with relevant staff at the regional level;
- the first draft was reviewed by staff from headquarters and regional staff nominated by the regional immunization advisors, and a meeting was held to discuss the comments and feedback received;
- a second draft was developed and then shared with regional advisors and was peer reviewed by external experts in immunization, who all provided feedback and comments;
- a third draft was developed to capture all comments received, with ongoing internal WHO discussions to refine the content and summarize important ideas for design/usability;
- a final review by selected headquarters staff was requested.

References[1]

1. Immunization in practice: a practical guide for health staff, 2015 update. Geneva: World Health Organization; 2015. (https://iris.who.int/handle/10665/193412).

2. Immunization in practice. Geneva: World Health Organization; 2001. (https://iris.who.int/handle/10665/64982).

[1] References accessed on 21 October 2025.

Document at a glance

Immunization in Practice is WHO's updated guide to support health workers in delivering effective, equitable and life-course-based immunization services. It is organized into seven practical modules, each focused on a key area of immunization to strengthen day-to-day service delivery.

Click below to explore a specific module.

MODULE 1

Diseases and vaccines

About this module

This module provides essential background information on diseases that have an international public health impact and are target diseases for national immunization programmes. It also provides information on vaccines used to prevent them. The diseases are listed in alphabetical order. At the end of each section, a table summarizes vaccine characteristics and the WHO position on the use of vaccine worldwide. This information is based on and aligns with published WHO position papers that summarize essential background information on diseases and their respective vaccines, and that provide vaccine and immunization recommendations concerning use in the global context. Resources that accompany this module are listed in the bibliography section.

Each country determines its own national immunization schedule and decides on vaccine product choice. Health workers should always refer to their national schedules and vaccine-handling instructions when providing vaccination services.

Immunization programmes provide opportunities to promote integrated services and improve the overall health of vaccine recipients. Different sections of this module introduce some of these: human papillomavirus vaccination as an opportunity to link to cervical cancer control and adolescent health services, and typhoid and cholera vaccination programmes linking to other disease control efforts, including health education and water, sanitation and hygiene improvements.

Contents

1 Cholera

1.1 Disease

1.1.1 What is cholera?

Cholera is a waterborne, acute enteric infection caused by serogroups of the bacterium *Vibrio cholerae* O1 or O139. Associated with poverty, poor sanitation and lack of clean water, cholera remains an important public health problem in many countries, occurring as an endemic disease in some regions and causing major epidemics in low- and middle-income countries *(1)*.

1.1.2 How is cholera spread?

Humans are the only known natural host for *Vibrio cholerae*. Cholera is spread by the faecal-to-oral route, through contaminated water or food. Cholera transmission is closely linked to inadequate access to clean water and sanitation facilities. Typical at-risk areas with inadequate or limited water, sanitation and hygiene (WASH) infrastructure include peri-urban slums as well as camps for internally displaced persons or refugees *(1)*.

1.1.3 What are the symptoms and signs of cholera?

Most people infected with *Vibrio cholerae* do not develop symptoms, although the bacteria are present in their stool for 1 to 10 days after infection and are shed back into the environment, potentially infecting other people. Only 1% to 25% of infected persons become symptomatic, after an incubation period varying from less than 24 hours to 5 days. The majority develop mild or moderate symptoms, which include diarrhoea, vomiting and dehydration. About 10% to 20% of those who become symptomatic experience severe disease, which rapidly leads to dehydration and, if left untreated, can lead to death in up to half of those severely affected *(1)*.

1.1.4 What are the complications of cholera?

If not promptly and adequately treated, individuals with symptomatic cholera can develop complications due to severe dehydration. These include kidney failure, shock, low potassium level and pulmonary oedema, and can lead to death within hours *(1)*.

1.1.5 What is the treatment for cholera?

Cholera is an easily treatable disease. The majority of people can be treated successfully through prompt administration of oral rehydration solution (ORS). The WHO/UNICEF standard ORS sachet is dissolved in 1 L of clean water. Adult patients may require up to 6 L of ORS to treat moderate dehydration on the first day. Severely dehydrated patients require

rapid administration of intravenous fluids. These patients are recommended antibiotic therapy, which reduces the duration of diarrhoea, the duration of symptoms and time spent in hospital, as well as the length of time the *Vibrio cholerae* is excreted in their stool. All patients should begin to eat safely prepared, regular local food as soon as they can safely do so. Breastfeeding should also be promoted. Zinc supplementation is an important supportive therapy in children from 6 months to 5 years; it can also reduce the duration and volume of diarrhoea and may prevent future episodes of other causes of acute watery diarrhoea. Mass administration of antibiotics is not recommended, as it has no proven effect on the spread of cholera and may contribute to antimicrobial resistance *(1)*.

1.1.6 How is cholera prevented?

The effective long-term solution for cholera lies in economic development and universal access to safe water and adequate sanitation. Actions targeting environmental conditions include the implementation of adapted, long-term, sustainable WASH solutions to ensure access to safe water and basic sanitation and the use of protective hygiene practices.

Vaccination with oral cholera vaccine (OCV) is a complementary cholera prevention and control measure that can be implemented in relevant settings as a part of comprehensive cholera control strategies or while other activities are being developed. Vaccination should not disrupt the provision of other high-priority health interventions to control or prevent cholera *(1)*.

1.1.7 What is needed for cholera control?

Cholera prevention and control should be a priority in areas at risk for cholera or where endemic cholera is present. WHO recommends the use of OCV in areas of endemic cholera, in humanitarian crises with high risk of cholera and during cholera outbreaks. These vaccines should be used in conjunction with other cholera prevention and control strategies. Appropriate case management, WASH interventions, surveillance and community mobilization remain cornerstones of cholera control *(1)*.

1.2 Vaccines

1.2.1 What is cholera vaccine?

Oral cholera vaccines are killed whole-cell vaccines. They are not embedded in routine immunization programmes and are indicated for use in limited contexts (that is, in endemic and emergency settings through mass vaccination campaigns, and for international workers and travellers to cholera-affected countries). All cholera vaccines are administered orally, and, in all contexts, two doses of the same vaccine are required for full protection. A mix of live, killed and conjugated vaccines are in development that have the potential of providing longer-term protection with an easier-to-administer schedule *(1)*.

Endemic and emergency settings

Currently, the only WHO-prequalified[2] oral cholera vaccine for use in endemic settings and emergency contexts is inactivated modified whole-cell cholera vaccine *(2)*. Two types are available: bivalent (O1, O139) and monovalent (O1) oral cholera vaccines. Monovalent OCV is a simplified but equally effective formulation. Its reduced number of vaccine components allows faster production of large volumes, which is important for emergency response. Bivalent OCV can be packaged in single-dose glass vials or in single-dose plastic tubes; monovalent OCV are packaged in single-dose plastic tubes. All are liquid and ready to use, and can be administered to all individuals over the age of 1 year *(1)*. These vaccine products are currently available for mass vaccination campaigns through the Global OCV Stockpile.

Vaccination of travellers

OCV recommended for use only among travellers to areas where there is a risk of cholera is inactivated whole-cell monovalent vaccine with recombinant cholera toxin B subunit (WC-rB5OCV). This product can be given to all individuals over 2 years of age and is administered with a buffer solution that requires 150 mL of clean water *(1)*.

1.2.2 How safe are cholera vaccines and what are the potential adverse reactions?

OCV has been shown to have a good safety profile. Millions of OCV doses have been administered in mass vaccination campaigns to date, with few adverse events reported. The adverse events consisted primarily of mild abdominal discomfort, pain or diarrhoea *(1)*.

Data from well-controlled studies on OCV use during pregnancy are limited. However, WHO recommends that pregnant and lactating women be included in OCV campaigns, as evidence indicates high potential benefit and minimal risks *(1)*.

1.2.3 When is cholera vaccine administered?

WHO recommends that OCV be used in areas with endemic cholera, in humanitarian crises with high risk of cholera and during cholera outbreaks. Along with vaccines, other cholera prevention and control strategies should always be implemented. OCV has been implemented in mass vaccination campaigns in areas experiencing an outbreak, in areas at heightened vulnerability during humanitarian crises and among populations living in highly endemic areas, known as hotspots *(1)*.

Individuals over 1 year of age in endemic settings and emergency contexts are eligible to receive monovalent or bivalent whole-cell OCV. Two doses, with a minimum interval of two weeks between each dose, must be given for full protection. Two doses of whole-cell OCV provide protection against cholera for at least three years *(1)*.

[2] The term "WHO prequalified" applies to vaccines and other medical products that have been assessed and verified by the World Health Organization to meet global standards of quality, safety and efficacy.

Individuals above 2 years of age who are travelling to areas where there is a risk of cholera are eligible to receive WC-rB5 OCV. Two doses must be given for full protection, with an interval of no less than seven days and no more than six weeks between the two doses. Two doses provide protection against cholera for two years. Children aged 2 to 6 years should be administered only half of the prepared vaccine solution. Children aged 2 to 5 years require a third dose for full protection *(1)*.

Key points about cholera

- Cholera is a waterborne, acute enteric infection, spread through direct faecal–oral contamination or through ingestion of contaminated water or food.
- Most individuals infected with cholera do not show any symptoms, while some may develop acute watery diarrhoea accompanied by severe dehydration.
- In the majority of people, cholera is easily and successfully treatable with the administration of ORS.
- Patients with severe cholera require intravenous rehydration and antibiotics. If left untreated, severe forms of the disease can lead to death in up to half of the patients.
- Cholera vaccination is a complementary prevention measure: improving access to clean potable water and adequate sanitation and promoting WASH practices remain the mainstays of prevention strategies to control cholera.

Table 1.1 Cholera vaccine (whole-cell OCV) summary *(1, 2)*

Type of vaccine	Inactivated oral whole-cell bivalent or monovalent vaccine
Total number of doses	2
Schedule	In endemic areas, in areas of humanitarian crises with high risk of cholera, and during cholera outbreaks, first dose as soon as possible after 1 year of age, with a minimum interval of 2 weeks between doses
Booster	None
Contraindications	• Hypersensitivity after a previous dose, or known allergies to any component of the vaccine • Age (<1 year)
Special precautions	None
Adverse events	• Mild: fatigue, headache, abdominal pain, nausea, vomiting, lack of appetite, diarrhoea • Serious: no signal of any serious issue was reported from mass vaccination campaigns
Dosage	1.5 mL
Route of administration	Oral only
Storage	Between +2 °C and +8 °C; do not freeze

2 Coronavirus disease

2.1 Disease

2.1.1 What is COVID-19?

Coronavirus disease (COVID-19) is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. WHO first learned of this new virus on 31 December 2019, following a report of a cluster of cases of so-called viral pneumonia, and announced "COVID-19" as the name of this new disease on 11 February 2020 *(3)*.

2.1.2 How is COVID-19 spread?

COVID-19 can be spread from an infected person's mouth or nose in small liquid particles when they cough, sneeze, speak, sing or breathe. These particles range from larger respiratory droplets to smaller aerosols. A person can be infected when aerosols or droplets containing the virus are inhaled or come directly into contact with the eyes, nose or mouth. Anyone infected with COVID-19 can spread it, even if they do not have symptoms. The virus can spread in poorly ventilated and/or crowded indoor settings where people tend to spend relatively long periods of time, as, under such conditions, aerosols can remain suspended in the air or travel farther than 1 m (long-range) *(3)*.

2.1.3 What populations are most at risk?

Anyone at any age can get sick with COVID-19. Older people and those with underlying medical conditions like cardiovascular disease, diabetes, chronic respiratory disease or cancer are more likely to develop serious illness or die. Currently, those at greatest risk of infection are: persons who have had prolonged and unprotected close contact (closer than 2 m for 15 minutes or longer) with a person with confirmed SARS-CoV-2 infection (with or without symptoms); people frequently in congregate settings (such as homeless shelters, assisted living facilities, college dorms); or people who live in or have recently been to areas with sustained transmission *(3)*.

2.1.4 What are the symptoms and signs of COVID-19?

COVID-19 affects different people in different ways. Most infected people will develop mild illness and recover without hospitalization. On average, it takes five to six days after infection until a person develops symptoms; however, this period can be up to 14 days.

The most common symptoms include fever, chills and sore throat. Less common symptoms include muscle aches and heavy arms or legs, severe fatigue or tiredness, runny or blocked nose, sneezing, headache, sore eyes, dizziness, new and persistent cough, tight chest or chest pain, shortness of breath, hoarse voice, numbness or tingling,

appetite loss, nausea, vomiting, abdominal pain or diarrhoea, loss or change of sense of taste and/or smell or difficulty sleeping. People with severe symptoms should seek immediate medical attention. Such symptoms include difficulty breathing (especially at rest), confusion, drowsiness or loss of consciousness, persistent pain or pressure in the chest, cold or clammy skin, bluish discoloration of the lips or skin and/or loss of normal speech or movement *(3)*.

2.1.5 What are SARS-CoV-2 variants?

It is normal for viruses to change and evolve over time as they are transmitted between people. When these changes result in a virus significantly different from the original, they are referred to as "variants." To identify variants, scientists map the genetic material of viruses (a process known as sequencing) and then look for differences between them to see if the genetic material has changed. Since SARS-CoV-2, the virus that causes COVID-19, has spread around the world, variants have been identified in many countries *(4)*. The current global epidemiology of SARS-CoV-2 is characterized by alpha, beta, gamma, delta and omicron variants. Like all viruses, SARS-CoV-2 will continue to evolve as long as it continues to be transmitted from one person to another. The more the virus is transmitted, the more likely it is to change and generate new variants. The best way to prevent future variants from emerging is to stop the transmission of the virus and help reduce COVID-19 infections.

2.1.6 What are the complications of COVID-19?

A minority of people with COVID-19 will require medical attention. Those most likely to have such severe disease are older people; those with underlying medical conditions like cardiovascular disease, chronic respiratory or liver or kidney disease; people with an immunocompromised condition, human immunodeficiency virus (HIV) infection or cancer; those with obesity; and pregnant women. However, severe disease can occur without any of these risk factors.

People with severe disease should receive treatment as soon as possible. The consequences of severe COVID-19 can include respiratory failure, sepsis, thromboembolism (blood clots), multi-organ failure (including injury of the heart, liver or kidneys) and death.

In rare situations, children can develop a severe inflammatory syndrome a few weeks after infection.

Some people who have had COVID-19, whether they have needed hospitalization or not, continue to experience symptoms. These long-term effects are called long COVID (or post-COVID-19 condition). The most common symptoms associated with long COVID include fatigue, breathlessness and cognitive dysfunction (for example, confusion, forgetfulness or a lack of mental focus or clarity). Long COVID can affect a person's ability to perform daily activities *(3, 4)*.

2.1.7 What is the treatment for COVID-19?

Most people will recover without needing any specific treatment or hospitalization. Treatments for COVID-19 should be decided on an individual basis between the patient and the health care professional looking after them. The choice will depend on the severity of the disease and the risk of the disease worsening. Apart from medication, among the most important, common, globally used treatments is oxygen for severely ill patients.

WHO does not recommend self-medication with any medicines, including antibiotics, as a prevention or cure for COVID-19. As the evidence base for COVID-19 treatment is evolving, WHO maintains Therapeutics and COVID-19: living guideline, which includes a list of recommended treatments with the evidence for each.

2.1.8 How is COVID-19 prevented?

COVID-19 vaccines protect against severe disease and death. People should get vaccinated, following local guidance on vaccination.

Respiratory hygiene practices can reduce transmission from viruses that cause colds, flu and COVID-19. Recommended strategies to help prevent the spread of COVID-19 include:

- frequently and thoroughly washing hands with soap and water or disinfecting hands with an alcohol-based sanitizer;
- covering the mouth and nose with a bent elbow when coughing or sneezing;
- cleaning and disinfecting frequently used surfaces such as door handles, faucets, phones; and
- staying home and self-isolating if you are unwell.

When there is moderate or high incidence of COVID-19 in the community, it is recommended that individuals wear a properly fitted face mask and isolate if symptoms develop or a positive COVID-19 test is confirmed *(3, 4)*.

2.2 Vaccines

2.2.1 What are the COVID-19 vaccines?

There are several types of COVID-19 vaccines that are listed by WHO for emergency use[3] or WHO prequalified:

- **mRNA vaccines**, which are genetically engineered, create proteins that safely activate an immune response by messenger RNA (mRNA).
- **Inactivated vaccines** use an inactivated or weakened version of the virus that does not cause disease but still generates an immune response.
- **Vectored vaccines** use a safe virus that cannot cause disease but serves as a vehicle to produce coronavirus proteins to generate an immune response.
- **Protein-subunit vaccines** contain harmless fragments of proteins or protein shells that mimic the COVID-19 virus to safely generate an immune response *(3, 4)*.

[3] The WHO Emergency Use Listing Procedure is a risk-based procedure for assessing and listing unlicensed products (vaccines, therapeutics, in vitro diagnostics) with the ultimate aim of expediting the availability of these products to people affected by a public health emergency.

2.2.2 How safe are COVID-19 vaccines and what are the potential adverse events following immunization?

COVID-19 vaccines are safe and effective in preventing severe disease and death *(5)*. Since 2021, billions of doses of COVID-19 vaccines have been administered globally with careful monitoring of their safety. The risks for developing severe COVID-19 in the priority groups for vaccination are far greater than any risks linked to the vaccine.

As with any other vaccine, some people experience mild to moderate adverse events following COVID-19 vaccination. These may include fever, tiredness, headache, muscle ache, chills, diarrhoea and pain or redness at the injection site. They can be managed with rest, plenty of non-alcoholic liquids and medication to manage pain and fever, if needed.

More serious or long-lasting adverse events following COVID-19 vaccines are possible but rare. Myocarditis has been reported after receipt of mRNA COVID-19 vaccines, with observed risk highest in males aged 12 to 39 years. Rare cases of thrombotic thrombocytopenia syndrome (TTS) have occurred in individuals following vaccination with vector-based vaccines.

2.2.3 When are COVID-19 vaccines administered?

WHO recommends:

- a single dose[4] for those who have never received any COVID-19 vaccine, especially those who are at high risk of severe illness, such as older persons, adults with chronic diseases, individuals with immunocompromising conditions and health workers with direct patient contact;
- a single dose for pregnant women, during each pregnancy, ideally during the second trimester or, alternatively, at any opportunity; and
- revaccination 6 to 12 months after the most recent dose for older adults, adults with comorbidities, persons who are immunocompromised and health workers with direct patient contact. Revaccination is not routinely recommended for healthy adults, adolescents and children, although guidelines may vary between countries, and local recommendations should be followed *(5)*.

For optimal protection, it is important to receive the recommended COVID-19 vaccine doses.

[4] Inactivated COVID-19 vaccines require two doses as a primary series.

Key points about COVID-19

- COVID-19 is a disease caused by a virus. The most common symptoms are fever, chills and sore throat, but there are a range of other symptoms.
- Most people make a full recovery without requiring hospital treatment. People with severe symptoms should seek medical care as soon as possible.
- People most likely to develop serious illness are: older people and those with underlying conditions like cardiovascular disease, diabetes, chronic respiratory or liver or kidney disease; people with immunocompromised condition, HIV infection, cancer or obesity; and pregnant women. However, anyone can get sick with COVID-19 and become seriously ill or die at any age.
- COVID-19 vaccines are safe and protect against severe disease and death. COVID-19 vaccines can be co-administered with other vaccines to adolescents and adults (including pregnant women).
- People should get vaccinated following local guidance on vaccination. Vaccination of health care workers is recommended.

3 Diphtheria

3.1 Disease

3.1.1 What is diphtheria?

Diphtheria is an infectious disease caused by the bacterium *Corynebacterium diphtheriae*. This bacterium produces a toxin that can harm or destroy human body tissues and organs. Diphtheria most commonly affects the upper airway (throat, tonsils, nose) or skin. Skin infection can result in ulcers. In rare instances, when diphtheria toxin gets absorbed into the bloodstream, it can result in toxic damage to vital organs such as the heart and kidneys. Diphtheria affects people of all ages, but most often it affects unimmunized children. In temperate climates, diphtheria tends to occur during colder months *(6)*.

3.1.2 How is diphtheria spread?

Diphtheria is transmitted from person to person through close physical contact and respiratory droplets. It can also be transmitted via contagious ulcers on the skin.

3.1.3 What are the symptoms and signs of diphtheria?

When diphtheria affects the throat and tonsils, the early symptoms are sore throat, fatigue, loss of appetite and slight fever. Within two to three days, a bluish-white or grey "pseudomembrane" forms in the throat and on the tonsils. This membrane is firmly attached to the soft palate of the throat and may bleed. If there is bleeding, the membrane may become greyish-green or black. The patient may either recover or develop severe weakness and die within six to ten days. Patients with severe diphtheria do not develop a high fever but may develop a swollen neck and an obstruction of the airways *(6)*.

3.1.4 What are the complications of diphtheria?

The most serious complication of diphtheria is respiratory obstruction followed by death. During the early phase of the illness, or even weeks later, patients may develop abnormal heartbeats that can result in heart block and failure. Some patients with diphtheria experience inflammation of the heart muscle and valves, and this may lead to chronic heart disease and heart failure *(6)*.

3.1.5 What is the treatment for diphtheria?

Individuals who develop diphtheria should be given diphtheria antitoxin and antibiotics (macrolide antibiotics, including azithromycin and erythromycin). Patients should be

isolated to avoid exposing others to the disease. About two days after starting antibiotic treatment, patients are no longer infectious, although it is essential to finish the course of prescribed antibiotics as instructed. To confirm the diagnosis, health workers should obtain cultures from suspected sites (for example, from the throat when the throat is affected). However, treatment should begin urgently without waiting for culture results *(6)*.

3.1.6 How is diphtheria prevented?

The most effective way to control diphtheria is to ensure and maintain a high population immunity through vaccination. Diphtheria vaccine is available in combination with tetanus and pertussis antigens, and as pentavalent and hexavalent vaccine. Pentavalent and hexavalent vaccines reduce the number of injections needed for infant vaccinations *(6)*.

3.2 Vaccines

3.2.1 What are diphtheria-containing vaccines?

Diphtheria-containing vaccines are available as a combination with tetanus toxoid (DT/Td); as a combination with tetanus and pertussis (DTP); as a pentavalent vaccine when it combines DTP with hepatitis B (HepB) and *Haemophilus influenzae* type b (Hib) vaccine antigens (DTP+HepB+Hib); and as a hexavalent vaccine when pentavalent vaccine additionally includes inactivated polio vaccine (IPV), resulting in DTP, HepB, Hib and IPV *(6)*. These vaccines are supplied in single-dose and multi-dose presentations *(2)*. Some pentavalent and hexavalent vaccine products are freeze dried (lyophilized) and require reconstitution (see Module 5, *Managing an immunization session*, section 4.2, on reconstitution of vaccines). Vaccines containing diphtheria toxoid should be stored at +2 °C to +8 °C without being frozen. If vaccines have been frozen, they should not be used. If freezing is suspected, the shake test can be performed to determine whether a vial is safe to use (see Module 2, *The vaccine cold chain*, section 8). Opened multi-dose vials must be handled according to national multi-dose vial policy (MDVP) (see Module 2, section 1.4, for WHO MDVP).

Diphtheria-containing vaccines are administered as 0.5 mL doses given intramuscularly in the anterolateral (outer) thigh in infants and in the deltoid muscle (upper arm) of children over 12 months of age and adults *(6)*.

3.2.2 How safe are diphtheria vaccines and what are the potential adverse events following immunization?

Diphtheria vaccines are among the safest vaccines available *(6)*. While serious reactions attributable to the diphtheria component of the vaccine, such as anaphylactic reactions, have not been described, local reactions at the site of injection are common. Local reactions and pain at the injection site occur more frequently among individuals who have already received several booster doses and usually improve without treatment. Among adults receiving boosters, increased rates of local reactions were more frequent with vaccines containing higher dose of diphtheria toxoid. Such observations have resulted

in the recommendation to provide low-dose diphtheria toxoid vaccine formulation (Td) for vaccination of individuals aged 7 years or older. The reduction of diphtheria toxoid minimizes local reactions, but it is sufficient to ensure immune response. WHO has created information sheets containing more detail on vaccine reaction rates, including for the DT combination vaccine.

3.2.3 When are diphtheria-containing vaccines administered?

Diphtheria-containing vaccine should be included in infant immunization programmes. For use in young children, the diphtheria toxoid is almost exclusively available in combination with tetanus toxoid as DT, or with tetanus and pertussis antigens (DTP). The WHO recommendation for diphtheria childhood vaccination is to follow the same schedule as for tetanus vaccine. A total childhood schedule of six doses is required: three primary infant doses and three booster doses at 12 to 23 months, 4 to 7 years, and 9 to 15 years. A three-dose primary series starting as soon as possible from 6 weeks of age, with a minimum interval of four weeks between doses, is recommended. Unvaccinated children aged 1 year and older should receive three doses, with an interval of at least four weeks between the first and second dose, and at least six months between the second and third dose. For all children over 4 years of age, Td-containing vaccine is preferred. Only Td vaccine should be used for children age 7 years and older and for all adults, including pregnant women, since these vaccines provide a low-dose diphtheria toxoid *(6)*.

Key points about diphtheria

- Diphtheria is spread from person to person through close physical contact and respiratory droplets.
- Symptoms of the disease include sore throat, fatigue, loss of appetite and mild fever.
- Individuals with the disease can experience complications such as abnormal heartbeat and inflammation of the heart muscle and valves, which can lead to heart block and failure.
- Individuals with diphtheria should be treated with diphtheria antitoxin and antibiotics.
- The most effective way to prevent the disease is to maintain a high level of immunization within a community.

Table 1.2 Diphtheria-containing vaccine summary *(2, 6)*

Type of vaccine	Toxoid
Total number of doses	3 to 5 (see Schedule)
Schedule: DTP or pentavalent or hexavalent for infant vaccination	For infant vaccination: • DTP1 or pentavalent or hexavalent starting at minimum 6 weeks of age, with DTP2 or pentavalent2 or hexavalent2 and DTP3 or pentavalent3 or hexavalent3 at intervals of a minimum of 4 weeks after the previous dose
Schedule: Diphtheria-containing vaccine for unvaccinated > 1 year of age	For children age 1 to 7 years who have not been previously vaccinated: • 3 DTP doses with interval of at least 4 weeks between the first and second dose and at least 6 months between the second and third dose For previously unvaccinated individuals 7 years of age and older: • Td1 and Td2 should be given 1 to 2 months apart, and Td3 should be given 6 to 12 months after Td2
Booster	When combined with tetanus vaccine, after 3 doses in infancy, 3 further doses at ages 12 to 23 months, 4 to 7 years and 9 to 15 years should be given using age-appropriate vaccine formulations to ensure long-term protection.
Contraindications	Anaphylaxis or hypersensitivity after a previous dose
Special precautions	None
Adverse events	Serious adverse events due to diphtheria toxoid alone have not been reported.
Dosage	0.5 mL
Injection site	• Anterolateral (outer) thigh in infants • Deltoid muscle of upper arm in children older than 12 months and adults
Injection type	Intramuscular
Storage	Between +2 °C and +8 °C; do not freeze

4 *Haemophilus influenzae* type b disease

4.1 Disease

4.1.1 What is *Haemophilus influenzae* type b?

Haemophilus influenzae is a bacterium commonly found in the nose and throats of children. There are six serotypes of *Haemophilus influenzae*, based on the bacteria's outer capsule. Of these six capsular serotypes, *Haemophilus influenzae* type b (Hib), causes the largest public health concern and is the only serotype that is currently vaccine-preventable. In the prevaccine era, Hib caused more than 90% of all serious *Haemophilus influenzae* disease *(7)*.

Hib can spread through the bloodstream and cause invasive infections, such as bacteraemic pneumonia, meningitis or sepsis, particularly in children younger than 5 years of age. Use of Hib vaccine has resulted in a dramatic decline in the incidence of Hib invasive infections, but infections continue to occur in unvaccinated children *(7)*.

4.1.2 How is Hib spread?

Hib is spread from person to person in droplets through sneezing and coughing. Children may carry Hib in their noses and throats without showing any symptoms or signs of illness (asymptomatic carriers), but they can still infect others.

4.1.3 What are the symptoms and signs of Hib disease?

Hib can cause mild illness such as ear infection or bronchitis, or a severe infection (invasive Hib disease). The most frequent types of invasive disease caused by Hib are meningitis, bacteraemic pneumonia, epiglottitis and sepsis. While Hib is not the only cause of these diseases, it should be suspected in any child with relevant symptoms and signs *(7)*.

Children with meningitis can have fever, headache, sensitivity to light, stiff neck and sometimes confusion or altered consciousness.

Children with pneumonia can have fever, chills, cough, shortness of breath, rapid or difficult breathing and presence of chest wall retractions.

Epiglottitis is inflammation of the flap at the entrance to the windpipe that covers and protects it during swallowing. Symptoms include sore throat, stridor (noisy breathing) and difficulty breathing and swallowing.

Sepsis is infection in the bloodstream, with symptoms that may, among others, include fever, shaking and/or chills, nausea and vomiting, shortness of breath and difficulty breathing.

4.1.4 What are the complications of Hib disease?

Invasive Hib disease generally requires hospitalization and can cause significant morbidity and mortality. In particular, children who survive Hib meningitis may develop permanent neurological disability, including brain damage, hearing loss and developmental disorders, in up to 40% of cases *(7)*.

4.1.5 What is the treatment for Hib disease?

Hib disease can be treated with appropriate antibiotics (such as ampicillin, cephalosporins and amoxicillin), symptomatic treatment and supportive treatment, depending on the presentation of the Hib disease and local patterns of antibiotic resistance. Hib that is resistant to some commonly used antibiotics (notably ampicillin) is now being seen in many parts of the world.

Pneumonia is treated with different antibiotic regimes, depending on clinical severity. Meningitis must be treated with intravenous antibiotics, and, if there are signs of low levels of oxygen in the blood or hypoxaemia, oxygen should be given. Epiglottitis as a medical emergency should be treated immediately with antibiotics and airway support *(7)*.

4.1.6 How is Hib disease prevented?

Hib disease is prevented by Hib-containing vaccine given in infancy or before 24 months of age. This vaccination is becoming increasingly important as Hib antibiotic resistance increases *(7)*.

4.1.7 What is needed for global Hib disease control?

The use of Hib vaccines should be part of a comprehensive strategy to control pneumonia, including exclusive breastfeeding for six months, handwashing with soap, improved water supply and sanitation, reduction of household air pollution and improved case management at community and health facility levels. Hib disease is included in the 2013 integrated Global Action Plan for Pneumonia and Diarrhoea, which outlines a “Prevent, Protect and Treat” framework, as well as the Defeating Meningitis by 2030 global road map.

4.2 Vaccines

4.2.1 What are Hib-containing vaccines?

Hib-containing vaccines prevent Hib disease. They do not protect against other serotypes of *Haemophilus influenzae* or other organisms that cause similar diseases.

Hib-containing vaccines are available as stand-alone monovalent and combination vaccines (pentavalent and hexavalent). Hib combined with DTP (diphtheria, tetanus and pertussis vaccines), hepatitis B and/or polio vaccines reduces the number of injections an infant has to receive while completing the recommended immunization schedule *(7)*.

Hib-containing vaccines are supplied as liquid or freeze-dried (lyophilized) powder formulations in single-dose and multi-dose presentations. Pentavalent vaccine, most commonly used globally, is available in two- and 10-dose vials. Pentavalent vaccine with a freeze-dried Hib component requires reconstitution (see Module 5, section 4.2, on reconstitution of vaccines). The diluent for pentavalent vaccine is the DTP+HepB component. Hib-containing vaccines must be stored at +2 °C to +8 °C and must not be frozen. Freezing does not damage stand-alone freeze-dried Hib vaccine but does damage liquid Hib and combination vaccines *(2, 7)*. If freezing is suspected, the shake test can be performed to determine whether a vial is safe to use (see Module 2, section 8). Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4, for WHO MDVP).

For infants, Hib-containing vaccines are administered as 0.5 mL doses in the anterolateral (outer) thigh. For older children (12 to 24 months of age), they may be given in the deltoid muscle (upper arm).

4.2.2 How safe is Hib vaccine and what are the potential adverse events following immunization?

Hib vaccine is one of the safest vaccines in current use. Mild events include injection site pain, redness or swelling in approximately 20% to 25% of recipients and fever in 2%. Serious adverse events after Hib vaccine are uncommon *(7)*.

WHO has created information sheets containing more detail on vaccine reaction rates, including for the Hib vaccine and combination vaccines.

4.2.3 When is Hib-containing vaccine administered?

Since serious Hib disease occurs mainly before 24 months of age, and infants are most at risk between 4 and 18 months of age, Hib-containing vaccines should be included in all infant immunization schedules. Any of three schedules may be followed:

- three primary doses without a booster (3p+0)
- two primary doses plus a booster (2p+1)
- three primary doses with a booster (3p+1).

The series should start from 6 weeks of age, or as early as possible thereafter. The interval between doses should be at least four weeks if three primary doses are given, and at least eight weeks if two primary doses are given. When given, the booster dose should be given at least six months after completion of the primary series. If the vaccination course has been interrupted, the schedule should be continued without repeating the previous dose.

Children who start vaccination late but are less than 12 months of age should complete the schedule. When a first dose is given to a child over 12 months of age, only one dose is recommended. Hib vaccine is not required for healthy children after 5 years of age *(7)*.

Key points about Hib disease

- Hib disease primarily affects children under 2 years of age.
- Asymptomatic carriers as well as sick individuals can spread Hib.
- Hib disease can affect different parts of the body. The most frequently seen serious diseases are meningitis and pneumonia.
- Hib conjugate vaccine protects only against the type b strain.
- In the prevaccine era, Hib caused more than 90% of all serious *Haemophilus influenzae* disease.
- Hib vaccination should be given in infancy as part of a comprehensive strategy to reduce childhood pneumonia.

Table 1.3 Hib-containing vaccine summary *(2, 7)*

Type of vaccine	Conjugate (capsular polysaccharide bound to a carrier protein)
Total number of doses	3 or 4 (see Schedules)
Schedules	Given as pentavalent or hexavalent, or as a separate injection at the same time as DTP, starting at minimum 6 weeks of age: • 3p+0: 3 primary doses given at intervals of a minimum of 4 weeks after the previous dose • 2p+1: 2 primary doses given with an interval of a minimum of 8 weeks between them, and booster given at least 6 months after the second primary dose • 3p+1: 3 primary doses given at intervals of a minimum of 4 weeks after the previous dose, and booster given at least 6 months after the third primary dose
Booster	As described under Schedules
Contraindications	Anaphylaxis or hypersensitivity after a previous dose, or known allergies to any component of the vaccine
Special precautions	Do not use pentavalent or hexavalent vaccines to provide a birth dose of hepatitis B vaccine
Adverse events	• Mild: injection site reactions (pain, tenderness), fever • Serious: uncommon – very few possible cases of anaphylaxis reported in post-marketing surveillance
Dosage	0.5 mL
Injection site	• Anterolateral (outer) thigh in infants • Deltoid muscle of upper arm in children older than 12 months and adults
Injection type	Intramuscular
Storage	Between +2 °C and +8 °C; do not freeze

5 Hepatitis B

5.1 Disease

5.1.1 What is hepatitis B?

Hepatitis B is caused by a virus that infects the liver. Among adults who get hepatitis B, 90% recover completely. But among infants infected during birth or before 1 year of age, 80% to 90% can develop chronic disease and serious complications *(8)*.

5.1.2 How is hepatitis B spread?

The hepatitis B virus (HBV) is spread by contact with infected blood and other body fluids in various situations:

- from mother to child during birth;
- during social interaction between children (for example, by cuts, scrapes, bites and/or scratches);
- from person to person during sexual intercourse; and
- through unsafe injections and/or transfusions, or needlestick accidents with infected blood.

HBV can be spread even in the absence of visible blood (for example, by sharing toothbrushes or razors, reuse of needles and syringes, sharing of food items or contact with HBV-contaminated surfaces). Overall, HBV is 50 to 100 times more infectious than HIV *(8)*.

5.1.3 What are the symptoms and signs of hepatitis B?

Acute hepatitis B does not often cause symptoms and signs, but, when it does, patients can have fatigue, nausea, vomiting, abdominal pain and jaundice (yellowing of the skin and eyes). Patients with chronic hepatitis B have signs related to liver failure (such as swelling of the abdomen, abnormal bleeding and changing mental status) as the disease progresses *(8)*.

5.1.4 What are the complications of hepatitis B?

A small proportion of acute infections can be severe (fulminant hepatitis) and lead to death. Other serious complications that occur in people with chronic infection include cirrhosis and liver cancer *(8)*.

5.1.5 What is the treatment for hepatitis B?

There is no specific treatment for acute hepatitis B. Clinical management is based on supportive therapy and relief of symptoms. Chronic hepatitis B can be treated with

interferon and other antiviral agents in some cases, but, while the treatment may slow down the progression of the disease, it is not curative *(8)*.

5.1.6 How is hepatitis B prevented?

Hepatitis B can be prevented by immunization. Since perinatal (up to 7 days of birth) transmission is an important cause of chronic infections globally, all infants should receive their first dose of hepatitis B vaccine as soon as possible (less than 24 hours) after birth, even in low-endemicity countries. After the birth dose, hepatitis B vaccine should be administered with DTP (diphtheria, tetanus and pertussis) and Hib, preferably in the form of a multivalent (pentavalent or hexavalent) vaccine *(8)*.

People who recover completely from acute hepatitis B are protected from becoming infected again throughout their lives.

5.2 Vaccines

5.2.1 What are hepatitis B-containing vaccines?

Hepatitis B vaccines are available in stand-alone or combination formulations (with DTP, Hib and IPV (inactivated polio vaccine) as quadrivalent, pentavalent and hexavalent vaccines). Stand-alone hepatitis B vaccine is a liquid supplied in single- or multi-dose vials. Pentavalent vaccine with a freeze-dried Hib component requires reconstitution (see Module 5, on reconstitution of vaccines).

Hepatitis B-containing vaccines must be stored at +2 °C to +8 °C. They are freeze sensitive; if freezing is suspected, the shake test can be performed to determine whether a vial is safe to use (see Module 2, section 7). Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4, for WHO MDVP). If hepatitis B vaccine vials stand for a long time, the vaccine may separate from the liquid. When separated, the vaccine looks like fine sand at the bottom of the vial. Before use, shake the vial to mix the vaccine.

Hepatitis B-containing vaccines are administered as 0.5 mL doses given intramuscularly in the anterolateral (outer) thigh in infants and in the deltoid muscle (upper arm) of children over 12 months of age and adults. Administration in the gluteal muscle (buttock) is not recommended *(2, 8)*.

5.2.2 How safe is hepatitis B vaccine and what are the potential adverse events following immunization?

Hepatitis B vaccine has an excellent safety profile. Mild reactions include local pain, myalgia and transient fever. Most reactions appear within 24 hours and tend to be less common in children than in adults (less than 10% versus 30%). Serious adverse events include anaphylaxis, with an estimated incidence of 1.1 per 1 000 000 vaccine doses administered *(8)*.

WHO has created information sheets containing more detail on vaccine reaction rates, including for the hepatitis B vaccine.

5.2.3 When are hepatitis B-containing vaccines administered?

All infants should receive hepatitis B vaccine at birth, preferably within the first 24 hours. Only stand-alone (monovalent) hepatitis B vaccine can be used for the birth dose. It can be given with other vaccines administered at birth (BCG and OPV vaccines). Hepatitis B combinations such as pentavalent and hexavalent vaccines are recommended for subsequent doses, with a minimum interval of four weeks between the doses. Reaching all children with at least three doses of hepatitis B vaccine should be the standard for all national immunization programmes.

Hepatitis B vaccine may also be used for older age groups at risk of infection, including patients who require frequent transfusions, dialysis patients, injecting drug users, household members and sexual contacts of known chronic hepatitis B patients, and health care workers.

If there is a delayed or interrupted schedule of vaccination for children under 12 months, adolescents or adults, three doses are recommended, with the second dose administered at least one month after the first, and the third dose six months after the first dose. If the vaccination schedule is interrupted, it is not necessary to restart the vaccine series. For catch-up vaccination, priority should be given to younger age groups, based on the risk for chronic infections *(8)*.

Key points about hepatitis B

- HBV is spread through contact with blood or other body fluids from an infected person. It is 50 to 100 times more infectious than HIV.
- Vaccination at birth is important: 80% to 90% of infants infected develop chronic disease, while 90% of healthy adults infected recover completely.
- All children should receive stand-alone (monovalent) hepatitis B vaccine at birth followed by two to three doses given with the DTP and Hib/IPV schedule, preferably pentavalent or hexavalent vaccine.
- Chronic hepatitis B infection can lead to cirrhosis, liver cancer, liver failure and death.

Table 1.4 Hepatitis B-containing vaccine summary *(2, 8)*

Type of vaccine	Recombinant DNA or plasma-derived
Total number of doses	3 or 4 (including birth dose)
Schedules	Hepatitis B birth dose followed by pentavalent or hexavalent vaccine doses with a minimum interval of 4 weeks between doses: • 3-dose primary series: stand-alone (monovalent) hepatitis B vaccine as soon as possible after birth (<24 hours), pentavalent1 or hexavalent1, pentavalent3 or hexavalent3 • 4-dose primary series: stand-alone (monovalent) hepatitis B vaccine as soon as possible after birth (<24 hours), pentavalent1 or hexavalent1, pentavalent2 or hexavalent2, pentavalent3 or hexavalent3 For the pentavalent/hexavalent schedule, see Table 1.2 in this module.
Booster	None
Contraindications	Anaphylaxis or hypersensitivity after a previous dose, or known allergies to any component of the vaccine
Special precautions	Do not use pentavalent or hexavalent vaccines to provide birth dose of hepatitis B vaccine; use only stand-alone (monovalent) vaccine.
Adverse events	• Mild: local pain, myalgia, transient fever • Serious: rare anaphylaxis
Dosage	0.5 mL
Injection site	• Anterolateral (outer) thigh in infants • Deltoid muscle of upper arm in children older than 12 months and adults
Injection type	Intramuscular
Storage	Between +2 °C and +8 °C; do not freeze

6 Human papillomavirus infection and cervical cancer

6.1 Disease

6.1.1 What is human papillomavirus?

Human papillomavirus (HPV) is a common sexually transmitted virus that causes genital warts and various cancers, with cervical cancer being the most prevalent. There are more than 200 known HPV genotypes and at least 12 types have been identified as causing cancer. While HPV can cause anogenital cancer and head and neck cancer in both sexes, it is of particular concern in women, since cervical cancers account for 93% of HPV-related cancers in women *(9)*.

6.1.2 How is HPV spread?

HPV spreads easily by skin-to-skin contact. Almost all sexually active individuals become infected with it at some point, usually early in their sexual lives. It is estimated that around 80% of people will be infected with at least one type of HPV at some point in their lives *(9)*.

6.1.3 What are the symptoms and signs of HPV infection and cervical cancer?

Most HPV infections do not cause symptoms or disease and usually clear spontaneously within one to two years without treatment. While about 90% of infections clear within two years, persistent infection with specific types of HPV (particularly types 16 and 18) may progress to precancerous lesions, which, if not detected and treated appropriately, can progress to cervical cancer. This progression usually takes more than 10 years. Symptoms appear only after the cancer has reached an advanced stage.

Symptoms and signs of cervical cancer include abnormal vaginal bleeding (after sexual intercourse and/or between menstrual periods); pelvic, back and/or leg pain; vaginal discharge; fatigue and weight loss. Anaemia, kidney failure and fistulae (abnormal opening between two organs) can also occur in advanced stages of cervical cancer *(9)*.

6.1.4 What is the treatment for cervical disease and cancer?

A comprehensive approach should be taken to prevent cervical cancer (see section 6.1.5). While there is no virus-specific treatment for HPV infection, screening of precancerous lesions is successful in preventing cervical cancer. If lesions are found early by screening

methods such as cytology-based screening, HPV testing or visual inspection with acetic acid, then they can be removed and cured effectively with localized treatment (such as cryotherapy and thermal ablation) *(9)*. If the cancer advances, the treatment is based on adequate staging of the disease and usually involves combinations of surgery, radiotherapy, chemotherapy and palliative care.

6.1.5 What can be done to prevent and control cervical cancer?

Comprehensive cervical cancer prevention and control consists of:

- primary prevention by vaccination against HPV infection for girls 9 to 14 years of age, health education warning against tobacco use, sexuality education and promotion of condom use for girls and boys and circumcision for boys;
- secondary prevention in women aged 30 to 49 years with a screen-and-treat approach, since vaccination does not protect against all cancer-causing HPV types; and
- tertiary prevention by treatment of invasive cancer at any age.

As of 2023, six HPV vaccines are available globally. All protect against the high-risk HPV types 16 and 18, which are known to cause 70% of cervical cancers. This protection is important, particularly in countries that lack resources to conduct high-quality screening programmes. HPV vaccination should be introduced as part of a coordinated strategy to prevent cervical cancer *(2, 9)*.

Cervical cancer screening remains recommended, even for vaccinated persons, since cervical cancer related to other HPV types may still occur. An HPV DNA test is recommended as a preferred screening method rather than cytology or visual inspection with acetic acid testing, with regular screening every five to 10 years starting at the age of 30. Women living with HIV should be screened every three to five years, starting at 25 years of age.

6.2 Vaccines

6.2.1 What are HPV vaccines?

All HPV vaccines are indicated for the prevention of cervical premalignant lesions and cancers caused by high-risk HPV types, which vary by vaccine product. Selected vaccines have indications against other HPV-related disease, as per their product labels.

HPV vaccines are available as bivalent, quadrivalent and nonavalent products *(9, 10)*. All HPV vaccines contain HPV 16 and 18 virus-like particles and protect against these high-risk HPV types. The quadrivalent and nonavalent vaccines also contain HPV 6 and 11 virus-like particles, and therefore protect against anogenital warts causally related to these types. Nonavalent vaccines contain additional virus-like particles and protect against high-risk HPV types 31, 33, 45, 52 and 58. HPV vaccines do not contain live biological products and are non-infectious.

The vaccines should be administered intramuscularly in the deltoid region. The standard dose is 0.5 mL.

6.2.2 How safe is HPV vaccine and what are the potential adverse events following immunization?

HPV vaccines have excellent safety profiles. Mild events include local injection-site reactions, such as pain, redness and swelling, which usually resolve without treatment. Mild systematic adverse events reported include headache, fever, dizziness and nausea. Adolescents are known to sometimes faint after any injection and should be seated during vaccination and for at least 15 minutes afterwards. Post-marketing surveillance has detected no serious safety issues to date except rare hypersensitivity reports, including anaphylaxis *(9, 10)*.

WHO has created information sheets containing more detail on vaccine reaction rates, including for HPV vaccines.

6.2.3 When is HPV vaccine administered?

The recommended primary target population for the HPV vaccination is girls aged 9 to 14 years, prior to becoming sexually active. A two-dose schedule with a minimum interval of six months is recommended from 9 years of age and for older age groups. As an alternative schedule, a single-dose schedule can be used in girls and boys aged 9 to 20 years *(9)*. Individuals known to be immunocompromised or HIV-infected should receive at least two HPV vaccine doses and three doses where possible.

If a girl becomes pregnant before she has been fully immunized, the remaining dose(s) should be postponed. Termination of pregnancy is not indicated if vaccination was carried out during pregnancy. Breastfeeding is not a contraindication for HPV vaccination *(9, 10)*.

Key points about HPV infection and cervical cancer

- Cervical cancer is the fourth-leading cause of cancer among women globally.
- Cervical cancer is caused by HPV, a sexually transmitted virus. Two types of HPV (types 16 and 18) cause 70% of cervical cancer cases.
- Cervical cancer develops many years after HPV infection and does not usually show symptoms and signs until it becomes advanced.
- HPV vaccination and the screening and treatment of precancerous lesions are effective ways to prevent cervical cancer.
- Girls aged 9 to 14 years are the primary target cohort for whom a two-dose HPV vaccination schedule is currently recommended. An alternative single-dose schedule, as an off-label option, can be used in boys and girls aged 9 to 20 years.

Table 1.5 HPV vaccines summary *(2, 9, 10)*

Type of vaccine	Recombinant, liquid
Total number of doses	2 (see Schedules)
Schedules	• Two-dose schedule: from 9 years until maximum licensed age, with minimal interval of 6 months between doses; 12-month interval is suggested for programmatic and efficiency reasons, with possibility of longer intervals (up to 3 to 5 years) if programmatically opportune • Alternative single-dose schedule can be used in females and males 9 to 20 years of age as off-label option • Multi-dose schedule is recommended for immunocompromised or HIV-infected persons (regardless of age or antiretroviral therapy status), with at least 2 doses with a minimum interval of 6 months between the first and the second dose (0, 6), or, where possible, 3 doses with a 0, 1 to 2, and 6 months dosing schedule
Contraindications	Anaphylaxis or hypersensitivity after a previous dose, or known allergies to any component of the vaccine
Special precautions	Vaccine recipients should be seated and observed for at least 15 minutes following administration of HPV vaccine, to prevent syncope and immunization stress-related responses and/or injury from fainting.
Adverse events	• Mild and self-limiting: injection site reactions (pain, redness, swelling), headache, dizziness, nausea • Serious: rare hypersensitivity reactions, including anaphylaxis
Dosage	0.5 mL
Injection site	Deltoid muscle of upper arm
Injection type	Intramuscular
Storage	Between +2 °C and +8 °C; do not freeze

7 Japanese encephalitis

7.1 Disease

7.1.1 What is Japanese encephalitis?

Japanese encephalitis is an infection of the brain caused by a virus. It is found mainly in WHO South-East Asia and Western Pacific Regions. In total, 24 countries are considered to have risk of transmission. Although traditionally considered a childhood disease, Japanese encephalitis can occur in all ages, particularly when the virus is introduced into new areas where the population has no pre-existing immunity. Japanese encephalitis virus is the principal vaccine-preventable cause of viral encephalitis in Asia *(11)*.

7.1.2 How is Japanese encephalitis spread?

The Japanese encephalitis virus is spread by mosquitoes and is transmitted to humans mainly by *Culex* species mosquitoes. The virus exists in a transmission cycle in nature between mosquitoes and animals, especially pigs and wading birds, which serve as its reservoirs. Humans may contract the disease when a mosquito that has bitten an infected animal then bites a person.

In temperate climate zones, Japanese encephalitis occurs more frequently during the warm season. In subtropical and tropical areas, the disease occurs at the highest rate during and shortly after the rainy season, although transmission can occur all year. People living in rural areas, especially where rice is grown, are most at risk *(11)*.

7.1.3 What are the symptoms and signs of Japanese encephalitis?

The majority of Japanese encephalitis infections result in mild symptoms or no symptoms at all. On average, only one in every 250 people infected with the virus develops symptoms. Initial symptoms, which usually appear five to 15 days after infection, are flu-like, with sudden onset of fever, chills, headache, tiredness, nausea and vomiting. In children, stomach or abdominal pain may be the most prominent symptom during the early stage of the illness. Signs of confusion or coma occur after three to four days. Seizures are common, especially among children *(11)*.

WHO has issued recommendations for the laboratory diagnosis of Japanese encephalitis and recommends surveillance and reporting of the disease.

7.1.4 What are the complications of Japanese encephalitis?

Japanese encephalitis is fatal in about 20% to 30% of cases. The case-fatality rate appears to be higher among adults, but, among survivors, sequelae (conditions or complications that follow Japanese encephalitis) might be more frequent in children. Among severe cases, about 30% of surviving patients have residual disabilities, such as brain damage and/or paralysis *(11)*.

7.1.5 What is the treatment for Japanese encephalitis?

There is no specific treatment for Japanese encephalitis. Since it is caused by a virus, antibiotics are not effective. Supportive clinical care should be provided to reduce symptoms and stabilize the patient *(11)*.

7.1.6 How is Japanese encephalitis prevented?

Immunization is the single most important measure to control Japanese encephalitis. Safe, effective and affordable vaccines are available and have been shown to dramatically decrease the incidence of the disease.

No effective method of environmental control of Japanese encephalitis transmission is known. Socioeconomic improvements and changes in agricultural practices may reduce viral transmission in some places. Added interventions such as bed nets and mosquito-control measures should not divert efforts from childhood Japanese encephalitis vaccination *(11)*.

7.2 Vaccines

7.2.1 What is Japanese encephalitis vaccine?

There are four types of vaccines that protect against Japanese encephalitis:

- inactivated Vero cell-derived vaccines (the virus is grown in Vero cells);
- live attenuated (weakened) vaccine available in single-dose and multi-dose vials;
- live recombinant vaccine grown in Vero cells, which combines parts of an attenuated Japanese encephalitis virus with an attenuated yellow fever vaccine virus; and
- inactivated mouse brain-derived vaccine (the virus is grown in mouse brains), a rarely used older type of vaccine. Ideally, this vaccine should no longer be used.

Three of these vaccines are WHO prequalified: one of the inactivated Vero cell-derived vaccines, the live attenuated vaccine and the live recombinant vaccine. No inactivated mouse brain-derived vaccines are WHO prequalified *(11)*.

7.2.2 How safe is Japanese encephalitis vaccine and what are the potential adverse events following immunization?

Japanese encephalitis vaccines have acceptable safety profiles. Among the adverse events observed, mild to moderate reactions may include pain, swelling or tenderness at the site or systemic reactions such as headache, flu-like symptoms or fatigue *(11)*.

WHO has created information sheets containing more detail on vaccine reaction rates, including for the Japanese encephalitis vaccines.

7.2.3 When is Japanese encephalitis vaccine administered?

Japanese encephalitis vaccine should be integrated into Expanded Programmes on Immunization in all areas where Japanese encephalitis constitutes a public health problem. The most effective immunization strategy in Japanese encephalitis-endemic settings is a one-time catch-up campaign, such as a Child Health Week, or an integrated campaign in the locally defined primary target population, followed by introduction of the Japanese encephalitis vaccine into the routine immunization programme *(11)*.

Key points about Japanese encephalitis

- Japanese encephalitis is found mainly in WHO South-East Asia and Western Pacific Regions.
- The disease is spread by infected mosquitoes.
- In temperate zones, Japanese encephalitis occurs during the warm season. In subtropical and tropical areas, the disease tends to coincide with the rainy season, although transmission can occur all year.
- The infection and illness can progress to encephalitis, a serious inflammation of the brain that is fatal in 20% to 30% of cases. It can also cause paralysis and permanent brain damage.
- There is no specific treatment for Japanese encephalitis.
- Immunization with Japanese encephalitis vaccine is the single most important control measure.

Table 1.6 WHO-prequalified inactivated Vero-cell derived Japanese encephalitis vaccine summary *(2, 11)*

Type of vaccine	Inactivated Vero cell-derived (WHO prequalified)
Total number of doses	2
Schedule	2 doses at 4-week intervals, with the primary series starting at >6 months of age in endemic settings
Booster	WHO position states that the need for a booster in endemic settings has not been clearly established
Contraindications	Known allergies to vaccine or any component of the vaccine
Special precautions	Postpone vaccination in persons with acute severe febrile conditions.
Adverse events	• Mild injection site reactions (pain, swelling, induration, tenderness) • Mild to moderate systemic reactions such as headache, muscle pain, flu-like symptoms and fatigue • No serious events were reported in clinical trials in adults and children
Dosage	0.25 mL for children aged <3 years, 0.5 mL for individuals aged >3 years
Injection site	• Anterolateral (outer) thigh in children • Deltoid muscle of upper arm in adults
Injection type	Intramuscular
Storage	Between +2 °C and +8 °C; do not freeze

Note: This table addresses WHO-prequalified vaccine product. If other Japanese encephalitis vaccine products/brands of inactivated Vero cell-derived vaccine are chosen, the manufacturer's instructions should be followed.

Table 1.7 Live attenuated Japanese encephalitis vaccine summary *(2, 11)*

Type of vaccine	Live attenuated virus vaccine
Total number of doses	1
Schedule	Single dose administered at ≥8 months of age
Booster	WHO position states that the need for a booster in endemic settings has not been clearly established
Contraindications	• Known allergies to vaccine or any component of the vaccine • Pregnancy • Any condition that results in a decreased or abnormal immune system response, including due to any infection (such as HIV), medication and/or congenital problems • Acute diseases, severe chronic diseases and chronic diseases with acute symptoms and/or fever • Encephalopathy (brain disease), uncontrolled epilepsy (seizures) or other diseases of the nervous system
Special precautions	• Review medical history and exercise caution in case of family or individual history of seizures or other chronic diseases, people with allergies and women who are lactating. • Postpone vaccination for at least 3 months if the person has been given immunoglobulin. • Ensure at least a 1-month interval between Japanese encephalitis and other live vaccines. • Women of childbearing age should avoid pregnancy for at least 3 months after vaccination.
Adverse events	• Mild: injection site reactions • Mild to moderate systemic reactions such as fever, vomiting, abnormal crying, drowsiness, appetite loss and irritability • No increased risk of allergic reactions has been reported.
Dosage	0.5 mL
Injection site	Upper arm
Injection type	Subcutaneous
Storage	Between +2 °C and +8 °C

Table 1.8 Live recombinant Japanese encephalitis vaccine summary *(2, 11)*

Type of vaccine	Live recombinant virus vaccine
Total number of doses	1
Schedule	Single dose administered at ≥9 months of age
Booster	WHO position states that the need for a booster in endemic settings has not been clearly established
Contraindications	• Known allergies to vaccine or any component of the vaccine • Pregnancy • Lactation • Any condition that results in a decreased or abnormal immune system response, including due to any infection (such as HIV), medication and/or congenital problems • Symptomatic HIV infection
Special precautions	• Postpone vaccination for acute febrile illness.
Adverse events	• Local injection site reactions are more common in children receiving their first dose (40%) than in adults (10%). • Systemic reactions include fever, vomiting, abnormal crying, drowsiness, appetite loss and irritability comparable to live attenuated Japanese encephalitis vaccine. • No allergic reactions were reported in clinical trials.
Dosage	Single dose
Injection site	Upper arm
Injection type	Subcutaneous
Storage	Between +2 °C and +8 °C

8 Malaria

8.1 Disease

8.1.1 What is malaria?

Malaria is a life-threatening disease caused by parasites that are transmitted to people through the bite of infected female *Anopheles* mosquitoes. Malaria is preventable and curable; however, if not promptly diagnosed and effectively treated, a case of uncomplicated malaria can rapidly progress to severe disease and death. Approximately 95% of malaria cases and deaths occur in sub-Saharan Africa; the remaining cases occur largely in South-East Asia and South America. Five species of parasites can cause malaria in humans; two of these species, *Plasmodium falciparum* and *Plasmodium vivax*, pose the greatest threat. Almost all malaria deaths are caused by *P. falciparum*. Most occur in African children under 5 years of age, with the highest burden concentrated among children under 3 years of age. Other vulnerable groups include pregnant women and HIV-exposed or HIV-infected people. *P. vivax* is a major cause of malaria outside of sub-Saharan Africa *(12)*.

8.1.2 How is malaria spread?

Malaria is transmitted through the bite of the female *Anopheles* mosquito: it spreads when a mosquito becomes infected with the malaria parasite after biting an infected person. In many endemic areas, malaria transmission occurs throughout the year, often with seasonal variation. The intensity of malaria transmission usually varies within a country *(12)*.

8.1.3 What are the symptoms and signs of malaria?

The first signs and symptoms of malaria usually begin within eight to 14 days after the bite from an infected mosquito. During this time, the parasites travel to the liver via the bloodstream. They mature and multiply in liver cells, after which they leave the liver, re-enter the bloodstream and infect the red blood cells. The parasites further multiply in the red blood cells, which then rupture and invade other red blood cells, continuing the cycle. The signs and symptoms of malaria may appear at this stage.

Initial symptoms are non-specific and typically include fever, headache and chills. These symptoms may be mild and difficult to recognize as malaria. In malaria-endemic areas, people who have developed partial immunity to malaria may become infected but have no symptoms. However, for those who have not developed a sufficiently strong immune response, malaria can rapidly progress to severe illness and death. This is why WHO recommends prompt diagnostic testing for anyone with suspected malaria *(12)*.

8.1.4 What are the complications of malaria?

If left untreated, malaria can progress to severe illness and death within 24 hours after first symptoms. Severe malaria may present as life-threatening anaemia, respiratory distress, reduced level of consciousness or coma or multi-organ failure. Those who survive severe malaria may have long-term sequelae: up to 25% of children who survive cerebral malaria may have persistent neurological problems, including impaired cognition, motor skills and visual coordination *(12)*.

8.1.5 What is the treatment for malaria?

The primary objective of the treatment for malaria is to ensure the rapid and complete elimination of the malaria parasites from the blood to prevent progression to severe disease, complications and death. WHO recommends that uncomplicated malaria be treated with artemisinin-based combination therapies. Severe malaria should be treated in hospital with appropriate antimalarial drugs and, if needed, blood transfusion. Because of frequent bacterial co-infection in children with severe malaria, antibiotics are often indicated. Recommendations on malaria are continuously reviewed and updated, and current WHO guidelines for malaria are available at the WHO website.

8.1.6 How is malaria prevented?

Up-to-date, substantial malaria control and prevention interventions have been scaled up. These include vector control (such as insecticide-treated nets, indoor residual spraying, larval source management); chemoprevention therapies (such as intermittent treatment during pregnancy and among school children, seasonal or perennial malaria chemotherapy); vaccination of children; and case management (testing, treating, tracking outcomes).

While most malaria prevention strategies are directed towards protecting young children, to diminish their exposure and risk of death from malaria, none are sufficiently efficacious to serve as a stand-alone intervention. The highest impact is achieved when interventions are strategically combined, depending on local data and context. Malaria vaccine is one of the high-impact interventions that can provide reductions in clinical malaria, severe malaria and malaria-associated deaths in children *(12)*.

8.2 Vaccines

8.2.1 What are malaria vaccines?

At the time of writing, two WHO-prequalified malaria vaccines are recommended for use. Both are pre-erythrocytic vaccines that prevent illness and death due to *P. falciparum* malaria in children; they are not designed to interrupt malaria transmission and are not recommended for use in adults. There is no known cross-protection with other *Plasmodium* species, including *P. vivax*.

The recommended malaria vaccines are recombinant and adjuvanted vaccines, which are available in the following two formulations:

- lyophilized powder, which needs to be reconstituted with the adjuvant suspension prior to administration, is supplied in two-dose vial presentation; and
- fully liquid, ready-to-use vaccines are supplied in one- and two-dose vials.

Malaria vaccines should be protected from light and stored at +2 °C to +8 °C, without being frozen. Malaria vaccines do not contain preservatives. Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4, for WHO MDVP). Malaria vaccines are administered as 0.5 mL doses given intramuscularly in the anterolateral (outer) thigh in infants and in the deltoid muscle (upper arm) of children over 12 months of age *(2, 12)*.

The malaria vaccination series should be completed with the same vaccine product, whenever feasible. However, if the product used for a prior dose is unavailable or unknown, the series should be completed with either of the available WHO-recommended malaria vaccines. Restarting the vaccination series is not recommended *(12)*.

8.2.2 How safe is malaria vaccine and what are the potential adverse events following immunization?

Malaria vaccines are safe and well-tolerated. The most commonly reported adverse reactions are fever, followed less frequently by irritability, and injection site reactions such as pain and swelling. There is a small risk of febrile seizures within seven days (usually within three days) of vaccination *(12)*.

8.2.3 When are malaria vaccines administered?

WHO recommends malaria vaccines be administered in children from 5 months of age,[5] in a four-dose schedule *(12)*. There can be flexibility in the timing of the fourth dose to align it with vaccinations in the second year of life. A fifth dose, given one year after the fourth dose, may be considered in areas where malaria risk remains high for children in the third year of life or beyond. WHO-recommended delivery approaches are as follows:

- **The age-based approach** consists of year-round delivery, with the first three doses (minimum interval of four weeks between doses) provided from 5 months of age, and a fourth dose given six to 18 months after the third dose, to prolong protection. Flexibility in the timing of the fourth dose is allowed to align it with vaccines given in the second year of life.
- **The seasonal five-dose approach**[6] consists of seasonally timed delivery of all doses: the first three doses (minimum of four weeks between doses) are provided just prior to the start of the peak transmission season. The two subsequent seasonal doses are provided annually.

[5] Countries may choose to give the first vaccine dose earlier than 5 months of age on the basis of operational considerations, to increase coverage or impact.

[6] For both seasonal and hybrid delivery, children who miss scheduled doses before the start of the high-transmission season can receive their doses at any time during that season.

- **The hybrid five-dose approach**[5] consists of the first three doses given through age-based administration (minimum of four weeks between doses) and the subsequent doses given seasonally, just prior to the start of the peak transmission season. A minimum of six months should be maintained between the third and fourth dose. This approach is applicable in areas with high seasonal malaria transmission or year-round transmission with seasonal peaks.

Key points about malaria

- Malaria is caused by parasites that are transmitted to people through the bite of infected mosquitoes.
- Initial symptoms of the disease are often mild and non-specific and are difficult to recognize as malaria.
- In infants and small children, and others who have not developed acquired immunity, malaria can progress to severe illness and death within 24 hours if left untreated.
- For those living in or visiting an area with malaria, as well as caregivers of young children, it is important to seek prompt diagnosis, testing and treatment for fever.
- Individuals with malaria should be treated with artemisinin-based combination therapies.
- No single intervention protects against all malaria: the highest impact is achieved when a mix of malaria control interventions is used together.

Table 1.9 Malaria vaccine summary *(2, 12)*

Type of vaccine	Subunit recombinant protein, adjuvanted
Total number of doses	4 or 5 (see Schedules)
Schedules	WHO-recommended age-based schedule: • Starting from 5 months of age,[a] first 3 doses of vaccine are given with minimum interval of 4 weeks between doses. • A fourth dose should be given 6 to 18 months after the third dose to prolong protection. There can be flexibility in the timing of the fourth dose to align it with vaccinations in the second year of life. • All doses are delivered year-round, with the vaccine series starting from 5 months of age. • As an alternative, the fourth dose can be given just before the seasonal peaks in malaria transmission (see hybrid schedule below). • A fifth dose can be considered in areas where malaria risk remains high for children in the third year of life and beyond. WHO-recommended seasonal 5-dose schedule: • Starting from 5 months of age,[a] first 3 doses of vaccine (with a minimum interval of 4 weeks between doses) should be completed just before the start of the peak transmission season. • Subsequent doses are given annually just prior to the peak transmission season. • Delivery of all doses should be seasonally timed. WHO-recommended hybrid 5-dose schedule: • Starting from 5 months of age,[a] the first 3 doses of vaccine should be given through age-based administration (with a minimum interval of 4 weeks between doses). • Subsequent doses should be delivered seasonally, just prior to the peak transmission season, with a minimum of 6 months between doses 3 and 4.
Booster	None
Contraindications	Hypersensitivity after a previous dose of malaria vaccine or hepatitis B vaccines or to any component of the vaccine. A history of febrile seizures does not constitute a contraindication for malaria vaccination.
Special precautions	Vaccination may be postponed in case of acute severe illness or high fever (≥38.5 °C).
Adverse events	• Mild: local injection site reactions (pain, swelling); systemic reactions (fever, irritability) • Serious: small risk of febrile seizures within 7 days after vaccination (usually within 3 days)
Dosage	0.5 mL
Injection site	• Anterolateral (outer) thigh in infants • Deltoid muscle of upper arm in children older than 12 months
Injection type	Intramuscular
Storage	• Between +2 °C and +8 °C; do not freeze • Keep protected from light

[a] For both seasonal and hybrid delivery, children who miss scheduled doses before the start of the high-transmission season can receive their doses at any time during that season.

9 Measles

9.1 Disease

9.1.1 What is measles?

Measles is a highly infectious disease caused by a virus. It remains a cause of death among young children globally, despite the availability of a safe and effective vaccine. More than 95% of measles deaths occur in countries with low incomes and weak health infrastructures *(13)*.

Because the disease is so infectious, it tends to occur as an epidemic with high death rates in settings such as refugee camps. Severe measles is particularly likely to occur in poorly nourished children, especially those who do not receive sufficient vitamin A, who live in crowded conditions and whose immune systems have been weakened by HIV/AIDS or other diseases.

9.1.2 How is measles spread?

Measles is spread through contact with nose and throat secretions of infected people and in airborne droplets released when an infected person sneezes, talks or coughs.

People with measles can infect others for several days both before and after they develop symptoms. The disease spreads easily in places where infants and children gather, such as health centres and schools *(13)*.

9.1.3 What are the symptoms and signs of measles?

The first sign of infection is a high fever, which begins approximately 10 to 12 days after exposure to the measles virus and lasts several days. During this period, the patient may develop a runny nose, a cough, red and watery eyes and small white spots (Koplik spots) inside their cheeks. About seven to 18 days after exposure, a slightly raised rash develops, usually on the face and upper neck. Over a period of about three days, the rash spreads to the body and then to the hands and feet. It lasts for five to six days and then fades *(13)*.

9.1.4 What are the complications of measles?

Unimmunized children under 5 years of age and especially infants are at the highest risk of contracting measles and suffering from its complications, which can include death. Infected infants may suffer from dehydration due to severe diarrhoea. Children may also develop malnutrition, inflammation of the middle ear, pneumonia and encephalitis (brain infection). Measles is a major cause of blindness among children in Africa and other areas of the world where it is endemic.

Pneumonia is the most common cause of death associated with measles. The pneumonia may be caused by the measles virus itself or by a secondary bacterial infection *(13)*.

9.1.5 What is the treatment for measles?

There is no specific antiviral treatment for measles, and case management focuses on supportive care and prevention, and treatment of complications and secondary infections. Antibiotics should be prescribed only for bacterial ear infections and pneumonia. Supportive care should be provided, including relieving common symptoms such as fever, cough, nasal congestion and/or rhinorrhoea (runny nose). General nutritional support and the treatment of dehydration with oral rehydration solution are important. Breastfeeding should be encouraged, where appropriate, and children with measles should be encouraged to eat and drink.

Vitamin A should be given to all severe measles cases, as it reduces the number of deaths from measles by 50%. Children should receive two doses of vitamin A supplement 24 hours apart to help prevent eye damage and blindness, with dosage adapted to their age *(13)*.

9.1.6 How is measles prevented?

Measles is prevented by vaccination with measles-containing vaccine (MCV). High coverage with a two-dose schedule is needed to prevent measles epidemics. Children who have recovered from measles have long-lasting, possibly lifelong, immunity to measles.

9.1.7 What is needed for global measles control?

The Global Measles and Rubella Strategic Framework (2021–2030) focuses on five core components:

- achieving and maintaining high levels of population immunity by providing high vaccination coverage with two doses of MCV;
- monitoring disease and evaluating programmatic efforts to ensure progress;
- developing and maintaining outbreak response and case management capacities;
- communicating to build public confidence and demand for immunization; and
- performing research and development to support cost-effective operations and to improve vaccination and diagnostic tools.

9.2 Vaccines

9.2.1 What are MCV?

MCV can contain monovalent measles vaccine or a combination of measles with rubella (MR), mumps and rubella (MMR) or mumps, rubella and varicella (MMRV) vaccines *(2, 13)*. For programmatic reasons, the same vaccine formulation should be used for all routine and supplementary doses. MMR and MMRV are not discussed in this module; national guidelines should be made available if either is used in a routine immunization programme.

Monovalent measles vaccine, MR and MMR are supplied as freeze-dried (lyophilized) powders with diluents supplied in separate vials. They must be reconstituted before use and only with the sterile diluent supplied (see Module 5, section 4.2, on reconstitution of vaccines). Currently, only live attenuated (weakened) vaccines are available on the market.

MCV must be stored at +2 °C to +8 °C and protected from sunlight, since they are sensitive to both heat and light. Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4, for WHO MDVP policy).

MCV are administered by subcutaneous injection. In countries where vitamin A deficiency is common, vitamin A supplements are often given at the same time as the vaccine.

9.2.2 How safe is measles vaccine and what are the potential adverse events following immunization?

Adverse reactions following measles vaccination are generally mild and transient. Local reactions include injection site pain and tenderness, which resolves in two to three days. Systemic reactions, which occur approximately seven to 12 days after vaccination, include fever of higher than 39 °C for one to two days in 5% to 15% vaccine recipients, and transient rash in about 2% of vaccine recipients. Serious events include anaphylactic reactions in 3.5 to 10 cases per 1 000 000 doses administered, and thrombocytopenia (decreased platelet count) in 1 per 30 000 to 40 000 doses administered. Except for anaphylactic reactions, adverse events are less likely to occur after the second dose of MCV (MCV2) *(2, 13)*.

WHO has created information sheets containing more detail on vaccine reaction rates, including for the MMR vaccine.

9.2.3 When are MCV administered?

All children should receive two doses of MCV. Very high (90% to 95%) and homogeneous coverage with both doses is required to prevent measles outbreaks. The first dose (MCV1) should be given at 9 to 12 months of age, depending on the epidemiological scenario (high-incidence or low-incidence/elimination settings). Because many cases of measles occur in children over 12 months of age who have not been vaccinated, routine delivery of MCV1 should not be limited to infants aged 9 to 12 months. All unvaccinated children

over 12 months should be offered MCV1 at every opportunity when the child comes in contact with health services.

MCV2 should be given between 15 and 18 months of age. Vaccinating in the second year of life reduces the number of unprotected children by providing a second vaccination opportunity. MCV2 may be linked to the timing of other routine immunizations (such as a DTP booster). Screening for measles vaccination at school entry helps ensure that all children receive two doses of MCV.

An additional dose of MCV (referred to as MCV0) should be given to infants from 6 months of age under the following circumstances:

- during a measles outbreak, as part of intensified service delivery;
- during campaigns in settings where the risk of measles among infants younger than 9 months of age remains high (for example, in endemic countries experiencing regular outbreaks);
- infants in internally displaced and refugee populations and in conflict zones;
- individual infants at high risk of contracting measles (for example, those in contact with known measles cases or in settings with increased risk of exposure during outbreaks, such as daycare facilities);
- infants travelling to countries experiencing measles outbreaks; and
- infants known to be HIV-infected or exposed (such as those born to an HIV-infected woman).

Two additional doses of measles vaccine should be administered to infants who were vaccinated with measles vaccine between 6 and 9 months, according to the national immunization schedule *(13)*.

Key points about measles

- Measles is a highly infectious viral disease that is spread from person to person through sneezing, coughing and close personal contact.
- The first sign of infection is a high fever, which begins 10 to 12 days after exposure and lasts one to seven days. A generalized rash develops seven to 18 days after exposure to the virus.
- Pneumonia is the most common cause of death associated with measles.
- Severe complications can be avoided through proper case management, including vitamin A supplementation.
- Measles can be prevented by immunization. All children should receive two doses of measles vaccine. Very high (90% to 95%) and homogeneous coverage is needed for both doses.

Table 1.10 MCV summary *(2, 13)*

Type of vaccine	Live attenuated (weakened) vaccine
Total number of doses	2
Schedule	• MCV1: 9 to 12 months of age • MCV2: generally, 15 to 18 months of age, at least 1 month after MCV1 • For infants at high risk, MCV0: 6 months (minimum age)
Contraindications	• Known allergy to vaccine components (including neomycin and gelatine) • Pregnancy • Severe congenital or acquired immune disorders, including advanced HIV infection/AIDS
Special precautions	None
Adverse events	• Mild and transient: injection site reactions within 24 hours of vaccination (pain, tenderness), systemic reactions about 7 to 12 days after vaccination (fever >39 °C, rash) • Serious: thrombocytopenia (decreased platelets), anaphylaxis
Dosage	0.5 mL
Injection site	• Anterolateral (outer) thigh in infants • Deltoid muscle of upper arm in children older than 12 months and adults
Injection type	Subcutaneous
Storage	• Between +2 °C and +8 °C • Keep all MCV away from heat and sunlight

10 Meningococcal disease

10.1 Disease

10.1.1 What is meningococcal disease?

Meningococcal disease is an infection caused by the bacterium *Neisseria meningitidis*, also known as the meningococcus. Twelve types of *N. meningitidis*, called serogroups, have been identified, six of which (A, B, C, W, X and Y) can cause disease and epidemics.

Meningococcal meningitis is an infection of the meninges, thin membranes covering the brain and spinal cord. Besides meningitis, meningococci can cause septicaemia (bloodstream infection) and pneumonia, and occasionally focal infections such as of joints (arthritis), the heart and heart lining (myocarditis, pericarditis), ears (otitis) and so on. Bacterial meningitis can cause serious brain damage and death in up to 70% of cases if left untreated.

Meningococcal meningitis occurs in small clusters throughout the world, with seasonal variation. The largest burden of invasive meningococcal disease occurs in an area of sub-Saharan Africa known as the meningitis belt, which includes all or part of 26 countries that are susceptible to outbreaks of meningococcal disease. While there is a marked disease seasonality, there are also annual outbreaks and large periodic epidemics, with irregular intervals between them. Before the introduction of a monovalent meningococcal A conjugate vaccine (MenACV), *N. meningitidis* serogroup A (NmA) had been the major cause of epidemics. While not underestimating the risk of NmA resurgence, the serogroups C, W and X (NmC, NmW, NmX) also continue to cause severe disease and epidemics in these epidemic-prone areas *(14)*.

10.1.2 How is meningococcal disease spread?

The only natural reservoir of meningococci are humans. The meningococcus is spread from person to person through respiratory droplets from the nose and throat of infected people/carriers after coughing or sneezing. Meningococcal disease is most common in young children, but older children and young adults living in crowded conditions can also be at high risk. Large population displacements or gatherings, such as pilgrimages and traditional markets, can facilitate transmission of meningococci *(14)*.

10.1.3 What are the symptoms and signs of meningococcal disease?

Symptoms of meningococcal meningitis appear between two and 10 days after infection (the average is four days). The most common symptoms have sudden onset and include intense headache, sensitivity to light, stiff neck, high fever, confusion and vomiting. Other signs include extreme tiredness, convulsions and coma. Infants may not have sudden onset of illness; they may appear only to be slow, inactive or irritable, or may feed poorly

and vomit. A less common but severe and often fatal form of meningococcal disease is meningococcal bloodstream infection or septicaemia, which is characterized by petechial rash (spots of bleeding into the skin), which can be followed by rapid shock and death *(14)*.

10.1.4 What are the complications of meningococcal disease?

Bacterial meningitis may result in loss of limbs, brain damage, hearing loss or a learning disability in 10% to 20% of meningococcal meningitis survivors. Death occurs in almost all untreated cases. Even when the disease is diagnosed early and adequate treatment is started, 5% to 10% of patients die, typically within 24 to 48 hours after the onset of symptoms *(14)*.

10.1.5 What is the treatment for meningococcal disease?

Meningococcal disease is potentially fatal and should always be viewed as a medical emergency. Admission to a hospital or health centre is necessary, to start treatment and reduce the risk of death from rapidly progressing disease. Meningococcal disease is treated with antibiotics such as third-generation cephalosporins and penicillin. It is very important to start the treatment as early as possible. Recovery may take some time *(14)*.

10.1.6 How is meningococcal disease prevented?

Several vaccines are available to protect against meningococcal serogroups A, C, W, Y and X. Countries must choose a vaccine based on the meningococcal serogroups most often identified locally. WHO recommends that countries with high (>10 cases/100 000 population/year) or intermediate (2–10 cases/100 000 population/year) endemic meningococcal disease rates and/or frequent epidemics conduct appropriate large-scale meningococcal vaccination programmes, with high-quality surveillance and vaccination programme evaluation.

For the countries of the African meningitis belt, WHO recommends the introduction of pentavalent meningococcal conjugate vaccine (Men5CV) into routine immunization programmes, and, additionally, to conduct preventive campaigns with Men5CV, at either the national or subnation level, in persons aged 1 to 19 years or 2 to 19 years, depending on the local schedule and level of risk. For countries that have already introduced MenACV into their routine immunization programmes, WHO recommends the switch to Men5CV as it becomes programmatically possible. To avoid the risk of resurgence of epidemics due to NmA, it is essential that routine immunization with MenACV is continued or introduced until it can be replaced with Men5CV *(14)*.

10.1.7 What is needed for meningococcal disease control?

WHO recommends a comprehensive approach to the prevention and control of meningitis in the African meningitis belt: preventive vaccination with Men5CV for meningococcal disease, and epidemic preparedness and response that relies on good surveillance, with early detection, reactive mass vaccination response to contain the epidemic,

and treatment and care. Countries should conduct a comprehensive meningococcal disease risk assessment to inform a Men5CV introduction strategy, in particular the decision to conduct the initial mass preventive campaigns in identified high-risk areas, as appropriate. Preventive and reactive strategies should be closely coordinated, as populations vaccinated during the reactive campaign will not need to be revaccinated during later mass preventive campaigns *(14)*.

10.2 Vaccines

10.2.1 What is meningococcal vaccine?

Currently, three types of vaccines are available.

- **Conjugate meningococcal vaccines** are available as monovalent A (serogroup A), monovalent C (serogroup C), tetravalent (A, C, W and Y), combination (serogroup C and *Haemophilus influenzae*) and pentavalent (A, C, W, Y and X) formulations. Meningococcal conjugate vaccines are preferred over polysaccharide ones, due to their potential for herd protection and their ability to induce higher and longer-lasting immunity, including in children under 2 years of age.
- **Polysaccharide meningococcal vaccines** have been available for over 30 years. Meningococcal polysaccharide vaccines are available as bivalent (serogroups A and C), trivalent (A, C and W), or tetravalent (A, C, Y and W) formulations. They are not effective in children younger than 2 years of age. Protection offered is short-lived (two to three years), and no herd protection is provided. While these vaccines have previously been widely used to respond to outbreaks, they should be used only as a last resource, such as in the event of a large outbreak that exceeds the meningococcal conjugate vaccine stockpile.
- **Protein-based meningococcal vaccine**, made from a combination of four protein components, is a vaccine against *Neisseria meningitidis* group B (NmB), against which polysaccharide and conjugate vaccines cannot be developed. The first NmB vaccine was licensed in 2014; currently, no NmB vaccine is prequalified by WHO.

Meningococcal vaccines are freeze dried and need to be reconstituted before use. They should be stored at +2 °C to +8 °C. Depending on the vaccine product, they may come in one-dose or five-dose vials *(2, 14)*. Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4, for WHO MDVP).

10.2.2 How safe are meningococcal vaccines and what are the potential adverse reactions?

Meningococcal vaccines have an excellent safety record. Mild injection site reactions are common (in up to 56% of vaccinations) and occur in all age group. Systemic reactions such as fever and irritability are less common and occur mostly in children. Serious adverse events following administration of polysaccharide vaccines include rare anaphylaxis (1 per 1 000 000 doses administered) and infrequent neurologic reactions such as seizures. No serious adverse events have been associated with conjugate meningococcal vaccines. Both polysaccharide and conjugate vaccines are safe and effective when used in pregnant women *(14)*.

10.2.3 When is meningococcal vaccine administered?

WHO recommends a single dose of Men5CV, administered by intramuscular injection, at 9 to 18 months of age, based on local programmatic and epidemiological considerations. The preferred injection site is the deltoid muscle, but, in children below 5 years of age, the outer aspect of the thigh may be used. Any children who missed vaccination at the recommended age should be vaccinated as soon as possible, with no upper age limit. The need for a booster dose has not yet been established. Co-administration with other vaccines, including with injectables when administered at different anatomical sites, is acceptable.

For countries still using meningococcal A vaccine as a single dose at 9 to 18 months of age, the 5µg presentation should be used for infants and young children, and 10 µg presentation for catch-up and periodic campaigns from 12 months of age onwards. If, in a specific setting, there is a compelling reason to vaccinate infants younger than 9 months of age, a two-dose schedule of 5µg presentation should be used starting at 3 months of age, with an interval of at least eight weeks between doses.

For monovalent meningococcal C conjugate vaccine, a single intramuscular dose is recommended for children aged over 12 months, teenagers and adults. Children aged 2 to 11 months require two doses administered at an interval of at least two months and a booster about one year later. If the primary series is interrupted, vaccination should be resumed without repeating the previous dose.

Tetravalent conjugate vaccines (A, C, W135, Y-D and A, C, W135, Y-CRM) should be administered as one single intramuscular dose to individuals aged over 2 years. A, C, W135, Y-D vaccines are also licensed for children 9 to 23 months of age and are given as a two-dose series, three months apart, beginning at the age of 9 months. If the primary series is interrupted, vaccination should be resumed without repeating the previous dose *(14)*.

Key points about meningococcal disease

- Meningococcal disease is caused by the bacterium *Neisseria meningitidis* and most commonly affects young children.
- The meningococcus is spread by contact with respiratory droplets from the nose and throat of the infected person.
- Meningococcal meningitis typically presents with sudden onset, which includes intense headache, fever, nausea, vomiting, light sensitivity and stiff neck. Infants may only be slow, irritable and feeding poorly.
- A petechial rash is the key sign of meningococcal septicaemia (bloodstream infection).
- Meningococcal disease can rapidly result in death and should always be treated as a medical emergency.
- Conjugate meningococcal vaccines are the preferred choice, due to their protection for children under 2 years of age and potential for herd immunity.

Table 1.11 Meningococcal conjugate vaccines summary *(2, 14)*

Type of vaccine	Purified bacterial capsular polysaccharide bound to protein; freeze dried; monovalent, quadrivalent, pentavalent presentations
Total number of doses	1 or 2, depending on vaccine product or age of recipient (see Schedules)
Schedules	Monovalent meningococcal A conjugate vaccine: • Single dose (5µg) at 9 to 18 months of age • Two doses (5µg) for infants 3 to 8 months of age, with an interval of a minimum of 8 weeks between the doses Monovalent meningococcal C conjugate vaccine: • Single dose at 12 months of age and older • Two doses for infants 2 to 11 months of age, with an interval of a minimum of 8 weeks between the doses Quadrivalent meningococcal A, C, W135, Y-D conjugate vaccine: • Single dose for children 2 years of age and older • Two doses for children 9 to 23 months of age, with an interval of a minimum of 12 weeks Quadrivalent meningococcal A, C, W135, Y-CRM conjugate vaccine: • Single dose for children 2 years of age and older Pentavalent meningococcal A, C, W, Y, X conjugate vaccine: • Single dose at 9 to 18 months of age
Booster	Recommended only after meningococcal C 2-dose schedule (for infants 2 to 11 months of age), 12 months after the second dose
Contraindications	Hypersensitivity after a previous dose, or known allergies to any component of the vaccine
Special precautions	Vaccination may be postponed in cases of ongoing acute febrile illness (≥38 °C) or active infection.
Adverse events	• Mild: local injection site reactions, systemic reactions (fever, irritability) • Serious: none associated with meningococcal conjugate vaccines
Dosage	0.5 mL
Injection type	Intramuscular injection
Injection site	• Anterolateral (outer) thigh in infants • Outer deltoid muscle of upper arm in children and adults
Storage	• Between +2 °C and +8 °C, protected from light • The diluent should not be frozen but should be kept cool. • Once the vaccine has been reconstituted, it should be kept at between +2 °C and +8 °C, protected from sunlight. It should be discarded 6 hours after reconstitution or at the end of the immunization session, whichever comes first.

11 Mumps

11.1 Disease

11.1.1 What is mumps?

Mumps is an infection caused by a virus. It is often characterized by the swelling of the salivary glands (parotitis). In males, mumps virus can infect the testicles, causing mumps orchitis.

Mumps most often affects children between 5 and 9 years of age. The mumps virus can also infect adults, in which case the complications are more likely to be serious *(15)*.

11.1.2 How is mumps spread?

The mumps virus is spread by saliva or respiratory droplets released when an infected person sneezes or coughs and by direct, close contact with an infected person. A person who has mumps can infect others from about two days before to about five days after salivary gland swelling.

Mumps infections frequently occur among large groups of people living in close, frequent contact in crowded settings (such as military barracks, boarding schools, detention facilities) *(15)*.

11.1.3 What are the symptoms and signs of mumps?

Between 20% and 40% of individuals infected with the mumps virus have no symptoms or signs. If symptoms do appear, they usually begin 16 and 18 days after infection (full range, 12 to 25 days). Symptoms include pain with chewing or swallowing. Fever and weakness can occur. Swelling of the salivary glands just below and in front of the ears (parotitis) is the most prominent sign and may occur on one or both sides of the neck. If mumps orchitis develops, the testicles usually become tender and swollen *(15)*.

11.1.4 What are the complications of mumps?

Complications from mumps are rare, but they can be serious, especially among adults. Orchitis, encephalitis (brain infection), meningitis (infection of the membranes covering the brain and spinal cord) and hearing loss are complications that can occur with mumps at any age. Death following mumps is rare and is mostly due to mumps encephalitis *(15)*.

11.1.5 What is the treatment for mumps?

There is no specific treatment for mumps. Since it is caused by a virus, antibiotics are not effective. Supportive treatment should be given to relieve symptoms. Most people with mumps recover completely within two weeks.

In general, infection is thought to confer lifelong protection against the disease, but symptomatic reinfections and recurrent parotitis have been reported *(15)*.

11.1.6 How is mumps prevented?

Mumps is prevented by immunization with mumps-containing vaccine. In countries implementing mumps vaccine, the combination MMR is recommended.

11.1.7 What is needed for global mumps control?

Routine mumps vaccination is recommended in countries with mature immunization programmes, in accordance with the coverage targets recommended for MR vaccination. Strategies to control mumps should be closely integrated with existing goals for measles and rubella control and elimination. Countries able to achieve sustained high coverage of MR vaccination and to attain measles and rubella control and/or elimination levels should consider introducing mumps-containing vaccine into their national immunization programmes, based on the burden of mumps and its public health priority *(15)*.

11.2 Vaccines

11.2.1 What are mumps-containing vaccines?

Mumps-containing vaccines such as MMR are supplied as freeze-dried (lyophilized) powders. They must be reconstituted before use (see Module 5, section 4.2, on reconstitution of vaccines). MMR vaccines should be protected from light and heat both before and after reconstitution. They should be kept at a temperature of between +2 °C and +8 °C. Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.45, for WHO MDVP).

Mumps-containing vaccines are administered by subcutaneous injection *(2, 15)*.

11.2.2 How safe is mumps vaccine and what are the potential adverse events following immunization?

Mumps-containing vaccine is very safe to use. Mild events include pain at the injection site (in 17% to 30% of those vaccinated) and parotid swelling (in 1% to 2%). Infrequently, depending on the vaccine virus strain used, aseptic meningitis (inflammation of the membranes covering the brain and spinal cord) has been reported. Children recover from this condition without long-term problems, although some may need to be hospitalized. There is no evidence to support an association between MMR and autism.

WHO has created information sheets containing more detail on vaccine reaction rates, including for the MMR vaccine.

11.2.3 When are mumps-containing vaccines administered?

Two doses of mumps-containing vaccines are required for long-term protection. The first dose should be given at the age of 12 to 18 months. The second should be given at least one month before school entry, although the age may range from the second year of life to about age 6 years. In areas where measles is common, the typical recommendation is for the first dose of MMR to be given to children at 9 months of age and the second dose at 15 months. Countries should decide on optimal timing to maximize programme coverage. The required minimum interval between mumps-containing vaccine doses is one month *(15)*.

Key points about mumps

- Mumps is transmitted in airborne droplets emitted by infected individuals when they cough or sneeze.
- Between 20% and 40% of individuals infected with mumps have no symptoms.
- The most prominent sign of mumps is swelling in the salivary glands.
- Complications from mumps are rare but can be serious, especially in adults.
- Mumps vaccine should be given in combination with measles and rubella vaccines (MMR) in high-performing immunization programmes, with coverage in accordance with the coverage targets recommended for MR vaccination.

Table 1.12 Mumps-containing vaccine summary *(2, 15)*

Type of vaccine	Live attenuated (weakened) vaccine
Total number of doses	2
Schedule	• Mumps1: 12 to 18 months of age • Mumps2: from the second year of life to school entry • Minimum 1 month interval required between doses • Programmes in areas where measles is common typically recommend the first dose of MMR vaccine at 9 months of age and the second dose at 15 months.
Contraindications	• Known allergy to vaccine components (including neomycin and gelatine) • Pregnancy • Severe congenital or acquired immune disorders, including advanced HIV infection/AIDS
Special precautions	None
Adverse events	• Mild and transient: pain at the injection site and parotid swelling • Serious: aseptic meningitis (depending on the vaccine virus strain used), orchitis (inflammation of the testicles), sensorineural deafness, acute myositis (inflammation in muscles)
Dosage	0.5 mL
Injection site	• Anterolateral (outer) thigh in infants • Deltoid muscle of upper arm in children older than 12 months
Injection type	Subcutaneous
Storage	• Between +2 °C and +8 °C • When using combination vaccines (MMR), keep them away from heat and sunlight.

12 Pertussis

12.1 Disease

12.1.1 What is pertussis?

Pertussis, or whooping cough, is a disease of the respiratory tract caused by the bacterium *Bordetella pertussis*. Because it is highly communicable and affects unvaccinated infants in particular, pertussis remains a public health concern globally, including in countries where vaccination coverage is high *(16)*.

12.1.2 How is pertussis spread?

Pertussis spreads very easily from infected to susceptible persons in droplets produced by coughing or sneezing. Untreated patients may be infectious and spread pertussis for three weeks or more after the typical cough starts. In many countries, the disease occurs in regular epidemic cycles of two to five (typically three to four) years *(16)*.

12.1.3 What are the symptoms and signs of pertussis?

About 10 days after infection, symptoms similar to a common cold appear: runny nose, watery eyes, sneezing, fever and a mild cough. The cough worsens to many rapid bursts. At the end of these bursts, the typical patient takes in air with a high-pitched whoop. Children may turn blue because they do not get enough oxygen during a long burst of coughing. Vomiting and exhaustion often follow the coughing attacks, which are particularly frequent at night *(16)*.

12.1.4 What are the complications of pertussis?

Pertussis can cause severe, life-threatening illness, especially in infants. Pneumonia is the main complication of pertussis. It has been found to occur in about 6% of cases in industrialized countries. The risk of pneumonia in infants under 6 months of age can be up to four times higher than that in older children.

Children may experience complications, such as convulsions and seizures, due to fever or reduced oxygen supply to the brain during bursts of coughing. There can also be nutritional deficiencies due to the difficulty of feeding and the consequences of vomiting after bursts of cough *(16)*.

12.1.5 What is the treatment for pertussis?

Treatment with an antibiotic, usually erythromycin, may reduce the severity of the illness. Because the medication kills bacteria in the nose and throat, antibiotics also reduce the ability of infected people to spread pertussis to others *(16)*.

12.1.6 How is pertussis prevented?

Prevention involves vaccination with pertussis-containing vaccine. This vaccine has been given in combination with diphtheria and tetanus vaccines (as DTP) for many years but is more recently being given in a pentavalent vaccine that covers hepatitis B and *Haemophilus influenzae* type b as well as DTP, or hexavalent vaccine, which has an additional inactivated polio vaccine (IPV) component. Pentavalent and hexavalent vaccines reduce the number of injections needed for infant immunization *(16)*.

12.2 Vaccines

12.2.1 What are pertussis-containing vaccines?

Pertussis vaccines are combination vaccines, combined with other antigens routinely given during infancy (DTP, pentavalent, hexavalent vaccines). There is no WHO-prequalified stand-alone pertussis vaccine. Two types of pertussis vaccines are available: whole-cell vaccines made from killed bacteria, and acellular vaccines based on one or more purified pertussis antigens.

Pertussis-containing vaccines are supplied in single-dose and multi-dose presentations. Combination pertussis-containing vaccines with a freeze-dried Hib component require reconstitution (see Module 5, section 4.2, on reconstitution of vaccines).

Pertussis-containing vaccines must be stored at +2 °C to +8 °C and must not be frozen. To determine whether a vial is safe to use if freezing is suspected, the shake test can be performed (see Module 2, section 8). Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4, for WHO MDVP).

Pertussis-containing vaccines are administered as 0.5 mL doses given intramuscularly in the anterolateral (outer) thigh in infants and in the deltoid muscle (upper arm) of older children and adults *(2, 16)*.

12.2.2 How safe is pertussis vaccine and what are the potential adverse events following immunization?

Safety information on the pertussis vaccine component is from studies on combination vaccines. Although local and systemic reactions are more commonly associated with whole-cell vaccines, both acellular- and whole-cell-containing vaccines have excellent safety records.

Mild adverse events are common and consist of local and systemic reactions such as pain, redness and swelling at the injection site, fever higher than 38 °C and irritability.

Serious events include prolonged or inconsolable crying, febrile seizures, hypotonic–hyporesponsive episodes (loss of muscle tone and awareness or consciousness) and rare anaphylaxis with some types of vaccine (1.3 per 1 000 000 doses with whole-cell pertussis vaccine) *(16)*.

WHO has created information sheets containing more detail on vaccine reaction rates, including for the DTP combination vaccines (acellular and whole-cell).

12.2.3 When are pertussis-containing vaccines administered?

WHO recommends a three-dose primary series, with the first dose starting as early as 6 weeks of age, with subsequent doses given four to eight weeks apart, at ages 10 to 14 weeks and 14 to 18 weeks. Ideally, all three doses of the primary series should be given by 6 months of age. For children who have not completed the primary series by that time, the vaccine may be given later, at the earliest opportunity. It is essential to complete a full primary series to obtain the full protective effect of the pertussis vaccine.

A booster is recommended for children aged 1 to 6 years, preferably between 1 to 2 years of age. The booster dose should be given at least six months after the last primary dose. If the vaccination series has been interrupted, it should be resumed without repeating previous doses *(16)*.

Schedules for combination vaccines are shown in the diphtheria and *Haemophilus influenzae* type b sections of this module.

Key points about pertussis

- Pertussis (whooping cough) is a disease of the respiratory tract.
- Pertussis is a bacterial infection spread from person to person by sneezing or coughing.
- Infants and young children are most likely to be infected, to have serious complications and to die from the disease.
- The most effective way to prevent pertussis is to vaccinate all infants with three doses of pertussis-containing vaccines.

Table 1.13 Pertussis-containing vaccine summary *(2, 16)*

Type of vaccine	Killed whole-cell or acellular
Total number of doses	3 (primary vaccination series)
Schedule	Primary 3-dose series with DTP or pentavalent or hexavalent vaccine, starting at minimum 6 weeks of age, with second and third doses at intervals of 4 to 8 weeks after the previous dose
Booster	Children between 1 and 6 years: 1 booster dose at least 6 months after the 3-dose primary series, preferably in the second year of life
Contraindications	Anaphylactic reaction following administration of whole-cell- or acellular-containing vaccines
Special precautions	None
Adverse events	• Mild local and systemic reactions: pain, redness and swelling at the injection site, fever >38 °C and irritability • Serious: prolonged or inconsolable crying, febrile seizures, hypotonic–hyporesponsive episodes (loss of muscle tone and awareness or consciousness) and rare anaphylaxis
Dosage	0.5 mL
Injection site	• Anterolateral (outer) thigh in infants • Outer deltoid muscle of the upper arm in children and adults
Injection type	Intramuscular
Storage	Between +2 °C and +8 °C; do not freeze

13 Pneumococcal disease

13.1 Disease

13.1.1 What is pneumococcal disease?

Pneumococcal disease is caused by infection with a bacterium called *Streptococcus pneumoniae* (also known as the pneumococcus) in different parts of the body. The pneumococcus is a common cause of serious diseases, such as pneumonia, meningitis (infection of the membranes covering the brain and spinal cord) and septicaemia (bloodstream infection), and milder ones, such as otitis media (middle ear infection) and sinusitis.

Pneumococcal diseases are a common cause of morbidity and mortality worldwide, although rates of disease and death are higher in developing countries, with the majority of deaths occurring in sub-Saharan Africa and Asia. It is most common in very young children and elderly people.

For infants, risk factors for pneumococcal disease include lack of breastfeeding and exposure to indoor smoke. HIV infection, sickle cell disease, asplenia (lack of a functioning spleen), chronic kidney disease and previous influenza virus infection are risk factors for all ages *(17)*.

13.1.2 How is pneumococcal disease spread?

Pneumococcal disease is spread from person to person by coughing, sneezing or close contact. Pneumococcus is transmitted by direct contact with respiratory secretions from patients and from people who have pneumococcus in their noses and/or throats (healthy carriers). In some groups, up to 70% may be healthy carriers *(17)*.

13.1.3 What are the symptoms and signs of pneumococcal disease?

Because the pneumococcus can affect many parts of the body, symptoms and signs vary, depending on the site of infection. Fever and shaking or chills can occur with all types of pneumococcal disease. Children with pneumonia can present with cough, rapid breathing and chest wall retractions; older patients may complain of shortness of breath and pain when breathing and coughing. Patients with meningitis can present with headaches, sensitivity to light, neck stiffness, convulsions and sometimes confusion or altered consciousness. Those with otitis or sinusitis may have pain, tenderness and/or discharge from the affected area *(17)*.

13.1.4 What are the complications of pneumococcal disease?

Pneumonia can be complicated by septicaemia (bloodstream infection) and/or empyema (pus in the space between the lung and the membrane covering it) and/or lung abscesses. Meningitis survivors may suffer complications, including hearing loss, neurodevelopmental disability, motor abnormalities and seizures *(17)*.

13.1.5 What is the treatment for pneumococcal disease?

Pneumococcal disease can be treated with antibiotics, such as amoxicillin. Some commonly used antibiotics are no longer effective in some geographic areas, since the pneumococcus is developing antimicrobial resistance *(17)*.

13.1.6 How is pneumococcal disease prevented?

Pneumococcal disease can be prevented by vaccination. While improved living conditions (such as reduced crowding and indoor air pollutants) and nutrition can reduce the risk of pneumococcal disease and death, these factors are less effective than vaccines *(17)*.

13.1.7 What is needed for global pneumococcal disease control?

The use of pneumococcal vaccine should be seen as complementary to the use of other pneumonia control measures, such as appropriate case management, promotion of exclusive breastfeeding for first six months of life and the reduction of known risk factors such as indoor pollutants and tobacco smoke. The 2013 integrated Global Action Plan for Pneumonia and Diarrhoea outlines a “Prevent, Protect and Treat” framework for ending pneumococcal disease.

13.2 Vaccines

13.2.1 What is pneumococcal conjugate vaccine?

The pneumococcus is a bacterium with an outer polysaccharide capsule. Many different serotypes (strains) of pneumococcus have been identified based on differences in this capsule. Pneumococcal vaccines have been developed based on the serotypes frequently found in severe pneumococcal disease patients.

There are two categories of pneumococcal vaccines *(17)*. Pneumococcal polysaccharide vaccines were used for many years. They contain the purified capsule of up to 23 serotypes of pneumococcus but produce only short-term protection and are not effective in infants and young children. Pneumococcal conjugate vaccines (PCVs) overcome the limitations of polysaccharide vaccines by conjugating or binding the capsule with a protein; this results in longer-lasting protection, makes the vaccine more effective in children and helps reduce carriage.

Each pneumococcal vaccine protects against disease caused by the pneumococcal serotypes that it contains. In most cases, the vaccine does not protect against serotypes

that it does not contain. The vaccine also does not protect against other bacteria that cause the same types of infections (pneumonia, meningitis, etc.) as the pneumococcus. The fact that the vaccine cannot protect against all causes of pneumonia should be emphasized in health education so that such illness is not misunderstood as a failure of the vaccine.

Two polysaccharide protein conjugate vaccines are available: the 10-valent (PCV10) and 13-valent (PCV13). The number indicates how many pneumococcal serotypes the vaccine contains (for example, PCV10 protects against 10 serotypes of pneumococcus).

PCVs in these presentations do not require reconstitution. They must be stored at +2 °C to +8 °C without being frozen, as they are freeze sensitive. If freezing is suspected, the shake test can be performed to determine whether a vial is safe to use (see Module 2, section 8). Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4 for WHO MDVP).

For infants and children, 0.5 mL of PCV is administered by intramuscular injection in the anterolateral thigh *(2, 17)*.

13.2.2 How safe is pneumococcal conjugate vaccine and what are the potential adverse events following immunization?

Pneumococcal conjugate vaccine is safe and well tolerated in all target groups. Mild events include soreness at the injection site in about 10% of vaccinated individuals; fever has been reported in less than 1% of individuals. No serious adverse events have been proven to date *(17)*.

WHO has created information sheets containing more detail on vaccine reaction rates, including for pneumococcal vaccines.

13.2.3 When is pneumococcal conjugate vaccine administered?

PCVs should be given priority in childhood immunization programmes, particularly in countries with high mortality in children under 5 years of age (more than 50 per 1000 live births). Three doses are required. They can be administered either as two primary doses plus a booster dose (2p+1) or three primary doses without a booster (3p+0), starting as early as 6 weeks of age. For the 2p+1 schedule, an interval of at least eight weeks is recommended between the two primary doses, but a shortened interval may be considered if there is a compelling programmatic reason to do so. The booster dose should be given between 9 and 18 months of age. If the 3p+0 schedule is used, a minimum interval of four weeks should be maintained between doses. In choosing between the 2p+1 and 3p+0 schedules, countries should consider programmatic factors, including timeliness of vaccination and expected coverage.

Once a series has been started, the same product should ideally be used for all three doses (for example, if PCV13 is used for the first dose, it should also be used for the second and the third dose). If this is not possible, the schedule may be completed with the available PCV.

Previously unvaccinated or incompletely vaccinated children, including those who have recovered from pneumococcal disease, should be vaccinated according to their age. Children aged 12 to 24 months require only two doses, with an interval of at least eight weeks between doses *(17)*.

Key points about pneumococcal disease

- Pneumococcal disease is a leading cause of death in children under 5 years of age, especially in developing countries.
- The pneumococcus can cause infections in different parts of the body; the most common severe diseases are pneumonia, meningitis and septicaemia.
- Healthy carriers as well as patients can spread pneumococcus.
- Pneumococcal vaccination should be given as part of a comprehensive "prevent, protect and treat" framework to reduce mortality and morbidity from childhood pneumonia.
- Each pneumococcal vaccine protects against disease caused only by the pneumococcal serotypes that it contains. The vaccine generally does not protect against other types of bacteria that cause the same type of infections (pneumonia, meningitis, etc.).

Table 1.14 Pneumococcal conjugate vaccine summary *(2, 17)*

Type of vaccine	Conjugate (pneumococcal polysaccharide bound to a carrier protein; does not contain any live bacteria)
Total number of doses	3
Schedules	• 3p+0: first dose as early as 6 weeks of age, with intervals of 4 to 8 weeks between doses • 2p+1: two primary doses, ideally completed by 6 months of age, starting as early as 6 weeks of age, with an interval of 8 weeks or more between doses • For infants ≥7 months who started vaccination late: a minimum interval of 4 weeks between doses is possible
Booster	• With 2p+1 schedule: one booster dose between 9 and 18 months of age • HIV+ infants and preterm neonates who receive three primary doses before 12 months of age may benefit from a booster dose during the second year of life.
Contraindications	Anaphylaxis or hypersensitivity after a previous dose, or known allergies to any component of the vaccine
Special precautions	Postpone vaccination if the child has moderate to severe illness.
Adverse events	• Mild: injection site reactions (pain, tenderness), fever • Serious: none proven
Dosage	0.5 mL
Injection site	Anterolateral (outer) thigh in infants and children
Injection type	Intramuscular
Storage	Between +2 °C and +8 °C; do not freeze

14 Poliomyelitis

14.1 Disease

14.1.1 What is poliomyelitis?

Poliomyelitis, or polio, is a highly infectious disease caused by poliovirus types 1, 2 or 3. These are called wild polioviruses, since they are the naturally occurring types that circulate and infect people.

If the vaccine virus is able to circulate uninterrupted for a prolonged period of time, it can change and acquire neurovirulence. This poliovirus is called vaccine-derived poliovirus. If a population is seriously under-immunized, there are enough susceptible children for the excreted vaccine-derived poliovirus to begin circulating in the community. These viruses are called circulating vaccine-derived polioviruses.

The lower the population immunity, the longer the viruses survive. The longer they survive, the more they replicate, change and exchange genetic material with other enteroviruses as they spread through a community. If a population is fully vaccinated against polio, it will be protected against the spread of both wild and vaccine-derived strains of poliovirus.

Polio mainly affects children younger than 5 years of age. One in 200 infections causes irreversible paralysis when the virus attacks the spinal cord nerve cells that control the muscles *(18)*.

Due to the Global Polio Eradication Initiative, which was launched in 1988, the number of countries still reporting wild poliovirus has been reduced from 125 to two in 2023.

14.1.2 How is polio spread?

Poliovirus spreads by the faecal-to-oral route. In areas with poor sanitation, it is thought to most commonly enter the body through the mouth when people eat food or drink water that is contaminated with faeces. The majority of infected people do not show symptoms but can still spread the disease. The virus multiplies in the intestine and is excreted by the infected person in faeces, which can pass on the virus to others *(18)*.

Polio does not respect borders. Any unvaccinated child is at risk, and polio can possibly spread to polio-free countries. For every case of paralysis, there are between 200 and 1000 infected children without symptoms. So, it is hard to detect polio and hard to prevent the virus from spreading. Children living in areas where population immunity levels are low are particularly vulnerable.

All children worldwide should be fully vaccinated against polio. Every country should seek to achieve and maintain high levels of coverage with any of the polio vaccines in use in their countries in support of the global commitment to eradicate polio.

14.1.3 What are the symptoms and signs of polio?

Following infection with poliovirus, approximately 25% of those infected develop a minor illness, usually with fever, headache, fatigue, vomiting, stiffness in the neck, pain in the limbs and sore throat. Paralysis occurs in less than 1% of those infected. Death occurs in approximately 5% to 10% of those paralysed *(18)*.

14.1.4 What is the treatment for polio?

There is no cure for polio, and it can be prevented only by vaccination. Safe and effective vaccines exist, such as oral polio vaccine (OPV) and inactivated polio vaccine (IPV).

Treatment consists of supportive, symptomatic care. A ventilator can help patients who have difficulty breathing. Orthopaedic treatment, regular physiotherapy and the use of braces can help reduce long-term crippling effects *(18)*.

14.1.5 How is polio prevented?

Polio, whether caused by wild or vaccine-derived viruses, can be prevented through vaccination with OPV and/or IPV. WHO recommends that all countries using only OPV add at least two doses of IPV to the routine immunization schedule. The response to circulating vaccine-derived polioviruses is the timely implementation of high-quality vaccination using the appropriate polio vaccine *(18)*.

14.2 Vaccines

14.2.1 What is polio vaccine?

OPV is a live attenuated (weakened) vaccine that contains poliovirus strains that have been weakened to reduce neurovirulence and transmissibility. OPV was first licensed as monovalent OPV (mOPV, containing type 1, 2 or 3) and subsequently licensed as trivalent OPV (tOPV, containing types 1, 2 and 3) as well as bivalent OPV (bOPV, containing types 1 and 3).

Until its withdrawal and “the switch” in 2016, tOPV was the vaccine of choice and was widely used in routine immunization programs. Currently, bOPV is used in routine immunization and supplementary immunization activities. Under certain circumstances, mOPV can be used in supplementary immunization activities; however, any type 2-containing OPV is used in outbreak response to type 2 poliovirus.

OPV is administered as two oral drops per dose and is highly heat sensitive. For long-term storage, OPV must be frozen. After thawing, it can be stored at +2 °C to +8 °C for six months or can be refrozen.

Novel OPV (nOPV) contains strains that are modified versions of the OPV strains with enhanced genetic stability. Currently, nOPV is available only for type 2 poliovirus (nOPV2) and is being used in outbreak response immunization. Global discussions are ongoing regarding the possible expanded use of nOPV2 in areas with persistent transmission, in line with evolving recommendations from SAGE and WHO.

IPV is an inactivated poliovirus vaccine, containing the three virus serotypes. It is available as a stand-alone product or in combination with diphtheria, tetanus, pertussis, hepatitis B and/or Hib. IPV is stable for three years at +2 °C to +8 °C; it must not be frozen. It is supplied in one-, five-, or 10-dose vials.

IPV is administered intramuscularly as a 0.5 mL dose. Alternatively, non-adjuvanted stand-alone IPV can be administered intradermally as fractional doses of 0.1 mL or one fifth of a full dose. Multiple studies have demonstrated that intradermal administration of fractional IPV is safe and immunogenic, but this use remains off-label *(2, 18)*.

14.2.2 How safe is polio vaccine and what are the potential adverse events following immunization?

Both OPV and IPV are safe and well tolerated. With OPV, vaccine-associated paralytic polio can occur in approximately 1 in 2 700 000 doses. Vaccine-associated paralytic polio usually occurs following the first dose of OPV, and this small risk declines further with subsequent doses. On rare occasions, over time, in areas of low vaccination coverage, the live attenuated (weakened) viruses contained in OPV can begin to circulate and regain the ability to cause paralytic cases (circulating vaccine-derived poliovirus).

IPV is one of the safest vaccines used in routine vaccination. Mild reactions are common and include injection site redness (0.5% to 1.5%), swelling (3% to 11%) and soreness (14% to 29%). These reactions are transient and spontaneously resolve within two to three days. No serious adverse events have been observed after vaccination with IPV *(18)*.

WHO has created information sheets containing more detail on vaccine reaction rates, including for the polio vaccines.

14.2.3 When is polio vaccine administered?

Different schedules are recommended, depending on the different vaccines in use in each particular country or region *(18)*.

Vaccination with bOPV and IPV: For all countries using OPV in their national immunization programme, WHO recommends three doses of bOPV and two doses of IPV. In polio-endemic countries and in countries at high risk of polio virus importation, WHO recommends a bOPV dose at birth, followed by the three bOPV primary doses and two IPV doses.

Sequential IPV–bOPV schedule: Where a sequential IPV–bOPV schedule is used, the initial administration of two doses of IPV should be followed by two or more doses of bOPV.

IPV-only schedule: For IPV-only schedules, a minimum of a primary three-dose series of IPV, administered beginning at 6 or 8 weeks of age, with a minimum four-week interval between doses, is recommended. Alternatively, a two-dose or fractional dose IPV schedule, starting at 14 weeks of age or older, with a second dose four months or more later, can be considered. An IPV-only schedule may be considered in countries in polio-free regions with an IPV routine schedule compliant with SAGE recommendations, a very low risk of importation and sustained high routine immunization coverage (DTP3 coverage higher than 90%). In the current epidemiological context, WHO recommends that only countries in this category consider moving from a combined bOPV–IPV schedule to an IPV-only schedule in their routine immunization programmes.

Key points about polio

- Polio is caused by wild type polioviruses 1, 2 and 3, and is easily spread by the faecal-to-oral and oral-to-oral routes.
- The majority of individuals infected do not have symptoms but can still spread the disease.
- Less than 1% of infections result in paralytic poliomyelitis; when paralysis occurs, it will lead to death in approximately 5% to 10% of cases.
- All children worldwide should be fully vaccinated against polio, and every country should seek to achieve and maintain high levels of coverage with any of the polio vaccines in use in their countries.

Table 1.15 Polio vaccine summary *(2, 18)*

Type of vaccine	• OPV: live attenuated (weakened) viral • IPV: inactivated viral
Total number of doses	• 3–4 OPV and 2 IPV • For combination vaccines containing IPV, a minimum of 3 doses are required.
Schedules	OPV plus IPV: • 3 OPV doses initiated as early as 6 weeks of age, with a minimum interval of 4 weeks. In endemic and/or high-risk countries, a dose should be administered at birth or within the first week of life. • 2 IPV doses[a,b] should be given: the first as early as 14 weeks of age (with OPV dose), and the second at least 4 months later (possibly coinciding with measles vaccination) Sequential IPV-OPV: • 2 doses of IPV starting from 2 months of age, with an interval between doses of 4 to 8 weeks, followed by at least 2 doses of OPV, also with an interval of 4 to 8 weeks between doses IPV only: • minimum of 3 doses beginning at 6 or 8 weeks of age, with an interval of at least 4 weeks between doses • Alternatively, a 2-dose or fractional dose IPV schedule, starting at 14 weeks of age or older, with a second dose 4 months or more later can be considered. This schedule is currently recommended for use after OPV cessation.
Booster	If the IPV-containing vaccine series is completed, there is no need for a booster. Based on SAGE recommendations, completeness of the primary series should be checked during other vaccine contacts.
Contraindications	• OPV: immunodeficiency disorders, those receiving chemotherapy and those with history of allergic reaction to OPV or to the trace antibiotics it contains • IPV: known hypersensitivity (allergy) or anaphylaxis after a previous dose
Special precautions	Postpone vaccination if the child has moderate to severe illness with fever.
Adverse events	• OPV: rare vaccine-associated paralytic polio • IPV: mild injection site reactions; no serious reactions observed
Dosage	• OPV: 2 drops into the mouth • IPV: 0.5 mL injection
Route of administration	• OPV: oral only • IPV: intramuscular injection, anterolateral (outer) mid-thigh in infants and children
Storage	• OPV: keep frozen; very heat sensitive; storage between +2 °C and +8 °C for a maximum of 6 months • IPV: between +2 °C and +8 °C; do not freeze

[a] This schedule may be carried out using full-dose IPV or intradermal fIPV (only when Salk IPV is used).

[b] Based on local context, an alternative early IPV schedule starting with the first IPV dose at 6 weeks of age (with DTP1/pentavalent1) and the second IPV dose at 14 weeks (with DTP3/pentavalent3) is possible. This schedule refers to only full dose administration (not fractional). However, this option is not in line with the post-cessation schedule recommendation.

15 Rotavirus gastroenteritis

15.1 Disease

15.1.1 What is rotavirus gastroenteritis?

Rotavirus gastroenteritis is a highly infectious diarrhoeal disease caused by strains of rotavirus infecting the small intestine. Rotavirus gastroenteritis is the leading cause of severe diarrhoea in infants and young children worldwide. It occurs everywhere, including in countries where sanitation standards and access to safe water are good.

Deaths occur mainly in infants between 3 and 12 months of age when they develop severe gastroenteritis following their first infection, are very vulnerable to the effects of dehydration and, often, do not have easy and timely access to health care *(19)*.

15.1.2 How is rotavirus spread?

Rotavirus spreads by the faecal-to-oral route. Large quantities of virus can be shed in the faeces of an infected child. Shedding can occur from two days before to 10 days after the onset of symptoms. Rotavirus is stable in the environment and can spread via contaminated food, water and objects *(19)*.

15.1.3 What are the symptoms and signs of rotavirus gastroenteritis?

Rotavirus gastroenteritis can range from mild loose stools to severe watery diarrhoea and vomiting, leading to dehydration. Symptoms usually begin one to three days after infection. Fever and vomiting can occur before diarrhoea. The diarrhoea lasts for three to seven days on average *(19)*.

15.1.4 What are the complications of rotavirus gastroenteritis?

Once vomiting and/or watery diarrhoea begins, infants can rapidly become severely dehydrated, leading to complications such as shock, kidney and liver failure, and death *(19)*.

15.1.5 What is the treatment for rotavirus gastroenteritis?

There is no specific antiviral treatment for rotavirus gastroenteritis. As with other causes of diarrhoea, key supportive measures are fluid replacement with oral rehydration solution (ORS) and treatment with zinc supplementation. Severe dehydration may require intravenous infusion in addition to ORS for the urgent replacement of fluid and electrolytes *(19)*.

15.1.6 How is rotavirus gastroenteritis prevented?

Over the past 30 years, global deaths due to diarrhoea from causes other than rotavirus gastroenteritis have decreased significantly, due to improved nutrition, hygiene and sanitation, and the availability of ORS and zinc. Improvements in sanitation and access to safe water are less effective for reducing rotavirus infections, and vaccination is important for prevention of severe rotavirus disease.

The first infection with rotavirus will give some, but not complete, immunity. The severity of infection tends to become less with each repeat infection *(19)*.

15.1.7 What is needed for global rotavirus gastroenteritis control?

The use of rotavirus vaccines should be part of a comprehensive strategy to control diarrhoeal diseases with the scaling up of both prevention (promotion of early and exclusive breastfeeding, handwashing, improved water supply and sanitation) and treatment (low osmolarity ORS and zinc) *(19)*.

15.2 Vaccines

15.2.1 What is rotavirus vaccine?

The currently available rotavirus vaccines (RVV) contain one or more live attenuated (weakened) virus strains. They are given orally to protect against rotavirus gastroenteritis. They do not protect against other causes of diarrhoea, a fact that is important to emphasize in health education.

Currently available RVV include two pentavalent and two monovalent products *(2, 19)*.

- Pentavalent human-bovine reassortant RVV liquid (RotaTeq) is available as a single dose (2 mL) in a squeezable plastic tube. This vaccine should be stored at +2 °C to +8 °C and protected from light; it should be used as soon as possible after removal from the refrigerator.
- Pentavalent human-bovine reassortant RVV is available in three different formulations: lyophilized, thermostable lyophilized and liquid (Rotasiil).
    - The freeze-dried (lyophilized) and thermostable freeze-dried formulations come in two presentations: a one-dose vial with a 2.5 mL diluent vial, or a two-dose vial with a 5 mL diluent vial. The lyophilized vaccine vial should be stored at +2 °C to +8 °C; the diluent should not be frozen but should be kept cool in either dry storage or a refrigerator. Thermostable vaccine vials may be stored at temperatures up to 25 °C; however, WHO recommends that the vaccine be stored at temperatures lower than 25 °C and that countries should ensure the availability of adequate storage facilities (conditioned rooms) with temperatures not exceeding 25 °C. For any presentation of this vaccine, it should be used immediately after being reconstituted. If not used immediately, it can be held for a maximum of six hours, provided that a syringe is used to cap the opening of the vial adapter and the entire assembly is stored at +2 °C to +8 °C.

- A ready-to-use liquid formulation comes as a single-dose (2 mL) squeezable plastic tube. It should be kept at +2 °C to +8 °C, protected from light, and should not be frozen.

- Monovalent rotavirus vaccine (Rotarix) is available as a ready-to-use liquid formulation in two presentations: a single-dose squeezable plastic tube and a multi-monodose presentation with a strip of five single-dose plastic tubes (each dose 1.5 mL). The vaccine should be kept at +2 °C to +8 °C, protected from light, and should not be frozen. It should be used immediately after opening.
- Monovalent human-bovine reassortant RVV (Rotavac) is a liquid in frozen form and is available in two presentations: five-dose and 10-dose glass vials with oral droppers (each dose 0.5 mL). Vials should be stored at -20 °C. Prior to administration, this vaccine should be fully thawed until liquid. Once opened, it should be kept at +2 °C to +8 °C and discarded no more than six hours after opening or at the end of the immunization session, whichever comes first.

15.2.2 How safe are rotavirus vaccines and what are the potential adverse reactions?

The available rotavirus vaccines are safe and well tolerated. Intussusception has been associated in the past with rotavirus vaccines; no other serious adverse events have been identified. Rotavirus vaccines are generally not recommended for infants with a history of intussusception. The benefits of the currently available rotavirus vaccines are far greater than the potential risks.

WHO has created information sheets containing more detail on vaccine reaction rates, including for rotavirus vaccines.

15.2.3 When is rotavirus vaccine administered?

WHO recommends that the first dose of rotavirus vaccine be administered as soon as possible after 6 weeks of age, to ensure induction of protection prior to exposure to rotavirus. A minimum interval of four weeks should be maintained between doses. Only monovalent human RVV (Rotarix) should be administered as a two-dose schedule, while all others (RotaTeq, Rotavac, and Rotasiil) should be administered in a three-dose schedule.

If a child younger than 24 months of age misses a rotavirus dose or series for any reason, WHO recommends rotavirus vaccination for that child. Because of the typical age distribution of rotavirus gastroenteritis, rotavirus vaccination of children older than 24 months of age is not recommended.

Rotavirus vaccinations may be administered simultaneously with other vaccines of the childhood immunization programme *(19)*.

Key points about rotavirus gastroenteritis

- Rotavirus is the most common cause of gastroenteritis in infants and young children.
- The disease spreads by the faecal-to-oral route, and the virus is stable in the environment.
- Severe disease can lead to rapid dehydration resulting in shock and death if fluids are not replaced quickly by ORS and, if needed, intravenous infusion.
- Vaccination is the best prevention for rotavirus gastroenteritis, since safe water and sanitation measures are less effective in preventing rotavirus infections than in preventing other causes of diarrhoea.
- Rotavirus vaccination prevents only rotavirus gastroenteritis and should be included as part of a comprehensive treatment and prevention strategy to control diarrhoea.

Table 1.16 Rotavirus vaccine summary *(2, 19)*

Type of vaccine	Live attenuated (weakened)
Total number of doses	2 or 3, depending on a vaccine product
Schedule	First dose as soon as possible after 6 weeks of age, with a minimum interval of 4 weeks between doses
Booster	Not recommended at this time
Contraindications	• Hypersensitivity after a previous dose, or known allergies to any component of the vaccine • Severe immunodeficiency, including severe combined immunodeficiency (but not HIV infection) • Prior history of intussusception
Special precautions	Vaccination may be postponed in the case of ongoing acute gastroenteritis or fever with moderate to severe illness.
Adverse events	Serious: intussusception
Dosage	• Pentavalent RVV (RotaTeq, Rotasiil): 5 mL • Monovalent human RVV (Rotarix): 1.5 mL • Monovalent human-bovine reassortant RVV (Rotavac): 0.5mL
Route of administration	Oral only
Storage	• Pentavalent RVV (Rotasiil): +2 °C to +8 °C • Pentavalent RVV (RotaTeq): +2 °C to +8 °C; do not freeze • Monovalent human RVV (Rotarix): +2 °C to +8 °C, protected from light; do not freeze • Monovalent human-bovine reassortant RVV (Rotavac): keep frozen at -20 °C; once thawed and opened, keep at +2 °C to +8 °C and discard 6 hours after opening or at the end of the immunization session, whichever comes first

16 Rubella and congenital rubella syndrome

16.1 Disease

16.1.1 What are rubella and congenital rubella syndrome?

Rubella is an infection caused by a virus and is usually mild in children and adults. Congenital rubella syndrome (CRS) is a group of birth defects that occur when the rubella virus infects a foetus. A woman infected with the rubella virus early in pregnancy has a 90% chance of passing the virus on to her foetus, and this can lead to death of the foetus or to CRS. The most common birth defect is hearing impairment, but CRS can also cause defects in the eyes, heart and brain *(20)*.

16.1.2 How is rubella virus spread?

Rubella is spread in airborne droplets released when infected people sneeze or cough. The virus spreads throughout the body and, in a pregnant woman, to the foetus, about five to seven days after infection. Infected individuals are most likely to spread the virus between days one to five of the rubella rash onset, but they can spread it from seven days before to about 14 days after the rash appears. Infants with CRS can shed the virus for a year or more *(20)*.

16.1.3 What are the symptoms and signs of rubella and CRS?

About seven to 14 days after exposure to the virus, mild fever, conjunctivitis (more often in adults) and swollen neck lymph nodes may occur, typically preceding a rash by five to 10 days. The rash most often begins on the face and neck before progressing down the body. It is an erythematous maculopapular rash, which means it is red and raised, but it is usually fainter than a measles rash. The rash typically lasts for one to three days. Studies have shown that 20% to 50% of rubella infections occur without a rash or are subclinical. Joint symptoms (arthritis, arthralgia) may occur in up to 70% of women infected as adults but are less common in men and children *(20)*.

Children with CRS usually show birth defects in infancy, such as cataracts, loss of hearing or other disabilities, but some do not show signs for two to four years. Infants who survive the neonatal period may have serious developmental disabilities and developmental delays.

16.1.4 What are the complications of rubella?

Complications of rubella tend to occur more often in adults than in children. Encephalitis occurs in about 1 in 6000 cases and is most common in women. Problems with bleeding occur in about 1 in 3000 cases, usually among children. Guillain-Barré syndrome has been reported rarely.

The most severe complication of rubella infection is CRS, which occurs when a woman is infected during early pregnancy. CRS causes multiple congenital abnormalities in up to 90% of infections and may result in miscarriage or stillbirth *(20)*.

16.1.5 What is the treatment for rubella and CRS?

There is no specific antiviral medication for rubella or for CRS. Supportive measures should be taken to alleviate symptoms *(20)*.

16.1.6 How are rubella and CRS prevented?

Rubella and CRS are prevented with safe and effective rubella vaccines. For infant immunization, rubella vaccine is usually given in combination with measles or measles and mumps vaccine (see sections 9 and 11 of this module).

For prevention of CRS, women of childbearing age are the primary target group and are most effectively protected indirectly through the herd immunity created by rubella immunization programmes in childhood *(20)*.

16.1.7 What is needed for global rubella and CRS disease control?

The global burden of rubella and CRS has decreased significantly over time due to vaccination, and the remaining burden can be readily addressed along with measles control efforts using combination vaccines (MR, MMR). Rubella and CRS are therefore part of the Global Measles and Rubella Strategic Framework described in section 9.1.7 of this module. WHO recommends universal introduction of rubella-containing vaccine in routine immunization programmes for the prevention of the burden of CRS in countries that have not yet introduced a rubella-containing vaccine *(20)*.

16.2 Vaccines

16.2.1 What are rubella-containing vaccines?

MR and MMR are supplied as freeze-dried (lyophilized) powders. They must be reconstituted before use (see Module 5, section 4.2, on reconstitution of vaccines). Rubella-containing vaccines must be stored at +2 °C to +8 °C *(2, 20)*. Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4, for WHO MDVP).

Rubella-containing vaccines are administered in 0.5 mL doses by subcutaneous injection.

16.2.2 How safe is rubella-containing vaccines and what are the potential adverse events?

Adverse events following immunization with rubella-containing vaccines are mild in children. Rubella vaccine may cause a temporary form of arthritis one to three weeks after vaccination in up to 1 in 4 post-pubertal females (those who have reached sexual maturity). This event is very rare in young children. Long-term joint disease has not been associated with rubella containing-vaccines, after reviewing the data from large studies *(20)*.

WHO has created information sheets containing more detail on vaccine reaction rates, including for the MMR combination vaccine.

16.2.3 When is rubella-containing vaccine administered?

The first dose of rubella-containing vaccine should be given at 9 to 12 months of age. It should be introduced into childhood immunization programmes with a preceding wide age-range campaign (9 months through 14 years) and through the two-dose schedule for MCV, to ensure that no children reach adulthood remaining susceptible. The same combined vaccine formulation should subsequently be used for all routine doses, outbreak response immunizations and campaigns. Countries should establish national schedules for older children, adolescents and adults as needed *(20)*.

Key points about rubella and CRS

- Rubella and CRS are caused by a virus.
- Rubella is normally a mild childhood disease. The rash associated with rubella infection may not occur in 20% to 50% of cases.
- Women who contract rubella early in pregnancy can pass the virus to their foetuses. This can lead to foetal death or CRS.
- CRS can include birth defects of the ears, eyes, heart and brain.
- WHO currently recommends that countries use rubella vaccine in conjunction with measles vaccine (MR or MMR), with the goal of rubella and CRS elimination.

Table 1.17 Rubella-containing vaccine summary *(2, 20)*

Type of vaccine	Live attenuated (weakened) vaccine
Total number of doses	1 (but when given in combination with measles and mumps, 2 doses are required for programmatic reasons)
Schedule	• 9 to 12 months of age with MCV • Refer to national schedules for older children, adolescents and adults
Contraindications	• Known allergy to vaccine components (including neomycin and gelatine) • Pregnancy • Severe congenital or acquired immune disorders, including advanced HIV infection/AIDS
Special precautions	None
Adverse events	• Mild and transient: pain, redness, induration at the injection site; low-grade fever and irritability in infant vaccinees; lymphadenopathy and myalgia in adult vaccinees • In some women, arthritis (joint inflammation) and arthralgia (joint pain)
Dosage	0.5 mL
Injection site	• Anterolateral (outer) thigh in infants • Deltoid muscle of upper arm in children older than 12 months and adults
Injection type	Subcutaneous
Storage	• Between +2 °C and +8 °C • When using combination vaccines (MMR), keep them away from heat and sunlight.

17 Seasonal influenza

17.1 Disease

17.1.1 What is seasonal influenza?

Seasonal influenza is a respiratory disease caused by influenza viruses A and B. Globally, it is estimated that seasonal influenza infects, with or without apparent symptoms of infection, 1 in 5 unvaccinated children and 1 in 10 unvaccinated adults each year. Each year, there are an estimated 1 billion cases of influenza globally, of which 3 million to 5 million are severe, and between 290 000 and 650 000 influenza-related respiratory deaths *(21)*. Both A and B viruses cause seasonal influenza epidemics and out-of-season outbreaks.

Groups at particular risk of severe influenza or complications include older adults, pregnant women and women up to two weeks postpartum, children under 5 years of age (particularly those under 2 years of age) and individuals with underlying health conditions, including chronic heart, lung, kidney and liver disease, metabolic and endocrine disorders (such as diabetes) and immunosuppressive conditions (such as HIV/AIDS, organ transplantation, etc.). Health workers are at increased risk of exposure to and transmission of influenza virus *(21)*.

17.1.2 How is seasonal influenza spread?

Influenza A and B viruses are spread mainly by droplets and aerosols originating from the respiratory secretions of infected people when they cough, talk or sneeze, and occasionally via contact with virus-contaminated fomites (that is, various contaminated objects or materials) *(21)*.

17.1.3 What are the symptoms and signs of seasonal influenza?

Infection can range from asymptomatic to severe illness and death. Symptoms of influenza usually occur after a one- to four-day incubation period and include any or all of the following: fever, cough, sore throat, runny nose, headache and muscle and joint aches. Signs of severe disease in children include difficulty breathing, faster breathing, poor feeding, irritability, dehydration and decreased alertness.

Confirmation of influenza infection requires diagnostic testing, as the symptoms cannot be distinguished from those caused by several other infectious agents. Diagnostic tests for influenza include rapid antigen testing (for example, “point-of-care” tests) and reverse transcription polymerase chain reaction (RT-PCR) *(21)*.

17.1.4 What are the complications of seasonal influenza?

Possible serious complications include pneumonia, myocarditis, encephalitis, myositis (inflammation in muscles), rhabdomyolysis (breaking down of skeletal muscles), sepsis and multiple organ failure. Secondary bacterial infection is a frequent complication in the elderly and people with certain chronic diseases, commonly caused by *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Haemophilus influenzae* or *Staphylococcus aureus*. Further, the risk of stroke and myocardial infarction is elevated in the weeks following influenza disease.

Pregnant women may be at increased risk of severe disease and complications for their babies, such as stillbirth, foetal death and low birth weight. Elderly persons have the highest risk of complications, hospitalization and mortality from influenza *(21)*.

17.1.5 What is the treatment for seasonal influenza?

Several antiviral drugs are available to treat influenza. For persons with suspected or confirmed influenza virus infection with or at risk of severe illness, WHO recommends administering oseltamivir as soon as possible as the first-line treatment. Oseltamivir is widely used, with accumulated safety data that include treatment in young children and pregnant women *(21)*.

17.1.6 How is seasonal influenza prevented?

To prevent seasonal influenza, WHO recommends annual vaccination for high-risk groups, including health workers, older adults, people with underlying conditions and pregnant women. Infants may be protected by passively acquired immunity from their mother for the first 6 to 9 months of their life. Children may also be vaccinated, based on the local burden of disease, available resources and competing health priorities. Other groups to be considered for vaccination include people at high risk of severe influenza who are living in crowded settings, such as prisons, refugee camps and group homes *(21)*.

Other measures to prevent influenza include hand hygiene, respiratory etiquette, wearing masks, physical distancing and isolation.

17.2 Vaccines

17.2.1 What seasonal influenza vaccines are available?

Inactivated and live attenuated (weakened) seasonal influenza vaccines are available as either trivalent or quadrivalent formulations *(2, 21)*. There is a need for determination of strain composition for new vaccines every year, and influenza vaccine is updated every season based on the circulating strains, to optimize and maximize the vaccine protection.

The current trivalent formulation includes two influenza A subtypes (H1N1 and H3N2) and one influenza B virus (Yamagata or Victoria lineage), while the quadrivalent contains the

two influenza A subtypes and the two influenza B lineages. WHO currently recommends vaccines without B Yamagata antigen: trivalent influenza A/H1N1, A/H3N2 and B/Victoria).

Inactivated influenza vaccines are available in single-dose and multi-dose vials and as prefilled syringes. There are high-dose inactivated vaccines and adjuvanted inactivated influenza vaccine.

- Since 2019, high-dose inactivated vaccines are available primarily for use in people aged 65 years or older.
- Since 2022, four adjuvants (aluminium salts, AF03, AS03 and MF59) have been licensed for use in influenza vaccines, to improve immune response in older adults and particularly in people with reduced immune system function.

Inactivated influenza vaccines are administered intramuscularly, into the deltoid muscle for individuals 1 year of age or older or the anterolateral (outer) thigh for infants aged 6 to 12 months.

Live attenuated influenza vaccines (LAIV) are administered as single-dose intranasal spray. They are not currently recommended for children under 2 years of age, older adults and persons with comorbidities, because vaccine effectiveness has not been consistently demonstrated in these groups. LAIV are not recommended during pregnancy.

Recombinant vaccines, registered for use in persons over 18 years of age, are not widely available. Next-generation and broadly protective vaccines are currently under clinical investigation.

Inactivated influenza vaccines and LAIV can be co-administered with other vaccines (including other routine childhood vaccines, COVID-19 vaccines, etc.) at the same visit. LAIV do not interfere with the immune response to MMR or varicella vaccines when administered at the same visit.

Influenza vaccines do not require reconstitution. They must be stored at +2 °C to +8 °C and should never be frozen.

17.2.2 How safe are influenza vaccines and what are the potential adverse events following immunization?

Inactivated influenza vaccines are safe and well tolerated by recipients of all ages, including individuals with underlying conditions and pregnant women *(21)*. Mild adverse reactions (such as mild pain at the injection site) are frequent but self-limiting, lasting no more than one to two days. Serious adverse events are rare; they include anaphylaxis in 0.2 to 1.5 cases per 1 000 000 vaccinations, and Guillain-Barré syndrome in 1 to 2 cases per 1 000 000 persons vaccinated. However, the data suggest that the relative and attributable risks of Guillain-Barré syndrome after seasonal influenza vaccination are lower than those after influenza illness.

Inactivated influenza vaccines are contraindicated in cases of known allergic reaction to a previous dose or to a vaccine component. People with known egg allergies may be given egg-based influenza vaccine but should be observed for at least 15 minutes afterwards in settings with appropriate medical care.

The safety of high-dose, adjuvanted and recombinant vaccines is comparable to that of traditional inactivated vaccines, with slightly higher reactogenicity *(21)*.

LAIV have generally been well tolerated in healthy children and adults *(21)*. When symptoms do occur, they include self-limiting mild nasal congestion or runny nose, sore throat and low-grade fever. High-grade fever occurs in fewer than 1% of LAIV recipients. LAIV have also been studied in people with various chronic conditions, including asthma, chronic obstructive pulmonary disease and cystic fibrosis. They do not appear to be associated with exacerbations of these conditions or other adverse events.

17.2.3 When and how are influenza vaccines recommended?

For high-risk groups, annual vaccination, before the start of the influenza season in temperate climates, should be incorporated into immunization programmes, following national policy. For countries in tropical and subtropical areas with multiple peaks or year-round activity, WHO recommends that seasonal influenza vaccine be given prior to the start of the primary period of increased influenza activity *(21)*.

Pregnant women can be vaccinated in any trimester of pregnancy, preferably prior to the start of the influenza season. Immunizing pregnant women also benefits their babies after birth through passively acquired immunity from their mother.

For elderly persons, vaccination is the most effective public health intervention to reduce their risk of death from influenza. It is important that health care workers receive the vaccine, to reduce the risk of transmission to patients and to reduce absenteeism.

An annual (seasonal) single dose is recommended for persons over 9 years of age, including pregnant women. Children aged 6 months to 8 years who have never been vaccinated should be given two doses at least four weeks apart, then one dose every subsequent season. Children aged 6 to 35 months should receive a paediatric dose.

Annual vaccination (or revaccination, if the vaccine strains are identical to the previous season's vaccine) is recommended. Previously vaccinated children aged 6 months to 9 years should receive only one dose.

Key points about seasonal influenza

- Seasonal influenza due to influenza virus types A and B results in significant morbidity and mortality worldwide and, each year, represents a public health problem with substantial socioeconomic implications.
- Health workers, pregnant women, older adults and individuals with underlying conditions are of the highest priority for vaccination.
- Annual vaccination is recommended, particularly for high-priority groups.

Table 1.18 Influenza vaccine summary *(2, 21)*

Type of vaccine	Inactivated influenza vaccines and LAIV seasonal influenza vaccines available as: • trivalent vaccines (with two subtypes of influenza A and one lineage of influenza B), or • quadrivalent vaccines (with two subtypes of influenza A and two lineages of influenza B) Currently WHO recommends trivalent vaccines (without Yamagata strain).
Total number of doses	Inactivated influenza vaccines: • 1 dose for individuals ≥9 years of age, including pregnant women and adults • 2 doses for children 6 months to 8 years of age (children 6 to 35 months should receive a paediatric dose) who have not been vaccinated before. If vaccinated before, one dose every season LAIV: • A single dose of the vaccine is appropriate for children aged ≥9 years and healthy adults.
Schedule	Annual
Contraindications	• Anaphylaxis or hypersensitivity after a previous dose, or known allergies to any component of the vaccine • People with known egg allergies may be given egg-based influenza vaccine, provided they are observed for at least 15 minutes afterwards in a setting where appropriate medical care is available. • LAIV are contraindicated in children with an acute episode of asthma at the time of vaccination and in children with severe asthma or with advanced immunodeficiency. • LAIV are not currently recommended for children under 2 years of age, older adults, pregnant women and persons with comorbidities.
Special precautions	Vaccination can be postponed in the case of moderate to severe illness (with temperature).
Adverse events	• Mild: frequent but self-limiting injection site reactions, fever • Serious: rare anaphylaxis, Guillain-Barré syndrome
Dosage	• Inactivated influenza vaccines: 0.5 mL • Paediatric dose (6 to 35 months): 0.25 mL
Administration/ Injection type and site	• Inactivated influenza vaccines: intramuscular – anterolateral (outer) mid-thigh in infants (6 to 12 months); deltoid muscle of upper arm in children older than 12 months and adults • LAIV: intranasally
Storage	Between +2 °C and +8 °C; do not freeze

18 Tetanus

18.1 Disease

18.1.1 What is tetanus?

Tetanus is caused by a toxin produced by the spores of the bacterium *Clostridium tetani*, which is present everywhere in the environment, particularly in soil and in the intestinal tract, faeces and saliva of animals and humans. Tetanus toxin affects the central nervous system, causing painful and prolonged muscle spasms that can lead to death *(22)*.

Neonatal tetanus (in newborns) and maternal tetanus are serious problems in areas lacking immunization programmes, antenatal care and clean and safe birth practices.

18.1.2 How is tetanus spread?

Tetanus is not transmitted from person to person. The spores, being resistant to heat and most antiseptics, can survive for years. The bacterium can enter the human body through contaminated wounds, including burn wounds containing dead tissue, and deep cuts from items such as nails, knives, tools and splinters; unhygienic deliveries and abortions; and poor postnatal hygiene and cord care practices. Tetanus can occur at any age. In newborns, infection can occur when tetanus spores are introduced through the umbilical cord during delivery (by using unclean instruments to cut the umbilical cord) or after delivery (by dressing the umbilical stump with substances contaminated with tetanus spores).

Infants and children may also contract tetanus when circumcision, scarification or skin piercing are performed under unhygienic conditions or when dirt, charcoal or other unclean substances are rubbed into a wound *(22)*.

18.1.3 What are the symptoms and signs of tetanus?

The incubation period is usually three to 21 days but can be as much as several months, depending on the wound. Higher mortality rates are associated with shorter incubation periods.

In children and adults, muscular stiffness in the jaw (trismus or lockjaw) is a common first sign of generalized tetanus, the most common clinical presentation. This is followed by stiffness in the neck, abdomen and/or back, difficulty swallowing, muscle spasms, sweating and fever. Newborns with tetanus are normal at birth but develop excessive crying and increasing difficulty sucking and breastfeeding between three and 18 days after birth *(22)*.

18.1.4 What are the complications of tetanus?

As the disease progresses, muscle spasms occur spontaneously and become more intense. This can lead to convulsive fits and fractures of the spine or other bones. Breathing becomes difficult as spasms become more frequent and prolonged, leading to respiratory failure and death. In neonatal tetanus, death can occur as a result of paralysis of the respiratory muscles and/or inability to feed. Long-term neurologic impairment has been described in survivors of neonatal tetanus.

18.1.5 What is the treatment for tetanus?

Tetanus at any age is a medical emergency requiring hospitalization and immediate treatment. The treatment includes anti-tetanus immunoglobulins, drugs to control muscle spasms, maintaining a safe airway, antibiotics and wound care. Supportive care should be provided, such as keeping patients in a dark and quiet environment, and patients should be carefully monitored *(22)*.

18.1.6 How is tetanus prevented?

Tetanus toxoid-containing vaccine (TTCV) protects against tetanus. Infants and children may receive combination vaccines, such as DTP (diphtheria, tetanus and pertussis), pentavalent (DTP+HepB+Hib), hexavalent (DTP+HepB+Hib+IPV) or DT. Anyone aged 7 years and older should receive Td, which contains tetanus toxoid and lower levels of diphtheria antigen *(22)*.

Neonatal tetanus can be prevented by vaccinating women of reproductive age with TTCV, either during or before pregnancy. Clean delivery procedures are needed, even when the mother has been vaccinated. Clean umbilical cord care for the newborn is equally important.

People who recover from tetanus do not have natural immunity and can be infected again. WHO recommends completing a six-dose schedule consisting of three primary infant doses and three booster doses, preferably completed by adolescence *(22)*.

18.1.7 What is needed for global tetanus disease control?

WHO, the United Nations Children's Fund (UNICEF) and the United Nations Population Fund (UNFPA) set 2015 as the target date for the worldwide elimination of maternal and neonatal tetanus, which means less than 1 case per 1000 live births per year in every district. While progress continues to be made, that goal has not been reached yet. Because the tetanus bacterium survives in the environment, eradication of tetanus is not feasible, and high levels of immunization need to be maintained to sustain elimination.

The strategies to achieve the maternal and neonatal tetanus elimination goal are improved vaccination coverage of pregnant women with TTCV, vaccination of all women of reproductive age in high-risk areas, promotion of clean delivery and cord care practices and improved surveillance and reporting of neonatal and non-neonatal tetanus cases.

After maternal and neonatal tetanus elimination, countries must maintain high coverage of pregnant women with TTCV through routine immunization; use all opportunities, such as mother-and-child health days and periodic intensification of routine immunization, to ensure high protection; promote school-based TTCV booster doses; encourage clean delivery and cord care practices; and maintain surveillance of cases *(23)*.

18.2 Vaccines

18.2.1 What is TTCV?

Tetanus toxoid vaccine is available as TT, which protects only against tetanus. It is also available in combination vaccines: DTP and DT, pentavalent (DTP+HepB+Hib) and hexavalent (DTP+HepB+Hib+IPV) vaccines. For booster doses, a tetanus-diphtheria combination with lower concentration of diphtheria antigen (Td) is strongly encouraged to also help maintain high diphtheria immunity throughout the life course.

TT vaccine is supplied as a liquid in single-dose and multi-dose vials and also in prefilled auto-disable syringes. To help maintain high diphtheria and high tetanus immunity during the life course, WHO encourages use of TTCV combinations with diphtheria toxoid. Combination tetanus toxoid-containing vaccines, which are freeze dried, require reconstitution (see Module 5, section 4.2, on reconstitution of vaccines). TTCV must be stored at +2 °C to +8 °C and must not be frozen *(2, 22)*. If freezing is suspected, the shake test can be performed to determine whether a vaccine is safe to use (see Module 2, section 8). Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4, for WHO MDVP).

TTCV is administered as 0.5 mL doses given intramuscularly in the anterolateral (outer) thigh in infants and in the deltoid muscle (upper arm) of older children and adults.

18.2.2 How safe is TTCV and what are the potential adverse events following immunization?

TTCV is considered very safe. Local and systemic reactions occur, and they are more common and more intense with each subsequent dose. Local reactions are mild and include injection site pain and redness in 50% to 80% of those who receive a booster vaccination. Systemic reactions, including mild fever, aches and malaise, occur in 0.5% to 10% of those receiving a booster injection.

Serious adverse events such as anaphylaxis are very rare (1.6 per 1 000 000 Td doses administered), while severe generalized adverse events such as brachial neuritis (inflammation of arm nerves) are extremely rare. Guillain-Barré syndrome has been reported rarely following TT vaccination, but results of population-level studies do not support an association between TT vaccination and Guillain-Barré syndrome *(22)*.

WHO has created information sheets containing more detail on vaccine reaction rates, including for the combination DTP vaccines.

18.2.3 When is TTCV given?

For long-term immunity against tetanus in all individuals, a total of six TTCV doses, given in a primary series of three doses and three booster doses, is recommended. The first dose of the primary series can be given from 6 weeks of age, with a minimum interval of four weeks between doses. The third dose of the primary series should be completed by 6 months of age. In case the start or the completion of the primary series has been delayed, the missing doses should be given at the earliest opportunity, with a minimum interval of four weeks between doses. Booster doses should be completed by adolescence and given at ages 12 to 23 months of age, 4 to 7 years and 9 to 15 years. Ideally, there should be at least four years between booster doses *(22, 23)*.

If tetanus vaccination is started during adolescence or adulthood, a total of five appropriately spaced doses are required to obtain lifelong protection. This means that pregnant women and their newborn infants are protected from tetanus if the mother received either six TTCV doses during childhood or five doses if first vaccinated during adolescence/adulthood. If they have no reliable information on previous vaccination, pregnant women should receive at least two doses of TTCV (Td), with four weeks between the doses and the second dose at least two weeks before the birth *(22, 23)*.

Key points about tetanus

- Tetanus is caused by a toxin produced by the spores of the bacterium *Clostridium tetani*, which is present everywhere in the environment.
- The bacterium can enter the human body through a contaminated cut, injury or puncture wound from items such as dirty nails, knives, tools, wood splinters, unhygienic deliveries and abortions and poor postnatal hygiene and cord care practices.
- Neonatal and maternal tetanus are serious problems in areas where immunization programmes, antenatal care and clean and safe birth practices are lacking. Clean delivery and cord care practices should be ensured.
- Most newborns who contract tetanus will die.
- The best way to prevent tetanus is to give a six-dose schedule of three primary infant and three booster doses of TTCV.

Table 1.19 Tetanus-toxoid vaccine summary *(2, 22, 23)*

Type of vaccine	Toxoid
Total number of doses	• 6, if starting in infancy: 3 primary and 3 booster doses • 5 doses appropriately spaced, if starting in adolescence or adulthood
Schedule	Primary series for infant vaccination: TTCV as DTP1/pentavalent1/hexavalent1 starting at minimum 6 weeks of age, with 2 more doses at intervals of minimum 4 weeks after the previous dose
Booster	To be completed by adolescence and given at 12 to 23 months, 4 to 7 years and 9 to 15 years. Ideally, there should be at least 4 years between the booster doses.
Contraindications	Anaphylaxis or hypersensitivity after a previous dose, or known allergies to any component of the vaccine
Special precautions	None
Adverse events	• Mild: injection site reactions (pain, redness), mild fever, aches, malaise • Serious: uncommon, very rare such as anaphylaxis (1.6 per 1 000 000 Td doses administered); extremely rare brachial neuritis
Dosage	0.5 mL
Injection site	• Anterolateral (outer) thigh in infants • Deltoid muscle of upper arm in children older than 12 months and adults
Injection type	Intramuscular
Storage	Between +2 °C and +8 °C; do not freeze

19 Tuberculosis

19.1 Disease

19.1.1 What is tuberculosis?

Tuberculosis (TB) is an infectious disease caused by the bacterium *Mycobacterium tuberculosis*, which most often affects the lungs but can also affect other parts of the body, including the bones, kidneys, joints and brain.

TB is preventable and curable. Not everyone who is infected with TB bacteria develops TB disease. WHO estimates that about a quarter of the global population has been infected with TB bacteria, and about 5% to 10% of them will develop TB disease at some point in their life *(24)*.

19.1.2 How is TB spread?

TB is spread from one person to another through the air, often when a person with TB in their lungs (pulmonary TB) coughs or sneezes. TB spreads rapidly, especially in areas where people are living in crowded conditions, have poor access to health care and/or are malnourished. People with TB disease in their lungs can infect others directly, but infectiousness diminishes rapidly after the start of effective treatment.

A person can contract bovine tuberculosis, another variety of TB, by consuming contaminated unpasteurized dairy products made with milk from infected cattle.

People of all ages in all countries can develop TB. People with TB infection who have weakened immune systems (such as people with diabetes or HIV) are more likely to develop TB disease. Infants and young children (especially those younger than 2 years of age) are at higher risk of developing severe forms of disease associated with a high rate of mortality *(24)*.

19.1.3 What are the symptoms and signs of TB?

The TB infection may persist for months or even years before TB disease develops. The symptoms of TB include general weakness, weight loss, fever and night sweats. For pulmonary TB, symptoms also include persistent cough, coughing up of blood and chest pain. In young children, however, the only sign of pulmonary TB may be stunted growth or failure to thrive. Other symptoms and signs depend on the part of the body that is affected. For example, in tuberculosis of the bones and joints, there may be swelling, pain and crippling effects on the hips, knees or spine *(24)*.

19.1.4 What are the complications of TB?

TB can present in many ways and may be very difficult to diagnose. Untreated TB can result in debility and death. This may be more rapid in immunocompromised people *(24)*.

19.1.5 What is the treatment for TB?

TB disease is curable. It is most commonly treated by a standard six-month course of four antibiotics: isoniazid, rifampicin, ethambutol and pyrazinamide. In some cases, drug-resistant TB bacteria do not respond to the standard drugs. Treatment for drug-resistant TB is more complex *(24)*.

In the case of TB infection (where the patient is infected with TB bacteria but not ill), TB preventive treatment can be given to stop the progression to disease. This approach uses the same (or similar) drugs as TB treatment, but for a shorter time. Recent treatment options have shortened the duration of treatment to only one or three months, as compared to six months. Other approaches to prevent TB include TB infection control to stop transmission and action on a broad set of TB determinants (such as poverty, diabetes, smoking, alcohol, malnutrition, HIV).

The course of TB drugs is provided to the patient with information, supervision and support by a health worker or trained volunteer. This support can be provided in person or remotely. Without such support, treatment adherence can be difficult. If the treatment is not properly completed, the disease can relapse after the initial cure or become drug resistant and can continue to spread.

19.1.6 How is TB prevented?

The predominant approach to preventing TB is through vaccination with the existing vaccine bacille Calmette–Guérin (BCG) at or soon after birth. While BCG has demonstrated significant effectiveness in several populations, protection has not been consistent against all forms of TB and in all age groups. BCG effectiveness decreases at adolescence, and, for this reason, several new TB vaccine candidates are being developed for use in this age group, as well as for adults and older adults *(24)*.

19.2 Vaccines

19.2.1 What is BCG vaccine?

BCG vaccine is administered to protect infants against tuberculosis.

BCG vaccine is supplied in freeze-dried (lyophilized) powder form. It must be reconstituted with a diluent before use (see Module 5, section 4.2, on reconstitution of vaccines). BCG vaccine must be stored at +2 °C to +8 °C after reconstitution *(2, 24)*. Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4, for WHO MDVP).

19.2.2 How safe is BCG vaccine and what are the potential adverse events following immunization?

BCG is injected intradermally (between the layers of the skin). About 95% of BCG vaccine recipients experience a reaction at the injection site that usually resolves within two to five months to leave a superficial scar. When BCG vaccine is injected, a small raised lump usually appears at the injection site and then disappears within 30 minutes. After about two weeks, a red sore (about the size of the end of an unsharpened pencil) forms. This sore usually lasts for another two weeks and then heals, leaving a small scar about 5 mm across. This reaction is considered normal, and the scar is a sign that the child has been effectively immunized.

Severe events include swelling and abscesses in about 1 per 1000 to 10 000 doses. Swollen glands (in the armpit or near the elbow) and/or abscesses sometimes occur because an unsterile needle or syringe was used, too much vaccine was injected or, most commonly, the vaccine was injected incorrectly under the skin (subcutaneously) instead of into the top layer (refer to Module 5, section 4.8, for intradermal injection technique).

Serious events following immunization with BCG include generalized infection in about 1 per 230 000 to 640 000 doses of vaccine given, primarily in people living with HIV or those with severe immune deficiencies. However, if HIV-infected individuals, including children, are receiving therapy (antiretroviral therapy), are clinically well and immunologically stable, they should be vaccinated with BCG *(24)*.

WHO has created information sheets containing more detail on vaccine reaction rates, including for the BCG vaccine.

19.2.3 When is BCG vaccine administered?

WHO recommends BCG vaccination at birth in countries or settings with a high incidence of TB and/or high leprosy burden, as well as for high-risk children living in countries with low disease burden. A single dose of BCG vaccine should be given routinely at, or as soon as possible after, birth to all infants except those known to be severely immunocompromised.

Serious adverse events following immunization (AEFI) can occur in HIV-infected infants; however, the benefits of potentially preventing severe TB through vaccination at birth are outweighed by the risks associated with the use of BCG vaccine. WHO recommends that neonates born to women of unknown HIV status be vaccinated if they have no clinical evidence suggestive of HIV infection. For neonates with confirmed HIV infection, BCG vaccination should be delayed until antiretroviral therapy has been started and the infant has been confirmed to be immunologically stable.

BCG vaccination is recommended for unvaccinated older children with negative results to currently available tests for TB infection (i.e. TST – tuberculin skin test, or IGRA – interferon-gamma release assay) *(24)*.

Key points about tuberculosis

- TB usually affects the lungs but can affect other parts of the body, including the bones, kidneys, joints and brain.
- TB is spread through infectious particles in the air.
- The symptoms of TB disease include general weakness, cough, chest pain, weight loss, fever and night sweats.
- People who develop TB disease must complete a course of drug therapy to cure it and to avoid spreading it to others.
- The recommended TB prevention for infants and children is BCG vaccine given at, or as soon as possible after, birth and before 12 months of age.

Table 1.20 BCG vaccine summary *(2, 24)*

Type of vaccine	Live bacterial
Total number of doses	1
Schedule	At or as soon as possible after birth
Booster	None
Contraindications	• Known allergy to any component of the vaccine • Congenital or severe combined immunodeficiency, immunodeficiency syndromes (for example, HIV/AIDS, known or suspected congenital immunodeficiency, leukaemia, lymphoma or other malignant disease) • Patients undergoing immunosuppressive treatment (for example, corticosteroids, alkylating agents, biological response modifiers, antimetabolites, radiation)
Special precautions	Correct intradermal administration is essential – a specific syringe and needle are used for BCG (see Module 5, section 4.8).
Adverse events	• Severe: injection site abscess, regional lymphadenitis (lymph node inflammation) • Serious: generalized disease or infections such as osteomyelitis (bone infection)
Dosage	0.05 mL
Injection site	Outer upper left arm or shoulder
Injection type	Intradermal
Storage	Between +2 °C and +8 °C; do not freeze

20 Typhoid fever

20.1 Disease

20.1.1 What is typhoid fever?

Typhoid fever is a systemic febrile illness caused by *Salmonella Typhi* (*Salmonella enterica* serovar *Typhi*), which can spread through the body, affecting many organs. Typhoid fever is an important public health problem in settings, both rural and urban, where access to safe water and adequate sanitation systems is lacking. Children are at highest risk. Without treatment, it can cause serious complications and death *(25)*.

20.1.2 How is typhoid fever spread?

Salmonella Typhi lives only in humans. Typhoid fever usually spreads by the faecal-to-oral route, through food or water contaminated with *Salmonella Typhi*. Some people, even after they have recovered, continue to carry typhoid bacteria in their gallbladder and intestines, and can spread it to others through shedding of bacteria in their faeces *(25)*.

20.1.3 What are the symptoms and signs of typhoid fever?

Symptoms of typhoid fever can appear seven to 14 days after infection and include prolonged high temperature that gradually increases each day, headache, extreme tiredness, nausea, abdominal pain, vomiting and constipation or diarrhoea. Diarrhoea is more common among younger children. Some people may develop a rash or faint pink spots, usually on the chest or stomach. If not treated with antibiotics, the bacteria can cause severe damage, usually around the third week after the symptoms first appear *(25)*.

20.1.4 What are the complications of typhoid fever?

Complications are more frequent among non-treated patients. When people are not immediately treated with appropriate antibiotics, 1 in 10 will experience complications, which develop usually around the third week of infection. The most common life-threatening complications are internal bleeding in the digestive system (intestinal haemorrhage) and perforation or splitting of a section of the digestive system or a bowel (intestinal perforation) *(25)*.

20.1.5 What is the treatment for typhoid fever?

Typhoid fever can be effectively treated with antibiotics. It is important to take antibiotics for the full length of treatment prescribed. Strains of *Salmonella Typhi* are increasingly becoming resistant to antibiotic treatment globally, and some are extremely resistant, which means that only a few antibiotics still work on them. This is why vaccination to

prevent typhoid fever is important. Severe symptoms such as persistent vomiting and diarrhoea may require hospitalization, where antibiotic injections, fluids and nutrients can be intravenously administered. Serious complications, such as internal bleeding and intestinal perforation, may require surgery *(25)*.

20.1.6 How is typhoid fever prevented?

Effective strategies for prevention and control of typhoid fever include access to safe water and adequate sanitation, adequate health education, hygiene, including appropriate hygiene among food handlers, and typhoid vaccination. Improvements to water supply, including filtration and chlorination, can reduce the burden of typhoid fever and have led to its elimination in many high-income settings.

Typhoid fever vaccines are recommended where typhoid fever regularly occurs and where outbreaks are occurring. When feasible and informed by epidemiologic data, a wide age-range (from 6 to 9 months to 15 years of age) catch-up campaign is recommended at the time of or immediately before typhoid vaccine introduction, to increase protection of unvaccinated persons and accelerate the impact of vaccine use *(25)*.

20.1.7 What is needed for typhoid fever control?

WHO recommends programmatic use of typhoid vaccines for the control of typhoid fever: introduction of vaccination is to be prioritized in countries with the highest burden of typhoid disease or a high burden of antimicrobial-resistant *Salmonella Typhi*.

All typhoid vaccination programmes should be implemented in the context of other efforts to control the disease, including health education, WASH improvements and the training of health professionals in diagnosis and treatment *(25)*.

20.2 Vaccines

20.2.1 What is typhoid fever vaccine?

There are three currently available types of typhoid vaccines: typhoid conjugate vaccines (TCV), unconjugated Vi polysaccharide vaccines and live attenuated (weakened) Ty21a vaccines. Among these, TCV is preferred at all ages for routine programmatic use because of its improved immunological properties, suitability for use in younger children and expected longer duration for protection. TCV consists of the purified Vi antigen, which is linked to a carrier protein. It is a liquid, ready-to-use injectable vaccine that, depending on the vaccine product, can come in one-dose or five-dose vials, which should be stored at +2 °C to +8 °C *(2, 25)*. Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4, for WHO MDVP).

20.2.2 How safe are typhoid vaccines and what are the potential adverse reactions?

The available TCV are safe and well tolerated *(25)*. Mild injection site reactions are common in any age group (1% to 10% of vaccine recipients) and include pain, redness, swelling or induration at the injection site. Less common are systemic reactions, such as fever and nausea; no serious adverse events have been reported.

Unconjugated Vi polysaccharide typhoid vaccines have also proved to be well tolerated and safe. A minimum of local injection site reactions and no serious adverse events were observed in settings where this vaccine was administered.

Live attenuated Ty21a oral vaccines were generally well tolerated, followed with transient fever and rash, and some gastrointestinal events (diarrhoea, vomiting).

WHO has created information sheets containing more detail on vaccine reaction rates, including for typhoid vaccines.

20.2.3 When is typhoid vaccine administered?

For primary vaccination, TCV is licensed as a single injectable dose in infants and children starting from 6 months of age. WHO recommends programmatic use of TCV as part of routine administration at the same time as other vaccine visits at 9 months of age, or in the second year of life.

When feasible and supported by epidemiologic data, and with consideration of operational issues and cost, WHO recommends catch-up vaccination with TCV in children up to 15 years of age, to accelerate the impact of vaccine use.

When unconjugated Vi polysaccharide typhoid vaccine is used, a single dose should be administered from 2 years of life onwards, with revaccinations every three years. No WHO-prequalified products of unconjugated Vi polysaccharide vaccines are available.

Live attenuated Ty21a vaccine requires a three-dose oral administration schedule, to be administered every other day, starting from 6 years of age, with revaccination every three to seven years in most endemic settings. No WHO-prequalified Ty21a vaccine products are available *(25)*.

Key points about typhoid fever

- Typhoid fever, caused by *Salmonella Typhi* (*Salmonella enterica* serovar *Typhi*), is a nonspecific febrile illness that can spread through the body and affect many organs.
- Typhoid fever usually spreads by the faecal-to-oral route, through contaminated food or water. Even after recovery, some people continue to carry typhoid bacteria in their body and can spread it to others.
- When people are not treated with appropriate antibiotics, they may experience complications, including life-threatening internal bleeding or perforation in the digestive system.
- Vaccination against typhoid fever should be implemented in the context of comprehensive efforts to control the disease.

Table 1.21 Typhoid fever conjugate vaccines (TCV) summary *(2, 25)*

Type of vaccine	Typhoid conjugate vaccine, fully liquid, ready to use
Total number of doses	1
Schedule	• Single dose at 9 months or in the second year of life • Minimum age 6 months, up to 45 to 65 years, depending on the vaccine product
Booster	Not recommended at this time
Contraindications	Hypersensitivity or known allergies to any component of the vaccine
Special precautions	None
Adverse events	• Mild local and systemic reactions: pain, redness, swelling, induration at the injection site, transient fever and nausea • No serious adverse events have been reported
Dosage	0.5 mL
Injection type	Intramuscular injection
Injection site	• Anterolateral (outer) thigh in infants • Outer deltoid muscle of upper arm in children and adults
Storage	Between +2 °C and +8 °C; do not freeze

21 Yellow fever

21.1 Disease

21.1.1 What is yellow fever?

Yellow fever is a mosquito-borne viral disease of humans and other primates. As of 2023, 34 countries in Africa and 13 countries in Central and South America are either endemic, or have regions that are endemic, for yellow fever *(26)*. Yellow fever is a high-impact, high-threat disease, with the risk of international spread, which represents a potential threat to global health security.

21.1.2 How is yellow fever spread?

Yellow fever is spread by several species of *Haemagogus* and *Aedes* mosquitoes, which typically bite during the day. In forest areas and humid regions of Africa and the Americas, people become infected by the bites of mosquitoes that have previously fed on infected nonhuman primates. During large epidemics in crowded urban areas, mosquitoes can spread the disease from person to person *(26, 27)*.

21.1.3 What are the symptoms and signs of yellow fever?

In many cases, infection with yellow fever virus can cause no symptoms or signs. For those that develop symptoms, signs usually appear three to six days after the infected mosquito bite and can include fever, headache, muscle pain, shivering, loss of appetite, nausea and vomiting, congestion of the conjunctivae and face and a relatively slow heart rate during fever.

Most symptoms resolve within a week, but approximately 15% of patients may develop more severe symptoms, such as jaundice (yellowing of the conjunctivae and skin), bleeding, and liver and kidney failure that can lead to death. Severe yellow fever can be confused with malaria, leptospirosis, viral hepatitis, other types of haemorrhagic fevers and poisoning *(26, 27)*.

21.1.4 What are the complications of yellow fever?

About 20% to 50% of patients who develop liver and kidney failure die, usually 7 to 10 days after the onset of the disease. Survivors may experience prolonged weakness and fatigue, but the liver and kidneys usually heal completely *(27)*.

21.1.5 What is the treatment for yellow fever?

There is no WHO recommendation for antiviral medication in yellow fever treatment. Supportive measures should be taken to alleviate symptoms. Severe cases usually require hospital care. Good and early supportive treatment in hospitals improves survival rates. Specific care to treat dehydration, liver and kidney failure, and fever improves outcomes. Paracetamol is used in mild cases that can be managed at home. Aspirin and similar medications should be avoided, since they may cause bleeding, particularly in the stomach and intestines *(26, 27)*.

21.1.6 How is yellow fever prevented?

Vaccination is the most important means of preventing yellow fever. Vaccination is recommended to protect people living in endemic and epidemic disease areas and travellers visiting these areas, and to prevent international spread by infected travellers. Routine vaccination of children is recommended in disease-endemic areas, which may be supplemented by campaigns to increase population coverage. Routine yellow fever vaccination has been very effective in endemic areas, but major outbreaks have occurred where coverage has decreased after the discontinuation of immunization campaigns. Measures to control mosquito populations (vector control) in urban areas should also be part of prevention strategies *(26, 27)*.

21.2 Vaccines

21.2.1 What is yellow fever vaccine?

Live attenuated (weakened) virus vaccines for preventing yellow fever are currently in use. They are supplied in freeze-dried (lyophilized) form and must be reconstituted with the diluent supplied by the manufacturer before use (see Module 5, section 4.2, on reconstitution of vaccines). Yellow fever vaccine must be stored at +2 °C to +8 °C and should not be frozen *(2, 27)*. Opened multi-dose vials must be handled according to national MDVP (see Module 2, section 1.4, for WHO MDVP).

Yellow fever vaccine is administered as a single 0.5 mL dose either subcutaneously in the upper arm or intramuscularly in the anterolateral thigh.

21.2.2 How safe is yellow fever vaccine and what are the potential adverse events following immunization?

Mild adverse events, such as injection site pain, headache, muscle ache, low-grade fever, itching, hives and other rashes are reported in up to 25% of vaccinated individuals.

Serious adverse events include hypersensitivity (allergy) or anaphylaxis (0.8 per 100 000 vaccinations) occurring most commonly in people with allergies to egg protein or gelatine. Yellow fever vaccine-associated neurologic disease (inflammation of different parts of the nervous system, including the brain) and viscerotropic disease

(affecting internal organs) have been reported. Rates of these serious events are very low (less than 1 in 100 000), but patients over 60 years of age receiving primary yellow fever vaccine doses seem to be at higher risk. Yellow fever vaccine-associated viscerotropic disease has been fatal in over 60% of cases *(27)*.

21.2.3 When is yellow fever vaccine administered?

A single dose of yellow fever vaccine is sufficient for life-long protection. In endemic countries, this vaccine should be integrated into routine immunization programmes. It is recommended for children aged 9 to 12 months receiving the vaccine at the same time as MCV, in accordance with each country's vaccination policy. For optimal immunization, the MCV and the yellow fever vaccine are administered during the same visit. If simultaneous administration is not possible, the vaccines should be given at least four weeks apart, to ensure full and effective coverage. Preventive mass immunization campaigns are also recommended in endemic countries with low yellow fever vaccine coverage. The vaccine should be administered to all individuals aged 9 months to 59 years in areas with reported cases to ensure comprehensive protection against the disease. Additionally, unvaccinated travellers aged 9 months to 59 years travelling to and from high-risk areas should receive yellow fever vaccine unless otherwise contraindicated. This approach maximizes protection and prevents the spread of yellow fever.

Yellow fever vaccine is contraindicated in children aged under 6 months and is generally not recommended for children aged 6 to 8 months, except during epidemics. It is also contraindicated for individuals with allergies to egg antigens and in HIV-infected individuals with CD4 T-cell values of under 200 per mm^3. For pregnant and lactating women, as well as individuals aged 60 years or older, a thorough benefit-risk assessment should be conducted.

Yellow fever vaccination provides effective immunity within ten days for 80% to 100% of people vaccinated, and within 30 days for more than 99% of people vaccinated *(27)*.

Key points about yellow fever disease

- Yellow fever is a viral disease spread by infected day-biting mosquitoes primarily in tropical zones of Africa and Central and South America.
- Yellow fever symptoms and signs can range from none to liver and kidney failure that leads to death. These symptoms can be easily confused with other diseases.
- No specific antiviral treatment is recommended at this time.
- A single dose of yellow fever vaccine is highly effective at preventing yellow fever, and, if not contraindicated, yellow fever vaccination should be given to all people aged 9 months or older living in or travelling to high-risk areas.

Table 1.22 Yellow fever vaccine summary *(2, 27)*

Type of vaccine	Live attenuated (weakened) vaccine
Total number of doses	1
Schedules	• In endemic areas: 9 to 12 months of age with MCV1 • In areas with reported cases: all persons aged ≥9 months • For travellers to high-risk areas: all persons aged ≥9 months
Booster	None
Contraindications	• Age <6 months; age 6 to 8 months, except during epidemics • Known allergy to egg antigens or after a previous dose • HIV infection with CD4 T-cell values <200 per mm^3
Special precautions	Carry out a risk-benefit assessment before administering to pregnant women or people aged >60 years
Adverse events	• Mild: injection site pain, headache, muscle ache, low-grade fever, itching, hives, rash • Serious: anaphylaxis, yellow fever vaccine-associated neurologic (affecting nerves) and viscerotropic disease (affecting internal organs), encephalitis in infants <6 months
Dosage	0.05 mL
Injection site	• Anterolateral (outer) thigh in infants and children (for intramuscular) • Outer upper left arm or shoulder for subcutaneous injection
Injection type	Subcutaneous or intramuscular
Storage	Between +2 °C and +8 °C

References[7]

1. Cholera vaccines: WHO position paper – August 2017. Weekly Epidemiological Record. 2017; 92(34):477–500 (https://iris.who.int/handle/10665/258764).

2. Prequalified vaccines [website]. World Health Organization (https://extranet.who.int/prequal/vaccines/prequalified-vaccines).

3. Coronavirus disease (COVID-19) questions and answers [website]. World Health Organization (https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-covid-19).

4. Tracking SARS-CoV-2 variants [website]. World Health Organization (https://www.who.int/activities/tracking-SARS-CoV-2-variants).

5. Coronavirus disease (COVID-19): vaccines and vaccine safety [website]. World Health Organization (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub).

6. Diphtheria vaccine: WHO position paper – August 2017. Weekly Epidemiological Record. 2017; 92(31):417–436 (https://iris.who.int/handle/10665/258683).

7. Haemophilus influenzae type b (Hib) vaccination: WHO position paper – July 2013. Weekly Epidemiological Record. 2013; 88(39):413–426 (https://iris.who.int/handle/10665/242126).

8. Hepatitis B vaccines: WHO position paper – July 2017. Weekly Epidemiological Record. 2017; 92(27):369–392 (https://iris.who.int/handle/10665/255873).

9. Human papillomavirus vaccines: WHO position paper (2022 update). Weekly Epidemiological Record. 2022; 97(50):645–672 (https://iris.who.int/handle/10665/365351).

10. Considerations for human papillomavirus (HPV) vaccine product choice, second edition. Geneva: World Health Organization; 2024. (https://iris.who.int/handle/10665/379113). License: CC BY-NC-SA 3.0 IGO.

11. Japanese encephalitis vaccines: WHO position paper – February 2015. Weekly Epidemiological Record. 2015; 90(09):69–88 (https://iris.who.int/handle/10665/242325).

12. Malaria vaccine: WHO position paper – March 2022. Weekly Epidemiological Record. 2022; 97(09):60–78 (https://iris.who.int/handle/10665/352337).

13. Measles vaccines: WHO position paper – April 2017. Weekly Epidemiological Record. 2017; 92(17):205–227 (https://iris.who.int/handle/10665/255377).

[7] All references were accessed on 25 May 2025.

14. Meningococcal vaccines: WHO position paper on the use of multivalent meningococcal conjugate vaccines in countries of the African meningitis belt – January 2024. Weekly Epidemiological Record. 2024; 99(01/02):1–10 (https://iris.who.int/handle/10665/375624).

15. Mumps vaccines: WHO position paper – March 2024. Weekly Epidemiological Record. 2024; 99(11):115–133 (https://iris.who.int/handle/10665/376287).

16. Pertussis vaccines: WHO position paper – August 2015. Weekly Epidemiological Record. 2015; 90(35):433–458 (https://iris.who.int/handle/10665/242413).

17. Pneumococcal conjugate vaccines in infants and children under 5 years of age: WHO position paper – February 2019. Weekly Epidemiological Record. 2019; 94(08):85–103 (https://iris.who.int/handle/10665/310970).

18. Polio vaccines: WHO position paper – June 2022. Weekly Epidemiological Record. 2022; 97(25):277–300 (https://iris.who.int/handle/10665/357168).

19. Rotavirus vaccines: WHO position paper – July 2021. Weekly Epidemiological Record. 2021; 96(28):301–319 (https://iris.who.int/handle/10665/342905).

20. Rubella vaccine: WHO position paper – July 2020. Weekly Epidemiological Record. 2020; 95(27):306–324 (https://iris.who.int/handle/10665/332952).

21. Vaccines against influenza: WHO position paper – May 2022. Weekly Epidemiological Record. 2022; 97(19):185–208 (https://iris.who.int/handle/10665/354265).

22. Tetanus vaccines: WHO position paper – February 2017. Weekly Epidemiological Record. 2017; 92(6):53–76 (https://iris.who.int/handle/10665/254583).

23. Protecting all against tetanus: guide to sustaining maternal and neonatal tetanus elimination (MNTE) and broadening tetanus protection for all populations. Geneva: World Health Organization; 2019 (https://iris.who.int/handle/10665/329882). License: CC BY-NC-SA 3.0 IGO.

24. BCG vaccines: WHO position paper – February 2018. Weekly Epidemiological Record. 2018; 93(08):73–96 (https://iris.who.int/handle/10665/260307).

25. Typhoid vaccines: WHO position paper – March 2018. Weekly Epidemiological Record. 2018; 93(13):153–172 (https://iris.who.int/handle/10665/272273).

26. Yellow fever [website]. World Health Organization (https://www.who.int/news-room/fact-sheets/detail/yellow-fever).

27. Vaccines and vaccination against yellow fever: WHO position paper – June 2013. Weekly Epidemiological Record. 2013; 88(27):269–283 (https://iris.who.int/handle/10665/242089).

Bibliography

Cholera [website]. World Health Organization (https://www.who.int/news-room/fact-sheets/detail/cholera).

Ending preventable child deaths from pneumonia and diarrhoea by 2025: the integrated global action plan for pneumonia and diarrhoea (GAPPD). Geneva: World Health Organization; 2013 (https://iris.who.int/handle/10665/79200).

Japanese encephalitis: vaccine preventable diseases surveillance standards. Geneva: World Health Organization; 2018 (https://www.who.int/publications/m/item/vaccine-preventable-diseases-surveillance-standards-je).

Measles and rubella strategic framework: 2021–2030. Geneva: World Health Organization; 2020 (https://iris.who.int/handle/10665/339801). License: CC BY-NC-SA 3.0 IGO.

Oral cholera vaccine stockpile [website]. World Health Organization (https://www.who.int/groups/icg/cholera/stockpiles).

Q&As on COVID-19 and related health topics [website]. World Health Organization (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub).

Therapeutics and COVID-19: living guideline. Geneva: World Health Organization; 2023 (https://app.magicapp.org/#/guideline/nBkO1E).

WHO guidelines for malaria. Geneva: World Health Organization; 2024 (https://doi.org/10.2471/B09146). License: CC BY-NC-SA 3.0 IGO.

WHO vaccine reaction rates information sheets [website]. World Health Organization (https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/guidance/reaction-rates-information-sheets).

MODULE 2

The vaccine cold chain

About this module

The purpose of the vaccine cold chain is to maintain product quality from the time of manufacture until the point of administration by ensuring that vaccines are stored and transported within WHO-recommended temperature ranges.

This module provides guidance for workers at the health facility level. It covers the use of cold-chain and temperature-monitoring equipment and the preventive maintenance of cold-chain equipment. The module describes the existing range of WHO-prequalified equipment at the time of publication. Up-to-date information on prequalified equipment is available on the WHO Performance, Quality and Safety website.

Some of the figures in this module show equipment from specific manufacturers. This is for illustrative purposes only and does not indicate WHO official endorsement of these products.

Contents

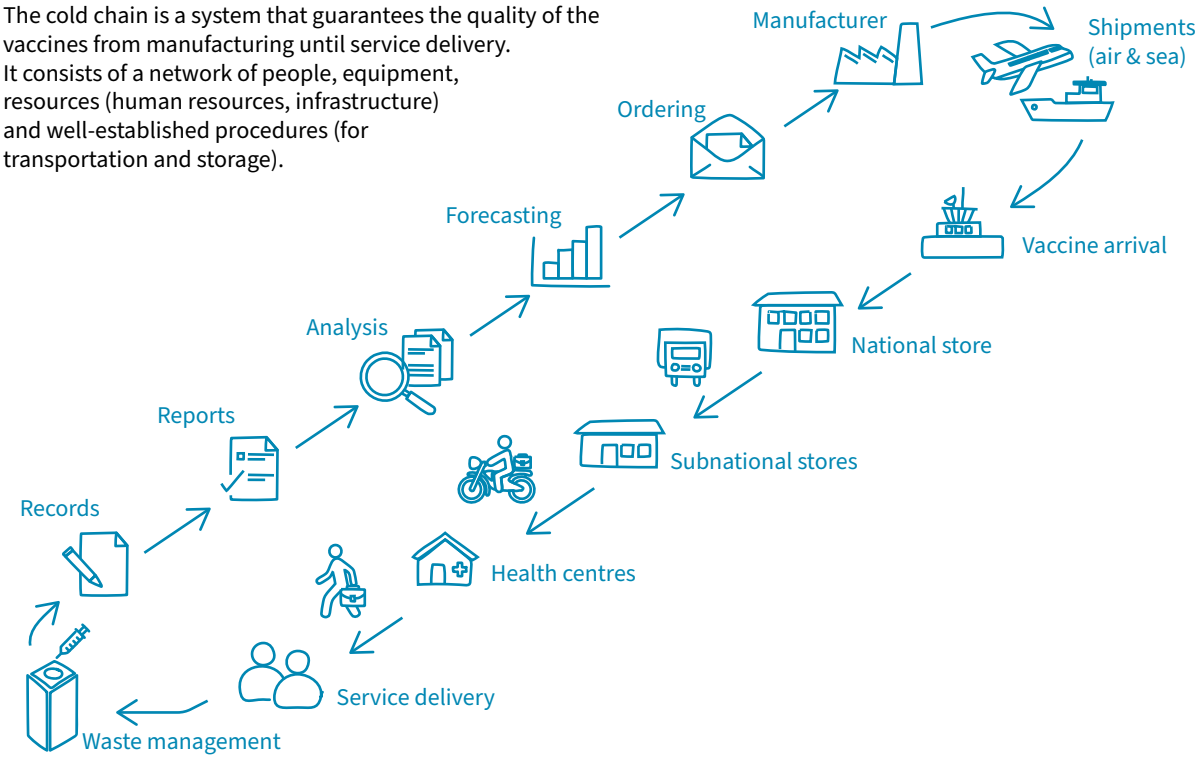
1 Managing the vaccine cold chain

A vaccine cold chain is a temperature-controlled supply chain that consists of a network of people, storage equipment and transport links that follow the standards for good management practices to keep vaccines within WHO-recommended temperature ranges at all times. Manufacturers, distributors, public health staff and health care providers share responsibility for ensuring the quality of vaccines from manufacturing until immunization service delivery. The vaccine cold chain can also store and distribute other temperature-sensitive health products as needed, as described in the WHO-UNICEF joint statement encouraging greater supply-chain integration of temperature-sensitive pharmaceuticals *(1)*.

Fig. 2.1 illustrates the complete cold-chain system. The right side shows the flow of vaccines to health facilities; the left side shows where data are collected, recorded, checked and analysed and how this information flows back up the chain. This sequence ensures that cold-chain performance is properly monitored and that the necessary information is gathered for vaccine forecasting and supply planning.

Fig. 2.1 The vaccine cold chain

The cold chain is a system that guarantees the quality of the vaccines from manufacturing until service delivery. It consists of a network of people, equipment, resources (human resources, infrastructure) and well-established procedures (for transportation and storage).



Source: WHO/EVM

To maintain a reliable vaccine cold chain at the lower supply-chain level, the following key procedures must be observed:

- store vaccines and diluents within the required temperature range at all supply-chain levels;
- pack vaccines and transport them to and from outreach sites according to recommended procedures;
- keep vaccines and diluents within recommended cold-chain conditions during immunization sessions.

1.1 Variation in vaccine temperature requirements

Vaccines are sensitive biological products. Some vaccines are sensitive to freezing, some to heat and some to light. Vaccine potency (its ability to protect the vaccination recipient adequately) can diminish when the vaccine is exposed to inappropriate temperatures and storage conditions. Once lost, vaccine potency cannot be regained. To maintain quality, vaccines must be protected from temperature extremes. Vaccine quality is maintained using a cold chain that meets specific temperature requirements. Fig. 2.2 shows recommended vaccine storage temperatures at each level of the cold chain. It is essential that all those who handle vaccines and diluents know the temperature sensitivities and the recommended storage temperatures for all the vaccines in the national schedule.

Fig. 2.2 Recommended vaccine storage temperatures by supply chain level (per typical supply cycle)

	Supply chain level:	National	Subnational	District	Service points	
	Storage duration:	Up to 6 months	Up to 3 months	1–3 months	Up to 1 month	
Temperature	Up to +25 °C	Rota[a]	Rota[a]	Rota[a]	Rota[a]	
	+2 °C to +8 °C	liquid[b] lyophilized[c] COVID-19	liquid[b] lyophilized[c] COVID-19 Ebola	liquid[b] lyophilized[c] OPV COVID-19 Ebola mpox	liquid[b] lyophilized[c] OPV COVID-19 Ebola mpox	WHO-prequalified COVID-19, Ebola, and mpox vaccines:[d] COVID-19: Bimervax , Covovax, Nuvaxovid, and Comirnaty Ebola: Ervebo, Mvabea, and Zabdeno mpox: MVA-BN
	-15 °C to -25 °C (-20 °C)	OPV lyophilized[e] Ebola mpox	OPV lyophilized[e] Ebola mpox	 Ebola mpox	 Ebola mpox	 Ebola: Zabdeno, Mvabea mpox: MVA-BN
	-60 °C to -90 °C (-80 °C)[f]	COVID-19 Ebola mpox	COVID-19 Ebola mpox			COVID-19: Comirnaty Ebola: Ervebo, Mvabea, and Zabdeno mpox: MVA-BN

[a] Rotasiil® vaccine can be stored at temperatures up to +25 °C, typically for around six months.

[b] Liquid vaccines: cholera, COVID-19, DT, DTP, DTP+combination, hepatitis A, hepatitis B, Hib, HPV, influenza, IPV, malaria, Men ACWY, mpox, PCV, rabies, rotavirus, Td, TT, typhoid PS

[c] Lyophilized (freeze-dried) vaccines: BCG, Hib, Japanese encephalitis (live attenuated), malaria, measles/MR/MMR, meningococcal A, mpox, rabies, rubella, rotavirus, respiratory syncytial virus (RSV), varicella, yellow fever

[d] Review individual package insert for COVID-19, Ebola and mpox vaccines for maximum storage duration at various temperatures.

[e] Storage of lyophilized vaccines at -15 °C to -25 °C is acceptable but no longer recommended.

[f] Using WHO-prequalified long-term passive device (PQS E004/041; YBC-5 P6) with phase change material frozen at ultra-low temperature allows storage of Ebola vaccines at district and health facility levels.

Source: WHO/EPI

Key points

- All vaccines have varying sensitivity to heat; hence the importance of keeping them at the right temperature during storage and transport.
- Diluents should never be frozen.
- If diluents are packaged with the vaccine, they should be stored at +2 °C to +8 °C.
- Keep bundled lyophilized (freeze-dried)-liquid combination vaccines at +2 °C to +8 °C. Never freeze them.
- Some vaccines can be stored and used outside of the standard cold chain of 2 °C to +8 °C for a limited period under a closely monitored controlled temperature chain (CTC). Refer to section 3.2 of this module for more information about vaccines licensed for use in a CTC.

1.2 Sensitivity to light

Some vaccines are very sensitive to light and lose potency when exposed to sunlight or strong artificial light. These include:

- bacille Calmette–Guérin (BCG)
- malaria
- measles-rubella (MR)
- measles-mumps-rubella (MMR)
- mpox
- rubella.

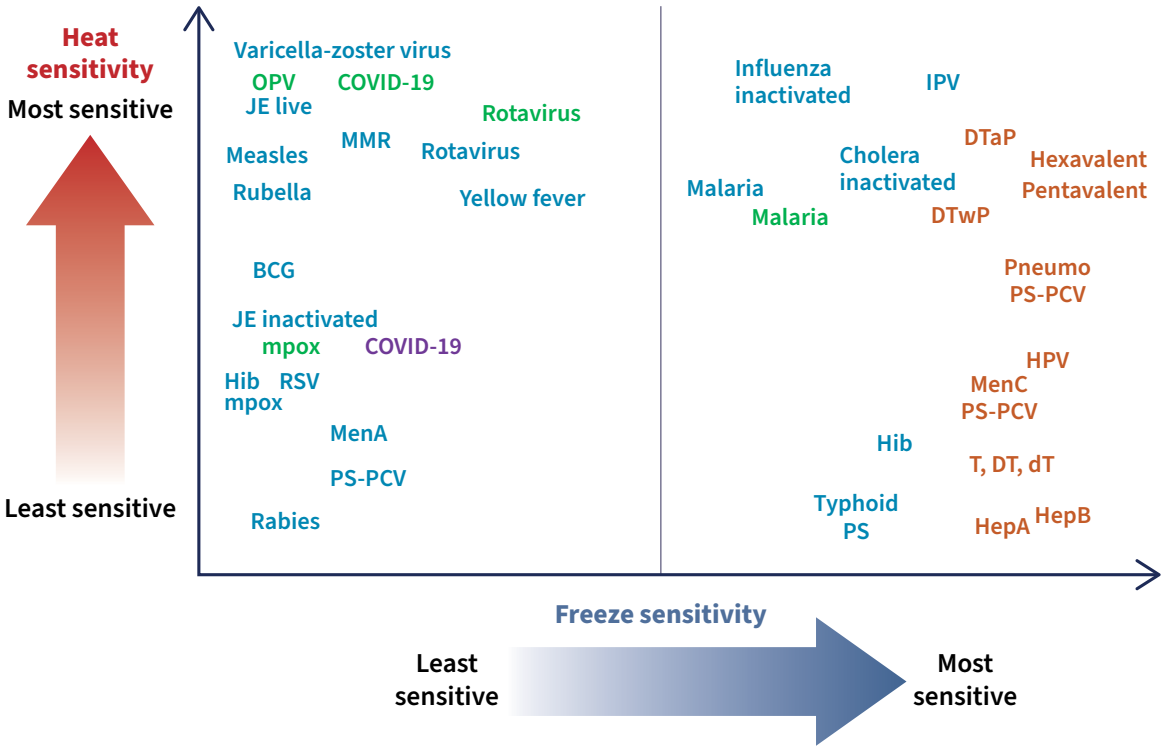
Such vaccines should always be protected from light. These vaccines are often supplied in dark glass vials, which give them some protection from light damage. They should be kept in their secondary packaging for as long as possible to protect them during storage and transportation.

1.3 Sensitivity to heat and freezing

All vaccines are sensitive to heat, but the level of sensitivity varies across vaccine products. The vaccine vial monitor (VVM) found on the vaccine vial label corresponds to the vaccine's heat stability level. See the WHO website on prequalified vaccines, which lists the VVM types for specific vaccines. *(2)*

Fig. 2.3 shows the relative sensitivity of selected vaccines to heat and freezing. The heat stability information shown for freeze-dried vaccines applies only to unopened vials; most freeze-dried vaccines rapidly lose potency after reconstitution. In addition, if they do not contain preservatives, opened multi-dose vaccine vials – whether lyophilized (freeze dried) or liquid – should be maintained at temperatures between +2 °C to +8 °C throughout the immunization session.

Fig. 2.3 Temperature sensitivity of vaccines



Legend (vaccine formulation)

Freeze dried · Liquid, no adjuvant · Liquid, with adjuvant · Liquid, with aluminium adjuvant

Note: Vaccines to the left of the centre line are not damaged by freezing. The diluent for MenA PS-PCV contains aluminium adjuvant and is freeze sensitive.

Source: WHO/EPI

Vaccines that are sensitive to freezing should be protected from sub-zero temperatures. Administering vaccine that has been damaged by freezing may cause sterile abscess. In addition, administering vaccine whose potency has been compromised by freezing creates a false sense of immunity and may undermine confidence in the immunization programme if recipients contract the disease against which they have been vaccinated.

Key points

- Vaccines lose potency over time, but loss of potency is accelerated by exposure to temperatures greater than +8 °C.
- Most liquid vaccines are damaged when frozen.

1.4 Multi-dose vial policy (MDVP)

MDVP is a set of guidelines from WHO that allows health care providers to use certain vaccines from opened vials in multiple doses, across different sessions, as long as the vaccines are stored properly and used within a specific time frame. The policy aims to reduce vaccine wastage, ensure safety and optimize immunization efforts. MDVP specifies a period for use once a multi-dose vial has been punctured with a needle. For example, the package insert may state that the vaccine must be discarded within 28 days of the first puncture with a needle (for example, if the vial is first punctured on 01 April 2024, the operational expiration date (see section 1.6 below) is 29 April 2024). The vaccine should not be used after the operational expiration date.

MDVP summary

"All opened WHO-prequalified multi-dose vials of vaccines should be discarded at the end of the immunization session, or within six (6) hours of opening, whichever comes first, unless the vaccine meets all four (4) of the criteria listed below. If the vaccine meets the four criteria, the opened vial can be kept and used for up to 28 days after opening. The criteria are as follows:

1. The vaccine is currently prequalified by WHO.
2. The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO.
3. The expiry date of the vaccine has not passed.
4. The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer-recommended temperatures; furthermore, the VVM, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing."

Source: WHO policy statement: multi-dose vial policy (MDVP). 2014 revision, p. i.

1.5 Vaccine expiration date

All vaccine products, like other medications, have an expiration (or expiry) date. The expiration date, which is determined by the manufacturer, is the final day on which the vaccine or diluent can be administered. Vaccines past their expiration date should never be used.

Determining when a vaccine or diluent expires is a critical step in maintaining proper stock management (see Table 2.1).

Table 2.1 Interpreting expiration dates

Expiration date format	Interpretation
Month/year	The product may be used up to and including the last day of that month.
Day/month/year	The product may be used only through the end of that day.

1.6 Vaccine shelf life

The shelf life determines how long a vaccine can be safely used. The shelf life is dynamic: its maximum length is the time between the manufacturing date and the expiration date. During this period, many factors can affect the shelf life, including changing the state of storage (such as from frozen to refrigerated) or preparing for administration at service delivery (for example, reconstituting vials, opening multi-dose vials). The shelf life also varies by product and type of transition.

The following conditions affect a vaccine's shelf life:

- **Reconstitution:** Once the vaccine is mixed with a diluent, reconstituted vaccines have a limited period for use. These vaccines must be discarded no more than six hours after reconstitution.
- **MDVP:** This policy provides a guide for health workers to identify which multi-dose vial vaccines can continue to be used for up to 28 days and which should be discarded no more than six hours after opening (see the box in section 1.4 of this module).
- **VVM:** When the VVM begins to darken, the vaccine must be used before other product. The vaccine should not be used once the VVM reaches the discard point (see section 3.1 of this module). Vaccines that have a valid VVM but have passed the labelled expiration date should not be used.
- **Manufacturer-shortened shelf life or expiration date:** This may apply when a vaccine is exposed to inappropriate storage conditions. The manufacturer might determine that the vaccine can still be used but will expire earlier than the expiration date on the label.

The shortening of the expiration date or shelf life because of any of the above conditions results in an "operational expiration date." The operational expiration date should be clearly marked on the vial label, and the vaccine should not be used after this date. It is important to follow the guidance provided by the manufacturer (check the package insert) and/or the national immunization programme policy when calculating the operational expiration date of a specific vaccine product. The operational expiration date replaces the manufacturer's expiration date but never exceeds it. If there is a difference between the manufacturer's expiration date and the operational expiration date, always use the vaccine by the earlier date.

1.7 Vaccine diluents

A vaccine diluent is a liquid used to reconstitute a lyophilized vaccine prior to administration. A vaccine diluent may be sensitive to heat or freezing and may require transportation and storage in the cold chain.

1.7.1 Diluent handling

Diluents vary widely in composition. Only the diluent assigned by the manufacturer for the specific vaccine and presentation should be used.

1.7.2 Diluent storage

All diluents should be managed according to standard vaccine storage and warehousing practices. Unless otherwise specified by the manufacturer, the correct temperature for long-term storage of diluents is +2 °C to +8 °C. Some diluents can be kept at room temperature in a temperature-controlled storage area.

- Diluent packaged with or attached to the vaccine should always be stored with the corresponding vaccine at +2 °C to +8 °C. If packaged separately and if the diluent requires refrigeration, matching vaccines and diluents should be stored in the same refrigerator, when possible.
- Diluent not packaged with the vaccine can be stored at room temperature only if the manufacturer's instructions allow it. In this case, the manufacturer's instructions regarding cooling before reconstitution should be followed.
- Diluents should never be frozen.

1.7.3 Diluent use

Vaccinators need to be adequately trained to ensure that the diluent they use to reconstitute a vaccine is the correct one assigned by the manufacturer. To support vaccinators, the health centre may provide appropriate job aids, such as posters, and ensure that a standard operating procedure is available for properly handling diluents and reconstituted multi-dose vials.

Module 5, *Managing an Immunization Session*, section 4.2 describes the steps for reconstituting vaccines. In terms of the cold chain, the following practices should be followed:

- During the immunization session, keep the diluent in the same storage container as the vaccine.
- The reconstituted product should be discarded at the end of the immunization session, or within six hours of opening, whichever comes first, unless it meets the four criteria in the WHO MDVP (see section 1.4 of this module).

2 Health facility-level cold-chain equipment

Different levels within the national cold-chain system require different equipment for transporting and storing vaccines and diluents within the required temperature range (see Table 2.2). To ensure optimal performance, cold-chain equipment used for immunization programmes at any level must comply with relevant technical specifications, as defined under WHO prequalification standards or as determined by national regulatory authorities.

Table 2.2 Cold-chain storage and transport equipment commonly used at different levels

Supply chain level	Vaccine storage equipment	Vaccine transport equipment
Primary level (national): receives vaccines from the manufacturer or supplier	• Cold or freezer rooms • Refrigerators and freezers (some)	• Cold boxes • Refrigerated vehicles
Intermediate level (province or district): receives vaccines from primary-level stores	• Cold or freezer rooms • Refrigerators and freezers	• Cold boxes • Refrigerated vehicles
Service delivery level (health centre/facility or health post): receives vaccines from intermediate-level stores	• Refrigerators (with or without water pack freezing/cooling compartments) • Cold boxes used for monthly or weekly outreach immunization sessions	• Cold boxes • Vaccine carriers • Long-term passive devices • Transportable powered vaccine storage devices

This module focuses on cold-chain equipment needed at the health facility/service delivery level.

There are two categories of cold chain equipment.

- Active cold-chain equipment, which requires a power supply (mains, solar) to effectively maintain vaccines at their recommended storage temperatures. This cold-chain equipment includes a walk-in cold room, walk-in freezer room, ultra-low temperature freezer, refrigerator, freezer and transportable powered vaccine storage device.
- Passive cold-chain equipment, which does not require a power supply. The vaccines are kept cool using appropriate coolant packs. This type of equipment includes cold boxes and vaccine carriers.

At least two persons in a facility should be responsible for managing its cold-chain system. They should know how to monitor the cold chain and what to do if temperatures are out of range. They should also have access to the facility's standard operating procedures and contingency plans.

One staff member at each facility must be primarily responsible for managing the vaccine supply and cold chain. The second should be able to fill in when the primary person is absent. Both should be adequately trained to perform their responsibilities, which include:

- ensuring that refrigerators are placed away from direct sunlight, with the back at least 12.5 cm from the wall;
- checking and recording vaccine storage temperatures twice daily (typically, in the morning and at the end of the session or day);
- ensuring proper storage of vaccines, diluents, water packs, syringes, safety boxes and so on;
- monitoring vaccine VVM, expiration date and shelf life;
- issuing the vaccine quantity required per session and tracking the quantity of opened and unused vials returned to a cold chain for the next session's use;
- recording information on cold-chain inventory and functionality, vaccine utilization (number of vials used), opened and closed vial wastage, and reporting it to the higher level;
- safely disposing of used or expired vaccine vials;
- planning and implementing preventive maintenance of cold-chain equipment;
- implementing the contingency plan to maintain vaccine quality in case of a cold-chain or power failure.

2.1 Refrigerators

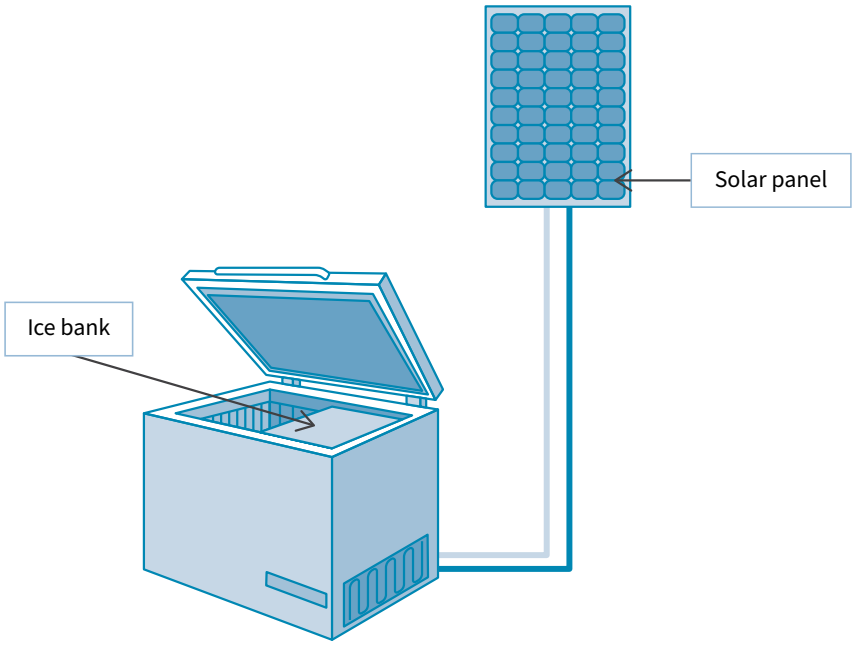
The choice of a health facility refrigerator should be based on the reliability of the available power supply and the combined capacity needed for vaccine and water-pack storage. Table 2.3 summarizes refrigerators by energy source (mains electricity and solar). Absorption refrigerators powered by gas or kerosene are no longer recommended and are not prequalified by the WHO. Most countries have replaced them with new solar refrigerators and main ice-lined refrigerators where appropriate. For information on WHO-prequalified cold-chain equipment, see the PQS catalogue website.

Table 2.3 WHO-prequalified vaccine refrigerators, by energy source

Energy source of vaccine refrigerator	Description
Solar energy[a] (also referred to as photovoltaic units)	• The solar direct-drive units powered directly by solar panels are the preferred model and have received WHO prequalification approval for vaccine storage (see Fig. 2.4). • No batteries are involved, reducing maintenance costs and the risk of battery failure, a common issue in older solar refrigeration systems. • Solar direct-drive refrigerators use thermal storage units (such as frozen water packs or phase-change material) that store cold energy during the day. This stored energy keeps the refrigerator cool during periods of low sunlight, ensuring that vaccines remain within the +2 °C to +8 °C range, even at night or on cloudy days. • Solar direct-drive refrigerators can maintain the required temperature for up to several days without sunlight. • Many models are classified as Category A equipment, meaning they provide complete freeze protection, which is critical for storing freeze-sensitive vaccines. • Solar refrigerators are more expensive to buy and install than electric refrigerators, but they have minimal running costs, apart from cleaning and preventive maintenance.
Electric (also referred to as compression units)	• Ice-lined refrigerators are the preferred option in areas with reliable mains electricity for at least eight hours per day. • Even with periodic breaks in electricity, the inner lining of the unit can preserve the +2 ˚C to +8 ˚C temperature when power is interrupted. • A few models can operate effectively on as little as four hours of electricity daily. • If the ice-lined refrigerator is not loaded properly, vaccines can be exposed to freezing temperatures. • New ice-lined refrigerators have been introduced to prevent freezing.

[a] Solar refrigerators with solar battery units connected to battery banks are no longer prequalified by WHO. Issues related to battery replacement have negatively impacted cold-chain equipment efficiency.

Fig. 2.4 Solar direct-drive cold-chain equipment



Domestic refrigerators lack reliable temperature control and may fail to maintain vaccine temperatures during power outages that are longer than 1–2 hours. Therefore, WHO does not recommend them for vaccine storage.

Since 2009, all WHO-prequalified ice-lined and solar direct-drive refrigerators have been fitted with thermostats that cannot be adjusted by the user. Provided that power cuts are not too long, the temperature in these refrigerators will remain between +2 °C and +8 °C.

Cold-chain equipment for vaccine storage can be categorized based on its freeze-protection features (see Table 2.4). Freeze protection is crucial because many vaccines, especially those stored at +2 °C to +8 °C, can be damaged by freezing temperatures.

Table 2.4 Types of WHO-prequalified vaccine refrigerators by freeze protection

Category	Description	Key features
Grade A (for example, modern solar direct-drive refrigerators; advanced vaccine refrigerators with digital temperature controls)	• Complete freeze protection for vaccines • No user intervention • Vaccine compartment temperature never falls below +2 °C, ensuring that vaccines are not exposed to freezing conditions regardless of where they are stored in the refrigerator	• Well-regulated thermostats • Insulated compartments that maintain temperatures in the safe range, even during power fluctuations • Additional heating elements or advanced cooling systems that prevent overcooling
Grade B (for example, older or basic models of refrigerators and freezers)	• Partial freeze protection • Requires one level of user intervention • Units can maintain temperatures between +2 °C and +8 °C, but they may allow brief periods where temperatures fall slightly below +2 °C • Vaccines might be at risk of freezing under certain circumstances, such as prolonged power outages in extremely cold ambient temperatures[a] • Requires using baskets or other items to avoid vaccine freezing	• Basic thermostat controls with limited precision • Less advanced insulation and cooling technologies compared to Category A • May rely on traditional electric or gas-powered systems
Grade C (for example, domestic refrigerators)	• No freeze protection • Requires more than one level of user intervention to avoid vaccine freezing • Significant risk that vaccines will be exposed to temperatures below +2 °C, especially if cold-chain equipment is used in areas with fluctuating power or very cold ambient temperatures • Requires using baskets and insulation barriers or cover to prevent freezing	• No automatic system to prevent freezing • Temperature regulation is less accurate, leading to potential freezing during cold weather or power issues • Often, health workers need to manually monitor and intervene to prevent freezing

[a] In cold climates where ambient temperature can drop below 0 °C, power cuts can cause the refrigerator's internal thermostat to not regulate internal temperature, causing storage temperature to drop below 0 °C, thus freezing stored vaccines.

2.1.1 Ambient temperature and temperature control

Ambient temperature (the temperature of the surrounding environment where the cold chain operates) can affect the performance of cold-chain equipment such as vaccine refrigerators and freezers. Monitoring both the ambient temperature and the internal temperature of the equipment is critical to maintaining vaccine efficacy and preventing spoilage due to freezing or overheating. Health workers trained as logisticians or cold-chain managers should ensure that vaccine refrigerators are used within their nominated ambient temperature range. This is the range between the upper hot zone temperature (+43 °C, +32 °C or +27 °C, depending on the equipment) and the minimum rated ambient temperature (the lowest external temperature at which the equipment can operate to effectively maintain the required internal temperature for the stored products). All users should be trained in the use of cold-chain equipment and should comply with procedures provided by the manufacturer. Recent prequalified cold-chain equipment models have stickers indicating the nominated ambient temperature range (see Fig. 2.5), with a red semi-circle showing the maximum rated ambient temperature, and a blue semi-circle showing the minimum rated ambient temperature. When selecting and deploying cold-chain equipment in a vaccine store or health facility, it is essential to ensure that the equipment's nominated temperature range is appropriate for the local ambient temperature conditions.

Fig. 2.5 Example of a refrigerator's minimum/maximum rated ambient temperature

Source: WHO/PQT

To prevent temperature fluctuations that could damage vaccines, it is crucial to place cold-chain equipment in areas with controlled ambient temperatures, such as in an air-conditioned room. Avoid setting up the equipment in a place with direct exposure to sunlight, such as next to windows or exterior doors. To ensure safe vaccine storage in facilities without air conditioning, use equipment designed to handle varying ambient temperatures (such as solar-powered or tropicalized refrigerators).

For the most part, recently procured cold-chain equipment falls under Category A, which does not require adjustment of the thermostat. However, some facilities may still be using older models, including older models of ice-lined or solar refrigerators, or domestic gas and kerosene refrigerators. These units require user intervention. Staff should keep in mind the following when managing older cold-chain equipment models:

- When a refrigerator was first installed, the thermostat would have been set so that the refrigerator compartment stayed between +2 °C and +8 °C during the coldest part of the day (typically the morning). Be aware that the freezing risk is greatest when the ambient room temperature is low.
- Once it is determined that the daily temperature range remains consistently between +2 °C and +8 °C, the thermostat is correctly adjusted. The setting should not be changed, even if electrical power is lost.
- Do not adjust the thermostat if the temperature occasionally rises a degree or so above +8 °C after a power cut or in very hot weather.

If there is a recurring problem with the temperature control in a refrigerator, follow the national standard operating procedures in notifying the appropriate personnel (such as a supervisor, refrigerator technician, etc.).

Never fully pack a health facility refrigerator; always leave plenty of space around the vaccines and diluents to allow air to circulate freely and to make vaccine handling easier (see section 5 in this module). Typically, a health facility refrigerator should be able to hold:

- at least one month's supply of vaccines and diluents in the refrigerator compartment;
- at least an additional two-weeks' safety (buffer) stock of vaccines and diluents;
- an equivalent of one- or two-weeks' stock of vaccines and diluents (at least 25% of the one-month supply of vaccines), in keeping with the policy for integration of other temperature-sensitive medicines into the service delivery cold chain;
- a minimum of four water packs in the freezer/cooling compartment (note that some solar direct-drive refrigerators cannot freeze water packs).

2.2 Passive storage devices

2.2.1 Cold boxes

A cold box is an insulated container lined with water packs to keep vaccines and diluents within the required temperature range during transport or short-term storage. Depending on the model, cold boxes, if unopened, can be used to store vaccines for up to two days when no electricity is available, when the health facility refrigerator is out of order or when a passive container is needed while the refrigerator is being cleaned and defrosted. Once packed, cold boxes should not be opened until the vaccine is needed.

Staff should know the cold box's "cold life" and "cool life," to use the equipment effectively and ensure that the quality of the vaccines is maintained. "Cold life" refers to the maximum time a closed cold box can maintain temperatures below +10 °C when lined with frozen or conditioned (partially thawed) water packs. WHO-prequalified cold box models

had a cold life of two to seven days when tested at a constant temperature of +43 °C. "Cool life" refers to the maximum time a closed cold box can maintain temperatures below +20 °C if lined with cool water packs. Current prequalified cold box models had a cool life of 12 hours to two days when tested at a constant ambient temperature of +43 °C. If the cold box model is WHO prequalified, its cold life and cool life can be referenced on the relevant WHO performance, quality and safety product sheet on the PQS website.

WHO-prequalified cold boxes come in regular (non-freeze-preventive) and freeze-preventive models (see Fig. 2.6). The freeze-preventive cold box has a barrier separating the vaccine storage compartment from the frozen water packs; the regular cold pack does not (see Table 2.5 for a summary of the features of the two types).

Fig. 2.6 WHO-prequalified cold boxes for vaccine transport

Regular/non-freeze-preventive cold box

Freeze-preventive cold box

The choice of cold box to be used for short-term storage at a health facility level should be based on the following factors:

- the vaccine and diluent storage capacity needed for the supply period, including the vaccine safety (buffer) stock and other supplies included in the policy for integration of other temperature-sensitive medicines;
- the cold or cool life required, which depends on the maximum time vaccines will be stored in the box (including transport time);
- the type and number of water packs compatible with the size of the cold box.

Different cold box models have different vaccine storage capacities and need different numbers and sizes of water packs. It is important to use the correct number and size of water packs, exactly as specified by the manufacturer. Check the WHO Performance, Quality and Safety website for more information on products prequalified by WHO.

Cold boxes can be used to carry monthly vaccine supplies from district stores to the health facility and also from the health facility to outreach sessions, if a vaccine carrier is too small. In general, a cold box in a health facility should be large enough to transport at least a one-month supply of vaccines.

2.2.2 Vaccine carriers

Vaccine carriers are smaller than cold boxes and easier to carry. Like cold boxes, vaccine carriers come in regular (non-freeze-preventive) and freeze-preventive models (see Fig. 2.7). A freeze-preventive vaccine carrier has a barrier separating the vaccine storage compartment from the frozen water packs; the regular carrier does not (see Table 2.5 for a summary of the features of the two types). Current prequalified vaccine carriers have a cold life with frozen water packs of between 18 and 50 hours at +43 °C and a cool life with cool water packs of between three and 18 hours.

Vaccine carriers are generally used for the following purposes:

- to transport vaccines and diluents to outreach sites and fixed immunization posts and to store them during health facility immunization sessions;
- to store vaccines temporarily when the health facility refrigerator is out of order or is being cleaned;
- to transport monthly vaccine supplies from the district store to small health facilities.

The choice of vaccine carriers should be based on the following factors:

- the type and quantity of vaccines and diluents to be transported;
- the cold life or cool life needed for the longest planned journeys;
- the transport method used (for example, the requirements for a vaccine carrier that will be carried for short distances on foot are not the same as those for one that will be transported for long distances on the back of a motorcycle).

Fig. 2.7 Regular and freeze-preventive vaccine carriers

Regular/non-freeze-preventive vaccine carrier

Freeze-preventive vaccine carrier

2.2.3 Advantages of using freeze-preventive passive devices

All freeze-preventive cold boxes and vaccine carriers have a barrier separating the vaccine storage compartment from the frozen water packs, to prevent direct contact. The main advantage of using freeze-preventive cold boxes and vaccine carriers is to prevent freeze-sensitive vaccines from freezing. Another advantage is saving time spent on conditioning (partially thawing) frozen water packs *(3)*. When using a freeze-preventive apparatus, frozen water packs can be taken directly from the freezer and placed in their compartments without conditioning.

Currently, freeze-preventive vaccine carriers/cold boxes tend to be slightly heavier and with smaller storage capacity than standard vaccine carriers/cold boxes; these factors should be considered when planning for vaccine transport.

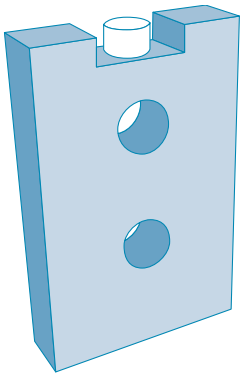
Table 2.5 Summary of passive cold-chain devices

Non-freeze-preventive devices	Freeze-preventive devices
General • Vaccines and coolant packs are loaded in the same compartment • To ensure vaccine quality, use with conditioned (partially thawed) frozen water packs or cool water packs so the inner temperature does not drop below 0 °C • Freezing risk if vaccine in direct contact with water pack, especially if improperly conditioned	**General** • Vaccines are loaded in an inner compartment. Frozen water packs are placed in separate compartments. The buffer layer controls temperature transfer from frozen water packs, creating a more stable temperature environment in the vaccine compartment. • To ensure vaccine quality, use with frozen water packs • No risk of vaccine freezing
Non-freeze-preventive cold box Larger box for district or facility distribution	**Freeze-preventive cold box** Larger box for district or facility distribution
Non-freeze-preventive vaccine carriers Smaller carrier for last-mile delivery (such as for outreach sessions or campaigns)	**Freeze-preventive vaccine carriers** Smaller carrier for last-mile delivery (such as for outreach sessions or campaigns)

2.3 Water packs

Water packs are flat, leak-proof plastic containers that can be filled with tap water (see Fig. 2.8). They are used to line the inside of the cold box or vaccine carrier in order to keep vaccines in the required temperature range. To protect the vaccines, it is important to use the correct number and size of water packs and follow the printed instructions from the manufacturer. To ensure optimal performance, WHO recommends the use of prequalified water packs. Table 2.6 describes the different uses of water packs for vaccine transport.

Fig. 2.8 Water pack



Source: WHO/EPI

Ideally, health facilities should have at least two complete sets of water packs for each of their cold boxes and vaccine carriers so that one set can be frozen or cooled in the freezer or refrigerator while the other is being used in the cold box or vaccine carrier.

The appropriate temperature of the water pack will depend on the type(s) of vaccines being transported, the ambient temperatures to which the cold box or vaccine carrier will be exposed and the duration of transport (see Table 2.6). The appropriate water pack strategy to use at the health facility level for transport or outreach operations will be guided by national policy and practice.

If cool water packs are used for outreach operations, there must be additional frozen or conditioned water packs at the outreach session to keep both reconstituted lyophilized (freeze-dried) vaccines and multi-dose vaccines that do not contained preservatives that have been opened cool, at between +2 °C and +8 °C. Exposure of reconstituted and open vials of liquid vaccines that do not contain preservatives to temperatures above +8 °C during immunization sessions can increase the risk of microbial growth.

Taking frozen, conditioned or cool water packs out of the vaccine carrier will shorten their cold/cool life. Therefore, during immunization sessions, water packs should not be removed from the carrier (for example, to be used to hold either open or closed vials). Open vials should be placed in the foam pad provided with the vaccine carrier, as described in section 2.4 of this module.

WHO strongly discourages using wet ice in plastic bags, as this may expose vaccines to freezing temperatures and potentially damage the vial label, making it unreadable.

Table 2.6 Water packs used for vaccine transport

	Frozen water packs	Conditioned frozen water packs	Cool water packs	Warm water packs
Definition	Water packs that have been frozen solid in a freezer at -25°C to -15 °C	Frozen in a freezer at -25 °C to -15 °C and then defrosted at room temperature so that ice has melted enough that it moves inside the container when shaken	Regular water packs that have been cooled in a refrigerator at +2 °C to +8 °C	Water packs that have been stabilized at room temperature, between +10 °C and +24 °C
Use	Used for the transportation of most heat-sensitive vaccines that are not damaged by freezing (such as OPV)	Can be used only with a freeze indicator in the carrier	Used when no freeze indicator is available	Used in cold climates to protect freeze-sensitive vaccines from exposure to ambient temperature below 0 °C during transport period. Warm water packs can protect vaccines under these conditions for only about eight hours.

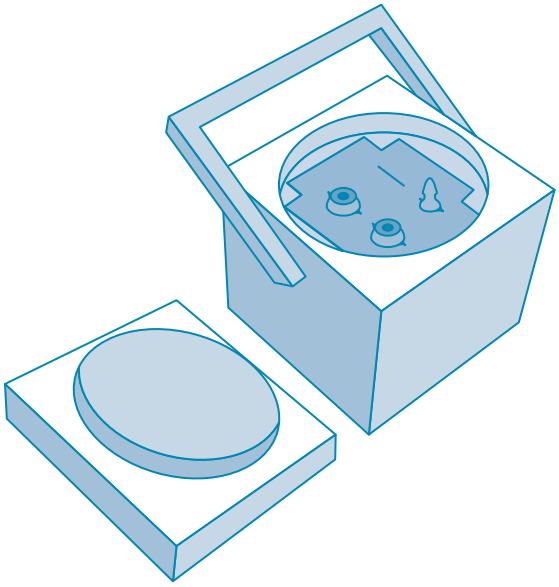
- Only vaccines with a VVM can be transported without coolant packs in emergency settings.
- Vaccines that are WHO prequalified and licensed for CTC use can be transported and used at the session site without coolant packs, provided a WHO-prequalified vaccine carrier is used (see section 3.2 of this module).
- Using freeze-preventive vaccine carriers with frozen water packs eliminates the risk of accidentally freezing freeze-sensitive vaccines during transport and use and eliminates the need for conditioning frozen water packs.
- At the point of vaccination, the diluent should be stored with the vaccine in the cold chain.

2.4 Foam pads

A foam pad is a piece of soft sponge-like material that fits precisely on top of the water packs inside a vaccine carrier (see Fig. 2.9) while still permitting the lid of the vaccine carrier to fully close. The foam pad provides insulation and protection for vaccines during transportation and storage. The manufacturer provides each vaccine carrier with a foam pad. The pad usually has slits in which vaccine vials can be inserted snugly.

The foam pad should be used during an immunization session as a temporary lid and to securely hold opened vials while protecting unopened vials in the cool chamber below. Opened vials of heat-sensitive vaccines can be protected from heat damage during immunization sessions if they are inserted in the foam pad.

Fig. 2.9 Vaccine carrier foam pad



Source: WHO/EPI

WHO recommends using the manufacturer-supplied foam pad in the vaccine carrier. Health workers are encouraged to keep the pad clean, protected from damage and free from dirt and dust. If the original pad is damaged or lost, staff can prepare a new one using a similar foam material available locally. Annex 2.1 provides instructions for preparing a homemade foam pad.

3 Monitoring vaccine temperatures

It is essential to monitor and record the temperature of vaccines throughout the supply chain, until they are administered. This is the only way to prove that they have been kept at the right temperature during storage and transport. Temperature monitoring prevents wastage of vaccines due to heat or freezing. It also alerts workers to any problems with equipment and procedures. For guidance on monitoring temperatures, see *How to monitor temperatures in the vaccine supply chain*.

Vaccine cold-chain temperature monitoring has evolved, with new technologies allowing more effective and efficient monitoring systems. Regardless of the temperature-monitoring tool or device used, health workers are encouraged to always check the vaccine temperature twice daily. This allows timely implementation of corrective actions, thereby preserving vaccine quality and preventing closed vial wastage.

This section describes the types of temperature-monitoring devices used in health facilities, which are generally equipped with one or two vaccine refrigerators, cold boxes and vaccine carriers. All WHO-prequalified temperature-monitoring devices used in cold-chain equipment aim to keep the equipment in optimal working condition and ensure that the vaccines remain safe and potent.

3.1 Monitoring cumulative heat exposure using VVM

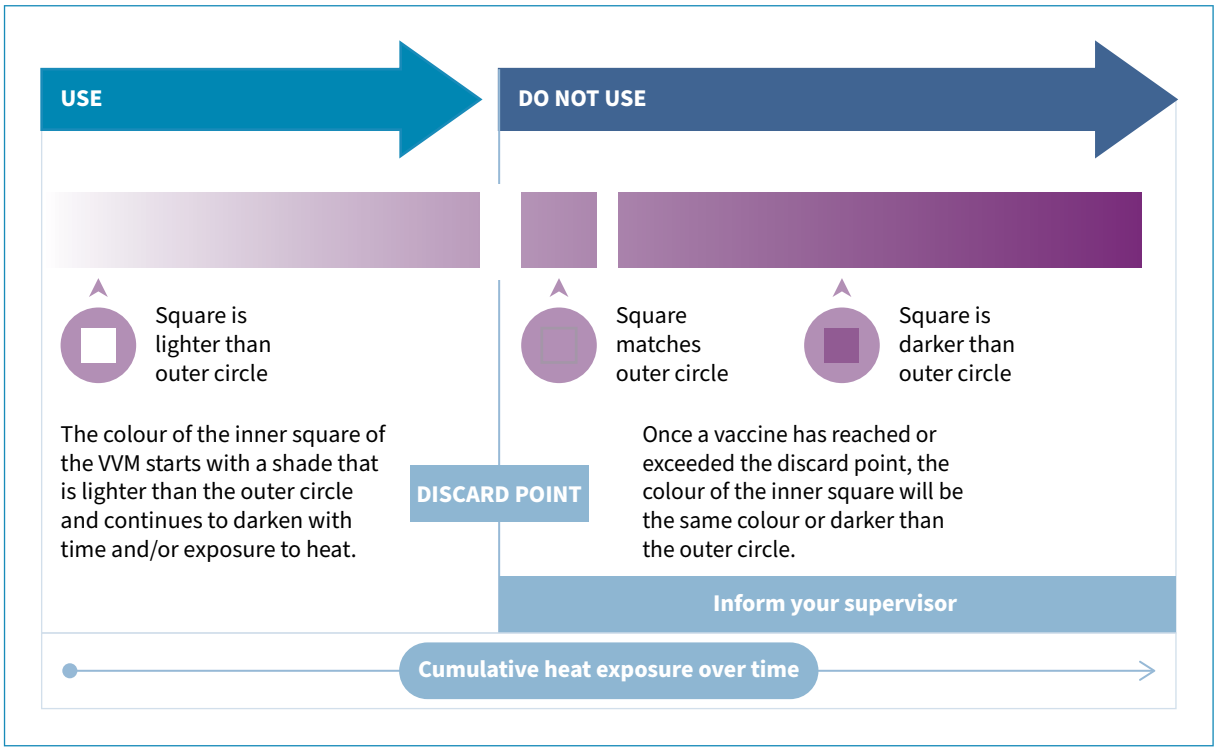
A vaccine vial monitor is a label containing a heat-sensitive material that is placed on a vaccine vial, ampoule or dropper by the manufacturer to register cumulative heat exposure over time through a gradual change in colour (see Fig. 2.10). The combined effects of time and temperature cause the inner square of the VVM to darken gradually and irreversibly. If the colour of the inner square is the same colour or darker than the outer circle, then the vaccine has been exposed to too much heat, is no longer potent and should be discarded.

There are currently six types of VVMs, which match the vaccine's heat sensitivity: VVM2, VVM7, VVM11, VVM14, VVM30 and VVM250. The VVM numeral is the number of days it takes for the inner square to reach the colour of the outer circle if the vial is exposed to a constant temperature of 37 °C or more (for example, the VVM14 on a vaccine vial constantly exposed to 37 °C will reach the discard point after 14 days of exposure). The VVM type is decided by the manufacturer and WHO during the regulatory approval process for each vaccine.

VVMs are used to:

- ensure that heat-damaged vaccines are not administered;
- decide which vaccines can safely be kept after a cold-chain break occurs, thus minimizing unnecessary vaccine wastage;
- decide which vaccine should be distributed and used first.

Fig. 2.10 VVM sequence



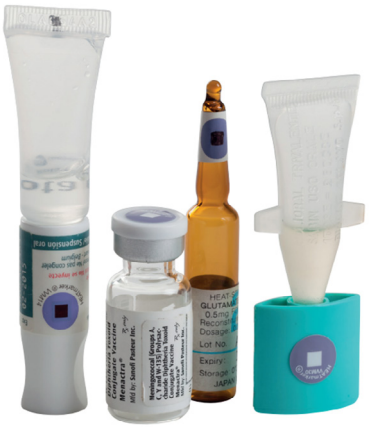
Source: WHO/EPI

A batch of vaccines showing significant heat exposure, as indicated by moderate darkening of the VVM, should be distributed and used before a batch that shows lower heat exposure, even if the former has a longer expiry date. The VVM status of vials should always be checked and recorded on the arrival voucher when the vaccine first reaches the health facility. It must also be checked prior to vaccine distribution and administration. At the immunization session, check the VVM before the vaccine is opened, to see whether it has been damaged by heat. Use the vial only if the expiry date has not passed and the VVM has not reached the discard point. VVMs do not measure exposure to freezing temperatures. If the vaccine is freeze sensitive and freezing is suspected, then the shake test must be conducted (see section 8 of this module).

The location of the VVM on a vial or ampoule (see Fig. 2.11) is associated with specific guidance for handling opened multi-dose vials of vaccine.

- **WHO-prequalified vaccines with the VVM printed on the vaccine vial label:** The vaccine vial, once opened, can be kept for subsequent immunization sessions up to 28 days, regardless of the formulation of the product (liquid or freeze dried).
- **WHO-prequalified vaccines with a VVM sticker attached in another location (such as the vial cap or the neck of the ampoule):** Once the vial is opened, the VVM is detached. In this instance, the vaccine must be discarded within six hours of opening or at the end of the immunization session, whichever comes first, regardless of the formulation of the product (liquid or freeze dried).

Fig. 2.11 Location of VVMs on ampoules and vials



Source: WHO/EPI

Both VVM status and expiration dates are tools to assist health workers in deciding whether or not a vaccine can be administered.

Within the effective vaccine management application (The App – EVM [who.int]) is a VVM guide tool that health workers can use to determine if the vaccine is still good to distribute/administer based on the VVM status and expiration date. If the VVM has started to darken, the app provides an estimate of how many days remain to use the vaccine. This enables health workers to determine which vaccine to distribute and use first, which is one of the basic strategies to minimize vaccine wastage.

3.2 Monitoring peak temperature exposure of vaccines under a CTC

An increasing number of vaccines are being examined to determine their compatibility with a CTC, which would allow their use at ambient temperatures. CTC is a short-term vaccine management strategy to facilitate the delivery and use of vaccines without the constraints of the cold chain. A CTC typically involves a single excursion of the vaccine into ambient temperatures not exceeding a specified threshold temperature, and for a specific number of days, just before administration. An "excursion" refers to a temperature reading outside the recommended range for a product.

Only vaccines that have been licensed and prequalified by WHO specifically for CTC use can be used in a CTC. For those specific vaccines, WHO defines a CTC as the on-label use of the vaccine outside the traditional +2 °C to +8 °C cold chain for a limited period of time, at temperatures of up to +40 °C, just before administration (see Table 2.7). Countries can adopt the CTC approach for carefully chosen circumstances, such as for special strategies (door-to-door, mobile team, outreach, school-based or disaster-response vaccination) or mass vaccination campaigns.

Table 2.7 Vaccines licensed and labelled for CTC use (as of October 2023)

Vaccine	Maximum temperature for CTC use	Number of days of CTC application
OCV (Shanchol)	+40 °C	14 days
Meningitis A (MenAfrivac)	+40 °C	4 days
Meningitis ACYWX	+40 °C	15 days
HPV (Gardasil)	+40 °C +42 °C	4 days 3 days
HPV (Gardasil 9)	+40 °C	4 days
Typhoid (Typbar)	+40 °C +55 °C	7 days 3 days

Another temperature-monitoring tool is a peak temperature threshold indicator, which is an indicator that changes colour from light grey to black as soon as the temperature exceeds +40 °C (see Fig. 2.12). Peak temperature threshold indicators and VVMs are complementary, and both are required. A peak temperature threshold indicator measures peak temperature exposure, while a VVM measure cumulative heat exposure. VVMs cannot measure short-exposure temperatures higher than those accepted by CTC criteria. Peak temperature threshold indicators help health workers ensure that vaccine has not been exposed to temperatures higher than +40 °C during the implementation of CTC.

Fig. 2.12 Vaccine carrier with a peak temperature threshold indicator and no frozen water packs

Health workers should be trained to:

- understand the conditions under which the CTC can be used;
- maintain standard cold-chain precautions up to the point that the vaccine enters the CTC;
- effectively monitor temperature exposure during the duration of the CTC until the vaccine is completely used.

Video resources about CTC and its implementation in the field are available on the WHO YouTube channel.

The following conditions should be met when using a vaccine in a controlled temperature chain:

- The vaccine should be licensed for use in a CTC by the relevant regulatory authorities, with a label that specifies the conditions.
- The vaccine is used within the time and temperature limits for CTC use specified on the label and/or package insert.
- The vaccine is not being used and delivered alongside vaccines that require a +2 °C to +8 °C cold chain.
- Immediately before its use, the vaccine is kept under CTC during a single period not exceeding the maximum allowed time specified on the CTC label.
- The ambient temperatures are not expected to exceed +40 °C during immunization activities.
- The vaccine is accompanied by a VVM and a peak threshold indicator, which are monitored regularly. Vaccines under CTC should never be used when either the VVM or the peak temperature threshold indicator reaches the discard point.
- Vaccines used in CTC should not be returned into the cold chain.

3.3 Using temperature-monitoring devices

Health workers must be appropriately trained in the use of temperature-monitoring devices. They should know how to read and interpret the temperature-monitoring devices used in their refrigerators. To effectively use these devices, health workers should conduct a regular temperature check at least twice daily and promptly perform corrective actions when a temperature alarm is received or an excursion is detected. In such cases, standard operating procedures and contingency plans should be observed.

3.3.1 30-day electronic temperature recorders

A 30-day electronic temperature recorder may be placed in a vaccine refrigerator or integrated into the refrigerator's temperature monitoring device (for example, an electronic monitoring system, a remote temperature monitoring device, etc.). A 30-day electronic temperature recorder records the refrigerator temperature at no more than 10-minute intervals and shows the daily temperature highs and lows as well as the alarm history for the previous 30 days. The device triggers alarms if the temperature of the refrigerator drops to −0.5 °C or below for a continuous period of 60 minutes (low-temperature alarm) or if it exceeds +10 °C for a continuous period of 10 hours (high-temperature alarm). As long as the temperature remains within the recommended range, the device displays "OK" or a check symbol.

Several types of 30-day electronic temperature recorders are prequalified by WHO (see Fig. 2.13 for two examples). On newer models, data can also be downloaded to a computer. Current models have built-in batteries with a battery alarm feature; the device must be discarded when the battery expires, which is typically every two or three years.

A 30-day electronic temperature recorder should be placed in an accessible position where it can be read easily and is unlikely to be damaged. This will vary depending on the type of refrigerator.

- If the refrigerator is used to store vaccines that are not freeze sensitive, place the device on top of the load, in the warmest part of the refrigerator.
- If the refrigerator is used to store any freeze-sensitive vaccines, the device should be placed in the coldest part of the refrigerator that is being used to store these vaccines. This will be in the bottom of a basket in chest (top-load) refrigerators or nearest to the evaporator plate in front-opening models and absorption units.
- 30-day electronic temperature recorders should not be used in vaccine freezers.

Fig 2.13 30-day electronic temperature recorders

Source: WHO/PQT

Specific steps need to be taken to respond to temperature alarms. In the case of a high-temperature alarm, check:

- that the refrigerator is connected to the active power supply;
- that the refrigerator door is tightly closed;
- that the refrigerator's compressor is well ventilated (that there is enough space between the refrigerator and the wall and that this space is not obstructed);
- for significant dust accumulation on the compressor/evaporator;
- that the refrigerator is not directly exposed to sunlight or heat. If possible, place the refrigerator unit away from doors and windows and block its exposure to sunlight.

In the case of a low-temperature alarm, check:

- if the refrigerator functions in a very low ambient temperature, such as an unregulated air-conditioned room;
- the items in the refrigerator, ensuring that no frozen water packs or other frozen products are stored in the unit.

For both types of alarms, perform corrective actions to address their cause. Afterwards, monitor the temperature for at least 10 hours. If the alarm or temperature excursion persists for more than 10 hours, report the incident to your supervisor and follow national standard operating procedures for notifying appropriate personnel (such as a refrigerator technician).

3.3.2 Electronic freeze indicators

Electronic freeze indicators are small digital devices that are placed with freeze-sensitive vaccines during transport or storage (electronic freeze indicators are not needed in refrigerators where a 30-day electronic temperature recorder is used). The devices have a visual indicator that shows whether the vaccine has been exposed to freezing

temperatures (see Fig. 2.14). Once the alarm indicator has been triggered, the device is no longer usable and should be discarded. Otherwise, the device can be used until the built-in battery expires (between three and five years, depending on the specific model and its usage).

Observe the following practices when using a freeze tag monitor:

- If the device monitor is showing that the vaccine has not been exposed to freezing (usually indicated as a check mark), the supply can be safely used.
- If the device monitor indicates freeze exposure, immediately report the incident to your supervisor and follow the standard operating procedures for notifying the appropriate personnel (such as a refrigerator technician). Keep the freeze-sensitive vaccine in a clearly labelled separate container in the cold chain and wait for instructions from your supervisor.

Fig. 2.14 Electronic freeze indicators

Source: WHO/PQT

3.3.3 Integrated digital thermometers

Current prequalified vaccine refrigerators and freezers are equipped with integrated digital thermometers (see Fig. 2.15). An internal temperature sensor monitors the storage compartment, and an instantaneous temperature reading is displayed on the unit's control panel. Solar direct-drive refrigerators typically have a device powered by an integrated photovoltaic cell; these do not work at night or in dim light and may have to be activated by shining a light onto the display.

Fig. 2.15 Vaccine refrigerator with integrated digital thermometer

Source: WHO/PQT

Specific steps need to be taken when an integrated thermometer indicates an excursion. In the case of a high temperature, check:

- that the refrigerator's door is tightly closed;
- that the compressor is well ventilated (that there is enough space between the refrigerator and the wall and that this space is not obstructed);
- for significant dust accumulation on the compressor/evaporator;
- that the refrigerator is not directly exposed to sunlight or heat. If possible, place the refrigerator unit away from doors or windows and block its exposure to sunlight.

In the case of a lower temperature, check:

- if the refrigerator functions in a very low ambient temperature, such as in an unregulated air-conditioned room;
- the items in the refrigerator, ensuring that no frozen water packs or other frozen products are stored in the unit.

3.3.4 Remote temperature-monitoring systems

Remote temperature-monitoring systems continuously monitor vaccine temperatures. They can trigger alarms when temperatures fluctuate outside the appropriate range and can alert health workers, enabling rapid reaction to prevent damage to vaccines *(4)*.

In addition, remote temperature-monitoring systems:

- allow routine and systematic review of cold-chain equipment performance and guide planning for maintenance and repair;
- promote accountability for ensuring corrective follow-up actions are implemented;
- enable regular collection of data for making informed decisions at all levels.

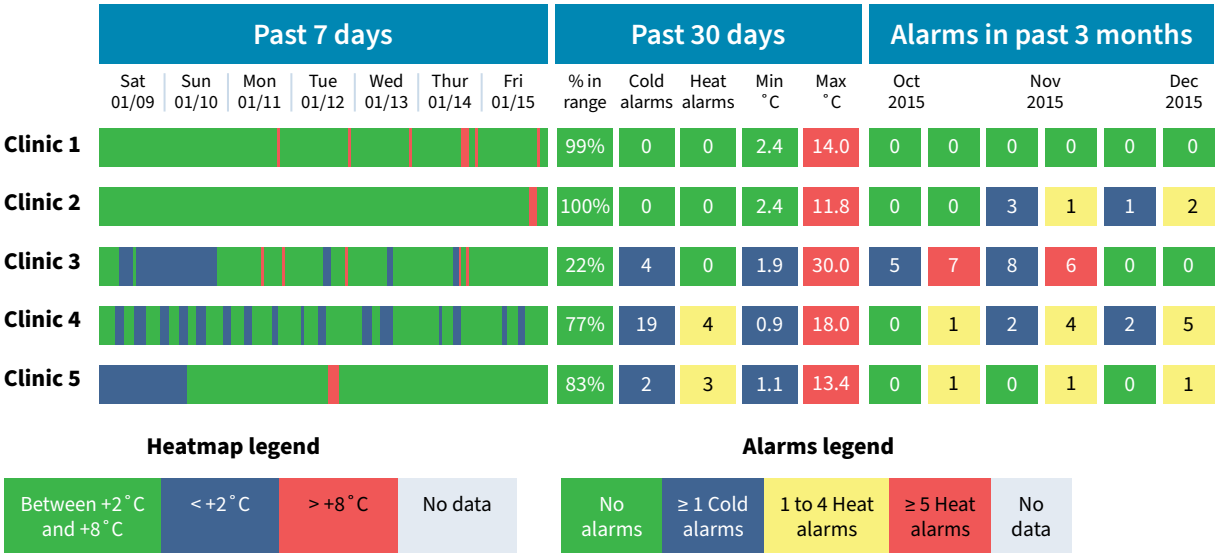
Remote temperature monitoring is often used in monitoring cold-chain equipment temperature in central and subnational stores. Some countries have expanded the use of remote temperature-monitoring systems to lower levels, when appropriate. Some remote temperature-monitoring devices are handheld; others need to be mounted externally (see Fig. 2.16). Remote temperature-monitoring devices provide SMS alerts for temperature excursions and simple data reports on a real-time dashboard.

Fig. 2.16 Remote temperature-monitoring devices

Source: Multilog Burkina Faso, ©WHO/Denis Karaga (left); Temperature monitoring unit Chad (right)

Remote temperature-monitoring devices provide technicians with remote access to data on the functionality status of refrigerators. By analysing the temperature data (see sample in Fig. 2.17), technicians can recognize temperature excursions and are able to remotely provide an accurate diagnosis of the most common issues, including flat batteries in solar refrigerators, improperly adjusted thermostats, power outages, loose wiring connections, decommissioned refrigerators, failed compressors and poorly installed solar panels.

Fig. 2.17 Sample visualization of data from a remote temperature-monitoring device



© ColdTrace

Remote temperature-monitoring systems save time and maintenance costs, as technicians, upon detecting an issue, can call and advise the health worker responsible for managing the cold-chain equipment at the facility on corrective actions, such as adjusting the thermostat, cleaning the solar panel and so on. Technicians can then prioritize visiting facilities experiencing issues when they cannot identify the problem remotely.

When determining whether to use a remote temperature-monitoring system, the following factors should be considered.

- Remote temperature-monitoring devices require access to cellular data services. With weak or no internet connection, the device cannot transmit data, upload on the central server or send alarms.
- Some remote temperature-monitoring devices run on rechargeable batteries, requiring constant connection to mains powerline or another power supply. Without this connection, the device will go offline.
- Some remote temperature-monitoring devices run on long-life internal batteries, which require regular replacement.

3.4 Electronic monitoring systems

In 2026, WHO will be prequalifying cold-chain equipment that complies with the electronic monitoring system requirements. Electronic monitoring systems aim to enable standardized and inter-operable data collection from cold-chain equipment ("inter-operable" means that cold-chain equipment data collected from an electronic monitoring system can be transmitted, accessed and analysed using other information management systems). In addition to storage temperature measurements, an electronic monitoring system collects

information on cold-chain equipment performance and diagnostics. The historical data are stored locally in the cold-chain equipment and available for local access. The electronic monitoring system has a machine-to-machine interface that allows easy upgrades for data display and remote data access, without a complicated setup.

The following data are monitored by an electronic monitoring system:

- storage temperature
- door openings
- power availability
- compressor runtime
- equipment identification
- error codes.

There are three levels of EMS.

- **Level 1: Basic local data logging with USB data access.** At this level, the data logger is integrated into the cold-chain equipment. It measures the performance data listed above and stores them in an internal memory for at least one year. A USB port is provided to enable data access by computers, mobile phones or other devices that are compliant with the electronic monitoring system, in a standardized raw format and as a PDF report. The motivation for providing local data access is to enable service technicians to access the history of the cold-chain equipment's performance, even if the unit is unpowered, to aid in diagnosing performance issues. In addition, a machine-to-machine interface consisting of a USB port and a power output port allows equipment-monitoring devices to access the data for display and transmission purposes. Note that Level 1 does not enable a visual display.
- **Level 2: Advanced local monitoring.** Level 2 functionality includes the logging and data access capabilities of Level 1 and adds a local data display that allows health care workers or service technicians to monitor performance without needing to download data to a separate computer or smartphone. Visual and audible alarms prompt action from local users when urgently needed.
- **Level 3: Remote and local monitoring.** Level 3 includes the capabilities of Levels 1 and 2 and adds remote data transmission, allowing data access directly from the cold-chain equipment and through remote access. This functionality allows service technicians to check the data remotely and diagnose problems before a site visit. SMS or email alarms prompt remote users when something is wrong. The data can also be automatically routed to a dashboard or future electronic logistics management information system (eLMIS) to be available for aggregated visualization or reporting.

A local data record is available via USB regardless of data transmission to remote databases. This is to maintain data access for local health care workers and service technicians and to provide the machine-to-machine data connection for upgradability in the future.

With the ability to locally access cold-chain equipment performance data collected through an equipment-monitoring device, health workers are encouraged to use electronic monitoring system data to improve cold-chain equipment management practices and monitor the need for corrective maintenance.

Specific steps need to be taken when the electronic monitoring system signals a temperature alarm. In the case of a high-temperature alarm, check:

- that the refrigerator door is tightly closed;
- that the refrigerator's compressor is well ventilated (that there is enough space between the refrigerator and the wall and that this space is not obstructed);
- for significant dust accumulation on the compressor/evaporator;
- that the refrigerator is not directly exposed to sunlight or heat. If possible, place the refrigerator unit away from doors and windows and block its exposure to sunlight.

In the case of a low-temperature alarm, check:

- if the refrigerator functions in a very low ambient temperature, such as in an unregulated air-conditioned room;
- the items in the refrigerator, ensuring that no frozen water packs or other frozen products are stored in the unit.

3.5 Recommended equipment for monitoring vaccine temperature in health facilities

Table 2.8 summarizes temperature-monitoring options for health facility storage and transport, in order of preference.

Table 2.8 Options for monitoring vaccine temperature at health facility level

	Vaccine refrigerator	Cold boxes and vaccine carriers
Best practice	• Electronic monitoring systems • Remote temperature-monitoring devices, when suitable • Integrated digital thermometer • 30-day electronic temperature recorder • Vaccine vial monitors (VVMs), when supplied	When using conditioned frozen water packs • Electronic freeze indicator • VVMs, when supplied When using cool water packs • VVMs, when supplied When using warm water packs • Freeze indicator • VVMs, when supplied
Minimum requirement	• Integrated digital thermometer • 30-day electronic temperature recorder • Electronic freeze indicator • VVMs, when supplied	• VVMs, when supplied

3.6 Monitoring equipment for WHO-prequalified refrigerators

Wherever possible, health facility refrigerators should be equipped with 30-day electronic temperature recorders, and facility staff should be trained in their use and what actions to take in case of alarms. In the absence of a 30-day electronic temperature recorder, an electronic freeze indicator is the next best choice. A freeze indicator shows whether freeze-sensitive vaccines have been exposed to sub-zero temperatures, the most common cause of vaccine damage. The least desirable choice is a stem thermometer (a thermometer with a long stem attached to the display) alone. A thermometer indicates the temperature only at the time a reading is taken, which is no more than 14 times per week. The temperature also has to be manually recorded, which makes it prone to error. By contrast, a 30-day electronic temperature recorder takes at least 1000 readings a week.

3.7 Temperature-monitoring equipment for WHO-prequalified cold boxes and vaccine carriers

Regular cold boxes and vaccine carriers: If conditioned frozen water packs are being used to transport freeze-sensitive vaccines, include an electronic freeze indicator in the load. Freeze indicators are not needed if cool water packs are used. If warm water packs are used to protect freeze-sensitive vaccines in very cold climates, use freeze indicators, since the temperature of the load may drop below 0 °C on a long journey.

Freeze-preventive cold boxes and vaccine carriers: Where frozen water packs are used in a freeze-preventive vaccine carrier, an electronic freeze indicator is not necessary.

4 Monitoring cold-chain temperatures

The data gathered from temperature-monitoring devices must be recorded and analysed on a regular basis to demonstrate that vaccines are being stored and transported at the correct temperatures. This section reviews temperature monitoring of vaccine refrigerators, cold boxes and vaccine carriers at the health facility level.

4.1 Monitoring vaccine refrigerator temperature

A standard manual temperature-recording chart should be attached to the door of every vaccine refrigerator. Readings should be taken twice a day, for at least five days per week but preferably every day, including weekends and holidays. Take daily readings from the same temperature-monitoring device. Read the 30-day electronic temperature recorder and write the data on the chart. If there is no 30-day electronic temperature recorder, check the integrated digital thermometer or, where necessary, the stem thermometer, and record the data. Recording temperatures in this way provides evidence that the refrigerator is being monitored and that regular readings are being taken. The data can also help identify performance trends, sometimes before automatic alarms are generated.

Manual readings should be recorded on the temperature chart, using the following procedure:

- Check the refrigerator temperature first thing in the morning and at the end of the working day.
- Record the temperature by date and time on the chart (an example designed for a 30-day electronic temperature recorder is shown in Fig. 2.18). When a chart is completed, replace it with a new one. Keep completed charts in a file for future reference.

Fig. 2.18 Sample vaccine refrigerator temperature-monitoring chart

This chart is designed for use with 30-day electronic temperature recorders. Twice-daily temperatures are recorded on the chart, and the space below is used to record alarm events.

Temperature monitoring chart for temperature logger device

Cold room/refrigerator number:	IRL # 1	Start date: <dd/mm/yyyy>	03 Oct 2025	Key: FI = freeze indicator (status OK or X)	
Equipment model:	MFR 123	Location:	Erehwon HC		

Day	1		2		3		4		5		6		7		8		9	
°C	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
+16																		
+15																		
+14																		
+13																		
+12																		
+11																		
+10																		
+9																		
+8																		
+7	x			x														
+6		x	x		x													
+5						x			x									
+4							x	x		x								
+3											x	x	x					
+2														x				
+1															x	x		
0																	x	
-1																		x
-2																		
-3																		
-4																		
-5																		
FI (X or OK)																		
>+8 °C alarm	Once every 24 hours, enter high alarm status and maximum temperature recorded by the continuous temperature monitoring device																	
Alarm or OK	OK		OK		OK		OK		OK		OK		OK		OK		OK	
Max °C	+7.5		+6.5		+6.3		+4.5		+5.2		+3.3		+3.0		+1.8		+0.2	
<-0.5 °C alarm	Once every 24 hours, enter high alarm status and maximum temperature recorded by the continuous temperature monitoring device																	
Alarm or OK	OK		OK		OK		OK		OK		OK		OK		OK		OK	
Min °C	+5.8		+5.4		+4.8		+3.5		+3.6		+2.8		+1.7		+0.8		-0.5	
Initials	J	J	J	J	J	J	FC	FC	FC	FC	FC	FC	FC	FC	FC	FC	FC	J

Day	10		11		12		13		14		15		16		17	
°C	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
+16																
+15																
+14																
+13																
+12																
+11																
+10																
+9																
+8																
+7																
+6												x				x
+5						x		x		x			x		x	
+4					x		x		x		x			x		
+3				x												
+2																
+1			x													
0																
-1	x	x														
-2																
-3																
-4																
-5																
FI (X or OK)																
>+8 °C alarm																
Alarm or OK	OK		OK		OK		OK		OK		OK		OK		OK	
Max °C	-0.8		-0.5		+5.2		+5.4		+5.3		+6.1		+5.5		+6.1	
<-0.5 °C alarm																
Alarm or OK	OK		OK		OK		OK		OK		OK		OK		OK	
Min °C	-1.5		-1.3		+0.9		+3.5		+3.8		+3.6		+4.6		+3.9	
Initials	J	J	J	J	J	J	J	J	J	J	J	J	J	J	J	J

Day	18		19		20		21		22		23		24		25		26		27		28		29		30		31
°C	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	

Province:	Jazir	Month:	October	Remarks:	Thermostat incorrect adjusted by temporary health worker. Corrected on 12 Oct.
District:	District 9	Year:	2025		
Health care:	Erehwon	Supervisor:	AG		

Source: WHO/EPI

4.2 Taking action when a vaccine refrigerator's temperature is out of range

If the temperature of the refrigerator is below +2 °C, notify a supervisor according to the agreed protocol (such as via text, phone call or email) and take corrective action, including the following procedures:

- Regulate the air-conditioning unit of the room, if any.
- If using a combined unit, check whether the freezer door closes properly. If the seal is damaged, follow standard operating procedures to call a technician to make repairs.
- If the temperature has fallen below 0 °C for any length of time, using the shake test to check whether freeze-sensitive vaccines have been damaged by freezing (see section 8 of this module).

Slight heat exposure is less damaging than freezing exposure to most liquid vaccines and diluents.

If the temperature is above +8 °C, notify a supervisor and take corrective action, including the following procedures:

- Make sure that the refrigerator is working. If it is not working, check whether the power supply (electricity or solar) is adequate.
- Check whether the door of the refrigerator or the freezer compartment closes properly; if the seal is broken, the temperature will fluctuate. Follow standard operating procedures to request a repair.
- Check whether frost is preventing cold air in the freezing compartment from entering the refrigerator compartment. Defrost if necessary.
- If the power supply and door seal are in working order and the frost level is less than 10 mm, adjust the temperature-control knob to a higher number.[1] This will make the refrigerator cooler.
- If the temperature cannot be maintained between +2 °C and +8 °C, store vaccines in other cold-chain equipment that can maintain this temperature range until the refrigerator is repaired.

To avoid freezing vaccines, do not adjust the thermostat to a cooler (higher number) setting after a power cut or when vaccines arrive.

[1] Thick ice and frost on the refrigerator wall reduce the unit's cooling efficiency; it is necessary to defrost the unit when the ice formation reaches a thickness of 10 mm.

4.3 Maintaining the correct temperature in cold boxes and vaccine carriers

To maintain the correct temperature in cold boxes and vaccine carriers, proceed as follows:

- Place the correct number and type of coolant packs in the cold box or vaccine carrier.
- Ensure that the coolant packs are properly prepared according to the type of cold box/vaccine carrier used.
- If using conditioned frozen water packs in regular cold boxes or vaccine carriers, put an electronic freeze indicator in each box or carrier containing freeze-sensitive vaccines.
- Keep the cold box or vaccine carrier in the shade.
- Keep the lid of the cold box or vaccine carrier tightly closed.
- Use the foam pad to hold opened vials at the top of the vaccine carrier during an immunization session; keep the hard carrier lid closed whenever possible.
- During the immunization session, keep vaccines at the recommended temperatures after opening them. If they do not contain preservative, it is important to keep opened multi-dose vaccine vials (both lyophilized or liquid) cooled at temperatures between +2 °C and +8 °C.
- At the end of the immunization session, follow national policy in handling remaining vials. In general, this means:
  - discarding all opened vials of vaccines that do not contain preservative (that is, all reconstituted vaccines and some liquid multi-dose vaccines);
  - discarding all opened and unopened vials with unreadable, peeled-off or damaged vial labels;
  - checking the vaccine expiration date and discarding all unopened vials that have expired;
  - checking the VVMs of all unopened vials and returning the unopened vials with VVMs that are not past the discard point to a working refrigerator or cold box as soon as possible;
  - where multi-dose vial policy is applied, check the VVMs of all opened vials that contain preservative and return those with VVMs that are not past the discard point to a working refrigerator or cold box as soon as possible. Mark these vaccines “Use first” for the next immunization session.

5 Arranging vaccines inside cold-chain equipment

Vaccines must be arranged inside cold-chain equipment in a manner that helps ensure that they remain in good condition, with minimum risk of exposure to damaging temperatures. This section describes how to arrange vaccines inside vaccine refrigerators, cold boxes and vaccine carriers.

5.1 General rules for using vaccine refrigerators

Health facility refrigerators are used to store vaccines and diluents. Wherever possible, vaccines and diluents should be stored only in a WHO-prequalified refrigerator.

Several types of refrigerators are available, and the arrangement of items inside them varies according to the type (see Table 2.9). However, several general rules apply, as described below.

DO's when arranging the vaccines in the health facility refrigerator:

- If vaccines and/or diluents are supplied in their original cartons, arrange the boxes so that there is at least a 2 cm space between stacks. This allows air to circulate freely and also makes it easier to handle the vaccines and conduct inventories.
- Mark the cartons clearly and ensure the markings are visible when the door is opened.
- If vaccines or diluents are not supplied in their original boxes (for example, as individual vials, ampoules or tubes), use a plastic tray, plastic box or other arrangement to store the vaccines in an orderly fashion, grouping them by product. Arrange the items with sufficient space for air circulation using locally made stacking boxes.
- If diluent is packaged with the vaccine, store the complete packaged product in the refrigerator. If diluents are supplied separately from the vaccine, store them in the refrigerator together with the vaccine if there is adequate space. If there is no adequate space, store them in a cool dry place and then cool the required number of diluents in the refrigerator for at least 24 hours before they are used.
- Place vaccines with VVMs that show the most heat exposure (that is, somewhat darker squares, but not as dark as the surrounding circle) in a separate container in the refrigerator, clearly marked "Heat-exposed vials – use first." If there are other vaccines of the same type in the refrigerator, the vaccines with the darkest squares should always be used first, even if the expiry date is later than the vaccines with the lighter squares.
- If a MDVP is in place, follow the instructions for handling opened multi-dose vials exactly as described in the national policy. If an opened multi-dose vial will be used for the next session, the vial must be placed in a separate container in the refrigerator and clearly marked "Opened vials – use first." (See section 1.4 of this module for a summary of WHO MDVP; local policy may be different.)

If other heat-sensitive supplies, such as drugs, ointments, sera and samples, have to be stored in the same refrigerator as vaccines and diluents, make sure they are properly stored, clearly labelled and separated from the vaccines and diluents. Follow the recommendations in the WHO-UNICEF joint statement on cold chain integration of temperature-sensitive health products *(1)*.

DON'Ts when arranging the vaccines in the health facility refrigerator:

- Never store food or drink in a vaccine refrigerator.
- Do not open the door unless it is essential to do so.
- If there is a freezer compartment, do not use it to store vaccines and diluents.
- Do not keep vaccine in the following conditions in the refrigerator:
  - expired vaccines;
  - with VVMs that have reached, or are beyond, their discard point;
  - reconstituted vaccine unused for more than six hours or left over at the end of an immunization session.

  Discard all these items immediately, according to your national guidelines. Refer any questions to a supervisor.

Table 2.9 Double- versus single-compartment vaccine refrigerators

Type	Front opening	Top opening
Single compartment: recommended for health facility-level vaccine storage. A separate freezer for water pack freezing should be used.[a]	• Prequalified ice-lined models powered by mains or solar electricity • These models do not have water pack-freezing compartment	• Solar direct-drive models with a lining containing a phase-change material to protect the vaccine overnight and during cloudy periods • The phase-change material freezes at around +5 °C, so vaccine can be in contact with lining without risk of damage • Current models do not have a freezer compartment
Double compartment: recommended for subnational and district levels. Not recommended at the health facility level, to eliminate the risk of freezing vaccines.	• Models not pre-qualified by WHO that are powered by mains • Typically these have an water pack-freezing compartment	• Current models do not have a freezer compartment

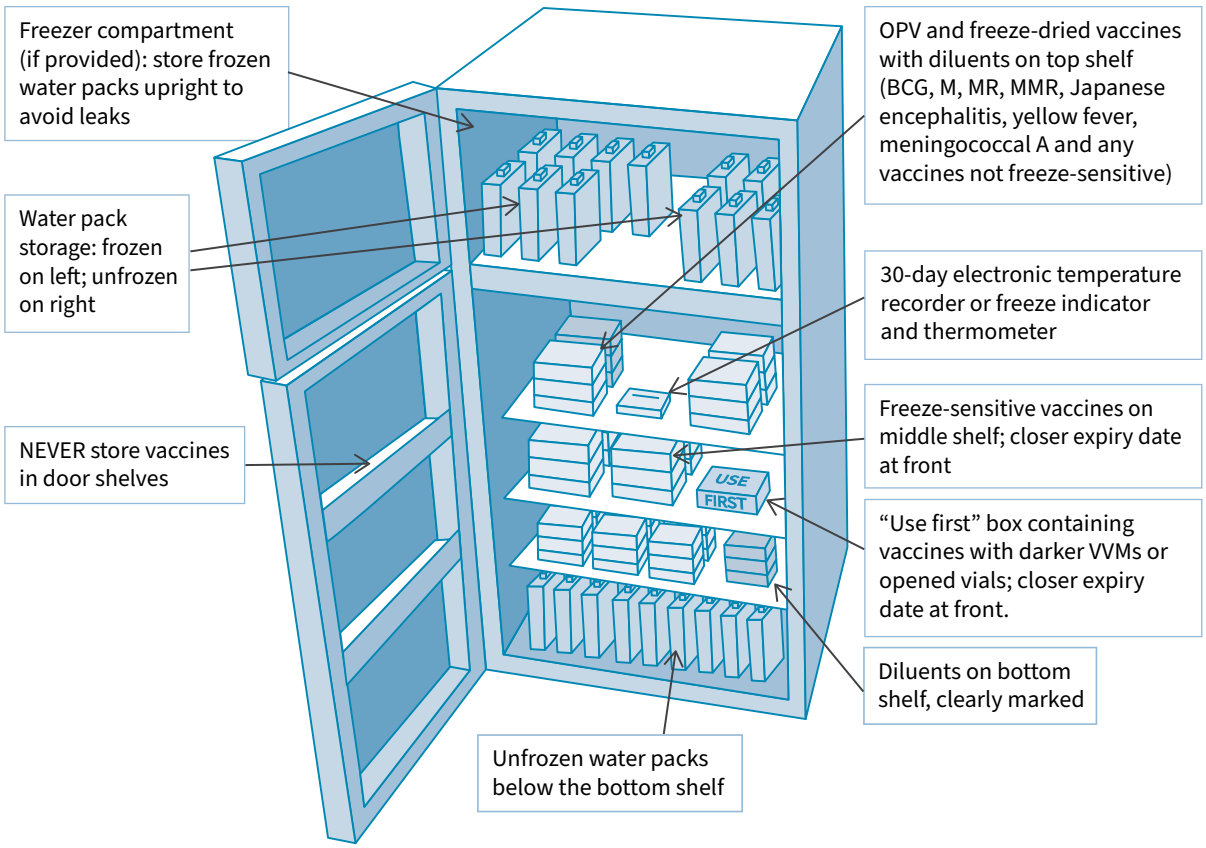
[a] Any locally available freezer can be used for water pack freezing.

5.2 Rules for using front-opening refrigerators

The following rules apply when using front-opening refrigerators (see Fig. 2.19).

- Never put freeze-sensitive vaccines in contact with, or close to, the evaporator plate in the refrigerator.
- Put water packs or plastic bottles full of coloured water in the space below the bottom shelf. This helps to stabilize the temperature if there is a power cut. Never drink the water.
- Store the following vaccines on the top shelf: polio, measles, MR, MMR, yellow fever, Japanese encephalitis, influenza, mpox and any other vaccines not damaged by freezing.
- Store diluents and the following freeze-sensitive vaccines on the middle or lower shelves: DTP, DT, Td, TT, HepB, DTP+HepB, DTP+HepB+Hib, Hib, HPV, rotavirus, malaria, meningococcal A conjugate, oral cholera vaccine (OCV), rabies, typhoid and any other freeze-sensitive vaccines.
- Store the diluents together with the freeze-dried vaccine with which they are supplied, on the appropriate shelf. If there is not enough space on the shelf, put the diluents in the bottom shelf of the refrigerator, clearly labelled so they can be easily paired with the matching vaccine.
- In case the health facility is using a refrigerator not prequalified by WHO, do not put vaccines or diluents in the door shelves. The temperature is too warm for vaccine storage, and the vaccines are exposed to room temperature each time the door is opened.

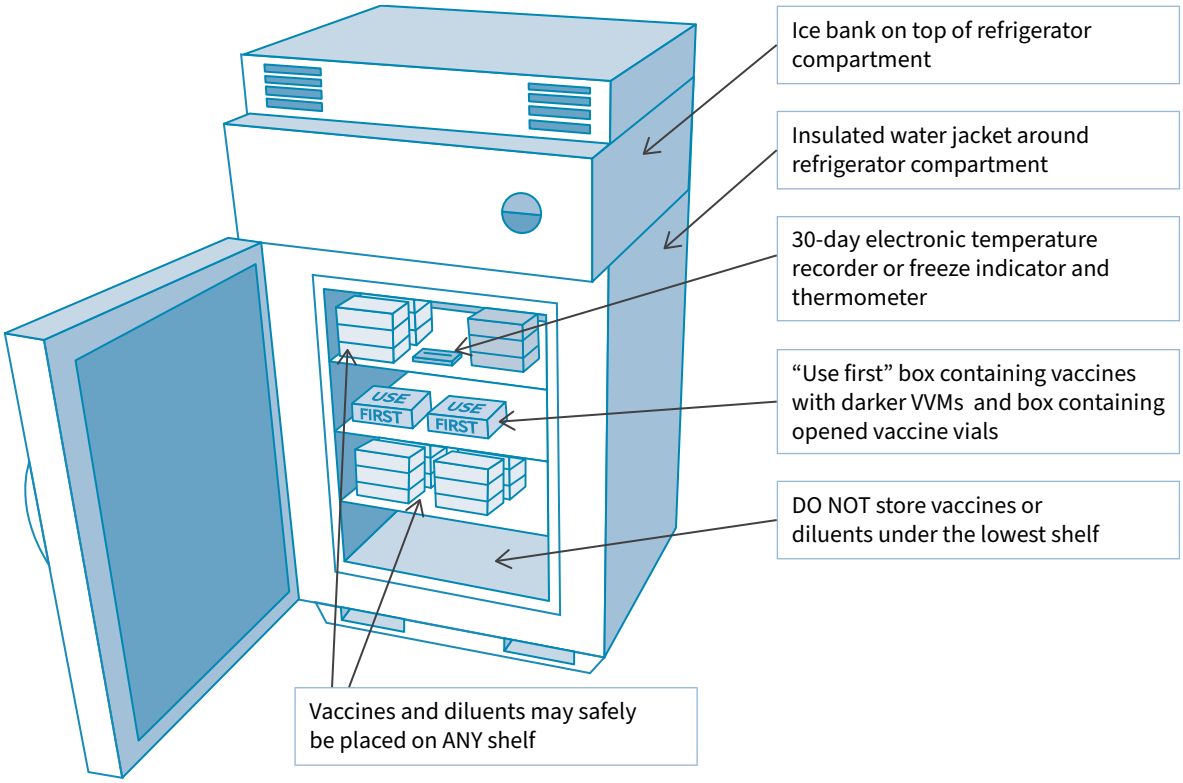
Fig. 2.19 Vaccine and diluent arrangement in a front-opening vaccine refrigerator with a freezer compartment



Source: WHO/EPI

Fig. 2.20 shows the recommended arrangement of vaccines and diluents in a front-opening ice-lined refrigerator. This model has very little variation in the temperature inside the refrigerator compartment, so vaccines and diluents can be placed safely on any of the shelves. However, in humid climates, condensation may form inside the unit. Cartons and vials should be stored in plastic boxes with tightly fitting lids to reduce the risk of moisture damage. Never store vaccines below the bottom shelf: this area may be wet because it collects and drains the condensation from the top and walls of the compartment.

Fig. 2.20 Vaccine and diluent arrangement in a front-opening ice-lined refrigerator without a freezer compartment



Source: WHO/EPI

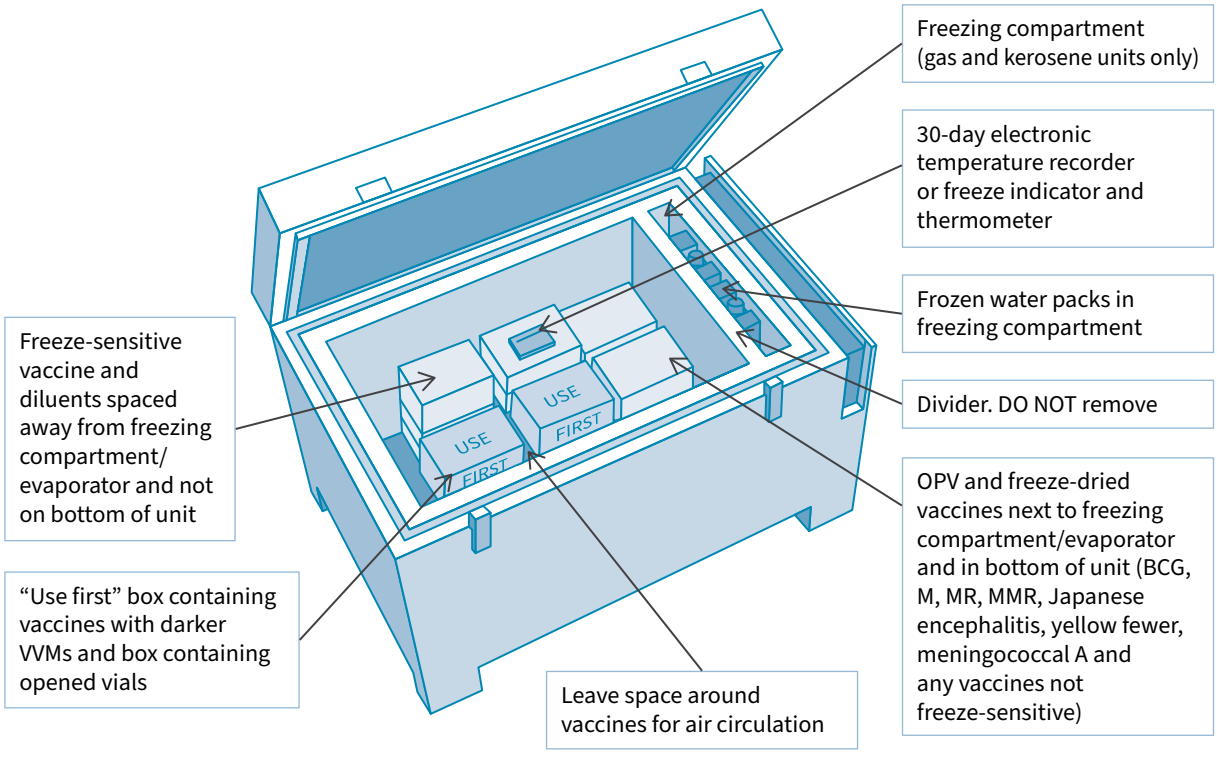
5.3 Rules for using top-opening refrigerators without baskets

Some top-opening refrigerators are supplied without baskets. Fig. 2.21 shows the arrangement of vaccines and diluent in a top-opening refrigerator without baskets.

The following rules apply to refrigerators without baskets:

- Put the opened vials for use in the next session and vaccine with somewhat darkened VVMs or close to the expiration date at the top for easy access and make sure they are clearly labelled "Use first."
- Never put freeze-sensitive vaccines in the bottom of gas and kerosene refrigerators or next to the freezer compartment, as there is a risk of freezing in these areas.
- Store the following vaccines in the bottom of the refrigerator and closest to the freezing compartment: polio, measles, MR, MMR, yellow fever, Japanese encephalitis, influenza, mpox and any other vaccines not damaged by freezing.
- Place diluents and the following freeze-sensitive vaccines at the top of the compartment and well away from the freezing compartment, if any: DTP, DT, Td, TT, hepatitis B, pentavalent, hexavalent, Hib, HPV, rotavirus, malaria, meningococcal A conjugate, OCV, rabies, typhoid. Store the diluents together with the freeze-dried vaccine with which they were supplied. If this is not possible, make sure the diluents are clearly labelled so they can be easily paired with the matching vaccine.

Fig. 2.21 Vaccine and diluent arrangement in a top-opening refrigerator without baskets



Source: WHO/EPI

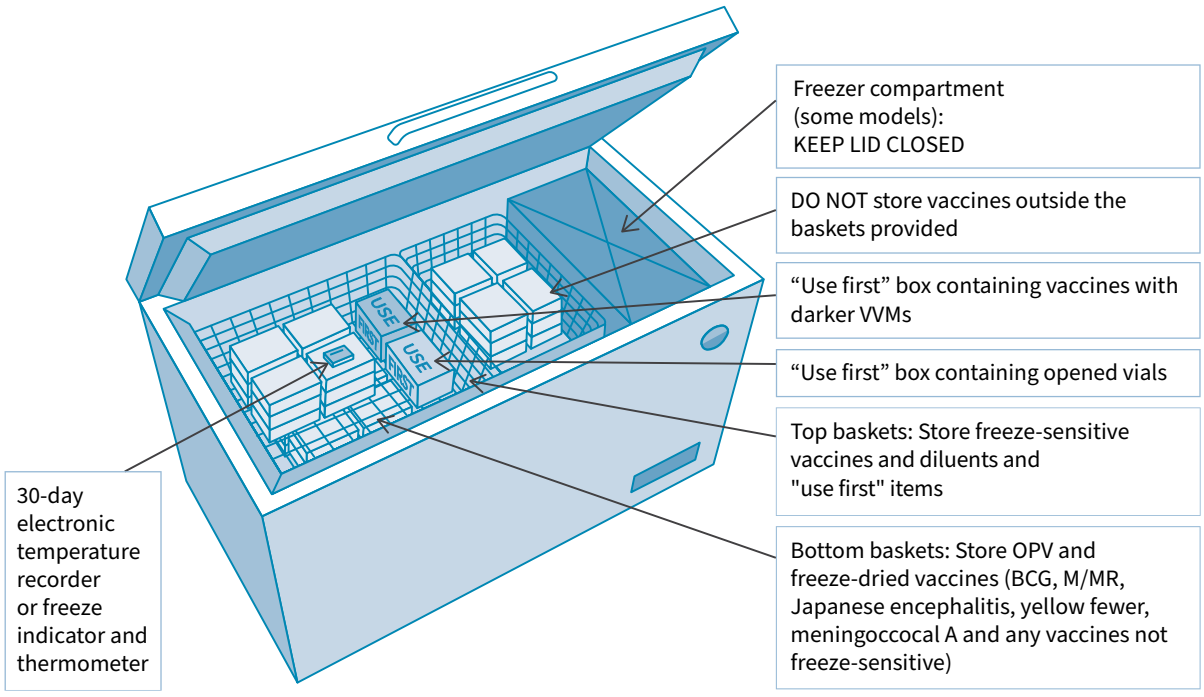
5.4 Rules for using top-opening refrigerators with baskets

Many top-opening ice-lined refrigerators are supplied with baskets for storing vaccines. Top-opening solar direct-dive models typically do not have an ice lining, but they generally have baskets.

Fig. 2.22 shows how these refrigerators should be organized. The following rules apply:

- Always store vaccines and diluents in the baskets provided.
- If there is an internal lid on the freezer compartment and/or the refrigerator compartment, always replace it before closing the main lid.
- Some solar direct-drive refrigerators have an ice bank at one end. Never remove frozen water packs from this area.
- Some solar direct-drive refrigerators have a separate water pack-freezing compartment. Follow the manufacturer's instructions on the use of this feature.
- Use the bottom baskets to store measles, MR, MMR, mpox, BCG, OPV, yellow fever, Japanese encephalitis and any other vaccines not damaged by freezing.
- Use the top baskets to store products for immediate use as well as diluents, DTP, DT, Td, TT, hepatitis B, malaria, multivalent vaccines (for example, pentavalent, hexavalent), Hib, HPV, rotavirus and/or any other freeze-sensitive vaccines. Never put freeze-sensitive vaccines in the bottom baskets, as, in some models, there is a risk of freezing in these areas.
- Store the diluents together with the freeze-dried vaccine with which they were supplied. If this is not possible, make sure the diluents are clearly labelled so they can be easily paired with the matching vaccine.

Fig. 2.22 Vaccine and diluent arrangement in a top-opening refrigerator with baskets



Source: WHO/EPI

6 Preparing frozen water packs and cool water packs

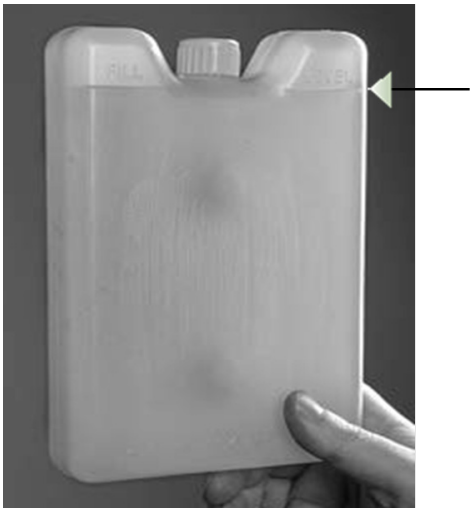
If the vaccine refrigerator has a freezer compartment, it can be used to freeze water packs and store frozen ones. Cool water packs must be prepared and stored in a separate refrigerator, not in a refrigerator used to store vaccines. Every health facility should have at least two sets of water packs that correspond in size and number to its stock of cold boxes and vaccine carriers.

6.1 Filling and checking water packs

New water packs are supplied empty and must be filled before use.

- Fill each pack with clean water, up to the fill line (see Fig. 2.23). Do not overfill: always leave a little air space at the top.
- Do not add salt or other solution to the water.
- Fit the stopper and screw the cap on tightly.
- Check water packs for leaks by laying them on their side (see Fig. 2.24). If leaking, adjust the cap until no leak is observed.

Fig. 2.23 Correct water level when filling water packs



Source: WHO/EPI

It is unnecessary to empty and refill water packs unless they have leaked. If the pack has leaked, top up the water and ensure the cap is fixed securely.

Fig. 2.24 Checking filled water packs for leaks

Source: WHO/EPI

Before using a water pack, hold it upside down and squeeze it to ensure it does not leak. If the pack has been damaged, discard it.

6.2 Freezing water packs

When freezing water packs, always follow the manufacturer's instructions for the cold-chain equipment and never overload the freezing compartment. If the compartment has a door or lid, ensure it is properly closed.

Before loading the water pack into the freezer, ensure each water pack is filled to the correct water level and is without leaks. Wipe the water packs dry and place them in the deep freezer (-15 °C to -25 °C) for at least 24 hours. Arrange the water packs upright or on their sides so that the surface touches the evaporator plate. Depending on various factors, it can take 24 hours or more to fully freeze a batch of water packs.

The more packs in the freezing compartment, the longer they will take to freeze. If too many water packs are placed in the unit, they may not freeze at all. Keep extra, unfrozen water packs that do not fit into the freezer in the bottom part of the main refrigerator compartment to keep this section cold in case of a power failure. When these extra water packs are placed in the freezer, they will freeze relatively quickly because they are already cold. Never store frozen water packs in the vaccine refrigerator compartment; this will lower the temperature and increase the risk of freezing vaccines.

Most mains electric ice-lined refrigerators and domestic refrigerators or those not prequalified by WHO have a separate freezing compartment; these models can freeze up to six large or 12 small water packs every 24 hours.

Some recent solar direct-drive refrigerators can also freeze water packs. However, their freezing capacity depends on the amount of sunshine available, and it may not be possible to freeze water packs in cloudy weather. The water packs will melt slightly overnight when there is no power, and there may be some liquid water in the packs at the beginning of the day, but this is normal.

Older solar direct-drive models do not have a water pack freezing compartment. Instead of an ice lining, some solar direct-drive models have a bank of standard water packs in a compartment that looks like a freezer compartment. These water packs must never be removed for use in vaccine carriers.

6.3 Conditioning frozen water packs

Frozen water packs taken directly from the freezer are not suitable for immediate use unless freeze-preventive cold boxes/vaccine carriers are used. If only regular (non-freeze-preventive) cold boxes or vaccine carriers are available and the frozen water packs are not correctly conditioned, it is very likely that freeze-sensitive vaccines will be frozen and destroyed. Wrapping vaccines in newspaper or other materials does not protect against freezing.

WHO recommends using conditioned water packs for transporting vaccines in regular cold boxes and vaccine carriers except where cool water packs are used instead. A frozen water pack is correctly conditioned when it has melted enough to allow the ice to move inside the pack. To condition a frozen water pack, perform the following procedures:

- Remove the required number of frozen water packs from the freezer compartment. The quantity and type of pack required are often shown on the inside lid of the cold box or vaccine carrier.
- Allow the frozen water to thaw by placing the packs on a clean flat surface in a single layer, exposed to ambient temperature. Leave gaps of about 5 cm between packs.
- Wait until all packs are properly conditioned. The pack should have “sweat” (condensation or droplets of water, as shown in Fig. 2.25). There must be liquid water inside every pack.
- Check if each frozen water pack has been conditioned by shaking it and listening for water (see Fig. 2.26). The ice cores should move inside the packs when shaken.

This process will take at least 30–45 minutes in hot weather and much longer in cooler conditions (for example, from 90 to 120 minutes at +20 °C).

Fig. 2.25 Condensation on a conditioned water pack

Source: WHO/EPI

Fig. 2.26 Shaking a frozen water pack to check if it is properly conditioned

Source: WHO/EPI

Unconditioned frozen water packs may be used in a regular cold box for distributing polio vaccines from the district to the health facility or to an outreach post. Follow national protocol for distributing polio and other heat-sensitive vaccines.

6.4 Preparing cool water packs

When cool water packs are used for vaccine transport, the health facility must be equipped with a separate refrigerator for preparing these packs. This refrigerator must not be used for storing vaccines. The thermostat should be set as low as possible to ensure the water packs are cooled to +5 °C or below.

If a cool water pack strategy has been adopted for outreach operations, one or more cool water packs must be brought to the session to ensure that opened multi-dose vaccine vials are kept at recommended temperatures.

7 Packing vaccines in cold boxes and vaccine carriers

The following procedures apply to packing vaccines in both cold boxes and vaccine carriers.

- Take the required number of frozen water packs from the freezer.
- If using a regular cold box/vaccine carrier, condition the frozen water packs, following the procedures described in section 6.3 of this module, and pack them in the appropriate spots in the box or carrier.
- Pack the vaccine and diluents inside the cold box or vaccine carrier.

The remainder of this section describes procedures specific to the type of cold box and carrier.

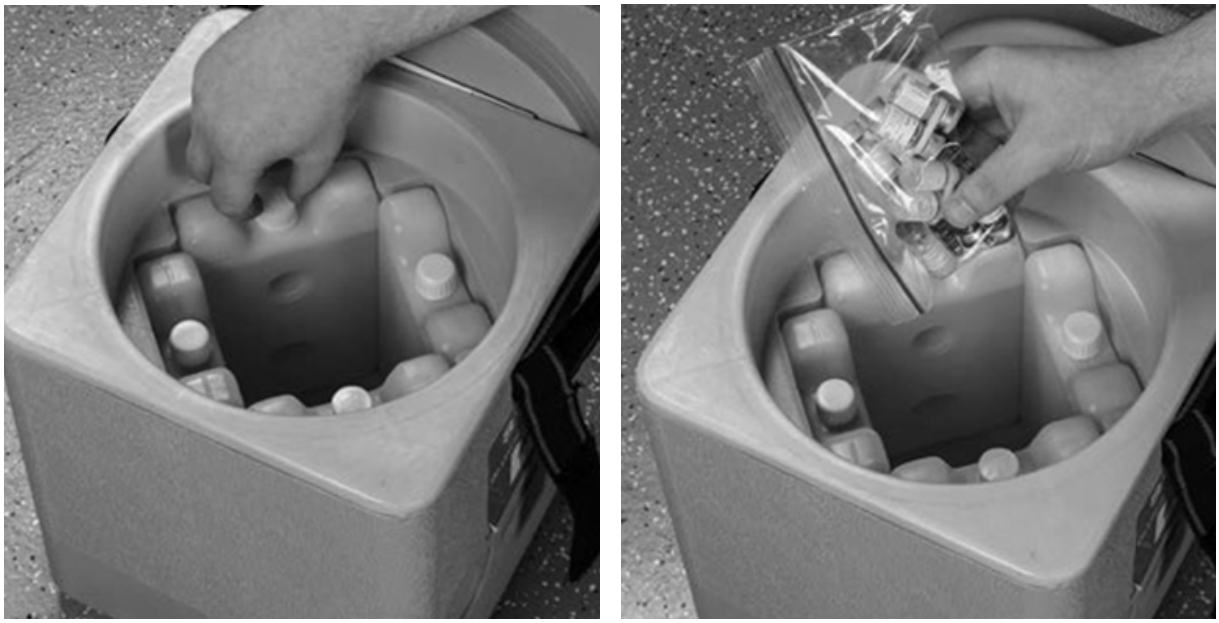
Regular cold box:

- Place the required number of conditioned frozen water packs or cool packs against the sides of the cold box.
- Keep the vaccines and diluents in their original carton to protect them from damage due to condensation. Carefully arrange them inside the cold box.
- Place an electronic freeze indicator with the vaccines. (This is not needed if cool water packs are used.)
- Close the cold box lid tightly. Do not open unless necessary.

Regular vaccine carrier:

- Place four conditioned frozen water packs against the sides of the vaccine carrier.
- Keep the vaccines in their original carton if the storage compartment is big enough. If not, transfer the vaccine vials into a reusable/waterproof container or bag to protect them from damage due to condensation and place them in the middle of the vaccine carrier (see Fig. 2.27).
- Place an electronic freeze indicator with the vaccines. (This is not needed if cool water packs are used.)
- Place the foam pad on top of the vaccine.
- Close the vaccine carrier lid tightly. Do not open unless necessary.

Fig. 2.27 Correct placement of water packs and vaccine inside a regular vaccine carrier



Source: WHO/EPI/IIP 2015

Freeze-preventive cold box:

- Place the required number of frozen water packs or cool packs in their designated compartment.
- Keep the vaccines and diluents in their original carton to protect them from damage.
- Carefully arrange the vaccine cartons inside the cold box.
- Close the cold box lid tightly. Do not open unless necessary.

Freeze-preventive vaccine carrier:

- Place four frozen water packs in their designated compartment.
- Keep the vaccines in their original carton if the storage compartment is big enough. If not, remove the vaccine vials from the box and place them in the vaccine carrier. Place the foam pad on top of the vaccine.
- Close the vaccine carrier lid tightly. Do not open unless necessary.

Remember:

- Arrange the water packs in the cold boxes and/or vaccine carriers exactly as shown in the manufacturer's instructions (some models have instructions printed on the lid).
- Place vaccines in the carrier on the session day (note that vaccine carriers may not store vaccines effectively beyond 12 hours).
- Do not drop or sit on the vaccine carrier.
- Keep the vaccine carrier in a shaded area, away from direct sunlight.
- Once the vaccine carrier is packed, do not leave its lid open.

8 The shake test

8.1 What is the shake test?

The shake test is used to check whether aluminium-based, adsorbed, freeze-sensitive vaccines have been damaged by exposure to temperatures below 0 °C. After it has thawed, a vial of vaccine that has been frozen no longer has the appearance of a cloudy liquid but tends to form flakes that settle at the bottom of the vial.

The shake test requires two vials of the same vaccine from the same manufacturer and with the same batch number. One of these is a vial that you suspect has been frozen (test vial) and the other is a vial that you have deliberately frozen solid overnight (control vial). Allow the test and control vials to melt completely before performing the shake test. The procedures for performing this test are outlined in section 8.3. The result is interpreted based on the vaccine sedimentation rate. If the test vial settles at the same speed as the control vial, it has been frozen. If it settles more slowly, it has not been frozen.

8.2 When is the shake test needed?

If a freeze indicator is activated, or temperature recordings show negative temperatures, freeze-sensitive vaccines may have been damaged. If this occurs, notify your supervisor. If authorized, carry out the shake test on a sample of the freeze-sensitive vaccines.

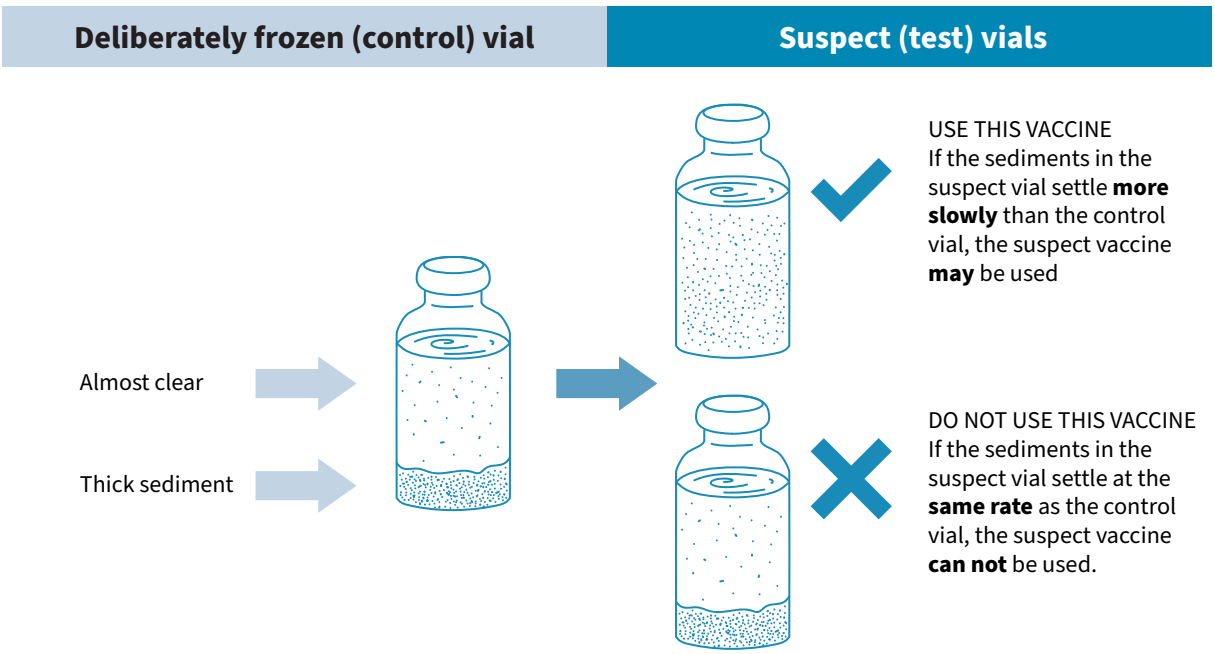
8.3 How is the shake test done?

There is only one correct way to conduct a shake test, and so the following protocol must not be altered. The test procedures should be repeated with all suspect batches. In the case of international arrivals, the shake test should be conducted on a random sample. However, if there is more than one lot in the shipment, the random sample must include a vial taken from each lot.

1. Take a vial of vaccine of the same type and batch number, and from the same manufacturer, as the vaccine you want to test.
2. Clearly mark the vial as “Frozen.” This serves as the control vial.
3. Freeze the control vial in a freezer or the freezing compartment of a refrigerator until the contents are completely solid.
4. Let the contents of the vial thaw. Do not heat it!
5. Take a vial from the batch that you suspect has been frozen, clearly marking the vial as “Test.”
6. Hold the “Frozen” vial and the “Test” vial together in one hand.

7. Shake both vials vigorously for 10 to 15 seconds.
8. Place both vials upright on a flat surface side by side and observe them continuously until the shake test is finished. Use an adequate source of light to compare the sedimentation rates between vials. (If the vials have large labels that conceal the vial contents, turn both vials upside down and observe sedimentation in the neck of the vial.)
9. Compare the "Frozen" vial to the "Test" vial (see Fig. 2.28). If the "Test" vial sediments slower than the "Frozen" vial, then the vaccine has not been damaged. If the sedimentation is similar in both vials or the "Test" vial sediments faster than the control vial, then the vaccine is damaged.
10. If the vaccine has not been damaged, use the vaccine batch.
11. If the vaccine is damaged, notify your supervisor. Set aside all affected vaccine vials in a container marked "DAMAGED VACCINE FOR DISPOSAL – DO NOT USE." Discard all affected vaccine once you have received permission to do so. Fill in a Loss/Adjustment Form.

Fig. 2.28 Comparing the deliberately frozen (control) vial next to the suspect (test) vial



Source: WHO/EPI

9 Preventive maintenance of cold-chain equipment

The primary goal of an equipment maintenance and repair system is to eliminate or avoid unnecessary or unplanned equipment downtime. Maintenance activities can be divided into two major categories: preventive maintenance (also referred to as planned maintenance) and corrective maintenance. This section focuses on preventive maintenance of equipment commonly used in health facilities and lowest distribution points.

Preventive maintenance refers to procedures that reduce the likelihood of equipment failure and extend the life of equipment (for example, calibration, part replacement, lubrication, cleaning). Preventive maintenance activities are conducted in a systematic manner before equipment failure and are based on a schedule set by time, distance or cycles of operation *(5)*.

Basic preventive maintenance includes the following:

- defrosting
- cleaning the solar panels (as applicable)
- maintaining space between equipment and the wall for air flow
- keeping the fan clean
- calibration
- parts replacement
- lubrication
- cleaning the unit both inside and outside.

Health workers are encouraged to ensure that each piece of cold-chain equipment has a maintenance log with updated information on preventive and corrective maintenance activities. In addition, there should be clear standard operating procedures and contingency plans in case of prolonged power failure or temperature excursion, including activities such as defrosting the refrigerator.

Implementing a preventive maintenance strategy will result in lower repair costs and fewer unexpected equipment failures. In contrast, a maintenance system that simply reacts to equipment failures will probably result in higher total cold-chain equipment costs and put vaccine potency and availability at risk.

9.1 Defrosting vaccine refrigerators

A refrigerator works well only if it is properly installed and then cleaned and defrosted regularly.

Thick ice in the freezer compartment and on the evaporator plate does not keep a refrigerator cool. Instead, it makes the refrigerator work harder and uses more electricity or solar power. Refrigerators should be defrosted regularly or when the ice is more than 0.5 cm thick, whichever comes first.

To defrost and clean a refrigerator, follow these steps:

- Remove all the vaccines and transfer them to another refrigerator or to a cold box or vaccine carrier lined with conditioned water packs.
- Switch off the electrical supply for a mains refrigerator.
- Leave the door open and wait for the ice to melt. Never try to remove the ice with a knife or ice pick; this can permanently damage the refrigerator. To speed melting, a pan of hot water can be placed inside the appliance and the door closed.
- Clean the inside of the refrigerator and door seal with a clean damp cloth.
- Restart the refrigerator. Do not adjust its thermostat.
- When the temperature in the main section falls to +8 °C or lower (but not less than +2 °C), arrange the vaccines, diluents and water packs in their appropriate places.

Solar direct-drive refrigerators should be defrosted only on a sunny day. A solar direct-drive refrigerator should generally be defrosted in the early morning. It will have partly defrosted overnight, so this will speed up the process. Defrosting in the early morning will also allow the refrigerator to make best use of the day's supply of solar power.

If a refrigerator needs to be defrosted more than once a month, check for these common problems:

- Staff are opening the door too often (more than three times daily).
- The door is not closing properly.
- The door seal needs to be replaced.

9.2 Maintaining solar power systems

Solar panels need to be cleaned, checked and maintained. Tasks can be divided into daily, periodic and annual.

Daily

- Check the status of the control panel display. Take appropriate action as described in the instruction manual if the status is not normal.

Periodically

- Clean dust or snow off the solar array. The frequency with which this needs to be done will vary. In very dusty areas, clean the array weekly. Remove any snow accumulation as soon as possible. Do not attempt to carry out this task unless you have the correct access and safety equipment and have received training in safe working at heights. Make sure you have somebody to help you and to hold the ladder.
- Never stand on corrugated roof sheets or tiles: use a properly designed roof ladder.
- Clean the array in the early morning or evening when the sun is weak.
- Use a soft cloth dampened with water. Wipe gently, starting at the top and working downwards.
- Do not lean or stand on the array panels, as you may damage them.
- Report any damage to wiring or hardware to your supervisor.

Once a year

- Make sure the solar panels are not shaded by trees, plants, new buildings or overhead cables between 9:00 and 15:00. If vegetation is creating shade, arrange for it to be cut back. If there is shading from newly constructed buildings or new overhead cables, contact your supervisor. In such cases, the solar array may have to be moved or increased in capacity.
- Check the electric cables between the solar array, the charge regulator and the refrigerator. Inspect grounding/lightning protection. If you see any damage, contact your supervisor.

9.3 Managing vaccine refrigerator breakdowns

Refrigerator and freezer breakdowns can be prevented or minimized if regular preventive maintenance is implemented. If a vaccine refrigerator stops working, first protect the vaccines from damage, then check the cause of the problem and have it fixed as soon as possible.

Move the vaccines to other cold-chain equipment until the refrigerator is repaired. For a problem that can be solved quickly, a cold box or vaccine carrier lined with conditioned frozen water packs can be used for temporary storage. For a problem that might take longer to solve, another refrigerator is needed. Always keep a freeze indicator with the freeze-sensitive vaccines, except when using freeze-preventive passive cold-chain devices.

To restore the refrigerator to working order, take the following actions:

- Check the electricity, gas, kerosene or solar power supply and plan to deal with any interruptions.
- If a lack of electricity, gas, kerosene or solar power is not the problem, contact your supervisor and ask for a repair service visit. Do not attempt to repair the refrigerator yourself unless the problem is a simple one that you have been trained to deal with.
- Record the breakdown on the daily temperature-monitoring chart.

See Annex 2.2 for procedures for preventive maintenance for health facilities that are still using absorption-type refrigerators (powered by gas or kerosene).

9.4 Maintaining cold boxes and vaccine carriers

Vaccine carriers and cold boxes must be thoroughly dried after use, with their lids propped open. If they are left wet with their lids closed, they will become mouldy. Mould and damp can affect the seal of the cold boxes and vaccine carriers and may contaminate the vaccines. If possible, store cold boxes and vaccine carriers with the lids open.

Knocks and sunlight can cause cracks in the walls and lids of cold boxes and vaccine carriers. These expose the insulation and increase the risk of heat exposure to the vaccines inside. If a cold box or vaccine carrier wall has a small crack, use adhesive tape to cover it until an undamaged container becomes available.

References[2]

1. World Health Organization and United Nations Children's Fund (UNICEF). Temperature-sensitive health products in the Expanded Programme on Immunization cold chain; 19 November 2020 (https://iris.who.int/bitstream/handle/10665/336748/WHO-2019-nCov-Immunization-Cold_Chain-2020.1-eng.pdf).

2. Prequalification of medical products, prequalified vaccines [website]. World Health Organization (https://extranet.who.int/prequal/vaccines/prequalified-vaccines).

3. World Health Organization, United Nations Children's Fund (UNICEF) and PATH. Guidance on selecting, commissioning and using freeze-preventive containers. World Health Organization; 25 October 2021 (https://apps.who.int/iris/handle/10665/341700).

4. United Nations Children's Fund (UNICEF). Remote Temperature Monitoring implementation guide; 21 April 2016 (https://www.technet-21.org/en/resources/guidance/remote-temperature-monitoring-implementation-guide).

5. World Health Organization, United Nations Children's Fund (UNICEF) and EVM. How to develop a repair and maintenance system for cold chain equipment. Geneva: World Health Organization; March 2017 (https://iris.who.int/bitstream/handle/10665/255751/WHO-IVB-17.05-eng.pdf).

Bibliography

Aide-memoire for prevention of freeze damage to vaccines. Geneva: World Health Organization; 3 November 2019 (https://iris.who.int/server/api/core/bitstreams/512b29f6-2175-4f20-9d9b-8d40fd37b22b/content).

[2] All references were accessed on 23 October 2025.

Centers for Disease Control and Prevention (CDC). Vaccine storage and handling toolkit; 29 March 2024 (https://www.cdc.gov/vaccines/hcp/downloads/storage-handling-toolkit.pdf).

Effective Vaccine Management. Setting the standard for the vaccine supply chain [website]. World Health Organization (https://evm2.who.int/Public/Requirements).

Essential Programme on Immunization: supply chain and logistics [website]. World Health Organization (https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/supply-chain).

How to monitor temperatures in the vaccine supply chain. Geneva: World Health Organization; July 2015 (https://iris.who.int/bitstream/handle/10665/183583/WHO_IVB_15.04_eng.pdf).

PQS catalogue [website]. World Health Organization; 23 June 2021 (https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx).

World Health Organization. Controlled temperature chain (CTC) – delivering vaccines more easily [video]. YouTube; 19 June 2015 (https://www.youtube.com/watch?v=_wnt_3fkxBo).

World Health Organization. Controlled temperature chain (CTC) – implementing in the field [video]. YouTube; 19 June 2015 (https://www.youtube.com/watch?v=dLq8q0mOquk).

Annex 2.1 How to prepare a homemade foam pad

Materials: locally available foam, ruler or measuring tape, cutter, pencil and paper

Key considerations:

- WHO recommends that careful attention be paid to the material, including its thickness and cleanness, when creating a homemade foam pad.
- Ensure that the foam is about 2.5 to 5 cm thick, similar to the ones supplied by the manufacturer.
- Specific carriers may have variations, so always check the manufacturer's specifications for precise measurements, if available.

Instructions:

1. Measure the diameter of the inner circle of the vaccine carrier that holds the original foam pad.
2. Draw on paper and cut out a pattern of a circle with the correct diameter for the foam pad. If there are various models of vaccine carriers with different foam pad sizes, create a pattern for each of them.
3. Use the pattern to cut the foam with a cutter.
4. Cut about 5 or more slits on one side of each foam pad. These will hold the opened vials in place when in use.
5. Check to make sure the homemade foam pad fits snugly in the vaccine carrier and that the lid can be tightly closed.

Annex 2.2 Preventive maintenance for absorption-type refrigerators and freezers

Maintaining gas-powered absorption-type refrigerators

Daily:

- Check that the burner flame is blue. If it is not, clean the gas burner and gas jet as described in the equipment manual. Adjust the thermostat or flame control setting as necessary.
- Make sure there is enough gas in the bottle. If not, change the bottle. Always change the bottle before it is completely empty and always keep a spare bottle.

Periodically:

- Check weekly that you have enough gas for at least another week. If not, obtain a new supply immediately.
- Carry out the following tasks at least once a year and always clean the flue if the flame has been smoking.
  - Clean the flue and baffle as described in the equipment manual.
  - Clean the gas burner and gas jet as described in the equipment manual.
  - Check the gas line connections for leaks. Brush soapy water onto the connections. If bubbles form, there is a leak. Gas leaks are dangerous. Contact your supervisor unless you have been trained to repair leaks.

Maintaining kerosene-powered absorption-type refrigerators

Daily:

- Fill the tank with clean kerosene. Always fill the tank before it is completely empty.
- Always keep enough spare kerosene to ensure you never run out. Never use any other fuel (for example, diesel or gasoline) in a kerosene-powered refrigerator.
- Check that the flame height and colour is correct for the type of burner. If the flame smokes, turn it down a bit. If it still smokes, clean or trim the wick, burner, flue and baffle as shown in the instruction manual. Always clean the flue if the flame has been smoking.

Weekly:

- Clean the burner, flue and baffle as shown in the instruction manual.
- Trim the wick as shown in the instruction manual. Use a wick trimmer if possible.
- Check that there is enough kerosene for at least another week. If not, replenish the supply immediately.

Periodically:

- Check the fuel tank to see if there is sediment at the bottom. If there is, blow out the burner and remove the tank. Remove the burner from the tank. Empty out the dirty kerosene. Flush the tank with a little clean kerosene. Wipe the outside of the tank with a clean cloth dipped in kerosene. Replace the burner and refill the tank.
- Replace the wick when you cannot turn it up any more to trim it. Use the correct type of wick and follow the instruction manual. Always keep two spare wicks in a safe place.

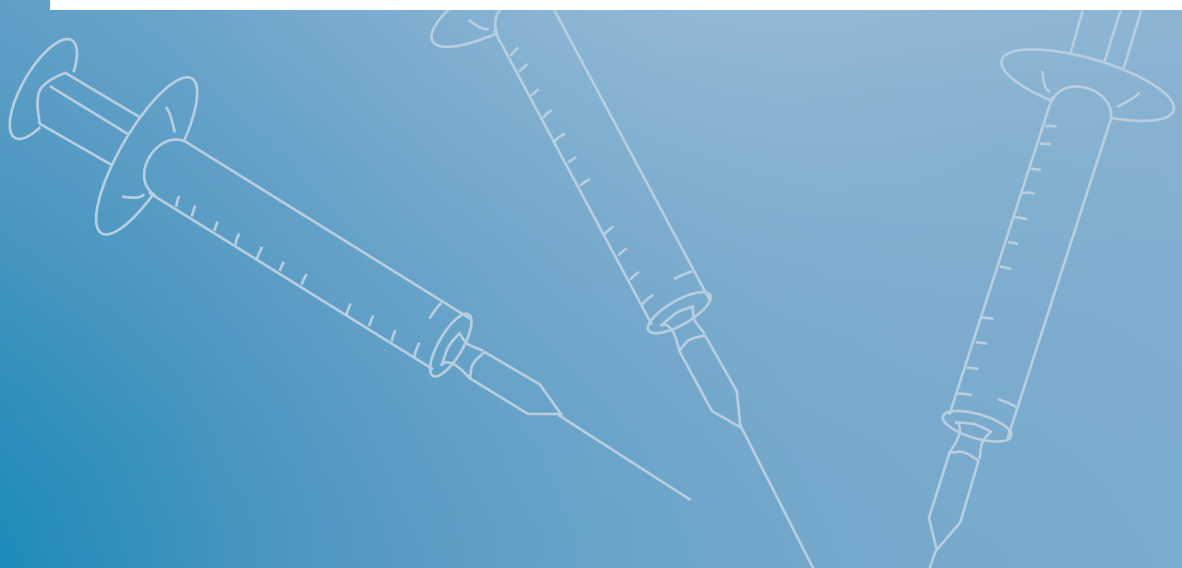
MODULE 3

Ensuring safe injections and management of immunization waste

About this module

This module discusses practices that health workers should follow to ensure that they deliver immunization injections in the safest possible manner.

The first two sections focus on the safety of the vaccine recipient, discussing vaccine devices and appropriate practices that contribute to safe immunization sessions. The third section focuses on health workers, describing ways to prevent needlestick injuries. The last two sections address the issue of the management of immunization waste and describe disposal practices that help ensure the safety of waste handlers, the community and the environment.



Contents

1 Using safe injection equipment and techniques

Injections are among the most common health care procedures. Immunization programs are meant to protect the population from vaccine-preventable diseases (VPD), and most of the vaccines in a national immunization programme are administered via injection. It is crucial, then, to ensure that health workers always use safe injection practices.

WHO defines a "safe injection" as one that does not harm the recipient, does not expose the provider to any avoidable risk and does not result in waste that is dangerous for the community *(1)*.

Safe injection is supported by proper equipment, including single-use syringes and needles. Auto-disable syringes have an internal mechanism that blocks the barrel after a single use, safeguarding against multiple use of the same device. Reuse prevention syringes have a built-in safety mechanism that prevents their reuse for vaccine reconstitution.

WHO recommends the "systematic and exclusive use of auto-disable syringes for the delivery of vaccines and reuse prevention syringes for the reconstitution of vaccines during routine immunization services and mass vaccination campaigns" *(2)*. Auto-disable and reuse prevention syringes with sharps injury-protection features are highly recommended choices to help ensure safe injection *(3)*.

This section describes the proper use of three types of equipment used to administer injectable vaccines:

- auto-disable syringes
- hypodermic syringes with reuse prevention features
- prefilled auto-disable injection devices.

1.1 Using auto-disable syringes for immunization

Auto-disable syringes used for fixed-dose immunization have the following features:

- a self-locking mechanism that allows only one use;
- a fixed needle (usually 23 G x 25 mm, but various sizes are available);
- a specific scale mark showing the quantity to be administered. The scale has only two markings, the zero line and the nominal capacity line.

Fig. 3.1 shows samples of some WHO-prequalified auto-disable syringes.

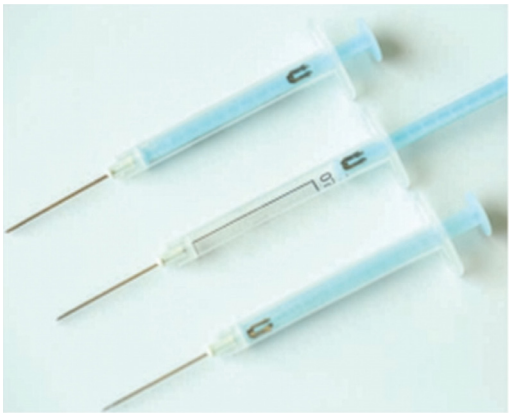
The syringe auto-disable features that prevent reuse may include clips, flanges and other mechanisms inside the barrel of the syringe. Different types of locking mechanisms are triggered at different times: some syringes lock their plunger at the start of the injection (so that the plunger can be depressed but not pulled back), while others do so at the end. Auto-disable syringes that lock at the start of the injection are preferred. Some auto-disable syringes are retractable, meaning that the needle can be pulled back into the barrel of the syringe. This mechanism adds stick-injury protection to reduce the risk of needlestick injuries.

Auto-disable syringes are recommended for all types of immunization sessions, for a number of reasons.

- They are sterilized and individually packed.
- They are disposable and can be used only once.
- They prevent transmission of blood-borne infection.
- They eliminate the risk of contamination of other vials.

Auto-disable syringes are supplied in the following volumes: 0.05 mL, 0.5 mL (used for most vaccines), 0.1 mL (used for BCG), 0.2 mL, 0.25 mL, 0.3 mL and 0.65 mL.

Fig. 3.1 Samples of WHO-prequalified auto-disable syringes



Source: WHO PQ catalogue

1.1.1 General steps for using auto-disable syringes for vaccine administration

While each type of auto-disable syringe requires a specific technique, the general steps are similar for all such syringes. All auto-disable syringes have a plunger that can move back and forth only once. Generally, once the plunger is depressed past the point of the safety mechanism, it cannot be pulled back. Weak spots in the plunger will cause it to break if the user attempts to pull it back a second time. This prevents refilling and reuse of the syringe.

Below are the general steps to follow when using auto-disable syringes. Health workers should adapt these steps, in line with the manufacturer's instructions, for the type of syringe they are using.

1. Select the appropriate auto-disable syringe based on the required dose volume and needle gauge.
2. Before removing the syringe from its package, always check its expiration date.
3. Peel the package open from the syringe plunger's (not the needle's) end and take out the syringe.
4. Take off the needle cap without touching the needle. Remove the plunger cap, if present.
5. Insert the needle into the vaccine vial. Its tip should be as close as possible to the bottom of the vial.
6. Pull the plunger back to fill the syringe just past the volume mark. Always keep the needle tip in the fluid as you pull back the plunger, especially when taking the last dose from a vial. When taking the last dose, be sure to empty the full contents of the vial into the syringe.
7. Remove the needle from the vial. To remove air bubbles, hold the syringe upright (with the needle pointing upwards) and tap it with your finger to move the air bubbles to the top. Then push gently on the plunger to push the air bubbles out.
8. Administer the injection (see Module 5, *Managing an immunization session*, section 4, for details on giving vaccinations). At the beginning or the end of the injection, the plunger will automatically lock, preventing the syringe from being reused.
9. Do not recap the needle after use.
10. Dispose of the used needle and syringe directly in a safety box (if available, a needle cutter can be used to dispose of the needle) (see section 4.1 of this module).

Health workers should not move the plunger of a syringe unnecessarily and should not inject air into a vaccine vial when using an auto-disable syringe, as this might disable the syringe.

1.2 Using hypodermic syringes with reuse prevention features

Hypodermic reuse prevention syringes, which are recommended for reconstituting vaccines, are disposable syringes with self-locking mechanisms that allow only one-time use (see Fig. 3.2). Features of reuse prevention syringes are essentially the same as those of auto-disable syringes. The main differences are that reuse prevention syringes allow for variable dosing, and some of them allow multiple plunger aspirations. Like auto-disable syringes, some models include a weak spot in the plunger that causes it to break if the user attempts to pull back on the plunger after the injection. Reuse prevention syringes are available in 2 mL, 5 mL and 10 mL sizes.

Fig. 3.2 Samples of WHO-prequalified reuse prevention syringes

Source: WHO guidelines on safe injection practices

1.2.1 General steps for using reuse prevention syringes for reconstituting vaccines

As with auto-disable syringes, each type of reuse prevention syringe requires a specific technique for its use. But for all types of reuse prevention syringes, the plunger can go back and forth only once, so health workers should take care not to move it unnecessarily.

Below are the general steps to follow when using reuse prevention syringes. Health workers should adapt these steps, depending on the manufacturer's instructions for the type of syringe they are using.

1. Select the appropriate reuse prevention syringe, based on the required volume for dilution.
2. Before removing the syringe from its package, always check its expiration date.
3. Peel the package open from the syringe plunger end and take out the syringe, leaving the plastic cap in the packaging.
4. If the needle is not attached to the syringe, securely fit it onto the hub of the syringe and remove the cap without touching the needle.
5. Check the expiration dates on both the vaccine and diluent and ensure that only the diluent supplied for the vaccine is used.
6. Open the diluent vial and insert the needle, ensuring that the tip of the needle reaches the bottom of the vial.
7. Pull the plunger back to draw the recommended volume of diluent into the syringe.
8. Remove the needle from the vial. If necessary, remove air from the syringe by holding it upright (with the needle pointing upwards) and tap it with your finger to move the air bubbles to the top. Then push gently on the plunger to push the air bubbles out, ensuring that the required volume of diluent is maintained in the syringe.
9. Insert the needle into the vaccine vial and push the plunger in completely to ensure that all the diluent goes into the vaccine vial.
10. Remove the needle from the vial and ensure that the syringe is locked.
11. Dispose of the needle and syringe directly in a safety box without recapping.
12. Gently rotate or invert the vial to thoroughly mix the vaccine with the diluent, or follow the manufacturer's instructions.
13. Check the appearance of the reconstituted vaccine. Reconstituted vaccine may be used if the colour and appearance match the description on the vaccine package insert. Use the auto-disable syringe to administer the vaccine (see Module 5, section 4).

1.3 Using prefilled auto-disable injection devices

Prefilled auto-disable injection devices are single-dose packets of vaccine with or without a needle attached (see Fig. 3.3). The vaccine is contained in a sealed syringe or bubble-like reservoir that prevents it from coming into contact with the needle until its administration. Every prefilled auto-disable injection device is sterilized and individually packed. This type of injection device can also be used only once. Some prefilled devices are equipped with a vaccine vial monitor (VVM) (see Module 2, *The vaccine cold chain*, section 3, for a description of VVMs).

Fig. 3.3 Samples of prefilled AD syringes

Source: reproduced with permission from *Fluarix® Vaccine Guide – National Vaccine Support Group*

In addition to having the same advantages as regular auto-disable syringes, prefilled auto-disable vaccination devices:

- are easy to use (they do not require vaccine reconstitution);
- facilitate administration of an accurate dose;
- simplify planning, as the vaccine and syringe are in the same set and so separate orders are not needed;
- reduce vaccine wastage that can occur with multi-dose vials;
- minimize waste generated by the immunization session.

Some vaccines may be available in compact prefilled auto-disable injection devices. These compact devices are intended primarily to facilitate vaccination services for particular priority groups at the last mile (such as home vaccination of newborns for hepatitis B or of women for tetanus toxoid), whether during outreach sessions or mass campaigns.

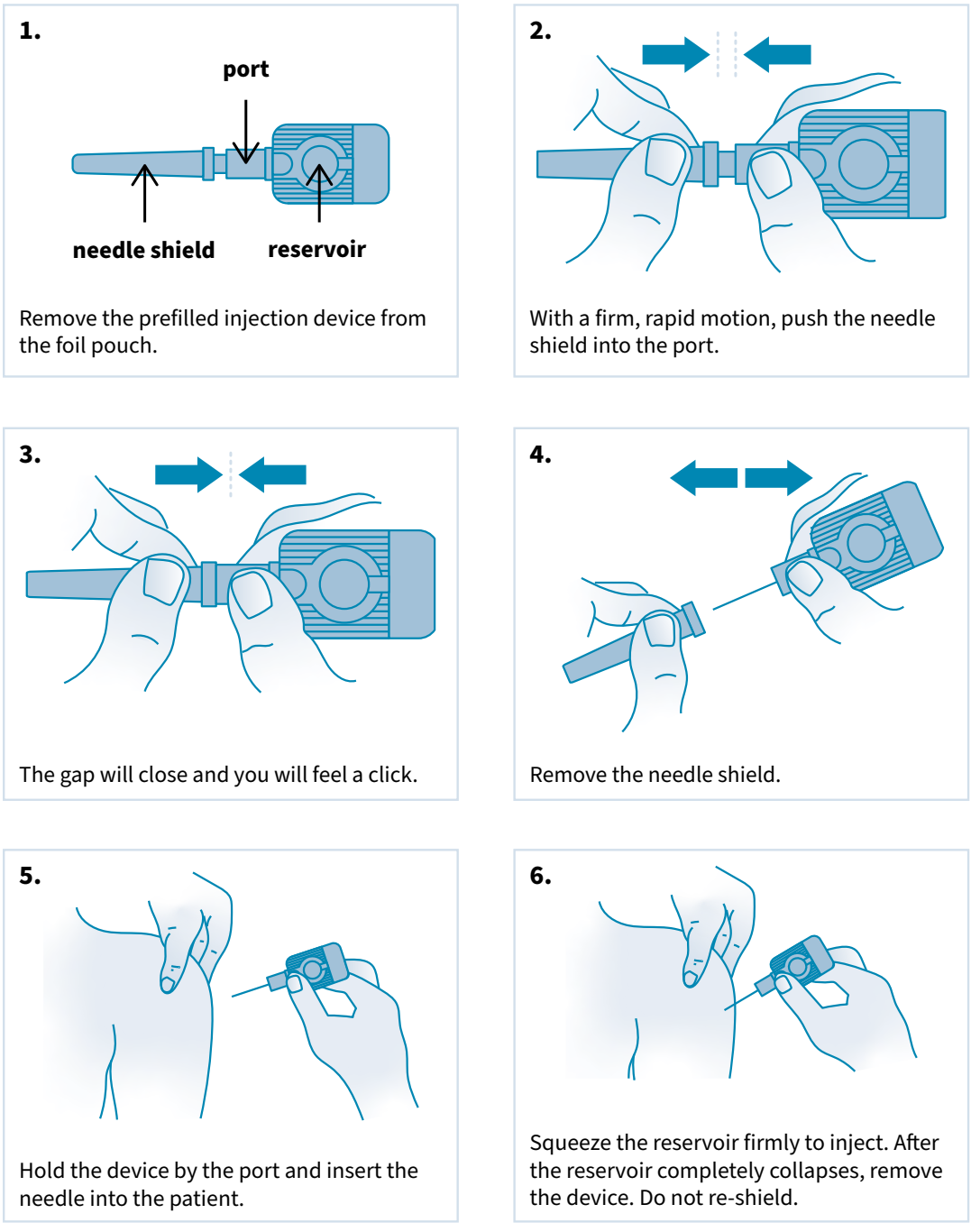
1.3.1 General steps for using prefilled bubble-like injection devices

Below are the general steps to follow when using prefilled auto-disable injection devices. Such devices may differ in presentation, depending on the manufacturer. Some come fitted with a needle; other do not. Always follow injection safety practices and the manufacturer's instructions when preparing and administering the vaccine from a prefilled syringe.

1. Always check the expiration date and VVM status, if any, before use.
2. Prepare or activate the prefilled bubble-like injection device by pushing the needle shield (or cap) into the port (see Fig. 3.4). This opens the fluid path between the needle and the reservoir that contains the vaccine.

3. Remove the needle shield without touching the needle.
4. Insert the needle into the injection site, using the appropriate technique (see Module 5, section 4, for details on injection technique).
5. Deliver the dose by squeezing the reservoir until it is empty.
6. Do not recap the needle after use.
7. Dispose of the entire device directly in a safety box.

Fig. 3.4 Use of prefilled bubble-like auto-disable devices



2 Good injection practices

WHO recommends the following general steps for good injection practices:

1. clean work space;
2. hand hygiene;
3. sterile new syringe and needle, with auto-disable/reuse prevention and/or injury protection feature whenever possible;
4. sterile vial of medication and diluent;
5. skin disinfection;
6. appropriate collection of sharps;
7. appropriate waste management.

2.1 Practices to improve injection safety during immunization sessions

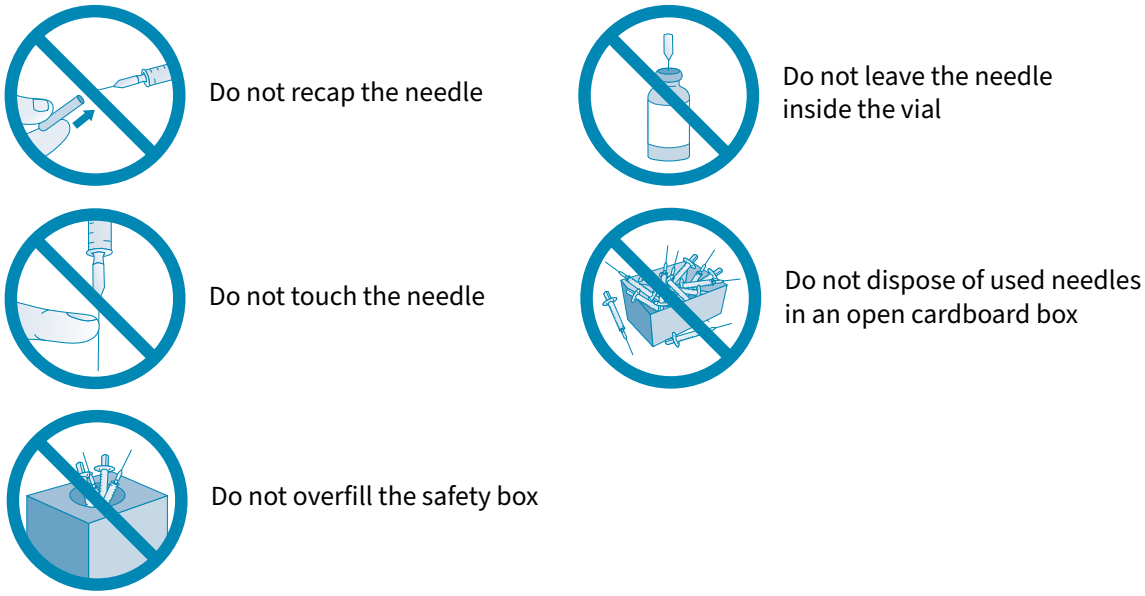
The following are good practices to improve injection safety during immunization sessions.

1. Always check the vaccine, diluent and syringe expiration dates, VVM status and physical appearance before beginning the immunization session.
2. Follow the manufacturer's product-specific recommendations for storage, handling and use of vaccines and diluents.
3. When using diluents:
   a. cool the diluent at +2 °C to +8 °C or store it with the vaccine for at least 30 minutes before reconstitution;
   b. use the correct diluent for reconstituting freeze-dried vaccines;
   c. never freeze a diluent or use a frozen diluent.
4. Prior to administration, ensure that the right vaccine is given to the right person at the right dosage, route and site, and at the right time.
5. Prepare injections in a clean, designated area free from blood and body fluid contamination.
6. Ensure that the auto-disable and reuse prevention syringe packaging is intact, and without any sign of contamination, by inspecting the packaging very carefully. Discard the needle and syringe if the package has been punctured, torn or damaged.
7. Prepare each dose immediately before its administration. Do not prepare several syringes in advance: doing so creates a risk of vaccine contamination and confusion, especially when multiple vaccines are used in a session; also, once the vaccine is drawn out of the vial and into the syringe, it no longer benefits from the vial's VVM for monitoring the correct temperature for the vaccine.
8. Never touch any part of a needle.
9. Never leave a needle inserted in the rubber cap of a vial.
10. Follow safe procedures to reconstitute vaccines and always use a new needle for reconstituting a new vial.
11. Use a new auto-disable or reuse prevention syringe and needle for every vaccine recipient.

12. Ensure that the person to be vaccinated is properly positioned to facilitate the administration of the vaccine at the correct site and to minimize movement and risk of injury to both the vaccinator and individual receiving the vaccination (see Module 5, section 4, for a discussion of positioning children for vaccination).
13. Keep vaccine and sharps away from the reach of children.
14. Follow the multi-dose vial policy for opened vials.
15. Dispose of used auto-disable and reuse prevention needles and syringes directly in a safety box without recapping.
16. Do not dispose of used needles in an open cardboard box and do not overfill the safety box.
17. Discard a needle that has touched any non-sterile surface before use.

Fig. 3.5 illustrates unsafe immunization practices that must be avoided.

Fig. 3.5 Unsafe immunization practices



2.1.1 Planning and injection safety

In addition to using safe injection devices and following safe practices, effective planning plays a role in promoting health workers' adherence to injection safety protocols. Planners should ensure that:

- a sufficient supply of vaccines is available and that the vaccines are kept at appropriate cold-chain temperatures;
- an adequate number and the right type of auto-disable and reuse prevention syringes and needles are available at the health facility to provide uninterrupted routine immunization services;
- an adequate quantity of safety boxes are available for disposal of used sharps;
- the facility has a safe area to temporarily store used safety boxes filled with sharps while waiting for final disposal.

2.2 Adverse events following immunization (AEFI) due to poor injection practices

Improper injection techniques and practices could lead to an AEFI. Table 3.1 summarizes incorrect practices and their possible consequences. More information about safe practices can be found in Module 5 and Module 6.

Table 3.1 Incorrect immunization practices that may result in AEFI

Incorrect practice	Possible AEFI
Non-sterile injection due to: • reuse of disposable syringe or needle • use of non-sterilized syringe or needle • contaminated vaccine or diluent • prefilling syringes (for example, during MR supplementary immunization activities)	Infections such as local abscess at injection site, sepsis or toxic shock syndrome Transmission of blood-borne infections such as hepatitis or HIV Death
Reconstitution error due to: • inadequate mixing of vaccine • reconstitution with incorrect diluent • substitution of a drug for vaccine or diluent • inappropriate reuse of reconstituted vaccine at subsequent session • using diluent that has been frozen or is not the same temperature as the vaccine (for example, warm diluent) during reconstitution	Local abscess at injection site Ineffective vaccine Negative effect of wrongly added drug (such as insulin, oxytocin, muscle relaxants) Death
Injection at incorrect site, such as: • BCG given subcutaneously • DTP/DT/dT/TT given too superficially • injection into buttocks	Local reaction or abscess Nerve damage resulting in paralysis
Incorrect vaccine transportation/storage, leading to: • VVM changing colour • clumping of adsorbed vaccine	Local reaction Vaccine may be ineffective
Contraindications ignored	Avoidable serious reaction

3 Preventing needlestick injuries

Needles can be dangerous. They can injure health workers and, if contaminated with hepatitis B, hepatitis C, HIV or other blood-borne infections, they can transmit diseases.

Needlestick injuries can happen at any time, particularly during and immediately after an injection. This risk is increased when:

- health workers recap needles or walk around carrying used needles;
- children are not positioned or secured properly during injections;
- safety boxes are overfilled, causing some needles to stick out of the box;
- unsafe disposal practices are used, leaving people and/or animals exposed to used needles and syringes.

This section describes steps to prevent needlestick injuries by addressing potential risks related to handling equipment, workspace arrangements, positioning of children and disposal of waste.

3.1 Setting up the immunization work area to minimize risk of injury

To minimize the risk of needlestick injury, health workers should arrange their workspace following several general rules.

- Ensure that the immunization area is well organized, with convenient access to injection devices and to safety boxes for their disposal. Ensure that safety boxes are placed within arm's reach of vaccinators so they do not have to move to dispose of used needles and syringes. The vaccinator should be able to see the opening of the safety box when discarding needles. Each vaccinator should have a separate safety box, especially at busy sites.
- The vaccinator should be between the vaccine recipient and all needles and sharp objects.
- The vaccinator should be able to dispose of used needles and syringes directly in the safety box without putting them down on other surfaces.
- The vaccinator should have only one vaccine recipient at a time in the workspace (where the vaccine recipient is a child, they are accompanied by a caregiver).
- Other items such as cotton swabs, tally sheets and so on should be within easy reach of the vaccinator.

See Module 5, section 1, for further recommendations regarding the set-up of a workspace for an immunization session.

3.2 Minimizing the need to handle needles and syringes

In general, the more that injection equipment is handled, the greater the risk of needlestick injuries. The following are practices that health workers can use to reduce the risk of injury due to handling of equipment.

- Use a new needle and syringe for every vaccine recipient.
- When ready to administer the vaccine, draw the recommended volume of vaccine into the syringe, administer the injection and dispose of the syringe in the safety box without putting it down between steps.
- Do not recap the needle after use.
- Do not remove the used needle from the syringe with your hands (use a needle cutter, if available).
- Do not carry used syringes and needles around the work site for any reason.
- Do not leave a needle in a vaccine vial.
- Do not manually sort through the needles and syringes in a safety box. Close the box securely when it is three quarters full.
- Do not dispose of used vials in the safety box for used syringes and needles.

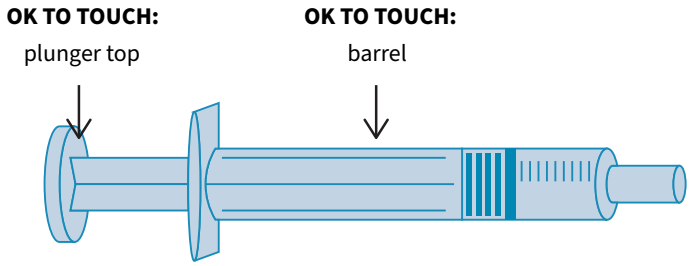
Where possible, avoid recapping a needle. However, if recapping cannot be avoided – for example, if an injection is delayed because a child is too agitated – use the one-hand technique of placing the cap on a table or tray and reinserting the needle by sliding it inside without using the other hand. Take care not to let the needle touch the table's surface.

3.3 Handling syringes and needles safely

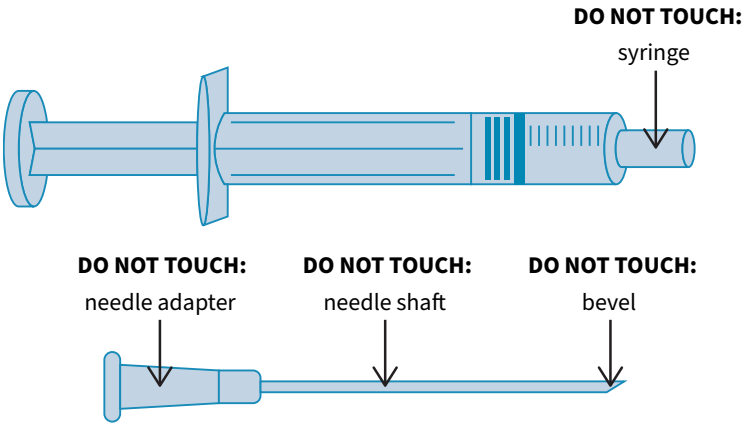
Any part of the syringe that is touched becomes contaminated. Although the barrel and plunger of a syringe have to be touched to prepare and give an injection, care should be taken to avoid touching parts that come into contact with the vaccine or the individual being vaccinated (see Fig. 3.6).

Fig. 3.6 Handling syringes and needles

a. Parts of a syringe that may be touched



b. Parts of a syringe and needle that must not be touched



Do not touch:

- the shaft of the needle
- the bevel of the needle
- the adapter of the needle
- the adapter of the syringe
- the plunger seal of the syringe.

If any of these parts are touched or touch an unsterile surface, discard the needle and syringe in the safety box and get new sterile ones.

3.4 Positioning children correctly for injections

Unexpected motion at the time of injection can lead to needlestick injuries. This is most likely to occur when children are not positioned properly before injections are given. To minimize this risk, consult the directions for the positioning of children for vaccination in Module 5, Table 5.2.

3.5 Practising safe disposal of all medical sharps waste

Used sharps must be placed in a safety box, which is then disposed of properly. Procedures for safe disposal of sharps are outlined in section 4 of this module.

4 Managing immunization waste

Immunization sites generate various types of waste. Inadequate management and unsafe disposal of waste generated by injection activities can have a negative impact, either directly or indirectly, on the health of medical staff, waste handlers, the community and the environment.

The following types of waste are generated by immunization activities.

- Used sharps (most hazardous/infectious):
  - needles
  - broken glass/vials.
- Waste materials possibly contaminated by body fluid (hazardous/infectious waste):
  - opened or expired vaccine vials
  - syringes without needles
  - gloves, gowns, masks
  - gauze, dressings, cotton swabs
  - containers for medical purposes.
- General waste (non-infectious):
  - packages, boxes, papers
  - disposable cups
  - tissue paper/towels
  - advocacy campaign materials.

Various practices at the service facility level can reduce the risks associated with immunization waste.

- Segregate items into infectious and non-infectious waste.
- Collect whole syringes and needles in a puncture-resistant, leak-proof container that has a biohazard symbol or colour coding to indicate the type of waste it contains.
- If needle cutters are available, use them to remove needles from syringes immediately after use.
- Collect non-sharp infectious waste in bags with colour coding and/or a biohazard symbol to indicate the type of waste they contain.
- Store bags of infectious waste and filled sharps containers in a secured place prior to transportation to a treatment facility or final waste-disposal site.
- Ensure that personal protective equipment (PPE) and hand-washing facilities are available for all waste handlers.
- Immunize all health staff against the hepatitis B virus.
- Monitor waste-collection practices regularly and provide supportive supervision and timely corrective actions, as needed.
- Ensure that staff are aware of standard operating procedures and have access to job aids at the facility to remind them of proper procedures.

4.1 Disposing of used syringes and needles

Sharps waste are considered infectious waste and can cause serious health and environmental problems if not properly managed and disposed of. Unsafe disposal can result in needlestick injuries and can cause transmission of blood-borne infections. Collecting sharps waste in safety boxes or similar containers both decreases the risk of injury during handling and helps ensure proper final disposal.

Sharps waste poses dangers to both human health and the environment. Leaving used syringes and needles in the open or on the ground puts the community at risk. Most frequently, children are the unfortunate victims of needlestick injuries arising from improper disposal of needles.

Inappropriate treatment of waste also leads to environmental pollution. Low-temperature incinerators and open burning release toxins into the air, and they should be used only as temporary emergency or last resort solutions when no other options are available (see section 5 of this module). Throwing used needles and syringes into bodies of water can contaminate the natural environment and injure wildlife.

4.1.2 Using safety boxes for disposing of used sharps

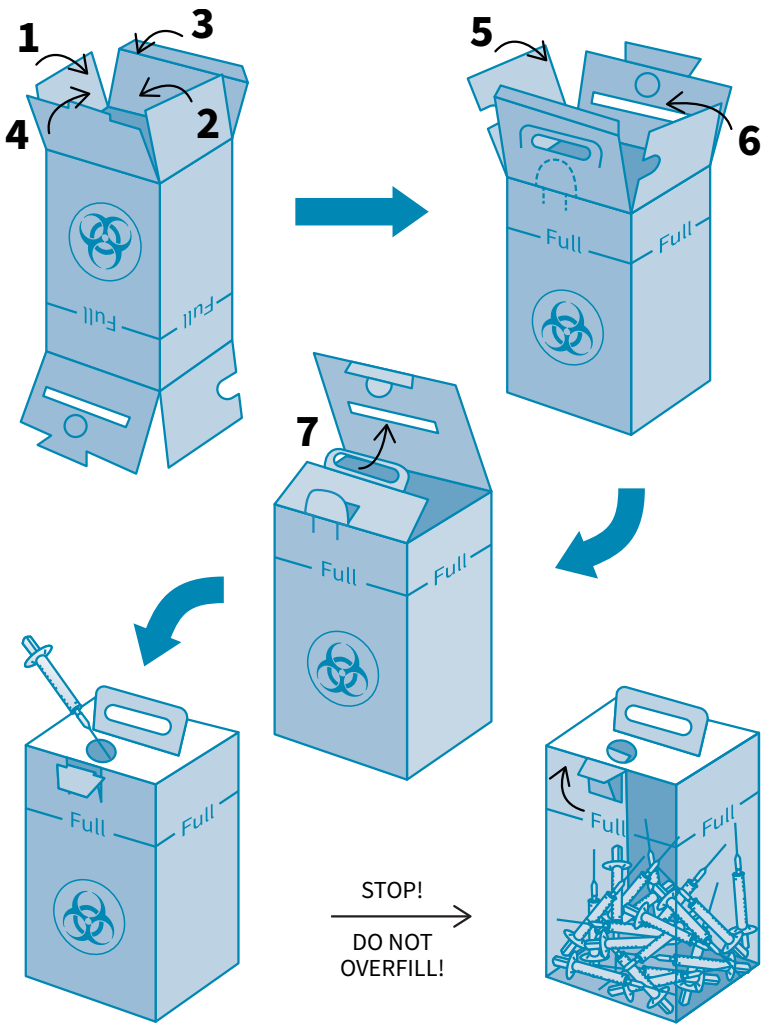
As noted earlier, all used injection equipment should be disposed of in a safety box immediately after use. Safety boxes are waterproof, tamperproof containers that needles cannot pierce. Reusable, sterilizable sharps containers made of metal or heat-resistant plastic may also be available for use with an autoclave shredder system.

WHO-prequalified standard safety boxes come in different sizes, ranging from 2.5 L to 15 L:

- A 2.5 L safety box can hold approximately 50 to 75 needles and syringes.
- A 5 L safety box can hold approximately 100 to 150 needles and syringes.
- A 10 L safety box can hold approximately 200 to 300 needles and syringes.
- A 15 L safety box can hold roughly 300 to 450 needles and syringes.

Safety boxes require proper assembly before use (see Fig. 3.7). Many come with illustrated instructions printed on the side of the box.

Fig. 3.7 Safety box assembly and use



It is a common practice to dispose of the needle and syringe in the same safety box. However, if needle removers or cutters are available, used needles and syringes should be separated immediately after each injection. After cutting the needle from the syringe, keep it in the needle cutter's sharps container; the defanged syringe may be placed in the safety box or appropriate waste container. The opening in the top of all safety boxes should remain closed when the boxes are not in use. Safety boxes should be used only for needles and syringes. Other immunization waste should be disposed of in separate waste containers.

Safety boxes should be securely closed when they are three quarters full. Used needles and syringes should never be transferred from safety boxes to other containers. All injection equipment must be destroyed using proper waste-disposal methods.

Do not use a safety box to dispose of immunization waste such as:
- empty or discarded vials
- cotton pads
- dressing materials
- intravenous bags or tubes
- latex gloves
- any plastic materials or waste products.

Dispose of these items in a separate waste container.

In order to avoid needlestick from filled safety boxes, observe the following practices:
- Never squeeze safety boxes, or lean, sit or stand on them. Do not shake safety boxes or handle them more than necessary.
- Take extra care when carrying safety boxes to temporary storage or disposal sites. Maintain a safe distance so that the box does not come in contact with your body, as some needles may be sticking out of the box and can cause needlestick injury.
- Hold the box by the handle on top (or above the level of the needles and syringes if there is no handle).
- Keep safety boxes in a secure dry place that is out of the reach of children and any other people in the area.
- Train staff on safe handling; do not assign untrained staff to handle safety boxes.
- Used needles and syringes must never be dumped in open areas where people might step on them or children might find them, whether inside safety boxes or loose. They should never be disposed of with general non-sharp types of waste.

4.1.3 What to do if safety boxes are not available

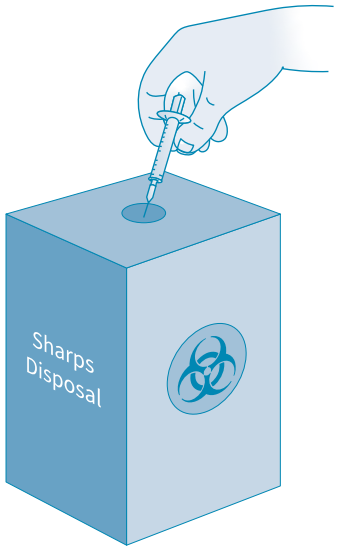
If safety boxes are not available, locally available materials can be used to create a functional and safe sharps container. Strong cardboard boxes, metal cans or thick plastic containers may be used to collect needles and syringes and transport them to a site where they can be properly treated (buried, incinerated, or autoclaved and shredded – see section 5 of this module). Like safety boxes, such containers should be sealed when they are three quarters full. They should not be reused once filled. Emptying sharps containers for reuse increases the risk of accidental needlestick injuries and infections.

If a safety box is not available, a sharps container can be made and used safely.
- Find a strong cardboard box (a local shop may have some). Ideally, the walls of the box should be thick and strong enough to keep needles from piercing through and causing needlestick injuries.
- If needed, place one box inside another to create a stronger container to prevent needles from piercing through.
- Close the box securely on the top and bottom, sealing it with strong adhesive tape or similar material.
- Cut a small hole in the top: it should be just big enough for a needle and syringe to enter (maximum diameter, 38 mm).

- Mark the box with a biosafety hazard or colour-coded sticker to indicate that it is a disposal container for infectious waste (see Fig. 3.8).
- When the box is three quarters full, seal the opening.
- While waiting for final disposal, keep the box in a secure room that can be accessed only by authorized personnel. Dispose of the box in the same way as a standard safety box, following national policy for proper and safe disposal of sharps wastes (see section 5 of this module).

Alternatively, health workers can use a sturdy, puncture-proof plastic bottle or container that can be tightly sealed for on-site sharps disposal.

Fig. 3.8 Example of a homemade safety box



4.1.4 Safe storage and disposal of filled safety boxes

Filled safety boxes should be stored in a secured restricted area – separate from the storage area for general waste – until they can be transported to sites where they can be treated and/or destroyed appropriately. The safe storage area should be free from weather damage, animal access and unauthorized entry.

Infectious waste should be collected within 2 to 4 days, depending on weather and storage conditions. Preferably, such waste should be transported in a designated vehicle. Waste-disposal staff should maintain a log of each infectious waste collection and make sure the vehicle used is regularly cleaned and disinfected.

Preferred treatment methods for used sharps, needles and syringes that are kept together include autoclaving. If these items were collected separately, needles can be autoclaved, while syringes can be microwaved. For final disposal of treated sharps, it may be possible to recycle metal and plastic, depending on existing recycling programs. Otherwise, needles can be buried in a sharps pit, while syringes can be shredded and disposed of in a landfill. Both may also be transported to an incineration facility for final disposal. (See section 5 of this module for a discussion of various disposal methods.)

4.2 Managing other immunization waste

Other immunization waste can be categorized as hazardous waste and general waste.

- Hazardous waste includes used and expired vaccine vials and materials potentially contaminated with body fluid such as cotton swabs, dressings, gloves and so on.
- General waste includes packaging materials (such as cartons, plastic), paper towels, paper and so on.

Segregation of the waste materials should follow local waste-management policy and/or recycling programs. The containers used to segregate the different types of waste should be properly labelled and stored safely until they are collected and transported to a final disposal site. The storage for general waste and hazardous waste should be different from the storage for infectious waste.

Used and expired vaccine vials, contaminated cotton swabs, dressings, gloves and so on, can be treated by autoclaving, dipping in chlorine solution or boiling. After treatment, the vials may be recycled or crushed for disposal in a secured waste-disposal pit. General, non-infectious, waste, like packaging materials, paper, plastic bottles and so on, can be managed through regular domestic waste disposal.

5 Waste-management systems at the district level

Within a given district, waste generated by immunization delivery is dispersed among many health centres and is also generated in relatively smaller quantities in routine immunization contexts. District management teams should plan and budget with health facilities in order to implement a sustainable system to safely minimize, segregate, handle, collect, transport and dispose of such waste. Waste-management approaches include, but are not limited to, the following:

- where central treatment plants exist, outsourcing the waste collection and treatment to certified waste treatment/disposal plant operators and/or certified landfill operators;
- clustering or centralizing treatment (clustering/grouping health facilities around selected treatment/disposal sites);
- decentralized on-site treatment of waste generated in each facility.

5.1 Waste treatment and disposal methods

This section describes several methods commonly used to treat and/or dispose of safety boxes filled with used syringes and needles. Of those methods discussed below, autoclaving and microwaving avoid the pollution associated with incineration. They are considered as best available techniques and meet best environmental practices, although all methods of waste disposal must comply with national and subnational environmental and health regulations.

5.1.1 Autoclaving

Waste-treatment autoclaves can range in size from about 20 L to over 20 000 L. The operation of autoclaves requires the proper combination of temperature/pressure and exposure time to achieve disinfection. A minimum temperature-exposure time criterion of 121 °C for 30 minutes is recommended for sharps waste. Since the autoclave does not eliminate the physical hazard from sharps, the use of a post-treatment shredder that is designed to minimize handling is also recommended. The two-stage treatment process of autoclave sterilization followed by mechanical shredding reduces the waste volume. The capacity of shredders will vary, depending on the type (speed and torque) and throughput. (“Throughput” refers to the rate at which a system or process can produce or handle items over a specific period and is a measure of how much output is generated in a given timeframe.)

5.1.2 Microwaving

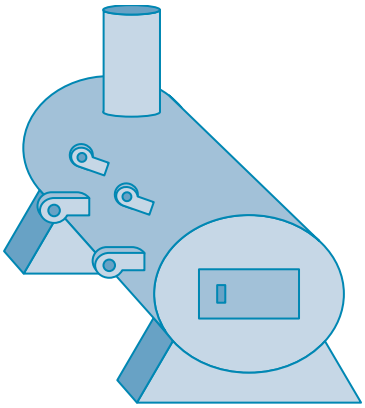
Like autoclaves, microwave systems avoid the pollution associated with incineration. Microwaving uses heat and pressure to kill infectious agents. High-frequency microwaves are used to expose waste to a temperature of 100 °C to 110 °C. Efficient heating rises up to 110°C for 20 minutes to obtain full decontamination. Microwaving can be adapted to any type of medical waste (such as sharps, glass, solids, liquids). As with autoclaving, shredding can be combined with microwaving to reduce the waste volume.

5.1.3 Incineration

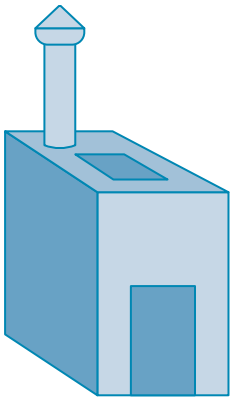
Incineration can completely destroy needles and syringes. Fires burning at temperatures higher than 800 °C will kill microorganisms and reduce the volume of waste to a minimum. Properly functioning incinerators ensure the most complete destruction of needles and syringes. High temperature, double-combustion incinerators with air filters produce less air pollution than incinerators burning at lower temperatures (see Fig. 3.9). Some hospitals have on-site incinerators. Others transport the waste to cement factories to incinerate in high-temperature kilns.

The compound in which incineration takes place must be secure. Staff members conducting the incineration should wear safety glasses, heavy gloves and any other PPE, as required by local and national guidelines.

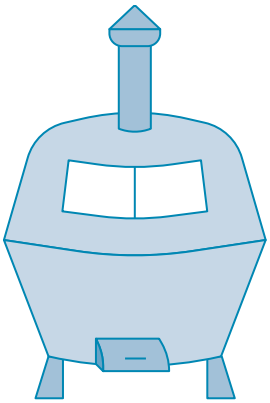
Fig. 3.9 Common types of incinerators



High-temperature (>800 °C) double-combustion incinerator with filtration



High temperature (800 °C) double-combustion incinerator without filtration



Auto-combustion incinerator (400 °C to 800 °C)

5.1.4 Solar melting system

In settings where needle removers or cutters are used to defang syringes, solar melting system can be used to melt the syringe plastic into a cake. Solar melting systems use concentrated solar energy (generated using mirrors or lenses that focus sunlight onto a small area) to treat and dispose of medical waste. They offer a sustainable and effective solution for managing health care waste, using renewable energy to transform hazardous waste into safe, reusable materials.

5.1.5 Needles pit

Needles can be disposed of in a safety pit. These pits are usually 2 m deep and 1 m in diameter and are lined with concrete. The pit should have a concrete lid with a capped metal pipe set in it (see Fig. 3.10). Used needles are dropped through the metal pipe and into the pit. When the pit is about two thirds full, cement is poured through the metal pipe to seal the opening.

Before being disposed of in a safety pit, sharps waste is first disinfected using an autoclave, microwave or chemicals. If disinfection equipment and facilities are not available, disposal in a needles pit is not recommended, due to risk of disease transmission. Prior to disposal, sharps may be mutilated or destroyed by cutting or breaking.

Fig. 3.10 Needles pit

5.1.5 Encapsulation

In the encapsulation process, sharps waste is placed in hard containers, such as metal drums, to which an immobilizing material (such as cement, bituminous sand or clay) is added. When the immobilizing material is dry, the container is sealed and buried in a local landfill or a pit at the health care facility (see Fig. 3.11).

Fig. 3.11 Encapsulation and disposal pit

5.1.6 Burial in a disposal pit

Used injection equipment that has not been encapsulated may also be buried in a disposal pit. The site should be chosen carefully – there should be enough space for a pit that is large and deep enough for safety boxes to be buried with minimum risk of contaminated sharps being released into the surroundings and doing harm.

If a disposal pit is to be used, several steps must be followed.

- Choose a site where people will not dig or build latrines in the future.
- Choose a qualified staff person to supervise the burial of wastes, using appropriate equipment.
- Fence off and clear the area.
- Dig a pit at least 2 m deep. Make sure that buried materials will not escape from the pit (for example, that the pit will be secure during the rainy season).
- When ready to bury them, take the filled safety boxes to the pit site and place them in the hole. Do not open or empty the boxes.
- After placing the boxes in the pit, immediately cover them with at least 30 cm of soil. If possible, cover the site with concrete when the pit is full.

Only qualified staff wearing appropriate PPE should perform this task.

IMPORTANT: The two options for burning waste that are described in sections 5.1.7 and 5.1.8 are to be considered as last-resort options: they are not in keeping with WHO policy for the treatment of waste.

5.1.7 Burning in a metal drum

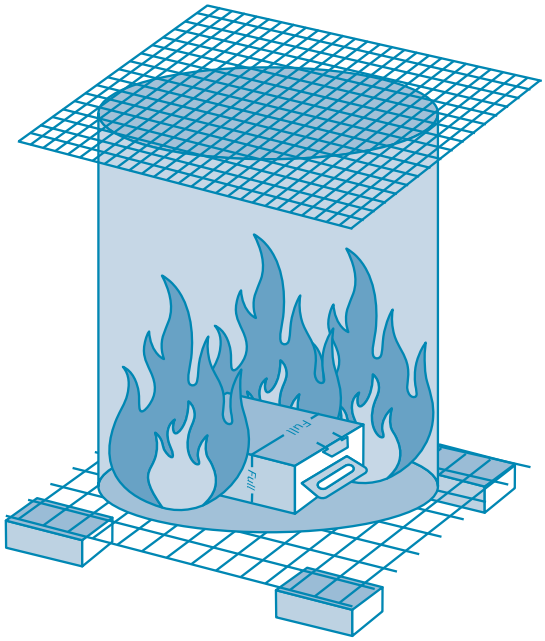
This option should be considered only as a short-term emergency response, since low-temperature burning produces toxic emissions and is a public health and environmental hazard.

If contaminated sharps must be destroyed by burning in a metal drum or container (see Fig. 3.12), several steps must be followed.

- Choose a site in an unused area that is as far from occupied buildings as possible. The area should be fenced and cleared.
- Choose a qualified staff person to supervise the burn, using appropriate equipment.
- Place four bricks on the ground in a square pattern.
- Put a metal screen or grate on top of the bricks.
- Remove both ends of a 210 L steel drum. This will allow air to flow through the drum and its contents to burn better. If a metal drum is not available, build a cylinder from sheet metal, bricks or clay. A chimney may be added to the removable top of the drum or container.
- Place the drum on top of the metal screen or grate that is sitting on the bricks.
- Put the filled, sealed safety boxes in the metal drum. Mix paper, leaves or other flammable material among the safety boxes to help them burn.
- Sprinkle a small amount of kerosene, if available, on the boxes and other material in the drum.
- Place a fine metal screen over the top of the drum to reduce flying ashes.
- Put wood, paper or other flammable material under the drum and ignite the material.
- Warn people to stay away to avoid smoke, fumes and ash from the fire.
- Allow the fire to burn until all of the safety boxes have been destroyed.
- Once the fire is out, allow the residue at the bottom of the drum to cool and carefully collect it. Bury it in an unused location, covering it with at least 30 cm of soil. If possible, seal the residue pit with cement once it is full.

Only qualified staff wearing appropriate PPE should perform this task.

Fig. 3.12 Burning safety boxes in a metal drum



5.1.8 Burning in an open pit

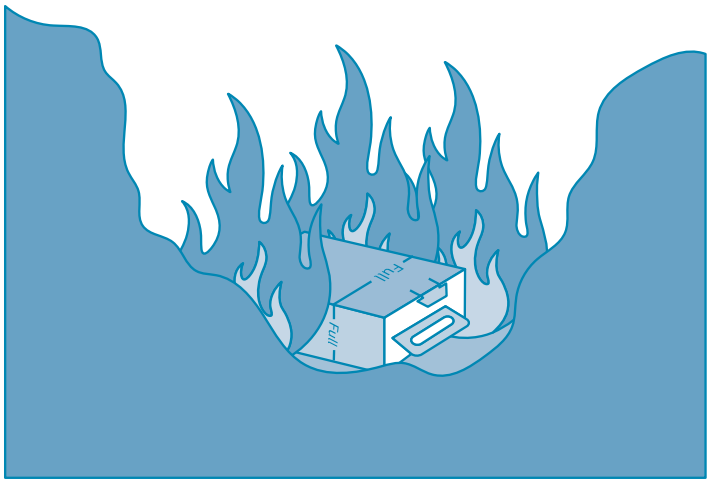
This option should be considered only as a last resort, since it produces toxic emissions and is a public health and environmental hazard. It is always preferable to collect safety boxes for later disposal at a more appropriate treatment site.

If burning waste in an open pit (see Fig. 3.13) is the only option, several steps must be followed.

- Choose a site in an unused area that is as far from occupied buildings as possible. The area should be fenced and cleared.
- Choose a qualified staff person to supervise the burn, using appropriate equipment.
- Dig a pit at least 1 m deep, but not so deep that it will be difficult to start the fire. Staff should not have to enter the pit to start the fire.
- Place the filled, sealed safety boxes in the pit. Mix paper, leaves or other flammable materials with the boxes to help them burn.
- Sprinkle a small amount of kerosene, if available, on the boxes and ignite the fire.
- Warn people to stay away to avoid smoke, fumes and ash from the fire.
- Let the fire burn until all boxes are destroyed and then follow the instructions for burying residue at section 5.1.7.

Only qualified staff wearing appropriate PPE should perform this task.

Fig. 3.13 Open burning in a pit



IMPORTANT: The remains of safety boxes, including needles, should be buried after burning, whether a metal drum or an open pit was used. The remains should be carefully collected and then buried deep in a pit, controlled landfill or similar location where people cannot access them.

References[1]

1. Aide-memoire for a national strategy for the safe and appropriate use of injections. Geneva: World Health Organization; 2000 (https://iris.who.int/handle/10665/66696).

2. World Health Organization and United Nations Children's Fund (UNICEF). Joint policy statement: promoting the exclusive use of injection safety devices for all immunization activities; February 2019 (https://cdn.who.int/media/docs/default-source/immunization/supply-chain/rup_jointstatement-highlighted.pdf).

3. WHO guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health care settings. Geneva: World Health Organization; 2016 (https://iris.who.int/bitstream/handle/10665/250144/9789241549820-eng.pdf).

[1] All references were accessed on 23 October 2025.

MODULE 4

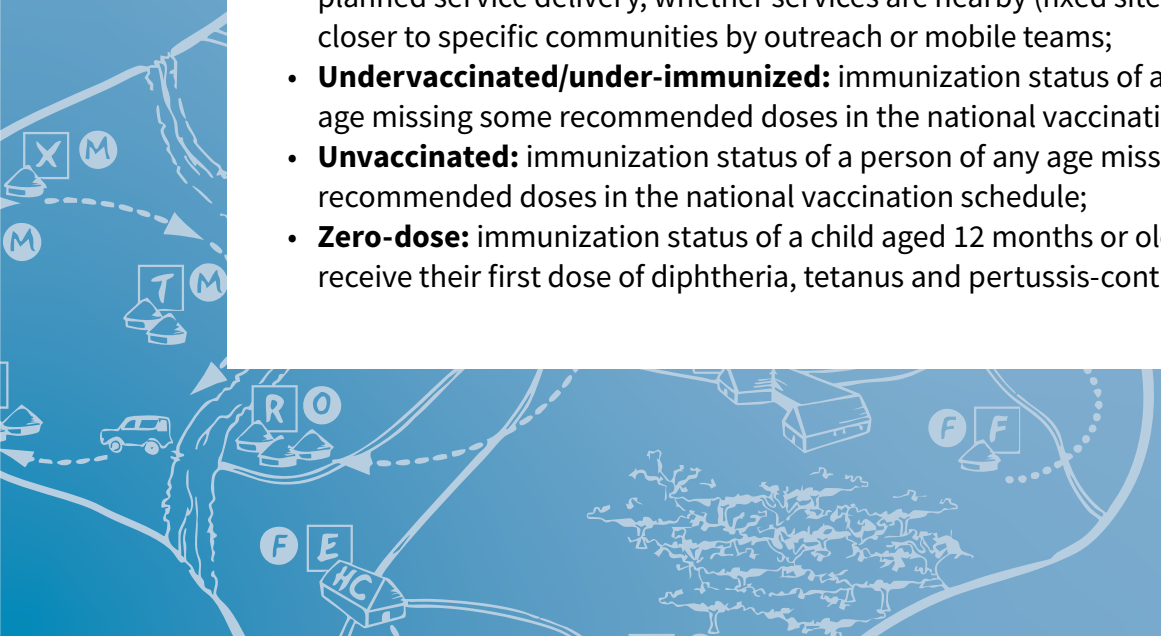
Microplanning for reaching every community

About this module

This module discusses the process of microplanning to ensure that immunization services reach every community. Section 2 discusses the use of maps at the district and health centre levels, and the importance of updating them regularly to include all population centres and groups in the catchment area and to flag high-risk areas. The module next describes how to identify priority, high-risk health centres and communities based on numbers of unimmunized children. It then addresses how to identify barriers to service access and utilization in priority communities and how to make a workplan for solutions. The module concludes with a discussion of making a session plan, including frequency and stock considerations.

Key terms used in this module:

- **Microplan:** an operational plan that outlines how all population groups eligible for vaccination will be reached within a defined geographical area through planned service delivery, whether services are nearby (fixed site) or are brought closer to specific communities by outreach or mobile teams;
- **Undervaccinated/under-immunized:** immunization status of a person of any age missing some recommended doses in the national vaccination schedule;
- **Unvaccinated:** immunization status of a person of any age missing all recommended doses in the national vaccination schedule;
- **Zero-dose:** immunization status of a child aged 12 months or older who did not receive their first dose of diphtheria, tetanus and pertussis-containing vaccine.



Contents

1 Introduction to microplanning

Microplans are an important tool that health facility and district staff responsible for immunization use to plan for timely vaccination of all children, adolescents and adults. The main purpose of a microplan is to guide delivery and monitoring of routine immunization services. Microplans consider the needs of the local population in a defined area. They can also be used to advocate for resources to achieve immunization programme goals.

Making vaccines more accessible and bringing them closer to communities and individuals is a key part of planning. Some people – whether in permanent shelters, mobile nomadic/seasonal migrant communities or informal urban settlements – do not live near health services. But geographical barriers may not be the only, or even the primary, factor that limits access to and utilization of immunization services. Other factors such as inconvenient scheduling, lack of information or lack of opportunities, as well as gender-related barriers or hesitancy among minority groups, also make access difficult. These issues can affect people's health-seeking behaviours and the ability of health services to reach them. Many of these problems can be solved by improving scheduling days and times through consultation with the community, raising awareness and/or expanding outreach vaccination.

Microplanning involves creating or updating a detailed written plan, either on paper or electronically, through a collaborative process in order to improve access to and use of immunization services according to the national vaccination schedule. The national level provides guidelines or instructions on the methodology and instruments for microplanning. Led by district and health facility staff, the subnational and local levels adapt and use the process and tools to develop and regularly update their microplan. These plans are reviewed and adjusted at least annually, and more frequently in response to substantial changes in the population or administrative units, or major health or non-health emergencies. Microplanning for vaccination campaigns is often done separately from that for routine immunization, although information should be shared – for example, identification of new communities during a house-to-house campaign should be included in the routine immunization microplan for the area.

A country's immunization schedule lists the recommended ages for each vaccine dose for children, adolescents and adults. Microplans assist in forecasting provision of on-time vaccination doses and, in line with national policy, will include provisions to catch-up individuals who begin the immunization schedule late or who present missing multiple vaccine doses. As outlined in this module, a systematic microplanning process for essential immunization, (a) triangulates the most up-to-date population data, (b) engages different stakeholders, (c) addresses solutions through a workplan and (d) rationalizes immunization session planning.

2 Making or updating a catchment area map

Catchment area maps provide visual and spatial orientation on the location of communities, landmarks and boundaries. Every district and every health facility should display a map that clearly shows the location and relative size of the population groups in their catchment areas. Catchment areas are usually determined by national authorities to help ensure equitable access to health services. Specific health facilities are responsible for providing health services, including immunization, to the defined catchment areas and the population living in them. Immunization services in a rural area may have one health facility providing vaccination services; in urban or peri-urban settings, a catchment area has more facilities providing services. In areas with denser populations, people may get vaccinated in various health facilities, which are not always close to where they live.

District and health facility catchment area maps should be supplemented by a list of all age groups eligible for vaccination across the life course in the catchment area, with relevant operational details. A table listing the total population and number in each target age group in these communities should be displayed next to each map. The maps and tables should be updated regularly to reflect changes in the catchment areas, including new administrative divisions and new formal and informal settlements. High-risk areas should be clearly marked on each map. These priority areas are identified based on triangulation of data on numbers of at-risk, under-immunized and unvaccinated (or zero-dose) children, adolescents, pregnant women, older people and health care workers (see section 3 of this module) as well as special populations such as internally displaced people, migrants and religious communities, among other categories.

Microplans can be developed using geospatial data and geographic information system (GIS) applications. Digital maps can have layered satellite imagery displaying geographic terrain, infrastructure, health facilities (public and private), formal and permanent settlements, transport routes, distances and travel times.

When updating maps, staff should consider all sources of information, particularly microplans for supplementary immunization activities and school enrolment lists, especially for young children.

It is critical that community leaders and administrative officials be involved in all microplanning steps, including when staff are creating and updating local catchment area maps (see Module 7, *Building community support*, on the role of community engagement in enhancing the success of immunization programmes).

2.1 District map

A district catchment area map should display the important geographical features and population centres of the whole district, including, but not limited to the following:

- health facilities, with their catchment areas shown as boundaries and their distances to district facilities marked;
- urban communities, towns, villages, rural settlements, scattered and isolated households, and shelters for refugees or displaced persons;
- schools, including nurseries, preschools and primary, middle, secondary and postsecondary schools;
- community centres;
- cold-storage facilities and health facilities with cold storage;
- medical waste locations and health facilities with a medical waste facility;
- rivers, mountains, valleys and other major geographical features and landmarks;
- natural seasonal and climate phenomena, such as flood zones during the rainy season;
- landmarks and significant buildings where community members gather, such as places of worship, education facilities and marketplaces;
- roads, tracks and transit points.

Next to the district map, display a table (see Fig. 4.1 for an example) that includes:

- the total population and target populations by age group in the catchment area of each health facility, as estimated for the area;[1]
- approximate distances and travel times from communities to health facilities and from health facilities to the main district, as appropriate;
- health facility staff names and contact numbers and any other information that may be useful in district-level planning, coordination and supervision efforts.

Fig. 4.1 Sample form for district-level list of health facilities and their catchment area populations

Health facility name	**Total population in catchment area[a]**	**Target populations[b]**					**Distance between health facility and main district facility (km and travel time)**	**Name of contact person**	**Phone number of contact person**
		0–11 months	12–23 months	24–59 months	9–14 years	Pregnant women			

[a] Include source of population data

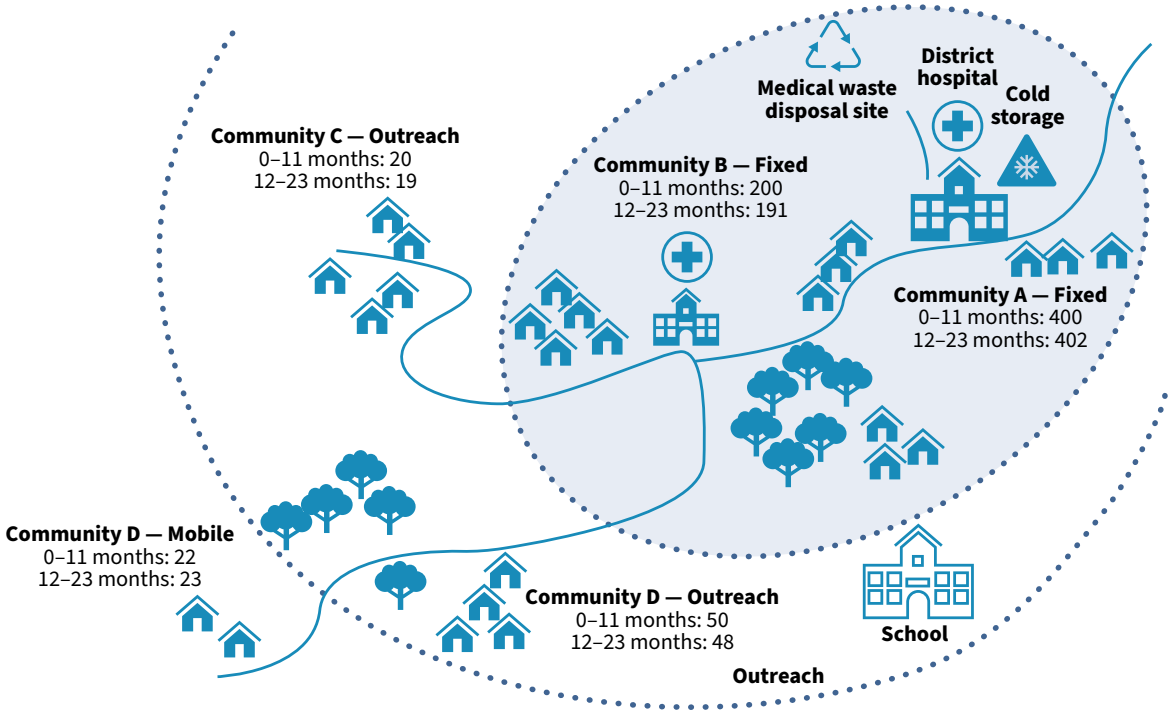
[b] Age ranges to be adjusted based on national guidance. Additional target groups can be added for adolescents and adults.

[1] The source for the target population varies by country. It may be provided at the national level or may be otherwise determined.

2.2 Health facility map

Each health facility should map all communities and points of interest relevant for the vaccination programme in its catchment area (see Fig. 4.2 for an example). Health facility staff should confirm community boundaries and settlements (permanent and temporary) with community leaders and local administrative authorities. Staff should update these maps regularly.

Fig. 4.2 Sample health facility map in a rural setting, showing number of children under 1 and 2 years of age



The health facility catchment area map should be an operational diagram with details on how immunization services are organized through fixed sites, outreach and mobile teams (as applicable). It should note the location of cold-chain storage facilities and waste-disposal sites. Separate maps should be created for supplementary immunization activities or other health campaigns and should be reviewed and compared with the immunization maps.

The health facility map should include:

- the location of every village, street and community in the catchment area, including new developments;
- settlements of urban poor and migrants, both within towns and cities and on the outskirts;
- settlements of mobile populations such as migrants, pastoralists/nomads, and unhoused and/or displaced persons in rural areas;
- cold-storage facilities and waste-disposal sites (if separate from the health facility);
- settlements or temporal shelters (formal or informal) for refugees or displaced persons;

- landmarks and significant buildings – for example, places of worship, marketplaces, nurseries, schools, motor parks, police and military barracks, commercial areas, factories and unique landmarks.

Include every community and mobile and scattered/formal/informal/seasonal settlement on the map, even if precise numbers are not available. Ensure, in particular, that the map includes communities of migrant workers, urban poor, ethnic minorities, new rural settlements, and groups in movement or unrest. The map should include unauthorized or temporary dwellings to ensure that no areas are missed.

Identify areas with underserved communities and collect GPS locations and information on these settlements to ensure high-risk communities are prioritized and receive immunization services.

Next to the health facility map, display a table (see Fig. 4.3 for an example) that includes:

- the total population and target populations, by age, in each community in the catchment area (target age groups across the life course are determined by national microplanning guidance);
- approximate distances and travel times from the health facility to each community;
- names and mobile phone numbers of health facility staff and community volunteers.

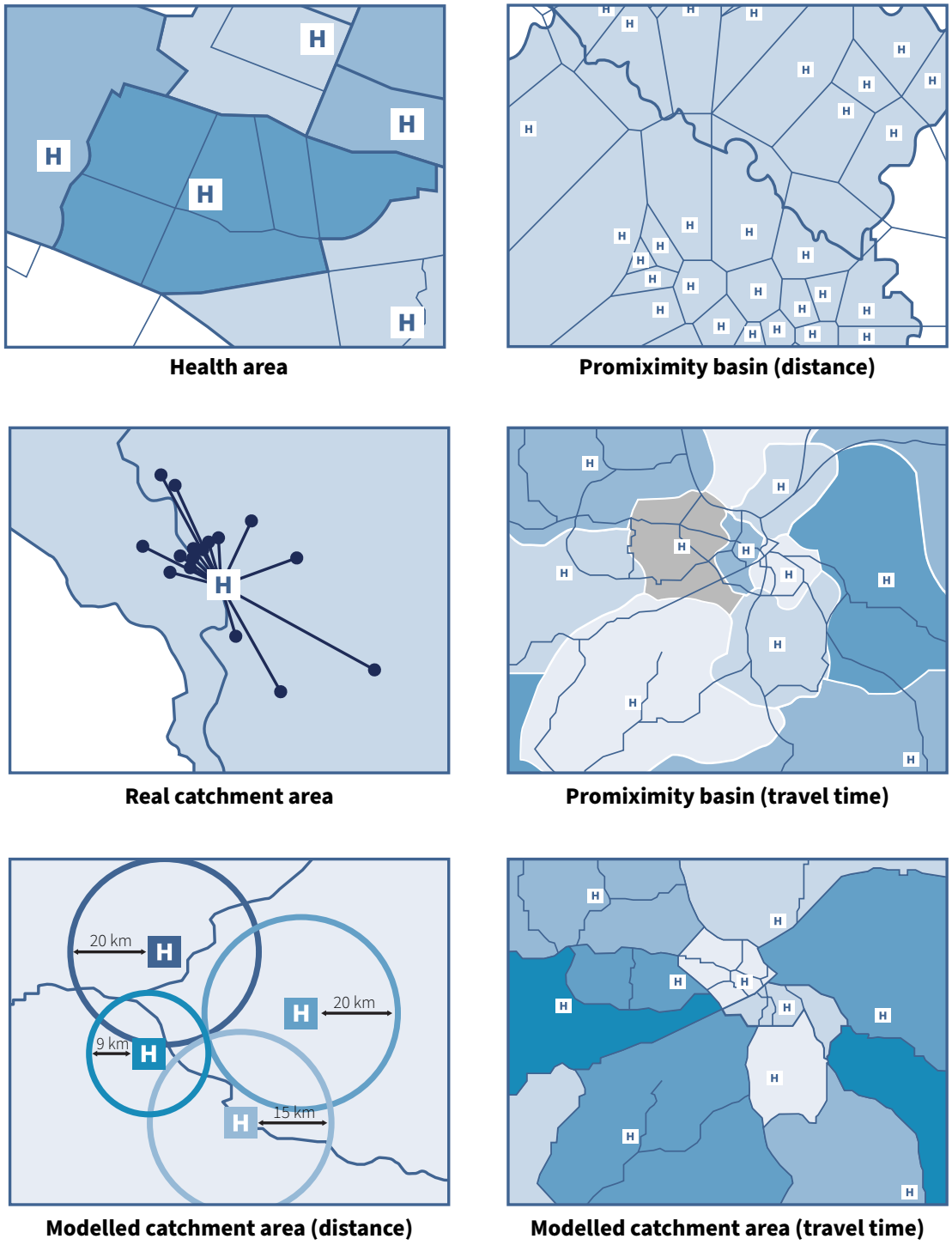
Fig. 4.3 Sample form for health facility list of catchment area communities and populations

Community name	**Total population in catchment area**[a]	**Target population**[b]					**Distance between community and health facility (km and travel time)**	**Name of contact person for community**	**Phone number of contact person**
		0–11 months	12–23 months	24–59 months	9–14 years	Pregnant women			

[a] Include source of population data.
[b] Age ranges to be adjusted based on national guidance. Additional target groups can be added for adolescents and adults.

Using geo-enabled maps can assist in visualizing and comparing different types of catchment areas and building an understanding of social and care-seeking patterns (Fig. 4.4). For example, comparison between a modelled catchment area and a mapped catchment area may show that some groups with reasonable access to a health facility do not make use of it or bypass it for another service. This type of information assists in planning demand-generation activities, service delivery and advocacy.

Fig. 4.4 Examples of common catchment area types developed through geo-enabled microplanning



Health area | **Promiximity basin (distance)**

Real catchment area | **Promiximity basin (travel time)**

Modelled catchment area (distance) | **Modelled catchment area (travel time)**

H – health facility

Source: Adapted from World Health Organization, *Geo-enabled microplanning handbook;* 2023.

Staff should compare maps made by health workers and those generated by GIS, as both provide operational insights. District and health facility maps should match, with greater detail in the health facility-level maps. Districts should have copies of the latest catchment area maps from each health facility to refer to as needed.

3 Identifying all eligible populations and prioritizing areas

An essential part of planning is to estimate the number of eligible persons and identify which areas require additional support to reach their targets.

3.1 Population estimates and data triangulation

Population estimates used in microplanning for immunization are typically either census-based (provided by a national statistical service) or obtained through manual counts of the local population.

Population estimates for children under the age of 1 year may be calculated by applying the appropriate (national or subnational) birth rate to the overall population. Depending on the context, the expected number of children under 1 year varies between 1% and 4% of the total population, so it is important to use the birth rate for the country or subnational area when available. To estimate the expected number of pregnant women, live births can be used as a proxy. The number of individuals to be vaccinated by target group can be provided by the district administration, based on each health facility's capacity and past vaccination performance.

To estimate the population to target in the microplan, compare and triangulate population data by relevant target age groups, using available sources such as:

- civil or population registration data;
- community mapping or census data;
- local assessments or head counts;
- population register databases;
- vaccination data, such as number of persons vaccinated (administrative data from the previous year, any campaign data), an electronic immunization registry and so on;
- other registries compiled by private facilities or nongovernmental organizations;
- school enrolments;
- surveillance data for vaccine-preventable diseases (VPD) and outbreak investigation reports.

Data triangulation involves looking at two or more existing data sources to answer a programme planning question, such as "How many children, adolescents and adults does the health facility plan to vaccinate?" By using and comparing available data, triangulation can address the limitations of relying on one source. If there appear to be major variances

in the size of the assigned target population for routine vaccination or those estimated through data triangulation, inform relevant programme and/or statistical service staff and discuss the issues with them.

As census-based projections get farther from the last census, the accuracy of estimated target populations decreases, particularly for small administrative areas. In reviewing the previous year's coverage data, pay particular attention to the number of vaccinated (numerators) and the target population (denominators) for that period for each target age group. Note that if the record of vaccine doses administered is either incomplete or inflated, this could result in an inaccurate planning figure. Similarly, the target population could be underestimated or overestimated, depending on the completeness of the data (for example, whether all settlements are included) or on population movement in or out of the area since the last estimate was made.

Microplanning is an opportunity to identify underserved communities, understand more about them and plan for their systematic inclusion and coverage. It is important to draw on local knowledge, some of which may be available only verbally, along with recent health and immunization programme data and evaluations to assess and agree upon planning assumptions and final figures for each target group.

While all health facilities will need resources and support to reach all eligible populations, some parts of the catchment area may need additional support. Two levels of analysis lead to the identification of priority health facilities and communities. These are:

1. at the district level, the analysis of health facility immunization coverage data for the past few years; and
2. at the health facility level, the analysis of community-level immunization coverage data for the past few years. Additional visits to communities identified in these analyses may be needed for understanding reasons for low coverage (see section 4 of this module).

3.2 Analysis of district immunization data

In identifying eligible groups and prioritizing areas in need of extra support, district and health facility teams can prioritize specific areas or groups based on recent programme performance. The district will review coverage data by health facility catchment area with attention to data quality. It should also review confirmed reports of VPD for the district or country, as these signal immunity gaps (see Module 6, sections 4 and 6 for more details). Areas with high numbers of unvaccinated (or zero-dose) and under-immunized children should be considered high priority for extra support, as these communities likely face the biggest health care access and demand-generation needs.

Fig. 4.5 Sample form for district immunization data analysis

Area details[a]					VPD[b] cases reported		Number of individuals vaccinated[c]					Immunization coverage (%)					Zero dose estimate (#)	Drop-out rates (%)			Priorization
District name	**Total population**	**Target population 0–11 months** (a)	**Target population 12–23 months** (b)	**Target population girls 9–14 years** (c)	**# (or incidence) measles cases**	**# (or incidence) of other VPDs** (diptheria, pertussis, yellow fever, polio, tetanus)	**DTP1** (d)	**DTP3** (e)	**MCV1** (f)	**MCV2** (g)	**HPV** (h)	**DTP1** (i)	**DTP3** (j)	**MCV1** (k)	**MCV2** (l)	**HPV** (m)	(a–d)	**DTP1-DTP3** (i-j)	**MCV1-MCV2** (k-l)	**DTP1-MCV1** (i-k)	High incidence or number of VPD cases, high unvaccinated & drop-out rates

[a] Add additional target groups and calculate catch-up or delayed doses administered among older groups separately.

[b] Adjust based on local epidemiology and VPD reportable diseases; each column will include only cases of one VPD.

[c] Add other vaccines/doses of interest.

Fig. 4.5 shows a sample format for the analysis of district immunization coverage and VPD surveillance data from the preceding 12 months. Such data facilitate the ranking and prioritizing of health facilities, uncovering indicators that point towards problems and show that additional support is needed. Such indicators may include unvaccinated children in the community, high drop-out rates from administrative data (numerators), stockouts during this period, outreach/mobile sessions that were cancelled or did not take place and so on. Other indicators such as facility birth rates and access to reproductive health care can also be considered as part of the planning process to enhance understanding of needs in specific catchment areas.

Prioritize health facilities, using district immunization and health data.

- Use all available information to understand potential reasons for issues, including information from community and administrative leaders, community health workers/volunteers, women's groups and local nongovernmental organizations.
- Consider which health facilities have data inconsistencies (for example, a health facility that shows negative values for under-immunized children). Also consider health facilities with known human resource challenges, including staff shortages, management issues or other problems.
- Using indicators that point to problems and suggest that support is needed, rank the health facilities; the health facility ranked 1 has the highest priority. Alternatively, health facilities can be ranked as high, medium and low priority.

For immunization coverage, analysis depends on the accuracy of the numerator and the denominator; if either is underestimated or overestimated, reported coverage will not reflect actual coverage.

Other age groups, health indicators and antigens of interest can be included in the analysis. In addition, the analysis might include a comparison of coverage of doses of different vaccines that are administered at the same visit, according to the national schedule.

3.3 Analysis of health facility data

The same data used for district-level analysis will be reviewed at the health facility catchment area level, by village, street and/or community. Fig. 4.6 shows a sample format for analysing health facility coverage and VPD surveillance data over time by community. Data to complete this table should be sourced from line-listed or aggregated data at the health facility level.

Prioritize communities, using health facility immunization data.

- List every community, including those that are new or temporary and that do not have regular access to services (for example, urban slums, distant rural communities).
- Complete the analysis of health facility data, using all available sources of information, including information from community and administrative leaders.
- Consider which communities have higher numbers of unimmunized and under-immunized (defaulter) children.

Fig. 4.6 Sample form for health facility data analysis

Area details[a]				VPD[b] cases reported		Number of individuals vaccinated[c]					Immunization coverage (%)					Zero dose estimate (#)	Drop-out rates (%)			Priorization
Community	**Target population 0–11 months** (a)	**Target population 12–23 months** (b)	**Target population girls 9–14 years** (c)	**# (or incidence) measles cases**	**# (or incidence) of other VPDs** (diptheria, pertussis, yellow fever, polio, tetanus)	**DTP1** (d)	**DTP3** (e)	**MCV1** (f)	**MCV2** (g)	**HPV** (h)	**DTP1** (i)	**DTP3** (j)	**MCV1** (k)	**MCV2** (l)	**HPV** (m)	(a-d)	**DTP1-DTP3** (i-j)	**MCV1-MCV2** (k-l)	**DTP1-MCV1** (i-k)	High incidence or number of VPD cases, high unvaccinated & drop-out rates

[a] Add additional target groups.

[b] Adjust based on local epidemiology and VPD reportable diseases; each column will include only cases of one VPD.

[c] Add other vaccines/doses of interest.

- When reviewing data from the preceding 12 to 24 months, look for any monthly variation in immunizations given in a community and note any seasonal changes (such as decreases during the rainy season) and where there may be inconsistencies in or questions about the data.
- Using indicators that point to problems and suggest that support is needed, rank the communities; the community ranked 1 has the highest priority. Alternatively, communities can be ranked as high, medium and low priority.

Other age groups, health indicators and antigens of interest can be included in the analysis. In addition, the analysis might include a comparison of coverage of different antigens that are supposed to be administered at the same visit, according to the national schedule.

3.4 Other population-based analyses

In addition to reviewing key immunization coverage and VPD surveillance data from the previous year (for example, as recorded in the formats shown in Figs. 4.5 and 4.6), additional context to inform microplan development can be gained from reviewing these data in more detail as well as by conducting other analyses. Examples of other analyses include the following.

- **Epidemiology and surveillance data for VPD:** Examine the number and type of VPD cases, deaths and locations at the district level. Case-based data should include age, sex and vaccination status, and should be for the previous year, with multi-year comparisons as relevant. Specific programme data such as vaccination status in non-polio acute flaccid paralysis cases can also be useful in identifying areas or groups where immunization coverage is suboptimal for specific vaccines (see Module 6).
- **Zero-dose (or, alternatively, unvaccinated) individuals and under-immunization:** In addition to estimating the number of zero-dose children at the district level and in health facility catchment areas (see Module 6, section 3), other data sources for zero-dose individuals can be reviewed. These can include rapid convenience monitoring or community-based surveys, if conducted. If, in the past 12 to 24 months, performance monitoring methods such as rapid convenience monitoring (also known as rapid convenience assessment) and/or lot quality assurance sampling have been used, the results should be reviewed and incorporated into microplans and triangulated with administrative coverage data. These methods provide data on under-immunized and/or unvaccinated persons and, in many instances, provide important contextual information, including reasons why the individuals were not reached.
- **Gender analysis/assessment:** Gender analysis aims at examining differences in roles and norms for women and men, girls and boys; the different levels of power they hold; their differing needs, constraints and opportunities; and the impact of these differences in their lives. A gender analysis or other assessments done at the national level can provide important information to inform service delivery considerations.

4 Identifying behavioural and social drivers of vaccination

During the process of updating microplans, it is vital to understand the causes of low uptake from the perspectives of the caregiver, community representatives and health workers. Participatory methods to develop the microplan contribute to an understanding of what people are thinking and feeling, and the motivation, social processes and practical issues that drive or hinder vaccination.

As part of the microplanning process, data collection, through household questionnaires, in-depth interviews and similar exercises with teams of health facility and district staff, provides an opportunity to learn about perspectives on vaccination directly from caregivers and other community members. Openness should be encouraged by those conducting these exercises. Community chiefs, leaders and volunteers must be engaged through participatory approaches before and throughout the data-collection process, and all genders should be involved.

To measure, understand and address the reasons for undervaccination, WHO developed a framework of behavioural and social drivers of vaccine uptake and its associated tools. Tools for identifying and assessing behavioural and social drivers of vaccine uptake include validated surveys and in-depth interview guides, along with guidance to support the gathering and use of data on these drivers.

The next section describes the use of some of the tools for behavioural and social drivers that can be used to inform microplanning. Section 4.1 is on the use of a childhood vaccination survey for caregivers; section 4.2 is on the use of an in-depth interview guide for community influencers. Refer to the WHO publication *Behavioural and social drivers of vaccination: tools and practical guidance for achieving high uptake* for a full range of resources on behavioural and social drivers and for guidance on adapting the tools for local needs and contexts.

Module 7 discusses in more detail how actively involving community members in immunization planning and activities enables vaccination services to be more responsive to local needs.

4.1 Assessment for caregivers on behavioural and social drivers of child vaccination

Fig. 4.7 shows a questionnaire for assessing the behavioural and social drivers of vaccination for children younger than 5 years, which can be adapted for the country context. The questionnaire may be adapted for use in household surveys in areas or among groups that are less likely to have fully immunized children, with the objective of understanding reasons for low uptake. This means conducting a rapid convenience monitoring of a few neighbourhoods or communities where there are known under-immunized or unimmunized (or zero-dose) children. For this assessment, select the neighbourhoods with the greatest number of drop-out children identified through the immunization register. Additionally, check vaccination information given by households against the immunization register. While a small sample will not be representative of the health facility catchment area or district, it will elicit information that will assist in tailoring microplans. Obtain the required permits and ethical approvals prior to data collection, anonymize all data and respect local principles of data privacy and protection.

4.1.1 How to complete the behavioural and social drivers of vaccination household questionnaire

Trained interviewers should read the survey questions and response options in Fig. 4.7 aloud to respondents. Interviewers should not read aloud instructions, which appear in square brackets or all capital letters. Interviewers should emphasize underlined words.

The questionnaire in Fig. 4.7 starts with the date, the location and the participant's basic demographic information. Once introductions have been made and participant consent obtained, the interviewer will confirm the number of children under 5 years of age in the household and ask a series of questions related to the youngest child.

Understanding caregivers' perspectives and experiences linked with undervaccinated and unvaccinated (or zero-dose) children will help in devising appropriate solutions for the workplan (discussed further in section 6 of this module).

Fig. 4.7 Behavioural and social drivers questionnaire for caregivers about child vaccination

	Question	Responses
Date	DATE / MONTH / YEAR	____ / ____ / _____
	PARTICIPANT ID	_____
	LOCATION	GPS COORDINATES: _____ CLUSTER NUMBER: _____ DISTRICT NAME: _____
Introduction	Hello, I am [INTERVIEWER] with [ORGANIZATION]. We are interviewing people to help improve children's vaccination in [COUNTRY NAME]. I know you are busy, so this will only take a few minutes. Your participation is completely voluntary and anonymous. If you do not want to answer a question or wish to stop the interview, please let me know.	
Consent	Would you be willing to take the survey?	☐ YES → Thank you very much. Do you have any questions before we begin? ADDRESS ANY QUESTIONS AND PROCEED. ☐ NO → Thank you very much. END INTERVIEW
Caregiver	AGE: How old are you?	_____ YEARS
	GENDER: This may seem obvious, but I have to ask the question. What is your gender? Would you say…	☐ Woman ☐ Man ☐ Nonbinary, *or would you* ☐ Prefer not to say?
	Are you the parent or primary caregiver of any children who are younger than 5 years old?	☐ YES ☐ NO IF "NO": Unfortunately, you are not eligible to participate in the survey. Thank you very much for taking the time to answer my questions. END INTERVIEW.
	NUMBER OF CHILDREN UNDER 5: How many children do you have who are younger than 5 years?	_____ CHILDREN
Child	IF MORE THAN ONE CHILD: The next questions are about your youngest child.	
	RELATIONSHIP TO CHILD: What is your relationship to your child? Would you say…	☐ Mother ☐ Father ☐ Grandparent ☐ Uncle or aunt ☐ Brother or sister, *or* ☐ Other? [If "OTHER": Please specify: _____]
	AGE OF CHILD: How old is your youngest child?	☐ Less than 1 year old ☐ 1 year old ☐ 2 years old ☐ 3 years old, *or* ☐ 4 years old?

Fig. 4.7 (continued)

	Question	Responses
	GENDER OF CHILD: Is your youngest child…?	☐ Female ☐ Male ☐ Non-binary, *or would you* ☐ Prefer not to say?
	VACCINATION STATUS: [COUNTRY NAME] has a schedule of vaccines for children. As far as you know, has your child had none of these vaccines, some of these vaccines or all of these vaccines?	☐ NONE ☐ SOME ☐ ALL
Motivation	[COUNTRY NAME] has a schedule of vaccines for children. Do you want your child to get none of these vaccines, some of these vaccines or all of these vaccines?	☐ NONE ☐ SOME ☐ ALL
Confidence	How important do you think vaccines are for your child's health? Would you say…	☐ Not at all important ☐ A little important ☐ Moderately important, *or* ☐ Very important?
	How safe do you think vaccines are for your child? Would you say…	☐ Not at all safe ☐ A little safe ☐ Moderately safe, *or* ☐ Very safe?
	How much do you trust the health workers who give children vaccines? Would you say you trust them…	☐ Not at all ☐ A little ☐ Moderately, *or* ☐ Very much?
Social processes	Do you think most parents you know get their children vaccinated?	☐ NO ☐ YES
	Do you think most of your close family and friends want you to get your child vaccinated?	☐ NO ☐ YES
	Do you think your religious leaders want you to get your child vaccinated?	☐ NO ☐ YES
	Do you think your community leaders want you to get your child vaccinated?	☐ NO ☐ YES
	Has a health worker recommended your child be vaccinated?	☐ NO ☐ YES
Practical issues	Have you ever been contacted about your child being due for vaccination?	☐ NO ☐ YES
	If it was time for your child to get vaccinated, would the mother need permission to take your child to the clinic?	☐ NO ☐ YES
	Do you know where to go to get your child vaccinated?	☐ NO ☐ YES
	Have you personally ever taken your youngest child to get vaccinated?	☐ NO ☐ YES

Fig. 4.7 (continued)

Question	Responses
Have you ever been turned away when you tried to get your child vaccinated?	☐ NO ☐ YES
How easy is it to get vaccination services for your child? Would you say…	☐ Not at all easy ☐ A little easy ☐ Moderately easy, *or* ☐ Very easy?
How easy is it to pay for vaccination? When you think about the cost, please consider any payments to the clinic, the cost of getting there, plus the cost of taking time away from work. Would you say…	☐ Not at all easy ☐ A little easy ☐ Moderately easy, *or* ☐ Very easy?
What makes it hard to get vaccination services for your child? Would you say… [READ ALOUD ALL RESPONSE OPTIONS, PAUSING AFTER EACH TO ALLOW RESPONDENT TO ANSWER "YES" OR "NO" AFTER EACH RESPONSE OPTION. RESPONDENTS MAY SELECT MULTIPLE RESPONSE OPTIONS.]	☐ Nothing, it's not hard [IF NOTHING, SKIP REST OF RESPONSES] ☐ Getting to the clinic is hard ☐ The clinic opening times are inconvenient ☐ The clinic sometimes turns people away without vaccinating ☐ The waiting time in the clinic takes too long ☐ Is there something else? [RECORD ANSWER: _____]
How satisfied are you with the vaccination services? Would you say…	☐ Not at all satisfied ☐ A little satisfied ☐ Moderately satisfied, *or* ☐ Very satisfied?
What is not satisfactory about the vaccination services? Would you say… [READ ALOUD ALL RESPONSE OPTIONS, PAUSING AFTER EACH TO ALLOW RESPONDENT TO ANSWER "YES" OR "NO" AFTER EACH RESPONSE OPTION. RESPONDENTS MAY SELECT MULTIPLE RESPONSE OPTIONS.]	☐ Nothing, you are satisfied [IF NOTHING, SKIP REST OF RESPONSES] ☐ Vaccine is not always available ☐ The clinic does not open on time ☐ Waiting times are long ☐ The clinic is not clean ☐ Staff are poorly trained ☐ Staff are not respectful ☐ Staff do not spend enough time with people ☐ Is there something else? [RECORD ANSWER: _____]

Source: Adapted from Behavioural and social drivers of vaccination: tools and practical guidance for achieving high uptake. Geneva: World Health Organization; 2022.

Summarize the findings from several questionnaires and focus reporting on the response rate, characteristics of the sample and how people responded to questions about motivation, confidence, social processes and practical issues (by percentage and number).

Partially immunized or unimmunized children identified in this exercise should be added to defaulter tracking lists for vaccination.

4.2 Discussion with community influencers

Fig. 4.8 shows a qualitative in-depth interview guide for a semi-structured discussion with community influencers or enablers on barriers to immunization. This participatory approach aims to gather information on community perceptions and ideas for improvement. In-depth interviews with community influencers complement information obtained from the caregivers' behavioural and social drivers assessment. The in-depth interviews are intended to be conducted in-person, with one individual at a time.

Ensure these interviews include representation from groups of interest (such as high-risk, marginalized, etc.) and address gender-related considerations, such as equally including both men and women.

The questions in Fig. 4.8 can be modified. The exercise is intended to take about an hour.

Fig. 4.8 Guide for in-depth interviews with community influencers

Introduction: Hello, I am [INTERVIEWER'S NAME] with [INSTITUTION OR ORGANIZATION NAME]. We are interviewing people to help improve vaccination services in [NAME OF COUNTRY].

The interview is expected to take _____ minutes. Your participation is completely voluntary and anonymous. The answers you give will be completely confidential. If you do not want to answer a question or wish to stop the interview, just let me know. Would you be willing to take part in an interview with me? [IF YES, Thank you very much.] [If audio recording the interview] Would you be happy for me to record our conversation? [IF YES, Thank you very much. AND PROCEED]

Tell me a little about yourself and your role in the community?

Probe:

- To what extent does your work involve immunization?
- Can you tell me more about that?
- Who do you work with to do that work?

Can you take me through the process you follow when you work in a community?

Probe:

[Note that this probe is for participants who work with families.]

When you visit a family:

- What do you talk about?
- What information can you not leave without saying?
- Do you follow up with families afterwards? How do you do that?

[Note: This question is for participants who work with other people and organizations; use as appropriate for participant.]

- How do you help the front-line health workers in working with families?
- How do you help with routine immunization?

What do you find works in helping families stay up to date with their children's immunizations?

Probe:

- What helps them not miss doses or appointments? [Note: this is to probe for practical issues.]
- What helps those who are hesitant about getting their children vaccinated?

What makes it difficult for families to stay up to date with immunization?

Probe:

- Can you give some examples of reasons people give when their child has fallen behind the vaccination schedule?
- Can you give some examples of reasons that people give for refusing vaccines for their children?
- Are you able to overcome these challenges? How?

If you had a chance, what would you do to improve immunization services in your area?

Source: Adapted from Behavioural and social drivers of vaccination: tools and practical guidance for achieving high uptake. Geneva: World Health Organization; 2022.

5 Assessing service delivery modalities, the cold chain and supervision needs

5.1 Service delivery modalities

Three main service delivery strategies for immunization are fixed, outreach and mobile (see Table 4.1). Microplans should include a combination of these strategies, with the aim of making vaccination services more accessible and convenient to communities and optimizing health worker scheduling. Staff should assess and adapt these strategies regularly, based on local knowledge. Changes incorporated in a microplan should be widely shared.

Table 4.1 Characteristics of immunization service delivery modalities

Type	Location	Access / travel time	Scheduling
Fixed	At a health facility	Services community members who have easy access to the health facility	Same day(s) every week
Outreach	At an "outreach site" such as a school or community site	Services areas around the health facility that staff can travel to and return from the same day	Same day(s) of the week every month
Mobile	Beyond the "outreach area"	Services areas not possible to cover in one day; requires an overnight stay by staff	Same day(s) of the week every month

Source: Adapted from Reaching every district (RED): a guide to increasing coverage and equity in all communities in the African Region. Brazzaville: World Health Organization; 2017.

Microplanning for immunization is an opportunity to consider other primary health care activities and to review the district's service delivery mix from the previous year. To do so, aggregate and compare the number of fixed, outreach and mobile (if used) sessions planned and the number completed. Compare across catchment areas the proportion of children vaccinated using each modality, and check if changes in the mix of service delivery types are needed to reach the target populations.

Focusing on high-priority catchment areas and communities identified from earlier analysis, see which service delivery modalities have been used in these areas and what adjustments may need to be considered. For example, two outreach sites may be able to be merged into one that serves two communities, or a new outreach site may make services more accessible for the target populations and may be able to jointly deliver other primary health care services.

5.2 Additional service delivery strategies

Based on the context, other service delivery strategies may be used to vaccinate children, adolescents and adults.

Periodic intensification of routine immunization: Periodic intensification of routine immunization refers to a range of time-limited, intermittent activities used to administer routine vaccinations, including catch-up doses, to undervaccinated populations. These intensification activities may be planned at the national or subnational level to reach groups and individuals who are usually the target of routine services but who have been missed or not reached. Periodic intensification of routine immunization doses are recorded on immunization cards as routine doses and are included in the administrative routine immunization coverage data. Periodic intensification of routine immunization activities can take many forms – examples include Child Health Days, Child Health Weeks and National Vaccination Weeks. These intensification programs will usually target a specific age group, such as children under 2 years, under 5 years or up to adolescence. Service delivery through such programs usually involves specific periodic intensification of routine immunization microplans, which can be harmonized with microplans for routine immunization *(1)*. Mapping where undervaccinated and unvaccinated (or zero-dose) children have been identified can inform future activities and updates to the microplan.

Supplementary immunization activities: Supplementary immunization activities deliver vaccination to all targeted individuals regardless of their vaccination status (prior history). To achieve disease control or elimination, the goal of supplementary immunization activities is to rapidly raise population-level immunity and reduce the number of susceptible individuals. Supplementary doses can be single- or multi-antigen and can be integrated with other preventive health services (such as administration of vitamin A, distribution of bed nets). Supplementary doses given are tallied but not included in the routine administrative coverage data. Typically, special microplans are developed for a supplementary immunization activity vaccination campaign. Supplementary immunization activity microplans can leverage an existing routine microplan, and useful updates from supplementary immunization activity microplanning can be brought back into a routine microplan *(2)*.

Use of school settings: School and daycare settings provide opportunities to integrate vaccine delivery with other health interventions aimed at reducing VPD and improving population health. Checking the vaccination status of children at daycare, preschool and primary and secondary school is a strategy to identify under-immunized children

and facilitate opportunities for them to receive missed vaccines doses. If the country mandates this approach, it can be incorporated into microplanning (that is, planning for when vaccination checks or outreach occurs and anticipating vaccination needs). A list of publications on school-based immunization is available at the Essential Programme on Immunization website.

5.3 Cold-chain equipment

As part of microplanning, it is important to ensure the availability of an adequate supply of functional cold-chain equipment, including for cold storage and transport up to the service-delivery point. The district should conduct an analysis of cold-chain equipment inventory for each health centre and identify and address any gaps (see Module 2, *The vaccine cold chain*, for more information). In the case of planning for supplementary immunization activities, the analysis of cold-chain storage should take into account the additional vaccines for the supplementary immunization activities to ensure that the available storage can accommodate both routine and supplementary vaccines.

Each health facility should have an equipment-maintenance plan, including a contingency plan to ensure that the vaccine cold chain is maintained in the case of unavoidable/unforeseen circumstances such as power failure, malfunctioning equipment, disasters such as flooding and so on.

5.4 Supportive supervision

Supportive supervision, which involves respectful supervisory visits to help staff improve their performance, reinforce their knowledge and skills and build relationships, is an essential way to identify and resolve issues and reinforce health workers' skills and motivation. It requires planning for availability of supervisors and their transportation, and aligning them with immunization services schedules. Personnel at the district level should apply the health facility prioritization discussed in sections 2–4 when planning monthly or quarterly supervisory visits, providing more frequent visits to prioritized health facilities and outreach locations.

To inform the supportive supervision component of the microplan, health facility and subnational immunization staff should analyse planned and completed supervisory visits from the previous six months or year, including information on problem-solving and follow-up actions.

6 Identifying solutions and preparing a workplan

This section is a guide to taking all the information collected (as described in sections 2–5 above) and applying it when planning solutions to overcome the identified barriers to access to and utilization of routine immunization services. Solutions should be added to a workplan to guide a practical approach, and a workplan should be developed for each priority community.

When devising a workplan, consider the service delivery modalities and additional opportunities for reaching all eligible populations. Also consider findings from data gathered on the behavioural and social drivers of vaccination. Annex 6.1 in Module 6 lists common problems and possible solutions. While not exhaustive, the examples may help staff complete a workplan.

6.1 Reducing missed opportunities for vaccination

Reducing missed opportunities for vaccination is a strategy of systematically checking vaccination status and vaccinating children when they present at health delivery points – at health facilities or hospitals, or outreach and mobile sessions – including for reasons other than to be vaccinated. Through microplanning and/or separately through a missed opportunities for vaccination assessment, reasons for missed vaccinations can be identified and solutions developed. Common interventions to reduce missed opportunities for vaccination can include displaying the immunization schedule in preventive care facilities; screening children on discharge from other health services; and issuing a referral paper or token along with reliable information on where and when to obtain vaccination (see Module 5) *(3)*.

6.2 Defaulter tracking and follow-up

Defaulter tracking is described in Module 5, section 6.3, on how to prepare a tracking list at the end of each immunization session; Module 6, section 1.4, provides a sample defaulter tracking form. Defaulter tracking may reveal information that can lead to adjustments in the microplan. For example, if children are missing on-time vaccinations due to transportation issues, the microplan may be adjusted to offer immunization sessions in a more accessible location.

6.3 Catch-up vaccination

"Catch-up" refers to the action of vaccinating an individual who, for whatever reason (for example, delays, stockouts, access, hesitancy, service interruptions and so on) has not received doses of vaccines for which they are eligible, per the national immunization schedule. It is sometimes called an "accelerated schedule" or a "delayed vaccination schedule" for children who begin the immunization schedule late or are missing multiple vaccine doses *(4)*.

The catch-up vaccination schedule, alongside operational guides for health workers, indicates minimum and maximum ages, minimum intervals permissible between doses for each vaccine and total doses required (which may vary by age).

An estimate of the target population requiring catch-up for vaccines missed the previous year can be approximated based on administrative data and drop-outs from the previous year's cohort.

A significant disruption in health services, such as in a conflict or post-disaster setting, can result in substantial accumulations of children missing essential vaccines who are eligible to receive (catch-up) those vaccines. Large numbers of missed children may prompt the need to update microplans and may require coordination across health facilities, and within or between districts, to remap populations and identify windows of opportunity for intensified catch-up vaccination efforts.

6.4 Integration

Immunization programmes that are integrated with the primary health system can more comprehensively address population health needs over time, make efficient use of resources and improve health outcomes, especially for those who are underserved. Factors to be considered when planning for integration include overlap of target age groups, compatibility of service delivery requirements and logistics.

When developing or revising a microplan, list other interventions that are already being delivered, or that can be delivered, with immunization (such as distribution of insecticide-treated bed nets, deworming tablets or vitamin A supplements, nutritional status screening, growth monitoring). Follow national guidelines and identify joint planning opportunities with other health sector areas.

6.5 Outline solutions

As part of the microplanning process, prioritization helps identify districts, health facilities and communities that may need tailored solutions to address challenges with health care access, utilization and demand. Fig. 4.9 shows a template that can be used for outlining solutions at health facility, community and district levels.

Using participatory and gender-responsive approaches, hold a brainstorming session with key health facility personnel, community health workers and volunteers, and community and district representatives.

- Identify the priority challenges and then narrow them down to a short list of about three that are the highest priority (working with a longer list of problems usually becomes too difficult for a practical approach). As appropriate, use existing data, analysis on reducing missed opportunities for vaccination and findings from data gathered on the behavioural and social drivers of vaccination to inform discussions on the main problems and potential solutions.
- Identify, discuss and build consensus on practical and feasible solutions to address prioritized problems, remembering that:
  - health facility problem-solving activities consider existing capacity and resources;
  - community activities consider the capacity of its volunteers, since additional resources are often not available;
  - district-level activities may provide support to the health facility with additional technical or financial resources.

Fig. 4.9 Sample solutions list

Community name:[a]			
Main problems Description of problems identified in the community	**Solutions**		
	Health facility activities	**Community activities**	**District activities**
1. [example]: Low attendance at outreach sessions	Agree with the community on the outreach session schedule and location Call the community contact person by mobile in advance of the session to confirm time, place	Mobilize caregivers by informing them in advance of the outreach session and then reminding them of the dates and encouraging attendance at the session	Ensure costs of outreach sessions are budgeted (transport and per diem) according to the health facility session plan Ensure all vaccines and related supplies are available at health facilities
2.			
3.			

[a] This template could also be used for a health facility or district.

6.6 Making a workplan to implement identified solutions

Fig. 4.10 shows a workplan format that staff can use to follow planned health facility and community activities over a 12-month period.

To develop a workplan and track progress:

- complete one form per area or activity – the same form can be used for both health facility staff and community workers;
- list the main health facility and community-level problem-solving activities from the solutions brainstorming exercise (see section 6.5), as compiled on a form like that shown in Fig. 4.9, defining activities as specific tasks for the person named on the form;
- make a schedule for completing the activities over the next 12 months (see Fig. 4.10). The person named on the form should track the progress of the activities/tasks as they are completed each month.

Alternatively, a Gantt chart can be developed listing activities by week or month with designated responsibilities.

Fig. 4.10 Sample format for workplan to achieve identified solutions

Name of health facility staff or community worker:												
Activities to be done by health facility staff or community worker	**Schedule by month**											
	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
1. [example]: Mobilize caregivers by informing them in advance and encouraging session attendance	☐ Do 1 week before session on [date]	☐ Do 1 week before session on [date]	☐ Do 1 week before session on [date]	☐ Do 1 week before session on [date]	☐ Do 1 week before session on [date]	☐ Do 1 week before session on [date]	☐ Do 1 week before session on [date]	☐ Do 1 week before session on [date]	☐ Do 1 week before session on [date]	☐ Do 1 week before session on [date]	☐ Do 1 week before session on [date]	☐ Do 1 week before session on [date]
2.												
3.												

7 Planning immunization sessions

An immunization session plan lists all communities served by the health facility and specifies how frequently each community will be reached, and through which service delivery modality, based on factors such as distance, target population, workload and other practical considerations. The quality and comprehensiveness of the plan are critical if all eligible populations are to receive safe and effective vaccines.

As described in section 6 of this module, the workplan lists clear activities to address issues that were identified during community discussions. In contrast, the immunization session plan charts out the operational aspects required to regularly reach all communities in the catchment area, integrating these with other primary health care services.

7.1 Health facility immunization session plan

Fig. 4.11 shows a sample format for an immunization session plan. Using this type of form, staff compile a list of communities and their distances from the health facility that is responsible for their immunization services. They also record the type of session needed – fixed (at the health facility), outreach (at a site in the community) or mobile (for rural communities) – which usually depends on the distance of the community from the health facility or on the travel time needed if the terrain is difficult. The type of session needed for urban communities may depend on social factors or convenience for the groups being served.

Fig. 4.11 Sample form for health facility overall immunization session plan

Community name	Target population groups[a]					Distance from health facility (est. travel time)	Sessions serving this community											
	0–11 months	12–23 months	24–59 months	9–14 years (girls)	Pregnant women		Fixed			Outreach				Mobile				
							Frequency	Location	HW (#)	Frequency	Location	HW (#)	Transport[b]	Frequency	Location	HW (#)	Transport[b]

[a] Age ranges to be adjusted based on national guidance. Include additional target age groups (adolescent, adult).

[b] Transport to include mode, contact name and number.

The frequency of sessions depends on the number of children, adolescents and adults expected at each session. In determining frequency, staff should consider reasonable workloads for vaccinators and acceptable waiting times for caregivers and children. In some countries, a low-volume facility may organize one or two immunization sessions per week, involving one to four health workers and immunizing approximately 15 children per session; a higher-volume facility may organize daily weekday sessions (five per week) with a team of two or more health workers administering vaccines to approximately 45 children each session.

Reviewing and adjusting immunization session plans: Session plans should be reviewed at least quarterly. Review of the immunization session plan should be informed by monitoring data and actively engaging with communities served (see Module 6, section 4). Any missed or incomplete immunization sessions should be rescheduled, and adjustments should be made to the location and modality of service delivery, as needed. The frequency and location of the immunization session and the number of resources required may need to be adjusted if population numbers change significantly or if routine health services or the availability of resources is disrupted.

7.2 Health facility outreach immunization session plan

Every health facility should make, display and monitor an outreach immunization session plan that shows the date and place of each session, the means of transport for staff and the names of the persons responsible for preparing and implementing transportation. The plan should include a community contact person who will communicate session dates and other reminders to the wider community. A sample format for an outreach session plan is shown in Fig. 4.12. Note that fixed sessions can be added to this form, if needed (write "fixed" in the transport column). When planning such sessions, follow national and district guidelines for microplanning.

Fig. 4.12 Sample form for health facility outreach session plan

Community name	Session frequency	Distance	Transport needed[a]	Person responsible for transport	Community contact name & mobile phone #	Date(s) scheduled & done	Month 1[b]	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
						Dates(s) scheduled:												
						Date(s) done:												
						Dates(s) scheduled:												
						Date(s) done:												
						Dates(s) scheduled:												
						Date(s) done:												
						Dates(s) scheduled:												
						Date(s) done:												
						Dates(s) scheduled:												
						Date(s) done:												
						Dates(s) scheduled:												
						Date(s) done:												
						Dates(s) scheduled:												
						Date(s) done:												
						Sessions done:												
						Sessions planned												
						% done												

[a] In the transport column, write “overnight” if needed to complete sessions in the community. Leave the transport column blank or write “fixed” in it if the community is served by fixed sessions at the health centre.

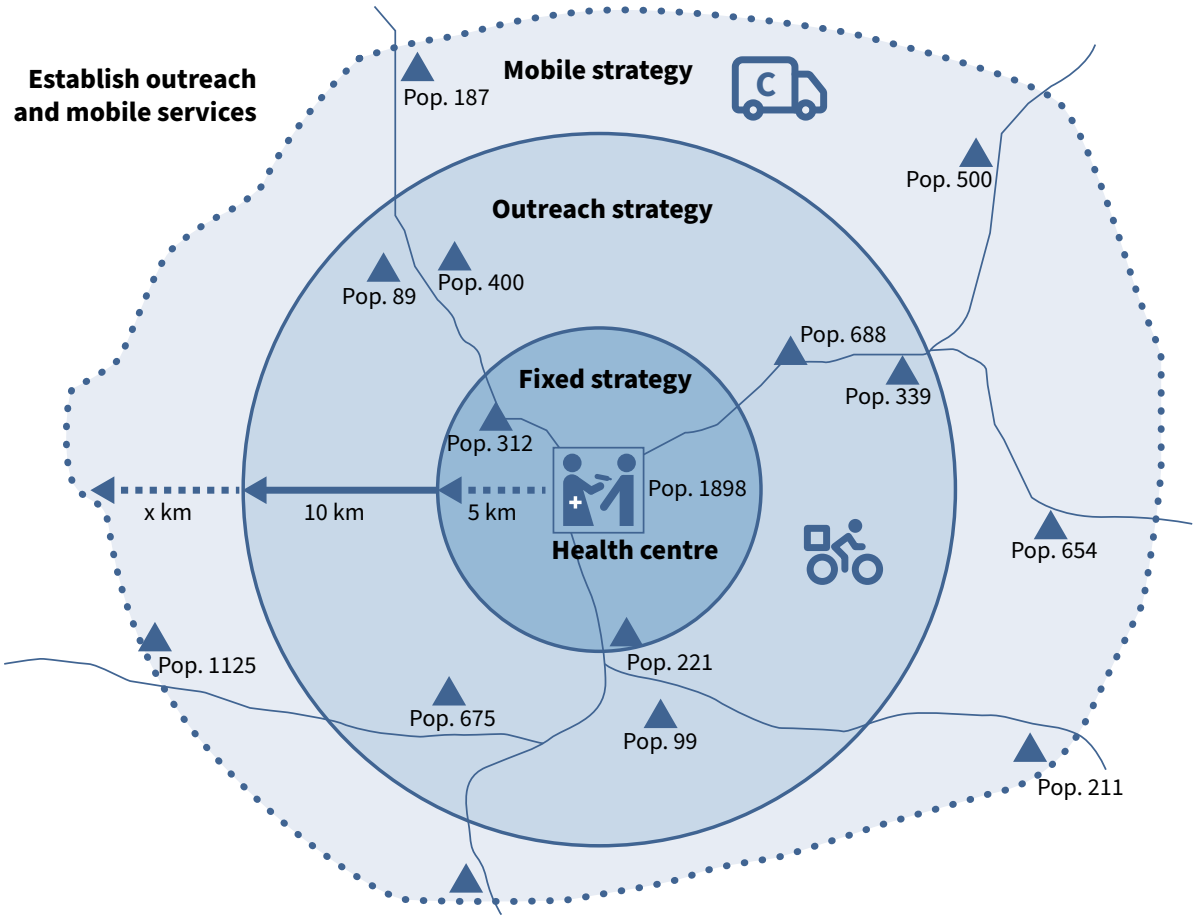
[b] Write all dates each month (for example, 2 dates if biweekly sessions).

Outreach sessions are often planned for rural communities that are 5 to 15 km from the health facility and for urban populations, using convenient locations such as markets, community facilities and schools. In some programmes and when transport and/or terrain present challenges, communities living more than 10 km away from the health facility may be served by mobile activities organized from the district level (see Fig. 4.13). Scheduling for outreach sessions may need to take into account seasonal rains or other factors that make populations hard to reach at certain times of the year.

Outreach session plans should be informed by gender analysis/assessment. Staff should be sure to take gender dynamics into account and tailor the outreach sessions accordingly.

Other activities, such as maternal/child health interventions, may be integrated in immunization sessions. Follow national guidelines on including additional staff, supplies and financial resources, as needed (see section 6.4 of this module).

Fig. 4.13 Illustration of fixed, outreach and mobile immunization service district requirements



Source: Adapted from Reaching every district (RED): a guide to increasing coverage and equity in all communities in the African Region. Brazzaville: World Health Organization; 2017.

7.3 Forecasting vaccines and related supplies

Vaccine forecasting helps estimate the number of doses of each vaccine and of associated commodities (such as syringes) that will be needed to reach defined target populations in the future, while accounting for some level of vaccine wastage (see Module 2). When forecasting, it is important to understand recent vaccine usage patterns at the district and health facility levels.

Review supply utilization in the previous year for each vaccine, differentiating between consumption and wastage. These recent vaccine utilization figures serve as points of comparison for the upcoming microplan.

Second-year-of-life vaccines: In forecasting requirements for vaccination in the second year of life, the size of the target population will be advised by the national statistics service or the number of surviving infants from the previous year's birth cohort. For example, if MCV2 is scheduled to be given to children at 18 months, then the target group for forecasting purposes for the current year is the number of surviving infants from the previous year.

The next step is to apply the target population figures to forecast how much of each vaccine and how many supplies are needed. Factors to consider include:

- vaccine product characteristics (such as presentation, formulation, inclusion in multi-dose vial policy);
- the vaccine wastage rate and number (for both open and closed vials);
- service delivery modalities;
- available cold-chain capacity.

Identify all vaccines and supplies needed for life course vaccination. These include vaccines in the national schedule; auto-disable and reuse prevention syringes for vaccine administration and reconstitution, respectively; safety boxes; adverse events following immunization (AEFI) kits; personal protective equipment; and forms such as registration booklets, tally sheets and immunization cards.

Using the session plan (Fig. 4.11), each health facility should calculate its supply quantities based on the national guidelines and known variations, such as increased numbers of children at immunization sessions where defaulters are expected for catch-up vaccination. Staff should take into account health facility wastage rates and similar factors for both vaccine vial and auto-disable syringe numbers. Include service delivery considerations for specific communities that may rely more on outreach or mobile teams. Quantities may be rounded off based on packaging and/or ease of dispensing from the vaccine store, pharmacy or stockroom. Various supply chain tools are available on the Essential Program on Immunization website.

Supplies for other activities integrated with immunization sessions (for example, the distribution of vitamin A, deworming tablets, etc.) can be added to stock lists, as directed by national guidelines.

Protection of health workers through vaccination is an important part of patient safety and infection-prevention and control programmes in health care settings, and of health workers' own health and safety. As part of microplanning for the adult cohort in district and health facilities, health workers and other adult groups must be included in vaccine forecasting and delivery.

The replenishment plan and schedule for the upcoming period should be agreed to by both district and health facility personnel. For the district, the lead time for stock distribution to lower levels should not exceed one to two weeks, depending on the context, and the lead time to service delivery points (health facilities) should be a few days.

7.4 Safety stock

Safety or buffer stock should be included in forecasting and the microplan. Safety stock is maintained at the district level to cover fluctuations in demand or delays in vaccine deliveries. The safety stock is equivalent to up to 25% of the supply needs for each year. The stock level should be regularly monitored and replenished as needed, to enable health facilities to respond to any demand surges, increase in planned target coverage and/or increase in the target population.

7.5 Health facility monthly stock plan

Monthly stock reports that estimate commodities usage and wastage are needed to plan for adequate supplies and avoid stockouts. Fig. 4.14 shows a sample format for a health facility stock plan, which provides an estimated monthly consumption figure based on expected immunization service activities. The estimated consumption figures should correspond with the total number of doses used at sessions held during the month. Stock data may be added to the monthly summary report, as shown in Module 6, section 3.

Fig. 4.14 Sample form for a health facility monthly stock plan

Monthly stock report						
Health centre name:			**Date report completed:**			
Stock month and year:			**Reported by:**			
Items For vaccines indicate presentation (i.e. # of doses per vial)	**Utilization**		**Opening stock**	**Order received**	**Closing stock**	**Order for next month**
	Consumption	**Wastage** (open- and closed-vial)				
BCG						
HepB						
OPV						
IPV						
DTP-containing vaccine						
PCV						
RV						
Measles-containing vaccine						
Other vaccines[a]						
AD syringe 0.5 mL[b]						
BCG AD syringe 0.05 mL						
RUP reconstitution syringe 5 mL + needle						
RUP reconstitution syringe 2 mL + needle						
Safety box						
AEFI kit[c]						
PPE[d]						
Home-based records						
Tally sheets						
Other items[e]						

[a] Other vaccines: include separate lines for other vaccines in the national schedule, and other vaccines the facility is providing in a non-routine manner.

[b] Syringe volume: include line for each syringe needed (for example, some COVID-19 vaccines use 0.3 ml or 0.2 ml and should be calculated separately, list for epinephrine).

[c] Forecast for epinephrine and administration syringe should be calculated separately.

[d] PPE: list each item on a separate line included in the district and national supply chain plan.

[e] Other items include: include other forms or items regularly used by the health facility and part of the district and national supply chain plan.

8 Monitoring and adjusting microplans

Through close monitoring of implementation, district and health facility staff should continuously examine their microplans for completeness and accuracy and update them regularly, especially if any missed area or population is identified. Supportive supervision visits provide opportunities to examine microplans and adjust them as needed.

Staff need to establish and nurture regular feedback loops between those implementing immunization activities and people in the communities, including caregivers, community health workers/volunteers and community influencers. Community engagement and feedback can include regular meetings, social listening approaches and other strategies, as identified by the community (see Module 7). In addition, staff should gather data using the same measures or indicators as behavioural and social drivers of vaccination assessments to identify changes in outcomes and corresponding improvements to interventions.

References[2]

1. Immunization Basics, USAID, and World Health Organization. Periodic intensification of routine immunization: lessons learned and implication for action. World Health Organization; 2009 (https://www.technet-21.org/en/resources/presentation/periodic-intensification-of-routine-immunisation-piri-lessons-learned-and-implications-for-action).

2. Planning and implementing high-quality supplementary immunization activities for injectable vaccines using an example of measles and rubella vaccines: field guide. Geneva: World Health Organization; 2016 (https://iris.who.int/bitstream/handle/10665/330568/9789241511254-eng.pdf).

3. Essential Programme on Immunization. Reducing missed opportunities for vaccination (MOV) [website]. World Health Organization (https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/implementation/reducing-missed-opportunities-for-vaccination#:~:text=Increasing%20Routine%20Immunization%20Coverage%20by,%2Fmobile%20services%20etc).

4. Leave no one behind: guidance for planning and implementing catch-up vaccination. Geneva: World Health Organization; 2021 (https://iris.who.int/bitstream/handle/10665/340749/9789240016514-eng.pdf).

Bibliography

Essential Programme on Immunization: school vaccination [website]. World Health Organization (https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/integration/school-vaccination).

Essential Programme on Immunization: supply chain tools [website]. World Health Organization (https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/supply-chain/supply-chain-tools).

[2] All references were accessed on 15 October 2025.

Annex 4.1 Checklist for microplanning

This checklist for microplanning summarizes the essential steps and outputs of the process. It can be used or adapted by district and health facility staff to create or update microplans.

- **Map of catchment area**
  - ☐ Existing maps already developed/used by local government and/or communities identified
  - ☐ All catchment areas delineated, including border areas, to include all communities
  - ☐ Areas of special populations (for example, high risk, marginalized, etc.) identified
  - ☐ Digital mapping/GIS applied, where useful, compared to maps created by health workers

  Outputs: District and health facility maps for all catchment areas updated

- **Eligible populations and prioritized geographic areas**
  - ☐ Population estimates for each target group are gathered from available sources and reviewed
  - ☐ Analysis of district immunization data, including reports from supervision, conducted and conclusions drawn
  - ☐ Analysis of health facility data conducted and conclusions drawn
  - ☐ Other data (community health worker data, epidemiological data, rapid convenience monitoring, etc.) reviewed and integrated into analysis

  Outputs: Analyses identifying all target groups, priority populations and geographic areas

- **Behavioural and social drivers of vaccination**
  - ☐ Childhood vaccination assessment(s) conducted with caregivers and findings summarized
  - ☐ Community discussions held and findings summarized

  Outputs: Data and insights on behavioural and social drivers of vaccination summarized for action

- **Service delivery mix**
  - ☐ Target populations reached by service delivery modality for previous year reviewed
  - ☐ Cold-chain requirements assessed
  - ☐ Supervision conducted in previous year reviewed

  Outputs: Analyses conducted to understand reach and performance of service delivery by modality, associated cold-chain requirements and supervision of staff

- **Immunization work plan**
  - ☐ Opportunities identified, including to reduce missed opportunities for vaccination
  - ☐ Drop-out strategy system defined
  - ☐ Catch-up vaccination approach determined
  - ☐ Integration considered and planned for
  - ☐ Solutions outlined

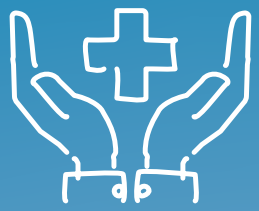
  Output: Workplan drafted, with solutions converted to activities

- **Immunization session plan**
  - ☐ Session location and frequency adjusted for upcoming period
  - ☐ Vaccine needs forecasted
  - ☐ District and health facility monthly stock planning, reporting and replenishment determined
  - ☐ Next update of microplan identified

  Outputs: Updated immunization session plan and stock forecast/replenishment plan

MODULE 5

Managing an immunization session



About this module

This module describes the tasks health workers (vaccinators, community health workers, logistician, etc.) need to perform to ensure that an immunization session meets the highest standards of quality.

The first section describes the preparation required at the health centre and at the immunization site before the individuals eligible for vaccinations arrive.

The next section discusses the communication strategies that should be implemented with caregivers and other community members during the session.

The module then proceeds with an assessment of eligibility, the correct technique for administering vaccines and instructions for closing the immunization session and recording data. Emphasis is placed on vaccinating all those who are eligible, reducing missed opportunities for vaccination and providing catch-up vaccination where needed.

The module concludes with a checklist that can serve as a reminder of safe vaccination procedures before, during and after the immunization sessions. While the examples focus mainly on childhood immunization, life-course vaccination is encouraged, and the same principles can be applied to vaccination in older age groups.

Contents

1 Preparing for the session

Preparation for immunization sessions should follow the microplan that was developed for the immunization site (see Module 4). Good preparation for a session ensures smooth administration of the vaccines. Preparation includes ensuring adequate staffing and sufficient doses and immunization devices, setting up a welcoming and safe workspace, accessing the appropriate cold-chain equipment and so on. Such preparation begins well before the day of the session.

The same key steps should be followed to prepare for all immunization sessions, but the order of the steps may vary by vaccination site. For example, for outreach sessions, vaccines must be packed for transport at the health centre before the workplace is prepared at the remote site. In such cases, community staff and/or volunteers should set up the outreach vaccination site as much as possible before the health workers arrive.

1.1 Plan the immunization session

Each health centre should have a plan showing where and when immunizations will be given. Depending on the plan, immunization sessions may be held daily, weekly, every two weeks, monthly or quarterly at fixed and/or outreach sites. The frequency of the sessions depends on the size of the community being served, the workload for staff, seasonal barriers and the resources available, as described in Module 4, section 7. Also, in some health facilities, immunization services are provided as part of the primary health care package rather than as a separate activity. In such cases, ways to integrate these services should be considered at the planning phase.

Health centre staff should make efforts to get to know the community and learn how to best organize sessions, including choosing suitable days and hours and tracking those who are due and overdue for immunization. Place signs at the site in advance of the session to let people know when immunizations will be available.

1.2 Prepare the workspace

Careful preparation and a positive, welcoming manner help ensure a safe and productive immunization session. Setting up a safe immunization site involves planning flow of vaccine recipients to prevent crowding, to ensure that those coming to the health centre are properly serviced and to reduce the risk of accidental needlestick injury to the health worker or members of the community. The arrangement of the immunization space will depend on whether the session is being held in a fixed or outreach site, and whether immunization is part of other services being provided at the same time and place (for example, nutrition screening, antenatal care and/or health education).

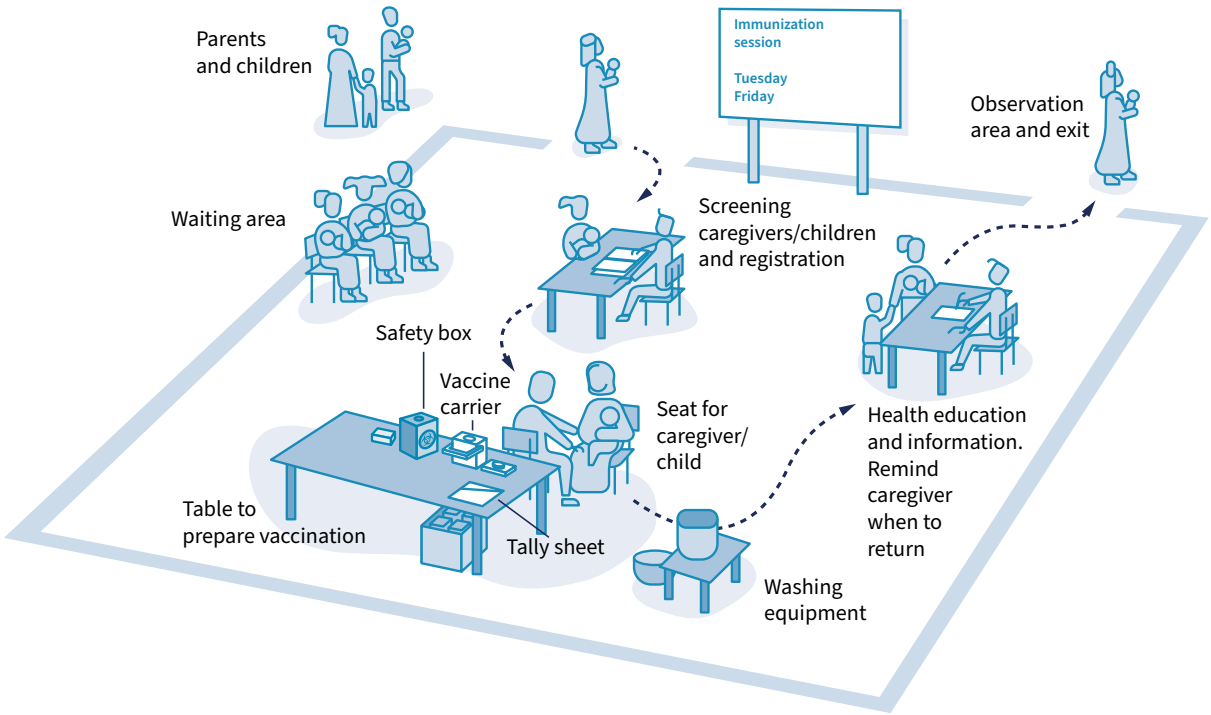
Fig. 5.1 illustrates the basic requirements for a fixed or outreach site. The ideal site will be:

- easily accessible to the target communities and identified with an "Immunization Clinic" sign;
- located in the same place each time;
- operational during the same time slots each week;
- in a clean, well-lit and well-ventilated area, out of the sun, rain and dust, close to water, sanitation and hygiene (WASH) facilities;
- near a sheltered/shaded area where those needing vaccination can wait;
- large enough to provide space to have separate stations for individual registration and assessment, immunization, private screening and health education;
- quiet enough to allow health workers to interact with the vaccine recipients and caregivers.

Fixed session sites should be close to the outpatient waiting room or registration area, to enable those coming to the health centre for other health reasons to be screened and vaccinated during the same visit (if eligible).

Whenever possible, a separate observation room or space should be available for those who have just been vaccinated in order to monitor for potential adverse events following immunization (AEFI). If possible, a room with two doors should be used, to facilitate better flow.

Fig. 5.1 Sample floor plan for flow during immunization session



1.3 Prepare vaccination equipment

Review the list of vaccines, injection materials and other required materials before all sessions. Annex 5.1 of this module includes a sample checklist of items to be confirmed before the immunization session.

In addition to vaccines and injection materials, a basic list of supplementary items includes:

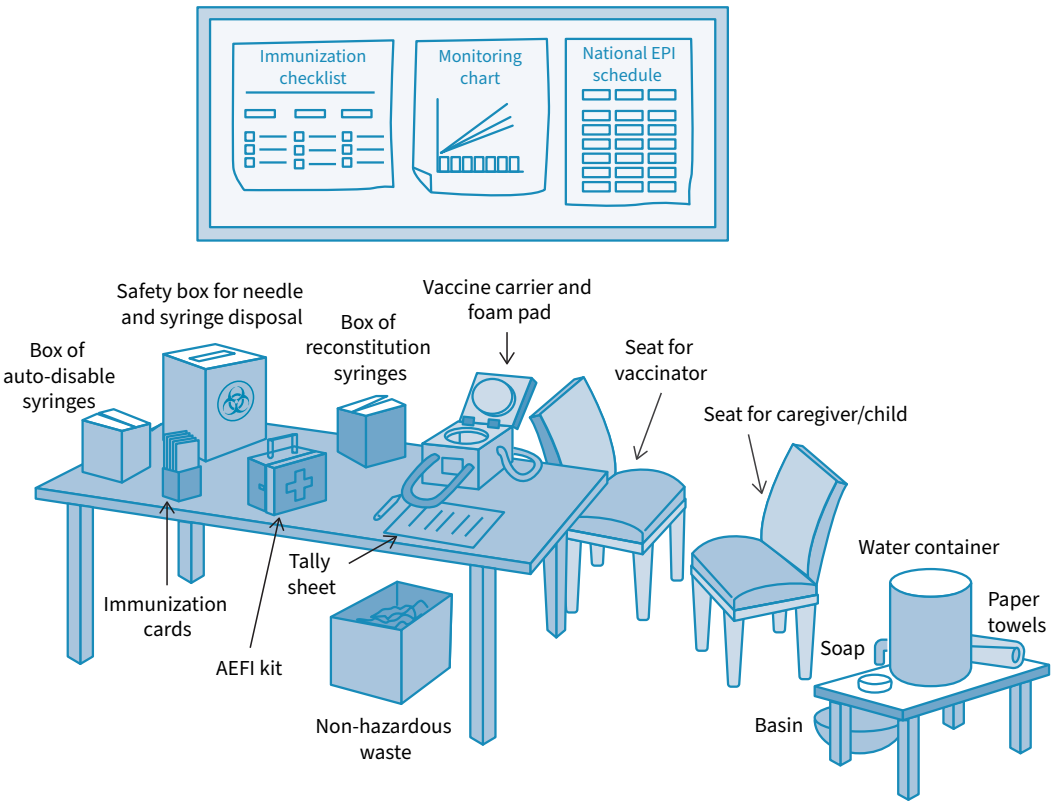
- an AEFI kit;
- a water container, basin, soap and towel for hand washing and drying, and/or hand sanitizer;
- a metal filer to open ampoules, if needed;
- an immunization register;
- new immunization/health cards;
- immunization tally sheets;
- cotton wool;
- a container for waste that cannot be discarded into a safety box;
- paper, pencils and pens;
- laptops or tablets (if applicable);
- table(s);
- stools and/or chairs.

Plan the layout of the immunization workspace so that:

- there are separate tables for immunization and other health services, if these are taking place at the same time;
- at any given time, only the one individual to be vaccinated, or only one child with a caregiver, is near the immunization workspace;
- the health worker is positioned between the vaccine recipient and all needles and other sharp objects;
- the safety box is close enough to the health worker so they can dispose of used needles without setting them down or moving around with them. At busy sites, each health worker giving injections should have a separate safety box;
- the hand-washing equipment or sanitation supply is next to the immunization table. Health workers must wash/sanitize their hands prior to giving the first immunization, after coming in contact with dirt or blood or when dealing with sick individuals;
- all tools needed for recording and reporting (cards, tally sheets, etc.) are on the table.

See Fig. 5.2 for an example of the layout of an immunization station.

Fig. 5.2 Sample arrangement of an immunization station



1.4 Prepare the coolant-packs

Before taking out the necessary number of vaccine doses from the refrigerator, make sure the coolant-packs are prepared properly, are in sufficient quantity and are appropriate for the type and size of the vaccine carrier. The objective is to keep the vaccine and diluent at +2 °C to +8 °C throughout the session. Therefore, the coolant-packs should be prepared according to the type of vaccine carrier used and the climate zone where the session is being held (see Module 2, *The vaccine cold chain*). Include an electronic freeze monitor in non-freeze-preventive vaccine carriers to monitor for freezing of vaccines.

1.5 Pack all required vaccines and safe injection supplies

For sessions at a health facility (that is, a fixed vaccination site), take all required vaccines from the refrigerator before the start of the session to reduce the number of times the refrigerator is opened.

For outreach sessions, place enough vaccine in a cold box or vaccine carrier to ensure that all individuals eligible for vaccination on that day receive the required doses, since a refrigerator will not be nearby during the session. Add extra vaccine to meet unexpectedly high demand at the session. For example, an extra 10% can be added to the estimated need. Ideally, the quantity of each type of vaccine should be calculated from a list of children and adults who are due and overdue in the outreach area. When such lists are not available, the quantity can be estimated based on the demand from previous sessions, especially if demand has been consistent throughout sessions.

Ensure that an adequate number of auto-disable syringes and safety boxes are available. One auto-disable syringe is needed for each dose of injectable vaccine, and a buffer stock of 10% should be added. Separate calculations for two types of syringes, auto-disable and BCG auto-disable, are needed in most programmes. In addition, one reconstitution syringe and needle is required for each vial of vaccine that requires reconstitution. Ensure that an adequate number of safety boxes are available for the number of syringes used (see Module 3, section 4.1, for guidelines on the capacity of safety boxes).

1.6 Verify that vaccines can be used

Before opening the refrigerator, estimate the number of doses for each vaccine that are needed for the session. After opening the refrigerator, check the temperature and the freeze indicator inside the appliance (see Module 2, section 3). If the vaccines have been exposed to freezing, do the shake test on the freeze-sensitive vaccines, as described in Module 2, section 8.

Select vaccines from the refrigerator in the following order:

1. opened vials kept in the “use first” box in the refrigerator (if in agreement with national multi-dose vial policy (MDVP) (see Module 2, section 1.4 for WHO MDVP);
2. unopened vaccine vials that have been returned from outreach sessions or have been outside of the refrigerator and returned (usually also in the “use first” box);
3. vaccine vials with vaccine vial monitors (VVMs) that have started to change to a darker colour but are not past the discard point;
4. all other vaccines.

In general, vaccines should be organized in the refrigerator by expiry date, with those having the closest expiry date kept in front and used first.

When selecting vials from the refrigerator, check each vaccine and diluent vial ampoule and:

- use only vials/ampoules in good condition;
- discard vials/ampoules that are damaged and/or have no label;
- discard any vials/ampoules that have passed their expiry date;
- discard any vials/ampoules with VVMs past the discard point;
- do not use any vials/ampoules with fluid that has changed colour or contains particles. Seek the advice of a supervisor if any such vials/ampoules are found.

2 Communicating during vaccination sessions

Health workers play a crucial role in protecting communities from vaccine-preventable diseases (VPD). In addition to administering vaccines, they are considered the most trusted sources of health information in many settings. A health worker's interaction with the community significantly influences acceptance of health services, including willingness to be vaccinated.

Communicating with respect and courtesy is essential while delivering vaccination services. This section provides recommendations for health workers on the key content and the manner of communication during vaccination sessions.

2.1 Respectful communication

The following principles guide how health workers should approach conversations during vaccination sessions:

- **An open exchange rather than one-way communication:** While health workers are tasked with imparting health information, it is equally important for them to create opportunities for meaningful, two-way conversations by actively listening to and showing empathy for people's questions and concerns and responding with accurate information.
- **An opportunity to shape engagement towards better health:** Community members should feel empowered to make decisions about their health, rather than having decisions imposed on them. By guiding people with accurate and credible information through two-way communication, health workers can aid the decision-making process of community members and strengthen their intention to agree to a vaccine.
- **An important contribution to a positive service experience:** Respectful communication significantly influences the overall health service experience of community members. A positive experience encourages further uptake of immunization and other health services.

2.1.1 Essential skills and attitudes for respectful communication

Health workers should continuously improve on the following essential skills and attitudes in communicating with community members:

- **Active listening:** Patiently understand what is being said and felt, withhold the urge to instantly correct or pass judgment and check that you understand the question or concern before responding.

- **Being self-aware:** Be mindful of your reactions, including your tone of voice and body language, to avoid perceived disrespect or dismissal of concerns. Remain patient and kind, even when the beliefs and attitudes of community members differ from your own.
- **Communicating clearly:** Confidently discuss vaccines and the diseases they prevent in language that people in the community can easily understand (for example, plain speech in the local language/dialect).
- **Responding with empathy:** Show genuine concern for each individual's health and well-being.
- **Displaying cultural sensitivity:** Many social and cultural factors in a community can influence an individual's thoughts, feelings and actions in relation to vaccination. Recognize, respect and respond appropriately according to an individual's cultural background and beliefs while ensuring that your response is consistent with scientific evidence.
- **Integrating gender-responsive approaches:** Promote gender equality by using respectful communication free from gender-based stereotypes. Understand and address the different communication needs and satisfy the preferences of all genders, where possible. See section 2.3 of this module.

Health workers can organize short peer-to-peer learning sessions to practise the above skills and attitudes.

2.2 Communication strategies for the vaccination sessions

The way a health worker interacts with children, caregivers and other individuals at a vaccination session has a huge impact on how they respond.

2.2.1 A welcoming and affirming approach

- Greet all community members, including caregivers, in a friendly manner. Thank them for coming for their vaccination and for their patience if they had to wait. Affirm the importance of their decision to vaccinate. (See box below.)
- In simple language, provide information on the vaccines to be given, the diseases that the vaccines protect against and the route of administration. Use available instructional materials (such as a poster, chart or vaccination card). See Module 1, for information on the different VPD.
- If you notice that the individual has missed or is late for any doses, respectfully explore the reasons for the missed dose and gently explain the importance of immunizing on schedule. Be sure to approach the conversation in a non-judgmental and non-stigmatizing manner.
- As applicable, ask if there are any contraindications to the vaccine or vaccines to be administered (see section 3.2 of this module).

Example of how to greet a community member who has come for vaccination

"Thank you for coming for baby Emma's vaccination. You've made the right choice in ensuring she remains healthy. She's due for her second dose of measles vaccine today. This vaccine is important to protect her from measles, a serious disease."

2.2.2 Sharing information on the safety of vaccines

Below are some messages that you may wish to use when explaining the safety of vaccines and potential adverse events. Note that not all messages will be relevant (for example, messages on multiple injections will not be necessary if a child is receiving a single-dose vaccine during the visit).

- Vaccines have been tested to be safe and effective. Health authorities monitor vaccines to ensure they continue to be so.
- Like any medicine, vaccines can have side-effects. These are usually minor and of a short duration, such as a sore arm or a mild fever. These are normal and should be expected as the body builds immunity.
- Serious side-effects are possible but extremely rare. A person is far more likely to be seriously harmed by the disease than by the vaccine that prevents it.
- Injections may cause temporary discomfort, which is normal. Caregivers can soothe children by:
  - providing extra comfort by giving hugs or letting the child play with a toy;
  - giving extra fluids, including breast milk, if a fever develops;
  - applying a cold compress to the injection site to ease local reactions;
  - giving them paracetamol (vaccinators must specify the appropriate dose and timing for each child).
- There are some possible minor reactions related to specific vaccines:
  - DTP vaccines may leave some children with irritability, loss of appetite and malaise.
  - BCG vaccines leave a lump at the injection site for several weeks. The lump ulcerates and leaves a scar. If the injection site becomes infected, caregivers should see a health worker.
  - The measles vaccine can cause mild fever, rash and conjunctivitis, up to 6–12 days after vaccination.

  If a child's condition worsens or the reaction continues for more than 1–2 days, the caregiver should bring the child to the health centre.
- It is safe and effective to give several vaccines at the same time. This offers good protection and avoids multiple visits to the health facility.
- Even if a child receives rotavirus and pneumococcal vaccines, they may still develop diarrhoea or pneumonia from other causes. Caregivers should be aware of treatment methods and danger signs of dehydration.

2.2.3 Addressing questions and concerns

Prior to the vaccination, invite questions and concerns and respond to them respectfully.

- Ask an open-ended question to invite questions or concerns (see the box below).
- Actively listen to and understand questions or concerns. When needed, ask further questions to elicit more information before responding.
- Start your response by acknowledging the questions, concerns and experiences of the caregiver or vaccine recipient (see the box below). If you are unsure of what response to make, refer the question to your colleague or supervisor and tell the caregiver/vaccine recipient that you will get back to them as soon as possible.
- Confirm that you have adequately responded to all the concerns of the individual and ask if they have any further questions or if any clarification is needed.
- Repeat your recommendation for timely vaccination.

> "How do you feel about the information I shared?"
>
> "What questions do you have about what we just discussed?"
>
> "I understand you're concerned about the side-effects of the vaccine. Having these questions is normal. We want what is safe for baby Emma."

If the individual agrees, proceed with the vaccination. If the vaccination is being given to a child, explain the most appropriate positioning to the caregiver (see section 4.5 of this module).

2.2.4 Key points to emphasize after the vaccination

After the vaccination, share the following key points with the caregiver or vaccine recipient.

- **Where and when to return for the next dose:** Explain that the immunization schedule must be followed to ensure full protection. Use the immunization card as an instructional guide. Explain to the caregiver that if their child cannot come on the return date, the next vaccination can be given at another location or on another date close to the due date. Congratulate the caretaker if their child has completed a series.
- **Keeping the immunization card:** Remind the caregiver to keep the immunization card and to bring it to the next vaccination appointment.
- **Referrals for other services given during immunization sessions, as per national policy:** Such services may include the tetanus, diphtheria and acellular pertussis (Tdap) booster vaccine for pregnant women.
- **Upcoming vaccination campaigns:** If any such campaigns are planned in the coming months, inform the community member about the date and location and what vaccine or vaccines will be given.
- **Other measures to help keep the community safe and healthy:** Additional specific information may be useful, depending on the context. In general, encourage handwashing; for mothers, promote exclusive breastfeeding for the first six months of life and appropriate complementary feeding after the first six months.

2.2.5 Encourage questions and feedback

- Ask if the caregiver or vaccine recipient has any further questions and answer them respectfully. Provide them with contact information (for yourself or another health worker or the medical officer) for further inquiries and offer other supporting materials if available.
- Invite community members to give feedback on the service, using available tools. Module 7, section 2 explains the importance of feedback and provides some examples of how to collect it.
- Thank the vaccine recipient or caregiver again for deciding to get vaccinated or to vaccine their child, emphasizing the importance of vaccination for their own or their child's health and the health of the community.

2.3 Gender-responsive approaches

Gender inequality and gender-related barriers to immunization can prevent both men and women from accessing vaccinations, although these barriers can affect men and women in different ways. In many contexts, women face challenges at home because of gender inequality, and they may have limited decision-making power and restricted access to resources. Since women are often the primary caregivers for children, these barriers can negatively impact their ability to seek timely immunization services for their children.

The perceived quality of care and the acceptability and accessibility of health services can influence the utilization of immunization services, especially for women. Health workers who engage in disrespectful and patronizing communication and display discriminatory attitudes help reinforce existing gender stereotypes and traditional norms, leading to negative experiences for female community members, including caregivers.

Gender-related barriers can also affect men. For instance, due to traditional gender roles, health services may be unwelcoming to men who bring their children for vaccinations, thus reinforcing negative stereotypes and deepening traditional roles.

To help ensure that all community members are vaccinated and receive a high-quality immunization experience, health staff should consider and attempt to address potential gender barriers that may discourage caregivers and other community members from getting vaccinations for themselves and/or their children. For more information and concrete examples of how gender impacts immunization, see *Why gender matters: immunization agenda 2030*.

3 Assessing eligibility

Health workers need to have a good understanding of their national immunization schedules to ensure that everyone benefits from vaccination.

Health workers should make efforts to vaccinate children, adolescents and adults according to the national schedule. However, if vaccinations are delayed for any reason, most vaccines are safe and effective to administer with no upper age limit. It is almost always better to vaccinate late rather than never. Nonetheless, there are a small number of vaccines for which upper age limits do apply.

Every health contact, whether in a fixed vaccination site or during an outreach visit (including school-based sessions), should be used as an opportunity to review the immunization status of each eligible person and offer catch-up vaccine doses that have been missed or delayed. Children visiting a health centre or outreach/mobile sessions for other services should be screened for vaccination. If eligible, they should be vaccinated or referred for vaccination, as per the national schedule.

3.1 How to assess eligibility for immunization

Whenever an individual (child, adolescent or adult) visits a health facility, they should have their immunization status reviewed according to their current age and then should be given all outstanding vaccines, as appropriate. If there is no immunization session that day, a vaccination appointment should be made for the earliest possible time.

The steps below should be followed at any health care visit as well as at any immunization session. While the steps refer to a child visiting a health centre, they can be adapted for adolescents or adults.

1. Verify the child's age on the immunization card.
    - If the caretaker does not have or bring an immunization card, check if a record for the child exists in your register. If it does not, ask the caregiver the child's age. If the immunization card does not exist, do not criticize the caregiver, as this may deter them from coming back for future doses.
    - If the caregiver does not know the child's age, estimate it by asking when the child was born. Use a notable community event (such as a certain season or celebration) as a reference point. A local events calendar can help with this. The caregiver's peers may also be able to help in ascertaining a child's age, as the child in question may have been born around the same time as their children.
2. Verify which vaccines the child has received by reviewing the immunization card.
    - If the child does not have an immunization card but has come to the health facility before, check the register and provide a new card. Fill in the information from the register and include the last dose administered.

- If the child is new to the health facility, ask the caregiver some questions to prompt recall of each vaccine the child should have received. Fill out a new home-based record.
- Check for a BCG scar (usually on the left arm/shoulder) if there is no record or recall.
- If the child's immunization status is in doubt and there are no known contraindications (see section 3.2 of this module), you can proceed with the vaccination. It is safe to revaccinate individuals who have been previously vaccinated. Proceed to step 3, regardless of whether you have seen a card, recall or BCG scar.

3. Verify all vaccines the child needs during this session to allow for efficient preparation for their vaccination visit.
   Follow the national schedule, while remembering these general points:
   - If the child is eligible for more than one type of vaccine, it is safe to give the vaccines at different injection sites during the same session.
   - Never give more than one dose of the same vaccine at one time.
   - If a vaccine is overdue, do not restart the schedule. Simply provide the next dose in the series.
   - If there is a delay in starting the immunization schedule, give the vaccine(s) and make an appointment for the next dose at the interval recommended in the national schedule.

3.2 Assess possible contraindications

For the first dose of a vaccine, assess the general status of the child to rule out signs of serious illness. For a subsequent dose in a vaccine series, ask the caregiver whether any adverse events, including anaphylaxis, occurred following the previous dose(s).

All children should be immunized, with a few exceptions.

- Do not give a subsequent dose of a vaccine to a child with a history of anaphylaxis (a severe hypersensitivity reaction) to the vaccine or to an ingredient contained in a vaccine.
- Do not give a vaccine if the caregiver still objects to immunization of a sick child even after you have explained that children with mild fever can be vaccinated. Schedule an appointment and ask the caregiver to come back when the child is well.

Refer to Table 5.1 for guidance on vaccinating HIV-infected children.

Table 5.1 Recommendations for immunization of HIV-infected children

Vaccine	Asymptomatic HIV infection/HIV+	Symptomatic HIV infection/AIDS CD4 cell count less than 200cells/mm³ unless specified otherwise
IPV, pneumococcal, DTP-containing, hepatitis B-containing, Japanese encephalitis, tetanus toxoid, meningococcal, influenza (inactivated)	Vaccinate	Vaccinate
Rotavirus	Vaccinate	Do not vaccinate
OPV	Vaccinate	Do not vaccinate children with symptomatic HIV infection or low CD4 T-cell values (<15% (or <750 for infants aged <12 months; <500 for those aged 1–5 years; and <200 for those aged ≥6 years)
BCG	Vaccinate, if HIV-infected individuals, including children, are receiving antiretroviral therapy (ART), are clinically well and immunologically stable (CD4 >25% for children aged <5 years or CD4 count ≥200 if aged >5 years)	Do not vaccinate
Measles- and/or mumps- and/or rubella-containing	Vaccinate	Do not vaccinate An additional dose of MCV should be administered when immune reconstitution has been achieved, such as when the CD4 cell percentage reaches 20–25%; where CD4 cell count monitoring is not available, children should receive an additional dose of MCV 6–12 months after initiation of ART
Yellow fever	Vaccinate	Do not vaccinate (pending further studies)

3.2.1 Immunizing sick children

Often health workers do not like vaccinating a child who is sick. Children can have many illnesses, and delaying immunization puts them at risk of vaccine-preventable diseases when they could receive the protection safely. Use the following guidelines when deciding whether to vaccinate a sick child.

- For children with a minor illness and/or a fever below 38.5 °C, vaccinate as usual. Such illnesses include respiratory tract infections, diarrhoea and similar mild infections without significant fever.
- For very ill children who need to go to hospital, or children who have a very high fever, vaccinate if possible. A senior health worker may have to decide in each case, but children do need protection from diseases that could be transmissible in hospital (for example, measles).
- For malnourished children, vaccinate as usual. Malnourished children develop immunity after vaccination. If they do not receive vaccines, they are more likely than well-nourished children to die from VPD.

3.2.2 Immunizing children with other health issues

The following are *not* contraindications:

- allergies or asthma, with the exception of a known allergy to any ingredient contained in a vaccine;
- ongoing treatment with antibiotics;
- family history of adverse events following immunization;
- prematurity or low birth weight (follow the same schedule as that for a full-term infant);
- any disabilities;
- history of jaundice at birth;
- recent or upcoming surgery;
- chronic noncommunicable diseases of the heart, lung, kidney or liver;
- stable neurological conditions, such as cerebral palsy or Down syndrome;
- family history of convulsions, seizures or fits.

Children with these conditions or in these circumstances should still be immunized.

3.3 Catch-up vaccination

"Catch-up vaccination" refers to the action of vaccinating an individual who, for whatever reason (for example, delays, stockouts, barriers to access, hesitancy, service interruptions, etc.), has not received doses of vaccines for which they are eligible according to the national immunization schedule. Catch-up vaccination aims to complete an individual's immunization series as quickly and safely as possible, thereby providing immunity and preventing outbreaks.

Refer to your national catch-up policy and adhere to the following general principles. For further information on general principles, see WHO Table 3: Recommendations for interrupted or delayed immunization.

- Most vaccines are safe and effective to administer with no upper age limit. While timely vaccination should always be the aim, it is almost always better to vaccinate late rather than never. There are a small number of vaccines for which upper age limits do apply but, for most VPD, providing vaccines late will still result in protection against morbidity and mortality.
- If the delay between doses exceeds the minimum delay, in most cases it is not necessary to restart the vaccine series (except for the vaccines against typhoid and cholera). Simply provide the next needed dose in the series.
- If there has been a delay in starting primary vaccination, immunize the child. Calculate the appropriate timing for subsequent doses, instruct the caregiver when to return to complete the series and write all information in the child's immunization card.

No one should miss out on the right to receive the protection that vaccines offer simply because they were unable to access services within the recommended timeframe.

3.4 Reducing missed opportunities for vaccination *(1, 2, 3)*

A "missed opportunity for vaccination" refers to any contact with health services by a person who is eligible for vaccination (for example, is unvaccinated or partially vaccinated and is free of contraindications to vaccination) that does not result in that person receiving one or more of the vaccine doses for which they are eligible. Key strategies to reduce missed opportunities for vaccination include the following.

- Routine screening for immunization status should be done for all children who visit health services for any reason. Ideally, eligible children should be immunized immediately, but, at a minimum, they should be given an appointment for immunization for the earliest possible date.
- Vaccine wastage should not be a reason not to vaccinate a child. A multi-dose vaccine vial should be opened, even if there are not enough vaccine recipients present to use all its contents.
- All health workers should be in the habit of asking for and reviewing immunization cards for each child at routine and curative visits, regardless of the reason for seeing the child. If the vaccination card or home-based record is not available, the health worker should use other means (such as registers, information from the caregiver) to check the vaccination status of the child and then provide the appropriate vaccines for their age, including any catch-up vaccinations.
- Health care providers working in other areas of the health service should be trained to support screening and referral for vaccination. This can include screening children and the implementation of integrated management of childhood illnesses-based algorithms.

4 Vaccine administration

Immunization is a routine procedure for health workers but can be frightening for children and others attending the session. There are many things a health worker can do to make an immunization experience a safe and positive one. This section focuses on techniques for injection preparation and administration and on the comfortable and safe positioning of children and other vaccination recipients.

4.1 Preparing for the vaccination session

First, use an aseptic technique to prepare vaccines.

- Start with handwashing: use soap and water and dry your hands thoroughly. An alternative is to use hand sanitizer.
- Work on a clean/disinfected table.
- Set up the table as discussed in section 1 of this module.

Prepare vaccines individually for each recipient; do not prefill syringes. Injectable vaccines can be ready to use or can require reconstitution (mixing) with diluent (see section 4.2 of this module). Whenever possible, prepare the vaccine away from the caregiver or vaccine recipient. Be aware that injection materials may cause anxiety. If it is not possible to prepare the vaccine in a separate area, turn away slightly to shield the recipient and caregiver from the preparation. Try to talk to the caregiver or vaccine recipient while preparing injections in order to reassure them.

4.2 Reconstituting vaccines

Common vaccines that need to be mixed with diluent before use include BCG and vaccines against yellow fever, measles, MR and MMR, and malaria. The correct diluent must be used (see box).

Points to remember about diluents

- Always use diluent from the same manufacturer as the vaccine.
- Diluent is not interchangeable: different vaccines have different diluents. Administering a vaccine with the wrong diluent can lead to serious adverse events, including death.
- During the session, the vaccine and diluent should ideally be kept in the same carrier and at the same temperature of +2 °C to +8 °C.
- Vaccines should be reconstituted with diluent immediately before use.
- Unused reconstituted vaccine must be handled according to national MDVP. (WHO MDVP is outlined in Module 2, section 1.4.)

The steps for reconstitution are as follows.

1. For vials with VVMs, double check that the vaccine and diluent can be used.
2. Double check each vial/ampoule to make sure it is not past its expiry date and read the label carefully.
3. If using a vial with a metal cap, use a file to lift the pre-cut centre of the cap and bend it back. If using a vial with a plastic cap, flip the cap off with your thumb or slowly twist it, depending on the specific instructions for the type of vial.
4. If using a non-scored glass ampoule, hold it between your thumb and middle finger, supporting the top with the index finger. Scratch the ampoule neck with a file, and then gently break off the top, taking care to avoid injury from the sharp glass. If you injure yourself, discard the ampoule, since the contents may have been contaminated. Cover your wound before opening a new ampoule.

WHO recommends syringes with reuse prevention features for the reconstitution of vaccines (see Module 3, section 1, for a discussion of recommended vaccination devices).

5. Using a reuse prevention reconstitution syringe, insert the needle into the vial or ampoule containing the diluent and draw out all the diluent.
6. Insert the needle of the reconstitution syringe into the vaccine vial and empty all the diluent; depress the plunger slowly to avoid frothing inside the vial.
7. Draw the fluid slowly and gently in and out of the vial several times or gently swirl the vial to mix the diluent and vaccine; take care not to touch the rubber membrane or opening of the vial.
8. Remove the reconstitution needle and syringe from the vial and discard them in the safety box.
9. Put the reconstituted vaccine vial on the foam pad of a vaccine carrier, along with any other open vaccine vials. Remember to write the time of reconstitution on the vaccine vial.

4.3 Giving multiple injections

Recent recommendations for new vaccines and catch-up dose schedules often mean giving two (or more) injections to a child during the same session. Giving multiple injections at the same time is more difficult than giving only one, but it is a skill that health workers need to acquire. With practice, giving injections quickly and safely with little distress to the vaccine recipient and caregiver will become routine. However, even the most experienced vaccinator should take time to review their injection technique and seek out refresher materials that might improve their skills.

The order in which vaccines are given can help make administering them easier. In general, the suggestion is to give oral vaccines first, while the child is still calm, and then follow with the injectable ones. Rotavirus vaccine should be given before polio since it has a larger volume, and it may be better to give it when the child is most calm.

It is safe to give multiple vaccine injections during one visit. Multiple injections during the same visit are better than spacing injections because they protect children, increase efficiency and lead to fewer visits to the health facility. Concerns about multiple injections can be addressed through reassurance, clear communication and pain-reduction techniques.

4.4 Techniques for reducing pain *(4)*

Managing pain does not decrease the efficacy of the vaccine. Not addressing pain at the time of vaccination may have a negative impact on health-related attitudes and behaviours and may lead to delays in or avoidance of future vaccinations. The following general measures that health worker can take to help minimize pain are recommended across all age groups.

- When interacting with vaccine recipients and caregivers, be calm and well informed. Use neutral language (such as “Here I go” rather than “Here comes the sting”) and avoid language that increases anxiety, promotes distrust or is falsely reassuring or dishonest (such as “It will only hurt for a second”).
- Ensure the proper positioning of the vaccine recipient, according to their age. For young children, instruct the caregiver how best to hold the child, depending on the vaccine site. Instruct older populations to sit upright, although provide the opportunity for those with a history of fainting to lie down.
- Do not aspirate the needle during intramuscular injections, as this may increase pain due to longer contact time and lateral movement of the needle.

4.4.1 Age-specific techniques for reducing pain

- For young children, the caregiver should be present throughout and after the vaccination procedure.
- Children younger than 3 years of age should be held by caregivers throughout the procedure. To help alleviate fear and distress, children around and over the age 3 can be seated on the caregiver’s lap.
- If culturally acceptable, infants should be breastfed during or shortly before the vaccination session. Where oral vaccines are being co-administered with injectable vaccines, it is best to proceed with the administration of the oral rotavirus vaccine, then the oral polio vaccine (if OPV is used), and then ask the caregiver to breastfeed the infant while you administer the injectable vaccines.
- For children under the age of 6 years, ask the caregiver to provide distractions to divert attention away from the pain to something more pleasant (such as toys, videos, music, conversation).
- For adolescents, distraction is not effective, and there are no additional evidence-based, age-specific recommendations available for this group beyond the general measures for all age groups. See section 4.11 of this module for a discussion of intramuscular injections for adolescents.
- For adults, distractions using breathing interventions (such as breath holding or slight coughing that does not lead to moving of the fixed arm) are recommended.

4.5 Positioning the child for vaccination

The positioning of the child for vaccination depends in part on the vaccination site. Countries often choose one injection site for each vaccine (for example, pneumococcal vaccine or PCV should always be given in the left thigh, and pentavalent always in the right thigh). Administering a particular type of vaccine in the same site for each child can help during follow-up (for example, if the card is lost and recall questions need to be asked, or if any adverse events occur).

In addition to the injection site, the choice of position will depend on the number of vaccines to be given, the age of the child and the materials available. The aim of positioning is to keep the child still and the caregiver and vaccinator comfortable. Table 5.2 shows different positions for vaccinating, along with the advantages and disadvantages of each. Prior to the immunization encounter, it can be useful to review the positions and picture your movements and those of the child and caregiver.

Check that the caregiver is willing to hold the child while the injection or injections are given. If the caregiver is unable or unwilling to hold the child, ask someone else to help.

4.6 Positioning the child for oral vaccine administration

The technique described here is based on the administration of one rotavirus vaccine and one OPV, but it applies to other oral vaccines as well.

1. Position: Have the caregiver use the cuddle position (with the child lying across the caregiver's lap with the head supported), with the child's head tilted slightly back (see Table 5.2).
2. Administration: Standing to one side of the child, open the child's mouth by squeezing the cheeks between your thumb and index finger, using gentle pressure (firm squeezing can cause distress).
   - For vaccines in tubes, angle the tube towards the inner cheek. Administer the entire contents by squeezing the tube several times.
   - For OPV, let two drops of vaccine fall from the dropper onto the tongue. Do not let the dropper touch the child.
3. Disposal: Discard the used oral vaccine tube into the appropriate waste container (see Module 3, section 4, on proper disposal practices).

Table 5.2 Vaccination positions

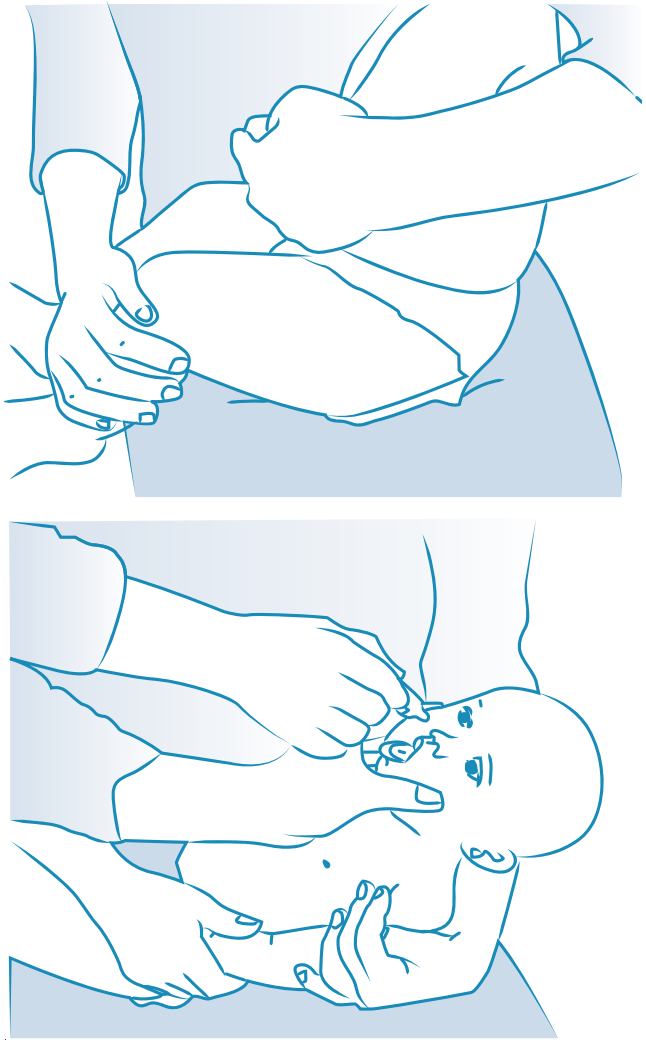
Child's position	Illustration	Directions for caregiver/ vaccinator	Advantages	Disadvantages
Cuddle position: semi-recumbent on caregiver's lap		Caregiver: • Sit on a chair holding the child sideways on your lap, with one of your arms behind the child's back. • Tuck the child's inside arm around your back or against your body. • Bring your arm around the child's back to hug their shoulders and upper body close to your body. • Tuck the child's legs between your own to secure them or hold them with your free arm. Vaccinator: • Position yourself to avoid strain while giving vaccines at the correct angle.	• Child's outside arm and legs are securely held by caregiver • Child comforted by close physical contact and eye contact with caregiver • Leg and arm injections possible without position change	• Delay between injections if two intramuscular injections are given because position change is required • Possibility that secure restraint may not occur after position change

Table 5.2 (continued)

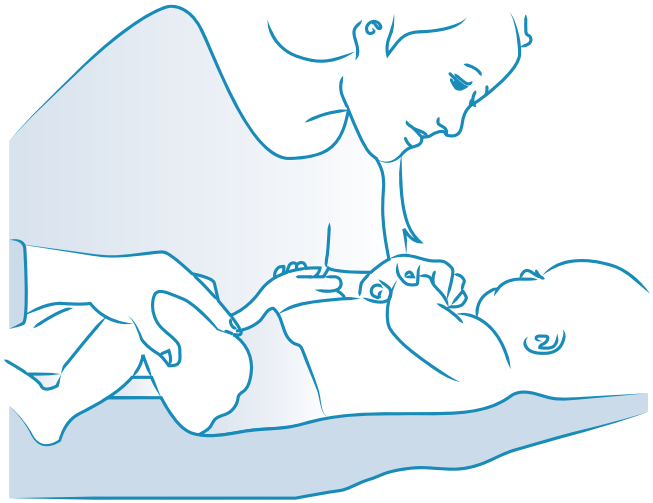
Child's position	Illustration	Directions for caregiver/ vaccinator	Advantages	Disadvantages
Bed position: lying on back on flat surface		Caregiver: • Lay the child, with both legs bare, on a bed or other flat surface. • Stand on one side of the bed and hold the child's hands and arms. Vaccinator: • Stand at the child's feet and use your non-injecting hand to gently cup the slightly bent knee of the leg to receive the vaccine.	• Child's arms held securely by caregiver • Child comforted by close physical contact and eye contact with caregiver • Injection in both legs possible without change in position of child	• Vaccinator responsible for restraint of child's legs

Table 5.2 (continued)

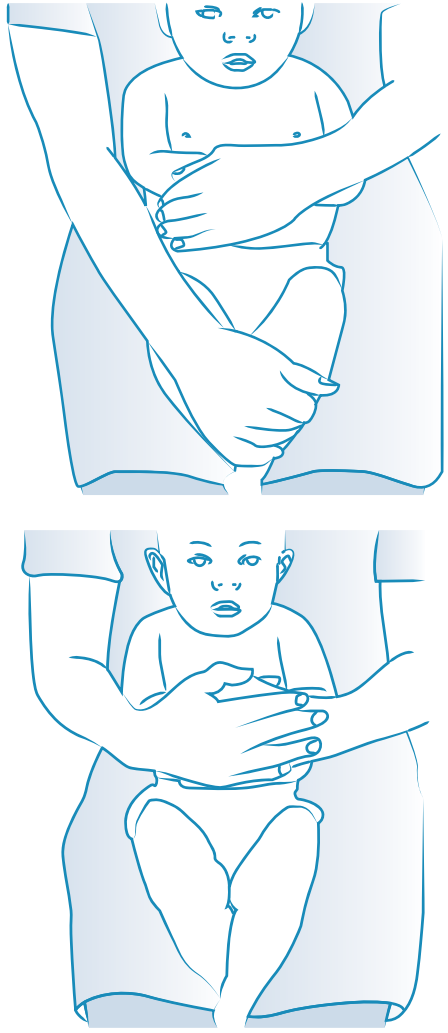
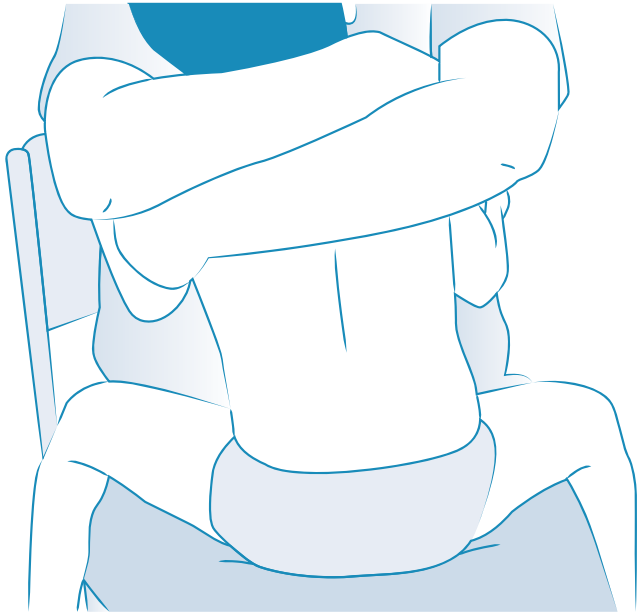
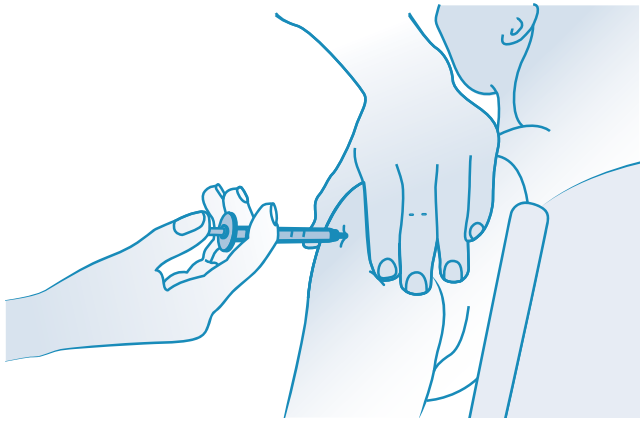
Child's position	Illustration	Directions for caregiver/ vaccinator	Advantages	Disadvantages
Upright position: sitting upright on caregiver's lap, facing straight outwards		Caregiver: • Sit on a chair, holding the sitting child on your lap, with the child facing straight outwards. • Rest the child's back against your chest. • Encircle the child's upper body and arms with one of your arms. Place your other arm across their knee, using your hand to hold their lower legs. Alternatively, use both of your arms to hug the child's upper body, and tuck the child's lower legs between your knees, with one of their feet behind the other. Vaccinator: • Stand on the side of the first injection site and at the level where the injection can be given at a 90-degree angle.	• Child's arms and legs held securely by caregiver • Multiple injections possible without change in position	• Security of leg restraint dependent on caregiver: if too tight, child's muscles tense, if too loose, child's leg may jerk out of restraint • No eye contact with caregiver

Table 5.2 (continued)

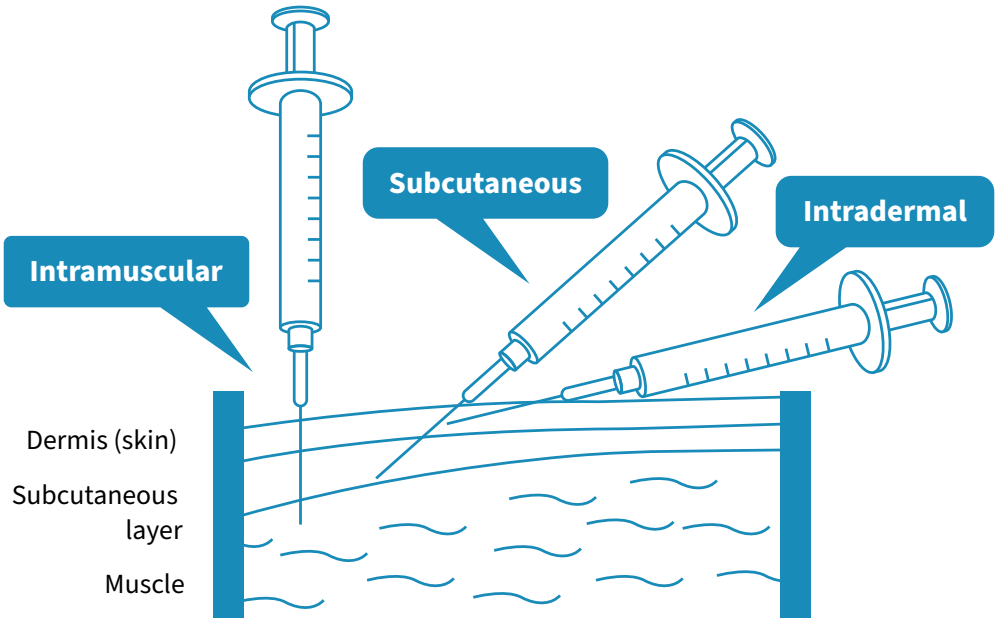
Child's position	Illustration	Directions for caregiver/ vaccinator	Advantages	Disadvantages
Straddle position: child >12 months of age vaccinated sitting upright on caregiver's lap, facing towards them with legs straddling over caregivers'		Caregiver: • Sit on a chair, holding the child facing you and sitting astride your lap. • Encircle the child's upper body and arms with your arms. • If necessary, use one of your arms to secure the child's leg. Vaccinator: • Stand on the side of the injection site.	• Child's arms tucked securely under caregiver's arms • Child comforted by close contact with caregiver • Multiple injections possible without change in position	• Child's thigh muscles may be tense • Vaccinator responsible for restraint of legs (unless caregiver helps)
Independent position: adolescent/adult to be vaccinated sitting on chair		• See section 4.11 of this module	• Good access to deltoid	• Restraint, if required, dependent on vaccinator

4.7 Types of injections

Vaccine injections can be intradermal, subcutaneous or intramuscular (see Fig. 5.3). Good injection practice includes administering all injectable vaccines with a single-use auto-disable syringe. To use auto-disable syringes correctly, remember that the plunger of an auto-disable syringe can go back and forth only once. To avoid disabling the syringe before the injection is complete:

- do not draw up air to inject into the vaccine vial when filling the auto-disable syringe
- do not aspirate the needle when you insert it for the injection.

Fig. 5.3 Needle positions for intradermal, subcutaneous and intramuscular injections



4.8 Intradermal injection

BCG is the main vaccine that is injected intradermally (into the layers of the skin) for slow absorption. It is usually given in the left upper arm. To measure and inject the very small dose (0.05 mL) accurately, a special syringe and needle are used.

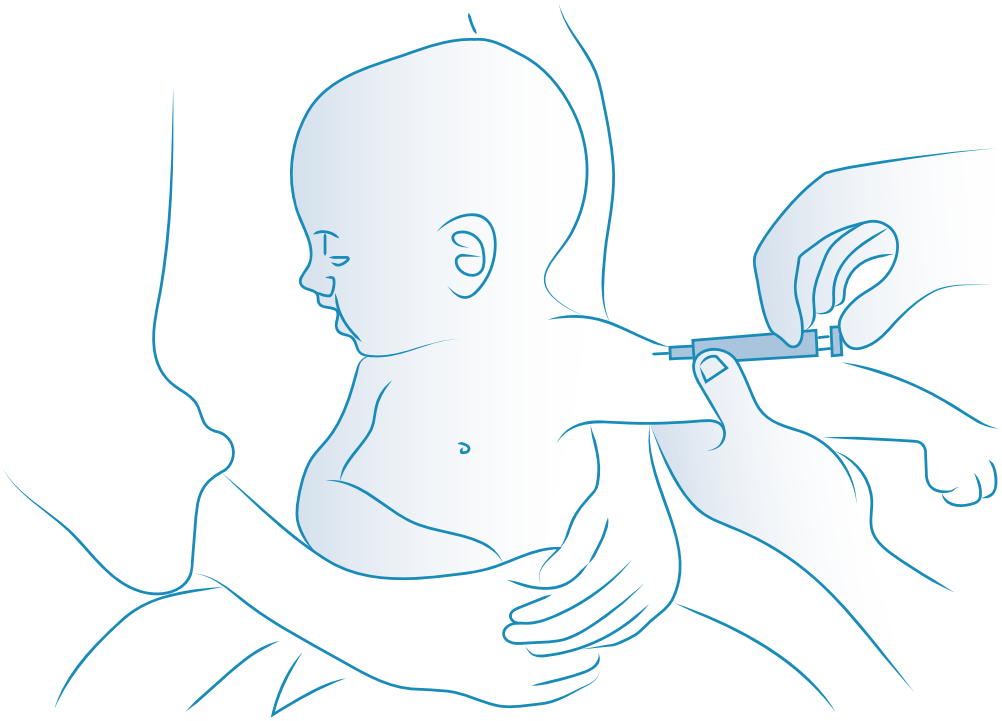
4.8.1 How to give BCG intradermally

1. Position: Have the caregiver use the cuddle position (with the child lying across the caregiver's lap with the head supported) (see Table 5.2).
2. Administration (see Fig. 5.4):
   - Hold the syringe barrel with fingers and thumb on the sides of the barrel and with the bevel (hole) of the needle facing upwards.
   - Lay the syringe and needle almost flat along the child's skin.
   - Insert the tip of the needle under the surface of the skin just past the bevel.

- Keep the needle close to the skin at the same angle as you inserted it.
- Place your other thumb on the lower end of the syringe near the needle to hold the needle in position, but do not touch the needle.
- Hold the plunger end of the syringe between the index and middle fingers. Press the plunger in slowly with the thumb. If you feel no resistance to the plunger, you are not in the right place and should reposition the needle.
- A pale, flat-topped swelling with small pits like an orange peel should appear on the skin.
- Remove the needle smoothly at the same angle as it went in.
- The caregiver may hold a clean swab gently over the site if it is bleeding. Do not rub or massage the area.
- Soothe the child.

3. Disposal: Discard the needle and syringe immediately into the safety box.

Fig. 5.4 BCG intradermal injection



When an intradermal injection is given correctly, the syringe plunger is hard to push. If the plunger goes in too easily, the injection may be too deep. Stop injecting immediately, correct the position of the needle, and give the remainder of the dose, but no more. If the whole dose has already gone in, count the child as having received a dose of vaccine, even though it was given subcutaneously rather than intradermally. Do not repeat the dose.

The risk of AEFI from an intradermal injection, such as abscesses or enlarged glands, is greater if the vaccine is given incorrectly, so the technique is very important. It is better to ask for help from a supervisor or other colleague than to give BCG incorrectly.

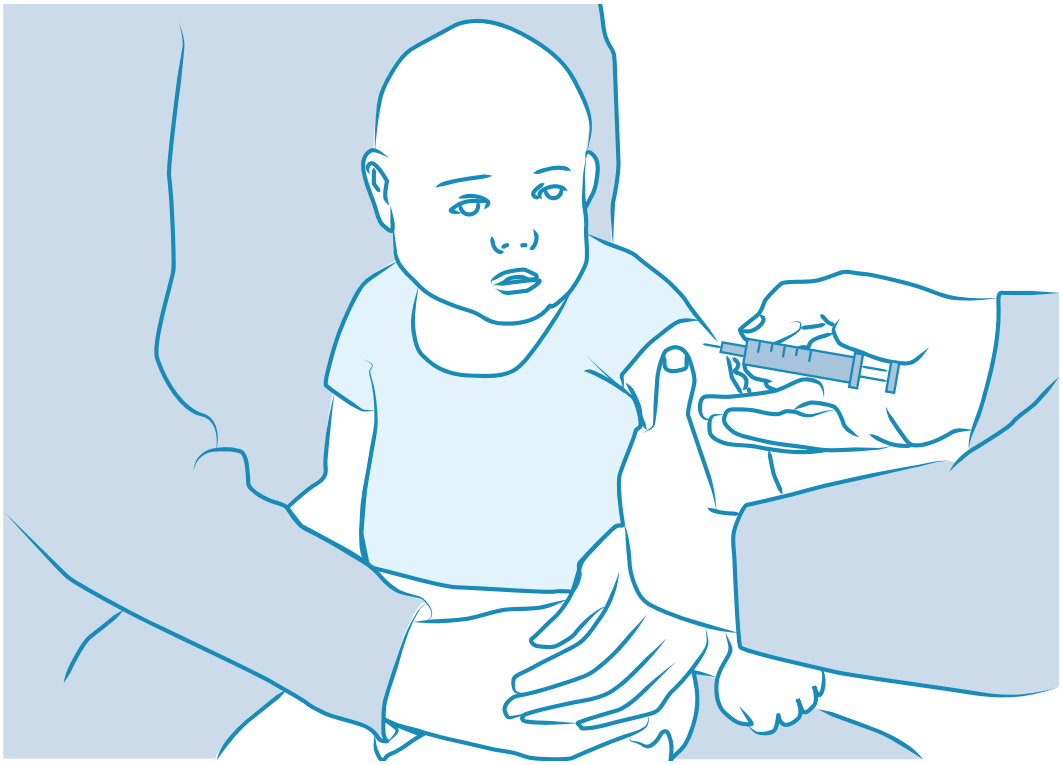
4.9 Subcutaneous injection in the upper arm

A subcutaneous injection is given into the layer below the skin on the upper arm. The exact injection site (right arm or left arm) may be specified in your country; be sure to check and always use the side specified.

4.9.1 How to give a subcutaneous injection

1. Position: The position depends on the age of the child, the number of vaccinations to be given and what is easiest and most convenient for the vaccinator.
2. Administration (see Fig. 5.5):
   - Hold the syringe barrel with fingers and thumb on the sides of the barrel and with the bevel (hole) of the needle facing upwards.
   - Pinching the skin and flesh on the child's upper arm with your fingers, quickly push the needle into the grasped skin; the needle should point towards the shoulder at a 45-degree angle.
   - Depress the plunger smoothly, taking care not to move the needle under the skin.
   - Pull the needle out quickly and smoothly at the same angle as it went in.
   - The caregiver may hold a clean swab gently over the site if it is bleeding. Do not rub or massage the area.
   - Soothe and distract the child.
3. Disposal: Discard the syringe and needle straight into the safety box.

Fig. 5.5 Subcutaneous injection



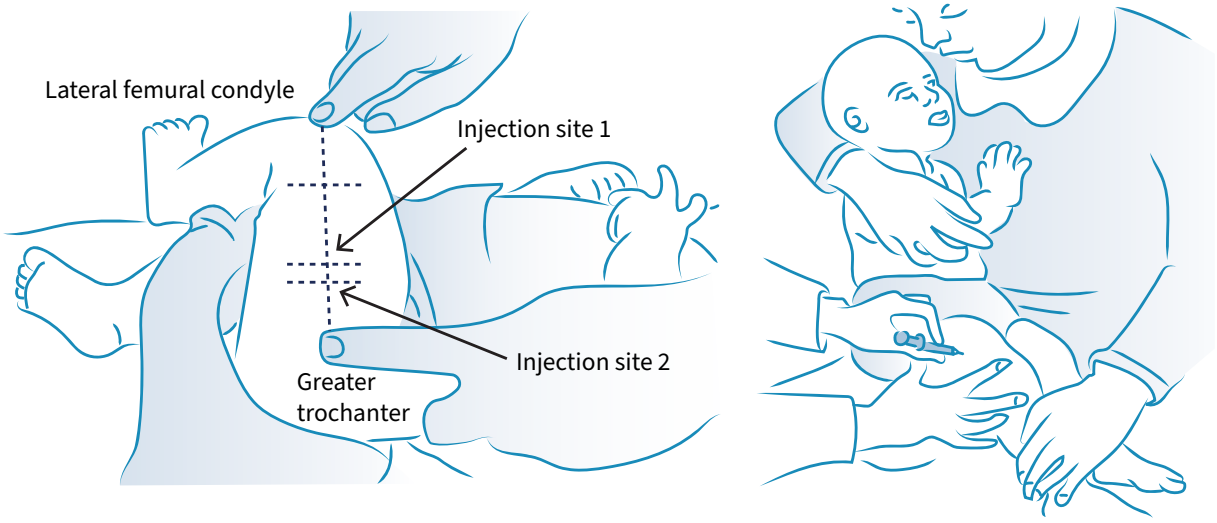
4.10 Intramuscular injection in children

In children younger than 15 months, the deltoid muscle of the upper arm is not a safe site for an intramuscular injection, as it is not developed enough to absorb the vaccine, and the radial nerve is close to the surface. As an alternative, use the muscle on the upper outer part of the thigh as the injection site. The deltoid muscle may be used in older children, adolescents and adults (see section 4.11 of this module).

4.10.1 How to give an intramuscular injection to a child

1. Position: The position depends on the age of the child, the number of vaccinations to be given and what is easiest and most convenient for the vaccinator.
2. Administration (see Fig. 5.6):
   - Hold the syringe barrel with fingers and thumb on the sides of the barrel and with the bevel (hole) of the needle facing upwards.
   - Gently stretch and support the skin on the upper, outer thigh with the other hand and quickly push the needle at a 90-degree angle down through the skin into the muscle.
   - Depress the plunger smoothly, taking care not to move the needle under the skin.
   - Pull the needle out quickly and smoothly at the same angle as it went in.
   - The caregiver may hold a clean swab gently over the site if it is bleeding. Do not rub or massage the area.
   - Soothe and distract the child.
3. Disposal: Discard the needle and syringe immediately into the safety box.

Fig. 5.6 Intramuscular injection sites in children



Source: New Zealand Ministry of Health handbook

4.11 Intramuscular injection in adolescents and adults

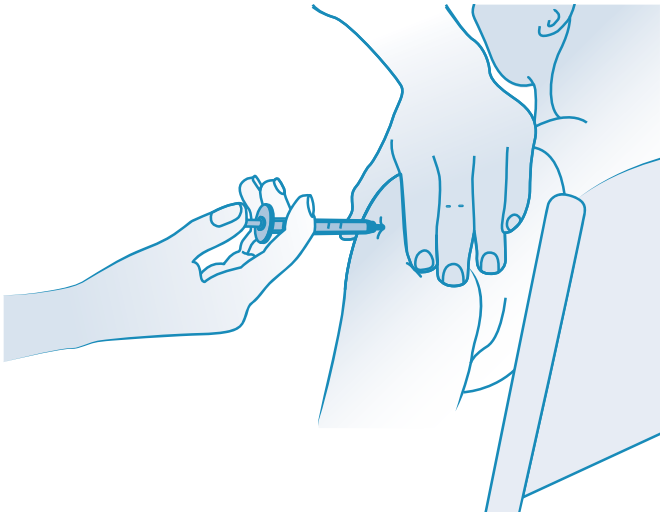
Unlike very young children, adolescents and adults may suffer the stress of anticipation prior to immunization. If they have had a previous bad experience with vaccination, their anxiety may be more severe. Observe the group waiting for immunization. Watch for signs of anxiety. If anyone is crying, pale or showing any other signs of distress, it is best to take them aside to be reassured, comforted and immunized first, to reduce the potential for anxiety to spread among the others waiting for their vaccination.

- Allow time for discussion about the vaccine and the disease(s) it protects against, if this is what the individual wants. Ask if they have any questions. Complete your own pre-immunization check.
- Unless it is against national policy, allow the person to choose in which arm they would like to receive the injection. Choice gives a feeling of having some control in what may be a frightening situation for them.
- Talk calmly and be patient. They might like to have a support person with them, or another vaccinator may be able to calm and distract them.
- Providing privacy for the administration of vaccines (for example, by setting up a screen or a curtain) will help support anxious individuals.
- Explain what you will say when you are about to give the injection and how it may feel.
- Use neutral words. Avoid language that increases anxiety, promotes distrust or is falsely reassuring or dishonest (for example, phrases such as “It will only hurt for a second”). It may help to liken the sensation to a minor sting or prickle. Use words such as “booster” rather than “needle” or “shot.”

4.11.1 Steps for intramuscular injections in adolescents and adults

1. Position: Most individuals will be comfortable sitting on a chair (see Table 5.2). Those who are prone to fainting may feel better lying down.
2. Administration (see Fig. 5.7):
   - With your palm resting on the shoulder of the vaccine recipient, hold the injection site gently between your thumb and forefinger. This touch is comforting to the person, and it will alert you of any potential movement. Talk about how important it is for them to remain still and then distract then by chatting about nonrelated subjects like their favourite school subject or hobby.
   - Holding the barrel of the syringe, use a quick, smooth action to insert the needle at a 90-degree angle all the way down through the skin to the muscle. Keep chatting while you do this. Distraction is an important aid to reduce injection discomfort.
   - Depress the plunger smoothly and steadily, taking care not to move the needle.
   - Pull the needle out, quickly and smoothly, at the same angle as it went in.
   - Do not rub the arm. A clean swab may be held over the site.
   - Provide comfort, reassurance and distraction.
3. Disposal: Discard the needle and syringe immediately into the safety box.

Fig. 5.7 Intramuscular injection sites in adults



Quick tip

For adolescents receiving the HPV vaccination, it may be beneficial if the vaccination is done privately, rather than in front of the whole group. Fear of pain, or instances of fainting, may affect the larger group. This can cause mass psychogenic reactions and a crisis situation against HPV vaccination. Existence of social media has led to the rapid spread of fears beyond a single vaccination site or school.

Practical suggestions to reduce fear and distress among adolescents include:

- using a screen for privacy
- having other vaccination recipients wait outside the vaccination room
- managing only small groups of adolescents at one time.

Individuals vaccinated should be seated and observed for 15 minutes in a comfortable area to detect and address any adverse events and reactions, including dizziness.

5 Closing the session

Materials must be stored safely or disposed of after immunization sessions. Sites and non-disposable equipment must be cleaned and maintained for their next use.

5.1 Discard or store opened vials, depending on the vaccine type

Refer to national policy on open multi-dose vials and act accordingly (for WHO MDVP, see Module 2, section 1).

After outreach sessions, the following steps are required for the proper handling and storage of vaccines and supplies.

1. Pack the vaccine carrier:
   - Check the frozen water packs to make sure that the ice has not melted. If conditioned frozen water packs have completely melted and/or the thermometer in the vaccine carrier shows a temperature above +8 °C, all vaccines inside the vaccine carrier should be discarded unless they have VVMs that show they are still safe to use.
   - Place unopened vaccines and opened vials for which the MDVP is applicable inside the vaccine carrier.
   - Put empty vials and opened vials of reconstituted vaccines in a separate container for transportation to a disposal site.
2. Return usable vaccines to the refrigerator:
   - Return vaccines with acceptable VVMs and readable labels to the “use first” box in the refrigerator and record the refrigerator temperature.
   - Put the coolant-packs into the freezer.
3. Clean the vaccine carrier:
   - Wipe the carrier with a damp cloth and check it for cracks. Repair any minor cracks with tape and leave the carrier open to dry.
4. Store other supplies:
   - Place immunization registers, tally sheets, unused auto-disable syringes and immunization cards in their designated storage areas.

5.2 Dispose of used vaccine vials and injection equipment safely

Safety boxes containing used needles and syringes must be disposed of properly according to national policy.

5.3 Leave the site clean and tidy

Specifically, after using an outreach site:

- do not leave anything behind that might be a health threat to the community;
- do not leave the place untidy – in addition to removing all hazardous waste, collect and dispose of all non-infectious waste;
- clean tables, chairs and other equipment and return them to their owners.

5.4 Acknowledge community support

Thank all who have helped to organize the session (community health workers, volunteers, etc.) and remind them of the date of the next session.

6 Recording data

Accurate and reliable records are vital, not only for the individual but also to track the immunization status of communities through monthly and annual reporting (see Module 6, *Monitoring and surveillance*, for details). During a session, individual immunization cards and health centre records (such as registers, reminder cards and tally sheets) must be completed. Tally sheets need to be totalled after the session, and these totals need to be added to programme monitoring data.

6.1 Complete the child immunization and reminder cards

Complete child immunization and reminder cards, using the following steps.

- Write the date for each vaccine that has been administered in its corresponding section on the card.
- Mark the next immunization due date on the card if another dose is needed.
- Ensure that the caregiver understands when and where to return for the next dose(s) of vaccine(s).
- If new vaccines are not included on immunization registers and/or reminder cards, ask your supervisor for instructions about how to record them on all reporting tools.
- Use the immunization card to update the defaulter tracking list (also called catch-up or overdue tracking list) kept at the health facility, as shown in Module 6, section 1.
- Return the immunization card to the caregiver.
- Explain to the caregiver that the immunization card must be kept in good condition since it is an important document for future health care visits.
- Remind the caregiver that the card should be taken for review whenever the child visits the health centre.

6.2 Prepare a summary of the session

Calculate the total numbers of vaccines given, supplies used and stock remaining for inclusion in the tally sheet and monthly report data.

6.3 Prepare a defaulter tracking list

At the end of each session, use the immunization register and/or reminder cards to make a list of children who were due for vaccines but did not attend the session. The list should be used for defaulter tracking and for programme monitoring activities (as described in Modules 4 and 6). Inform community members who help with defaulter tracking of the

children on the list. Ask them to mobilize the defaulters for the next immunization session. The vaccination defaulters list should be shared with curative service staff in the facility so that they can screen individuals coming to health facility and can refer or vaccinate those with incomplete vaccinations.

References[1]

1. Methodology for the assessment of missed opportunities for vaccination. World Health Organization; 2017 (https://iris.who.int/handle/10665/259201).

2. Planning guide to reduce missed opportunities for vaccination. World Health Organization; 2017 (https://iris.who.int/handle/10665/259202).

3. Intervention guidebook for implementing and monitoring activities to reduce missed opportunities for vaccination. World Health Organization; 2019 (https://iris.who.int/handle/10665/330101).

4. World Health Organization = Organisation mondiale de la Santé. (2015). Reducing pain at the time of vaccination: WHO position paper – September 2015 = Réduction de la douleur au moment de la vaccination. Note de synthèse : position de l'OMS – septembre 2015. *Weekly Epidemiological Record = Relevé épidémiologique hebdomadaire*, *90* (39), 505–510. World Health Organization = Organisation mondiale de la Santé (https://iris.who.int/handle/10665/242426).

Bibliography

Essential Programme on Immunization. Increasing vaccination demand and uptake [website]. World Health Organization (https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/demand).

Immunization in practice: a practical guide for health staff – 2015 update. World Health Organization; 2015 (https://iris.who.int/handle/10665/193412).

Why gender matters: immunization agenda 2030. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/351944).

World Health Organization. Table 3: Recommendations for interrupted or delayed immunization; 4 December 2024 (https://www.who.int/publications/m/item/table-3-who-recommendations-for-routine-immunization).

[1] All references were accessed on 23 October 2025.

Annex 5.1. Immunization session checklist

This checklist is a reminder of key points described in this module and is meant to reinforce positive actions.

Before the immunization session

Did you:

Y N **Check** if sufficient quantities of vaccines and diluents are available for the session?

Check vials for the following and take appropriate action:

- Y N Expiry dates?
- Y N Open vial dates?
- Y N VVM status?
- Y N Freezing status?

Y N **Place** vials in the appropriate place in the immunization area?

Ensure sufficient supplies are available for the session including:

- Y N Auto-disable syringes?
- Y N Reconstitution syringes?
- Y N Safety box?
- Y N AEFI kit?
- Y N Immunization register?
- Y N Immunization tally sheets?
- Y N Blank immunization cards?

Y N **Wash** your hands with soap?

For selected clients attending the immunization session

Did you:

Y N **Greet** the client and caregiver?

Y N **Review** the client's immunization card?

Y N **Determine** eligible vaccinations based on the national schedule, client's age and possible contraindications?

Y N **Reconstitute** each vaccine with its matched diluent (for lyophilized [freeze-dried] vaccines)?

Y N **Fill** syringes just before administration using aseptic technique?

Y N **Administer** each vaccine according to recommended technique and correct injection site?

Y N **Immediately dispose** needles/auto-disable syringes in safety boxes after each injection?

Y N **Record** all vaccinations in register and on tally sheet and immunization card?

Y N **Communicate** key messages, including potential AEFI and date of next visit?

After the immunization session

Did you:

Y N **Correctly assess** if open vials can be used in the next session in accordance with national multi-dose vial policy?

Y N **Discard** open vials that should not be used?

Y N **Record** date of opening on vials that can be used and place them in the "use first" box in the refrigerator?

Y N **Return** unopened vials to the refrigerator?

Y N **Complete** session summary report?

Y N **List** the names of children who missed vaccination and require follow up?

Y N **Handle** full safety boxes correctly?

Y N **Take** appropriate action to ensure sufficient vaccine stock for the next session?

Y N **Inform community** of date and time of next session?

MODULE 6

Monitoring and surveillance

About this module

This module explains how to collect and report data for the monitoring of immunization services and the surveillance of vaccine-preventable diseases (VPD) and adverse events following immunization (AEFI). Monitoring and surveillance are included together, since data from both are usually reported in a summary form forwarded to central levels. The process of recording the data is described first. This is followed by a description of the summary reporting process and the ways in which these data can be analysed and used.

Monitoring of immunization services helps to improve performance and identify and solve any problems of access and utilization detected in communities with high numbers of unimmunized and under-immunized children. Surveillance of VPD helps guide disease-control activities by detecting outbreaks, identifying high-risk groups or areas and monitoring the impact of immunization services. Surveillance of cases of AEFI helps to identify the causes of adverse events and, if needed, triggers a review of proper vaccine handling and administration.

Examples in this module focus on children, but the methods can be applied to older age groups. The examples show paper-based recording and reporting, but data-collection principles apply to other modalities. While the use of electronic tools is encouraged by WHO, their implementation and instructions for use will depend on national or central authorities and objectives.

Contents

1 Monitoring systems and tools

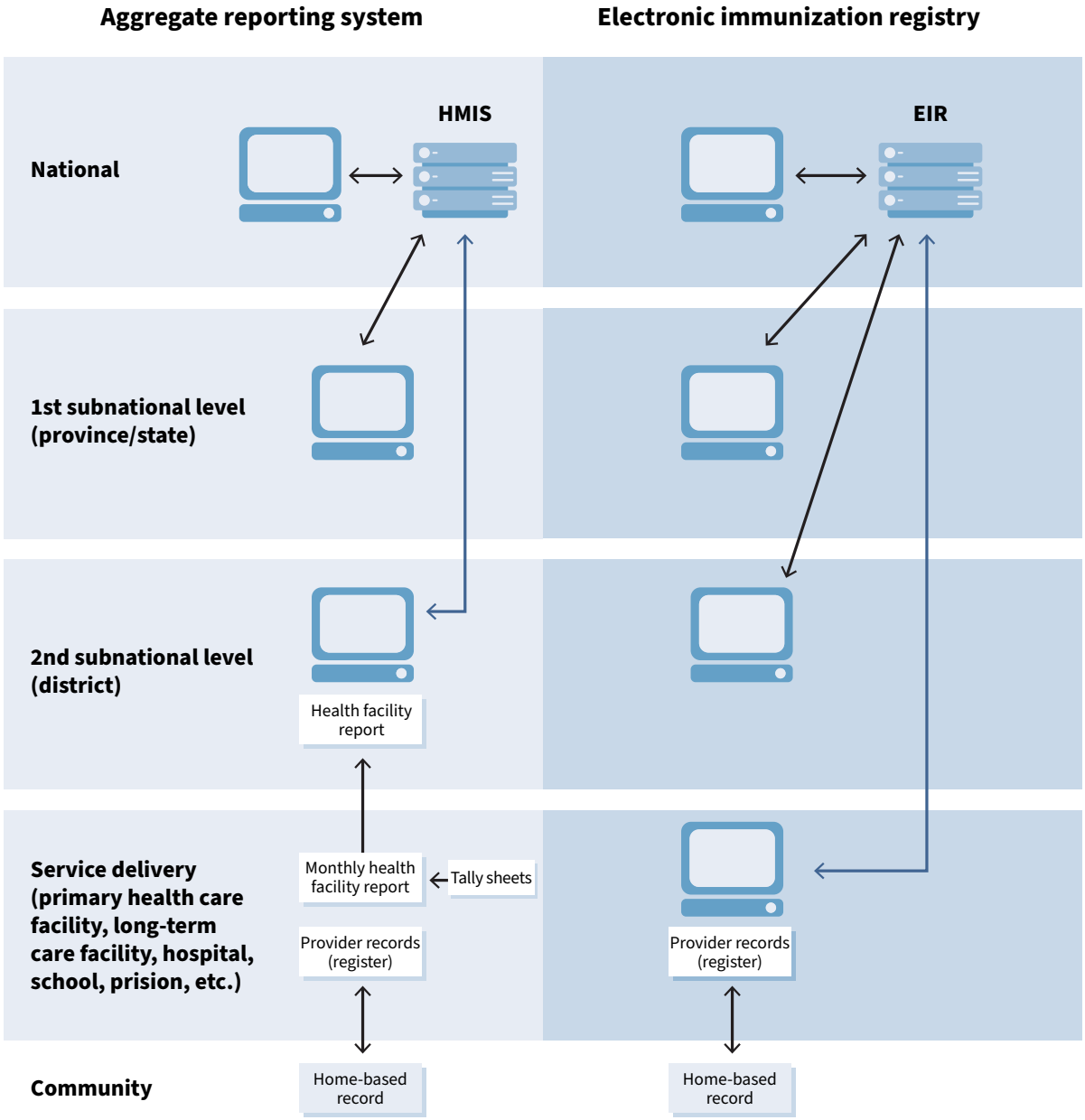
Every health facility needs a system to record immunization data.[1] Recording each vaccination on an immunization card and in a register allows health workers and families to keep track of vaccines received and the next doses that are due. Health workers can use these records to compile tracking lists and follow up with those who need to complete their vaccinations. Tracking the numbers of vaccinations administered in each session also allows health workers to monitor progress by comparing vaccinations to coverage targets.

Most countries use paper as well as digital tools to manage immunization programmes. Fig. 6.1 shows the two most common ways in which countries organize systems to record and report immunization data. As shown on the left, aggregate reporting systems summarize the numbers of doses administered by reporting period. Facility staff first use paper tools to record every dose and send periodic reports (generally monthly) to district administration. District staff then typically enter these data by facility into a (digital) health management information system.

Alternatively, countries can use electronic immunization registries, as shown on the right side of Fig. 6.1. An electronic immunization registry registers every immunization record separately in a digital system, from which data can be accessed directly at all levels. In this case, there is no need for periodic summary reports or tally sheets. Children can get either a paper vaccination card or a digital certificate, and a paper-based register is optional – some countries with an electronic immunization registry use them as back-up in case connection problems occur with the digital system.

[1] This module focuses on tools related to recording, reporting and analysing vaccinations and the immunization status of children in the target population of a health facility. There are other data-recording and -reporting tools used by immunization programmes, notably to manage vaccine supply chains, cold-chain equipment and cases of vaccine-preventable diseases. These are described in different modules of this book.

Fig. 6.1 Two types of data flow



This module will not further describe digital tools, because they differ so much between countries, and instead will focus on the use of paper tools, which are similar in many countries. However, where available, always refer to country-specific training material and standard operating procedure.

1.1 The immunization register

The immunization register is used to record the immunizations received by each child. It is often a book or a form that stays in the health facility. More and more countries also use electronic systems to register vaccinations, as described below. Paper books are often referred to as "registers", while electronic, population-wide systems are referred to as "registries". The main purpose of an immunization register is to track the immunization services provided to each vaccine recipient over time. Separate registers may be kept for children, adolescents and adults. They are important for several reasons:

- They are the health facility's primary source of information on a person's immunization status and needed vaccinations. This information is particularly helpful if a person attends a follow-up visit without their immunization card.
- They help identify people who miss scheduled vaccinations and who need to be added to the tracking list for catch-up vaccination.
- They are useful tools for the prevention and control of outbreaks (for example, to identify undervaccinated children amid an outbreak or to retrieve the immunization history of a case).
- They are needed in the management of adverse events following immunization (AEFI) (for example, to identify the lot number associated with an AEFI).

Health facilities may keep separate registers, or different sections in the same register, for each community they serve. This approach may be helpful to monitor whether communities are left behind and to prioritize access and outreach for vulnerable populations. Some countries may also use specific registers for outreach activities and/or people who present from outside their catchment area. Sometimes these outreach registers are temporary, and the people reached through outreach are later transcribed into a permanent register at the fixed location.

The examples below focus on childhood registers, but similar considerations apply to registers for adolescents and adults. Children can be entered in the immunization register at birth or on their first visit to the facility. In either case, it is important to register birth doses.

1.1.1 Information commonly included in the childhood immunization register

A register includes the following information for each child registered:

- a unique identification number or any other identifier that may be useful for tracking;
- the date of registration (date of the first visit or birth);
- the child's name, birth date, sex;
- any other information, per national policy (ethnicity, nationality, etc.);
- the name, address and phone/mobile number of the caregiver(s);
- the date, doses and lot number for each vaccine;
- whether vitamin A supplementation was given;
- an indication whether the child has completed all the recommended vaccinations (has fully vaccinated status);
- protected at birth status, which indicates whether the child was protected for neonatal tetanus.

A representative child immunization register example is shown in Fig. 6.2. This format groups vaccinations by visit. Often the label "1st doses" is replaced by the expected age of the child (for example, "10 weeks"). Alternative formats exist (such as grouping doses by vaccine). The format used in a health facility should reflect the national immunization schedule and guidelines.

A new month can be started at the top of the next page even if there are some lines left on the current page, or a few lines may be left open to clearly separate months. This will make it easier to find infants returning without their immunization cards and to compile overdue tracking lists.

Key points

- Fill in all information for each child and vaccination clearly and legibly on the register line.
- Mark vaccinations in the register only after they are given, and record the indicated vaccination information (such as lot number) completely.
- When a child returns for a follow-up visit, find the register line for the child using the immunization card (or the child's name and age and/or month of first vaccination if the card is not available), verify the vaccines to be administered and check the immunization card.

Fig. 6.2 Child immunization register example

MONTH and YEAR: **Health facility and/or person responsible for vaccination:**

ID No	Registration date[a]	Name of child	DOB[b]	Sex	Name of caregiver	Address and mobile/ phone number	Birth doses			PAB from NT[d] (Y/N)	1st doses				2nd doses					3rd doses				MCV1	MCV2	Vit A			Remarks – completed/ died/moved
							OPV0	BCG	HepB[c]		RV1	OPV1	PCV 1	penta1	RV2	OPV2	IPV1	PCV2	penta2	OPV3	IPV2	PCV3	penta3			1	2	3	

Note: This example is for a three-dose pentavalent (penta), four-dose oral polio vaccine (OPV), two-dose inactivated polio vaccine (IPV), rotavirus vaccine (RV), and three-dose pneumococcal conjugate vaccine (PCV) schedule. The register format always depends on the vaccines that are included in the national immunization schedule.

[a] Usually date of first visit.

[b] DOB: Date of birth.

[c] Only one birth dose of HepB is required; write if given <24h or >24h after birth.

[d] Protected at birth from neonatal tetanus – ask mother at pentavalent1 contact.

1.1.2 How to complete an immunization register

Ideally, children are registered at birth along with their birth doses, and they receive a vaccination card at that time. When a caregiver brings a child for vaccination, the health worker first asks to see the child's immunization card or, if no card is available, asks whether the child was previously vaccinated and, if so, where.

- For an unvaccinated child on their first visit, the health worker makes a new entry in the register book and issues a new immunization card. A unique identification number for each child is sometimes assigned in the register and copied onto the immunization card.
- For a returning child, the health worker locates the corresponding entry in the register, based on the card or the child's name, age and the month of the first immunization.
- For children who started their vaccine schedule in a different facility but are moving to this facility, the health worker copies the vaccination history from the immunization card into the facility register. If no card is available, either the entire vaccination series is started over, or it is picked up based on the caregiver's recall of previous visits (national policies may differ). If the caregiver is not able to recall the vaccines given, or national policy does not accept recall as a valid input, the immunization schedule should be started again to ensure that the child is protected (see Module 5, section 3, on assessing eligibility for immunization). In this case, the child should receive all age-appropriate doses.
- If a caregiver brings a child only a single time to a certain facility but intends to complete the schedule somewhere else, the child should still be vaccinated and their card updated. However, the visiting child is not typically entered into the register, although sometimes a separate visitor register is available, in which the vaccination is recorded (national policies may differ).

Vaccinations should be registered only after being administered: record on the register the date of vaccination and the lot number used for each vaccine that was administered. After this, the immunization card is updated, and the caregiver is informed of the next vaccinations and possible adverse events.

1.1.3 Alternative systems to record and keep immunization records at a facility

Classic paper-based immunization register formats have a few challenges that reduce their practicality and usefulness.

- As the number of vaccines and doses has increased over time, forms have become less manageable, with limited space to enter vaccination dates.
- The addition of new vaccines or additional doses, or any changes to the schedule, require new books to be printed and distributed in a timely manner.
- People move more frequently, while registers stay behind in the health facility. Personal home-based records or electronic systems are more useful to assure the continuity of care for people who move from one facility to another.
- There may be issues with data quality and completeness of vaccinations recorded on the paper-based register, as there are no automated checks in place.

Two alternatives to paper-based registers are a card-filing system and an electronic immunization register.

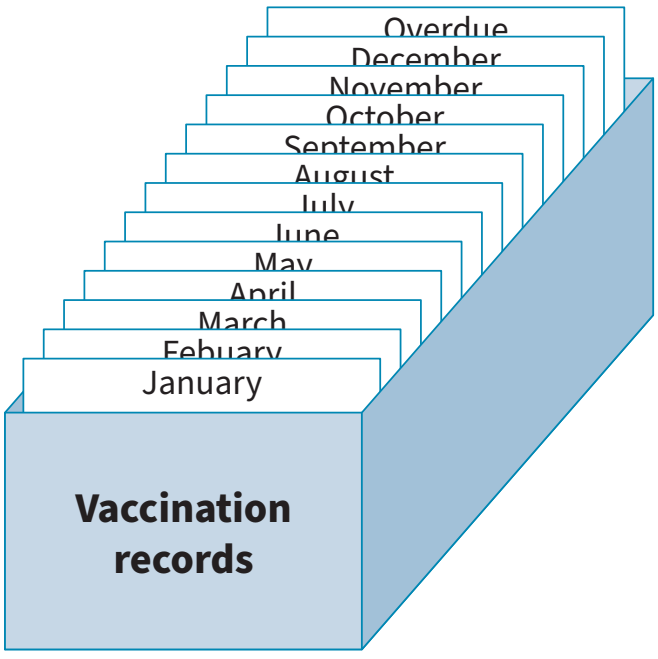
a) Card filing systems

In a card-filing system, copies of immunization cards (one per child) are maintained and stored in the facility. The cards are filed in a box, or sometimes in bags, organized by the month when the next vaccination is due (see Fig. 6.3). For example, if a child receives a series of first doses in January, their immunization card is updated and then placed in the box behind the appropriate divider (February for a monthly interval or March for an interval of two months, and so on, depending on national schedules). In February or March, if the child receives their second dose(s), the record is updated and placed in the section for the month when the third doses is due. If the child does not come for the second dose of a pentavalent vaccine in the month it is due or does come but is not vaccinated (whether due to stockouts or other reasons), the card will remain in that month.

At the end of each month, the health worker reviews all the cards remaining in that month's section, which are the cards of children who were scheduled for, but did not receive, a vaccination dose. These cards should be moved to the "Overdue" section of the filing system, and the names of the children who have missed vaccinations should be added to the defaulter (catch-up) tracking list.

In some countries, this system is used in addition to, not as an alternative to, a register book, requiring that the data be entered twice. The card filing system described here facilitates overdue tracking, and it is easier to enter all relevant data on a card compared to a line in a book. That said, a register book may still be preferred for archiving purposes.

Fig. 6.3 Sample system for filing immunization record cards



b) Electronic immunization registries

Electronic immunization registries aim to record each child's vaccinations electronically, making retrieval and archiving potentially easier. If these records are kept in a central database that is accessible online, they can be retrieved and updated from any health centre and can be used to monitor coverage, produce due and overdue lists, send reminders and so on. As the functions and use of electronic immunization registries differ by system and country, please refer to national documentation and training material if such a registry is in use in your country.

1.2 The immunization card

An immunization card is used to record the immunizations a child has received. It may be a separate document or part of a general infant or mother/child health record, such as a Family or Child Health Booklet. The immunization card is important for several reasons.

- It serves to remind caregivers when to return to the clinic for the next dose(s) of vaccine(s).
- It provides key information about vaccines and schedules to caregivers and families.
- It helps the health worker determine a child's immunization status and vaccinate them accordingly.
- It enables continuity of care (for example, if the child moves to another location, the new health worker can easily determine the child's vaccination status).
- It is important in coverage surveys.
- It is important in the case of an adverse event following immunization, as it helps investigators establish which vaccines and lots preceded the event. It might also contain a contact number or instructions for caregivers.

The specific format of the immunization card depends on the vaccines that are included in the national immunization schedule. Some countries have complemented or replaced cards with digital certificates, either stand-alone or as part of a national electronic immunization registry. Examples of immunization cards are available from the vaccination card repository on TechNet.

Key points

- The immunization card may be the only record of immunization status available for health workers if registers are not well maintained or if families move from one health facility to another.
- Each child should have a card with vaccinations marked correctly and written clearly and legibly.
- See Module 5, section 6, for the process of filling in and explaining the card to caregivers during the immunization encounter.
- In case the card is lost, a new card may be issued with the dates of previous vaccinations given, as per the register or other record.

1.2.1 Information commonly included on an immunization card

An immunization card usually includes the following information:

- a unique identification number for the child (the same number written in the immunization register (see Fig. 6.2);
- the child's name, birth date, sex;
- the name and address of the caregiver(s), including mobile/phone number, if available;
- the date, dose and lot number of each vaccine given (this applies to doses provided during supplementary immunization activities (campaigns) as well as doses provided through routine services);
- the date and dose of vitamin A supplementation given, if applicable;
- whether the infant was protected at birth from neonatal tetanus;
- the date, dose and lot number of each tetanus toxoid (TT) vaccine given to the mother (optional);
- the due date for the next immunization(s);
- the country immunization schedule (optional);
- a growth-monitoring chart (optional);
- the reason why a vaccine was not administered, if applicable;
- any AEFI that the child experienced after receiving a vaccine.

The infant's caregiver should be reminded to keep the immunization card in a safe place and to take it to all immunization and other health care visits.

1.2.2 How to use an immunization card

Complete the card by writing down the date for each vaccine administered or vitamin A supplement given. Include doses of TT given to the mother if she is eligible and the card has space to enter it (this will depend on national protocol; there may be a separate women's immunization card).

Mark the next appointment date on the card and tell the caregiver when and where to return for the next vaccination.

Key points

- Remember to mark the next appointment date on the immunization card and explain the importance of timely vaccination. Make sure that the appointment corresponds to a planned immunization session.
- Inform the caregiver of the next appointment verbally as well as in writing on the card.
- Always return the immunization card to the caregiver.
- Remind the caregiver to keep the immunization card in a safe place and to take it to all health care and immunization visits.

1.3 The tally sheet

Tally sheets are forms that are marked every time a health worker administers a dose of vaccine (see the sample in Fig. 6.4). They are used to monitor performance (calculate coverage) and to facilitate monthly reporting. A new tally sheet can be used for each session, week or month. The categories in a tally sheet are determined by national policies but should include vaccine, dose and ages. Some countries also collect data by sex of the child, to enable them to monitor coverage between males and females. Any new category for tallying and reporting increases the reporting burden for health workers and should be introduced only when absolutely required. The specific format of the tally sheet depends on the vaccines that are included in the national immunization schedule. HPV and other vaccines given to older age groups may be recorded on separate tally sheets.

1.3.1 Information commonly included on a tally sheet

Tally sheets record vaccinations, which are marked by the health worker after a child receives a dose. The dose is also recorded in the immunization register and on the immunization card, and the caregiver is informed of which vaccinations were given (see Module 5, section 2, for more on communicating with caregivers).

1.3.2 How to use a tally sheet

Mark the tally sheet for every dose received. On a preprinted form such as that shown in Fig. 6.4, fill in or put a line through a “0” for each dose given; other forms may require you to make a new mark next to each vaccine and dose. Vaccinations are considered “timely” if administered in the year they are scheduled (for example, by the age of 1 year for infant vaccines such as pentavalent3 or MCV1, or by the age of 2 years for MCV2). However, children who have passed that age should still be vaccinated, in accordance with national policies, and the vaccinations should be marked on the tally sheet as delayed or catch-up vaccinations.

Fig. 6.4 Sample tally sheet for childhood vaccinations

Session tally						
Name of health facility:				Date of session:		
Place of session:				Type of session: fixed/outreach/mobile		
Name of staff completing tally:						
			Timely vaccinations		Delayed (catch-up)	
Vaccine		Vaccine lot #	Age <1 year		Age >1 year	
			tally	total	tally	total
BCG			00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000			
HepB (<24h)			00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000			
HepB (>24h)			00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000			
Polio (OPV and/or IPV)	OPV0		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000			
	polio1		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	polio2		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	polio3		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	polio3+		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
RV	RV1 (Up to 2 yrs)		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	RV2 (Up to 2 yrs)		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
Pentavalent	penta1		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	penta2		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	penta3		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
PCV	PCV1		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	PCV2		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	PCV3		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
			Age 9–12 months		Age >12 months	
MCV1			00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
			Age 15–18 months		Age >18 months	
MCV2			00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
			Age <1 year		Age >1 year	
Vitamin A			00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	

Fig. 6.4 (continued)

Women		Pregnant women		Non-pregnant women	
TT1		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
TT2		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
TT3		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
TT4		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
TT5		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
TOTAL TT					
TOTAL TT2+TT3+TT4+TT5					

At the end of each immunization session or month, add up the number of marks recorded during the session or month. This gives the total number of immunizations given with each vaccine and each dose in its series. These numbers should be the same as the information in the immunization register. Keep the tally sheet for the supervisor to review.

Table 6.1 describes common errors and correct practice in tallying.

Table 6.1 Common mistakes in tallying

Mistake in tallying	Possible problem that may occur	Correct practice
Tallying before the vaccination is given	The child may not receive the vaccination	Give the dose first, then mark it on the tally sheet
Tallying at the end of a session according to number of doses contained in the used vials	Wasted doses may be counted	Tally each dose given (as above)
Tallying all vaccines under one age group (to include those outside the targeted age)	Will result in inaccurate coverage data	Separate tally for children under 1 and over 1 year old

1.4 The catch-up tracking list

The catch-up, overdue or defaulter tracking list groups all people who miss scheduled vaccinations for any reason and need to be contacted to complete or continue their schedule (see Fig. 6.5). Reasons for missed vaccinations may include health facility problems (such as cancelled sessions or vaccine stockouts) and/or issues at the individual level (such as lack of awareness that a vaccination is due or hesitancy around vaccination).

1.4.1 Information commonly included on a catch-up list

A catch-up tracking list usually includes the following information:

- the name of the child;
- the caregiver's name and contact information, including address and phone/mobile number(s);
- the age of the child;
- the vaccinations needed;
- the reasons for missing previous vaccinations, if known.

Fig. 6.5 Sample catch-up tracking list

	Name	**Caregiver's name**	**Contact information** (address, phone/ mobile number if available)	**Age**	**Vaccinations needed**	**Reason for missed vaccination** (vaccinated, declined, moved, lost to follow up, deceased)
1						
2						
3						
4						
5						

1.4.2 How to use the tracking list

At the end of each month, review the immunization register or card filing system to identify children who may not have received vaccinations when due. Add the names and contact details of any children who missed vaccinations to the tracking list, as per national catch-up policies. Listing overdue children every month makes it easier to find them and make sure their schedules are completed.

Strategies to catch up include direct contact with caregivers and, where necessary, enlisting the support of community health workers, village health committees and/or local leaders. Module 7 gives more detail on working with communities to support vaccination programmes. Local innovations aim to involve the entire community in efforts to support childhood vaccination, including by sharing data on the immunization status of children in a community to encourage catch-up vaccination where needed. See, for example, *My village my home: a tool to optimize immunization coverage*.

2 Monthly summary reports

The immunization monitoring, vaccine-preventable disease (VPD) and AEFI surveillance data collected with the tools described in section 1 of this module need to be consolidated into a summary form, either manually or electronically, for transmission from the health facility to the district level. There, paper reports are typically entered into the digital health management information system, where they are available for use by all levels of the health system.

At each level, the data should be analysed and used to improve the programme, as discussed in section 3. The format of a summary report should be defined at the national or central level and should be standard for all health facilities. The frequency of reporting should also be determined by national authorities. This section discusses a monthly report, but reports may be done weekly, quarterly and/or annually, based on national requirements. Samples of monthly summary reports are shown in Figs. 6.6 and 6.7.

Health workers should ensure that reports are complete, accurate and submitted on time.

- **Complete:** All sections of the summary reports should be filled in and no parts left blank. All reports due from different services and/or outreach sites should be received and their data included in the summary report.
- **Accurate:** All summary reports should contain figures that correspond to the actual figures from the health facilities and that are double-checked for correct calculations and totals.
- **Timely:** All summary reports should be submitted to the next level before the assigned deadline (according to the national policies/norms). Summary reports completed and submitted on time help to ensure prompt and effective disease control response.

Copies of reports, with dates and signatures, are sent to the next administrative level, and the originals are stored at the health facility (see section 2.5 of this module). District, provincial and national levels should keep track of the completeness and timeliness of reporting by more peripheral levels and remind them of missing or late reports. Higher levels should provide the district with feedback, through supportive supervision, using specific examples from its reported data (see Module 5, section 5.4, for a description of supportive supervision).

2.1 Vaccination data

Fig. 6.6 is an example of how a facility might report on immunization sessions and doses administered for each vaccine. A sample monthly report is also shown for HPV vaccination (Fig. 6.7). The vaccine tally may be the easiest source of data to use when completing this part of the summary report, but, in countries where no tallies are used, vaccine records (for example, daily registers) can be used. Many electronic immunization registries can create monthly reports automatically.

Fig. 6.6 Sample monthly summary report for childhood vaccination

Health facility: **District:** **Month/year:**

Sessions planned: **Sessions held:** **Population under 1 year:**

No	Date	Place of session	Session type[a]	Infants PAB[b] from NT	Vaccinations and Vit A given to children <1 year of age																		Vaccinations and Vit A given to children >1 year of age												MCV2		Others
					BCG	HepB		Polio (OPV and/or IPV)					RV		PCV			Pentavalent			MCV1	Vit A	Others	Polio (OPV and/or IPV)				PCV			Pentavalent			MCV1	Vit A			
						<24h	>24h	OPV0	1	2	3	3[c]+c	1	2	1	2	3	1	2	3				1	2	3	3+[c]	1	2	3	1	2	3				Age 15–18 months	Age >18 months	
1																																						
2																																						
3																																						
4																																						
5																																						
6																																						
7																																						
8																																						
9																																						
10																																						
11																																						
12																																						
Total																																						

[a] Session type: fixed or outreach.

[b] Protected at birth from neonatal tetanus (based on TT vaccination status of mother).

[c] Combination IPV/OPV schedules may require a final dose of OPV with IPV – follow the national schedule.

Fig. 6.7 Sample monthly summary report for HPV vaccination

Month/ year of report: 01/2018

District: _____ Town/village: _____

Service delivery site: _____

Vaccination strategy: _____

Year of birth/age	No. of HPV1 doses given						No. of HPV2 doses given						Comments
2009/ 9 years	9yrHPV1:						9yrHPV2:						
	8					Total	10					Total	
2008/ 10 years	10yrHPV1:						10yrHPV2:						
	0						15						
2007/ 11 years	11yrHPV1:						11yrHPV2:						
2006/ 12 years	12yrHPV1:						12yrHPV2:						
2005/ 13 years	13yrHPV1:						13yrHPV2:						
2004/ 14 years	14yrHPV1:						14yrHPV2:						
2003 or earlier/ 15 + years	15yrHPV1:						15yrHPV2:						

2.2 VPD surveillance data

The first section of Fig. 6.8 shows a sample VPD report. The VPD tally and line lists are the sources of data for this part of the summary report. Monthly case totals for each VPD should be entered into the corresponding row of the form.

If there are no cases of a disease during the reporting period, the number zero should be reported in the summary. This is called "zero reporting" and is important, since it shows an absence of cases presenting to the health facility rather than a forgotten point in data collection.

Fig. 6.8 Sample monthly summary report for childhood vaccination

Compiled VDP report

Target diseases	Total	Age			Sex		Vaccination status						Number of deaths
		<1 year	1–4 years	>5 years	M	F	Doses					Vaccination status unknown	
							0	1	2	3	3+		
Polio/AFP													
Measles													
Rubella													
Diphtheria													
Pertussis													
Neonatal tetanus													
Other tetanus													
Other diseases[a]													

Stock report

Item	Start balance[b]	Received[b]	End balance[b]
RV			
OPV			
PCV			
Pentavalent			
BCG			
Measles/MR			
Other (vitamin A, yellow fever)			
Auto-disable syringes (BCG)			
Auto-disable syringes (others)			
Safety boxes			
Immunization cards			

Fig. 6.8 (continued)

Adverse events following immunization (AEFI) report[c] (report serious events immediately to your supervisor for further investigation)

Type of event	Number of cases
Serious events (A)	
Non-serious events (B)	
Total AEFI (A+B)	
Additional comments (if any):	

Notable activities during the reporting period (supervisory visits, training events, social mobilization activities, etc.)

Date of report: _____ Name of reporter: _____ Designation: _____ Signature: _____

[a] Add other vaccine preventable diseases (yellow fever, Japanese encephalitis, etc.) according to region.

[b] Enter vaccine vial size where applicable; count the number of vials and multiply by doses per vial to give the number of doses.

[c] Follow country policy on adverse event reporting – serious events, particularly death, usually require immediate reporting.

2.3 AEFI surveillance data

Any AEFI recorded during the month should be tallied by the type of event (serious or non-serious) as shown in the lower left block in Fig. 6.8 and entered into the corresponding section of the monthly summary report form. Ensure that all rows are completed.

2.4 Additional information

2.4.1 Vaccine usage and wastage patterns

The usage and wastage of vaccine vary from one session to another. It is useful to monitor these patterns regularly at all immunization points to improve supply and to avoid stockouts. Stock cards provide the data for this part of the summary report. Using the data from the stock cards or other records, staff should enter the number of vaccine vials in stock at the start of the month (start balance), the number received during the month (received) and the number of vials in stock at the end of the month (end balance) into the corresponding boxes in the monthly summary form.

Staff at health facilities should regularly record vaccine stock data in stock cards or ledgers and report stock balances and use through the summary form.

2.4.2 Specific problems encountered during the reporting period

A narrative description of any problems, such as stockouts, transportation problems, cold-chain failure and so on, should be added to the summary report as needed to prompt review and improvement of service-related issues.

Other data that may be added to the form include the following:

- community engagement activities that were conducted during the period;
- the number of sessions conducted and planned, including by fixed, outreach or mobile strategy;
- immunization campaign activities conducted during the reporting period.

2.5 Data and report storage

For purposes of verification and retrieval, data must be stored at each different administrative level. Data can be stored in hard copy or electronically. At the health facility, tally sheets, registers and reports should be stored for a specific period depending on national standard operating procedure. Where computers are used, backups (hard copies and/or electronic copies) must be kept to avoid data loss in the case of system failure. Stored records are also useful for supervisory visits and immunization service reviews.

The following types of data should be stored at each health facility for a period of three years, or as long as required by national policy:

- immunization registers
- copies of vaccination cards (if applicable)
- tally sheets
- defaulter tracking lists
- monthly reports
- target population data used in microplanning (see Module 4)
- immunization monitoring charts (see section 3 of this module)
- case/outbreak charts and reports
- supervisory visit reports or book
- stock cards/book/registers
- cold-chain maintenance records.

3 Analysis of immunization data

Data collected and summarized in reports are useful only when analysed and interpreted regularly and used to improve service delivery. This section describes the initial analysis of monitoring data that begins at the health facility level. The most important indicators for the monitoring of immunization performance are coverage and drop-out rates.

"Immunization coverage" is the percentage of a target population that was vaccinated with a certain vaccine and dose. It can be estimated in a coverage survey, or by comparing the number of vaccinations administered during a period to the estimate of all targeted children in the same period.

$$\textit{Coverage for any vaccine and dose (\%)} = \frac{\textit{vaccinations administered during a period}}{\textit{target population estimate for period}} \times 100$$

The "drop-out" rate is the percentage of children who started a course of a vaccine but did not complete the final dose.

$$\textit{Drop-out rate between dose 1 and 3} = \frac{\textit{number of } 1^{st} \textit{ doses} - \textit{number of } 3^{rd} \textit{ doses}}{\textit{number of } 1^{st} \textit{ doses}} \times 100$$

Beyond coverage and drop-out rates, it is also worth analysing the absolute numbers of vaccinated, unvaccinated and under-vaccinated children for each vaccine. The number of children who are completely left out are sometimes referred to as "zero-dose children." This term refers to those children who are older than 1 year and have not received pentavalent1.

3.1 Vaccination coverage charts

Creating a chart showing doses administered and drop-out rates is one way to monitor immunization service progress. This type of chart tracks monthly progress towards immunization service goals. The number of doses administered can be compared to the number of children eligible to receive them, and rates of vaccination can then be calculated. Charts can be produced at every level of the health system by combining data manually or electronically. Fig. 6.9 shows a completed monitoring chart.

3.1.1 How to make a monitoring chart showing doses administered and drop outs

Vaccine doses administered and drop-out rates can be charted using the following steps (the descriptions reflect the sample form in Fig. 6.9).

1. Obtain the figures for the annual and monthly target population who should receive immunization services.

   The overall aim is to vaccinate every eligible person in the catchment area, including those who are hard to reach. Population estimates are obtained either top-down (i.e. from census-based data provided by a national statistical service) or bottom-up (i.e. through local population counts). Estimates for children under the age of 1 year are calculated by applying the appropriate (national or subnational) birth rate to the overall population. Depending on the context, the expected number of children under 1 year of age varies between 1% and 4% of a total population, so it is important to use the birth rate that best reflects the reality in your country and region.

   This system can be tricky to use at the health facility level for two reasons. First, often no census-based population estimates are available for catchment areas below district level. Second, several health facilities may serve the same catchment area, and people living in the vicinity of one facility may choose to attend a different one. Especially in urban or peri-urban areas, the concept of a catchment area does not apply very well. In those cases, the target number of children to be vaccinated can be assigned by a district administration, based on each facility's capacity and past vaccination performance. Determining a meaningful target – one that is attainable yet somewhat challenging – is key to the effective use of a monitoring chart.

   The monthly target population is the annual target population – that is, the number of children under the age of 1 – divided by 12:

   $$\textit{monthly target} = \textit{annual target population} \div 12$$

   Sample calculation: If the total population is 3900, and the birth rate is 3%, then the annual target population of children under the age of 1 is

   $$3900 \times 3\% = 117$$

   and the monthly target is

   $$117 \div 12 = 10$$

2. Label the chart and draw the ideal monthly target line.
   - Label the cells in the left (and/or right) column of the chart with the monthly and cumulative target numbers.
   - Label the cells near the bottom of the left-hand column with the selected vaccines.

- Draw a diagonal line from zero to the top right-hand corner to show the ideal rate of progress from month to month, based on the cumulative monthly target numbers.

3. Add the immunization data to the chart.

- Locate the space for the month being recorded in the row of cells underneath the graph and enter the monthly total of vaccine given.
- Calculate the cumulative total for the current month and add it to the cell next to the monthly total for that month:

$$\textit{current cumulative total} = \textit{current month's total doses} + \textit{previous month's cumulative total doses}$$

"Cumulative" means the total number of doses of vaccines given in the current month plus the monthly totals for the current calendar year to date (for example, the cumulative number of pentavalent3 doses given by the end of March is the total number of doses given in January plus the total number given in February plus the total number given in March).

4. Plot on the graph the cumulative total for each month being recorded.

- Add a symbol (such as a dot, triangle or square) to the graph, corresponding to the cumulative total recorded for the current month being recorded; the symbol should line up with the correct cumulative monthly number in the column on the left side of the chart.
- Connect the new symbol to the previous month's symbol with a straight line.
- Repeat this process for every month until the end of the year.
- Plot other immunizations given on the same chart, as needed, using different symbols and colours to distinguish the vaccines.

5. Calculate the total number of drop-outs between the first and last dose of the same vaccine series.

$$\textit{number of drop-outs} = \textit{cumulative total for the first dose} - \textit{cumulative total for the last dose of the vaccine series}$$

$$\textit{drop-out rate (\%)} = (\textit{number of drop-outs} \div \textit{cumulative total for the first dose}) \times 100$$

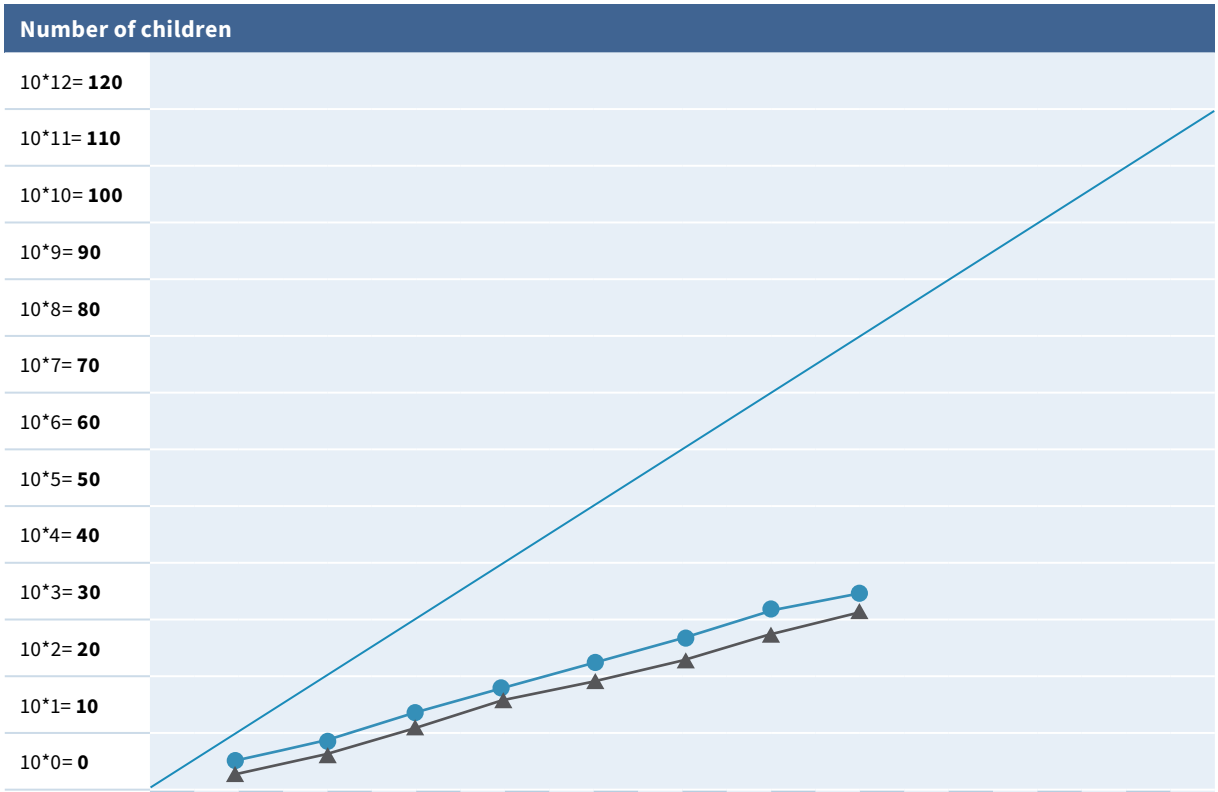
The drop-out rate can be seen in the sample graph: it is the gap between the lines for the first and last dose of a vaccine.

Sample calculation: If all 117 children in the annual target population received pentavalent1, but only 100 finished all three doses (i.e. received pentavalent3) during the year, then

$$\text{number of drop-outs} = 117 - 100 = 17$$

$$\text{drop-out rate} = (17 \div 117) \times 100 = 14.5\%$$

Fig. 6.9 Sample monitoring chart showing pentavalent1 and pentavalent3 data



Fill in at the end of the month	Jan	Cum. total	Feb	Cum. total	Mar	Cum. total	Apr	Cum. total	May	Cum. total	Jun	Cum. total	Jul	Cum. total	Aug	Cum. total	Sep	Cum. total	Oct	Cum. total	Nov	Cum. total	Dec	Cum. total
Total immunized pentavalent1	6	6	4	10	6	16	6	22	7	29	7	36	5	41	5	46								
Total immunized pentavalent3	4	4	3	7	6	13	6	19	6	25	6	31	5	36	5	41								
Drop-out (DO) (penta1 – penta3)		2		3		3		3		4		5		5		5								
Drop-out % (DO/penta1) *100		33		30		19		14		14		14		12		11								

● pentavalent1 coverage

▲ pentavalent3 coverage

The sample chart in Fig. 6.9 shows that, by August, this health facility had vaccinated less than half of its target number of children – the lines showing the number of children who had received pentavalent1 and pentavalent3 are far below the target line. There could be a number of explanations for this poor rate of vaccination: the initial target may have been too high, or service issues may have disrupted immunization sessions. Additionally, five more doses of pentavalent1 than pentavalent3 were administered, resulting in a gap of 11% in the number of children who received their first dose and those who received their last dose (the drop-out rate). Such a gap is a signal to review registers and look for any children who are overdue.

3.2 Vaccination coverage data analysis

Full analysis requires data that has been compiled by area. Figs. 6.10, 6.11 and 6.12 provide suggestions on how to compile and analyse vaccination coverage data (see also Module 4, section 3, for a discussion of prioritizing areas by the number of unimmunized and under-immunized children). The calculations given in Figs. 6.10 and 6.11 help define problems that cause children to remain unimmunized. Defining problems in detail helps identify potential solutions.

3.2.1 How to complete the compilation and analysis table (Fig. 6.10)

1. List each geographic area or community served in column a.
2. List the target population numbers for children less than 1 year of age in column b.
3. Enter the number of doses of each vaccine type administered to the target group during the preceding 12-month period in columns c, d and e. The vaccines used for analysis will vary by programme.
4. Calculate immunization coverage as follows:

$$\textit{immunization coverage (\%)} = \frac{\textit{number of children with all required doses of the selected vaccine during the past 12 months}}{\textit{annual target population}} \times 100$$

Example (using the data from section 3.1 above (that is, 117 children in the target population)):

$$\textit{immunization coverage (\%) in column g} = \frac{\textit{infants with all required doses of pentavalent in the past 12 months in column d}}{\textit{annual target population in column b}} \times 100 = (100 \div 117) \times 100 = 85\%$$

5. Calculate the number of unimmunized children:

$$\textit{unimmunized number} = \textit{annual target population} - \textit{doses of vaccine administered}$$

Example:

$$\textit{unimmunized penta3 in column j} = \textit{annual target population in column b} - \textit{doses of penta3 administered in column d} = 117 - 85 = 32$$

6. Calculate the drop-out rate. The drop-out calculation for a vaccine is shown in section 3.1 above.

Example:

$$\textit{drop-out rate penta1/penta3 in column l} = \frac{\textit{doses of penta1 in column c} - \textit{doses of penta3 in column d}}{\textit{doses of penta1 in column c}} \times 100 =$$

$$= \frac{105 - 85}{105} \times 100 = 19\%$$

7. Identify and categorize problems for each area.

In column n, enter the quality of access (good = coverage of 80% or better; poor = coverage of less than 80%) based on pentavalent1 coverage in column f. Note that the 80% cutoff is suggested here as a general indicator, and programmes may use different cutoffs to define good and poor coverage based on national policy.

In column o, enter the quality of utilization (good = a drop-out rate of less than 10%; poor = a drop-out rate of 10% or more) based on the pentavalent1 to pentavalent3 drop-out rate given in column l. Note that the 10% cutoff is suggested here as a general indicator, and programmes may use different cutoffs to define good and poor drop-out rates based on national policy.

Finally, use all these data to prioritize communities with respect to problem solving. Consider priorities from the lenses of low coverage, high drop-out and large numbers of unimmunized children.

Fig. 6.10 Sample format for compilation and analysis of health facility data

Community name	Compilation of immunization coverage data for the previous 12 months							Analysis of problem						
	Annual target population	Doses of vaccine administered			Immunization coverage (%)			Unimmunized (number)			Drop-out rates (%)		Identified problems	
	Children ≤1 year of age	Penta1	Penta3	MCV1	Penta1 (c/b)*100	Penta3 (d/b)*100	MCV1 (e/b)*100	Penta1 (b–c) ("zero-dose")	Penta3 (b–d)	MCV1 (b–j)	Penta1 – penta3 (c–d)/ c*100	Penta1 – MCV1 (c–e)/ c*100	Access (good, poor)	Utilization (good, poor)
a	b	c	d	e	f	g	h	i	j	k	l	m	n	o

Figs. 6.11 and 6.12 illustrate some ways of using data to understand the main issues with vaccination associated in a health facility (i.e. access or utilization) and to prioritize areas for focused activities. Coverage and drop-out rates for any vaccine can be used in such analyses; the choice may be set by national policy or made at more local levels.

Fig. 6.11 Access and utilization problem analysis flowchart

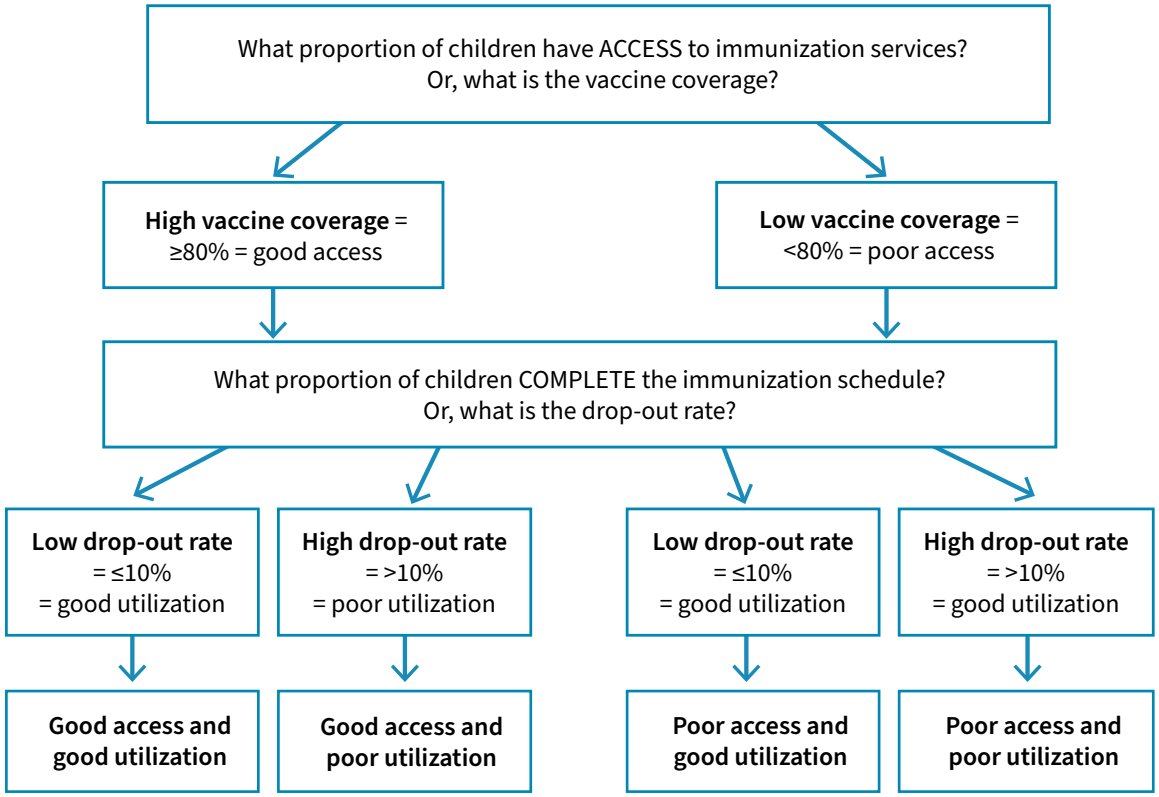


Fig. 6.12 Sample table showing use of data on measles immunization rates for children under 1 year of age to prioritize communities

Community name	Population	Population under 1 year	Measles coverage under 1 year	Unimmunized children under 1 year	Priority
A	100 000	4000	50%	2000	2
B	75 000	3000	60%	1200	4
C	120 000	4800	70%	1440	3
D	10 000	400	20%	320	5
E	250 000	10 000	75%	2500	1

3.3 Improvement of services

Problems can be broadly associated with access and utilization (see Fig. 6.11 for an illustration of different combinations of the two factors). These problems may be related to one or more communities or areas or may apply to the entire district.

Access problems result in children missing immunization sessions. Such problems may be due to:

- sessions not being held as planned;
- the session site and/or times being inconvenient or not advertised;
- cultural, financial, ethnic, gender or other barriers preventing access to and use of immunization services.

Utilization problems result in infants not coming back to complete the full series of immunizations. These problems may be caused by:

- caregivers' lack of information about the complete immunization schedule;
- poor service quality, lack of respect for caregivers or other problems in the relationship between health workers and the community;
- missed opportunities for vaccination (for example, because of supply shortages or incorrect assessment of contraindications).

The table in Annex 6.1 lists commonly encountered problems. While it is not exhaustive, it can serve as a guide to finding solutions.

The microplanning process, which includes identifying possible solutions, is described in Module 4. Discussion about problems and solutions should occur at the community and health facility level, and also at the district or more central levels as needed. Solutions should be prioritized for implementation. Problems that affect the district level should generally be addressed before those that affect local levels. At any level, changes are likely to be more feasible when implemented with available resources.

Supervisory visits from more central levels can also be helpful in identifying problems and solutions. Annex 6.2 shows a sample checklist for such visits. Like the table in Annex 6.1, it is not exhaustive but can serve as a guide for health workers and supervisors.

4 VPD surveillance

4.1 What is VPD surveillance?

VPD surveillance involves systematically collecting, reporting on and analysing health-related data on cases of suspected and confirmed diseases. The VPD surveillance system may be part of national communicable disease surveillance, outbreak surveillance or other surveillance systems, as part of a comprehensive VPD surveillance system. The list of diseases under surveillance varies by country.

4.2 Why is VPD surveillance important?

VPD surveillance is an important component of a strong immunization programme. Surveillance is essential to:

- monitor trends in diseases over time (for example, by age, geographic distribution and vaccination status of cases), including after new vaccines are introduced;
- monitor the effectiveness of immunization programmes (for example, an increase in coverage should lead to a decrease in VPD);
- prevent outbreaks and detect and respond to them in a timely manner;
- monitor progress towards disease control, elimination, or eradication goals.

4.3 Role of health workers in VPD surveillance

The role of health workers in VPD surveillance systems varies widely between countries, so this section provides a general overview for health staff who work with children in health facilities and/or the community. Vaccinators should consult with their supervisors for the specifics of their role in this area of surveillance.

The first step in the surveillance system is to detect suspected cases by using a standardized case definition. Typically, any health care worker who encounters a person with the symptoms included in the standard case definition should report the case to the surveillance system, using the reporting form and protocol specified by their country. Even if zero cases were detected in a reporting period, this information is critical to the surveillance system and should be reported (this is referred to as “zero reporting” or, in some countries, “negative reporting”).

It is important to know to whom to report a suspected case and in what time frame, as certain diseases may need to be reported immediately, while others should be reported on a weekly or monthly basis. For example, a vaccinator doing a household visit to a child on the defaulter list may encounter a 3-year-old sibling with fever and rash. In this case, the vaccinator would inform the community health worker or health facility surveillance officer,

depending on the country's standard operating procedure, that there is a child with fever and rash who should be investigated as a suspected measles case. Additionally, it is important to share case definitions with community health workers and/or community volunteers so they can report VPD they see in their communities. The community health worker or surveillance officer would then carry out the next steps in the surveillance pathway, including investigating the case and taking lab specimens for laboratory testing, as indicated.

If a patient with a suspected or confirmed VPD needs medical attention, the vaccinator should notify the appropriate personnel at the health facility, and the patient may need to be kept under specific infection control policies, per health facility guidelines. Guidance regarding infection control can be found in *Strengthening infection prevention and control in primary care*.

4.4 Common reportable VPD

Table 6.2 lists examples of clinical syndromes associated with various VPD. Patients presenting with these syndromes may or may not have a VPD but should be reported to the surveillance system for investigation, as indicated by the country's standard operating procedures.

Table 6.2 Examples of common clinical syndromes included in VPD surveillance

Clinical syndrome	Associated VPD
Diarrhoea (including watery and bloody)	Rotavirus Cholera
Fever, rash	Measles Rubella Varicella Dengue
Acute flaccid paralysis	Polio
Meningoencephalitis (ME) / acute encephalitis syndrome (AES)	Meningococcus Pneumococcus *Haemophilus influenzae* type b (Hib) Japanese encephalitis
Prolonged fever	*Salmonella* serotypes *Typhi* and *Paratyphi*
Severe acute respiratory illness (SARI) / influenza-like illness (ILI)	Influenza Pertussis COVID-19 Respiratory syncytial virus (RSV)
Meningitis/pneumonia/sepsis	Meningococcus Pneumococcus *Haemophilus influenzae* type b (Hib) Group B streptococcus

If vaccinators in your country are also responsible for investigating cases, taking specimens for laboratory testing or other activities in the surveillance system, they should refer to regional and country-specific guidelines and resources that outline the steps in these processes.

4.5 Reporting on VPD in your area

Report and record the number of confirmed cases of each VPD. These numbers can be displayed in each facility on a simple chart. If there are no cases of a disease during the reporting period, report a "zero," since it shows an absence of cases presenting to the health facility rather than a forgotten point in data collection.

4.6 The VPD tally sheet

VPD cases should be tallied when they are seen at a health facility or outreach site. The total number for each type of disease should be added for reporting to central levels. This is often done weekly or monthly in a summary form that includes a summary of vaccination status (see for example, the sample monthly summary form in Fig. 6.8). If there are no cases of a disease during the reporting period, report a "zero." Copies of this form may be made for daily or weekly tallies at health facility and outreach sites and then can be compiled for the monthly report.

4.6.1 Information commonly included in a VPD tally sheet

The VPD included in the tally should match the list of diseases that must be reported to national or central authorities. A case definition for each disease on the list should be obtained from the national or central level to help make the reporting more accurate. Age, sex and vaccination status of the patient are usually required. Health facility patient records (consultation registers) should be adapted as needed to allow space for this and other information required by national authorities.

4.6.2 How to use a VPD tally sheet

If cases of VPD are tracked in curative service (that is, patient care) tally sheets on a daily or weekly basis, take the numbers from the matching lines on these sheets to calculate the monthly tally, which is then used in the monthly summary report. If curative service visits are entered in a register without being added to tally sheets, review the consultation register for the total number of cases of each VPD each month. If no consultation register is kept, or if curative care for cases is done within immunization services, keep line lists for VPD as described in section 4.8 below and tally them for the monthly summary. Use the tally to review trends in cases of specific reportable diseases and proceed with reporting as required by country policy. Some diseases may need to be reported immediately on a case-by-case basis.

4.7 The disease-specific initial case report

Certain VPD require immediate investigation and reporting to the next higher level. If health facility staff encounter a suspected disease, they should consult national guidelines as to which suspected diseases should be investigated and reported on disease-specific forms, and within what time frame. Some diseases require immediate reporting and

investigation because the disease is prone to outbreaks and/or is near elimination or eradication (for example, measles and polio). It is critical to respond quickly to any such diseases to avoid outbreaks. Per national guidelines, some other diseases may need to be reported on a weekly or monthly basis.

Case definitions should be included in national guidelines, and staff should have access to forms showing all the information they need to complete disease-specific reports. Staff should also know who is responsible for receiving the report and how to contact them. If the same staff are responsible for conducting the case investigation, it is critical that they are familiar with the national guidelines for case investigation and the case investigation forms. Case investigation forms must be filled out completely: for example, the case investigation form needs to be updated with lab result information to ensure that the case can be appropriately followed up and that interventions can be conducted in the community, if indicated.

4.8 The line list

For certain VPD that need information for each case (case-based surveillance) and in specific disease outbreaks, suspected cases may need to be listed individually on a line list, with details of the history, including immunization status, management of each patient and other information. A line list usually includes the following information:

- unique case identification number (see note following this list);
- the patient's name;
- patient's address (for children, the address of the caregiver) and mobile/phone number, if available;
- patient's date of birth;
- patient's sex;
- date of onset of symptoms;
- date of first presentation to the health facility;
- vaccination status;
- relevant symptoms (based on the standard case definition of the disease);
- whether and when a specimen was collected;
- date and results of any laboratory confirmation tests (also based on the standard case definition);
- treatment given (may not be required for all diseases);
- final diagnosis and outcome.

Note: Each country should have a format for the unique case identification number – it typically includes codes for the year, country and district, and a number representing the order in which the case was identified. The last number is used to put the cases in order (for example, "1" for the first case registered, "2" for the second and so on). The same number should be used on follow-up visits for the same case. Do not enter the same case more than once, even if the patient returns to the health facility for follow-up. This case identification number is not linked to the immunization register or the AEFI cases.

Fig. 6.13 shows a sample line list for suspected measles cases.

Fig. 6.13 Sample of a health facility-level measles line list

Measles suspected cases

Health centre: **Date list started:**

District: **Date list ended:**

Row 1: Case ID Row 2: Last name, First name Row 3: Address/ contact details	# measles vaccine doses received	Possible source of infection[a]	Date of birth	Sex	Date of rash onset	Date of first visit to health centre	Symptoms (Y or N)				Lab specimen (date)	Type of specimen	Lab specimen results	Outcome[b]	Final classification[c]
							Fever	Cough	Coryza	Conjunctivitis					

[a] Possible source of infection = contact/relationship and/or Case ID number.

[b] Outcome: R = recovery; S = recovery with sequelae; M = mortality.

[c] Final classification: C = clinically confirmed; E = confirmed by epidemiologic linkage; L = laboratory confirmed; D = discarded.

4.8.1 How to use a line list

After determining that a case meets the standard case definition of a reportable disease, write or enter the case identification number in a new line and fill in all the items across the line for that case. The format of the line list may vary by disease and disease control activity requirements, but the column headings in Fig. 6.13 should serve as a guide to providing all the necessary information.

4.9 Analysis of VPD data

Surveillance data can be used to show trends and alert health authorities to possible outbreaks. Further analysis of the trends might include a breakdown of cases by area, or by age and sex, to better identify those at high risk and to define a targeted response. This type of analysis is often conducted at the district or more central levels but can begin with individual health facility data. It is critical that results of data analyses are shared with every level of the health system, and that these analyses are used to inform action down to the lowest level at which surveillance is conducted.

High-risk or most-affected areas in the health facility catchment can be identified simply by tracking cases on a map, as shown in Fig. 6.14. Cases can be marked on the district and health centre catchment area maps prepared for microplanning, as described in Module 4, section 2.

Fig. 6.14 Sample catchment area map showing location of measles cases in a two-month period

Each “x” represents one case

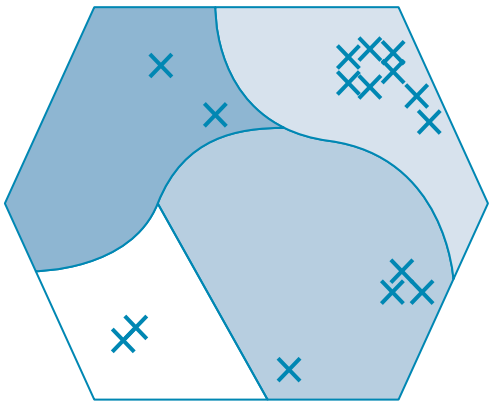


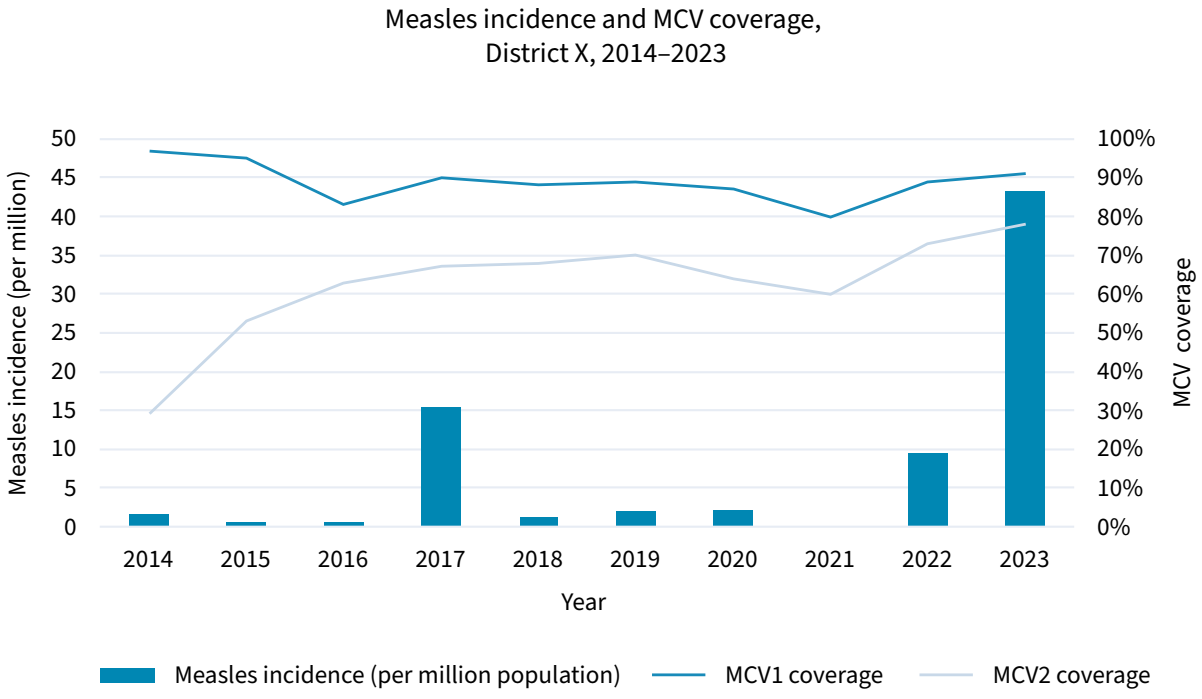
Fig. 6.15 is a sample chart showing the age and sex distribution of cases during an outbreak. These data are useful for evaluating an unidentified disease or an unusual pattern of a familiar disease (for example, measles cases occurring in older age groups).

Fig. 6.15 Sample chart of age and sex distribution of cases in a disease outbreak

Age	0–5 months	6–11 months	1–4 year	5–9 years	10–14 years	15–34 years	35–64 years	65+ years	Total
Male	1	1	0	0	5	26	15	3	51
Female	2	2	0	0	6	35	15	5	65
Total	3	3	0	0	11	61	30	8	116

Case data can be compared with immunization data to illustrate disease patterns or to evaluate the impact of control activities. Such comparisons are usually done over a longer time frame and from the district or higher levels using population-level measures (such as incidence). Accurately reported peripheral health facility-level data are needed for such analyses. Fig. 6.16 shows a sample graph comparing measles cases (charted as incidence per 1 000 000 people) with vaccination coverage over time.

Fig. 6.16 Sample comparison of immunization data with VPD incidence (for measles)



5 AEFI surveillance

5.1 What is an AEFI?

An AEFI is any untoward medical occurrence that follows administration of a vaccine; it does not necessarily have a causal relationship with the use of a vaccine. It may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. A reported adverse event can be an actual result of a vaccine and vaccination process or a coincidental event only temporarily associated with it. Table 6.3 describes cause-specific types of AEFI.

Table 6.3 Cause-specific categorization of AEFI

AEFI type	Definition
Vaccine product-related reaction	An AEFI caused or precipitated by a vaccine due to one or more of the properties of the vaccine product itself (for example, persistent screaming after DTP vaccination, anaphylaxis)
Vaccine quality defect-related reaction	An AEFI caused or precipitated by a vaccine due to one or more quality defects of the vaccine product, including its administration device, as provided by the manufacturer (for example, a potential for some vials to contain glass particles as a result of breakage during the manufacturing process, which may cause redness and swelling at the injection site)
Immunization error-related reaction	An AEFI caused by inappropriate vaccine handling, prescribing or administration, and thus preventable (for example, use of product after the expiry date, failure to adhere to sterile technique during vaccine administration, inappropriate procedure with a multi-dose vial)
Immunization anxiety-related reaction	An AEFI arising from anxiety about the immunization (for example, fainting in older children or adolescents during or after vaccination)
Coincidental event	An AEFI caused by something other than the vaccine product, immunization error or immunization anxiety (for example, febrile seizures following vaccination that are confirmed to be caused by malaria). Coincidental events may be predictable from background rates of health issues naturally occurring in the community (for example, fever reported incorrectly as an AEFI).

By seriousness and frequency, AEFI can be common, minor reactions or rare, more serious reactions:

- Common, minor vaccine reactions such as local site reactions, fever and systemic symptoms (for example, headache, myalgia, abdominal pain) can result as part of the immune response. They are usually short-lived and settle on their own.
- Serious reactions (for example, seizures, hypotonic-hyporesponsive episodes, thrombocytopenia) are very rare and, in general, do not result in long-term problems or death. Anaphylaxis, while potentially fatal, is treatable and does not have any long-term effects. While the terms “serious” and “severe” are often used as synonyms,

they do not mean the same thing. “Severe” is used to describe the intensity of a specific event, which may be of minor medical significance (for example, mild, moderate and severe headache). “Serious” is a term used to describe outcomes usually associated with events that are a threat to a person’s life or functioning.

5.2 What is AEFI surveillance and why is it important?

Surveillance of AEFI through systematic collection of data provides valuable information to improve safety and maintain public confidence in vaccines. The major goal of AEFI surveillance is early detection and appropriate and timely response to adverse events to minimize the negative impact on the health of individuals and on the immunization programme. Among the objectives of immunization safety surveillance is to ensure and facilitate causality assessment of serious (death, hospitalization, disability, congenital anomaly) and unexpected or unusual reported AEFI (see Fig. 6.17 for an illustration of the AEFI surveillance process). Improperly managed AEFI have the potential to derail immunization coverage in a country. Any vaccine safety issue, real or perceived, may lead to rumours and undermine confidence in vaccination, with significant consequences for vaccination coverage and disease occurrence. Health workers should be encouraged to report all AEFI that come to their attention. Ultimately, all relevant information on the AEFI should be communicated to the vaccine recipient or caregiver, the community, health staff and the media to maintain public trust in vaccines and immunization programmes. Detailed procedures for reporting, investigation and causality assessment of AEFI are described in the *Global manual on surveillance of adverse events following immunization*.

Fig. 6.17 The AEFI surveillance process

5.3 Roles and responsibilities of health workers in AEFI surveillance

For effective AEFI and immunization safety surveillance, participation of health workers at all levels of the immunization programme (including national, subnational and intermediate), and at the service provider level, is critical. The roles and responsibilities of the key players at various implementation levels of the AEFI surveillance system may vary depending on a country's operational structure and setting. This section provides an overview of roles and responsibilities for health workers at the provider level.

Table 6.4 describes the range of possible responsibilities for vaccinators with respect to AEFI surveillance. Vaccinators should always consult with their supervisors about their role in this area of surveillance.

Table 6.4 Responsibilities of vaccinators in AEFI surveillance

Detection of AEFI	Before the vaccination, tell the vaccine recipients and/or caregivers what adverse effects to anticipate, and ask the caregiver to inform them of any unusual symptoms following the vaccination. If a person who has received a vaccine needs treatment, provide it to them or refer them to the nearest health facility. When a patient visits a health facility, ask about previous vaccinations.
Recording of AEFI	Document all AEFI cases when notified of them, and enter all necessary data into the AEFI reporting form recommended by the country and any relevant registers. All necessary AEFI reporting forms should be supplied and available at the health facility level.
Reporting of AEFI	Routinely report the AEFI, as instructed in the AEFI reporting form. In the case of serious events (including death) or unusual AEFIs, immediately report the event by telephone to the next administrative and operational level.
Investigation of serious AEFI	Preliminary investigation may be done at this level after approval from a supervisor, if there is adequate capacity to carry it out. Conduct all investigations of reportable serious AEFI as specified in the national guidelines as early as possible and share findings with the appropriate administrative and operational level. For very serious cases such as deaths, investigation should be done in coordination with the national and subnational authorities, as outlined in the national guidelines.
Corrective actions	Base actions on the findings of the AEFI investigation. Actions at the provider level, particularly if relating to immunization error, should be taken immediately (for example, additional training, repair of cold-chain equipment, changing the local logistics, etc).
Analysis of AEFI	Depending on the existing capacity, analysis may be limited to basic variables. Keep separate line-listing and individual AEFI reports.
Communication of and public education about the findings of AEFI investigation and causality assessment	Communicate with caregivers and community according to the country's set procedure. Higher operational levels should keep health workers informed about the status of investigation, results and conclusions. While the public should be provided with timely and accurate information, communication with public and media should follow the country's standard operating procedures.

5.4 Reporting AEFI

The first important step in AEFI surveillance is case detection. The person who first notifies the health system about an AEFI (i.e. brings the event to the attention of the system) may be a vaccine recipient, a caretaker or an associated person who detects the AEFI (for example, hospital staff, health facility worker, volunteer). Health facility staff should then complete the AEFI reporting form and transmit the report onward manually (through a paper reporting form) or electronically (through electronic tools such as VigiMobile). The reporting chain may vary depending on the country's established reporting system. Suspicion alone is sufficient grounds for reporting, and the health facility staff are not expected to assess causality.

5.4.1 Which AEFI should be reported?

Health workers must immediately report the event (whether minor or serious) that is of concern to them or the person(s) who brought it to their attention. Events may include the following:

- all serious AEFI;
- unusual or new events associated with a newly introduced vaccine;
- AEFI that may have been caused by an immunization error;
- significant events of unexplained cause occurring within 30 days after vaccination;
- events causing significant parental or public concern;
- any other event of concern (for example, local reactions occurring at increased frequency, even if not severe).

National or central authorities should provide country guidelines with a list of reportable events or adverse events of special interest (AESI) unique to the national context and/or for new vaccines introduced, to be reported immediately, using the established procedure. Reportable events should have their standardized case definition, which serve for reporting purposes, not to prove causality. Reporting of minor AEFI such as fever or minor local reactions is optional; however, monitoring and recording crude numbers for minor reactions is helpful, to identify issues related to a particular batch of vaccine (for example, pain and swelling at the vaccination site, fever).

5.4.2 When to report an AEFI

An AEFI should always be reported as quickly as possible to allow for an immediate decision on the need for subsequent actions. In the case of clustered events or an event causing a high level of public interest and concern, it is appropriate for the health worker to urgently contact (via phone or email) a higher administrative or operational level.

5.4.3 How to report an AEFI

Health workers should use a standardized AEFI reporting form, recommended and authorized by the country health authority (see section 5.5). The AEFI reporting forms should always be available to health workers in paper format or accessible in electronic format or through tools such as VigiMobile. The way to forward the reports to a higher level should be communicated to health workers by their supervisors or programme managers through specific training and should be in accordance with the national procedure.

The AEFI data from all completed reporting forms (serious and non-serious) from health facilities should be line-listed at the supervisory level. The data should be periodically reviewed for clustering (with regard to place, time, vaccine administered) of all cases (serious and non-serious), or any unusual or significant reported events that may need further analysis.

Health workers should tally the AEFI reports by type for the monthly summary. The example given in Fig. 6.8 asks for the total number of serious and non-serious events during the month. National authorities should provide guidance on which AEFI should be included in which category in summary reports.

5.5 AEFI reporting form

The AEFI reporting forms should be straightforward (based on the 25 core variables recommended by WHO), to ensure easy input of essential information by health workers. Fig. 6.18 provides an example of an AEFI form proposed by WHO. It is important that health workers enter all the minimum required information on the form, as this is the basis for decisions regarding the need for further investigation.

Fig. 6.18 Sample AEFI reporting form

*** Patient's name or initials:**

*** Patient's full address:**

Telephone:

Sex: ☐ M ☐ F (Pregnant – Trimester I ☐ II ☐ III ☐ /Lactating ☐)

***Date of birth (DD/MM/YYYY):** ____ /____ /_____

OR Age at onset : ☐☐ Years ☐☐ Months ☐☐☐ Days

OR Age group: ☐ 0 < 1 year ☐ 1–5 years

☐ >5 years–18 years ☐ >18 years–60 years ☐ >60 years

AEFI reporting ID number:

***Reporter's name:**

Institution:

Designation & department:

Address:

Telephone & email:

Date patient notified event to health system (DD/MM/YYYY): ____ /____ /_____

Today's date (DD/MM/YYYY): ____ /____ /_____

Health facility (or vaccination centre) name

Vaccine							Diluent		
Name of vaccine (generic)	*Brand name incl. name of manufacturer	*Date of vaccination	*Time of vaccination	Dose (1st, 2nd, etc.)	*Batch/ lot number	Expiry date	*Batch/ lot number	Expiry date	Time of reconstitution

***AEFI**

☐ Severe local reaction ☐ >3 days ☐ beyond nearest joint

☐ Seizures ☐ febrile ☐ afebrile

☐ Abscess

☐ Sepsis

☐ Encephalopathy

☐ Toxic shock syndrome

☐ Thrombocytopenia

☐ Anaphylaxis

☐ Fever ≥38°C

☐ Other (specify) _____

Date and time AEFI started (DD/MM/YYYY): ____ /____ /_____ ☐☐ Hr ☐☐ Min

Describe AEFI (signs and symptoms):

***Serious: Yes / No** ⟶ If Yes ☐ Death ☐ Life threatening ☐ Disability ☐ Hospitalization

☐ Congenital anomaly ☐ Other important medical event (Specify _____)

***Outcome:** ☐ Recovering ☐ Recovered ☐ Recovered with sequelae ☐ Not recovered ☐ Unknown

☐ Died. If died, date of death (DD/MM/YYYY): ____ /____ /_____ Autopsy done: ☐ Yes ☐ No ☐ Unknown

Past medical history (including history of similar reaction or other allergies), concomitant medication and dates of administration (exclude those used to treat reaction) other relevant information (for example, other cases). Use additional sheet if needed.

First decision-making level to complete:

Investigation needed: ☐ Yes ☐ No If yes, date investigation planned (DD/MM/YYYY): ____ /____ /_____

National level to complete:

Date report received at national level (DD/MM/YYYY): ____ /____ /_____ AEFI worldwide unique ID:

Comments:

* Compulsory field

Source: Reporting form for AEFI [website], World Health Organization

5.6 AEFI investigation

The ultimate goal of an AEFI case investigation is to find the cause of an AEFI (that is, whether it was caused by the vaccine or vaccination process or is coincidental) or cluster, and to implement follow-up actions. Investigation of AEFI in a timely, comprehensive and methodical way followed by adequate communication are important to maintain public confidence in the immunization programme.

At the national level, criteria should be established to define the modalities of serious AEFI investigation. The technical units and authorities at the subnational and national level responsible for AEFI surveillance need to ensure that all serious reports requiring investigation are investigated adequately and in a timely way. While the investigators may be at different administrative and/or operative levels in various countries, the starting point for investigation is a completed AEFI reporting form, which helps in making a decision about the need for further investigation. Close communication between all levels and stakeholders in AEFI investigations is vital.

An AEFI investigation should be guided by the AEFI investigation form and should follow standard principles of epidemiological investigation (time, person, place), and should be prompt and complete. The investigator will need to focus on the reported reaction and patient, but will also have to examine storage, handling and administration of vaccine. If an error in the immunization process is identified, necessary corrective actions should be taken. However, the investigator should seek to identify system problems rather than blaming individuals. More information on AEFI investigations, including a sample AEFI investigation form, can be found in the *Global manual on surveillance of adverse events following immunization*. Practical guidance for preparing for an AEFI investigation can be found in *Aide-memoire on AEFI investigation*, and electronic tools to assist with AEFI investigation are available at the WHO website.

5.7 Analysis of AEFI data

At the service delivery level, health workers should line-list all reported AEFI data related to minor and serious AEFI cases, collated from the standard AEFI reporting form. Line-listing may help initial identification of clustering or any unusual or significant reporting events that need further analysis.

In addition, AEFI data need to be tabulated by place, person, time, vaccine and type of event. Filtering AEFI by different variables may indicate directions for further analyses. It also facilitates the identification of any common immunization errors. For example, an increased number of abscesses at the injection site reported from one vaccination post can likely be due to immunization error, and further investigation will be necessary to confirm causality.

Reports from the health facility level compiled at higher levels can be used for various analyses. These include analysis of vaccine reaction rates by specific vaccine, comparison of vaccine reaction rates with background rates (in unvaccinated individuals) and estimates of expected vaccine reaction rates in vaccinated individuals.

Analysis of grouped AEFI reports based on specific criteria can help health authorities clarify whether observed reaction rates are higher than expected and, if so, are more likely to be related to the vaccine than to coincidence in that specific group. This information can facilitate investigation of and response to serious AEFI.

WHO has developed information sheets on observed rates of vaccine reactions, which provide details on selected vaccines that are relevant to the analysis of reported events.

6 Supervising monitoring activities

6.1 Quick checklist for supervising activities

Every facility that provides immunization services should have basic planning and monitoring tools. The cost of reproducing and distributing these tools needs to be included in the local/national budget. Ideally, their provision to facilities is tracked though the logistics management information system.

All health facilities should have the following tools, which supervisors can use when monitoring the activities of the facility:

- a map of the catchment area
- a session plan for outreach and fixed sessions
- a workplan (updated every quarter)
- stock cards or book
- a cold-chain temperature log (if applicable)
- vaccination cards
- an immunization register
- tally sheets
- reporting forms
- a monitoring chart
- chart of reported cases
- a system for tracking defaulters.

A supervisory checklist, useful for supportive supervision, is provided in Annex 6.2.

6.2 Checking data quality

During the supervisory visit, supervisors should look for the following data quality problems and take action to improve the quality:

- coverage rates over 100% (may be due to a denominator problem or to overreporting);
- large month-to-month variations in doses, which may indicate either a programme issue (such as stockouts) or a data quality issue (such as incomplete or incorrect summary reports and tally sheets);
- discrepancy between doses that should be given at the same time (for example, DTP1 and OPV1, measles and yellow fever);
- discrepancy between the number of persons immunized and the number of vials used during the period;

- inconsistency between the number of vaccinations for each month across the different reporting tools (register, tallies, reports);
- large changes in the target population compared to previous periods (normally, target estimates should not differ significantly from year to year).

Bibliography

AEFI investigation assistance module [online application]. Geneva: World Health Organization (https://investigation.gvsi-aefi-tools.org/#step-1).

Aide-mémoire on AEFI investigation. Geneva: World Health Organization (https://cdn.who.int/media/docs/default-source/pvg/global-vaccine-safety/new-aide-memoire-aefi.pdf?sfvrsn=66340a11_4).

Brief overview of anaphylaxis as an adverse event following immunization (AEFI) and practical guidance on its identification, case management and response in a primary care setting. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/342195). License: CC BY-NC-SA 3.0 IGO.

Core variables [website]. World Health Organization (https://www.who.int/publications/m/item/core-variables).

Global manual on surveillance of adverse events following immunization. Geneva: World Health Organization; 2016 (https://iris.who.int/handle/10665/206144).

Home-based records [website]. TechNet (https://www.technet-21.org/en/topics/home-based-records).

Strengthening infection prevention and control in primary care: a collection of existing standards, measurement and implementation resources. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/345276).

VigiMobile [online application]. Uppsala Safety Monitoring Centre; 2025 (https://who-umc.org/pv-products/vigiflow/vigimobile/).

WHO vaccine reaction rates information sheets [website]. World Health Organization (https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/guidance/reaction-rates-information-sheets).

Annex 6.1. Common problems associated with poor access and utilization

	Examples of common problems	Examples of solutions: activities to be included in workplan
Supply quantity	Stockouts of vaccine(s), auto-disable syringes, diluents, safety boxes, immunization cards	• Request immediate supplies from district level • Review stock-recording system • Review vaccine usage and wastage rates and take appropriate action to address them, as necessary • Review methods of estimating needs
Supply quality	Expired, frozen or heat-exposed vaccine(s) in stock	• Review stock-recording system • Review methods of estimating needs • Review management of cold-chain equipment
Staffing quality	Some staff without recent training	• Inform supervisor and select subjects for "on-the-job" training/supportive supervision on practices such as: ◦ using auto-disable syringes ◦ new vaccines ◦ reading VVMs ◦ implementing MDVP
	Irregular supervisory visits	• Include supervisory visits schedule in district workplan
Staffing quantity	Vacant position of health worker, general staff shortage	• Inform supervisor and district authorities, and take steps for recruitment • Request temporary assignment from district level and consider volunteers for some duties • Ensure staff available for each session
Service quality and demand	Poor attendance at sessions and poor utilization in some areas	• Meet with the community to discuss possible reasons for low attendance and suggested solutions • Consult the community and change workplan to make sessions more convenient for the community • Check whether all planned sessions have been held; aim to improve reliability by holding all planned sessions • Screen all children for immunization whenever they visit the health facility, and give them all of the vaccines they are eligible to receive • Review use of true contraindications to ensure that children are vaccinated if at all possible
	Caregivers lose or do not bring immunization cards	• Set up a defaulter tracking system to keep complete records (register, reminder cards) at the health facility, and take these along during outreach sessions
	Caregivers fear AEFI; rumours that injection practices are not 100% safe	• Inform caregivers about benefits of immunization and reassure them about AEFI • Review safe injection practices: ensure supply of auto-disable syringes, use safety boxes and other safe disposal practices • Meet community members to discuss rumours • Review information on AEFI and how to report them

Annex 6.1 (continued)

	Examples of common problems	Examples of solutions: activities to be included in workplan
Service quantity and demand	Unreliable information about catchment population	• Request community help or rely on community health workers to list of all households, families, newborns • Map catchment area and make sure to include all populations • Compare population data from various sources including data from National Immunization Days (use the NID <5 population and divide by 5 for target of children <1)
	Inaccurate coverage data	• Check record-keeping and reporting systems for completeness • Review all tally sheets and reports
	Some areas distant and underserved	• Discuss with supervisor and organize mobile team approach from district/province • Discuss service with the communities and arrange adequate sessions, dates and times
	Transport, funding and logistics not available for some outreach sessions	• Identify which sessions were not held and why • Look for alternative transport for vaccinators to reach outreach locations (for example, public transport, sharing with other programmes) • Use data to advocate for appropriate resources (for example, to show how certain communities are underserved because of a lack of transport and logistics)
	Poor attendance at antenatal care clinics and/or poor tetanus toxoid (TT) 2+ coverage	• Promote value of antenatal care, including TT immunization during any contact with pregnant women • Inform the community about dates of antenatal care clinics. Find out if session timing or venue is inconvenient; if so make appropriate changes in next quarter's workplan • Use all opportunities to give TT immunization, including when mothers accompany infants for childhood immunizations

Annex 6.2. Supervisory checklist during visits to a health facility

Checklist	Explanation or action
A. Recording practices of routine immunization activities	
1. Are there tally sheets for children's vaccinations, and do they have entries for the last immunization day?	Main concern is regular use of tally sheet and monitoring session activities.
2. Are registers used for recording individual information about children's immunizations?	Each health facility should have a book or electronic system where each child's immunization history can be registered and traced back.
3. Are individual immunization cards used, updated and given to the caregiver at the time of the immunization visit?	Blank cards should be available in the health facility. Immunization cards are often integrated in "Road to Health" or other health cards. The original vaccination cards should be given to caretakers.
4. Can a child's vaccination history be easily and rapidly found in the health facility's books?	A new dose should be entered in the health facility's registers in the location where previous doses have been entered.
5. Is there a mechanism in place to track vaccine doses that are due or to track defaulters?	Check how the health facility knows when an infant should return for a vaccine dose.
6. Can copies of previous reports from this health unit be found in the health facility?	Copies of all reports from current and previous year should be available.
7. Are the health unit reports filled in correctly and completely?	Check whether reports have been filled in correctly.
8. Is the book for vaccine stock and syringe supply up to date?	Check the stock book against available stock (count doses in the refrigerator).
9. Observe a minimum of five vaccinations. Were all vaccinations correctly registered on the tally sheet, the health facility's register and the child's health card? Are caregivers told when the next dose should be received?	Check the tally sheet, the register and the card after immunization, and check the return date.
10. Are health staff aware of how to report an adverse event?	Ask health staff what is supposed to be done if an child becomes severely ill or dies after a vaccination. Ask them to show you any forms that are to be used for such events.
11. Is the cold-chain temperature-monitoring chart completed daily?	Check the chart and compare the latest reported temperature with the actual temperature in the refrigerator.
12. Is protected at birth status checked at the moment DTP1 is given?	Mothers of unprotected newborns should receive TT and be told when to get next dose. TT dose must be recorded on a vaccination card.

Annex 6.2 (continued)

Checklist	Explanation or action
B. Demographic information	
1. Does the health facility have data on the number of children born in its catchment area, and does it have a target set for the number of children that should be vaccinated during the calendar year?	Discuss any differences between denominators used in health facilities, districts and higher levels. Discuss ways to collect denominator information from the community (for example, birth register), campaign data or other sources. Discuss if the target was set up by the district or health facility level. Compare target to total population.
2. Does the health facility have a session plan, with a map showing the catchment area, including the outreach villages, and strategies for reaching populations (fixed, outreach, mobile)?	Check that the session plan shows how all the target population can be reached regularly. Pick a remote village from the map and ask the health facility when this village was last visited and will next be visited, according to a written plan.
C. Core outputs/analyses	
1. Does the health facility have an up-to-date chart or table (preferably on display) showing the number of vaccinations by reporting period for the current year?	Monitor that coverage chart is up to date and plotted correctly. Check if charts are available for DTP1, DTP3 and measles.
2. Is there a monthly chart/graph of VPD cases (broken down by VPD)?	Ask how these data correspond to coverage data (for example, whether there are more cases in areas with poor coverage). Ask when the last VPD outbreak was, whether it was investigated and why it occurred. If vaccinators have additional surveillance roles, supervisors should review surveillance elements, per country guidelines.
3. Is there a monitoring of drop-out rate?	Discuss the importance and reasons for drop-outs.
4. Is there a monitoring of vaccine wastage?	Discuss the reasons for wastage and any ways it might be reduced. Ask whether the multi-dose vial policy is being practised.
D. Evidence of using data for action	
1. Are areas of low access identified, and is there evidence of actions taken to deal with them?	If there is low access (evidenced by low BCG or DTP1 coverage) in certain areas, discuss what strategies are being used to reach these areas.
2. Have reasons for any high drop-out levels been identified, and are there plans/actions to deal with them?	Discuss whether there are any programmatic and/or managerial practices that can be changed.
3. Is there a standard system in place to follow up defaulting children (those who don't come back for subsequent doses)? When was the last time a child was followed up?	Ask whether the defaulter register is being used, and, if so, how. Are there reminder cards? Is the community informed? Are there follow-up visits?
4. Are there ever stockouts of vaccine or syringes? How are data used to prevent stockouts?	Discuss what action is being taken to obtain more supplies when stock levels go below the reserve level.
5. Is there interaction with the community regarding immunization? Ask for information on "what" and "when."	Determine whether health staff are actively involved in any community committees or meetings on health, follow-up of defaulters, investigations of outbreaks, addressing rumours of AEFI and so on.

MODULE 7

Building community support

About this module

This module on building community support provides recommendations to guide health workers and communities in working together to plan, provide and promote vaccination services, improve service quality and build resilient immunization programmes.

Strategies to build community support for vaccination will vary depending on local needs, context, resources and capacities. This module is based on general principles and best practices and is intended as a guide for contextualizing strategies at the local level.

Contents

1 Why engage with communities?

1.1 Introduction

Engaging with communities is essential in ensuring the success of public health services, as it fosters the building of community trust in the health system. In immunization programmes, community engagement is crucial in achieving high vaccine confidence and uptake. Actively involving community members in immunization planning and activities enables vaccination services to be more responsive to local needs, leading to improved vaccine uptake and increased trust in the immunization programme.

The Immunization Agenda 2030 (IA2030), a global strategy for vaccines and immunization, emphasizes people-centred approaches as one of its core principles *(1)*. Meaningful engagement of communities – both as a beneficiary and a valued resource – is essential in achieving IA2030's goals of equitable access to vaccines, reducing vaccine-preventable diseases and strengthening immunization systems.

1.2 What is community engagement?

Sustained engagement is essential in building community support for immunization. WHO defines "community engagement" as "a process of developing relationships that enable stakeholders to work together to address health-related issues and promote well-being to achieve positive health impact and outcomes" *(2)*.

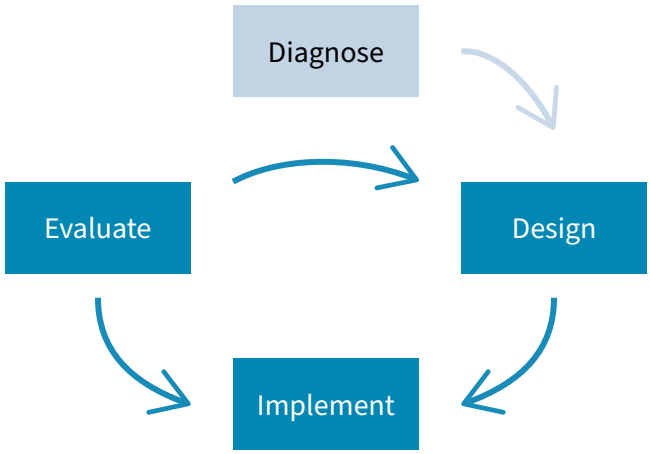
As the most trusted sources of health information, health workers influence vaccination decisions through their positive interactions with the community. Collaboration between health workers and communities in planning, providing and evaluating vaccination services builds and strengthens relationships. Meaningful engagement fosters community trust and ownership of the immunization programme and empowers local leadership, leading to wide acceptance of vaccination and increased vaccine uptake.

Community engagement aims to mutually benefit the community and the immunization programme. As beneficiaries, communities should receive accurate information, equitable access and quality vaccination services. As a valued resource, communities can provide critical insights and feedback to improve the immunization programme.

In this module, a "community" refers to a group of people defined by geography (such as a village) or affiliation (such as a religion or sector). "Communities" include individuals and groups such as civil society organizations and professional groups.

Community engagement must be integrated across immunization programme activities. The process of community engagement is iterative, and this module aligns with the four stages of the process cycle described in WHO and UNICEF, *Human-centred design for tailoring immunization programmes (HCD-TIP):* diagnose, design, implement and evaluate (see Fig. 7.1) *(3)*.

Fig. 7.1 The HCD-TIP process cycle



- **Diagnose:** Understand the community's needs
- **Design:** Plan with the community
- **Implement:** Involve the community in immunization activities
- **Evaluate:** Listen to community feedback and sustain collaboration

1.3 Benefits of sustained community engagement

Community engagement is at the heart of building people's trust and of their acceptance and use of vaccines. Immunization programmes should be designed and tailored to the needs and social and cultural preferences of people and communities.

Sustained engagement means that communities are well informed, actively involved and regularly consulted. It offers several key benefits:

- **Enhanced service quality and responsiveness:** Engaging with the community helps health workers understand the community's experiences and needs, which in turn informs tailored interventions.
- **Greater equity for underserved populations:** By building strong community links, health workers and communities can improve access to services for underserved populations.
- **Fostering community ownership and trust:** Involving community members in the immunization programme encourages them to take ownership and actively support their own and their community's health. When communities feel listened to and respected, trust in the health system is strengthened.
- **Resilience to vaccine-related events:** Engaging the community in service planning and delivery helps ensure their continued support during events that could affect

vaccine confidence and uptake, such as safety concerns, widespread misinformation or policy changes like vaccine withdrawal.

- **Community readiness to tailored strategies:** An engaged community can readily adopt and efficiently roll out activities beyond routine immunization. These may include new vaccine introductions, vaccination campaigns, catch-up vaccination and outbreak response immunization, among others.
- **Addressing inequities:** Engaging with the community can help identify and implement local solutions to overcoming inequities related to gender, socioeconomic status, geographic location, disability and ethnicity, among others.
- **Boosting health worker job satisfaction:** Collaborating on problem solving and celebrating shared successes with the community enhance health worker job motivation and satisfaction.

1.4 Roles of health workers in community engagement

Aside from delivering vaccination services, health workers can play key roles in community engagement through the following:

- **raising awareness:** educating communities on health issues, including health services such as vaccination and how to access them;
- **facilitating dialogues and collaboration:** bringing together diverse community sectors and stakeholders and creating opportunities for participation in the design, delivery and evaluation of vaccination services;
- **partnering with organizations:** collaborating with organizations to support capacity in implementing vaccination activities, including gathering of local data to inform planning;
- **advocating to leaders and officials:** raising awareness of local contexts to influence policy and decisions related to and support for vaccination.

1.5 Equitable community engagement

By fostering meaningful and inclusive community engagement, immunization programmes can address diverse equity barriers, ensuring that all people regardless of gender, socioeconomic status and physical ability, among other factors, have equal access to life-saving vaccines.

Gender-related barriers and other inequities can prevent people from getting vaccinated. These barriers impact vaccination demand, through people's willingness and ability to seek health care, and supply, in the design and delivery of health services.

Equitable and gender-responsive community engagement is crucial in overcoming these barriers. Understanding and addressing the different needs, concerns and preferred channels of all community groups are central to successful engagement. Communities must be actively consulted and involved, especially those in underserved areas, to ensure that their unique needs and preferences are reflected in the design and implementation of vaccination programmes.

2 Diagnose: understand the community

Understanding and building the support of the community for vaccination involves collecting and analysing data from various sources. Module 4 explains how to gather and use data to identify eligible populations and prioritize areas for vaccination. This is an important first step in microplanning.

Module 4, section 4 also highlights the importance of routinely collecting and analysing data on behavioural and social drivers of vaccine uptake. Data on behavioural and social drivers reveal reasons for low uptake and enable evidence-informed planning and measurement of the effectiveness of interventions.

When collecting and using data at a community level to guide local engagement strategies, it is important that women, men, girls and boys are equally consulted. A gender-responsive lens must be integrated in any situation analyses, assessments and plans.

This section supplements Module 4, providing further guidance on collecting and using available data at a community level to guide local engagement strategies with the communities themselves and to enhance their support for vaccination. Immunization programmes can facilitate these processes by developing capacity among health workers or engaging with partners (such as local academic institutions, community-based and civil society organizations) for data collection.

Health workers can approach such data collection in two main ways: by listening to community feedback or by systematically gathering data using a behavioural and social drivers of vaccine uptake survey, priority indicator questions or interview guides.

2.1 Identify community representatives

A community representative is anyone who is trusted and influential and represents the wider community's interests. Depending on the context, a rapid mapping of community representatives will offer adequate insight into their roles, influence and connections with respect to guiding planning and subsequent engagement activities. These representatives can be identified during microplanning as part of stakeholder analysis.

Community representatives can be drawn from:

- community health workers;
- local leaders (for example, elected officials, village chiefs);
- local health professionals (for example, doctors, nurses);

- religious groups and faith-based organizations;
- community groups (for example, mothers' or fathers' groups, women's groups, youth groups);
- civil society organizations, professional groups, parent-teacher associations;
- local groups associated with other areas of social and economic development (for example, agricultural extension workers);
- other key stakeholders and influencers in the community (for example, digital influencers, known personalities).

In particular, civil society organizations can provide essential support for mobilizing and informing communities, session logistics and defaulter tracking. Civil society organizations often provide services to marginalized and underserved populations and so can help ensure their participation in immunization and other health care services. Civil society organizations can also advocate for recognizing vaccination as a child's right and for programme financing at different government levels.

2.2 Listen to community feedback and narratives

Various tools can be used to facilitate ongoing listening to community feedback and narratives. Online and offline sources may be considered, including the following:

- **at the immunization site:** exit interviews, feedback boxes, community score cards;
- **in the community:** in-depth interviews, meetings to discuss immunization and other health services, rapid assessments, coverage surveys or online surveys in community groups;
- **through other channels:** websites, texts on mobile phones, hotlines.

In particular, it is important to identify common issues or opportunities to enhance vaccine service quality and/or to engage influential stakeholders based on insights from community listening and feedback systems.

Community feedback can also help identify common questions, rumours, beliefs or influence that are specifically relevant to the most disadvantaged populations. To gather community feedback, identify community representatives or leaders who may be closely involved in health advocacy, service provision and developing and disseminating information on vaccination. Insights gathered from community feedback will inform the interventions identified in section 3 of this module.

2.3 Gather local data

The tools on behavioural and social drivers of vaccination provide a structured way to collect, analyse and use data to implement and evaluate a wide range of interventions to increase vaccination.

Surveys or qualitative interview guides to better understand behavioural and social drivers of vaccination offer valuable insights to guide implementation and evaluation of

tailored interventions. At minimum, a short-form survey would consist of five selected behavioural and social drivers "priority questions" corresponding to "priority indicators" for use as a rapid survey or for integration into existing assessments or other monitoring activities. For the recommended list of priority indicators, consult *Behavioural and social drivers of vaccination*. A full survey may consist of 20 to 25 questions (see, for example, the behavioural and social drivers of child vaccination survey for caregivers shown in Fig. 4.7 in Module 4).

To further understand drivers or barriers to uptake, data may be disaggregated or stratified based on different demographic characteristics (such as sex, socioeconomic status or literacy level) or measures such as motivation for vaccination.

To complement survey questions on the behavioural and social drivers of vaccine uptake, in-depth interview guides provide a "deep dive" into specific issues for prioritized populations. The interview guides can be easily adapted and used by local leaders (for example, community leaders or subnational programme managers) as a basis for semi-structured conversations to better understand beliefs and experiences in relation to vaccination. A guide for in-depth interviews with community organizers about the behavioural and social drivers of childhood vaccination is shown in Fig. 4.8 in Module 4.

Routine tracking of data on behavioural and social drivers can provide insights on how to improve interventions to increase vaccine uptake. Data can also be triangulated with other programme data and insights sourced through community listening, digital listening and feedback systems to generate added insights. Continuous gradual programme improvements are possible, using comparable data on the behavioural and social drivers of vaccine for monitoring and evaluation.

Importantly, key findings from any community listening or data collection activity must be shared on a timely and regular basis with community representatives and local stakeholders in programme planning. If local communities are not connected to their own information and data, then there are limits to how they can contribute, support planning and share benefits from its future use.

3 Design: plan services with the community

Participation of community representatives in planning is a starting point for designing effective and sustainable interventions that are responsive to local needs and experiences.

3.1 Involve community representatives in planning

- **Invite selected representatives from the community and civil society organizations to serve as focal points in planning.** Use insights from the diagnose stage (see section 2 of this module) to identify community representatives who can best provide insights on the priority issues identified. A broader set of community representatives and volunteers can be engaged in the other activities described in the subsequent sections.
- **Brief the selected community representatives prior to the planning session.** Explain the purpose of planning and emphasize the importance of their insights and local knowledge in increasing vaccination uptake in their community. Share relevant background information, such as immunization coverage in local areas, to support their active participation in the proposed meeting.
- **Reach a joint understanding of the main causes of low uptake and explore solutions to address them.** Use key findings from community listening and data collection from the diagnose stage (see section 2 of this module) to further explore with community representatives the top reasons for low uptake. This interaction is important in further strengthening the community's ownership and the accountability of the collected information. Explore options for improved or new tailored interventions to address these reasons while considering the available resources. The range of tailored interventions are described in section 4 of this module.
- **Invite community representatives to provide input on improving service delivery.** Areas of discussion may include the following.
  - Service locations and schedules: Identify adjustments to the locations and times for services at both fixed and outreach sites to reach more children. Explore if special sessions (such as ones during evenings or weekends) are needed to accommodate caregivers who cannot attend during routine vaccination schedules.
  - Safety considerations: Adjust session schedules to accommodate seasonal changes (such as heavy rains, flooding or snow) or security issues that may impact access.
  - Integrated health services: Discuss the acceptability and feasibility of integrating immunization with other health services based on national guidelines and community needs, such as vitamin A supplementation, bed net distribution or deworming.
  - Defaulter tracing: Discuss the role of local leaders and volunteers in tracing children who are not on track with their vaccinations and in supporting them for timely vaccinations.

- **Define and agree on roles for the community.** Discuss the opportunities for the broader community to be involved in immunization (see section 4 of this module). Work with representatives on mobilizing community volunteers and agreeing on their roles. As appropriate, include budgeted activities in the plan, identify measures for monitoring and consider options for resource mobilization to support community engagement.

3.2 Engage community members in tailoring communication products

Design immunization materials, messages and interventions that are appropriate to the context and promote positive gender norms, roles and stereotypes. For instance, ensure that all immunization-related messaging and materials depict women as equal and active participants, not just as mothers and caregivers, and show men actively caring for children.

Choose communication channels and platforms that address differences in access that may be related to education and literacy, mobility, workload or social practices.

4 Implement: involve the community in activities

In the implement stage, a range of tailored activities may be carried out to support community representatives in contributing to increasing vaccination.

When identifying members of community engagement teams, it is crucial to consider factors related to equity, such as gender, disability, race and other characteristics, that may influence the inclusivity and effectivity of vaccination activities. Ensure that members of groups experiencing inequities are represented in community engagement teams, depending on local context.

It is also important to ensure that appropriate support systems are in place to enable effective implementation and to keep processes on track. These may include coordination mechanisms, regular review meetings, stakeholder check-ins, rapid listening or assessments.

4.1 Mobilize community representatives and volunteers

- **Prior to vaccination activities:** Brief the community representatives and volunteers to ensure that they are well prepared to engage with other community members effectively. During the briefing session, volunteers should:
  - feel safe to ask questions and have their own concerns addressed;
  - be oriented with respect to their roles and catchment areas;
  - receive key information, such as the location and timing of vaccination services, vaccines to be given, eligibility, answers to common questions and where to direct further inquiries;
  - receive relevant training (for example, on having meaningful conversations with those unsure of vaccinating) and supporting materials such as question and answer sheets and job aids.
- **After vaccination activities:**
  - Provide community representatives and volunteers with feedback on their support and inform them of other opportunities to assist.
  - Show appreciation for their efforts and provide incentives, if available. Note that, in addition to monetary incentives, non-monetary incentives such as certificates and public recognition may also be effective.
  - Gather feedback and consider these as inputs for future planning.

4.2 Engage community members in disseminating information

Community members can be involved in the following activities in disseminating information on vaccination.

- **Conduct home visits:** Health workers, community leaders, representatives and volunteers can organize into teams to conduct home visits prior to upcoming immunization sessions in fixed or outreach sites. During home visits, teams:
  - explain the importance and benefits of vaccination;
  - provide information on dates and times of the vaccination sessions, the location of the fixed or nearest outreach site, who is eligible to be vaccinated and what vaccines and other health services will be available;
  - remind caregivers to bring their child's immunization card on the vaccination day. The immunization card can be used as a teaching aid as well as a vaccination due-date reminder;
  - ask if there are questions and concerns. Respond to these questions and concerns or refer the questions to health authorities who are able to respond. If available, provide contact information for the local hotline where people can seek advice if questions arise after the visit.

- **Conduct community meetings:**
  - Community representatives and health workers can also work with local leaders to organize community meetings to discuss the items above and provide a safe space for questions and concerns. Annex 7.1 of this module provides some tips on conducting community meetings.
  - Traditional and religious community leaders can promote immunization and provide practical information, such as session locations and schedules, during community announcements and after religious services.
  - For school-based immunization, parent–teacher association (PTA) meetings or similar occasions can provide opportunities for health staff and community educators to remind caregivers about the importance of immunization and to relay practical information.

- **Engage in online conversations:** Encourage community members to:
  - share digital campaign materials, if available, within their networks;
  - share correct information and their own positive experience with vaccination;
  - participate in online conversations that promote vaccination, respond to questions where possible or direct questions to credible online resources.

  Gently remind community members not to engage with or share misinformation. Report to health authorities any rumour or misinformation that is increasingly being shared.

- **Share resources for information campaigns:**
  - Encourage local business owners to support information campaigns by printing cobranded materials or merchandise and/or posting information materials in high-traffic areas of their businesses.
  - Engage with community radio and local online journalism, if available, for programming and content on vaccination.

Addressing vaccine hesitancy and refusals: some suggestions

"Vaccine hesitancy" is a motivational state of being conflicted about, or opposed to, getting vaccinated. It may be influenced by questions and concerns that, when properly addressed, can lead to vaccine uptake. Proactively listening and understanding and then engaging with tailored strategies are important approaches in communicating with hesitant individuals.

For those who firmly refuse vaccination, share the key risks of not getting vaccinated while keeping the conversation short and positive. It is important to keep open the opportunity to engage with such individuals more strategically. Before sharing further information, ask if they are willing to learn more about vaccines. Additional approaches are to:

- demonstrate understanding of reasons for refusal;
- explore key influencers for the person's or sector's decision;
- engage with the identified influencer(s) (for example, a local religious leader) to gain their support for vaccination;
- encourage the influencer(s) to share accurate information, dispel myths and promote vaccine acceptance with those who refuse.

4.3 Link communities to services

Community members can play a crucial role in connecting communities to vaccination services through a range of activities. As a vital first step, reminders of the importance of vaccination and service delivery locations are essential.

Added actions for community members may include the following:

- **Identifying target populations:** Work with health workers to identify children, mothers, newborns and pregnant women needing immunization, especially among new entrants to the community. Ensure that they are added to the immunization registers.
- **Identifying missed children and defaulters:** Keep track of new and defaulter children and other eligible populations who need to complete immunization series, and help them make the necessary connections to vaccination services.
- **Improving access by providing transport options:** Facilitate transport options for families and health workers to vaccination sites, especially in remote or underserved areas. This can include organizing community transport or coordinating with local services to provide rides.

- **Addressing refusals:** Work with health workers to identify trusted community influencers who can help understand and address vaccine hesitancy. These influencers can listen, determine the causes of hesitancy and respond as appropriate (for example, share accurate information, dispel myths and encourage vaccine acceptance). In places where resistance to vaccination is based on traditional or religious beliefs, it is essential to engage religious leaders, since their cooperation is usually needed to help improve acceptance of services.

4.4 Support vaccination sessions

The community can play an important role in supporting vaccination before, during and after an immunization session.

- **Before immunization sessions:**
  - Help with community announcements: Use practical and locally appropriate methods, taking into account specific needs and preferences of women and men, boys and girls to inform the community about vaccination (methods may include SMS alerts, whistles, horns, drums, megaphones or loudspeakers). If outreach or facility-based services are postponed or rescheduled, communicate these changes promptly. Timely communication helps maintain public confidence and service usage.
  - Assist in organizing the vaccination site: With the guidance of health workers, help set up the vaccination area, ensuring it is comfortable, organized and welcoming. Arrange seating, manage crowd-control measures and set up information booths or areas for educational materials.
- **During and after vaccination sessions:**
  - Assist with flow: Help manage the flow of caregivers and vaccine recipients to ensure that the process is smooth and orderly, which helps reduce waiting times. This includes directing people to waiting areas and the vaccine-administration area, and ensuring that they follow safety protocols.
  - Provide health education: Share information with caregivers in the waiting area about the benefits of vaccines, potential side effects and the importance of returning for follow-up doses. Use local languages and culturally appropriate methods to communicate effectively.
  - Record data: Assist health workers in maintaining and filing records. This involves updating registries and ensuring that all data are correctly entered.
  - Conduct exit interviews: Collect feedback from caregivers as they leave the health facility or outreach site. This feedback can provide valuable insights into their experience and help identify areas for improvement. Studies show that empowering community members to get involved in monitoring the performance of vaccination services for children in their communities is an effective approach to improving the quality of service.
  - Following-up on defaulters: To facilitate tracking and completion of schedules, appointed community focal points may liaise with health workers for a list of those who missed vaccination (defaulters) and are eligible for vaccination at the next session.

4.5 Report diseases

Community members can contribute by identifying and referring suspected cases of reportable vaccine-preventable diseases (VPD) to their local health facilities (see Module 6). Health care facilities should provide clear aids to support this function.

5 Evaluate: listen to community feedback and sustain collaboration

5.1 Facilitate feedback from communities

Section 2 of this module provides details on various tools for gathering community feedback, such as exit interviews, feedback boxes, score cards and hotlines as well as structured surveys and interviews on the behavioural and social drivers of vaccine uptake.

Community feedback can identify health workers' practices that may affect a community member's service experience, encouraging health workers to engage in the most useful practices and modify those that community members perceive as unhelpful. It can also highlight health system problems that result in missed opportunities, leaving children unvaccinated. Examples of system-level problems include:

- too many attendees at a session, leading to long wait times;
- too few attendees at a session, leading to a sub-optimal use of time and resources;
- vaccine stockouts;
- restricted dates, times and/or location for vaccination sessions;
- health workers postponing vaccination of a mildly ill child or hesitating to give multiple injections at the same visit.

Health staff can immediately address such problems when they are identified, discuss issues further with community representatives in planning sessions and provide feedback on planned and achieved improvements.

5.2 Keep community representatives and the broader community updated

Health workers should provide regular feedback to communities to promote ongoing participation and sustained engagement. Community meetings should be established as a routine practice (for example, quarterly) and before and after significant immunization activities such as campaigns, introduction of new vaccines or responding to vaccine-related events.

Below are some examples of what to include in community engagement activities.

- **Share immunization programme updates:** Include information on immunization coverage, drop-out rates and cases of VPD in the community or district. Include updates on any new vaccination policies, or changes to existing ones, and their implications for the community.
- **Share success stories:** Aside from sharing data, use storytelling to highlight how coverage goals have been met, fostering community pride and ownership in these achievements. Additionally, documenting success stories is important in leveraging past experiences to guide future planning.
- **Reiterate shared goals:** Emphasize the goals of the immunization programme and the community in improving coverage and reducing the incidence of VPD, and encourage ongoing participation.
- **Acknowledge contributions:** Use feedback meetings to acknowledge and thank the community for their contributions. This includes recognizing the efforts of community health workers, community representatives, volunteers and caregivers.
- **Share updates on actions taken in response to previous feedback:** Inform the community about actions taken and improvements made in response to their previous feedback. This demonstrates that their inputs are valued and acted upon.
- **Share new insights and narratives arising from recent feedback and local data:** Discuss the alignment of feedback and local data with their experiences, illustrate specific ways that these data will be used to further improve vaccination services, and reinforce the commitment to continuously enhance service quality.
- **Gather further feedback:** Use meetings to discuss what went well, what challenges were faced and how to improve future sessions. Encourage open dialogue to gather different perspectives.

Use insights from these discussions to inform the next planning session. This helps sustain community engagement and ensures that planning is responsive to community needs. Identify and involve community representatives who can participate in future planning sessions. Their ongoing involvement ensures that the community's voice continues to be heard.

5.3 Build commitment of local leaders

Update local officials and other relevant community leaders, including civil society organizations, on the vaccination status of the community, especially areas with low uptake, cases of VPD, potential for outbreaks, issues needing attention and needed resources. Advocate for support, as local resources may be available to help address these issues.

References[1]

1. Immunization Agenda 2030: a global strategy to leave no one behind. Geneva: World Health Organization; 2020 (https://www.who.int/publications/m/item/immunization-agenda-2030-a-global-strategy-to-leave-no-one-behind).

2. Community engagement: a health promotion guide for universal health coverage in the hands of the people. Geneva: World Health Organization; 2020 (https://iris.who.int/bitstream/handle/10665/334379/9789240010529-eng.pdf).

3. World Health Organization and United Nations Children's Fund (UNICEF), Human-centred design for tailoring immunization programmes (HCD-TIP). Geneva: World Health Organization; 2022 (https://iris.who.int/handle/10665/354457).

Bibliography

A practical guide to identifying, addressing and tracking inequities in immunization. Copenhagen: WHO Regional Office for Europe; 2024. Copenhagen: WHO Regional Office for Europe; 2023. (https://iris.who.int/bitstream/handle/10665/378201/WHO-EURO-2024-9917-49689-74446-eng.pdf).

Behavioural and social drivers of vaccination: tools and practical guidance for achieving high uptake. Geneva: World Health Organization; 2022 (https://iris.who.int/handle/10665/354459).

Why gender matters: immunization agenda 2030. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/351944).

World Health Organization. Conversations to support vaccine uptake; 2025. (https://www.technet-21.org/en/topics/programme-management/uptake).

World Health Organization. Helping people get vaccinated: quick tips for community representatives; 2024 (https://www.technet-21.org/en/resources/tool/quick-tips-for-community-representatives-2).

[1] All references were accessed on 23 October 2025.

Annex 7.1 Conducting community meetings

Community meetings allow everyone's voice to be heard, concerns raised and issues addressed together. It is important to keep meetings as a safe and collaborative space. The following recommendations apply to meetings with community representatives or the broader community. Adapt them as needed for the local context.

Scheduling the meeting

- Propose the meeting to community representatives, explaining its purpose. Invite their suggestions on the best time and place and on other community members to be invited. Ensure representation from various community sectors, as applicable.
- Through discussions with community representatives, agree on the meeting objectives, the duration of the meeting and who will be the facilitator or facilitators (a health worker and a community representative can jointly facilitate).
- For broad community meetings, ask community representatives to inform others about the meeting and let them know what will be provided (for example, health education materials, snacks).

Setting the meeting

- Choose a venue conducive to collaborative discussions, with good ventilation, lighting, minimal distractions and accessibility for persons with disabilities.
- Arrange seating in a circle or similar setup where participants can see each other. Facilitators should sit on the same level as the participants.
- Encourage active participation from all attendees. Having separate meetings for men and women may be more culturally appropriate in some settings.

Facilitating the meeting

- Open the meeting by thanking attendees and acknowledging their commitment to their community's health. Emphasize the importance of their participation and assure them that all opinions are welcome without judgement.
- Explain the objectives and timing of the meeting. Emphasize the shared goal of improving immunization services and protecting the community from VPD.
- If appropriate, assign note-takers from both the community and health services.
- Speak clearly, avoid jargon and use the participants' preferred language. Confirm understanding and encourage questions.
- For issues raised, brainstorm ideas for solutions and reach an agreement through informal voting, if needed.
- Before closing, ask volunteers to summarize key points and commitments. Review follow-up actions for both health services and the community.

- Thank everyone for attending and participating, and remind them of the next meeting scheduled, if applicable.

After the meeting

- Finalize and disseminate the meeting notes, if applicable.
- Monitor the implementation of the commitments made during the meeting

For further information please contact:

World Health Organization
20, avenue Appia
CH-1211 Geneva 27