IMMUNIZATON HANDBOOK 2022

For Health Care Professionals

REVISION 2

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National Immunization Program

Health Protection Agency

DISCLAIMER

This Immunization Handbook, which has been prepared for, and is published by, the Health Protection Agency, Ministry of Health, is for the assistance of those involved in providing immunization services in Maldives. While the information and advice included in this handbook are believed to be correct, no liability is accepted for any incorrect statement or advice. No person proposing to administer a vaccine to any other person should rely on the advice given in this handbook without first exercising his or her professional judgement as to the appropriateness of administering that vaccine to another person.

THE CONTRIBUTORS- REVISION 2 (2022)

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Ministry of Health
Republic of Maldives

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Maldives

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CONTENTS

FORWARD

This handbook has been designed to provide comprehensive information on immunization, to support those involved in vaccination in the Maldives.

In order to provide up to date information, in a rapidly expanding environment in the immunization field, this booklet is a new version to the previous edition of the immunization handbook has been revised. As the epidemiological pattern of the VPD has changed over the years and more cost-effective vaccines are available, this edition includes updated immunization schedule, catch-up schedule and updated information on vaccine cold chain.

This new edition of the Immunization Handbook by National Immunization Program is aimed to help health professionals to provide quality immunization services. Producing such a publication was possible through the dedication and voluntary time commitment on the part of those involved. I would like to extend my sincere thanks to all the contributors for completing this very important and timely task.

Maimoona Aboobakuru

Director General of Public Health

MAIN SOURCES

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01

IMMUNIZATION PROGRAM IN MALDIVES

IMMUNIZATION PROGRAM IN MALDIVES

The Republic of Maldives is highly committed to provide basic health services to all with special emphasis on children and women. The National Program on Immunization is considered a successful program in Maldives, because of its remarkable progress made during the past 25 years. The NPITH is a universal programme and its goal is to protect the life of under five children from premature death and disability from vaccine preventable diseases.

The NPITH was launched in 1976 as the National Expanded Program on Immunization (EPI) with financial support from Danish Scout Aid DENMARK and technical support from WHO. This program was initiated with the implementing of six antigens to prevent Diphtheria, Whooping cough, Tetanus, Poliomyelitis, Tuberculosis and Measles

The Republic of Maldives officially launched the Expanded Program on Immunization (EPI) in 1985 and was intensified throughout the islands and atolls and immunization service was made available to all target groups (infants and pregnant mothers) by 1988. The program also aims at women of childbearing age (CBA) and pregnant women to give TT vaccine against maternal and neonatal tetanus.

Hepatitis B vaccine was introduced in 1993. Measles vaccine was replaced by MR vaccine in 2006 and followed by MMR in 2007. Pentavalent (DTP- HepB- Hib) vaccine started at national level in 2013. TT vaccine was replaced by Td vaccine in 2015. „ IPV introduced in 2015.

Similarly, Government of Maldives introduced one dose of IPV into routine immunization schedule on April 2015. Type 2 components of OPV were withdrawn on 18 April 2016 by switching from tOPV to bOPV as a part of global switch.

1.1 KEY ACHIEVEMENTS OF THE IMMUNIZATION PROGRAMME IN MALDIVES

The immunization programme in Maldives has grown over the years, various new vaccines have been introduced and many mile stones achieved. The health workers in the field, continuously contribute to making these milestones and sustaining them. See Table 1 below to know how the system evolved and some important activities and events in immunization.

Table 1: Key Achievements of the Immunization

Year	Details
1967	Immunization in Maldives started
1972	BCG introduced
1972	TT for pregnant women
1983	Measles vaccine introduced
1991	OPV introduced
1993	Hepatitis B vaccine introduced

Table 1: Key Achievements of the Immunization

Year	Details
2000	Polio free status achieved in Maldives
2003	Monthly vaccination sessions started at island level
2005	• Measles two doses introduced to children • MR campaign with target age group of 6-12 year Males and 6-35 years females
2006	• MR campaign with target age group of 6-12 year Males and 6-35 years females • Injectable Cholera Vaccine replaced by Oral Cholera Vaccine • EPI review conducted
2007	• MMR mop up campaign for school entry • MMR introduced
2008	• EPI guideline developed • Comprehensive multi year plan developed • EPI coordination committee formalized (NCIP/MTAGI)
2010	H1N1 vaccination for high risk groups
2012	• AEFI and pentavalent guideline developed • EPI review conducted
2013	Pentavalent vaccine introduced into National Schedule
2014	• Travel vaccine brings under immunization mandate • Web based Vaccine Stock supply management (wVSSM) introduced
2015	• TT vaccine replaced with Td • IPV vaccine Introduced • MTAGI charter finalized (2015-2018) • Polio free status achieved along with SEAR – 27.03.2014 • National Committee for Certification of Poliomyelitis Eradication and Verification of Measles, Rubella/CRS Elimination (NCCPEVMR) ToR finalized
2016	• Switch from tOPV to bOPV • cMYP for immunization developed (2016-2020)
2017	• Measles vaccine replaced with MR (27th April) • MR Campaign with a target of children age 8-14 years who have not received two doses of MCV and vaccinate all adolescents and young adults in the age group of 15-25 years.
2018	DPT booster vaccine introduced to the routine immunization schedule in 12th December for 4 years old children
2019	• HPV vaccination Campaign with a target of girls who are age 10-14 years old. 2 doses given six months apart. (21st March 2019) • Introduction of HPV vaccine to national Immunization schedule (for 10 year old girls- 2 doses given at six month apart) (01st July 2019)

1.2 GOALS OF IMMUNIZATION PROGRAMME

- National Immunization Program aims to reduce mortality and morbidity by protecting children from the vaccine preventable diseases.

1.3 OBJECTIVES AND STRATEGIES OF NATIONAL PROGRAM ON IMMUNIZATION (EPI)

- National Immunization Program aims to reduce mortality and morbidity by protecting children from the vaccine preventable diseases.

1.4 OBJECTIVE OF IMMUNIZATION ACHIEVEMENT:

- Strengthen routine immunization services to achieve 100% coverage for all EPI antigens at National level.
- Target to achieve 100% Td coverage among women of child bearing age.

1.5 OBJECTIVES OF DISEASE REDUCTION:

- Control Tuberculosis, Diphtheria, Pertussis, Hepatitis-B, Mumps and Hemophilus Influenzae-B
- Maintain Polio free status
- Sustain Maternal Neonatal Tetanus elimination (MNTE) Status
- Sustain Measles elimination status
- Sustain Rubella elimination status.

1.6 STRATEGIES FOR ACHIEVING OBJECTIVES:

• Development of EPI Micro-plan in all Atolls addressing the following components and its effective implementation:
- Organization of EPI sessions and main-taining quality
- Planning and Implementation based on monitoring and data analysis
- Planning and management for utilization of human and other resources
- Planning for supportive supervision
-Involvement of Community to imple-ment EPI work plan

• Safe Injection practice and safe disposal of sharp waste and expired / unused vaccine disposal

• Strengthening management of Adverse Events Following Immunization (AEFI)

• Strengthening Disease Surveillance

• Special Immunization Activities like SNID/NID, Measles/MR Campaigns when necessary

1.7 IMMUNIZATION SCHEDULE

Table 2 shows the 2022 National Immunization Schedule

Route of Injection	Dose	Dieseases Prevantable	Vaccine	Eligible Age
Intraderma (Deltoid)	0.05 ml	Tuberculosis	BCG	At Birth
Intramuscluar (Lateral Thigh)	0.5 ml	Hepatitis B	HEPATITIS B 0	
Oral	2 drops	Poliomyelitis	bOPV1	2 months
Intramuscluar (Lateral Thigh)	0.5 ml	Diphtheria, Pertussis, Tetanus, Hepatitis B & Hib	PENTAVALENT 1	
Oral	2 drops	Poliomyelitis	bOPV2 (Poliomyelitis)	4 months
Intramuscluar (Lateral Thigh)	0.5 ml	Diphtheria, Pertussis, Tetanus, Hepatitis B & Hib	PENTAVALENT 2	
Oral	2 drops	Poliomyelitis	bOPV3	6 months
Intramuscluar (Lateral Thigh)	0.5 ml	Poliomyelitis	IPV (Poliomyelitis)	
Intramuscluar (Lateral Thigh)	0.5 ml	Diphtheria, Pertussis, Tetanus, Hepatitis B & Hib	PENTAVALENT 3	
Subcutaneous (Lateral Thigh)	0.5 ml	Rubella & Measles	Rubella Measles	9 months
Oral	100000 IU	-	Vitamin A 1	
Subcutaneous (Lateral Thigh)	0.5 ml	Measles, Mumps & Rubella	MMR (Measles, Mumps & Rubella)	18 months
Oral	200000 IU	-	Vitamin A 2	
Intramuscluar (Deltoid)	0.5 ml	Diphtheria, Pertussis & Tetanus	DPT Diphtheria, Pertussis & Tetanus	4 years
Intramuscluar (Deltoid)	0.5 ml	Cervical Cancer	HPV (Human Papilloma Virus)	10 years (girls only)

1.8 CATCH UP SCHEDULE

Table 3 shows the Travel Vaccination Catch up Schedule

Anitigen		Age of 1st Dose	Doses in Primary Series	Minimum Interval between doses	Interrupted Primary Series	Doses for those who started vaccination late	
						Below 12 months	Above 12 months
BCG		As soon as possible after birth	1 dose	NA	NA	1 Dose (if not given at earlier)	1 dose (For unvaccinated TST- or IGRA-negative older children, adolescents and adults from settings with high inci dence of TB and/or high leprosy burden and those moving from low to high TB incidence/ leprosy burden settings)
Hepatitis B		At birth or as soon as possible within in 24 hrs	Birth Dose <24 hrs	4 weeks	Resume without giving previous dose.	*if child presents at <2 months give Hep B single dose f/b Penta 3 doses wihth minimum interval of 4 weeks. *if child presents at >2 months of age, start with pentavalent 3 dose series with minimum interval of 4 weeks	3 doses as Pentavalent if age is less than 6 years. if >6yrs give hepatitis B seperately as 3 doses with 4 weeks between 1st and 2nd and minimum 6 months between 1st and 3rd dose (0,1,6 months)
Polio	OPV	2 months	3 doses (2,4,6 months)	4 weeks	NA	3 doses	3 doses
	IPV	6 months	1 dose (6 months)	NA	NA	1 dose	1 dose
Pentavalent (DPT+Hep B+Hib)		2 months	3 doses (2,4,6 months)	4 weeks	Resume without giving previous dose.	3 doses	3 doses with intervals of 2 months between 1st, 2nd & 3rd dose after 6 months from 1st dose (0,1,6 months) (if 6-7 years of age use TD, if >7 years use Td)
Measles/MR		9 months	1 dose	NA	NA	1 dose	1 dose (if less than 18 months) Use MMR 2 doses 4 weeks apart (if age more than 18 months and not received measles)

MMR	18 months	1 dose	NA	NA	NA	1 dose of MMR, (if recieved measles) 2 doses of MMR at 4 weeks interval (if not recieved measles by age 18 months)
DPT Booster	4 years	1 dose	NA	NA	NA	1 dose (If 6-7 years of age use TD, if >7 years use Td)
HPV	10 years (girls only	2doses (0,6 months)	5 months	resume without repeating previous dose	NA	2 doses of HPV at 6 months interval (if below 15 years) 3 doses at 0,1,6 months (if above 15 years)

1.9 TRAVEL VACCINATION

Table 4 shows the Travel Vaccination

Vaccine	Number of Doses	Route of Administration	
Oral Polio Vaccine	1 dose (2 drops)	Oral	Annually
Meningitis	1 dose (0.5 ml)	Intramuscular	Once every 3 years (depends on the manufacturer)
*Yellow Fever	1 dose (0.5 ml)	Intramuscular	Once in a lifetime
Seasonal Influenza	1 dose (0.5 ml)	Intramuscular	Annually
*Oral Cholera	** 1 dose (0.5 ml)	Oral	Once in every 6 months

* Travelers traveling to endemic countries
**As primary dose 3 doses are given to children between 2-5 years

02

GENERAL IMMUNIZATION PRINCIPLES

GENERAL IMMUNIZATION PRINCIPLES

It is necessary to have knowledge of the immune system to understand the first principles of vaccinology. The immune system is an extremely complex inter-connected system, but understanding certain aspects involved in the process of inducing specific immunity through vaccination inform vaccination practice.

As protective immunity develops over time, the timing of vaccine doses, along with a basic understanding of the different types of vaccines, becomes important.

2.1 IMMUNITY AND IMMUNIZATION

Immunity is the biological state of being able to resist disease or a toxin: the primary objective of vaccination is to induce an immunological memory against specific diseases, so that if exposure to a disease-causing pathogen occurs, the immune response will neutralize the infection or toxins it releases before disease can occur.

2.1.1 IMMUNE RECOGNITION

One of the primary ways in which the immune system achieves elimination of pathogens and other unwanted foreign material is being able to distinguish 'self' from 'non-self'. Each cell in the body is equipped with a type of molecule that identifies the individual from any other, much like a 3D barcode. Pathogens not only lack the individual's 'self' marker, they also contain 'virulence factors' that alert the immune system to danger.

Antigens (antibody generators) are the drivers of the specific immune response. Antigens are molecular shapes, such as part of a protein or glycoprotein, that the immune system recognises as foreign and can trigger an adaptive immune response. While some vaccines contain the entire weakened or attenuated organism (live viral vaccines like measles, mumps and rubella vaccines), increasingly, newer vaccines contain purified or recombinant protein antigens (as in acellular pertussis, HPV or pneumococcal vaccines).

The first process that occurs when a foreign antigen, such as a vaccine antigen, is introduced to the body is the recognition that the antigen is non-self by triggering an inflammatory response. The antigen is taken up at the local site (such as the injection site) by specialist phagocytic cells called antigen-presenting cells – macrophages and dendritic cells. Once inside the antigen-presenting cells, the foreign protein (or microbe) is dismantled into tiny fragments that are displayed on cell surface alongside a 'self' molecule. These antigen-presenting cells carry the antigen to through the lymph to the local lymph node where the adaptive immune response is initiated.

2.1.2 INDUCTION OF THE ADAPTIVE IMMUNE RESPONSE

The response that occurs the first time an antigen is 'seen' by the immune system is called the primary immune response.

The adaptive immune responses occur in lymphoid tissue, primarily in the spleen and in the 500–600 lymph nodes distributed throughout the body.

The adaptive immune response to most vaccines occurs at the draining lymph node proximal to the site of injection. The spleen and lymph nodes are densely populated with important effector lymphocytes of the immune response: T-cells and B-cells. In the lymph node, the vaccine antigen is presented to the specific T-cells and B-cells.

Among the trillions of specific T and B lymphocytes (there are ~1016 possibilities), there usually exists a match for the antigen. Cells that recognize the antigen are activated through communication with the antigen presenting cell and the primary immune response can be initiated. This process and the response matures over a period of four to six weeks.

An early outcome of the interaction between these antigen-presenting cells and T and B lymphocytes is the production of antibody-producing B-cells. Antibody can be measured in the blood as soon as 4–7 days after this interaction, but is usually more effectively measured weeks to months later. Initially, this is low in quantity and of low affinity for the antigen (it binds weakly to the antigen), and primarily consists of the antibody subtype immunoglobulin M (IgM), often referred to as 'early antibody'. It peaks at around 10 days then declines relatively quickly (see Figure 1.1).

For most vaccine-preventable diseases this process is too slow following infection, and disease occurs before an effective immune response can be mounted. Injecting a part or a weakened version of the pathogen in the form of a vaccine, readies the immune system so that it can mount a more rapid and effective response when the wild disease is encountered.

2.1.3 DEVELOPMENT OF IMMUNE MEMORY AND THE SECONDARY RESPONSE

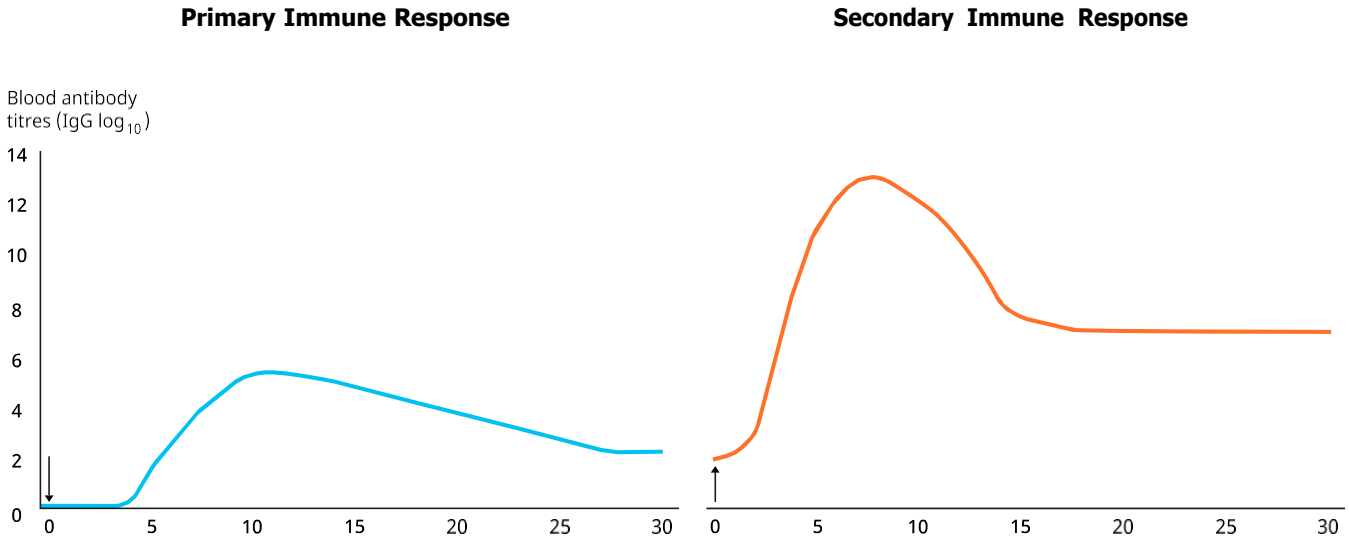
The response that occurs the second time an antigen is 'seen' by the immune system is called the secondary immune response.

During the primary immune response, over a period of around two months, cells that are less specific for the specific antigen are deleted, and those that are highly specific are retained and multiply within the lymph node. Antibody production also switches from IgM to more specific IgG or IgA subtypes. During this time immunological memory cells also develop, but it takes around four months, after the initial antigen is cleared, to fully form immune memory.

The next time the same antigen is introduced, either as a pathogen component or as a further dose of vaccine, the immunological memory cells that recognise it will be activated and begin to proliferate. Highly specific antibody (primarily of the IgG subtype, but also IgA) is rapidly produced in large amounts. The lag phase is much shorter than the primary immune response (see Figure 2.1), at just 1–4 days; the antibody level peaks very quickly and lasts much longer.

The immune system has been readied by the vaccine; if the actual disease pathogen enters the body, then it is recognised promptly and neutralised by the immune system preventing it from causing disease.

Figure 1: Comparison of primary and secondary immune responses to proteincontaining vaccines

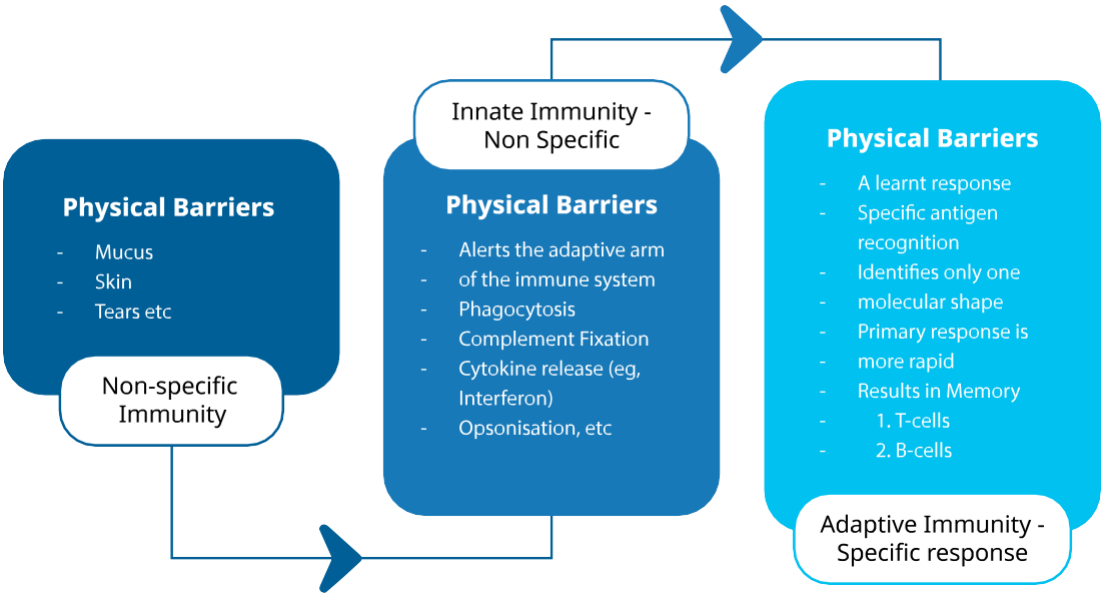


INNATE IMMUNITY

Most infectious microbes (also known as micro-organisms) are prevented from entering the body by barriers such as skin, mucosa, cilia and a range of anti-microbial enzymes. Any microbes that breach these surface barriers are then attacked by other components of the innate immune system, such as polymorphonuclear leucocytes (neutrophils), macrophages and complement.

This innate immune response is a pre-programmed non-specific response that does not involve learnt or adaptive mechanisms. The cells and proteins of the innate immune system can recognise common microbial markers or virulence factors and can kill microbes without the need for prior exposure. The chemical messages (cytokines) and cells of the innate immune system also interact with the cells of the adaptive immune system (eg, lymphocytes) to induce a cascade of events that leads to adaptive, antigen-specific immunity and immune memory, as summarised in Figure 2.2.

Figure 2: Summary of non-specific innate and adaptive (specific) immunity



2.1.4 ACQUISITION OF ADAPTIVE IMMUNITY

Specific immunity can be actively produced by directly responding to an antigen. This is termed adaptive or learnt immunity, in which the immune system learns to respond to specific antigens. Passive immunity is provided by transferring antibody from an immune person to temporarily protect another.

NATURALLY ACQUIRED IMMUNITY

Naturally acquired immunity occurs either actively by experiencing the infection or passively through the transfer of maternal antibodies from mother to fetus or infant (transplacentally or in breastmilk).

ARTIFICIALLY ACQUIRED IMMUNITY

'Artificially' acquired immunity occurs either actively through vaccination or passively through administration of immunoglobulin (IG).

While actively acquired immunity lasts from years to life, passively acquired immunity lasts from weeks to months as the transferred antibodies decay and are not renewed.

2.1.5 MATERNALLY DERIVED IMMUNITY

The passive transfer of antibody from mother to fetus provides an opportunity to provide protection to the neonate against several diseases before they are old enough to be vaccinated themselves. Maternal vaccination boosts the immunity of the mother, inducing high levels of maternal antibody. This antibody is actively transported across the placenta to concentrate at protective levels by birth (in term infants).

Important diseases that maternal vaccination is effective at preventing include neonatal tetanus, influenza and pertussis in the infant for the first weeks or months of life (see section 4.1 and the relevant disease chapters).

2.2 FROM PERSONAL PROTECTION TO COMMUNITY (HERD) IMMUNITY

By protecting individuals, vaccination can also protect the wider community. This herd immunity occurs when the vaccine coverage is high, meaning an infectious case is unlikely to encounter susceptible contacts, so transmission stops.

The whole population benefits when a vaccine prevents carriage and transmission of a human-only pathogen, such as polio virus, measles virus or Streptococcus pneumoniae, and circulation of these pathogens can be reduced and even eliminated. This phenomenon, called herd or community immunity, can prevent infections spreading and therefore protect vulnerable members of the population, such as the very young, the very old, or those with underlying conditions that increase their risk from infectious diseases (ie, the immunocompromised). These individuals may not themselves be able to receive some vaccines (eg, live vaccines) or may not mount a sufficiently effective immune response to other vaccines.

The population benefits depend on the disease itself, the nature of the vaccine and the proportion or target group of the population needed to be immunised to prevent the disease from spreading. A recent example of herd immunity in New Zealand is the significant reduction in rotavirus hospital discharge rates in children aged under 5 years following the July 2014 introduction of rotavirus vaccine for infants (see section 18.3.2).

2.2.1 REPRODUCTION NUMBER AND HERD IMMUNITY THRESHOLD

A measure of the infectiousness of a disease is the basic reproduction number (R0). This is the number of secondary cases generated by a typical infectious individual when the rest of the population is susceptible. In other words, R0 describes the spreading potential of an infection in a population.1 Measles is one of the most infectious diseases, with an R0 of 12-18 (Table 1.1). In other words, one person with measles is likely to infect up to 18 other susceptible people. Pertussis is similarly infectious.

If a significant proportion of the population are immune, then the chain of disease transmission is likely to be disrupted. The herd immunity threshold (H) is the proportion of immune individuals in a population that must be exceeded to prevent disease transmission. For example, to prevent measles or pertussis transmission, 92-94 percent of the population must be immune (Table 2.1).

R0 must remain above 1 for an infection to continue to exist. Once R0 drops below 1 (such as in the presence of an effective vaccination programme), the disease can be eliminated. The greater the proportion of the population that is immune to the infection, the lower the R0 will be. For example, data2 indicates that a quadrivalent HPV vaccine programme with 70 percent coverage in young women may lead to the near disappearance of genital warts from the heterosexual population because the R0 for HPV types 6 and 11 (causing genital warts) falls to below 1.

Table 5: Approximate basic reproduction numbers (in developed countries) and implied crude herd immunity thresholds[a] for common vaccine-preventable diseases[b]

Infection	Basic reproduction number (R_0)	Crude herd immunity threshold, H (%)
Diphtheria	6-7	83 -85
Influenza	1.4 - 4	30 - 75
Measles	12 - 18	92 - 94
Mumps	4 - 7	75 - 86
Pertussis	5 - 17	80 - 94
Polio	2 - 20	50 - 95
Rubella	6 -7	83 - 85
Varicella	8 - 10	Not defined

Notes

a. The herd immunity threshold (H) is calculated as $1-1/R_0$.

b. The values given in this table are approximate: they do not properly reflect the range and diversity among populations, nor do they reflect the full immunological complexity underlying the epidemiology and persistence of these infections.

c. The R_0 of influenza viruses varies among subtypes.

d. This is complicated by uncertainties over immunity to infection and variation related to hygiene standards.

Adapted from: Fine P, Mulholland K, Scott J, et al. 2018. Community Protection. In: Plotkin S, Orenstein W, Offit P, et al (eds). Plotkin's Vaccines (7th edition). Philadelphia, US: Elsevier. Table 77.2.

2.3 THE IMPORTANCE OF IMMUNISATION COVERAGE

High immunisation coverage means more individuals are protected; it is also vital for achieving herd immunity. High coverage reduces the spread of disease to those who have not been vaccinated for medical reasons (eg, children with leukaemia while receiving treatment) or because of age (eg, infants who are too young to respond to some vaccines). High coverage also reduces the spread of disease to those who may not mount an effective immune response to vaccines because of an underlying condition (eg, those on immunosuppressive regimes).

The World Health Organization (WHO) and the Maldives government target for immunization coverage is for at least 95 percent of children to be fully vaccinated by age 2 years. The Maldives target includes a marker for on-time immunization of 95 percent by age 8 months, as well as at ages 2 years and 5 years.

2.4 CLASSIFICATION OF VACCINES

There are two broad categories of vaccine type: live attenuated (weakened) and nonlive, which includes inactivated or whole killed, subunit and nucleic acid vaccines. Examples of the different types of vaccines are summarised in Table 6.

Table 6: Classification of vaccines, with examples

Live attenuated	Non-live Inactivated or whole killed	Subunit	Nucleic acid	Non-replicating viral vector
Measles	Poliomyelitis (IPV)	Toxoid: • Diphtheria • Tetanus	COVID-19 (mRNA-CV)	COVID-19 (Ad26-CV and ChAd-CV)
Mumps		Polysaccharide: • Pneumococcal (23-valent)		
Rubella	Hepatitis	Conjugate: • Pneumococcal (10- and 13valent)		
Varicella		• Haemophilus Influenzae type b		
Rotavirus		Meningococcal C and ACWY Recombinant: • COVID-19 (rCV)		
Tuberculosis (BCG)	Some influenza vaccines	• Hepatitis B • Human papillomavirus		
		• Meningococcal B		
Zoster		Zoster (rZV) Other subunit: • Pertussis, acellular • Influenza		

Note: Travel vaccines have been omitted from the above table.

2.4.1 LIVE ATTENUATED VACCINES

Live vaccines contain pathogens, usually viruses, which have been weakened (attenuated) so that they are able to replicate enough to induce an immune response but not cause disease. Immunity from live vaccines is usually very long-lived. The live vaccines on the National Immunisation Schedule are MMR, varicella, rotavirus and herpes zoster vaccines.

2.4.2 NON-LIVE VACCINES: WHOLE KILLED AND INACTIVATED VACCINES

Killed vaccines contain whole bacteria that have been killed. The whole-cell pertussis vaccine is an example of a killed vaccine. There are no killed vaccines on the Schedule. Inactivated vaccines contain viruses that have been inactivated in some way, such as splitting, so they are unable to replicate or cause disease. Examples of inactivated vaccines are influenza, hepatitis A and polio vaccines.

2.4.3 NON-LIVE VACCINES: SUBUNIT VACCINES

Subunit vaccines contain microbial fragments or particles that can induce an immune response which protects against disease. These are produced using a range of methods including recombinant engineering, detoxification processes and splitting and purification.

TOXOID VACCINES

In some bacterial infections (eg, diphtheria and tetanus), the clinical manifestations of disease are caused not by the bacteria themselves but by the toxins they secrete. Toxoid vaccines are produced by harvesting a toxin and altering it chemically (usually with formaldehyde) to convert the toxin to a toxoid. The toxoid is then purified. Toxoid vaccines induce antibodies that neutralise the harmful exotoxins released from these bacteria.

RECOMBINANT VACCINES

Recombinant vaccines, such as those used against COVID-19 (rCV), hepatitis B virus (HBV) and human papillomavirus (HPV), are made using a gene from the (diseasecausing) pathogen. The gene is inserted into a cell system capable of producing large amounts of the protein of interest. The protein produced can generate a protective immune response. For example, the gene for the hepatitis B surface antigen (HBsAg) is inserted into yeast cells, which replicate and produce large amounts of HBsAg. This antigen is purified and used to make vaccine. The advantage of this approach is that it results is a very pure vaccine that is efficient to produce.

POLYSACCHARIDE AND CONJUGATE VACCINES

Polysaccharides are strings of sugars. Some bacteria, such as Streptococcus pneumoniae and Neisseria meningitidis, have large amounts of polysaccharide on their surface, which encapsulate the bacteria. The polysaccharide capsules protect the bacteria from the host's immune system and can make the bacteria more virulent. Historically, it has been difficult to stimulate an effective immune response to these polysaccharide capsules using vaccines, particularly in children aged under 2 years.

2.4.4 NON-LIVE VACCINES: NUCLEIC ACID VACCINES

Recent developments in vaccine technology have allowed the use of messenger ribonucleic acid (mRNA) to deliver the genetic code to our dendritic cells make specific viral proteins. Since mRNA is easily destroyed by ubiquitous ribonuclease enzymes, it is protected inside a lipid nanoparticle that also facilitates uptake by the dendritic cells. Inside the dendritic cell, ribosomes and vaccine mRNA generate the viral protein which is then presented to the T and B cells in the lymph nodes. For example, the mRNA COVID-19 vaccine (mRNA-CV) provides the instructions to make the SARS-CoV-2 virus spike protein and induces an effective humoral and cellular immune responses against this virus.

2.4.5 NON-LIVE VACCINES: NON-REPLICATING VIRAL VECTOR VACCINES

Another recent development in vaccine design is the use of adenoviruses as a vector to deliver the instructions to human cells to make antigens. The adenovirus is genetically modified to be unable to replicate (non-replicating or replication deficient), and as such are non-live vaccines, but can deliver its double-stranded DNA into the cell's nucleus as would normally occur during an adenovirus infection. The viral DNA contains a transgene, a portion that codes for the target antigen protein. Only this portion of the viral DNA can be expressed, thus preventing the vector from reproducing. The presence of the adenovirus triggers an immune response killing the infected cell and thereby releasing the new protein (antigen) to activate a specific immune response. For example, ChAdOx1 vector COVID-19 vaccine (ChAd-CV) uses a chimpanzee adenovirus and the Ad26 vector COVID-19 vaccine (Ad26-CV) uses a human adenovirus (Ad26) to produce SARS-CoV-2 spike proteins.

03

DISEASES PREVENTED BY VACCINATION

DISEASES PREVENTED BY VACCINATION

The National EPI Programme and Travel Health targets to prevent following vaccine preventable diseases;

Table 7: Vaccine used by diseases

Name of Diseases	Name of Vaccines
Childhood Tuberculosis	BCG Vaccine
Hepatitis-B	Hepatitis-B Vaccine
Diphtheria, Whooping cough, • Tetanus, Hepatitis-B and Haemophilus • Influenzae-b	Pentavalent Vaccine (DPT+Hep-B+ Hib)
Poliomyelitis	Oral Polio Vaccine (OPV) and Inactivated Polio Vaccine (IPV)
Measles, Rubella, Mumps	Measles, Rubella (MR) and Measles, Rubella and Mumps (MMR) Vaccine
Tetanus and diphtheria	Td
Human papillomavirus infection and cervical cancer	HPV vaccine

3.1 CHILDHOOD TUBERCULOSIS

WHAT IS TUBERCULOSIS?

Tuberculosis is caused mycobacterium tuberculosis. It usually affects the lungs but can affect other parts of body including the bones, joints and brain. People of all ages can contact Tuberculosis but children less than 3 years and elderly people are highest risk of infection.

Not everyone who is infected with TB bacteria develops the disease. People who are infected and who do not develop the disease do not spread the infection to others.

HOW IS TB SPREAD?

TB is spread from one person to another through the air, often when an infected person coughs or sneezes. TB spreads rapidly, especially in areas where people are living in crowded conditions, have poor access to health care, and are malnourished. A person can contract bovine tuberculosis, another variety of TB, by consuming raw milk from infected cattle.

People with TB infection who have weakened immune systems (for example, people with HIV/AIDS) are more likely to develop the disease.

WHAT ARE THE SIGN/SYMPTOMS OF TB?

In most cases, children with symptomatic TB develop chronic symptoms.
The common symptom of TB includes:
- General weakness, weight loss,
- Fever and night sweats.

IN PULMONARY TUBERCULOSIS, THE SYMPTOMS INCLUDES:

- persistent cough,
- coughing up of blood and
- chest pain.

IN YOUNG CHILDREN, 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.

WHAT ARE THE COMPLICATIONS OF TB?

Tuberculosis may affect any part of the body and if untreated miliary Tuberculosis and TB meningitis may lead to death.

WHAT IS THE TREATMENT FOR TB?

People with TB must complete a course of therapy, which usually includes taking two or more antituberculosis drugs for at least six months. This therapy is called Directly Observed Treatment Schedule (DOTS).

HOW IT IS PREVENTED?

Vaccination before 12 months of age with bacille Calmette-Guérin vaccine (BCG) can protect against TB meningitis and other severe forms of TB in children.

BCG VACCINE

WHAT IS BCG VACCINE?

BCG vaccine is supplied in freeze-dried powder (lyophilized) form. It must be reconstituted with a diluent before use. BCG Vaccine and Diluents should come from same manufacturer. Both the BCG vaccine and diluents should be at +2°C to +8°C before reconstitution and stored between +2 °C and +8 °C after reconstitution. Opened multi-dose vials must be discarded at the end of session or six hours after reconstitution, whichever, comes first.

HOW SAFE IS BCG VACCINE AND WHAT ARE THE POTENTIAL ADVERSE EVENTS FOLLOWING IMMUNIZATION?

Severe events after BCG vaccination include swelling of the gland in armpit and abscesses. Abscesses 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 instead of into the top layer.

A mild reaction at the site of injection occurs in almost all children. 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 – the scar is a sign that the child has been effectively immunized.

WHEN IS BCG VACCINE ADMINISTERED?

BCG should be given routinely at, or as soon as possible after birth to all infants except those known to have HIV or any condition that results in a decreased or abnormal immune system response.

BCG should be given at birth to all infants regardless of HIV exposure. Infants with known HIV-positive mothers should be followed closely to monitor for any BCG-related complications. BCG vaccine is not recommended after 12 months of age because the protection provided is less certain.

Table 8: BCG containing vaccine summary

Type of vaccine	Live bacterial
Number of doses	1
Schedule	At or as soon as possible after birth
Booster	None
Contraindications	Known HIV infection or other immune deficiency
Adverse events	• Severe generalized disease or infections such as osteomyelitis (bone infection), abscess; regional lymphadenitis • Mild: injection site reactions
Special precautions	Correct intradermal administration is essential – a specific syringe and needle are used for BCG

Dosage	0.05 ml
Injection site	Outer upper left arm
Injection type	Intradermal
Storage	• Between +2 °C and +8 °C • Do not freeze

3.2 DIPHTHERIA

WHAT IS DIPHTHERIA?

Diphtheria is caused by the bacterium Corynebacterium diphtheriae. This bacterium produces a toxin that can cause obstructive pseudmembrane in the upper respiratiory tract or destroy human body tissues and organs like heart and nerve. One type of diphtheria affects the throat and sometimes the tonsils. Another type, which is more common in the tropics, causes ulcers on the skin.

Diphtheria affects people of all ages, but most often, it strikes unimmunized children. In temperate climates, diphtheria tends to occur during the colder months.

HOW DIPHTHERIA SPREADS

Diphtheria is transmitted from infected to susceptible individuals through sneezing and cough. The bacteria are also transmitted from person to person through close physical contact and contaminated usable articles like toys, towel of infected persons.

WHAT ARE THE SYMPTOMS AND SIGNS OF DIPHTHERIA?

1-3 Days When diphtheria affects the throat and tonsils, early signs and symptoms are;
1. Sore throat,
2. Loss of appetite and
3. Slight Fever, cough and coryza
4. After two or three days, typical asymmetric white or grayish- membranes gradually form in the throat or tonsils and can bleed

4-6 Days
1. Patients with severe disease may show
2. Fever
3. Severe weakness
4. Swelling of the neck and glands
5. Grayish-white pseudo-membrane may extend in to the nasal cavity and the larynx causing obstruction of the airways

To confirm the diagnosis, health workers should obtain throat swab cultures from suspected cases.

WHAT ARE THE COMPLICATIONS OF DIPHTHERIA

The most severe 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 failure. Some patients with diphtheria experience inflammation of the heart muscle and valves, and this may lead to chronic heart disease and heart failure.

WHAT IS THE TREATMENT FOR DIPHTHERIA?

Children who develop diphtheria should be given diphtheria antitoxin and antibiotics like erythromycin or penicillin. They should be isolated to avoid exposing others to the disease. About two days after starting antibiotic treatment, patients are no longer infectious.

HOW IS DIPHTHERIA PREVENTED?

The most effective way to prevent diphtheria is to maintain a high level of immunity in the community with three doses of DPT combined pentavalent vaccine (DPT-HepB-Hib vaccines). Pentavalent vaccines are conjugate liquid vaccines in combination with five vaccines DTP, Hepatitis B and Hib vaccine.

Table 9: Diphtheria-containing vaccine summary

Type of vaccine	Toxoid
Total Number of doses	3
Pentavalent or DTP	1st dose at age of 2 months, 2nd dose at 4 months and 3rd dose at 6 months.
For infants	-
Contraindications	Anaphylaxis or hypersensitivity (allergy) after a previous dose
Adverse events	• Severe adverse events due to diphtheria toxoid alone have not been reported • Mild: injection site reactions, fever
Special precautions	None
Dosage	0.5 ml
Injection site	• Anterolateral (outer) thigh in infants • Deltoid muscle of upper arm in older children and adults
Injection type	Intramuscular
Storage	• Between +2 °C and +8 °C • Do not freeze

3.3 PERTUSSIS

WHAT IS PERTUSSIS?

Pertussis or whooping cough is a disease of respiratory tract caused by the bacterium Bordetella Pertussis. The bacteria usually live in the mouth, nose and throat. The disease is highly communicable and affects un-immunized children and most dangerous in children aged less than one year.

HOW PERTUSSIS SPREADS?

Pertussis spreads very easily from person to person in droplets produced by coughing or sneezing. Untreated patients may be infectious and spread pertussis for up to three weeks after the typical cough starts.

WHAT ARE THE SYMPTOMS AND SIGNS OF PERTUSSIS?

Symptoms start after 10 days after infection with runny nose, watery eyes, sneezing, fever and a mild cough. The cough worsens with too 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.

WHAT ARE THE COMPLICATIONS OF PERTUSSIS?

Pneumonia is the main complication of pertussis. The risk of pneumonia in infants under six 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.

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.

HOW IS PERTUSSIS PREVENTED?

Prevention involves immunization with 3 doses of pertussis containing pentavalent vaccine (DPT-HepB-Hib vaccines).

3.4 TETANUS

WHAT IS TETANUS?

Tetanus is caused by the bacterium *Clostridium tetani*, which is present in soil everywhere. Infection with this bacterium occurs when soil enters a wound or cut. A toxin released by the bacterium causes severe, painful muscle spasms that can lead to death. Maternal tetanus is consequence of un-cleaned delivery or abortion practices and neo-natal tetanus occurs when un-clean instruments are used to cut the umbilical cord or when contaminated materials are used to cover umbilical stump.

HOW IS TETANUS SPREAD?

C. tetani usually enters the body through a wound and in neonate through unhealed umbilical stump, particularly when the stump is cut with an unsterile instrument.

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. The risk of death from the disease increases as the incubation period decreases.

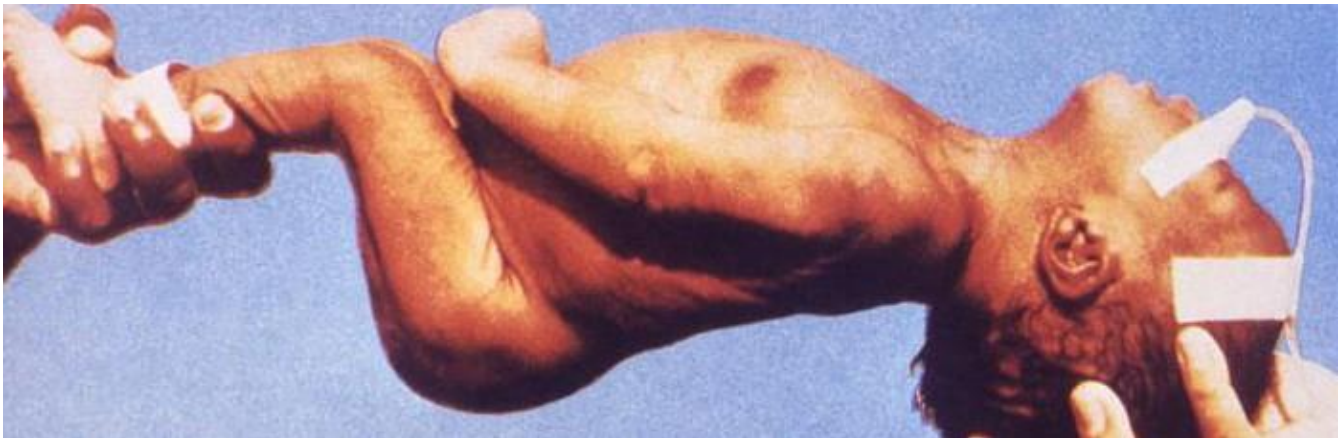
In children and adults, muscular stiffness in the jaw (lock-jaw) is a common first sign of tetanus. This is followed by stiffness in the neck, abdomen and/or back, difficulty swallowing, muscle spasms, sweating and fever.

NEONATAL TETANUS:

Any neonate with normal ability to suck and cry during the first 2 days of life and who, between 3 - 28 days of age, cannot suck normally and becomes stiff or has spasms (i.e. jerking of the muscles). Any neonatal death between 3-28 days of age in which the cause of death is unknown will be considered as a suspected NT Case.

TETANUS IN ADULT (MOTHER)

Tetanus is characterized by painful muscular contractions. The disease usually presents with a descending pattern. The first sign is trismus or lockjaw, followed by stiffness of the neck, difficulty in swallowing and rigidity of abdominal muscles. Other symptoms include elevated temperature, sweating, raised blood pressure and episodic rapid heart rate.



WHAT ARE THE COMPLICATIONS OF TETANUS?

When muscles used in breathing are affected, respiratory failure and death can occur. Pneumonia is also common. Fractures of the spine or other bones may occur as a result of muscle spasms and convulsions. Long-term neurologic impairment has been described in survivors of neonatal tetanus.

WHAT IS THE TREATMENT FOR TETANUS?

Tetanus at any age is a medical emergency best managed in a referral hospital. Antitetanus immunoglobulin, antibiotics, wound care and supportive measures are needed.

HOW IS TETANUS PREVENTED?

Tetanus toxoid-containing (TTCV) vaccine protects against tetanus. Infants and children may receive combination vaccines as DTP or pentavalent (DTP+HepB+Hib) or DT. Anyone older than seven years of age should receive dT, which contains tetanus toxoid and lower levels of diphtheria antigen.

Neonatal tetanus can be prevented by immunizing women of reproductive age with tetanus toxoid, either during or before pregnancy. Clean delivery procedures are needed even when the mother has been immunized. 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 completion of a six-dose schedule.

WHAT IS NEEDED FOR MAINTAINING NEONATAL TETANUS ELIMINATION?

Elimination of neonatal tetanus, means less than one case per 1000 live births per year in every district. Because the tetanus bacterium survives in the environment, eradication of tetanus is not feasible and high levels of immunization need to be maintained even after elimination.

The strategies to achieve the maternal and neonatal tetanus (MNT) elimination goal are improved vaccination coverage of pregnant women with TT-containing vaccines, 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 tetanus cases. Maldives have already achieved MNT elimination. To sustain the elimination status, it must maintain high coverage of pregnant women with TTCV through routine immunization

WHAT ARE TETANUS TOXOID-CONTAINING VACCINES?

Tetanus toxoid vaccine is available as TT, which protects only against tetanus and neonatal tetanus. It is also available in pentavalent, DTP and dT/DT combinations.

TT vaccine is supplied as a liquid in single- and multi-dose vials and also in prefilled auto-disable syringes. Tetanus toxoid-containing vaccines must be stored between +2 °C and +8 °C without being frozen. They are freeze-sensitive. If freezing is suspected, the Shake Test (annex) should be performed to determine whether a vial is safe to use. Opened multi-dose vials must be handled according to national multi-dose vial policy. Tetanus toxoid-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.

HOW SAFE IS TETANUS TOXOID VACCINE AND WHAT ARE THE POTENTIAL ADVERSE EVENTS FOLLOWING IMMUNIZATION?

Tetanus toxoid is very safe. Severe events are rare and include anaphylaxis (1.6 per 1 million doses). Mild events include injection site pain, redness and/or swelling. These are more common after later doses than earlier ones, and may affect between 50% and 85% of people who receive TT booster doses. Fever may develop in 10% of those vaccinated.

WHEN ARE TETANUS TOXOID-CONTAINING VACCINES GIVEN?

For long-term immunity against tetanus in all individuals, five doses of TTCV are recommended in childhood: three doses in the primary series given in infancy in the form of pentavalent vaccine, one booster dose between four and seven years of age using dT vaccine, and a second booster dose with dT between 12 and 15 years of age. For women, one additional dose of dT is recommended during pregnancy to ensure protection throughout reproductive age and probably for life. Three childhood doses of pentavalent are considered equivalent in protection to two doses of TT or Td given in adulthood.

Table 10

Recommended Schedule	Immunization with diphtheria –tetanus-pertussis(DPT) and diphtheria toxide (Td) vaccine required to obtain long term protection against tetanus				
	Number of Doses	Interval between doses	Dosage	Injection site	Route
Childhood Vaccine not Completed	Td / TT1	15 Years	0.5ml	Outer upper arm	Intramuscular
	Td / TT2	Minimum 28 days after TT1			
	Td / TT3	Minimum 6 months after TT2			
	Td / TT4	Minimum 1 year after TT3			
	Td / TT5	Minimum 1 year after TT4			
3 Doses of DPT/ Penta Completed	Td / TT3	At age of 15 years or first pregnancy	0.5ml	Outer upper arm	Intramuscular
	Td / TT4	At least 4 weeks after previous dose			
	Td / TT5	Minimum 1 year after TT4 or next pregnancy			
Adolescents and Pregnant women with 4 doses of childhood DPT/ Penta	Td / TT4	At age of 15 years or first pregnancy	0.5ml	Outer upper arm	Intramuscular
	Td / TT5	Minimum 1 year after TT4 or next pregnancy			

Note: DT should be used for children less than 7 years, who had severe reaction due to pentavalent (mostly due to pertussis component), whereas for older age group dT/Td should be used.
http://www.who.int/wer/2006/wer8120.pdf?ua=1

When second booster is recommended, it is advised to vaccinate in every ten years for adolescents.

3.5 HEPATITIS B

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 one year of age, 90% develop chronic disease.

HOW IS HEPATITIS B SPREAD?

The hepatitis B virus is spread by contact with infected blood and other body fluids in various situations: a) from mother to child during birth; b) with cuts, scrapes, bites, and/or scratches; c) from person to person during sexual intercourse; and d) through unsafe injections and/or transfusions. Overall, hepatitis B is 50 to 100 times more infectious than HIV. Young children rarely develop acute clinical disease, but many of those infected in the early age and become chronic carriers.

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. Chronic hepatitis B patients have signs related to liver failure (such as swelling of the abdomen, abnormal bleeding and changing mental status) as the disease progresses.

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.

WHAT IS THE TREATMENT FOR HEPATITIS B?

There is no specific treatment for acute hepatitis B. Chronic hepatitis B can be treated with interferon and antiviral agents in some cases.

HOW IS HEPATITIS B PREVENTED?

Hepatitis B can be prevented by immunization. Since perinatal or postnatal transmission is an important cause of chronic infections globally, all infants should receive their first dose of HepB as soon as possible (less than 24 hours) after birth. After the birth dose, HepB vaccine should be administered in the form of pentavalent (DTP+HepB+Hib) vaccine at 2, 4, 6 months.

WHAT ARE HEPATITIS B-CONTAINING VACCINES?

Hepatitis B (HepB)-containing vaccines are available in stand-alone or combination (pentavalent or quadrivalent DTP+HepB) formulations. Heptitis B containing vaccines must be stored between +2 °C and +8 °C. They are freeze-sensitive. If freezing is suspected, the Shake Test (Annex,) should be performed to determine whether a vial is safe to use. Opened multi-dose vials must be handled according to national multi-dose vial policy. HepB-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. Shake the vial to mix it before using each dose.

HOW SAFE IS HEPB VACCINE?

HepB vaccine has an excellent safety profile. Severe adverse events include anaphylaxis in about one per million vaccine doses administered. Mild events include injection site pain in 3-29% of those vaccinated, redness or swelling in about 3%, headache in about 3% and fever in 1-6%.

WHEN ARE HEPB-CONTAINING VACCINES ADMINISTERED?

All infants should receive HepB vaccine (only stand-alone HepB) vaccine at birth, preferably within the first 24 hours. It can be given with BCG vaccine. HepB combinations pentavalent vaccine is recommended for subsequent doses. Subsequently, three doses HepB containing pentavalent vaccine as per national schedule.

3.6 HAEMOPHILUS INFLUENZAE TYPE B (HIB)

WHAT IS HIB?

Haemophilus Influenzae type b (Hib) is one of six types of bacterium which is responsible for more than 90% of systemic infections in children. The disease burden is highest among those aged between 4 months and 18 months. The most important manifestations of Hib infection are;

1) Pneumonia
2) Meningitis

Other important but less frequent manifestations of Hib infection include septicemia, septic arthritis, osteomyelitis, pericarditis and cellulitis.

HOW IS THE DISEASE SPREADS?

Hib is primarily transmitted by droplets (sneezing, coughing) from nasopharyngeal secretions and also transmitted from person to person through usable articles like toys and towel of infected persons.

WHAT ARE THE SYMPTOMS AND SIGNS OF BACTERIAL MENINGITIS?

Children with pneumonia can have fever, chills, cough, rapid breathing and chest wall retractions.

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

Seen less frequently, but still serious, it causes epiglottitis resulting in stridor (noisy breathing) and breathing difficulty; and septicemia resulting in fever, shaking or chills, and further spread of the bacteria.

WHAT ARE THE COMPLICATIONS OF HAEMOPHILUS INFLUENZAE TYPE B (HIB)?

If proper treatment cannot be given early the infected children can suffer severe complications. Children who survive Hib meningitis 15% to 30% may develop permanent neurological disability, including brain damage, hearing loss, and mental retardation. 5% to 10% cases of Hib meningitis are at risk of dying.

PREVENTION

Immunizing with 3 doses of Hib containing pentavalent vaccines as per National Schedule will prevent Hib disease.

3.7 POLIOMYELITIS

WHAT IS POLIOMYELITIS?

Poliomyelitis, or polio, is a highly infectious disease caused by poliovirus types 1, 2 or 3. They are the naturally occurring wild polioviruses (WPV) types that circulate and infect people.

Polio mainly affects children of less than five years of age. One in 200 infections causes irreversible paralysis when the virus attacks the spinal cord nerve cells that control the muscles.

HOW IS POLIO SPREAD?

Poliovirus spreads by the faecal-to-oral route. In areas with poor sanitation, it is thought to more 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.

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 and sore throat. Paralysis occurs in approximately 1% of those infected. Death occurs in approximately 5–10% of those paralyzed.

Less than 1% of all poliovirus infections result in flaccid type paralysis mainly in lower limbs which is asymmetric and sensation remain intact. The affected limb gradually become weak and paralysis may be permanent.

WHAT ARE THE COMPLICATIONS OF POLIOMYELITIS?

The paralysis of the affected limb gradually turns to permanent disability.

WHAT IS THE TREATMENT FOR POLIO?

There is no cure for polio. Treatment consists of supportive, symptomatic care.

HOW IS POLIO PREVENTED?

Polio can be prevented through immunization with oral polio vaccine (OPV) and/or inactivated polio vaccine (IPV). Three doses of bOPV are given at 2, 4, 6 months as tOPV has been switched to bOPV. And 1 dose of IPV is given at 6 months (with last dose of OPV).

WHAT IS POLIO VACCINE?

Oral Polio Vaccine (OPV) is a live attenuated polio vaccine that contains types 1, 2 and 3 individually or in in combination (types 1, 2 and 3, or 1 and 3). Maldives currently has switch from trivalent OPV to bivalent OPV (type 1 and 3). It is supplied in multi-dose vials. It is very heat-sensitive and must be kept frozen during long-term storage. After thawing, it can be kept at a temperature of between +2 °C and +8 °C for a maximum of six months or can be refrozen. OPV vaccines are stored at central level for a maximum period of 6 months at -15°C to - 25°C and at atoll level for 3 months. This vaccine is also preserved at island level at +2°C to +8°C for 1 month.

Inactivated poliovirus vaccine (IPV) is liquid suspension providing protection against all 3 types of poliovirus. It is stable outside the cold chain but should be stored between +2 °C and +8 °C. It must not be frozen.

It is supplied in one-, five- or ten-dose vials. bOPV is given orally and IPV is injected intramuscularly as a 0.5 ml dose.

HOW SAFE IS POLIO VACCINES?

Both OPV and IPV are extremely safe. With OPV, vaccine-associated paralytic polio (VAPP) can occur in approximately 1 in 2.7 million doses especially from P2. VAPP usually occurs with 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. This is known as circulating vaccine-derived poliovirus.

IPV is one of the safest vaccines in routine use. No serious adverse events have been linked to it. Mild events include injection site redness in less than 1% of those vaccinated, swelling in 3-11% and soreness in 14-29%

WHEN IS POLIO VACCINE ADMINISTERED?

OPV is administered orally as 1st dose at the age of 2 months, 2nd dose at 4 months and 3rd dose at the age of 6 months. IPV is given intramuscularly at the age of 6 months.

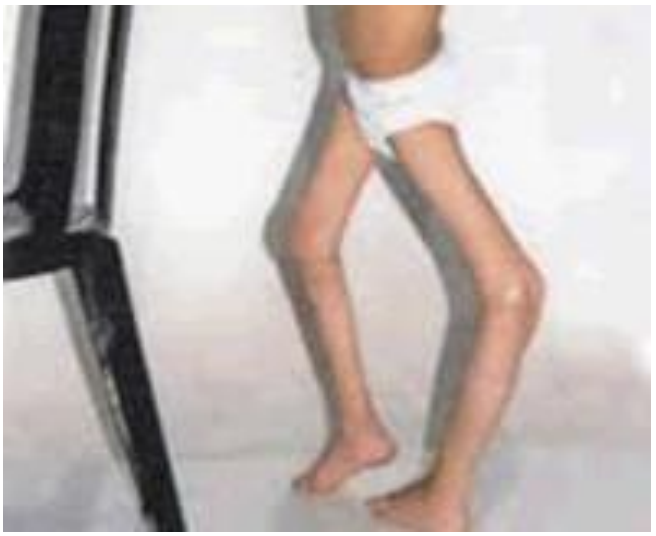


Table 11: Polio vaccination summary

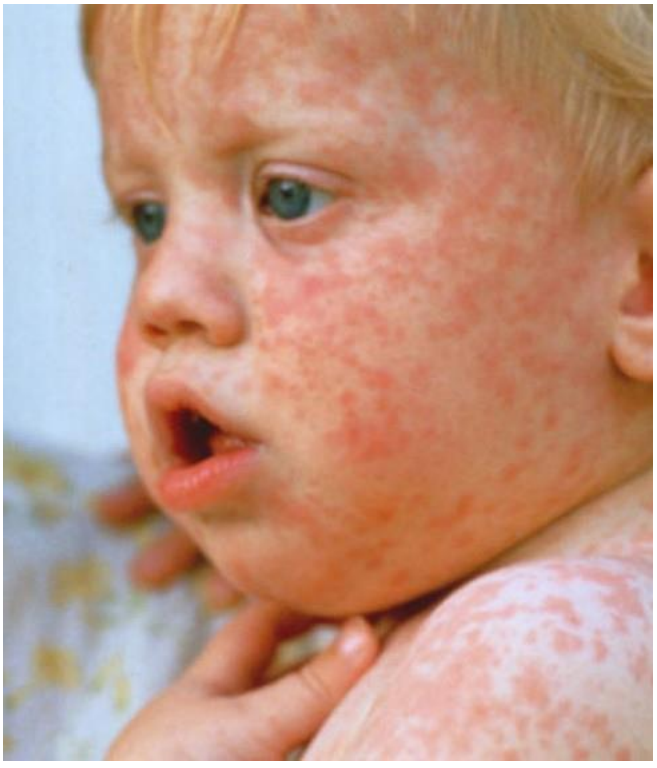
Type of vaccine	OPV – Live attenuated (weakened) viral; IPV – Inactivated viral
Total number of doses	3-4
Schedule OPV plus IPV	• Doses of bOPV- 1st dose at 2 months, 2nd dose at 4 months and 3rd. dose at 6 months • IPV dose should be given at 6 months of age (with 3rd dose of bOPV dose).
Contraindications	Known hypersensitivity (allergy) or anaphylaxis to a previous dose
Adverse events	• bOPV - Rare vaccine-associated paralytic polio (VAPP) • IPV - No known serious reactions; mild injection site reactions do occur
Special precautions	Postpone vaccination if the child has moderate to severe illness (with temperature ≥39 °C)
Dosage	• bOPV – 2 drops into the mouth • IPV – 0.5 ml injection
Route of administration	• bOPV - Oral only • IPV – Intramuscular injection; anterolateral (outer) mid-thigh in infants and children
Storage	• bOPV - Keep frozen; very heat sensitive; storage in temperatures of between +2 °C and +8 °C is possible for a maximum of 6 months • IPV – between +2 °C and +8 °C; do not freeze

3.8 MEASLES

WHAT IS MEASLES?

Measles is a highly infectious disease caused by a virus. It kills more children than any other vaccine preventable diseases in the world. More than 95% of measles deaths occur in countries with low incomes and weak health infrastructures.

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.



HOW MEASLES SPREADS

Measles is spread through airborne droplets released when an infected person sneezes or coughs. People with measles can infect others for several days before and after they develop symptoms.

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.

WHAT ARE THE COMPLICATIONS OF MEASLES?

Infected infants may suffer from dehydration due to severe diarrhea and may also develop malnutrition, inflammation of the middle ear (5–15%), pneumonia (5-10%) and encephalitis. Measles is a major cause of blindness among children. Pneumonia is the most common cause of death associated with measles.

WHAT IS THE TREATMENT FOR MEASLES?

There is no specific antiviral treatment for measles. Antibiotics should be prescribed only for bacterial ear infections and pneumonia. General nutritional support and the treatment of dehydration with oral rehydration solution are important.

All children diagnosed with measles should receive two doses of vitamin A supplement given 24 hours apart to help prevent eye damage and blindness. Vitamin A supplementation reduces the number of deaths from measles by 50%.

HOW IS MEASLES PREVENTED?

Measles is prevented by immunization with measles-containing vaccine (MCV). High coverage with a two-dose is needed to prevent measles epidemics.

WHAT ARE MEASLES-CONTAINING VACCINES?

Measles-containing vaccines (MCVs) include measles only (M) or a combination of measles with rubella (MR) and combination with rubella and mumps (MMR).
M, MR and MMR are supplied as freeze-dried (lyophilized) powders with diluents in separate vials. They must be reconstituted before use with only the diluents supplied. Once reconstituted, the vaccines must be discarded at the end of the session or SIX hours after reconstitution whichever comes first. Timing of reconstitution has to be written at vaccine label. Measles-containing vaccines must be stored between +2 °C and +8 °C and protected from sunlight. MCVs are administered by subcutaneous injection. Each doses is 0.5 ml.

HOW SAFE IS MEASLES VACCINE AND WHAT ARE THE POTENTIAL ADVERSE EVENTS FOLLOWING IMMUNIZATION?

All MCVs are safe and effective. Serious events are rare and include anaphylaxis in 1-3.5 per one million doses administered, severe allergic reaction in one per 100 000 doses, and thrombocytopenia (decreased platelet count) in one per 30 000 doses. Encephalitis (brain infection) has been reported rarely but there is no definite proof that the vaccine was the cause. Mild events are more common and include local injection site pain and tenderness, fever (in 5–15%) and rash (in about 5%), which can occur five to 12 days after vaccination.

WHEN ARE MEASLES-CONTAINING VACCINES ADMINISTERED?

All children should receive two doses of MCV containing vaccine. Very high (90-95%) coverage with both doses is required to prevent measles outbreaks. The first dose (MR1) should be given at 9 months of age (after 270 days). If the dose is missed it can be given within 12 months of age. 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' ages nine to 12 months. All unvaccinated children over 12 months should be offered MCV1 using every opportunity when the child comes in contact with health services.

A second dose of Measles will be given at 18 months in the form of Measles, Mumps and Rubella (MMR) vaccine.

Note: In measles outbreaks or in areas where there is a high rate of both HIV infection and measles, the first dose of MCV1 may be offered as early as age six months. Two additional doses of measles vaccine should be administered to these children according to the national immunization schedule. In such situations, please follow guidance from HPA.

Table 12: Measles-containing vaccines summary (MCV = M, MR, or MMR)

Type of vaccine	Live attenuated (weakened) viral
Total number of doses	2
Schedule	• MCV1 as MR: 9 months of age; • MCV2 as MMR: 18 months at least 1 month after MRV1
Contraindications	• Known allergy to vaccine components (including neomycin and gelatin) • Pregnancy • Severe immune disorders, including advanced HIV infection/AIDS
Adverse events	• Serious: thrombocytopenia, anaphylaxis, encephalitis • Mild: fever, rash 5-12 days following administration
Special precautions	None
Dosage	0.5 ml
Injection site	Anterolateral thigh or upper arm depending on the child's age
Injection type	Subcutaneous
Storage	• Between +2 °C and +8 °C • Keep all MCV/MR/MMR vaccines away from sunlight

3.9 RUBELLA

WHAT ARE RUBELLA AND CONGENITAL RUBELLA SYNDROME?

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

HOW IS RUBELLA VIRUS SPREAD?

Rubella is spread in airborne droplets when infected people sneeze or cough. The virus spreads throughout the body and in a pregnant woman, to the fetus, about five to seven days after infection. Infants with CRS can transmit the virus for a year or more.

WHAT ARE THE SYMPTOMS AND SIGNS OF RUBELLA AND CRS?

About 7 to 14 days after exposure to the virus, mild fever, conjunctivitis (more often in adults) and swollen neck lymph nodes may occur and then be followed by erythematous maculopapular rash five to 10 days later. The rash most often begins on the face and spreads towards the feet, but usually fainter than a measles rash. The rash typically lasts for one to three days. Studies have shown that 20-50% of rubella infections occur without a rash. Up to 70% of adult women may have joint pain and stiffness.

WHAT ARE THE COMPLICATIONS OF RUBELLA?

Rubella infection occurring just before conception and during early pregnancy may result in Miscarriage, fetal death, or congenital defects known as congenital rubella syndrome (CRS) (deafness, blindness due to cataracts and mental retardation).

HOW IS RUBELLA PREVENTED?

One dose of MR vaccine at 9 months and one dose of MMR vaccine at 18 months of age protect Children from Rubella Disease and Congenital rubella Syndrome (CRS).

3.10 MUMPS

WHAT IS MUMPS?

Mumps is an infection caused by paramyxoviru virus. Most often it involves the salivary glands. Mumps virus can affect testis causing mumps orchitis.

Mumps most often affects children of between five and nine years of age. The mumps virus can also infect adults, in which case the complications are more likely to be serious.

HOW IS MUMPS SPREAD?

The mumps virus is spread by airborne droplets released when an infected person sneezes or coughs and by direct contact with an infected person. A person who has mumps can infect others from about six days before to about nine days after salivary gland infection.

WHAT ARE THE SYMPTOMS AND SIGNS OF MUMPS?

About one third of individuals infected with the mumps virus have no symptoms or signs. Sign and symptoms usually begin 14-21 days after infection. Symptoms include pain on chewing or swallowing. Fever and weakness can occur. Swelling of the salivary glands, just below and in front of the ears, is the most prominent sign and may occur on one or both sides of the neck.

WHAT ARE THE COMPLICATIONS OF MUMPS?

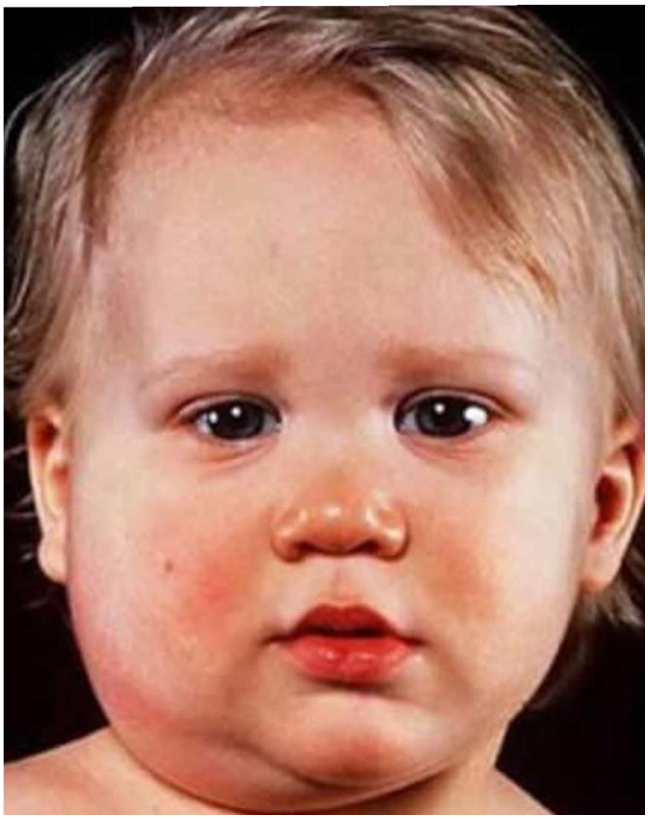
Complications from mumps are rare, but they can be serious. In men and teenage boys, mumps orchitis may cause sterility. Encephalitis and hearing loss are other rare complications that can occur with mumps at any age.

WHAT IS THE TREATMENT FOR MUMPS?

There is no specific treatment for mumps. Supportive treatment should be given to relieve symptom

HOW IS MUMPS PREVENTED?

Mumps is prevented by immunization with mumps-containing MMR vaccine. One dose of MMR vaccine given at 18th Month protects children against Mumps. People who recover from mumps are thought to have lifelong immunity against the virus.



3.11 HUMAN PAPILLOMAVIRUS INFECTION AND CERVICAL CANCER

WHAT IS HUMAN PAPILLOMAVIRUS?

Human papillomavirus (HPV) is a common sexually transmitted virus that causes genital warts and various cancers. There are more than 100 types of HPV. Some types cause only genital warts and other cause cancer of the anus, external genitalia and oral cavity in both sexes. It is known to be the cause of 99% of cervical cancers.

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.

WHAT ARE THE SYMPTOMS AND SIGNS OF CERVICAL CANCER?

Most HPV infections are asymptomatic and usually clear within a few months. About 90% of infections clear within two years, but some infections continue. Infection that continues can progress to cervical cancer with specific types of HPV (particularly types 16 and 18). This progression takes 20 years on average and tends to cause symptoms 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, renal failure and fistulae can also occur in advanced stages of cervical cancer.

WHAT IS THE TREATMENT FOR CERVICAL CANCER?

If cervical cancer is caught early by screening methods it can be cured effectively with localized treatment (e.g. cryotherapy). Treatment of advanced cancer is complicated and usually involves combinations of surgery, radiotherapy and chemotherapy.

WHAT CAN BE DONE TO PREVENT AND CONTROL CERVICAL CANCER?

It should be comprehensive and consists of:

a) Primary prevention by vaccination against HPV infection for girls nine to 13 years of age and health education warning against tobacco use, sexuality education and promotion of condom use, and male circumcision;

b) Screening at least once for women between 30 and 49 years of age even after vaccination, since vaccination does not protect against all cancer-causing HPV types

c) Tertiary prevention by treatment of invasive cancer at any age.

WHAT IS HPV VACCINE?

Two HPV vaccines are currently available worldwide:
1) bivalent vaccine, Cervarix®, which protects against HPV types 16 and 18,

2) quadrivalent vaccine, Gardasil®, which protects against four HPV types (6 and 11 (which cause genital warts), and 16 and 18).

The bivalent HPV vaccine used in Maldives was a single dose. These vaccines do not require reconstitution. They must be stored between +2 °C and +8 °C. Opened multi-dose vials must be handled according to national policy. Both vaccines are administered intramuscularly in two or three separate 0.5 ml doses.

Gardasil four valent HPV vaccine used in Maldives is a single dose vaccine. These vaccines do not require reconstitution. They must be stored between +2 °C and +8 °C. Opened multi-dose vials must be handled according to national policy. Both vaccines are administered intramuscularly in two or three separate 0.5 ml doses.

HOW SAFE IS HPV VACCINE AND WHAT ARE THE POTENTIAL ADVERSE EVENTS FOLLOWING IMMUNIZATION?

Both HPV vaccines are well tolerated and have excellent safety profiles. Serious events include rare anaphylaxis with quadrivalent vaccine (1.7-2.6 per million doses). Mild events include local injection site reactions (pain, redness and swelling). These usually resolve without treatment. Other mild events reported include 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.

WHEN IS HPV VACCINE ADMINISTERED?

The recommended target population for the prevention of cervical cancer is females aged nine to 13 years, prior to becoming sexually active. For females younger than 15 years, a two-dose schedule with an interval of six months is recommended. Even those females who are over 15 years at the time of the second dose are adequately protected by two doses. There is no maximum recommended interval between doses. However, an interval of no greater than 12-15 months is suggested in order to complete the schedule promptly and before the start of sexual activity. For females over 15 years of age, or who are known to have a compromised

immune system (that does not respond normally) and/or are HIV-infected, a three-dose schedule (at 0, 1 or 2 and 6 months) is recommended.

If a girl gets pregnant before she has been fully immunized, the remaining dose(s) should be postponed since it is not licensed for use in pregnancy.

Table 13: Summary of HPV vaccines for girls aged between 9 and 13 years

Type of vaccine	Recombinant protein capsid, liquid vaccine
Total number of doses	2
Schedule – bivalent (HPV types 16 and 18) Cervarix® quadrivalent (HPV types 6, 11, 16 and 18) Gardasil®	• 0 and 6 months • There is no maximum interval between doses – as long as the girl is under 15 years of age at the time of the first dose, two doses are sufficient • If the interval between doses is less than 5 months, a third dose should be given at least 6 months after the first dose. Note: For females ≥15 years of age, or who are known to have a compromised immune system and/or are HIV-infected, a 3-dose schedule (at 0, 1 or 2 and 6 months) is recommended
Contraindications	Anaphylaxis or hypersensitivity (allergy) after a previous dose
Adverse events	- Severe: rare anaphylaxis - Mild: injection site reactions; fever, dizziness, nausea
Special precautions	- Postpone vaccination for pregnancy - Adolescents should be seated during injections and for 15 minutes afterwards since they sometimes faint
Dosage	0.5 ml
Injection site	Deltoid muscle of upper arm
Injection type	Intramuscular
Storage	Between +2 °C and +8°C Do not freeze

3.12 PNEUMOCOCCAL DISEASE

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.

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.

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 in and on 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.

WHAT ARE THE COMPLICATIONS OF PNEUMOCOCCAL DISEASE?

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

WHAT IS THE TREATMENT FOR PNEUMOCOCCAL DISEASE?

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

HOW IS PNEUMOCOCCAL DISEASE PREVENTED?

Pneumococcal disease can be prevented by vaccination. While improved living conditions (e.g. reduced crowding and indoor air pollutants) and nutrition can reduce the risk of pneumococcal disease and death, they are less effective than vaccines for prevention. Sections 10.8-10.10 and Table 1.16 below describe pneumococcal conjugate vaccine.

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, which is discussed in Section 19 of this module.

WHAT IS PNEUMOCOCCAL CONJUGATE VACCINE?

The pneumococcus is a bacterium with an outer polysaccharide (or sugar) capsule. Many different strains, or serotypes, 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. Pneumococcal polysaccharide vaccines were used for many years; they contain the purified capsule of up to 23 serotypes of pneumococcus but only produce short-term protection and are not effective in infants and young children. Pneumococcal conjugate vaccines (PCV) overcome the limitations of polysaccharide vaccines by conjugating, or binding, the capsule with a protein; this results in longer-lasting protection and makes the vaccine more effective in children.

Each pneumococcal vaccine protects against disease caused by the pneumococcal serotypes that it contains; it is unlikely to protect against serotypes that it does not contain. It 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 it is not misunderstood as a failure of the vaccine.

Available pneumococcal conjugate vaccines are listed in Table 1.15 below. 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 a temperature of between +2 °C and +8 °C without being frozen. They are freeze sensitive. If freezing is suspected, the Shake Test should be performed to determine whether a vial is safe to use (see Module 2 (The vaccine cold chain), Section 7). Opened multi-dose vials must be handled according to national multi-dose vial policy (see Module 2, Section 5 for WHO policy).

For infants and children, 0.5 ml of PCV is administered by intramuscular injection in the anterolateral thigh.

Table 14: Pneumococcal vaccines

Vaccine	Formulation	Presentation
PCV10	Liquid	Single-dose vial
PCV10	Liquid	• 2 dose, preservative-free vial • Prefilled syringe
PCV13	Liquid	• Single-dose vial • Prefilled syringe

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. No severe adverse events have been proven with use of these vaccines to date. Mild events include soreness at the injection site in about 10% of those vaccinated; fever has been reported in less than 1%.

WHEN IS PNEUMOCOCCAL CONJUGATE VACCINE ADMINISTERED?

PCVs should be given priority in childhood immunization programmes, particularly in countries with high mortality in children under five years of age (more than 50/1000 live births). Three doses are required and can be given as a three-primary (3p+0) or, as an alternative, two-primary-plus-one booster (2p+1) schedule. The 3p+0 schedule can be started as early as six weeks of age, with a minimum interval of four weeks between doses. The 2p+1 schedule is shown in *Table 1.16* below. In choosing between schedules factors such as the epidemiology of the disease, likely coverage, and the timeliness of vaccination should be considered.

Once a series has been started, the same product should ideally be used for all three doses; for example, if PCV10 is used for the first dose, it should be used for the second and third doses also. If this is not possible, the schedule may be completed with the available PCV.

Previously unvaccinated or incompletely vaccinated children, including those who recover from pneumococcal disease, should be vaccinated according to their age. Children 12-24 months require only two doses, with an interval of at least eight weeks.

Key points about pneumococcal disease:

• Pneumococcal disease is a leading cause of death in children under five 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 package to protect, prevent and treat and to reduce mortality and morbidity from childhood pneumonia.

• Each pneumococcal vaccine protects against disease caused only by the pneumococcal serotypes that it contains. It does not protect against other bacteria that cause the same types of infections (pneumonia, meningitis, etc.).

Table 15: Pneumococcal conjugate vaccine summary

Type of Vaccine	Conjugate (pneumococcal polysaccharide bound to a carrier protein; does not contain any live bacteria)
Total number of doses	3
Schedule – 3p+0	First dose as early as 6 weeks of age with 4–8 weeks interval between doses
Schedule – 2p+1	• 2 primary doses ideally completed by six 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 9–15 months of age • HIV+ infants and preterm neonates who receive 3p doses before 12 months of age may benefit from a booster dose during the second year of life
Contraindications	Anaphylaxis or hypersensitivity (allergy) after a previous dose

Adverse Events	• Severe: none known • Mild: injection site reactions and fever
Special Precautions	Postpone vaccination if the child has moderate to severe illness (with temperature ≥39 °C)
Dosage	0.5ml
Injection Site	Anterolateral (outer) thigh in infants and children
Injection Type	Intramuscular
Storage	• Between +2 °C and +8 °C • Do not freeze

3.13 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 of between three and 12 months of age when they develop severe gastroenteritis following their first infection and are very vulnerable to the effects of dehydration.

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.

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.

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.

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.

HOW IS ROTAVIRUS GASTROENTERITIS PREVENTED?

Over the past 20 years, global deaths due to diarrhoea from other causes 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 has become important for prevention of severe rotavirus disease in particular. Sections 12.8-12.10 and Table 16 describe rotavirus vaccines.

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

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 (exclusive breastfeeding for six months, vitamin A supplementation, safe drinking water, hygiene/handwashing with soap, and sanitation) and treatment (low-osmolarity ORS, zinc and continued feeding). The 2013 integrated Global Action Plan for Pneumonia and Diarrhoea outlines a "Prevent, Protect and Treat" framework, which is discussed in Section 19 of this module.

WHAT IS ROTAVIRUS VACCINE?

The currently available rotavirus vaccines (RV) 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.

Two oral rotavirus vaccines are available: Rotarix® (RV1 or monovalent RV), which contains one strain; and RotaTeq® (RV5 or pentavalent RV), which contains five strains.

Rotarix® comes in single-dose freeze-dried (also called lyophilized) powder and in liquid forms. Freeze-dried RV1 must be reconstituted using diluent in a prefilled oral applicator. Liquid Rotarix® is ready to use in an oral applicator or a squeezable tube. All of these must be stored between +2 °C and +8 °C without being frozen. They should be used immediately after reconstitution or opening. If not used immediately, reconstituted freeze-dried vaccine can be stored between +2 °C and +8 °C or at ambient temperatures of less than 25 °C and used within 24 hours (see Table 1.18). **Currently in Maldives Rotarix® is available.**

RotaTeq® is a ready-to-use liquid that should be stored at a temperature of between +2 °C and +8 °C without freezing. It should be used as soon as possible after being removed from the refrigerator.

HOW SAFE ARE ROTAVIRUS VACCINES AND WHAT ARE THE POTENTIAL ADVERSE REACTIONS?

The available rotavirus vaccines are safe and well tolerated. There is a low risk of intussusception (about one to two per 100 000 infants vaccinated; see box on intussusception). Both are approved for administration with other vaccines in infant immunization programmes. Mild adverse reactions include irritability, runny nose, ear infection, vomiting and diarrhoea (in 5% or more of children vaccinated).

Rotavirus vaccines are generally not recommended for infants with a history of intussusception. Studies show a much smaller increase in risk (five to 10 times lower) of intussusception after the first dose of Rotarix® or RotaTeq® than with an earlier vaccine called RotaShield® that was withdrawn from the market. The benefits of the currently available rotavirus vaccines are far greater than the potential risks.

WHAT IS INTUSSUSCEPTION?

• Intussusception is a folding or telescoping of one segment of the intestine within another.

• Intussusception usually results in a blockage of the intestine (bowel obstruction).

• Intussusception occurs primarily in infants; peak incidence is between four and 10 months of age.

• Symptoms and signs of intussusception include abdominal pain sometimes accompanied by a lump that can be felt on examination, vomiting, stools with blood and mucus, and lethargy.

• These are not specific and may be caused by other bowel diseases, but intussusception should be considered as one of the possible diagnoses in relevant cases.

• Early diagnosis and treatment of intussusception are essential to save the intestine and the child.

• A child that has any of the above symptoms should be taken immediately to the nearest hospital for urgent evaluation and appropriate treatment.

WHEN IS ROTAVIRUS VACCINE ADMINISTERED?

Rotarix® is given on a two-dose schedule along with pentavalent1 and 2 (the first two doses of DTP+HepB+Hib vaccine). RotaTeq® is given on a three-dose schedule along with pentavalent1, 2 and 3. For both vaccines, there should be a minimum interval of four weeks between doses.

WHO recommendations encourage early vaccination (first dose of RV to be given as soon as possible after six weeks of age), but allow infants to receive rotavirus vaccine together with pentavalent vaccine (DTP+HepB+Hib) regardless of the time of vaccination.

Because rotavirus disease mainly affects very young children, vaccination after 24 months of age is not recommended. The duration of protection of RV is not yet known, but boosters are also not recommended.

KEY POINTS ABOUT ROTAVIRUS GASTROENTERITIS

• Rotavirus is a 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 16: Rotavirus vaccines summary

Type of Vaccine	Live attenuated (weakened) viral
Number of doses	• 2 for RV1 (monovalent RV, Rotarix®) • 3 for RV5 (pentavalent RV, RotaTeq®)
Schedule – Rotarix®	• First dose with pentavalent1; second dose with pentavalent2, with a minimum interval of 4 weeks. • Not recommended after 24 months of age
Schedule – RotaTeq®	• First dose with pentavalent1; second dose with pentavalent2; third dose with pentavalent3, with a minimum interval of 4 weeks. • Not recommended after 24 months of age
Booster	Not recommended at this time
Contraindications	• Severe allergic reaction to previous dose • Severe immunodeficiency (but not HIV infection)
Adverse Events	• Severe: intussusception • Mild: irritability, runny nose, ear infection, diarrhoea, vomiting
Special Precautions	• Should be postponed for acute gastroenteritis and/or fever with moderate to severe illness • Not routinely recommended for history of intussusception or intestinal malformations that possibly predispose to intussusception
Dosage	• Rotarix®: 1.5 ml of liquid • RotaTeq®: 2 ml
Route of Administration	Oral only
Storage	• Between +2 °C and +8 °C • Do not freeze

3.14 SEASONAL INFLUENZA

WHAT IS SEASONAL INFLUENZA?

Seasonal influenza is a respiratory disease caused by influenza viruses A and B. In temperate climates, it can occur primarily in winter epidemics. In tropical climates, it can occur year-round with high attack rates and deaths. Globally, seasonal influenza can affect 5–10% of adults and 20–30% of children each year. Children under five years of age, pregnant women, the elderly (over 65 years of age) and people with HIV/AIDS, asthma, and other chronic heart or lung conditions are at greater risk.

HOW IS SEASONAL INFLUENZA SPREAD?

Influenza A and B viruses are spread mainly in droplets and aerosols released when an infected person coughs or sneezes.

WHAT ARE THE SYMPTOMS AND SIGNS OF SEASONAL INFLUENZA?

Symptoms of influenza usually occur after a one- to four-day incubation period and include fever, cough, sore throat, runny nose, headache and muscle and joint aches. Signs of severe disease in children include difficulty breathing, increased respiratory rate, poor feeding, irritability, dehydration and decreased alertness.

WHAT ARE THE COMPLICATIONS OF SEASONAL INFLUENZA?

Bacterial pneumonia is a frequent complication in the elderly and people with certain chronic diseases. Two of the bacteria that are often found, Streptococcus pneumoniae and Haemophilus influenzae, are discussed in previous sections of this module.

Pregnant women are at increased risk of severe disease and death, and complications for their babies, such as stillbirth, preterm delivery, neonatal death and low birth weight. Elderly persons (age 65 years or over) have the highest risk of mortality from influenza.

WHAT IS THE TREATMENT FOR SEASONAL INFLUENZA?

Several antiviral drugs are available to treat influenza but these are most often used in high-income countries.

HOW IS SEASONAL INFLUENZA PREVENTED?

Annual vaccination is recommended to prevent seasonal influenza, particularly for high-risk groups. WHO recommends that pregnant women should be the first priority for influenza vaccine. Children aged six to 59 months, the elderly (over 65 years of age), people with chronic conditions and health care workers may also be vaccinated based on the local burden of disease, available resources and competing health priorities. Sections 14.7-14.9 and Table 17 describe influenza vaccines.

WHAT IS SEASONAL INFLUENZA VACCINE?

Most seasonal influenza vaccines are trivalent, containing two strains of influenza A and one strain of influenza B, which are chosen based on known circulating strains. Both inactivated and live attenuated (weakened) trivalent vaccines are available. A quadrivalent live attenuated (weakened) vaccine was licensed in the USA in 2012.

Inactivated influenza vaccines are usually available in multi-dose vials that have preservative (thiomersal). Preservative-free, single-dose vials and prefilled syringes are in limited supply and more expensive. They do not require reconstitution and must be stored at a temperature of between +2°C and +8 °C without freezing.

Inactivated influenza vaccines are administered intramuscularly in 0.5 ml doses.

Live attenuated (weakened) vaccines are administered as nasal sprays and are generally used for healthy individuals between two and 49 years of age.

The rest of this section focuses on inactivated influenza vaccines since they are recommended for pregnant women at any time, children six to 59 months of age and persons of 50 years of age and older.

HOW SAFE ARE INACTIVATED INFLUENZA VACCINES AND WHAT ARE THE POTENTIAL ADVERSE EVENTS FOLLOWING IMMUNIZATION?

Inactivated influenza vaccines are considered safe. Severe adverse events have included anaphylaxis in 0.7 per million vaccinations, Guillain-Barré syndrome in one to two per million (in older adults) and oculo (eye)-respiratory syndrome in 76 per million. Mild events include local injection site reactions in 10-64%, fever in 12% of children aged one to five years and fever in 5% of children aged six to 15 years.

Inactivated influenza vaccines are contraindicated in cases of known allergic reaction to a previous dose or to a vaccine component, including egg protein.

WHEN ARE INACTIVATED INFLUENZA VACCINES ADMINISTERED?

Annual vaccination for high-risk groups should be incorporated into immunization programmes following national policy. WHO recommends that pregnant women have the highest priority. Pregnant women can be vaccinated in any trimester. Ideally, influenza vaccine should be made available throughout the year and it may be given at the same time as tetanus vaccine. Immunizing pregnant women also benefits their babies after birth since the vaccine is not given to infants before six months of age.

A single dose is recommended for those over nine years of age, including pregnant women. Children aged six to 59 months are at high risk of severe disease and should be given two doses at least four weeks apart.

Children aged six to 35 months should receive a pediatric dose. For elderly persons (over 65 years of age) vaccination is the most effective public health intervention to reduce their risk of death from influenza.

Health care workers are an important group to vaccinate to reduce the risk of transmission to patients.

Annual vaccination (or re-vaccination, if the vaccine strains are identical) is recommended. Previously vaccinated children aged six to 59 months require only one dose.

KEY POINTS ABOUT SEASONAL INFLUENZA

- Seasonal influenza due to influenza virus types A and B results in significant disease and economic burden each year.
- Pregnant women are the highest priority for vaccination in order to protect young infants (vaccine cannot be given to those under six months of age).
- Additional risk groups to be considered include children six to 59 months, as well as the elderly over age 65 years. The elderly are most at risk of death.
- The main complication is bacterial pneumonia, which can be fatal.
- Annual vaccination is recommended, particularly for high-risk groups.

Table 17: Inactivated influenza vaccines summary

Type of Vaccine	Inactivated viral: tri- or quadrivalent for 2 strains of influenza A and1-2 strains of influenza B
Total number of doses	• 1 for ≥9 years of age, including pregnant women and adults • 2 for children 6-59 months of age (children 6-35 months should receive a pediatric dose)
Schedule	• Annual • For children 6-59 months of age, 2 doses with an interval of 4 weeks minimum Previously vaccinated children aged 6-59 months require only 1 dose
Contraindications	Known hypersensitivity (allergy) or anaphylaxis to a previous dose or to a vaccine component such as egg protein

Adverse Events	• Severe: rare anaphylaxis, Guillain-Barré syndrome, oculo-respiratory syndrome • Mild: injection site reactions and fever
Special Precautions	May postpone vaccination in case of moderate to severe illness (with temperature >39 °C)
Dosage	0.5 ml
Injection Site	Outer (anterolateral) mid-thigh in infants and children; upper arm (deltoid) adults
Injection Type	Intramuscular
Storage	• Between +2 °C and +8 °C • Do not freeze

3.15 MENINGOCOCCAL DISEASE

WHAT IS MENINGOCOCCAL DISEASE?

Meningococcal meningitis is an infection of the meninges (membranes covering the brain and spinal cord) caused by the bacterium Neisseria meningitidis (also known as the meningococcus). Each Neisseria meningitidis bacterium has a capsule and, depending on the type of this capsule, it is put in a serogroup. Neisseria meningitidis serogroups A, B, C, X, W135 and Y cause most cases of meningococcal meningitis. It occurs globally, but in the sub-Saharan Africa meningitis belt, epidemics occur every two to three years. Since the 1980s, the intervals between major epidemics of meningococcal meningitis have become shorter and more irregular.

The meningococcus bacterium can also cause septicaemia (bloodstream infection), which is less common but more severe and often fatal.

HOW IS MENINGOCOCCAL DISEASE SPREAD?

The meningococcus is spread from person to person via airborne droplets emitted from the nose and throat of infected people. Meningococcal disease is most common in young children, but older children and young adults living in crowded conditions can also be at high risk.

WHAT ARE THE SYMPTOMS AND SIGNS OF MENINGOCOCCAL DISEASE?

Meningococcal meningitis is marked by the sudden onset of intense headache, fever, nausea, vomiting, sensitivity to light and stiff neck. Other signs include lethargy, delirium, coma and convulsions. Infants may not have sudden-onset illness and a stiff neck; they may only appear to be slow, inactive, irritable or are feeding poorly and may be vomiting.

A petechial rash (petechiae are small spots of bleeding into the skin) is the key sign of meningococcal septicaemia, which can be followed by rapid shock and death.

WHAT ARE THE COMPLICATIONS OF MENINGOCOCCAL DISEASE?

Death occurs in almost all untreated cases. Even with early treatment, up to 10% of patients die. About 10–20% of meningococcal meningitis survivors sufferfrom complications, such as mental retardation, deafness, paralysis and seizures.

WHAT IS THE TREATMENT FOR MENINGOCOCCAL DISEASE?

Because the meningococcus is a bacterium, antibiotics such as ceftriaxone, chloramphenicol and penicillin G are effective. Each case should be considered as a medical emergency and referred to a hospital to reduce the risk of death from rapidly progressing disease.

HOW IS MENINGOCOCCAL MENINGITIS PREVENTED?

Several vaccines are available to protect against meningococcal serogroups A, C, W135 and Y. No vaccine protects against serogroup X at this time.

Countries must choose a vaccine based on the meningococcal serogroups most often identified locally. Sections 7.8-7.10 and Tables 1.10-1.12 describe meningococcal vaccines.

WHAT IS NEEDED FOR MENINGOCOCCAL DISEASE CONTROL?

Epidemic control relies on good surveillance with early detection and treatment of cases as well as immunization. A mass immunization campaign that reaches at least 80% of the entire population with vaccines against serogroups A and C can prevent an epidemic in areas where these serogroups are the cause of outbreaks.

WHAT IS A MENINGOCOCCAL VACCINE?

There are two categories of meningococcal vaccine, as shown in Table 1.10 below: polysaccharide vaccines with specific capsule serogroup antigens and polysaccharide-protein conjugate vaccines, which have serogroup antigens bound to a protein that helps increase the immune system response to the vaccine. Conjugate vaccines are preferred over polysaccharide vaccines due to their potential for herd protection and their increased ability to generate immunity, particularly in children under two years of age (this is similar for pneumococcal conjugate vaccines, see Section 10 of this module).

Meningococcal vaccines should be stored between +2°C and +8°C. Polysaccharide vaccines are generally given as a 0.5 ml dose subcutaneously. Conjugate vaccines are administered as a 0.5 ml dose intramuscularly.

Table 18: Meningococcal Vaccines

Meningococcal Vaccine Category		Serogroups (and other antigens)	How they a e supplied	
Polysaccharide	bivalent	A, C	Freeze-dried powder requiring reconstitution	Single or multi-dose vials
	trivalent	A, C, W135		
	quadrivalent	A, C, W135, Y		
Conjugate	monovalent	A or C		
	quadrivalent	A, C, W135, Y		
	combination	C, Hib		

HOW SAFE ARE MENINGOCOCCAL VACCINES AND WHAT ARE THE POTENTIAL ADVERSE EVENTS FOLLOWING IMMUNIZATION?

Meningococcal vaccines have an excellent safety record. Severe adverse events with polysaccharide vaccines include rare anaphylaxis (one per one million doses of vaccine administered) and infrequent neurologic reactions, such as seizures. Mild events include local injection site reactions in up to 56% and fever in less than 5% (most commonly in infants).

Conjugate vaccines have excellent safety profiles. No severe adverse events have been associated with them. Mild events include local injection site reactions, and fever and irritability in children.

Both conjugate and polysaccharide vaccines are safe and effective when used in pregnant women.

WHEN ARE MENINGOCOCCAL VACCINES ADMINISTERED?

For MenA conjugate vaccine (5µg), a one-dose schedule is recommended at nine to 18 months of age based on local programme factors. The vaccine should be administered by deep intramuscular injection, preferably in the anterolateral (outer) aspect of the thigh. There is no reason to expect interference when co-administered with other vaccines. The need for a booster dose has not been established. If in a specific setting there is a strong reason to vaccinate infants younger than nine months, a two-dose schedule should be used starting at three months of age, with an interval of at least eight weeks between doses.

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

Quadrivalent 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 two years. A,C,W135,Y-D is also licensed for children nine to 23 months of age, and given as a two-dose series, three months apart beginning at age nine months. If the primary series is interrupted, vaccination should be resumed without repeating the previous dose.

Meningococcal polysaccharide vaccines can be used for those over two years of age to control outbreaks in countries where limited economic resources or insufficient supply restrict the use of meningococcal conjugate vaccines. Polysaccharide vaccines should be administered to individuals over two years of age as one single dose. One booster three to five years after the primary dose may be given to persons considered to be at continued high risk of exposure, including some health workers.

KEY POINTS ABOUT MENINGOCOCCAL DISEASE

- Meningococcal disease is caused by a bacterium, Neisseria meningitides, 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 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.
- Meningococcal disease can be rapidly fatal and should always be treated as a medical emergency.
- Conjugate vaccines are the preferred choice due to their better protection of children under two years of age and herd immunity.

Table 19: Meningococcal polysaccharide vaccines summary

Type of Vaccine	Purified bacterial capsular polysaccharide; bivalent, trivalent or quadrivalent
Number of Doses	1
Schedule	2 years of age and older
Booster	One dose after 3-5 years if still at risk
Contraindications	Anaphylaxis or hypersensitivity (allergy) after a previous dose
Adverse Events	• Severe: Rare Anaphylaxis • Mild: Injection site reaction,
Special Precautions	Children under 2 years of age are not protected by the vaccine
Dosage	0.5ml
Injection Site	Upper arm
Injection Type	Subcutaneous
Storage	Between +2°C and +8°C

3.16 CORONAVIRUS DISEASE (COVID-19)

WHAT IS COVID-19?

COVID-19 is a respiratory disease caused by
SARS-CoV-2, a coronavirus discovered in 2019. The virus spreads mainly from person to person through respiratory droplets produced when an infected person coughs, sneezes, or talks. Some people who are infected may not have symptoms. For people who have symptoms, illness can range from mild to severe. Adults 65 years and older and people of any age with underlying medical conditions are at higher risk for severe illness.

HOW IS COVID-19 SPREAD?

The virus can 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.

SYMPTOMS OF COVID-19

People with COVID-19 have had a wide range of symptoms reported – ranging from mild symptoms to severe illness. Symptoms may appear 2-14 days after exposure to the virus. Anyone can have mild to severe symptoms.

Possible symptoms include:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

RISK GROUP

Risk factors for severe disease include older age, male, smoking, obesity and chronic medical conditions, including diabetes, cancer, chronic respiratory disease, cardiovascular disease, chronic kidney disease, hypertension and being immunocompromised. Increased incidence is well documented in some ethnic groups but seems primarily related to prevalence of the risk factors listed above. Increasing age is the most important risk factor for severe disease, due to declining immune function and high prevalence of comorbidities.

PREVENTING COVID-19

COVID-19 VACCINES

COVID-19 vaccines available in the Maldives effectively protect people from getting seriously ill, being hospitalized, and even dying–especially people who are boosted. As with vaccines for other diseases, you are protected best when you stay up to date. Health Protection Agency recommends that everyone who is eligible stay up to date on their COVID-19 vaccines.

HOW ARE THESE COVID-19 VACCINES GIVEN?

In Maldives, Pfizer vaccine is being administered for the age group of 5 years and above. The Pfizer-BioNTech COVID-19 Vaccine will be given as an injection into the muscle.

Primary Series: The Pfizer-BioNTech COVID-19 Vaccine is given for the primary series. The vaccine is administered as a 2-dose series, 3 weeks apart.

Booster Dose: The Pfizer-BioNTech COVID-19 Vaccine booster is given 6 months after the primary series.

Dosage: • For adults, 0.3ml • 0.2ml is given for children.

Name of the Vaccine	No. of primary doses	Duration between 2 doses
Covishield	2 doses (0.5ml)	4-8 weeks
AstraZeneca	2 doses (0.5ml)	4-8 weeks
Sinopharm	2 doses (0.5ml)	4-8 weeks
Pfizer-BioNTech	2 doses (0.5ml)	3 weeks (21days)

CONTRAINDICATION FOR VACCINATION

People with Severe allergic reaction to a previous dose of a Pfizer COVID-19 vaccine or to an ingredient of the vaccine should not get further doses of Pfizer vaccination.

PRECAUTIONS FOR PFIZER-BIONTECH COVID-19 VACCINE

• People with a history of allergies should be observed for 30 minutes after vaccination.

• People with Anaphylaxis or severe allergy to other vaccines or to other medicines.

• People with past history of myocarditis/ pericarditis, cardiomyopathy or severe cardiac conditions; should discuss with cardiologist or treating clinician on best timing of vaccine.

• If the person is having a bleeding disorder or has been taking a blood-thinning medication (anticoagulant), you should inform their
immunization provider before vaccination.

• People with weakened immune systems (immunocompromise)- should inform their immunization provider before vaccination.

• Contact National Immunization Program (NIP) for further clarifications.

WHAT ARE THE POTENTIAL ADVERSE EVENTS FOLLOWING IMMUNIZATION?

Like all vaccines, Pfizer-BioNTech COVID-19 Vaccine can cause side effects, although not everybody gets them.

Common side effects include;

• Injection site: pain and swelling
• Tiredness
• Headache
• Fever

There is a remote chance that these vaccines could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose. For this reason, your child's vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination.

Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Pfizer-BioNTech COVID-19 Vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low.

You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

04
COLD CHAIN

COLD CHAIN

Cold Chain consists of a series of storage and transport links, all of which are designed to keep the vaccine at the recommended temperature from the point of manufacture until it reaches the target beneficiary. To provide potent and effective vaccine to the beneficiaries, a vast cold chain equipment infrastructure is required with the network of Vaccine Stores along with requisite Walk-in-coolers (WICR), Walk-in-freezers (WIFR), Deep Freezers (DF), Ice lined Refrigerators (ILR), vaccine vans, Cold boxes from national level to the outreach sessions. As all these stores are linked & part of immunization supply chain (iSC), establishing the mechanism for transporting the vaccine in controlled temperature with appropriate mode (air/road/sea) too equally important.

The vaccines which are used in Maldives National Immunization Program are imported from foreign countries. These vaccines are imported in insulated shipping cartoon maintaining the right temperature. These vaccines are stored at central vaccine cold storage at Male.

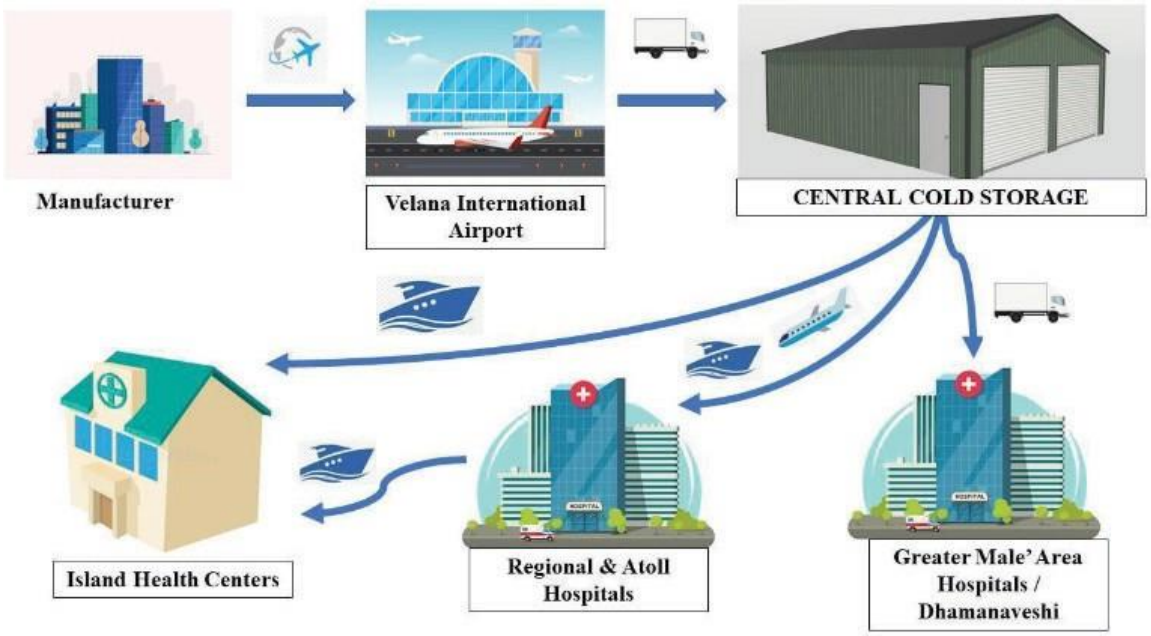


Figure 3: Cold chain system

These vaccines are sent from central Storage to Regional and Atoll Health Facilities. Hereby, vaccines are sent from atolls to islands in Cold Boxes and vaccine carriers. In addition to this, vaccines are sent to health facilities at GMR (including Kaaf Atoll islands) from central cold storage in cold boxes and vaccine carriers.

4.1. IMPORTANCE TO IMMUNIZATION SUPPLY CHAIN

One of the important elements for improving the immunization coverage with quality is holistic management of Immunization Supply Chain System (iSCS), which deals with cold chain and vaccine logistics along with human resource, infrastructure, Management Information System (MIS) and supportive supervision. iSCS is the backbone of immunization programme and plays a very important role in improving the Immunization coverage with quality by timely supply of safe and potent vaccines along with necessary logistics. The iSCS has evolved significantly over the decade, which includes technological advancement in cold chain equipment & its inventory management, temperature monitoring practices and real time management system.

In Maldives, Immunization Supply Chain is with four-tier referral structure as follows.

Primary Store :- One (1)

Primary Store is the entry point where vaccines are received directly from the manufacturers and stored at national level.

Regional Hospital (6) & Atoll Hospital (13)

These are the intermediate Vaccine Stores which receive vaccines from the Central Store and then distribute vaccines to the respective Island Health Facilities.

Island Health Facilities (165)

Island Health Facilities are the lowest distribution points. These are the facilities which receive vaccines from Atoll Hospitals.

Note: In GMR there are 6 immunization service points which receive vaccines from the central store.

VACCINE AND COLD CHAIN HANDLER

The staff (regular/contractual) assigned by the facility in charge, with the responsibility of vaccine and cold chain management at any level of vaccine stores is known as Vaccine and Cold Chain Handler. The role is not under a designated position, but mostly task-oriented.

Primary responsibility of vaccine and cold chain handler:

- Daily maintenance and cleanliness of cold chain equipment
- Daily temperature recording and reporting
- Monthly vaccine and logistics indent, receipt and storage
- Timely issue of vaccine to the lower store/sessions as per micro plan
- Timely update of stock and issue registers for vaccines and logistics breakdown reporting
- Monthly vaccine utilization including wastage reporting

4.2 SAFEGUARDING VACCINES

Vaccines are sensitive to heat, cold and light. Therefore, vaccines should be kept at the recommended temperature range from the time of manufacture to the time of use. Similarly, light-sensitive vaccines should be stored in cool and dark conditions.

Vaccine Management has an objective to maintain the safety and potency of vaccines during storage and transportation. The vaccines lose their potency if they are not stored or transported at the recommended temperature and condition.

If vaccines are not stored safely (within recommended temp) and used, it may lead to Adverse Event Following Immunization (AEFI). Hence all attempts should be made to retain the safety of the vaccine and maintaining the recommended temperature.

The damaged vaccines must be discarded and disposed off as per the Immunization Waste Disposal Guideline. Moreover, people who receive a vaccine that is not potent, are not protected adequately.

Vaccines lose their potency due to exposure to:

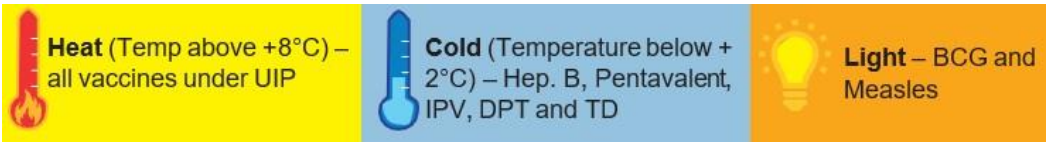


Figure 4: The sensitivity of different vaccines to heat and freezing

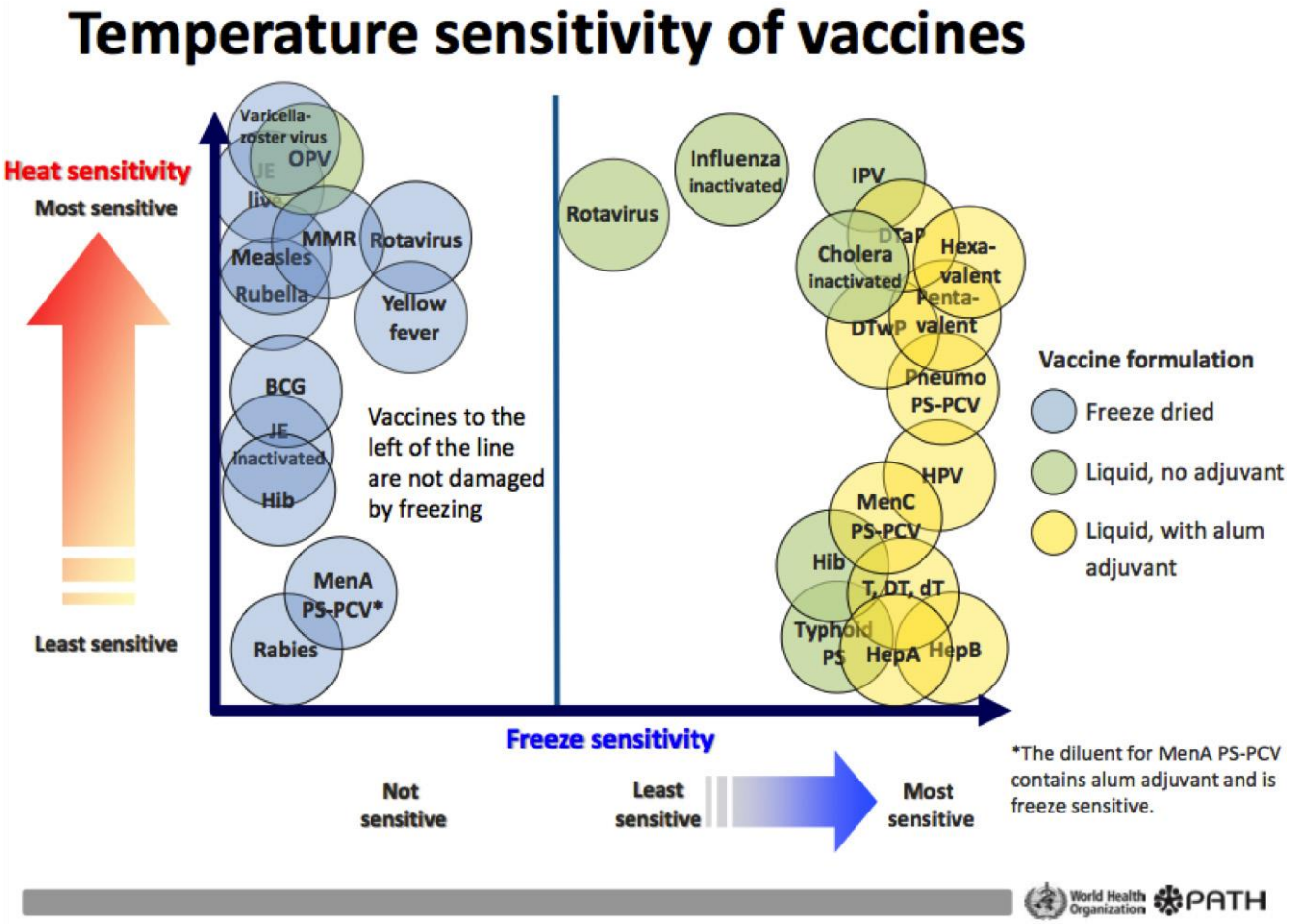


Figure 5: Cold chain system

The physical appearance of the vaccine may remain unchanged even after it is damaged which is permanent. Figure 5 shows the thermo-sensitivity of the vaccines used in the National Immunization Program.

Evidence suggests that freezing could occur at any level and the vaccine handlers should take precautionary steps to prevent vaccine freezing and discard vaccines that are damaged due to freezing.

VACCINE AND COLD CHAIN HANDLER

Besides sensitive to heat, BCG and Measles Vaccines are also light sensitive, which is why they are supplied in amber- colored vials. Therefore, they need to be kept away from light. After reconstitution at the session site the BCG and Measles vaccines are to be kept in the sponge of the vaccine carrier.

4.3 MONITORING COLD CHAIN

Cold chain equipment is used to maintain recommended specific temperatures for safe storage of vaccines. Performance of cold chain equipment is assessed based on its capability of maintaining the temperature desired. Cold chain system should be monitored regularly, to ensure right maintenance of temperature to safeguard the vaccine quality.

VACCINE DAMAGE

The physical appearance of the vaccine may remain unchanged even after it is damaged. The loss of potency due to either exposure to heat or cold is permanent and cannot be regained.

HEAT DAMAGE

All vaccines are damaged if exposed to high temperature (than recommended) in a short time or a small amount of heat over a long period of time, i.e. cumulative exposure.

Reconstituted BCG, Measles are the most sensitive to heat. These live vaccines do not contain preservatives and therefore, BCG & Measles should not be used after 6 hours of reconstitution.

After the adoption of Open Vial Policy (OVP), any open vial returned from the field has to be used within 4 weeks (28 days) from the date of opening, provided the VVM is in usable condition, vaccine has not been frozen and within expiry date. The vaccines which come under this policy are Hepatitis – B, OPV, DPT, Pentavalent, Td and IPV (All Vaccines except BCG Measles).

Checking for heat damage: The Vaccine Vial Monitor (VVM) is a label containing heat-sensitive material, which is placed on the vaccine vial to register cumulative heat exposure between the time period of exit from the manufacturing site till the time of use.

The combined effects of time and temperature causes the inner square of the VVM to darken gradually and irreversibly. Before opening & using a vial, always check the status of the VVM.

DOES A VVM MEASURE VACCINE POTENCY?

No, the VVM does not directly measure vaccine potency, but it gives information about a major factor that affects potency, i.e. heat exposure over a period of time. The VVM does not, however, measure exposure to freezing that contributes to the degradation of freeze-sensitive vaccines.

Vaccine vials with mentioned conditions are not to be kept in the cold chain with usable vaccines as these may be confused with those containing potent vaccines. Hence keep them in a red bag for disinfection and disposal.

FREEZE DAMAGE

The physical appearance of the vaccine may remain unchanged even after it is damaged. The loss of potency due to either exposure to heat or cold is permanent and cannot be regained.

Causes of freezing

- Improper storage.
- Cold climates and ambient temperature is less than 0°C.
- Storage and transport with frozen (non conditioned) ice packs.
- Incorrect adjustment or the defective thermostat/ Temperature Controller of ILR.
- Untrained staff handling vaccine/cold chain.

Steps for eliminating freezing

- Keep all freeze sensitive vaccines in the basket of the ILR with Pentavalent, Hep.B, IPV, Td and DPT at top following the order for vaccine storage.
- In case there is no/limited stock of vaccines like OPV, BCG & Measles and no basket for storing vaccines, then load freeze-sensitive vaccines at least 5 cm above from the bottom of the ILR. 5cm gap can be ensured by putting 2 layers of empty ice packs at the bottom of the ILR. However, it should be ensured that if baskets are available, it should be used for storing vaccines.
- Defrost if there is visible ice formation in ILR. There should not be any frost across the wall. In Deep freezer the ice/ frost across the wall should not be more than 5mm thick.
- Transport vaccines only with conditioned ice packs if transported in normal vaccine carriers.
- Check Thermostat setting (Any settings if required, then it is to be done by the Service Technician/ Engineer only)
- Place the thermometer with the most freeze-sensitive vaccines and check & record the temperature twice a day.
- Leave space between the vaccine boxes for air circulation.
- Conduct shake test if there is any suspicious vial exposed to freezing.

VACCINE AND COLD CHAIN HANDLER

• Report evidence of freezing to supervisors for corrective action

• If a freeze-sensitive vaccine is frozen solid, discard it immediately

• If a freeze indicator signals that freezing has occurred, thermometer shows

• < 0°C, immediately conduct the shake test on a sample of all affected vials in consultation with the I/C health facilities

PROCEDURE FOR CONDUCTING "SHAKE TEST"

Test Vial

• Take a vaccine vial you suspect that may have been frozen - This is "TEST" vial.

Control Vial

• Take a vaccine vial of the same antigen, same manufacturer, and same batch number as the suspect vaccine vial you want to test.

• Freeze solid this vial at (-) 20°C overnight in the DF, and this is the 'CONTROL' vial and label accordingly to avoid its usage.

• Let it thaw. Do NOT heat it.

• Hold the Control and the Test vials together between thumb and forefinger, and vigorously shake the vials for 10-15 seconds.

• Place both vials to rest on a flat surface, side-by-side observe them for 30 minutes.

• Compare for rate of sedimentation.

• If the sedimentation in the 'Test vial" is slower than in the "Frozen vial", the vaccine has not been damaged, it passed the shake test. Use the vaccine batch – it is not damaged.

• If the sedimentation is similar in both vials or if sedimentation is faster in the "Test" vial than in the "Frozen" vial, the vaccine is damaged, it failed in shake test. Do NOT use. Notify your supervisor.

CORRECT STORAGE AND USE OF DILUENTS

Only use the diluents supplied/packaged by the manufacturer with the vaccine, since the diluents are specifically designed for the needs of that vaccine, with respect to volume, pH level and chemical properties.

BCG vaccine and its diluent

The diluents should be stored in the ILR at the service point. If the ILR has space constraints, then the diluents may be stored outside the cold chain. However, diluents must be kept in ILR at least 24 hours before use or issuing to sessions to ensure that vaccines and diluents are at same temperature (i.e., +2° to +8°C) during reconstitution. Otherwise, it can lead to thermal shock; the death of some or all the essential live organisms in the vaccine. Store the diluents and droppers with the vaccines in the vaccine carrier during transportation.

Key Points to Remember

• Cold Chain is a system of storing and transporting the vaccines at recommended temperature from the point of manufacture to the point of use.

• It is crucial to maintain efficient cold chain right from the point of manufacture to its use among beneficiaries.

• Once vaccines lose their potency due to heat or freezing, they can no longer protect individuals from a disease and therefore, are useless and if used may lead to AEFI.

• Vaccine-potency once lost cannot be restored.

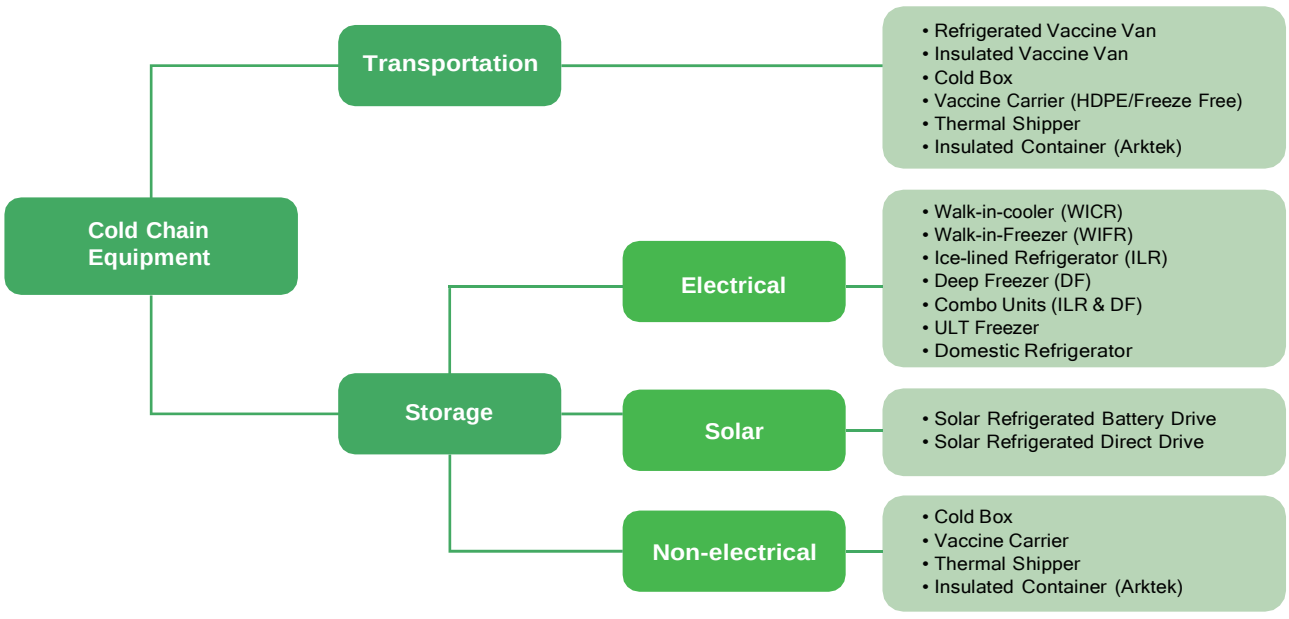
• Never use damaged vaccines as it gives false sense of security to the beneficiaries and affects credibility of the program adversely. Use of damaged vaccines does not give adequate protection to the beneficiaries. As a result, outbreak of vaccine preventable diseases may occur.

• Reconstituted BCG, Measles after opening, should not be used beyond 6 hours from the time of its reconstitution and should be kept at +2°C to +8°C. Use of reconstituted vaccines beyond 6 hours increases chances of AEFIs.

• If not utilized completely, these reconstituted vaccines should be discarded after 6 hours in the case of BCG, Measles.

4.4 COLD CHAIN EQUIPMENTS

Cold Chain Equipment is a set of equipment, which helps in providing recommended temperature for the vaccines to preserve their quality during storage and transportation from the site of manufacture till their administration to the target beneficiary. The equipment used under national immunization programme are classified as follows:



WALK-IN-FREEZERS (WIFR)

It is a pre-fabricated modular Polyurethane foam (PUF) insulated panel assembled cold room equipped with two identical Refrigeration units.

WIFRs maintains temperature within the recommended range of - 15°C to -25°C & are used for bulk storage of freeze vaccines, and also for the preparation of frozen ice packs required for vaccine transportation purpose.

WALK-IN-COOLERS (WICR)

The Walk-in-Cooler is a prefabricated modular Polyurethane foam (PUF) insulated panel assembled cold room equipped with two identical refrigeration units. WICRs requires mains power supply its operation.

WICRs maintains temperature within the recommended range of +2°C to +8°C & are used for bulk storage of immunization vaccines like, BCG, Hepatitis B, DPT, Pentavalent, IPV, Measles and TT.

Essential accessories, devices & equipment commonly associated with WICRs & WIFRs are as mentioned below.

Graphic chart Temperature Recorder

Temperature recorder measures cold/freezer room temperature continuously on circular chart. The chart rotation setting for completing one cycle normally is for seven days (week duration). Hence used chart paper needs to be replaced every week with new one. After one cycle the completed chart needs to be reviewed and signed by the supervisor. All temperature record should be kept for three years.

Real Time Temperature Monitoring System (RTMS)

With the advancement in technologies new approach is towards efficient use of RTMS. These are the programmable data loggers & uses GSM based/wifi enabled (like android phones) technologies by virtue of which remote monitoring/recording of real time temperature is possible.

Alarm Systems

An alarm system is there to provide alerts in case of temperature breaches if any. As soon as the temperature crosses the safe range an audio & visual alarm is there. The provision is there to mute the audio alarm, while the visual alarm goes off only after the temperature returns to normal range.

DEEP FREEZER (DF)

Deep Freezer operating principle is similar like any conventional type of refrigerator. For its operation, power supply requirement is 1 phase AC 230 Volts. Chest type (top opening lid) models of Deep Freezers are most common in use & preferred as cooling loss is comparatively minimum during door opening.

The cabinet temperature is maintained between -15° to -25° C. This is used for storing of OPV (Atoll level and above only) and also for freezing of ice packs. Unlike the ILR, the DF has got little or limited holdover time which is dependent on the number of frozen ice packs in it and the frequency of opening.

Remember: Diluents should never be kept in deep freezers. These should be stored under temperature between +2°C to +8°C at least 24 hours before use and should be transported along with the concerned vaccine (bundling).

Note: The DF which is used for storing vaccines should not be used for preparation of icepacks, as it may increase the cabinet temperature and can be potentially harmful to the vaccines. However adequate frozen ice packs can be kept permanently inside the Vaccine Storing DF for increasing the Hold-Over time.

ICE LINED REFRIGERATOR (ILR)

Ice Lined Refrigerator (ILR) is one of the most important link in the cold chain. ILR operating principle is similar like any conventional type of refrigerator. It operates on 1 phase AC 230 Volts. Chest Type models of ILRs are most common in use & preferred as cooling loss is comparatively minimum during door opening. ILRs maintain its cabinet temperature between +2°C to + 8°C and requires minimum 8 hours continuous electricity supply in a 24- hour period, so that it can work with optimum performance & keep the vaccine safe.

Note: At Health Center Level all routine immunization vaccines should be stored only in ILR.

Use: The ILRs are used for storing the routine immunization vaccines. In Maldives, the larger ILR is allocated to Primary Vaccine Store & regional hospital and smaller ILR to Atoll hospital & Island Health Centers, based on target population.

Remember:

• Keep all vaccines in the basket supplied along with the ILR.

• Leave space in between the vaccine boxes.

• Place a thermometer in the basket in between the vaccines.

• Keep freeze sensitive vaccines at the top of the basket.

• Keep heat sensitive vaccines in the bottom of the basket.

• The vaccines should be arranged as per their expiry dates. (Early expiry should be above the further expiry ones).

ILR maintains a cabinet temperature in the range of +2° to +8°C. However, within the cabinet temperature somewhat differs upper part and lower part. In most of the ILR models, the lower part is cooler compared to the upper part as the cooler air is heavier and settles down at the bottom of ILR. Hence upper part is preferred location for storing the freeze sensitive vaccines.

Hold over time for ILR depends on the following factors:

• Ambient temperature: More the ambient temperature less will be the hold over time.

• Frequency of opening of lid and use of basket.

• Quantity of vaccines kept inside with adequate space between the containers (Equipment empty/loaded).

• Condition of icepack lining (Frozen/partially frozen/ melted).

While storing the vaccine in ILRs, the following care should be taken:

• Keep the vaccine boxes containing the vaccines in neat rows.

• Different vaccines should be kept separately to facilitate easy identification.

• Keep about, 2 cm. space between boxes of vaccines for circulation of air. Keep a thermometer among the vaccines to ascertain the actual vaccine temperature.

• Store Freeze sensitive vaccines (DPT, TT, IPV, Penta and Hep. B) away from the bottom of the ILR to avoid freezing. Always keep the vaccines in the basket provided in the ILR. OPV,BCG and Measles vaccine to be stored at the bottom of the basket of the ILR.

• Diluents of freeze dried vaccines must be kept in the ILR at least for 24 hours before issuing vaccine for administration.

• This is to ensure that at the time of reconstitution, the vaccine and diluent are in the same temperature to avoid thermal shock to vaccines.

• Vaccines should be stored as per their heat and cold sensitivity.

Figure 6: Storing vaccines in the ILR

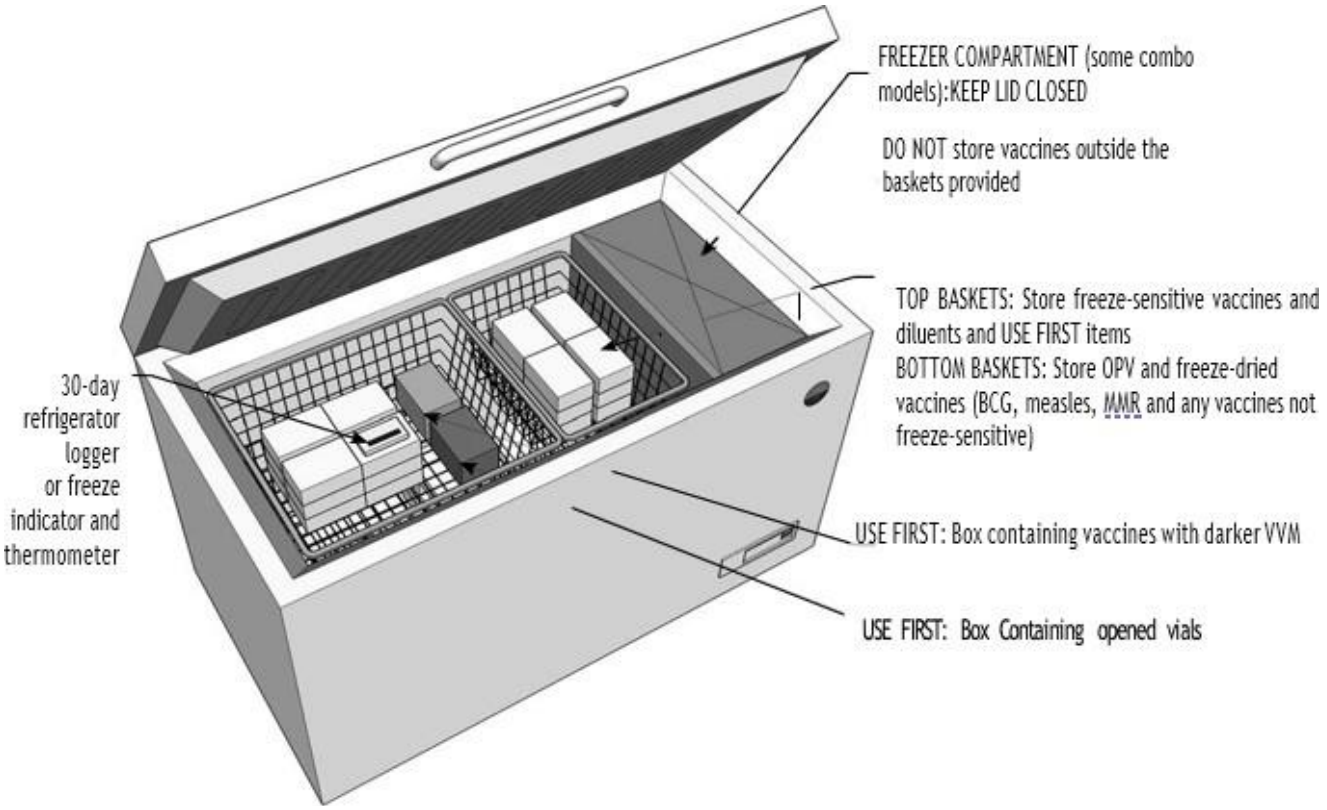
COMBINED ICE LINED REFRIGERATOR & FREEZER (COMBO UNITS)

Combo units operating principle is similar like any conventional type of refrigerator. For its operation, power supply requirement is 1 phase AC 230 Volts. Chest type (top opening lid) models of these equipment are most common & preferred as cooling loss is comparatively minimum during door opening.

The temperature maintained in ILR compartment is between +2°C to + 8°C whereas in the freezer compartment is in between -15° to -25° C. ILR is with hold over time because of Ice Lining all around however the DF section has got little or limited holdover time which is dependent on the number of frozen ice packs in it and the frequency of opening.

Use: As the name indicates, combo units are being used for storing the vaccine (ILR) & freezing the ice packs (DF) as well.

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



ULTRA-LOW TEMPERATURE (ULT) -FREEZER

ULT freezers usually make use of cascade refrigeration, to cool the freezer over its desired temperature range. For its operation, power supply requirement is 1 phase AC 230 Volts. ULT Freezer maintains a cabinet temperature in the range of -80° to -60°C. Two model versions are common in use upright freezer or chest freezer.

Use: The ULT freezer safeguards biological samples by keeping them at very low temperatures & under National Immunization Program it is specifically used for

- Storing the Covid Vaccine (Pfizer)
- Hold dry ice stock for repacking vaccine to transport further

The Medium range ULT freezers are used as back up for Vaccine Storage

The Vaccine Storage is as mentioned below:

- Before mixing, the vaccine may be stored in an ULT freezer between -80°C and -60°C.
- Store vaccine vials upright in the tray or box.
- Protect from light.
- Vaccine may be stored until the expiration date.
- As the expiration date approaches, contact the manufacturer to determine if it has been extended.
- Do not discard vaccine without ensuring the expiration date has passed.

ULT FREEZERS ARE DIFFERENT TO THE STANDARD EPI FREEZERS IN MANY DIFFERENT WAYS. THE MOST IMPORTANT ONES ARE:

- Operate at Extremely Low Temp & hence requires PPE especially insulated Gloves (cryogenic gloves)
- Sensitive to ambient temperature & hence requires air-conditioned area
- Very Short "hold over time" until temperature reaches -60°C (Limit for Pfizer Vaccine)
- Because of short hold over time requires backup generator for reliable back-up power supply.
- As traditionally built for Laboratory purpose, therefore fitted with sample trays & this lead to less space available for vaccine vials. Covid 19 Vaccine delivered in secondary packaging fits into these trays.

4.4 NON-ELECTRICAL (PASSIVE) COLD CHAIN EQUIPMENT

COLD BOX

Cold boxes are insulated containers which are lined with ice packs to keep vaccines and diluents cold during transportation and/or short period storage.

Uses/Application

- Cold boxes are used to collect and transport vaccine supplies from one vaccine store to another and from vaccine stores to health facilities.
- It is also used to temporarily store vaccines when the refrigerator is out of order or being defrosted.
- For storing frozen icepacks in emergency/before campaigns.

Cold boxes can be grouped into two range categories:

1. Short range: With a minimum cold life of 48 hours at 43°C ambient temperature.

2. Long range: With a minimum cold life of 96 hours at 43°C ambient temperature.

The HOLD OVER TIME: (at + 43°C ambient temperature) if the cold box lid is not opened at all).

The vaccine storage & transporting capacity (with conditioned Ice packs lined) of cold boxes ranges between 5 and 25 litres.

- Small Cold Box= 5 - 8 liters
- Large Cold Box = 20 - 22 liters

How to pack a Cold Box

• Fully condition the ice packs. To condition the ice packs, remove frozen ice packs from the freezer and allow standing at room temperature until the ice can be heard to rattle in the ice packs.

• Line the bottom, and sides of the box with conditioned icepacks (as per the diagram given on the lid of the cold box) before loading the vaccines in cardboard cartons or polythene bags.

• If a mixed group of vaccines is to be transported, place those that can be frozen (i. e. OPV/BCG/Measles) at the bottom of the box (the coldest spot).

• Place the other vaccines on top of those mentioned in 3 above. Place packing material between the Freeze sensitive vaccine and the ice pack to prevent vaccine from freezing. This ensures that the vaccines will not come in contact with any frozen surfaces and freezing of vaccines will be unlikely.

• Place a thermometer in the box in the middle of the vaccines, not in direct contact with ice packs.

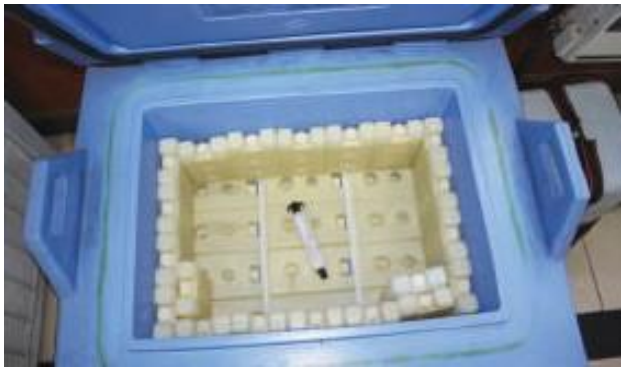
• Cover the vaccines with some more conditioned ice packs.

• Remember, cold air sinks, so the cold will still reach the bottom of the cold box.

• Record vaccine type(s), lot numbers, manufacturer names, quantity, date, time, and originating facility.

• Close the lid.

• Attach labels to the outside of the container to clearly identify the contents as being valuable, fragile, and temperature sensitive vaccines that require refrigeration immediately upon shipment arrival.



Don'ts

• Remove the rubber seal of the Cold Box.

• Place any weight or other cold boxes on the lid.

• Open the lid when not required.

Note: Ice packs are frozen in between -15°C to -25°C and therefore need to be conditioned before laying out in the cold boxes to prevent freezing of vaccines. To condition the hard frozen ice packs keep them out of deep freezer to allow them to 'sweat' and a cracking sound of water would be heard on shaking the icepacks. This will protect Freeze sensitive vaccines from getting frozen. Use `spacers' while using Cold Box, so that these vaccines do not touch ice packs directly, otherwise keep these vaccines in small cardboard cartons.

VACCINE CARRIERS

Vaccine carriers are insulated containers that, when lined with conditioned ice packs, keep vaccines and diluents cold during transportation. Vaccine carriers are smaller than cold boxes and are easier to carry when walking. Vaccine carriers are typically carried by a single health worker traveling on foot or by other means, where the combined journey time and immunization activity may range from a few hours to a whole day.

The vaccine storage capacity of vaccine carriers is between 0.8 to 3.4 liters. Under immunization program 1.7-liter capacity common in use.

Vaccine carriers can be grouped into two range categories:

1. Short range: With a minimum cold life of 15 hours at 43°C ambient temperature. (About 10-12 hours (Average)

2. Long range: With a minimum cold life of 30 hours at 43°C ambient temperature.

Uses/Application

• Carries small quantities of vaccines (16- 20 vials)

• Used for transporting vaccines from health facilities to outreach immunization sessions where refrigeration and ice are not available.

• To carry vaccine from service point (Island Health Clinics) to outreach sessions and bring back the open vials (Under the Open Vial Policy) from the session sites for storing & subsequent use.

How to pack a Vaccine Carrier

• Confirm that there are no cracks in the walls of the vaccine carrier.

• Take out the required number of ice packs from the deep freezer and wipe them dry. Keep them outside for conditioning before placing them into the carrier.

• Place four conditioned ice packs into the vaccine carrier along the sides.

• Wrap vaccine vials and ampoules in thick paper (e.g. plain white paper) before putting in polythene bag so as to prevent them from touching the ice packs. This would also help in absorbing the moisture as accumulation of moisture would damage the labels on the vaccine vials.

• Place the plastic bag in the center away from the ice packs.

• This will prevent labels from peeling off from the vials.

• Place foam pad on top of ice packs.

• If more than one vaccine carrier is being carried for a single session site, keep the whole range of the vaccines required for the day's use in each carrier so that only one carrier is opened at a time.

Points to remember:

• Never Store Vaccines in Vaccine Carriers

• Conditioned icepacks should only be placed in the vaccine carrier and the lid of the carrier should be closed tightly.

• The vials of Hep B, DPT, Penta, IPV and TT vaccines should not be placed in direct contact with the ice packs.

• Direct contact of ice packs spoils the vaccine.

• Give carton spacers between ice packs and vaccines to prevent direct contact with ice packs.

• Place vaccines & diluents in cartons or polythene bags to ensure labels are protected.

Do's

• Ensure that some ice is present in the ice packs while conducting immunization sessions.

• Ensure collection of vaccines in the vaccine carrier on the session day only.

• Close the lid tight & securely.

• Keep the interior of the vaccine carrier clean and dry after every use.

Don'ts

• Drop, knock or sit on the Vaccine Carrier.

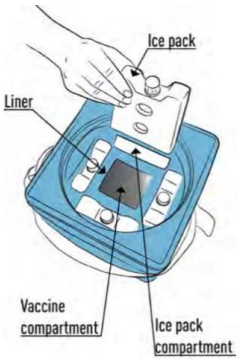
• Leave the vaccine carrier in the sunlight.

FREEZE PREVENTIVE VACCINE CARRIERS

Incorporation of freeze prevention features in vaccine carriers is recent development. These Freeze-Preventative Vaccine Carriers (FPVCs)/Freeze Free Vaccine Carriers (FFVC) are to reduce the risk of vaccine freezing during transport and allow health staff to use these carriers without the need to pre-condition coolant packs. To prevent direct contact between vaccines and coolant packs, these FPVCs have an insulated barrier lining, which separates the vaccine storage compartment from the coolant packs. Therefore, compared to standard VC models, FPVC have higher weights and volumes due to these integrated design elements which reduce the risk of freezing for vaccines.

On contrary to standard Vaccine Carriers FFVCs should be used with frozen coolant packs without conditioning. FFVCs should not be used with conditioned ice packs, as the use of conditioned ice packs will severely reduce the FFVC capacity to keep the vaccines cold. "If conditioned ice packs are placed into freeze-preventive equipment, it may take longer to get cold, and may not stay cold as long."

Freeze-preventive vaccine carriers are slightly larger and heavier than traditional carriers (weighing less than 8 kg, fully loaded). Additional weight and size accommodate the freeze-preventive liner while still allowing for a minimum 1.5-liter vaccine storage.



Benefits of Freeze-preventive carriers

Protect vaccines from freezing

Health workers often find it difficult to tell whether a vaccine has been exposed to freezing temperatures, which can result in vaccines with reduced potency being delivered. After placement in the carrier's vaccine compartment, freeze-sensitive vaccines are no longer at risk of freezing even when frozen ice packs are used, helping to protect the vaccine's potency.

Simplify preparation and reduce health worker burden

Freeze-preventive vaccine carriers allow the use of fully frozen ice packs, eliminating the time-consuming step of conditioning the ice packs. The use of conditioned ice packs (in which the ice is "slushy" and the ice cores are able to move freely inside the packs when shaken) has long been recommended by WHO to avoid freezing vaccines. However, the entire process of conditioning ice packs can take 30 to 60 minutes and has proven difficult to implement. Cold chain surveys have shown that this practice is frequently not enforced. During immunization training sessions, explaining how to properly condition ice packs takes time. Freeze-preventive carriers simplify the process, as conditioning of ice packs is unnecessary.

Points to remember:

• FFVCs should be used with frozen ice packs **(without conditioning)**

• Strong consideration should therefore be given to avoid using conditioned ice packs with FFVCs

• Freeze-preventive Vaccine Carrier do have a physical barrier separating the vaccine storage compartment from the ice packs, to prevent direct contact

• Each FPVC carry a permanent label with vaccine storage instructions attached to the inside of the lid, which describe how to use the coolant packs for that specific FPVC model

THERMAL SHIPPERS (PFIZER SOFTBOX)

The thermal shipping container is a passive device that contains dry ice as the energy source to maintain the required temperatures when maintained properly as defined by Pfizer instructions.

Cold life at -80° to -60 °C is product-specific. When fully loaded with dry ice (20kgs) and opened less than 2 times per day for no longer than 5 minutes per opening, the container can maintain ultra-low temperature (ULT) conditions for up to 8 days.

The dry ice in the thermal shipper will deplete over a number of days (duration will vary depending on use and care), which will impact how long the shipper holds the temperatures. The longer the thermal shipping container remains closed, the longer it will take for the dry ice to deplete.

Uses/Application

Under Immunization, Thermal Shipper Containers are specifically used during international/in-country shipment for transportation of vaccines (Pfizer-BioNTech COVID-19 vaccine) which requires ultra-low temperature.

If an ULT Freezer is not available, the thermal shipping container may be used as temporary storage following proper procedure of re-icing (An estimated 15 kg of dry ice are needed to replenish each thermal shipping container during each re- icing)

INSULATED CONTAINER (ARKTEK-YBC-5)

Passive Vaccine Storage Device (PVSD) that requires no power source.

- Storage capacity: 5-10L (~300 vials)
- Equipped with Vial Rack System & Temperature Logger

Hold Over Time

- Uses dry ice or special PCM (-80 °C) for maintaining the desired temperature & can keep vaccines cold for a month or more on a single set of frozen ice blocks.

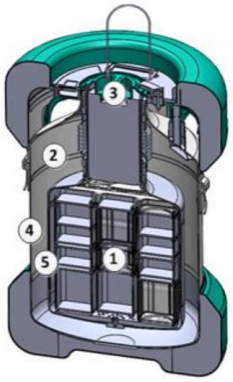
Uses/Application

- Vaccine Transport within the Temperature range: -80 °C to -60 °C.

- Remote/Temporary Storage Options.

- Under Immunization, PVSD are specifically used during in-country shipment for transportation of vaccines (Pfizer-BioNTech COVID-19 vaccine) which requires ultra-low temperature.

- If an ULT Freezer is not available, the PVSD may be used as temporary storage.



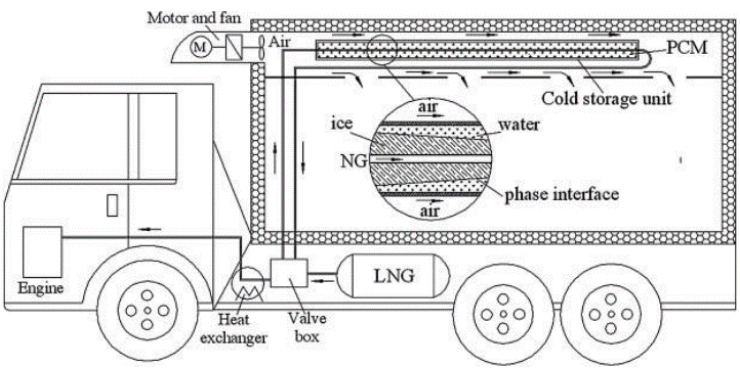
Arktek parts:
1. Vaccine cup stacks
2. Insulative vacuum space
3. Removable assess cap
4. Protective outer shell
5. Inner shell

4.5 VACCINE TRANSPORTATION

Vehicles & Equipment in Vaccine Transportation forms an important link in the entire cold chain system.

The types of transport vehicles used for Vaccine Transportation are:

- Refrigerated Vaccine Van
- Insulated Vaccine Van.



REFRIGERATED VACCINE VAN

It can be used for transportation of vaccines in bulk quantity. The refrigerated vaccine van can provide temperature range as per the specific requirement of vaccine like +2°C to +8°C or -15°C to -25°C. The use of Refrigerated vaccine van does not require the cold boxes or ice packs for vaccine transportation.

INSULATED VACCINE VAN

It is used for the transportation of the vaccine by road in bulk quantities. The insulation helps in maintaining the ambient temperature of the cargo unit which assists in maintaining the holdover time of vaccine containing cold boxes. All vaccines should only be transported in cold boxes with required number of frozen/ conditioned ice packs.

TYPES OF TRANSPORT EQUIPMENT USED FOR VACCINE TRANSPORTATION

- Cold box
- Vaccine Carrier
- Arktec (For Pfizer Vaccine Only)

ICE PACKS AND THEIR USE

Ice packs are a key component of the cold chain. Ice packs are plastic containers filled with water. Under the National Immunization Program the standard ice packs used for cold box and vaccine carriers are of 0.4/0.6 litre capacity.

Type: Water filled plastic containers.

Water fill: Do not fill the entire icepack. Fill it only up to the level mark on the side. Do not fill above the mark of maximum water level as shown in figure 14 as water requires space for expansion after freezing.

Usage:

- Helps in maintaining desired temperature range for safe vaccine storage.

- In functional ILR, if the basket is not available for storing vaccines, then two rows of empty icepacks are placed on the bottom of the ILR as the bottom of the ILR is cooler than the upper part.

Best frozen: In WIFR & DF under the temperature range of (-) 15°C to (-) 25°C.

Conditioning of ice packs:

- When ice packs are removed from a Deep freezer, its temperature is normally between -15°C to -25°C temperature.

- If placed immediately inside a cold box and vaccine carrier, freeze-sensitive vaccines may freeze accidentally.

- These ice packs need to be kept at room temperature to allow the temperature of ice at the core of the ice pack to rise to 0°C. This process is called conditioning. An ice pack is adequately "conditioned" as soon as beads of water cover its surface and the crackling sound of water is heard on shaking it.

- Conditioning is done to prevent freezing of the freeze sensitive vaccines.

- Freezing of vaccines can also take place during storage or during transport (Cold box, vaccine carrier).

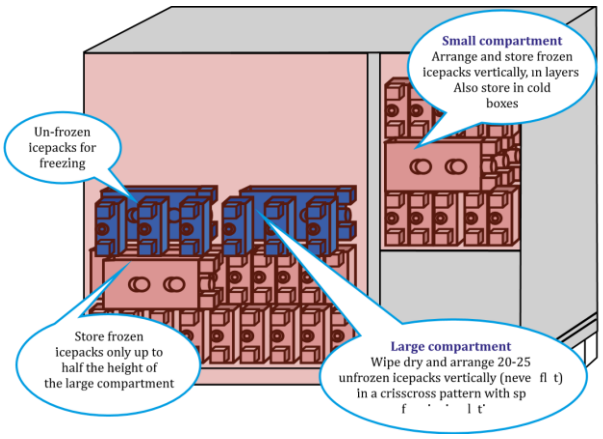
- Freeze sensitive vaccines can be damaged if they come in direct contact with the frozen ice packs.

- Conditioning of ice packs prevents freezing of vaccines during transport, in emergency storage in cold boxes.

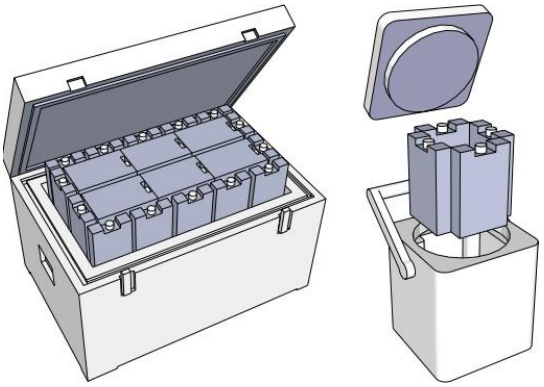
- To know whether an ice pack has reached the stage of conditioning, observe for sweating of ice packs and shake it to listen to the crackling sound of water.

- At the start of session day, bring out frozen ice-packs, from the deep freezer and close the door.

- Lay out on a table at room temperature leaving a 5 cm space all round each icepack till it sweats.



Cold Box



Vaccine Carrier

4.6 TEMPERATURE MONITORING & RECORDING

Vaccines are biological products that can lose their potency if exposed to excessive heat and/or freezing. Different vaccines have different sensitivity to freezing and heat; it is because of this phenomenon that monitoring the temperature of vaccines during storage and transportation is vital.

Temperatures should be continuously monitored throughout the supply chain. Temperature Monitoring also helps in verifying cold chain equipment functionality as needed to maintain vaccine potency and whenever temperature excursions detected, enable corrective action to be taken immediately.

Points to remember:

• Keep one thermometer in every equipment.

• Record the temperature twice a day making arrangements for weekends and holidays.

• Keep the booklet of 12 months temperature recording forms on the top of each unit and check daily to see that the temperature record is maintained.

• Preserve the temperature logbook (register) for minimum period of 3 years for all the cold chain equipment.

Temperature monitoring devices are used from the point of dispatch of vaccines to the point of use. They are used when shipping the vaccine from the manufacturer to primary vaccine stores, during storage at the primary vaccine stores, during transportation from primary store to intermediate/ atoll level stores and at Health Facilities (HFs) and out-reach services where vaccines are stored/transported and administered to the recipient.

The broader classification for these Temperature Monitoring Devices are:

• **Chemical:** VVM/Cold Chain Monitor Card/Alcohol Thermometer/Freeze Watch

• **Mechanical:** Dial Thermometer/Fixed Dial Thermometer/Stem Type Thermometer

• **Electronic (Digital):** 30/60 DTR, Freeze Indicator, Integrated Thermometer, User Programmable Data Logger, Real Time Temperature Monitoring Systems (RTMS),Alarm Unit/Strip-chart Recorders

• **Electromechanical:** Pen/Chart Recorder

VACCINE VIAL MONITORS (VVMS)

Vaccine vial monitors (VVMs) are the only temperature monitoring devices that routinely accompany vaccines throughout the entire supply chain. A VVM is a chemical indicator label printed on the vial level or cap by the vaccine manufacturer. It looks like a white square inside a violet circle. As the container moves through the supply chain, the VVM records its cumulative heat exposure through a gradual change in colour (Figure 2.10). If the colour of the inner square is the same colour or darker than the outer circle, the vaccine has been exposed to too much heat and should be discarded.

There are currently four types of VVM. These four types are VVM2, VVM7, VVM14 and VVM30. The VVM number is the time in days that it takes for the inner square to reach the colour indicating a discard point if the vial is exposed to a constant temperature of 37 °C.

The main purpose of VVMs is to ensure that heat-damaged vaccines are not administered. The VVM status is also used to decide which vaccines can safely be kept after a cold chain break occurs thus minimizing unnecessary vaccine wastage. In addition,

VVM status helps the user decide which vaccine should be used first – a batch of vaccine showing significant heat exposure should be distributed and used before a batch that shows lower heat exposure, even if its expiry date is longer.

VVM for liquid vaccines are attached to the label while for freeze dried vaccines to the cap. Remember that VVM does not measure the exposure to freezing temperature.

Table 20: Vaccine vial monitor

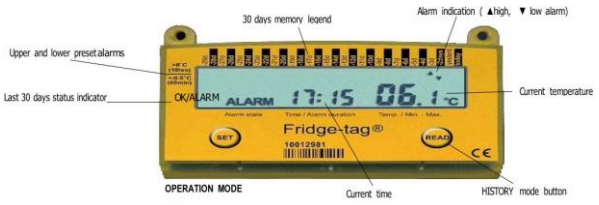
VVM Category	Time to end point		
	at +37°C	at +25°C	at +5°C
VVM 30 (High stability)	30 days	193 days	> 4 years
VVM 14 (Medium stability)	14 days	90 days	> 4 years
VVM 7 (Moderate stability)	7 days	45 days	> 4 years
VVM 2 (Least stable)	2 days	N/A	225 days

FRIDGE TAG (30 DAYS TEMPERATURE DATA LOGGER)

This device is used as a means for monitoring storage conditions in vaccine refrigerators in intermediate stores and health facility levels. The device may also be used as a secondary back-up temperature monitoring device in Cold Rooms.

This device is used to measure and log the temperature inside the refrigerator cabinet for a period of 30 days. (60/120 days versions too are available). The device makes it possible for users to read the maximum and minimum logged temperatures for each day via a 'history mode' function. If, at any time during the 30-day cycle, the temperature in the cabinet exceeds the high/low alarm setting for a certain period, the device will display the relevant alarm condition(s). At the end of the 30 days cycle the device will continue the temperature and alarm monitoring process by incrementally overwriting data older than 30 days.

As long as the temperature is within the allowed range, the OK sign is shown on the display. If the indicator is exposed to an out-of-range temperature the ALARM sign appears on the display. The device shows the actual temperature, all alarm violations over the previous 30 days (on a rolling basis), the daily minimum and maximum temperature of the last 30 days, and the time duration of any violation.



TEMPERATURE DATA LOGGER

Like Fridge Tag the HETL-01 is an electronic temperature data logger for the continuous monitoring of temperature of sensitive vaccines stored in cold chain equipment. The device comes with the following features.

- Factory-programmed alarms.
- Visual display for monitoring storage conditions in vaccine refrigerators over a 30 day period.
- Alarm indications displayed in the LCD display when the temperature exceeds.
- Data within 30 days can be viewed and downloaded by USB port to PC.
- Its operating Temperature: -20°C to +50°C & minimum logging interval: 6 Minutes.

• The device runs on battery (Lithium ion) & it is Non-replaceable.

• Activated life is 24 months after a maximum shelf life of one year.

ELECTRONIC FREEZE INDICATOR (FREEZE-TAG)

This device is used to monitor temperature during storage and in-country distribution. The irreversible freeze indicator is a single alarm electronic temperature indicator providing an irreversible display of temperature exposure relative to the alarm setting of < -0.5 °C for a continuous period of 60 minutes. If the indicator is exposed to conditions exceeding the alarm setting, the display changes from a '☑' to an "☒, informing the user of the triggered alarm state. The device contains an integrated push-button switch for field activation & dynamic "dot" icon which affirms active monitoring. The recorded data cannot be manipulated as it is reversible. The freeze indicator is placed in between freeze sensitive vaccines (Hepatitis B, DPT, TT, IPV, Pentavalent etc.)

REAL TIME TEMPERATURE MONITORING DEVICES (RTMD)

Real Time Temperature Monitoring Devices (RTMD) are the recent development & these devices are being used for real time monitoring of storage conditions at different levels of the vaccine cold chain.

BC141-Beyond Wireless

It provides detailed temperature logs to a central server via SMS, mail or GSM (Global System for Mobile)/GPRS (General Packet Radio Service) communication.

The features highlighted are as follows.

• Integrated audio-visual alarm (for any temperature excursion alerts).

• GSM Based (requires SIM card for its operation) & automatic transmission of data to a server with data access.

• Remote setup of alarm thresholds and alarm recipients through internet accessible dashboard Capable of alarm notifications via SMS, email and/or iOS & Android mobile applications.

• Event (Power failure, Door open) log is too there (Cold room applications).

• Configurable to suit specific applications.

Power Source: Main electricity (With Battery Backup) or Battery powered.

Sensor Type: Wired.

Temperature Monitoring Range: -30°C to +55°C (common for most of the devices).

4.7 RECOMMENDED STORAGE TEMPERATURE AND DURATION DIFFERENT EPI VACCINES AT DIFFERENT LEVELS

Table 21

Place	Duration of Storing	Temperature	
		OPV MR, MMR vaccine	BCG, Pentavalent, Hep-B and TT
Central Cold Room, Male'	6 Months	-15°C to - 25°C	+2ºC to +8ºC
Atolls	3 Months	-15°C to - 25°C	+2ºC to +8ºC
Island	1 Month	+2ºC to +8ºC	+2ºC to +8ºC
During Transportation			
Cold Box	4 Days	+2ºC to +8ºC	+2ºC to +8ºC
Vaccine Carrier	1 Day		

4.8 MULTI-DOSE VIAL POLICY

This applies to liquid vaccines i.e. OPV and Td. In routine immunization under the Multi dose Vials Policy any open vial of above vaccines can be used in subsequent sessions for a maximum period of 28 days provided that all the following conditions are met:

1. The expiration date has not passed
2. The vaccines are stored under appropriate cold chain
3. The vaccine vial septum has not been submerged
4. Aseptic technique has been used to withdraw all doses
5. The VVM had not reach the discard point

This **open vial policy** is applied only in fixed EPI sites where refrigerators are available. All opened vials meeting the all above criteria should be kept in the refrigerator with clearly written date of opening and can be used maximum for **a month (28 days).**

05

INJECTION SAFETY

INJECTION SAFETY

5.1 WHAT IS SAFE INJECTION?

A safe injection is an injection that does not cause harm to the beneficiary, the provider, or the community. Safe injections not only include safe administration, but also proper vaccine handling and reconstitution as well as safe collection and disposal of used syringes and needles.

5.2 CONSEQUENCES OF UNSAFE INJECTIONS

1. Development of bacterial abscess at the injection sites.

2. The most common serious infections transmitted by unsafe injections are hepatitis B, hepatitis C and HIV.

3. Poorly administered injections can also cause injuries or drug toxicities when the wrong injection site, drug, diluents or dose are used.

4. Health workers may acquire needle stick injuries due to mishandling of used syringes and needles.

Health workers should understand that reusing syringes and needles can cause cross-infection and put people at risk. Auto-Disable (AD) Syringes virtually eliminate the risk of patient-to-people transmission of blood-borne pathogens.

TO ENSURE INJECTION SAFETY FOLLOWING STEPS SHOULD BE TAKEN DURING VACCINATION

1. Wash or disinfect hands before preparing vaccines and giving injections.

2. Use only AD syringes during immunization session for each client for injectable vaccines.

3. Apply the appropriate injection techniques and correct dose.

4. Clean injection sites.

5. Do not recap used needles.

6. Handle used needles carefully to avoid pricks caused by needles.

7. Discard a needle that has touched any non-sterile surface (hands, environmental surfaces).

8. Use safety boxes for disposing of the used syringes. Safety boxes and containers need to be disposed of according to guidelines.

5.3 NEEDLE STICKS INJURIES

Needles frequently injure health workers and can inject small but dangerous amounts of blood infected with hepatitis-B, hepatitis-C, HIV or other germs. Needle sticks may occur during recapping or carrying used syringes and needles, through insecure positioning of the patient, particularly children, and through disposal practices that leave syringes and needles accessible to the public.

Precautions from getting needle prick:

- Use safety box in each session.
- After giving injection put used syringes in to the safety box.
- Don't do any other work at EPI session while holding the Syringe in hand.
- Don't recap the used syringes.
- Don't put pressure on safety box filled with used syringes.

5.4 AUTO DISABLE (AD) SYRINGES

AD Syringes are self-locking syringes that can be used only once. The plunger can go back and forth only once. So health workers should not move the plunger unnecessarily and should not try to inject air into the vial, as this will disable the syringe. Every AD syringe is sterilized and sealed by the manufacturer.

Main parts of AD syringes:

- Barrel
- Plunger
- Needle
- Needle cap
- Only Auto Disable Syringes should be used to provide vaccines through safe injection practice. Two types of AD Syringes are provided for the National Immunization Programme (0.05 ml for BCG vaccination and 0.5 ml AD syringe for all other vaccines).

Disposable syringes are used for reconstitution of vaccines.

HOW TO USE AUTO DISABLES (AD) SYRINGES

1. Wash hands well before use.

2. Peel open the syringe needle at the back of auto disable syringe package and remove syringes.

3. Remove the cap of the needle and immediately put it into the safety box. Do not recap it and do not touch the needle.

4. Take the vaccine vial and insert the needle to vial up to liquid to avoid air into the syringe.

5. Then take the vaccine from the vial by pulling the plunger slowly until the limit. After taking the vaccine into the syringe then remove the needle from the vial. Always keep in mind that needles must not be touched.

6. If there is air in the syringe, put the syringe in a vertical position and flick/tap by figure so that air will push to top. Then push the plunger slowly and air will come out from the syringe but remember do not push hard or fast or forcefully. Otherwise the plunger will be locked or the injection device automatically destroyed. (vaccine inside the syringe should not be less than 0.5 ml).

HOW TO GIVE VACCINES USING AD SYRINGES

1. Before giving the vaccine, clean the vaccination site with a cotton swab.

2. Hold the syringe barrel between thumb, index and middle fingers. Do not touch the needle.

3. The plunger can go back and forth only once, so health workers should not draw up air to inject into the vial as this will disable the syringe.

4. Insert needle with a smooth action.

5. It is not necessary to aspirate first.

6. Use your thumb to push the plunger without moving the syringe around.

7. Pull the needle out quickly and smoothly (less painful than doing it slowly).

8. Ask the parent to press the site gently with a clean swab for a few seconds (to stop bleeding and relieve pain).

9. Do not rub the area where the injection was given.

10. Discard the used syringes into the safety box.

Advantages of AD syringes:

- They can only be used once.
- Eliminate patient-to-patient disease transmission caused by the use of contaminated needles and syringes.
- They save time for health workers from the heavy work of sterilization.

COLLECTION AND DISPOSAL OF USED SYRINGES AND NEEDLES AT IMMUNIZATION SESSIONS

Needles cannot easily pierce them. Safety boxes require proper assembly before use as per instruction given in boxes. All used AD syringes and reconstituted syringes should be placed in safety boxes and once 3/4 filled (maximum 100 syringes in a box) safety boxes should be destroyed safely.

HOW TO USE SAFETY BOXES

For each immunization session there must be at least one safety box.

1. After giving the injection, the used syringe should be dropped immediately into the safety box.

2. Don't handle or shake the safety box unnecessarily. Never squeeze, sit or stand on the safety box.

3. Keep the safety box in a dry, safe place out of the reach of the children and general people until safe disposal.

4. When the safety box is not in use, close the opening on the top. Write down the date of first use and discard when it is full (2/3 of the box) or after 3 Months. Keep used vials and syringes in a separate safety box and label accordingly.

5. Do not fill the safety box until completely full. If the box is 3/4 full then close the box securely and send it for disposal as per the guideline.

Figure 7: Safety box and printed illustration and Instruction for fitting it.

PROCEDURES FOR DISPOSING SAFETY BOXES

The proper disposal of used safety boxes is one of the most important tasks in assuring immunization safety.

1. Following the immunization session or when the safety boxes is three quarters full, close the container.

2. Keep the safety boxes in safe place and out of reach of public.

3. Collect all safety boxes at Atolls and dispose them under the supervision of the EPI focal person.

If Incinerator is Available:

Used safety boxes should be burned in an incinerator. Incineration can completely destroy needles and syringes by burning at temperatures above 800°C. The high temperature kills microorganisms and reduces the volume of waste to a minimum.

If Incinerator is not available:

Pit burn:

Safety boxes may be burned and buried on premises in a controlled manner. A fence should restrict access to the pit. In unstable soils, the sides of the pit should be lined with brick or concrete to prevent collapse. A 10–15 cm layer of earth should be placed on each layer of waste, and the pit should be filled with soil or concrete when the contents reach 50 cm of the surface of the hole. Once closed, the site should be marked to prevent any future digging. Open dumping of safety boxes should be prohibited.

06

ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

6.1 WHAT IS AN AEFI?

An Adverse Event Following Immunization (AEFI) is any untoward medical event that follow immunization, and that does not necessarily have causal relationship with the immunization. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease. An AEFI may occur because of a program error or sensitivity to a vaccine or it may occur coincidentally. Whatever the cause, AEFIs must be taken seriously and the management must be rapid and professional.

To find the cause of an AEFI, the events must first be detected and reported. Reporting and investigating AEFI is important to identify ways to improve the programme and to respond to the concerns of the community. All AEFI should be reported if temporally related to immunization and unless otherwise specified. This includes all such events occurring within four weeks of an immunization.

6.2 TYPES OF AEFI

There are five categories of AEFI according to how it occurs.

Table 22: AEFI can be classified into 4 types, depending on the suspected cause of the reaction

Types of AEFI	Definition	Example
Vaccine product-related reaction	An event caused or precipitated by the active component or one of the other components of the vaccine (e.g. adjuvant, preservative or stabilizer). This is due to the inherent properties of the vaccine	High fever (>38.5 oc) following DPT vaccination
Vaccine quality defect-related reaction	An event that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer	Failure by the manufacturer to completely inactivate a lot of Inactivate Polio Vaccine (IPV)
Immunization error-related reaction	An event caused by inappropriate vaccine handling, prescribing or administration	Bacterial abscess due to unsterile injection
Immunization anxiety related reactions or Immunization stress related response	An AEFI arising from anxiety about the immunization process. ISRR: cover the entire spectrum of manifestations (symptoms and sign) of a stress response rather than a single symptom, anxiety	Physiological stress response to pain, such as change in heart rate or blood pressure: acute stress response Fainting spell in a teenager after immunization
Coincidental	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety	Pneumonia after oral polio vaccine administration

6.3 VACCINE PRODUCT RELATED REACTION

Vaccine product- related reaction, is an individual's reaction to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly.

Vaccine product- related reactions can be classified into **common- minor reactions and rare- more serious reactions. Table-2 and Table-3** provide a summary of frequency of common minor and rare serious reactions with an onset interval and a rate of occurrence.

COMMON MINOR REACTIONS

These are caused by the immune system response of the recipient to the vaccine. Some of the vaccine components can lead to reactions as well (e.g. aluminum adjuvant, stabilizers and preservatives).

Local reactions including pain, swelling and redness at the injection site can be expected in about 10% of vaccination. This is even more common with DPT injection. These reactions usually last a few days at the most and can be treated symptomatically. BCG causes a specific local reaction that starts as a papule **after two or more weeks** of vaccination and then becomes ulcerated leaving a scar. Measles vaccine may cause mild symptoms such as fever, rash and/or conjunctivitis, which are typically seen in a measles infection.

Mild fever, irritability, malaise and loss of appetite frequently occur with certain vaccines, which are usually self-limiting. However, such symptoms are usually mild, but can be quite serious in severely immuno-compromised children.

It should be mentioned that these minor reactions are common and usually expected, **which don't need to be reported as AEFI.**

Table 23: Summary of common minor vaccine reactions with management

Vaccine	Local reaction (pain, swelling, redness)	Fever	Irritability, malaise and non-specific symptoms
BCG	Common	Rare	Rare
Hepatitis B	Children up to 5%	1-6%	Rare
Penta Hib	5% - 15%	2-10%	Rare
MR /MMR	~10%	5-15%	5% rash
OPV /bOPV	None	Less than 1%	Less than 1%
TT	~10%	~10%	~ 25%
DPT[3]	Up to 50%	Up to 50%	Up to 60%
Management	• Cold cloth at injection site • Paracetamol[4]	• Give extra fluids • Wear cool clothing • Tepid sponge or bath • Paracetamol[4]	Symptomatic

[1] Diarrhea, Headache, and/or muscle pains

[2] Rate of local reactions likely to increase with subsequent doses, up to 50 to 85%

S with whole cell Pertussis vaccine; A cellular Pertussis vaccines rates are lower

[4] Paracetamol doses: up to 15 mg/kg every 4 hours, maximum of 4 doses in 24 hours

SERIOUS VACCINE REACTIONS

An AEFI is considered to be serious if results in death, is life threatening, requires in patient hospitalization or prolongation of existing hospitalization, clusters, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect.

These may occur in rare cases. Some of these do not lead to long-term effects (e.g. seizures, hypotonic hypo responsive episodes). Anaphylaxis, while potentially fatal, is treatable without leaving any long-term effects.

All serious vaccine reactions need to be reported as AEFI and require investigation.

Table 24: Summary of rare serious vaccine reactions, onset interval and rate by antigen

Vaccine	Reaction	Onset Interval	Number of events per million doses
BCG	• Suppurative lymphadenitis	2-6 months	100-1,000
	• BCG osteitis/ osteomyelitis	1-12 months	1-700
	• Disseminated BCG infection	1-12 months	2
Hepatitis-B	• Anaphylaxis	0-12 hour	1-2
Hib	• Nil / not known		
Measles	• Febrile seizures	5-12 days	333
	• Thrombocytopenia (low platelets)	15-35 days	33
	• Anaphylaxis	0-12 hour	~1
OPV	• Vaccine associated paralytic poliomyelitis (VAPP)	4 - 30 days	0.76-1.3 (1st dose) 0.17 subsequent doses
Td	• Brachial neuritis	2-28 days	5-10
	• Anaphylaxis	0-12 hour	1-6
	• Sterile abscess	1-6 weeks	6-10
DPT	• Persistent (>3 hours) inconsolable screaming	0-24 hours	1,000 - 60,000
	• Seizures[2]	0-3 days	570
	• Hypotonic hypo responsive episode (HHE)	0-24 hours	570
	• Anaphylaxis	0-12 hour	20
	• Encephalopathy	0-3 days	0-1

6.4 IMMUNIZATION ERROR-RELATED REACTIONS

Immunization errors are the most commonly reported adverse events. These occur as a result of inappropriate storage, transportation, reconstitution, preparation and administration of vaccines. It is extremely important that these AEFIs are reported and addressed for early correction. **Table-15** provides a list of some programme errors and types of AEFI.

An immunization error may lead to a cluster of events associated with immunization. These clusters are usually associated with a particular provider or health facility or even a single vial of vaccine that has been inappropriately prepared or contaminated.

Table 25: Immunization Error- related adverse events

Immunization Errors	Adverse Events/reactions
1. Error in vaccine handling: a. Exposure to excess heat or cold as a result of inappropriate transport, storage or handling of the vaccine and diluents. b. Use of vaccine after expiry date.	a. i) Failure to immunize as a result of inactivation of vaccine components. ii) Systemic or local reaction due to changes in the physical nature of the vaccine e.g. in injection site abscess, cellulitis, sepsis, toxic shock syndrome etc. b. Failure to vaccinate due to loss of potency
2. Error in vaccine prescribing or non-adherence to recommendations: Failure to adhere to a contraindication: Pentavalent vaccine given ignoring convulsion history with previous dose.	a. Anaphylaxis after vaccination to an individual known to have hypersensitivity. b. Disseminated infection with attenuated live vaccine agent after administration to an individual with known immunodeficiency and contraindicated for any live vaccine.
3. Failure to adhere to vaccine indications: dose, route/site: i. Incorrect dose. ii. Incorrect age group. iii. Incorrect site, equipment or injection technique i.e. Subcutaneous instead of intra-dermal for BCG or IM instead of SC, administration in the buttocks.	a. Local and or systemic reaction. b. Vaccine failure. c. Neurological, muscular, vascular or bony injury, Sciatic nerve damage.
4. Error in Administration: a. Use of incorrect diluent or incorrect vaccine other than the intended vaccine/diluent. b. Incorrect sterile technique or non adherence to multi-dose vial policy like reconstituted vaccine used after 6 hours or at subsequent session. c. Failure to ensure a safe environment during and immediately following immunization. d. Inadvertent administration of vaccine to someone for whom it was not intended.	a. i) Failure to vaccinate. ii) Reaction due to inherent properties of whatever was administered other than the intended vaccine/ diluent. b. i) Infection at the site of injection due to a microbial contaminant introduced during administration of the vaccine. ii) Infection beyond the site of injection due to a microbial contaminant introduced during administration of the vaccine. c. i) Head injury during a syncopal episode post-immunization e.g. via a needle stick injury or splash to the eye.

HOW HEALTH WORKERS CAN PREVENT AEFI DUE TO IMMUNIZATION ERROR

Immunization error, which can be prevented, is more often the cause of AEFI. An immunization or programmatic error is usually person-based rather than vaccine or technology-based (e.g. injection site abscess). It can generally be prevented through proper staff training and an adequate supply and proper use of safe injection equipment including effective supportive supervision. In addition, regular supervision will greatly contribute to the reduction of this unwanted phenomenon.

BASIC RULES TO AVOID IMMUNIZATION ERRORS

1. Reconstitute your vaccine only with the diluent supplied by the manufacturer.

2. Discard reconstituted vaccines after 6 hours or at the end of each immunization session whichever comes first (Remember, open vial policy applies only to liquid formulation of vaccines!).

3. Do not keep drugs or other substances in the vaccine refrigerator.

4. Use only AD syringe for each injection.

5. Full investigation of an AEFI is needed to pinpoint the cause and to correct inappropriate immunization practices.

6.5 COINCIDENTAL EVENTS

AEFIs can result from underlying or emerging conditions of vaccine as well as external exposures that can cause harm independent of immunization. These include but are not limited to:

1. Underlying or emerging condition(s) in the vaccine

2. Manifestation or complication of a congenital or inherited underlying disease condition or birth injury

3. Manifestation or complication of an underlying acquired disease condition that may or may not have been diagnosed prior to immunization

4. Psychological illness

5. Conditions caused by exposure to something other than vaccine

6. Infection due to agents such as bacteria, viruses, fungi or parasites

7. Adverse reaction due to recent or concomitant medication or use of illicit substances

8. Allergic and other hypersensitivity reaction due to exposure to allergens other than those present in the vaccine

9. Injury due to exposure to environment toxin

10. Injury due to trauma including surgery

6.6 IMMUNIZATION ANXIETY RELATED REACTION

Individuals and groups can react in anticipation to and as a result of an injection of any kind. Children or women might react out of fear or pain to an injection of any kind. This reaction is not related to the vaccine itself. Examples of injection reactions include fainting, light-headedness, dizziness, tingling around the mouth and in the hands; occasionally breath holding in younger children may lead to unconsciousness. In a group situation, mass hysteria is possible, especially if a vaccine is seen to faint or have some other reaction. These reactions are not related to the vaccine, but to the injection. Clear explanations about the immunization and calm, confident delivery will decrease the level of anxiety about the injections and thus reduce the likelihood of occurrence.

6.7 OBJECTIVES OF AEFI SURVEILLANCE

1. To detect and manage serious AEFI cases

2. To report AEFI using standard case definition

3. To take appropriate regulatory actions when serious and unexpected AEFIs detected

4. Identify unusual high rates of AEFI with specific vaccine lots and brands

5. Promptly address programmatic errors through implementation of corrective measures

6. Ensure that if any coincidental events are falsely blamed on immunization, to disseminate correct information to concerned authorities and public

7. Maintain confidence in the immunization programme by properly responding to concerns

8. Estimates AEFI rates in the population compared with local and global data

6.8 REPORTING AEFIS

To identify the cause of an AEFI, the events must first be detected and reported. All of the following adverse events should be reported if temporally related to immunization. Unless otherwise specified this includes all such events occurring within four weeks of a vaccine administration.

REPORTABLE AEFI

A. Serious cases that require an investigation within 24 hours:

1. Death attributed to vaccine
2. AEFI that resulted in hospitalization
3. Clusters of AEFI
4. Any AEFI causing significant parental or community concerns

B. Other AEFI that are of interest to monitor the safety and quality of immunization services:

1. Abscess at injection site
2. Fever as an adverse event following immunization
3. Hypotonic-hyporesponsive episode (HHE) as an adverse event
4. Induration at or near injection site
5. A local reaction at or near injection site
6. Nodule at injection site as an adverse event following immunization
7. Allergic reactions; rash
8. Seizures (febrile seizures or afebrile seizures)
9. Acute onset of flaccid paralysis (occurs extremely rare with OPV)

If the AEFI does not occur within the time frame specified, but there is a suspicion that the event may be related to vaccine, then these should also be reported. If the adverse event occurs outside of this time frame, the event is less likely to be due to vaccination.

6.9 AEFI REPORTING SYSTEM

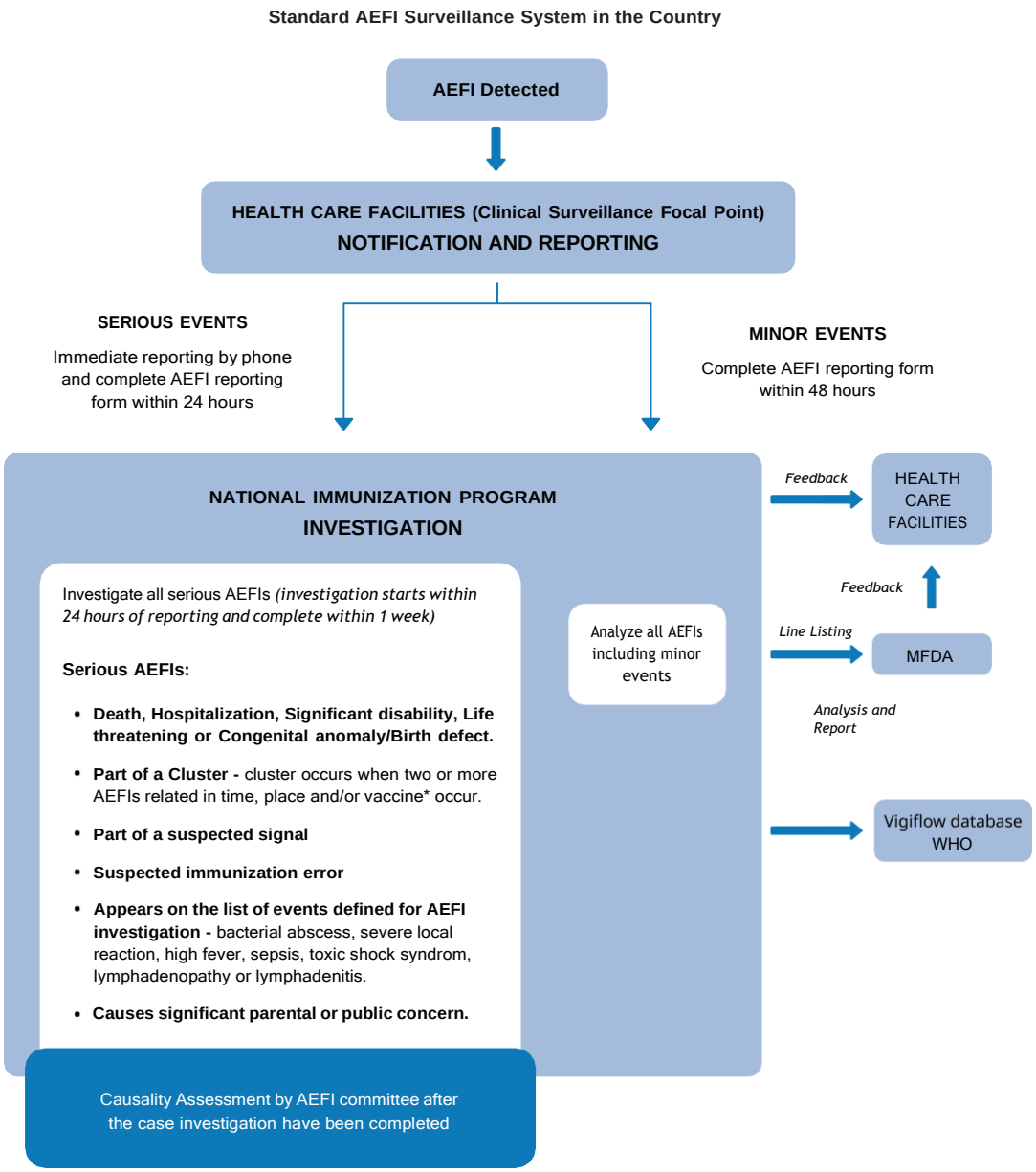
All health facilities should have identified focal points responsible for AEFI surveillance and reporting. These focal points are known as Clinical Surveillance Focal Points (CSFP).

INFORMATION ON AEFI IS REPORTED FROM FOLLOWING SOURCES:

1. Community: All health workers in EPI session or during house visits may detect AEFI cases and report.

2. Hospital/Health Facility: All designated hospital and health facilities will report AEFI cases from Outdoor (OPD) services: In OPD it is the responsibility of treating Medical Officer (MO) to report AEFI. In a high workload setting, MO/ OPD may refer the case to EPI Unit for reporting.

3. NGO clinics providing immunization services will report to the respective focal person of the Hospital. (For this purpose, AEFI reporting forms should be made available to these clinics) forms can be downloaded from the Ministry of health website.



Note: Vigiflow Database is the unique WHO global database of individual case safety reports (ICSRs). It is the largest database of its kind in the world, with over 25 million reports of suspected adverse effects of medicines, submitted, since 1968, by member countries of the WHO Programme for International Drug Monitoring. It is continuously updated with incoming reports.

ENCOURAGING HEALTH WORKERS ON REPORTING

The support of field staff is crucial for the success of any surveillance programme. Field workers are encouraged to report adverse events without fear of penalty. The aim is to improve the health care system or provide further training and not to blame individuals.

In order to encourage reporting the manager (e.g. Specialized Doctors, Nurses, and Medical Officers) is responsible to carry out the following activities:

1. Train staff on AEFI and its reporting

2. Increase awareness of health staff on importance of reporting

3. Give positive feedback and appreciation for reporting. It is essential that health workers be given feedback about the results of investigations and any actions taken as a result of the report.

The type of feedback that is given and the manner in which it is given depends on the audience. Managers should ensure that there is an ample supply of reporting and investigation forms in their institutions in order to facilitate timely reporting.

6.10 INVESTIGATION OF AEFIS

A case investigation is usually the first major action to be taken when an AEFI is reported and should begin without delay. Investigation should be initiated by the health workers who detects the AEFI or by the Clinical Surveillance Focal Point or by the doctor/ nurse who sees the case in health facility/hospital. With inadequate or incomplete data, an AEFI can be deemed either ineligible for causality assessment or unclassifiable.

PURPOSE OF AN INVESTIGATION

The ultimate goal of an investigation is to determine whether the vaccine or immunization process is responsible for the reported AEFI or to find another reason and correct it if possible and reassure the public. The purposes of investigating AEFI are:

• To confirm diagnosis of a reported AEFI and determine the outcome

• To investigate link between the vaccine administered and the AEFI

• To determine contribution of the operational aspects of the programme to the reported AEFI

• To determine whether a reported event was isolated or part of a cluster

• To determine cause of the AEFI so as to provide the best intervention/medical care and take any further action deemed necessary

• To determine whether un-immunized persons are experiencing the same medical event(s)

If the cause is determined to be an immunization error, the problem should be corrected quickly. If an AEFI is found to be coincidental, then the community can be reassured about the safety of the vaccine and the immunization programme. The act of investigating AEFI increases the confidence of the community in the health care system and the immunization programme in particular.

WHAT AEFI TO REPORT AND INVESTIGATE IMMEDIATELY

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

The following AEFIs must be reported and investigated:

1. All clustering of any AEFI.

2. All deaths that are believed by health workers, or the public, to be related to immunization.

3. All cases requiring hospitalizations that are believed by health workers, or the public, to be related to immunization.

4. All severe or unusual medical events about which health workers, or the public are concerned to be related to immunization.

The above 4 categories of AEFI are sometimes called **"trigger"** events because they stimulate or trigger a response, such as investigation and corrective actions. When adverse events are not recognized and no response is made then the threat to children's health is increased.

CLUSTER OF AEFI

A cluster is defined as two or more cases of the same or similar events, which are related in time, and have occurred within the same geographical unit (Atoll, Island, Community) or associated with the same vaccine (same batch/lot number) administered or same vaccination site, for e.g. two or more cases of abscess occurring following one immunization session in a community; repeated abscess cases following immunization by same vaccinator.

WHEN TO INVESTIGATE

AEFIs which resulted in death, hospitalization, and widespread community concern, or cluster, investigation should begin as soon as possible, ideally within 24 hours of detection. When an investigation is believed necessary, it is important to initiate it immediately so that the cause could be determined quickly and additional cases prevented (where possible), in order to avoid compromising the programme as a result of ongoing community concern.

WHO SHOULD INVESTIGATE?

In most cases, a preliminary investigation will be made by the community health workers, physician, nurse who detect the case in a health center/hospital. In case of death, hospitalization, cluster event, and event causing significant self /parental/community concern, Medical Officer, Nurse / Clinical surveillance focal person (CSFP) will initiate investigation and notify the National Immunization Programme. The detailed investigation will be carried out by a team. The National AEFI committee will coordinate the investigation and causality assessment.

Team Members for Investigation: at island and Atoll levels

A team comprising of the following members will investigate AEFI (guided by the central NIP and AEFI committee)

1. Clinical AEFI surveillance focal point

2. Public health unit

3. Quality Improvement Department (if available)

4. A medical consultant and/or Pediatrician (and / or other specialities as required)

5. May consider to add nursing in charge and or Medical in charge / Medical director

If all members of the team are not available, at least 2 members could start the investigation and one of them must be a doctor. They will call upon and ask the advice of any other member of the proposed team as and when needed. The medical director and nurse in charge of the health facility or hospital would need to be informed about the progress of the investigation even if they are not in the main investigation team.

NATIONAL LEVEL INVESTIGATION TEAM WITH AEFI COMMITTEE

The Public Health Programme Manager-NIP will initiate investigation if clusters are detected at national level or any AEFI with National NIP programme concern. A national level investigation team may be formed to investigate national level and support sub-national investigation teams to investigate trigger events with the following members (if necessary). During AEFI investigation the concerned authorities such as MFDA, QID MOH should be informed, even if they may not be in the main case investigation teams.

IMMEDIATE REPORTING AND INVESTIGATION

In case of death, hospitalization, cluster or any event causing significant parental /community concern the AEFI must be reported immediately to the Clinical Surveillance Focal Point (CSFP).

Once Focal point is notified of the events he will immediately notify the National Immunization Program (NIP). If these events occur in a facility other than Hospital, respective Focal person of Hospital will immediately notify to the National Immunization Program (NIP).

During line listing if any cluster is identified, the Focal point of the Health Center or Hospital will initiate investigation and take necessary actions to prevent further occurrence of similar events. If such a cluster is identified during compilation at Atoll level then the Atoll Focal Point will inform the National Immunization Program (NIP).

HOW TO HANDLE PARENTS/BENEFICIARY

Key points on how to handle the parent/beneficiary who has experienced an AEFI. This is one of the most crucial functions of the health workers, nurses and doctors when an AEFI has taken place.

- Communication with parents/beneficiary is a crucial part of managing an AEFI
- Listen sympathetically to parents and their concerns
- Reassure the parents and beneficiary but do not make false promises
- Assist the parent/caregiver to take beneficiary to hospital/Health facilities
- Keep the parent routinely informed of the progress of the beneficiary

07

ORGANIZATION VACCINATION SESSION AND MANAGEMENT

ORGANIZATION VACCINATION SESSION AND MANAGEMENT

As a health worker, you need to perform a number of important tasks to ensure the quality of an immunization session. They are as follows:

1. Preparing for the session
2. Communicating with caregivers
3. Assessing infants for vaccination
4. Giving vaccinations
5. Closing the session
6. Recording Data
7. Using the immunization session checklist

Immunization sessions must be arranged so that beneficiaries who attend for the first time will return for the subsequent doses. The session should be arranged and organized in such a way that they are convenient and comfortable for the parents / guardians. For this to be realized, make sure that logistics required are available and the environment safe and comfortable for the parents/guardians.

The preparations include:

• Making sure that vaccines, supplies, and equipments are available

• Arranging space for the convenience and comfort of health workers and parent/guardian

7.1 ARRANGEMENT AND PREPARATION OF SPACE FOR IMMUNIZATION

The arrangement of space in your health facility will affect how you perform your work and the time taken by parent/guardian during the immunization process. The space that you set up for immunizations should be:

• In a clean area not directly exposed to the sunlight, rain or drought

• Convenient for Health Worker who is preparing vaccines and immunizing

• Easily accessible to parent/guardian, but arranged in such away that it is not crowding around the immunization station

• Quiet enough for health workers to be able to explain what he or she is doing and give advice

7.2 ORGANIZING OUTREACH SESSIONS

If the outreach site is other than a health centre then make sure that it is well located and easy access to the target population as per developed microplan. The site should be cleaned, well ventilated and enough space for comfortable works of healthcare providers and for movement of clients.

The date, time and place for outreach sessions should be disseminated to all target communities by using various communication channels.

IMPORTANCE OF A WELL-ORGANIZED IMMUNIZATION SESSION

A well-organized immunization session facilitates health workers to effectively perform activities before, **during and after the session.**

Before session:

A. Basic characteristics and requirement of an organized immunization post:

1. Easily accessible to beneficiaries which is arranged such a way that they are not crowding the immunization area

2. It should be clean not directly exposed to sunlight, rain, or dust

3. People should be in a queue and space should be available where beneficiaries can sit before receiving doses of vaccine

4. Convenient space for the vaccinators for preparing injections

5. A table for vaccines and required equipment for the vaccinator

6. A table for the recorder for recording the information for the beneficiary in vaccination card/ immunization record

7. A chair on which a beneficiary /parents can sit for vaccination

8. Preparation for vaccination session should be like fixed session

B. Supplies and equipment needed for a session

1. Vaccines, diluents and other supplies

2. Vaccine carrier, icepack, foam pad

3. AD syringes for injection, disposable syringes for reconstitution

4. AEFI kit

5. Safety boxes

6. Cotton

7. Hand sterilizer

8. Vaccination records

9. Pencil, pen, scissors

C. Assessing/ Screening the beneficiary in the session

The purpose of assessing a beneficiary is to find out what vaccines he or she is eligible for and whether there is any reason not to give them.

1. Health worker should know the national immunization schedules

2. If a beneficiary is ill, facilitate proper treatment but make sure immunization is rescheduled

During session:

Preparing vaccine for use

1. Washing/disinfecting hands
By washing hands with soap and water or using sterilizer you remove the germs from them and help to prevent contamination.

2. Checking the vaccines and diluents
Before you use any vaccines and diluents for reconstitution and administration, check

a. Is the label still attached to the vial?

b. Is it the right vaccine or diluents?

c. What is the expiry date? Is it past its expiration date?

d. Is VVM Ok? Check the color change in the square.

UNSAFE IMMUNIZATION PRACTICES

	Do not recap the needle
	Do not leave the needle inside the vial
	Do not touch the needle
	Do not dispose of used needles in an open cardboard box

7.3 RECONSTITUTING VACCINES

Reconstituting vaccines means mixing a powdered form of a vaccine with a fluid called a diluent. All freeze-dried vaccines like BCG, Measles, MR and MMR vaccines must reconstitute before the vaccine can be injected.

Follow the steps below to mix BCG, Measles and MMR powder vaccines with a diluent.

STEPS TO RECONSTITUTE VACCINES SAFELY

1. Read the label on the diluent to be sure that it is the diluent provided by the manufacturer for that specific vaccine and vial size.

2. Check to make sure the expiry date has not passed.

3. Ensure the diluent temperature to 2-8°C prior to use for reconstitution.

4. Draw the entire contents of the diluent vial into the mixing AD syringe.

5. Empty the entire contents of diluent into the vaccine vial.

6. Discard the used mixing syringe and needle safely into safe box.

7. Do not leave the mixing needle in the vial; this is a common mistake that leaves the vial open to contamination.

8. Hold the neck of the vial between your fingers and shake gently to mix the contents until all of the vaccine powder has dissolved. Note the time the vaccine was reconstituted.

9. Keep the reconstituted vaccine cool and protected from light by placing the vaccine inside slits cut in the top of a foam pad that has been cut to fit a vaccine carrier. However Vials should not be placed in a cup of ice as it can damage or remove the vaccine vial label.

10. Discard all reconstituted vaccines at the end of the session or after 6 hours whichever comes first.

Key Points

- Diluents are never interchangeable. Use ONLY the diluent approved by the manufacturer to reconstitute the specific type of vaccine.
- Diluents should be at to 2-8°C before being mixed with the vaccine
- Do not reconstitute the vaccine until the person needing a particular vaccine is present.
- **Discard reconstituted vaccines after 6 hours of reconstitution or at the end of the immunization session, whichever comes first.**
- Use a new mixing syringe to mix each vial of freeze-dried vaccine.
- Do not leave a needle in the top of the vial.
- **Use the same syringe and needle to draw up the dose and to inject.**

7.4 RECONSTITUTION OF FREEZE-DRIED VACCINE

- Wash your hand with water and soap before reconstituting vaccines
- Flick or tap the ample with your finger to make sure that all of the vaccine powder is at the bottom of the vial/ample.
- Use a new disposable mixing syringe and draw all the diluents from the ampule (refer to the manufacturers guide on specific vaccine dilution) into the syringe. Use 5ml syringe to reconstitute Measles/Rubella and MMR and 2ml for BCG vaccine.
- Insert the diluents filled syringe into the vaccine vial/ampule and push the plunger slowly to mix diluents with powder.
- After use, put the mixing syringe and needle in a safety box.
- Put the reconstituted vaccine on the foam pad of your vaccine carrier.

VACCINE STORING AT IMMUNIZATION SESSION AND USE OF VACCINE

The following point should be considered to maintain potency of vaccine during conduction of EPI session:

1. Keep the vaccine carrier in the shade.

2. Don't open vials until target beneficiary arrive at the session.

3. Use only one vial of a vaccine at a time.

4. Keep reconstituted BCG and Measles and OPV vial in the slit of foam pad of vaccine carrier.

5. The vials should be shaken gently before withdrawing vaccine in the AD syringe every time. As because sediment may deposit at the bottom of vials during storing.

6. Frozen Pentavalent (DTP + Hep-B +Hib) and Td vaccine and frozen diluents must not be used in any way.

7. Time of reconstitution should be written on the vials at the time of reconstitution of BCG, Measles and MMR. So, reconstituted BCG, MR and MMR should be discarded at the end of the session or after 6 hours of reconstitution whichever comes first.

8. Immunization card should be checked and registration should be completed.

9. Used AD syringes should be put into the safety box immediately after use.

10. Vitamin A should be given with MR and MMR vaccines.

11. Td vaccine should be given to women on the basis of eligibility as per schedule.

12. Daily tally report should be prepared.

13. Parents should be informed when to come for the next dose.

Key messages for parents:

• Bring the child on the right date to complete the vaccination.

• Vaccination can be given if child suffers from **mild** fever, **mild** cough and diarrhoea.

• After vaccination the child may develop mild fever, pain or ulcer at the site of BCG injection, these are self-limiting and nothing to be worried about.

• Preserve vaccination card for future needs.

• Inform them to report any concerned event after vaccination to nearby health facilities.

7.5 POSITIONING CHILDREN CORRECTLY FOR VACCINATION

POSITIONING CHILDREN CORRECTLY FOR VACCINATION

• Unexpected movement at the time of injection can lead to accidental needle sticks and pain to the child.

• To prevent this, position the child securely before giving injections.

• Have the mother sit and place the child on her lap. Make sure one of the mother's arms is behind the child's back and one of the child's arms wraps around the mother's side.

• The mother may tuck the child's legs between her own to secure them, or she may hold the child's legs

• Health workers cannot hold the child because they need to use both hands for injection.

• Always tell the mother when you are about to give the injection.

ROUTE OF INJECTION AND TECHNIQUE FOR PENTAVALENT/IPV/HEPATITIS-B INJECTION:

Hold the syringe in right hand and insert needle in to the muscle at 90° angle in outer aspect of middle thigh.

FOR TD INJECTION:

Hold the syringe in the right hand and insert the needle into the muscle at 90° angle in the outer part of the upper arm.

FOR MEASLES / MMR INJECTION:

Hold the syringe in your right hand and insert needle in to the pinched up skin almost at 45° angle at the outer part of upper right thigh.

FOR BCG INJECTION:

- Stretch the skin out flat with your left thumb and forefinger.

- Hold the syringe in your right hand, keep the needle flat along the skin and insert the tip of the needle just under the surface, keeping the bevel of the needle facing up.

ORAL POLIO VACCINE (OPV):

- Ask the parent to hold the infant with the head supported and tilted slightly back.

- Open the infant's mouth gently, either with your thumb on the chin or by squeezing the infant's cheeks gently between your fingers.

- Let 2 drops of vaccine fall from the dropper onto the tongue. Don't let the dropper touch the infant's mouth.

Table 26: Summary of vaccination Sites and route of Vaccination

Vaccine	Site	
BCG	Intradermal - Left upper arm	Arm
Hepatitis-B	Intramuscular - Outer aspect of middle	Thigh
Pentavalent	Intramuscular - Outer aspect of the middle	Thigh
MR	Subcutaneous - Outer aspect of middle	Thigh
MMR	Subcutaneous - Outer aspect of middle thigh	
Td	Intramuscular - Outer part of the upper arm	
OPV	Oral - OPV is given in mouth	
IPV	Intramuscular - Outer aspect of the middle thigh	

5 key principles for giving vaccination:

1. Correct vaccine and correct dose
2. Right route
3. Right AD Syringe
4. Right site of injection
5. Non-touch technique

7.6 VITAMIN A SUPPLEMENTATION

• Check the expiry date on the label. If the expiry date has been reached, discard the bottle.

• Open the bottle and write the current date on the label so that you will know when to stop using it. Opened bottles of vitamin A capsules are good for one year.

• Open a capsule by cutting the tip or nipple off with a clean pair of scissors or a clean nail clipper.

• Squeeze the capsule firmly so that the drops fall into the mouth of the client. For a young child, you may need to pinch his or her cheeks gently to open the mouth.

Give the correct amount of vitamin A supplement: too much can cause harmful side-effects.

If you are giving Vitamin A to children ages 9 through 11 months and you have only 200 000 IU dose capsules, you need to know the number of drops in this size of capsule in order to be able to give a half dose (100 000 IU). To do that:

Step 1: Open one 200 000 IU capsule, and squeeze out the contents while counting the number of drops that are contained in it.

Step 2: Divide the total number of drops by two — this is the number of drops equal to a half-dose or 100 000 IU. It is safe to assume that all capsules in a batch contain the same number of drops. Label the box with the batch number and number of drops so that next time you do not have to waste a capsule to count the drops.

After Session:

A. Care of Equipment and space:

• Close the opening on the top of safety box.

• Keep the safety box in a secure place and out of reach of the children and public. If the box becomes 3/4 full then close the box securely and send it for burning in incineration.

• Take care of the vaccines after the immunization session- Liquid vaccines like OPV, TT can be used in subsequent sessions (if multi dose vial criteria permits), put in the return box in the refrigerator.

• Care of the other supplies (injection material) and equipment (vaccine carrier). Keep all equipment clean.

• Clean the space.

• Filling the records completely and accurately.

B. Clean waste of Vaccination center:

• Do not leave anything behind that might be a health threat to the community.

• Do not leave empty or opened vials at the site.

• Do not leave any syringes or needles at the site.

• Return tables, chairs, and other equipment to their owners.

• Thank the local people who have helped to organize the session and remind them when you will return.

08

REPORTING SYSTEM

REPORTING SYSTEM

Recording and reporting of accurate, reliable, and timely information is critical to the success of any program. Systematically and regularly recording the vaccinations given at each session ensures that services meet coverage targets, identifies defaulters and helps to actively follow up all those who need to complete their vaccinations.

8.1 DIFFERENT FORMS AND CARDS USED IN IMMUNIZATION

The following are the forms and cards used in immunization program.

1. Vaccination record
2. Daily tally sheet
3. Monthly vaccination report
4. Stock record
5. Temperature chart
6. AEFI Reporting Form
7. AEFI investigation form
8. VPD reporting form (AFP, Measles…)
9. Incident report
10. Vaccine Error form

USE OF DIFFERENT FORMS AND CARDS

Registration and Vaccination Information Book:

• Total target of the catchment area is known once the name of new born infants' after birth and name of eligible women are registered in the Registration and Vaccination Information Book.

• To track the starting date of vaccination and completion dates.

• Tracking each dose given to beneficiaries.

• Help health workers keep track of the immunization services. The follow-up can be made for the dropouts to complete the remaining doses.

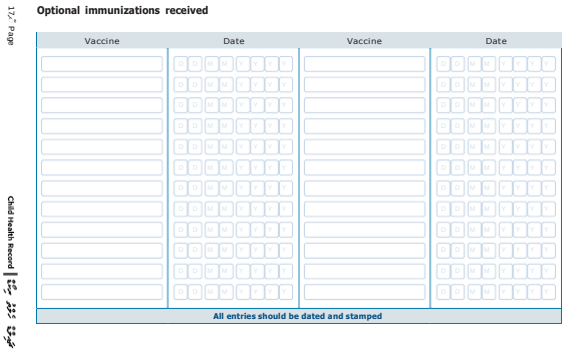
• Daily target for vaccination is determined on the basis of eligibility of each vaccine dose.

Keynote: Health workers should be urged to treat the Vaccination Record Book with respect and care as it may be the only permanent record of immunization available. The immunization register can also be used as a birth register.

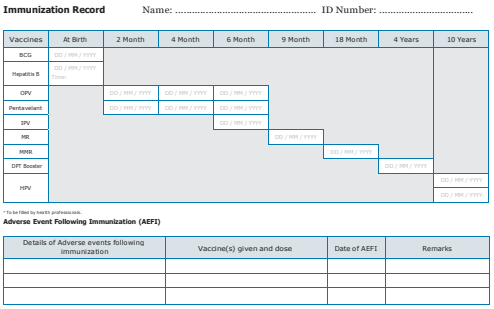
Vaccination Record Book:

Immunization Card:

The immunization card contains the immunization history and status. It is important that the information required in immunization cards are filled completely and accurately so that they can be used for tracking defaulters and providing caregivers and pregnant women with information on when to return for services.



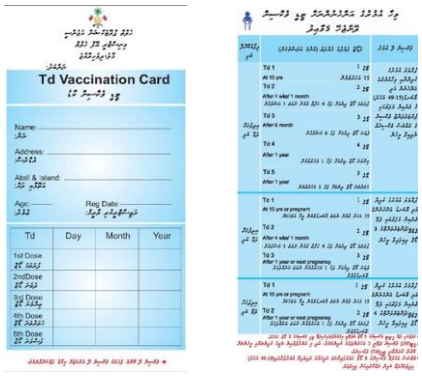
Vaccine Record Book(Vaccination Page):



Covid Vaccine Card:

Supplementary Card:

Td Card:



Travel Vaccine Card (Yellow Card):

TALLY SHEET

Tally sheets are forms on which the health workers mark after administering a dose of vaccine. At the end of each immunization session, the total number of tally marks recorded during the session should be tallied. This tells the number of immunizations that have been given by each vaccine and each dose. The information will be further used to monitor performance and prepare a monthly report. The monthly report should be prepared by compiling the daily tally sheets.

MONTHLY REPORT FORM

The immunization data collected needs to be consolidated in a summary form called Monthly report form. The monthly report form needs to be compiled and sent to the next level either manually or electronically.

At each facility the data should be analyzed and used to improve the programme performance.

8.2 PREPARING MONTHLY REPORT

The health worker or the person designated for preparing report should ensure that the reports prepared are:

- **Complete:** All the sections of the reports have been completed; no parts have been left blank and all reports due from the reporting sites have been received.

- **Timely:** Check for the deadline for reporting. The report from Islands should be submitted to atolls by 5th of next month and from atolls to NIP by 10th of next month (Report of January of Islands is to be sent by 5th February to atolls and from atolls to NIP by 10th February).

- **Accurate:** Check the totals and calculations before sending the report. Make sure that the reported figures are matched to the actual figures.

8.3 STORING DATA AND REPORTS

At the facility level, tally sheets, registers and reports should be stored for a specific period of 3 years.

8.4 ELECTRONIC IMMUNIZATION REGISTRY (EIR)

Electronic Immunization Registry (EIR) is the software to manage individual level immunization data of the people in Maldives. This system was developed on DHIS2 health information management platform and supported by the World Health Organization.

EIR captures all vaccines given from birth to death including all EPI and non-EPI vaccines. Vaccine stages covered in EIR are, at birth, 2 months, 4 months, 6 months, 9 months, 18 months, 4 years, 10 years (HPV), 15 years (Td), non-routine vaccines, pregnancy vaccines, traveler vaccines, health worker vaccination, influenza vaccination and special campaign vaccines.

In addition to capturing vaccines, EIR also consists of different modules for Adverse Events Following Vaccination (AEFI), Vaccine Preventable Disease (VPD) surveillance, incidence reporting and supportive supervision. System has a number of validation rules to ensure the accuracy of data. Data entry process is optimized with the user-friendly design of the data capturing app. Pending and missed vaccines are displayed on the same data entry page.

Captured information is automatically analyzed to dashboards for all the levels from health centre, island, atoll to the national level. Dashboards consist of indicators that measure vaccination performances and the vaccine coverages by the relevant place/area. Further customized data analysis is possible through the inbuilt data analysis and visualization apps in the DHIS2 platform.

EIR consists of a beneficiary portal through which the citizens can access their vaccination record and download Digital Vaccination Record and International Certificate of Vaccination or Prophylaxis.

Electronic Immunization Registry consists of a complete training package with a detailed user guide and simplified single-page data entry guides for each data entry step.

09

COMMUNICATION IN IMMUNIZATION

9.1 COMMUNICATION IN IMMUNIZATION

Communication is a two-way exchange and interaction between two persons or among persons. This exchange is a continuing process that allows the participants to reach a decision and agree on the needed action.

Effective communication by health workers to beneficiaries and parents/ community will help clarify doubts, fears and concerns about their benefits of vaccination to the beneficiary who needs protection against dangerous diseases, to the parents who want a healthy family and to the community in preventing the possible spread of diseases when not all children are immunized.

9.2 EFFECTIVE COMMUNICATION

Effective communication means listening to, understanding, encouraging, and working with individuals and communities to improve their health and the services available to them.

9.3 COMMUNICATION WITH THE COMMUNITY

Keeping community members updated on the progress of the immunization programme is important for increasing and sustaining their involvement and support of services. The strategies for communication with the community in **Table 27** will enhance communication and help to build a good relationship and rapport.

Table 27: Tips for effective communication with communities

Strategies for communicating with communities	Tips
Establish a good relationship with the community.	• Be warm, friendly and welcoming. • Show respect for the community members. • Praise and encourage the parents in the community for bringing their children for immunizations.
Listen to the community.	• Find out what the community already know by using terms they understand. • Respond to concerns about immunizations. Conduct meetings and home visits in a comfortable setting.
Provide information on the services available and the status of the immunization programme.	• Encourage input on priority health services and service delivery mechanisms and preferences. • Provide information on coverage, disease cases and progress, using basic language and non-scientific terminology. • Show concern for the community's situation. • Talk to caregivers about the importance of immunization for them and their infants.

Table 28: Tips for effective communication with parents at the fixed or outreach session

Interpersonal communication during session	Tips
Give information relevant to the mother's situation.	• Provide information on the vaccine(s) received, when they should come back for the next dose, and what to do if side- effects occur (while reassuring the parent that side-effects are rare). • Encourage parents to continue immunizing the child and complete the schedule • Show concern for the parents' particular situation. • Correct any misconceptions the parents may have.
Keep information simple and clear.	• Be straightforward. Use simple language understood by the parent. • Summarize the key information. • Thank the parent for bringing the child.
Get parents to provide feedback about what they have heard to make sure they have fully understood.	• Ask parents to repeat what they have heard to check for understanding. • If you ask, — "When will you bring your child for his next immunization?" and someone answers with the correct day or date, you know that he or she has understood you. Praise correct answers.

THE IDEAL HEALTH WORKER/CAREGIVER INTERACTION IN EPI SESSION

1. The health worker welcomes, greets and thanks the caregiver in a friendly manner for coming for vaccination and for her patience if she had to wait.

2. The health worker explains to the caregiver in simple terms and the local language the disease(s) against which the vaccination protects.

3. The health worker mentions possible minor side effects (which are normal reactions to vaccines) and explains how to handle them. Health worker also mentions that in extremely rare cases serious post-vaccination reactions may occur that should be reported immediately to the health facility for assistance.

4. If the child has a common mild illness, the health worker explains that vaccination is still safe and effective and important, and administers it.

5. After the vaccination is given, the health worker writes the date of the current vaccination(s) and other details on the immunization card.

6. If the vaccine received is one in a series (e.g. Penta1, 2, 3, OPV 1, 2, 3; or Measles1, MMR 1IPV1), the health worker explains to the caregiver the need for the child to complete the series to be fully protected against the disease(s). The health worker uses the vaccination chart on the immunization card as an instruction guide.

7. The health worker writes the date for the next vaccination on the immunization card and tells the caregiver about it. If appropriate, the health worker associates the date with a — trigger such as a holiday or seasonal event that will help the caregiver remember to bring the child back for vaccination. The health worker asks the caretaker to repeat the date, to be certain it has been understood.

8. The health worker explains to the caregiver that if she and/or the child cannot come on the return date, they can obtain the next vaccination at another location or another date but not before the due date.

9. The health worker reminds the caregiver that she should bring the immunization card (child growth development card) to the location where the child receives the next vaccination and advice to preserve it. This card should be kept like a birth certificate as it is mandatory for school entry.

10. The health worker congratulates the caregiver if the child is fully vaccinated.

11. The health worker asks the caregiver if she has any questions and politely answers all questions.

12. The health worker should ask to see the mother's vaccination record in order to determine her tetanus toxoid (TT/Td) status and advise her accordingly.

13. For the vitamin A to be given, the health worker explains to the caregiver that it is important to bring the child back in nine months and eighteen months (and give the dates) for subsequent vitamin-A supplementation to help protect the child from infections.

9.4 MASS COMMUNICATION

Communication through different media instead of direct person to person communication is called mass communication. e.g. Radio, Television, leaflet, poster, newspaper, folders, brochure, stickers, signboard etc.

Below are some suggestions on how the EPI manager and programme staff can work with the media to communicate information effectively on the immunization programme and activities:

Some suggestions on using the mass media (e.g. television, radio, newspapers)

• Develop an informed media network for accurate reporting on EPI and to be an ally.

• Inform the media in advance about EPI programme activities, specifying the date, place and participants of immunization so that these activities may be given wide media coverage.

• Sponsor the media to observe immunization activities and events so they can cover stories and broadcast information.

• Provide the media with human interest and success stories from the EPI programme like sufferings of children from EPI diseases, cost of treatment and sufferings of parents, benefits of EPI, reduction of infant disease and death and ultimate cost benefit of Vaccination.

• Prepare and issue regular press releases for the media to use in their broadcasts or articles.

• Organize regular interviews on EPI diseases, vaccination schedules, benefits with the media, involving different advocates of the programme (e.g. leaders, professional experts, etc).

9.5 ADVOCACY AND COMMUNICATION FOR STRENGTHENING ROUTINE IMMUNIZATION ADVOCACY

Advocacy is a process of gathering and communicating information to raise resources and/or gain political and social leadership acceptance and commitment, that will, in turn, assist a society in accepting the programme. The process involves promoting the benefits and value of the EPI service and presenting the rationale for the community's involvement in the Immunization Programme.

A process for conducting advocacy could include the following:

Holding group discussions and/or visits with leaders and the community to discuss:

• Importance of immunization services, including place of EPI session and EPI diseases.

• Vaccines protect diseases and benefits of vaccination.

• Possible side effects, and as far as possible addressing the community's concerns and requests.

• Importance of safe injection practices.

• Target groups of advocacy include community groups like islands leaders, religious leaders, private and business sector, NGOs, and community opinion.

9.6 SOCIAL MOBILIZATION

Social Mobilization is a process of bringing together all feasible partners to identify needs and raise awareness of, and demand for, a particular development objective. The goal is to increase participation, ownership, resource mobilization and capacity of the community to address the issue. Every opportunity should be utilized to mobilize the community for active participation and immunizing children.

Key stakeholders: Islands leaders, religious leaders, health care providers, NGOs, women and youth groups, clubs, teachers association, school programs and any other organizations in the area.

10

SUPPORTIVE SUPERVISION AND MONITORING

SUPPORTIVE SUPERVISION AND MONITORING

Supportive supervision is a process of helping staff to improve their work performance continuously. It is carried out in a respectful and non-authoritarian way with a focus on using supervisory visits as an opportunity to improve knowledge and skills of health staff. It encourages **open, two-way communication,** and building **team approaches** that facilitate problem-solving.

10.1 CHARACTERISTICS OF SUPPORTIVE SUPERVISION

- NOT repressive rather Positive incentives.
- Use of objective criteria
  - Quantitative indicators (e.g. timely vaccination).
  - Qualitative (e.g. supervisory checklist).
- Possible actions
  - On-site training by supervisor.
  - Resources utilization, distribution of resources/ materials.
  - Reorganization of work.

10.2 HOW TO DO SUPPORTIVE SUPERVISION

- Plan and prepare for the supervisory visit.
- Make the visit effective by setting performance expectations.
- Use of skills-based checklists.
- Provide ongoing assessment, monitoring and feedback over time.

10.3 TEACH AND LISTEN EFFECTIVELY

- Serve as coach and mentor, not policeman.
- Develop solutions together, do not blame.
- Give encouragement.
- Provide on-the-job training and technical guidance: verbal or printed materials.
- Record what is observed/discussed so **follow-up** can be done from one visit to the next.
- Set goals together.
- Be motivated and provide motivation.

10.4 WHEN TO DO SUPPORTIVE SUPERVISION

Take any opportunity

- Routine and scheduled visits to immunization sessions at facilities/ fields.
- Supervisory planned visits to immunization sessions.
- Regular meetings with Community health workers.
- Ad hoc meetings with Nurses and health workers.
- Any opportunity that involves contact with health staff to share information.

10.5 WHERE TO CONDUCT SUPPORTIVE SUPERVISION VISITS

The supervisor must use immunization data and information from previous supervision visits and assessment of performance from monitoring data to select priority areas for supervision. The most common criteria used for selecting priority areas include:

- Highest number of unimmunized.
- High drop-out rates.
- Low coverage rates.
- Poor reports from previous supervision visits.
- Areas with few or no visits in the past.
- Good coverage in the past but drop in coverage or low coverage now.
- Coverage rates above 100% or drop-out rates that are negative.
- Prioritized districts for new vaccine introduction.
- Areas submitting no reports or incomplete reports.

PREPARE STRUCTURE OF THE VISIT

- Prioritize locations for immunization session visits based on need.
- Choose a convenient time for all.

• Define objectives and know what topics/issues need follow-up from last visit.

• Have materials ready for demonstration/ training; prepare them in advance.

10.6 WHAT TO COVER DURING THE VISIT?

It is important to have a clear understanding of the main objectives of the visit. This could include main tasks to observe, or main topics on which training should be given, etc.

A review of previous supervision reports, checklists, or data analysis, can assist in identifying which issues to cover during supportive supervision visits.

• Always be prepared to use data: vaccination coverage, drop out, left out.

• Review the local data on site during the visit: target for vaccination, achievement, dropout.

• Bring summary data, monthly reports, etc. as reference material: daily report, monthly report.

• Prepare an agenda for the visit in advance. The agenda should include one or two issues that have already been identified as priorities for the area e.g. Cold chain management, injection safety and non-touch technique, immunization session organization etc.

10.7 OBSERVING IMMUNIZATION SESSION AT HEALTH-FACILITY

Supervisors can obtain a lot of information by simply observing the health- facility environment and immunization session.

For example, they may observe the following:

• Are injection practices correct?

• Is the immunization session site outreach or health facility clean?

• Are there any syringes or open safety boxes lying around that could pose a threat to the community?

• Are there frozen vaccines or expired vaccine vials in the refrigerator/in immunization sessions?

• Is the health worker interacting well with the community and informing about services?

• Other members of the community?

• Are IEC posters, monitoring charts, etc. displayed on the walls?

PROVIDE ON-SITE TRAINING AND POLICY UPDATE

• Provide on-site training based on locally identified need using appropriate methods like,

a. Short interactive lectures on site (about vaccination schedule/side effects/contraindications).

b. Group discussion (discussion with parents on vaccines against diseases, benefits etc).

c. Skills demonstration and practice (by giving injection - correct technique, route etc). Role play (Key messages to parents).

d. Person-to-person mentoring (during vaccination-tell vaccines given against the diseases, side effects, date of next dose, etc).

• Share new information and new policy directive in immunization.

FOLLOW-UP, USING SUPERVISION REGISTER

• Continuity, consistency and reinforcement.

• Keep a record of activities to ensure topics are not repeated unless necessary.

• Monitor rate and level of improvement.

USE OF CHECKLISTS

• Standardize structure and provide continuity for all.

• Can include areas of knowledge, practice and skill (what they know and do...).• Monitor rate and level of improvement.

• Also assessment of performance (how well they are doing it...).

• Identifies areas for future focus / need.

10.8 WHAT ARE THE REQUIREMENTS FOR SUPERVISION?

- Supportive Supervisory skills.
- Time.
- Costs per diem.
- Transportation.
- Written feedback and recommendations from previous supevision.
- Standardized supervisory checklists.

10.9 MONITORING IN NIP

Monitoring is a systematic and continuous process of collecting and examining data linked to implementation of NIP activities and measuring progress, identifying areas that need specific interventions.

WHY IS MONITORING IMPORTANT?

Monitoring is an important tool for mid-level managers. It can help improve the quality of the immunization programme by ensuring:

- All target population are immunized;
- Drop out and left out are calculated;
- Vaccines and safe injection equipment are delivers in correct quantities and on time;
- Staff are well trained and adequately supervised;
- Information on disease incidence and adverse events following immunization (AEFI) are collected and analyzed;
- The community has confidence in the vaccines delivered and the immunization service they receive.

FIVE GOLDEN RULES OF MONITORING

- Establish standard methods of sending/receiving immunization data.
- Establish a working routine.
- Check all incoming data (daily/monthly immunization reports, surveillance report).
- Monitor performance (completeness, accuracy, timeliness of reporting).
- Produce routine reports & feedback (Data compilation at atolls and central level and feedback).

BASIC TOOLS FOR MONITORING

Every health facility should have a system of recording immunization data. Following are the basic tools available in Maldives.

1. Immunization registers:

The Immunization registers have basic information which includes, identification number, date of registration, name, birth date, sex, address of parents and details of vaccination according to schedule. The immunization register helps health care providers to keep track of children and women.

2. Daily tally form:

This form includes the total number of daily-vaccinated beneficiaries of an immunization session.

3. Monthly reporting forms:

The Monthly Progress Report is a report of the Atolls/ Islands submitted by the health worker at the end of each month using a monthly reporting form.

The cumulative coverage will enable you to calculate the coverage of each antigen and the dropout rates. Since this is the basis of obtaining all coverage and epidemiological data at Atoll and national level.

4. Vaccine stock ledger/stock inventory:

Vaccine stock ledger/inventory is for maintaining the records especially for the number of vaccines in and out for that health facility.

5. Daily Temperature monitoring chart:

Temperature should be checked and marked in the monitoring sheet at least twice daily.

HOW TO PREPARE A TARGET, COVERAGE AND DROPOUT RATE; AND CALCULATE VACCINE WASTAGE RATE

1. Calculate the annual target population to receive immunization services of infants less than one year of age.

Use the most accurate existing population figures for infants under one year of age. These can be obtained from official census data or your own community census. If 2% is the estimated percentage of infants less than one year of age in any population.

For example: If the total population of an Island is 3600, then the annual target population of infants under one year would be 3600 x 2/100 = 72.

2. Calculate the monthly target population of infants less than one year of age to receive immunization services.

For example: If the annual target under one year is 72, the monthly target is 72/12 = 6.

That means each month 6 children should be vaccinated: 6 in January, another 6 in February, another 6 in March etc.

3. Calculate the monthly coverage of Penta 3 of infants less than one year of age.

For example: If the Atoll — A|| health facility has immunized 5 children for Penta 3 for the month of November and target of that health facility is 6 for the same month. So coverage is 5/6 X 100=83%. Penta 3 coverage is 83%.

4. Calculate the cumulative coverage for any antigen for 12 months.

For example: Cumulative means by repeated addition of monthly coverage. For example in atoll

— A|| number of children immunized for Penta 3 for month of January to December are 5, 6, 7, 4, 5, 6, 6, 6, 7, 5 and 6. Therefore, 71 is the total cumulative number for the year and for example 72 is the total target for the year in atoll.

Calculation for cumulative coverage = cumulative number of children for Penta 3/Total target for that year X 100. So for atoll —A| cumulative coverage is 69/72 X 100 = 96%. Therefore cumulative coverage for Penta 3 is 96%.

5. What is Drop out and Left out:

A beneficiary should receive all the antigens as per the NIP recommended schedule to ensure the vaccination is completed. The beneficiaries are considered as drop out when these beneficiaries miss any dose of the recommended antigens i.e the beneficiary received at least one or more doses but did not complete all.

The beneficiaries are considered as left out if they did not receive any doses of the NIP recommended antigens. In this situation, the beneficiary may be registered to offer the missed vaccination as per catch up schedule.

6. Calculate the total number of drop-outs between Penta 1 and Penta 3.

(DO in number) = total number of Penta 1 - total

Calculate the cumulative dropout rate (DO %) as follows:

$$DO\% = \frac{\left[\begin{array}{c}\text{Penta 1 cumulative total} \\ - \\ \text{Penta 3 cumulative total}\end{array}\right]}{\text{Penta 1 cumulative total}} \times 100$$

7. Calculate the wastage rate of Pentavalent vaccine given in a month:

For example: 216 Vials (doses) of Pentavalent were supplied and consumed for the sessions and 210 doses were given to the children. So calculation is: Penta doses consumed for the month - doses administer to children/ Doses consumed for the month X 100.

$$\text{Vaccine Wastage} = \frac{(216 - 200)}{216} \times 100 = 7\%$$

11

DISEASE SURVEILLANCE

DISEASE SURVEILLANCE

11.1 WHAT IS SURVEILLANCE?

Surveillance means data collection for action. Disease Surveillance is a regular system of collecting, analyzing and interpreting data and then using it to guide disease-control, elimination, eradication of diseases and immunization strategies.

Surveillance helps in the following ways:

- Predicting or detecting disease outbreaks for containment (**What** disease is occurring)
- Identifying high-risk populations (**Who** gets the disease)
- Identifying areas requiring special attention and where system performance is poor (**Where** the disease is occurring)
- Determining the frequency of occurrence of a disease in the community and magnitude of the problem (**When** the disease is occurring and how many get the disease)
- Identifying underlying causes (or risk factors) of the disease (**Why** the disease is occurring)
- Guiding response activities, including immunization (**How** the disease can be prevented, controlled or eliminated)

11.2 DIFFERENT STAGES OF DISEASE PREVENTION

CONTROL

Control of diseases is defined as a reduction in the incidence, prevalence, morbidity or mortality of an infectious disease to a locally acceptable level; E.g. Diphtheria has been reduced to status of control in Maldives.

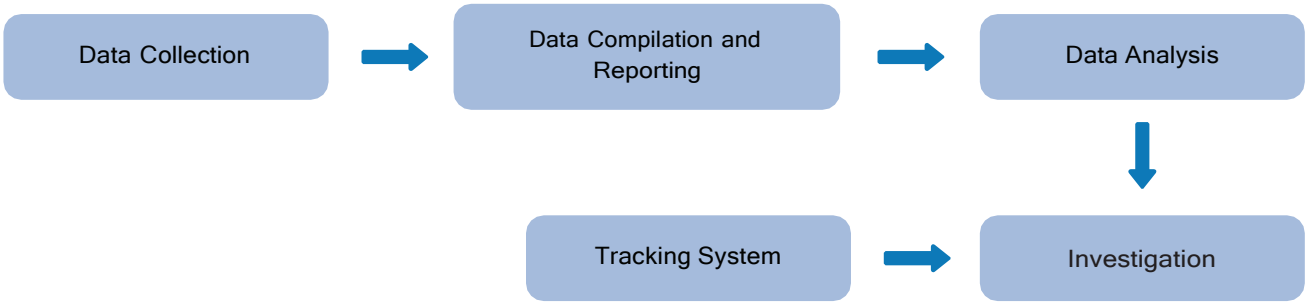
ELIMINATION

Elimination as reduction to zero of the incidence of disease or infection in a defined geographical area; cessation of transmission of the causative disease agent in human beings and may present in the environment. E.g. Neonatal Tetanus and Measles / Rubella have been eliminated in Maldives.

ERADICATION

Eradication is from permanent reduction to zero of the worldwide incidence of infection. i.e. complete extinction of the causative disease agent from human beings as well as from the environment. E.g. Smallpox has been eradicated in the whole world.

STEPS OF DISEASE SURVEILLANCE



Disease surveillance may be **facility-based or community-based?** Facility-based disease surveillance refers to the collection of data (actively or passively) from fixed sites. Community-based disease surveillance refers to collection of data from individuals in the community rather than from the fixed facilities.

11.3 REPORTABLE DISEASES (VPDS)

The following are the reportable diseases under Vaccine Preventable Disease Surveillance:

1. Acute Flaccid Paralysis -AFP (below 15 years of Children)

2. Neonatal Tetanus (birth to 28 days infants)

3. Measles (at any age)

4. Mumps (at any age)

5. Tuberculosis (below 5 years)

6. Diphtheria (at any age)

7. Whooping cough (at any age)

8. Rubella (at any age)

9. Tetanus (after neonate to any age)

10. H. Influenza disease of any type (below 5 years)

Aggregated data of Vaccine Preventable Disease must be reported in Daily Surveillance Formby Public Health Staff to Health Protection Agency (HPA). Any suspected reportable Vaccine Preventable Disease must be reported immediately to the public health unit and HPA.

For more information refer Communicable Disease Reporting Guide for Health Professionals available from Ministry of Health Website **(www.health.gov.mv)** or Health Protection Agency website **(www.hpa.gov.mv).**

11.3.1 AFP DISEASE SURVEILLANCE

Acute Flaccid Paralysis (AFP) surveillance is one of the most vital strategies of polio eradication. AFP is not a disease but it is a symptom. There are other diseases in addition to Polio that can present as AFP. So, It is imperative to identify all AFP cases and to investigate thoroughly to confirm whether the cases are Polio or not.

Case Definition of Acute Flaccid Paralysis (AFP)
Any child under 15 years of age with acute flaccid paralysis or any person at any age with paralytic illness if polio is suspected.

Any child less than 15 years old with:

• **Acute:** Rapid progression from weakness to paralysis (Sudden onset-).

• **Flaccid:** Floppy|| (as opposed to spastic or rigid).

• **Paralysis:** Inability to move the affected part (Weakness, loss of voluntary movement) **AND** the paralysis is **not** from birth or is **not** as result of an injury **OR Paralysis of any age diagnosed as Polio by Clinician.**

STEPS FOR AFP INVESTIGATION

1. All cases of AFP at the outpatient department, emergency room and inpatient ward in health care facilities should be identified by clinicians; Community Health Workers (CHW)/ Nurses should identify and immediately notify any suspected AFP case to Atoll Public Health Unit and Health Protection Agency Surveillance Focal Point.

2. The Health Protection Agency Surveillance unit will coordinate with the Atoll/Island PHU to investigate the case within 48 hours of notification and take appropriate actions.

3. If a case is identified in the home visit, the health worker immediately refers the case to the Health facility. The confirmed AFP case should be admitted in a nearby Health facility or Hospital for easy collection of stool specimens. **It is advisable that all cases from Atoll/Island to be referred to IGMH, after consulting IGMH Pediatric department.**

4. Collect two adequate stool specimens 24 - 48 hours apart and send to IGMH Laboratory, with filled up **Investigation Form for Acute Flaccid Paralysis.**

Adequate stool means that 2 stool specimens are collected at least 24 hours apart and within 14 days of onset of paralysis and fulfill all of the following criteria:

• Stool specimens are sufficient in amount (at least 8 grams- half of the adult thumb size);

• Stool specimens are preserved and transported maintaining cold chain (it is critical that the temperature is maintained between +2° to +8° Celsius, so that virus does not die);

• There is no leakage of specimen from the containers and;

• Both stool specimens arrive at IGMH within 72 hours of collection.

5. The community health workers should conduct home visit searching for additional AFP cases.

6. Conduct follow-up examination of identified AFP child on 60 days after paralysis onset and submit completed 60 Days Follow up Examination Form to HPA.

7. For cases without adequate stool samples and 60 days follow -up with residual paralysis or follow-up not done due to death or lost to follow-up – additional information form along with all medical records should be sent to HPA for Expert Review Committee (ERC) to classify the case. The CHW will assist physicians in conducting 60 days follow-up by visiting the case's house.

8. Attending a doctor at a health facility should teach how to exercise the affected parts of the child and advise the parents to continue physical exercise. The CHW should follow-up the case regularly.

DIFFERENTIAL DIAGNOSIS OF AFP

The most common differential diagnosis of acute flaccid paralysis includes paralytic poliomyelitis, Guillain-Barré syndrome, Transverse myelitis and Traumatic neuritis. Non Polio Enteroviruses (like Coxsackieviruses A and B echovirus, enterovirus 70 and enterovirus 71) infections have been implicated in polio-like paralytic disease and thus have been associated with AFP.

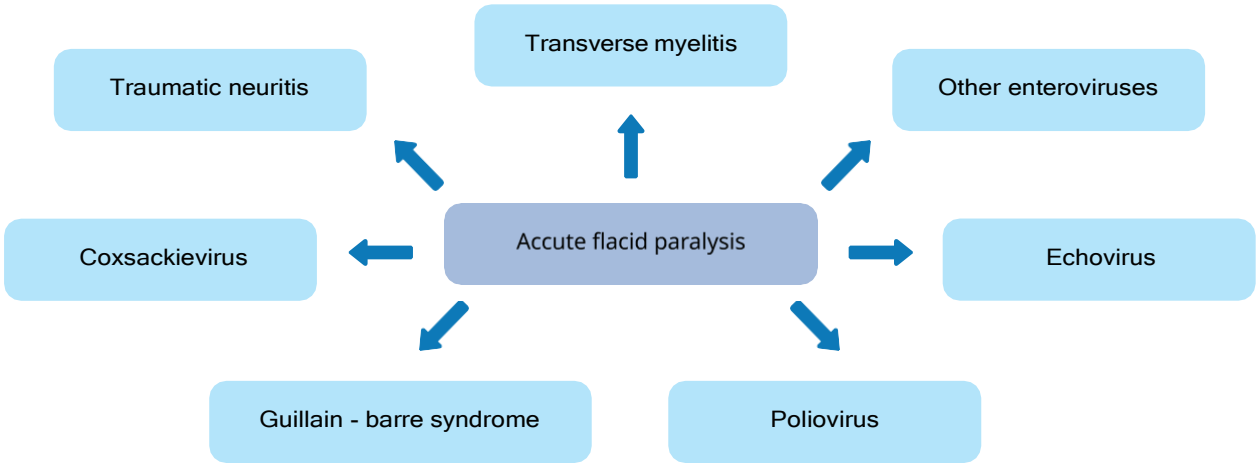


Figure 8: Differential Diagnosis of AFP

However, any disease that presents as AFP, even if diagnosed as a disease other than polio by the physician, must be **immediately** reported.

CLASSIFICATION OF AFP CASES

Final classification of AFP cases includes three possibilities:

1. Confirmed Polio

An AFP case is confirmed as Polio only by the isolation of Wild Polio Virus from any stool specimen.

2. Non Polio AFP

A non-polio AFP case (Discarded polio case) is an AFP case with no wild poliovirus isolated from any of the two stool samples by any WHO reference laboratory and fulfills any of the following criteria:

- The two specimens collected were adequate; or
- Inadequate stools but absence of residual paralysis during the 60+ days follow-up.
- Inadequate stools, but absence of residual paralysis during the 60+ days follow-up or 60+ follow-up investigation could not be done (either due to death or loss to follow-up); but after reviewing the history, clinical features and necessary investigation reports, NCIP/ERC is convinced that this case is not compatible with polio.

3. Case compatible with Polio

A case compatible with polio is an AFP case from whom adequate stool samples could not be collected and there was either residual paralysis on 60+ days follow-up or 60+ follow up could not be done (either due to death or loss to follow-up); and after reviewing history, clinical features and necessary investigation reports, the National Expert Review Committee (ERC) could not rule out possibility of poliomyelitis.

Table 29: AFP Surveillance Performance Indicators

	Indicators	Target
1	Annual Non-Polio AFP rate in children < 15 years old	>2/1 00000
2	Completeness of passive reporting from facilities	>90%
3	Timeliness of passive reporting from facilities	>80%
4	Suspected AFP cases investigated within 48 hours of notification	>80%
5	Confirmed AFP cases with 2 stool specimens collected within 14 days after paralysis onset	>80%
6	Stool specimens arriving at laboratory within 3 days after collection	>80%
7	Stool specimens arriving at laboratory in — good condition 1. Presence of un-melted ice or temperature <80°C 2. Adequate volume (8 grams) 3. No evidence of leakage 4. No evidence of desiccation (drying)	>90%
8	60+ follow up rate (Percentage of AFP cases with a follow-up investigation at least 60 days after onset of paralysis	>80%
9	Stool specimens with laboratory results within 14 days after specimen receipt	>80%
10	Stool specimens from which non-polio enterovirus (NPEV) was isolated	>10%

11.3.2 MEASLES, RUBELLA AND CRS SURVEILLANCE

Maldives has already achieved the Measles/Rubella elimination target in 2017. and moved toward sustaining Measles/Rubella elimination status. A well performing case based surveillance system and sustained high coverage with MR /MMR is crucial to maintain elimination status.

Measles/Rubella elimination is defined as the absence of endemic measles/rubella transmission in a defined geographical area (e.g. region or country) for >12 months in the presence of a well-performing surveillance system.

Case Definition of suspected Measles/ Rubella
A patient with fever and maculopapular (non-vesicular) rash, or a patient in whom a health-care worker suspects measles or rubella.

STEPS FOR MEASLES/RUBELLA SURVEILLANCE

Case detection and reporting

1. All Atoll hospitals/Health centres and Public Health Units including prominent private hospitals or practitioners are considered as “Reporting Sites” for reporting suspected measles / rubella cases.

2. All reporting Sites are required to report all suspected cases immediately. This includes cases detected by active review of hospital registers every week by the Public Health Unit of the Atolls and islands.

3. Even if no suspected cases are identified, sites should still send “zero-case reporting“ to HPA on the prescribed format **(annexure 9.4a).**

4. Health care workers should secure specimens collection from each measles/rubella suspected for laboratory confirmation. Serum samples should be collected from each suspected case and sent to the laboratory for Measles rubella IgM along with the throat swab.

5. All suspected dengue cases with fever and rash confirmed as negative by rapid diagnostic test should also be reported for investigation as a suspected Measles or Rubella case.

Case Investigation

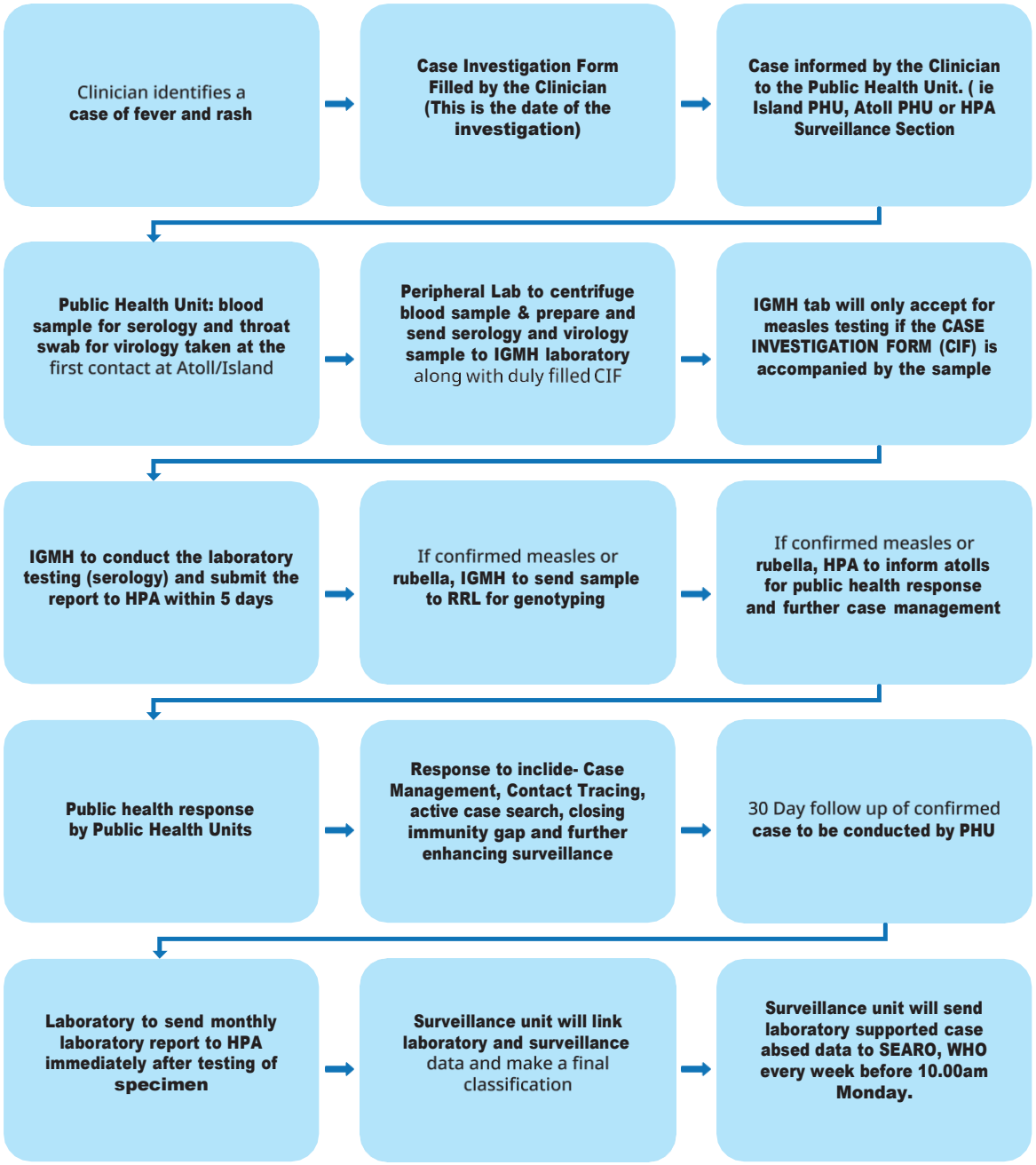
Epidemiologists/ clinician or specially trained health staff are responsible for case investigation of reported cases preferably within 48-hours of case reporting in each Atoll using standard Measles Rubella Case Investigation Form (MR-CIF).

Specimen collection and transportation

Serology: A blood sample should be collected on first contact with the patient on each Atoll. As the likelihood of detecting IgM antibodies decreases with time, blood specimens must be collected within 28 days of rash onset. Shipment of the serum sample after separating from the whole blood to IGMH laboratory should take place as soon as possible with all due care.

Virology: Throat swabs are the preferred sample for viral detection/isolation for both measles and rubella viruses and are best if done within 5 days of the onset of rash. For further genotyping, the samples should be sent to Regional Reference Laboratory in Bangkok.

FLOW-CHART FOR MALDIVES MEASLES AND RUBELLA SURVEILLANCE



Case classification

Classification of a suspected case of measles and rubella is done by the HPA at National Level. The classification is done by the HPA on the following basis:

Based on Laboratory Confirmed or Epidemiologically Linked or Clinical

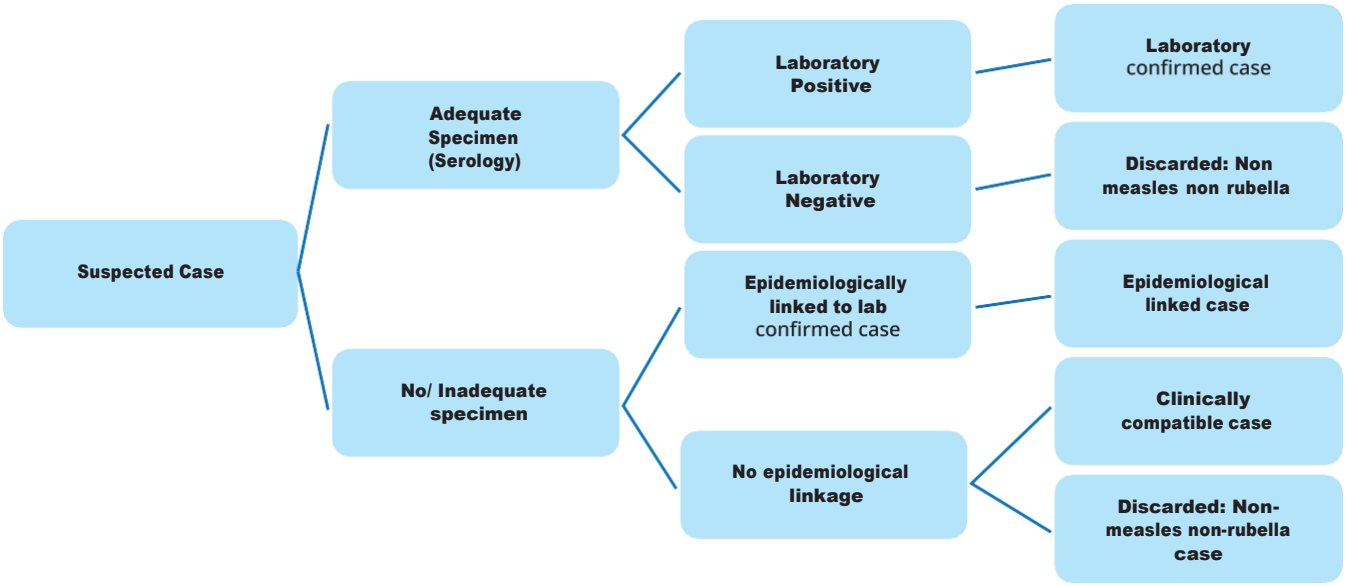
a. Laboratory-confirmed measles, or rubella, case: a suspected case of measles, or rubella that has been confirmed by a proficient laboratory.

b. Epidemiologically -linked confirmed measles, or rubella, case: a suspected case of measles, or rubella, that has not been confirmed by a laboratory but was geographically and temporally related, with dates of rash onset occurring between 7 and 21 days apart for measles (or 12-23 days for rubella) to a laboratory-confirmed case or, in the event of a chain of transmission to another epidemiologically confirmed measles, or rubella, case.

c. Clinically compatible measles case: a case with fever and maculopapular (non-vesicular) rash and at least one of cough, coryza or conjunctivitis, for which no adequate clinical specimen was taken and which has not been linked epidemiologically to a laboratory-confirmed case of measles or another laboratory-confirmed communicable disease. Large numbers of clinical compatible measles cases are an indication of failure of laboratory supported surveillance systems.

d. Clinically compatible rubella case: A case with maculopapular (non-vesicular) rash and fever (if measured) and one of arthritis/arthralgia or lymphadenopathy, for which no adequate clinical specimen was taken and which has not been linked epidemiologically to a laboratory-confirmed case of rubella or another laboratory-confirmed communicable disease.

e. Non-measles, non-rubella discarded case: a suspected case that has been investigated and discarded as non-measles and non-rubella case using (a) laboratory testing in a proficient laboratory or (b) epidemiological linkage to a laboratory-confirmed outbreak of another communicable disease that is neither measles or rubella.



Algorithm for Measles /Rubella classification

Based on origin of the virus:

a. Endemic measles, or rubella, case: a laboratory or epidemiologically- linked confirmed case of measles or rubella resulting from endemic transmission of measles, or rubella, virus.

b. Imported measles, or rubella, case: A case exposed to measles, or rubella, outside the region or country during the 7-21 days (12-23 days for rubella) prior to rash onset and supported by epidemiological or virological evidence, or both. (Note: for cases that were outside the Region or country for only a part of the 7-21 day interval [or 12-23 days for rubella] prior to rash onset, additional evidence including a thorough investigation of contacts of the case is needed to exclude a local source of infection).

c. Import-related measles, or rubella, case: a locally acquired infection occurring as part of a chain of transmission originating from an imported case as supported by epidemiological or virological evidence, or both. (Note: if transmission of measles cases related to importation persists for ≥12 months, cases are no longer considered to be import-related, they are considered to be endemic).

d. Unknown source measles, or rubella, case: a confirmed case for which an epidemiological or virological link to importation or to endemic transmission cannot be established after a thorough investigation.

Sometimes health workers may also encounter cases of fever and rashes around the date of immunization of the child and thus it is important to identify if it is vaccine associated or due to natural measles infection.

The following criteria apply:

Measles vaccine-associated illness is diagnosed when a suspected case that meets all five of the following criteria

i. the patient had a rash illness, with or without fever, but did not have cough or other respiratory symptoms related to the rash;

ii. the rash began 7-14 days after vaccination with a measles-containing vaccine;

iii. the blood specimen, which was positive for measles IgM, was collected 8-56 days after vaccination;

iv. thorough field investigation did not identify any secondary cases; and

v. Field and laboratory investigations failed to identify other causes.

vi. Or in a suspected case where virology is performed, the genotyping result indicating vaccine strain would also confirm vaccine - associated measles.

For details refer to “Measles, Rubella and Congenital Rubella Syndrome Surveillance Guide to Health Professionals, 2016”.

Case management

There is currently no specific treatment for measles infection. Vitamin A be administered to all children with acute measles. One dose (50,000 I.U. for infants aged less than 6 months, 100,000 I.U. for infants aged 6-11 months, and 200,000 I.U. for children aged >12 months) should be administered on the day of suspected measles diagnosis and one dose should be administered the following day. If the child has clinical signs of vitamin A deficiency (such as Bitot’s spots), a third dose should be given 4-6 weeks later.

Supportive treatment should be provided for a number of measles complications.

All hospitalized cases of measles should be isolated to prevent further transmission inside the hospital.

Every single case of measles or rubella is considered an outbreak and evokes public health response. Public health response to a case/outbreak of measles/ rubella should be conducted effectively as per national guidelines.

Measles and rubella surveillance performance indicators

Following are the indicators for monitoring progress towards sustaining elimination and are helpful in determining the current status and activities needed for forward.

Table 30: Measles and Rubella surveillance performance indicators and target

Indicators	Target
Disease incidence i. Annual incidence of confirmed measles cases ii. Annual incidence of confirmed rubella cases	
Proportion of surveillance units reporting measles and rubella data to the national level and on time	(target: ≥80%)
Reporting rate of non-measles non-rubella cases at the national level	(target: ≥2 per 100 000 population)
Proportion of second administrative level units reporting at least two non-measles non-rubella case per 100 000	(target: ≥80% of second-level administrative units)
Proportion of suspected cases with adequate investigation	(target: ≥80% of suspected cases)
Proportion of suspected cases with adequate specimen collection	(target: ≥80% of suspected cases, excluding epidemiologically linked cases)
Proportion of specimens received at the laboratory within 5 days of collection	(target: ≥80%)
Proportion of laboratory-confirmed chains of transmission (defined as two or more confirmed measles cases) with specimens adequate for detecting measles virus collected and tested in an accredited laboratory	(target: ≥80%)
Proportion of measles and rubella network laboratories that are WHO-accredited for serologic and, if relevant, for virology testing	(target: 100% of laboratories)
Completeness and timeliness of monthly reporting (including zero reporting) to the WHO Regional Office for specimens received for serologic and virology testing	(target: ≥80% of specimens received in the laboratory)
Proportion of specimens with serologic results reported by the laboratory within 4 days of receiving the specimen	(target: ≥80% of specimens received)
Proportion of laboratories (government and private) that conduct measles and rubella diagnostic testing that have adequate quality assurance mechanisms in place	(target: 100% of laboratories)
Proportion of virus detection and genotyping results (where appropriate) that are completed within 2 months of receipt of specimen	(target: ≥80% of specimens received)

11.3.3 SENTINEL SITE CRS SURVEILLANCE

The most common congenital defects related to CRS are cataracts, heart defects, and hearing impairment. These are the primary conditions under CRS surveillance. These conditions are most likely to be seen at secondary and tertiary health care facilities, which should be included as sentinel sites for CRS surveillance.

CASE DEFINITIONS FOR CRS

The case definitions for CRS surveillance include the following categories:

Suspected CRS case:

• Any infant less than one year of age in whom a health worker suspects CRS.

• A health worker should suspect CRS when an infant aged 0-11 months presents with heart disease and/or suspicion of hearing impairment and/or one or more of the following eye signs: white pupil (cataract), or larger eyeball (congenital glaucoma) or pigmentary retinopathy.

• A health worker should also suspect CRS when an infant's mother has a history of suspected or confirmed rubella during pregnancy, even when the infant shows no signs of CRS.

Clinically confirmed CRS case: An infant in whom a qualified physician detects at least two of the complications listed in (a) below or one in (a) and one in (b):

a. Cataract(s), congenital glaucoma, congenital heart disease, hearing impairment, pigmentary retinopathy;

b. Purpura, splenomegaly, microcephaly, developmental delay, meningoencephalitis, radiolucent bone disease, jaundice that begins within 24 hours after birth.

Laboratory confirmed CRS case: An infant who is a suspected case (who has 1 condition from group A) who meets the laboratory criteria for CRS case confirmation.

Congenital rubella infection (CRI): An infant who does not have clinical signs of CRS but who has a positive rubella-specific IgM test is classified as having congenital rubella infection (CRI).

CRITERIA FOR LABORATORY CONFIRMATION OF CRS

Laboratory criteria for confirmation of suspected CRS cases include the following:

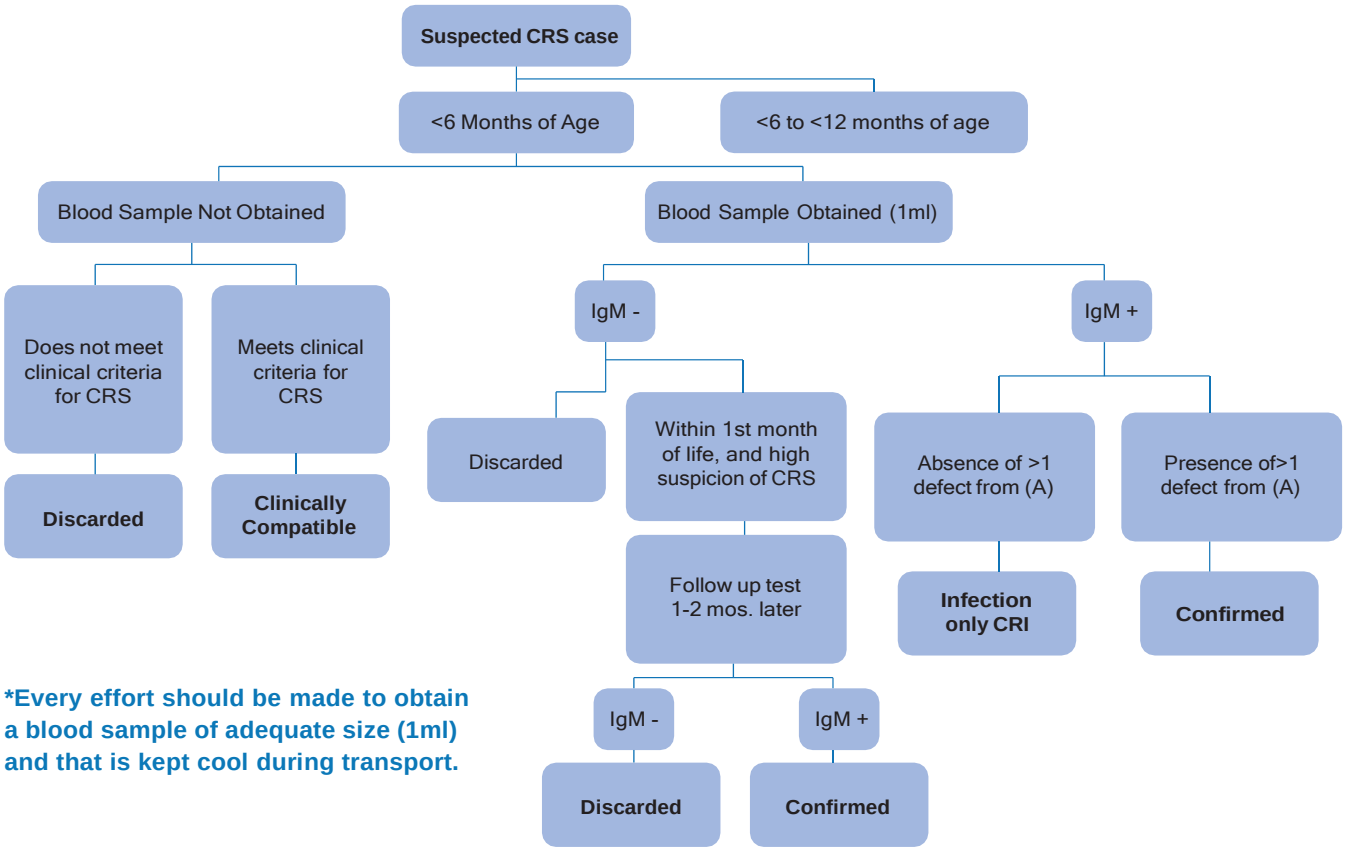
• Rubella IgM antibody detected, **or**

• Sustained rubella IgG antibody level as determined on at least two occasions between 6 and 12 months of age in the absence of receipt of rubella vaccine; **or**

• Rubella virus detection (e.g. nucleic acid detection by RT-PCR or rubella virus isolation) in an appropriate clinical sample (best results come from throat swabs, but nasal swabs, blood, urine, or cerebrospinal fluid specimens are also acceptable).

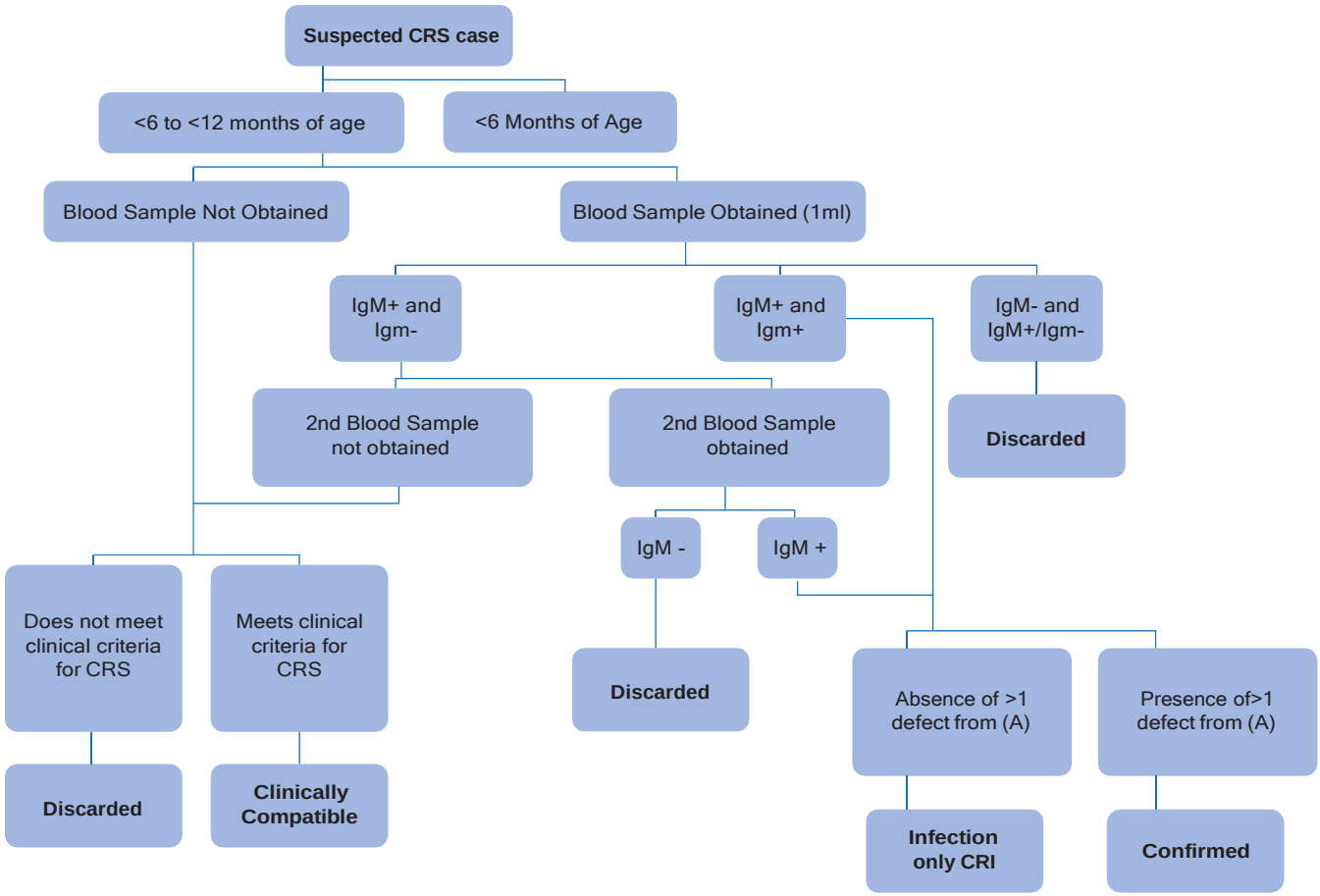
Efforts should be made to obtain clinical specimens for antibody levels and for viral isolation from infants at the time of the initial investigation. The clinical and laboratory data will be used to determine the final classification of each of the suspected CRS cases. Depending on the age of the suspected CRS case at initial testing, the following consideration should be made interpreting laboratory results and determining final classification of suspected CRS cases.

Flow-chart for classification of suspected CRS cases less than six months of age.



***Every effort should be made to obtain a blood sample of adequate size (1ml) and that is kept cool during transport.**

Flow-chart for classification of suspected CRS cases 6-12 months of age.



STEPS TO ESTABLISH SENTINEL SITE CRS SURVEILLANCE

1. Identify national CRS surveillance coordinators responsible for epidemiologic and laboratory components of the system.

2. Determine sentinel facilities at which infants with CRS are most likely to be seen.

2.1. Consideration for determining facilities

2.2. Responsibilities of local surveillance coordinators at sentinel sites include to:
- 2.2.1. conduct initial and refresher trainings for participating providers
- 2.2.2. initiate CRS surveillance activities
- 2.2.3. conduct surveillance quality assessment and monitoring
- 2.2.4. expand CRS surveillance and include other sites, as appropriate
- 2.2.5. analyze the CRS surveillance data on an annual basis, or more frequently if necessary
- 2.2.6. provide feedback to stakeholders involved in the CRS surveillance system
- 2.2.7. ensure infection control measure for CRS cases

ADDITIONAL APPROACH TO IDENTIFY CRS CASES: RUBELLA IN PREGNANCY REGISTRIES

Rubella in pregnancy registry can be used for follow-up of pregnant women exposed to rubella and their pregnancy outcome(s), as well as for identification of CRS cases. Rubella in pregnancy registries should be maintained at the local level so that comprehensive follow-up of pregnant women can occur, and infants born with CRS can be identified and diagnosed immediately and receive early interventions for any associated defects. The registry should include maternal contact and demographic data and pregnancy outcome (e.g. miscarriage, termination, infant with CRS, etc).

Table 31: Key Indicators for CRS Surveillance

Indicators	Target
Reporting rate of suspected CRS cases at the national level	(target: ≥1 per 10 000 live births)
Proportion of suspected CRS cases with adequate investigation	(target: ≥80% of suspected cases)
Proportion of suspected cases with adequate specimen collection	(target: ≥80% of suspected cases)
Proportion of confirmed cases with adequate specimen analyzed for virus detection	(target: ≥80% of confirmed cases)
Proportion of lab-confirmed cases with at least two negative tests for virus detection after 3 months of age, with at least a 1-month interval between tests	(target: ≥80% of confirmed cases)
Proportion of confirmed CRS cases detected within 3 months of birth	

11.3.4 NEONATAL TETANUS SURVEILLANCE

STRATEGIES FOR NT ELIMINATION

- Provision of Td 5-dose to all 15-49 years child bearing age women (CBAW)
- Provision of clean delivery services to all pregnant women
  - Clean surface/ bed
  - Clean hand
  - Clean cord with sterile instrument and thread
- SIA in high risk areas
- Effective surveillance for MNT

RATIONALE FOR NT

As Maternal and Neonatal tetanus (MNT) elimination has already achieved it is crucial to sustain functional NT Surveillance and high coverage with Tetanus Toxoid (Td) among pregnant women and in high-risk areas for all child bearing aged women (15-49 years), including improved access to clean delivery services.

Effective surveillance is critical for identifying areas or populations at high risk for NT and for monitoring the impact of interventions.

CASE DEFINITION OF NEONATAL TETANUS

Suspected case:

• Any neonatal death between 3- 28 days of age in which the cause of death is unknown; or

• Any neonate reported as having suffered from neonatal tetanus between 3-28 days of age and not investigated.

Confirmed NT case / Case definition of NT
Any neonate with normal ability to suck and cry during the first 2 days of life and who, between 3 - 28 days of age, cannot suck normally and becomes stiff or has spasms (i.e. jerking of the muscles).

Note: The basis for case classification is entirely clinical and does not depend on laboratory confirmation. NT cases reported by physicians are considered to be confirmed.

NEONATAL TETANUS CASE NOTIFICATION

All Neonatal tetanus cases should be immediately notified to DSFP. All health facilities, private practitioners and other health care providers must immediately report any case of NT (either living or dead) to the respective DSFP. The mother of the NT case should be vaccinated with TT /Td as soon as possible once the diagnosis is made regardless of her prior immunization status. The DSFP will send the LSO to investigate the case and take appropriate actions.

NT CASE REPORTING FROM COMMUNITY

All Community health workers/Nurses and NGO health workers should immediately bring the suspected NT case to the health facility to report and for treatment. All neonatal deaths should be reported to the immediate supervisor and should be investigated by the Medical Officer to identify NT.

Any neonatal death between 3-28 days of age in which the cause of death is unknown will be considered as a suspected NT Case.

NT CASE INVESTIGATION AND RESPONSE

Investigation and response to NT case confirmed at facilities or reported by field workers should follow a stepwise approach:

Step 1:

Interview the mother, examine the infant (if living) and complete the —Neonatal Tetanus Case Investigation Form;

Step 2:

Vaccinate the mother with TT regardless of previous vaccination status if vaccination has not already done;

Step 3:

Mobilize members of the investigation and response team to the island or neighborhood of the NT case. 5 *NT Case Investigation Forms*, the health worker's TT Registration Book, five-ten 10-dose vials of TT and sufficient supplies to vaccinate all who are eligible CBA women to receive TT vaccine in the island/Atoll;

Step 4:

Ask doctors, pharmacists, homeopaths, NGO workers local leaders etc if additional cases of NT or neonatal deaths (NDs) occurred in 3-28 days old babies in the past 6 months;

Step 5:

Investigate any additional cases of NT or ND and vaccinate the mothers of NT cases;

Step 6:

Conduct house-to-house visits in the whole Island (of about 1000 population) of the index case home to identify women of childbearing age who are eligible to receive TT. Record the findings on the worksheet on the back of the Neonatal Tetanus Case Investigation Form;

Step 7:

Vaccinate all eligible CBA women of that area including the mother of the case and register the doses in the Td Registration Book. This additional vaccination response is called Case Response Immunization (CRI); advice unvaccinated women to attend the next scheduled EPI outreach session;

Step 8:

Anticipate increased Td vaccine needs for the next scheduled EPI vaccination session.

After case investigation and response activities the case investigation form along with the case response information should be sent to EPI Unit, Male'.

11.4 HCWS ROLE IN DISEASE SURVEILLANCE

1. Identify and report all AFP, Fever with rash (non-vesicular), NT and other VPDs.

2. Report the AFP case of any children below 15 years of age to DSFP immediately.

3. Report information of live NT cases to supervisors or DSFP immediately.

4. Report Neonatal deaths (NDs) occurred in 3-28 days old babies in the past 6 months to supervisors weekly.

5. Report information of Measles cases to supervisors weekly.

6. Contact regularly with other health care providers for reporting of AFP, NT, Measles and other VPDs.

7. Create awareness and motivate the community peoples to report AFP, NT, Measles and other VPDs to CHW or supervisors. Awareness can be developed by organizing community group discussion, giving messages during Friday prayer, asking parents in EPI sessions and house to house visits.

8. Assist Medical Officer or Surveillance officer to identify houses of suspected cases, investigate the case, collect stool samples, and conduct ORI and CRI to protect children against diseases.

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ANNEX

AEFI REPORTING FORM

FORM 1

REPORTING FORM FOR ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Patient Name:	***Reporter's Name:***
Patient's full Address:	Institution:
NIC/PPN: Telephone:	Designation & Department: Address:
Sex: ☐ M ☐ F	
***Date of birth:** _ _ /_ _ /_ _	Telephone & E-mail:
Age at onset: _ _ *Years* _ _ *Months* _ _ *Days*	Date of reporting (by patient): _ _ /_ _ /_ _
OR Age category at onset: ☐ 0 < 1 ☐ 1-5 years ☐ > 5years-18years ☐ >18 years- 60 years ☐ >60 years	Date of report (by reporter): _ _ /_ _ /_ _

Health facility (place or vaccination centre) name & address:

Vaccine							Diluent (if applicable)			
*Name of vaccine	Name of the Manufacturer	*Date of vaccination	*Time of vaccination	Dose (1st, 2nd, etc.)	*Batch /Lot number	Expiry date	Name of diluent	*Batch /Lot number	Expiry date	Date and time of reconstitution

***Adverse event(s):**

- ☐ Severe local reaction ☐ >3 dys ☐ beyond nearest joint
- ☐ Seizures ☐ febrile ☐ afebrile
- ☐ Vasovagal syncope
- ☐ Anaphylaxis
- ☐ Fever ≥38°C
- ☐ Abscess
- ☐ Sepsis
- ☐ Brachial Neuritis
- ☐ Encephalopathy
- ☐ Toxic shock syndrome
- ☐ Thrombocytopenia
- ☐ Guillain-Barre Syndrome
- ☐ Bell's Palsy
- ☐ Other (specify)……

Date AEFI started (Date of first symptom): _ _ /_ _/_ _
Time:_____: _____

Describe AEFI (Signs & Symptoms):

Main Complaints:

Examination:

•GCS:	•Lungs:
•Pulse Rate:	•CVS:
•BP:	•P/A:
•Temperature:	•CNS:
•RR:	•Local Examination:
•SpO2	
•GRBS:	
•Capillary refill time: *(time taken for skin to come back to normal color after pressing fingertip for 5 seconds)*	

Diagnosis:

Treatment Given: | **Admitted:** (Y / N) | **Discharged:** (Y / N)

Discharge Advice:

Serious: Yes / No; ➔ **If Yes,** ☐ Death ☐ Life threatening ☐ Persistent or significant disability ☐ Hospitalization ☐ Congenital anomaly

Outcome: ☐ Observed for …. (mins) after vaccination ☐ Recovering ☐ Recovered ☐ Recovered with sequelae ☐ Not Recovered ☐ Unknown

☐ Died, If Died, date of death: _ _ /_ _ /_ _ Autopsy done: Yes ☐ No ☐ Unknown

Past medical history (including history of similar reaction or other allergies), concomitant medication and other relevant information (e.g., other cases). *Use additional sheets if needed:* ☐ Pregnant, if yes, Gestation: ☐ Lactating

First Decision making level to complete:

Investigation needed: ☐ Yes ☐ No If Yes, date investigation planned: _ _ /_ _ /_ _

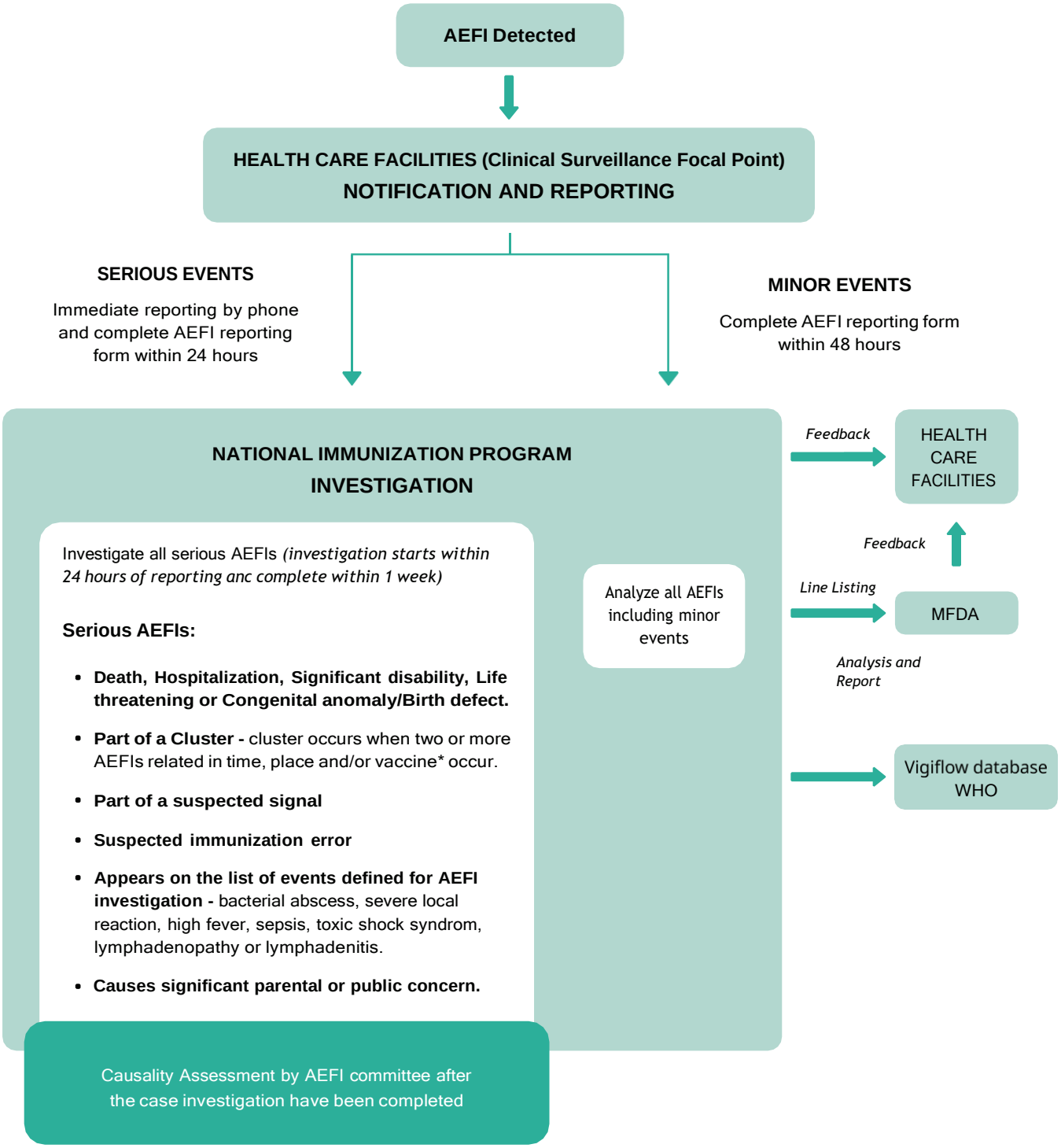
National level to complete:

Date report received at National Level: _ _ /_ _ /_ _	AEFI worldwide unique ID:
Comments:	

***Compulsory field**

Version: Nov 2021

Standard AEFI Surveillance System in the Country



AEFI MANAGEMENT

CLINICAL SURVEILLANCE FOCAL POINT/ PHU UNIT

AEFI surveillance focal point will assist in carrying out his/her responsibilities in AEFI reporting and investigation. **Doctor or Nurse from Health facilities will act as Surveillance Focal Point.** The focal point will be coordinating with the PHU/QID

ROLE OF SURVEILLANCE FOCAL POINTS

- Ensure appropriate case management of an AEFI
- Encourage Health care workers/vaccinators to report AEFI
- Communicate immediately with NIP in case of serious AEFI
- Report and investigate all the minor AEFIs with
- Assist to analyze AEFI data and maintain monthly line list and timely monthly report to NIP
- Provide feedback to vaccinators
- Assist in investigating AEFIs
- Report results of investigation to NIP
- Provide feedback to health care workers or vaccinators on results of investigation and corrective actions to be taken
- Monitor for clustering events
- Inform HPA/NIP immediately of deaths, hospitalization, clusters of events, events causing significant community concern
- Reassure the parents/ community
- Assist island focal points to deal with media

ROLE OF SURVEILLANCE FOCAL POINTS

- All AEFIs should be reported using the standard COVID-19 AEFI reporting form using the fastest means possible.
- When the AEFI is judged to be serious, refer to the diagram above. Reporting should also include a telephone call, direct conversation or notification to NIP.
- Reporting can be done by completing AEFI reporting form and also through the vaccination portal (AEFI reporting forms contain a minimum set of core variables in order to make the global evaluation of signals possible and thus help countries to evaluate the reported AEFIs). it is important to record the brand name, the manufacturer, as well as the batch numbers.
- The clinical surveillance focal point in coordination with PHU / QID and vaccinator will be usually responsible for providing most of the information required in the COVID-19 AEFI reporting form.
- When a COVID-19 standard AEFI reporting form is received, it should be reviewed for seriousness.
- AEFI is considered to be minor or NOT serious, detailed investigation and causality assessment will not be required; this should be noted on the form.
- Detailed investigation and causality assessment will be required if the AEFI is considered to be
  - a serious AEFI, i.e., death, hospitalization, significant disability, life threatening, congenital anomaly, birth defect or a medically important event or reaction, or part of a cluster;
  - or part of a group of events with an unexpected high rate or severity, or a suspected signal.

The surveillance focal points of Islands and Atolls should monitor the number of cases of each trigger event that have been reported by each health center/hospital each month. In this way, NIP and AEFI committee can identify patterns, such as clusters, within or across health centers/hospitals and take appropriate action.

Management of anaphylaxis

Anaphylactic reaction?

Asses Airway, Breathing, Circulation, Disability and Exposure (ABCDE)

Diagnosis – Look for:

- Acute onset of illness
- Life threatening Airway and/ or breathing and or Circulation problems
- And usually with skin changes

- Call for help
- Lie patient flat
- Raise patient's legs

Administer UNDILUTED Injection Adrenaline (1:1000) through deep intramuscular route to mid third of anterolateral thigh

- **0.01ml/kg for age <6 months (max 0.15ml)**
- **0.15ml for age 6months - 6 years**
- **0.3ml for age 6 years - 12 years**
- **0.5ml for age > 12 years of age and adults**
- Repeat dose of adrenalin maybe given 5 minute intervals at different sites (for maximum 3 doses if symptoms does not improve) and further doses if required maybe given in hospital setting (do not give adrenalin to the limb used for vaccination)
- **CPR should be initiated at any point if necessary**
- **MONITOR VITALS AND TRANSFER TO NEAREST EMERGENCY CARE**

AS SOON AS SKILLS AND EQUIPTMENT AVAILABLE

- Establish airway and give high flow oxygen
- Administer IV fluid (Normal saline or Ringer lactate) to maintain blood pressure

  20ml/kg in children

  500-1000ml in adults

- Administer Injection Pheniramine Maleate (Inj Avil 45.5mg/ 2ml), children IM only~ 0.3mg/kg/dose

  0.5-0.7ml age 1-2 years (~11-14 kg body weight)
  0.8-1.3ml age 3-5 years (about 20 kg body weight)
  1.0 -1.5ml aged 6-11 years (upto about 25 kg body weight)
  1.0-2ml age ≥12 years and adults

- Administer Injection Hydrocortisone IM or slow IV

  25mg age < 6 months
  50mg age 6 months to 6 years
  100mg age 6-12 years
  200 mg >12 years of age and adults

- Monitor and maintain vitals: Heart rate, respiratory rate, blood pressure, pulse oximetry and ECG

	Acute stress response (vasovagal syncope – VVS)	Anaphylaxis
At onset	VVS and general: occurs suddenly, before, at time of or soon after injection	Seconds to minutes after exposure, almost all cases within 1 hour
Skin	VVS and general: pale, cold, sweaty/clammy	Red, raised itchy rash, swollen eyes and face, generalized rash
Respiratory	VVS: normal to deep breaths General: rapid deep breathing	Noisy breathing, wheeze or stridor, persistent cough
Heart	VVS: slow pulse, transient hypotension General: normal or fast pulse or hypertension	Fast pulse, hypotension
Gastro–intestinal	VVS: nausea, vomiting General: nausea	Abdominal cramps, vomiting, nausea
Neurologic	VVS: transient loss of consciousness reversed by supine position General: fearfulness, dizziness, numbness, weakness, tingling around lips, spasms in hands and feet	May develop loss of consciousness not relieved by supine position

https://www.who.int/publications/i/item/978-92-4-151594-8

ASSESSMENT

In anaphylaxis 2 or more systems are affected and usually presents with skin rash.

System	Sign and symptoms
Cutaneous	• Injection site(s) redness, swelling or hives Facial flushing, itching, hives or welts and their extent, angioedema, other rashes.In general, the sooner the onset, the more rapidly evolving and severe the anaphylactic reaction
Respiratory	• Hoarse cry/voice, stridor (a high-pitched noisy sound occurring during inhalation), cough, wheezing, shortness of breath or labored breathing, use of accessory muscles, etc. • Respiratory rate
Cardiac	• Pulse rate (assess for rapid, weak, irregular pulse). • Pallor or cyanosis around perioral area • Capillary refill time (if a compromise in perfusion is suspected) • Blood pressure, if required equipment is available • Level of consciousness (impairment might reflect hypoxia)
Gastrointest-inal system	• Nausea, vomiting, diarrhea, abdominal pain • In general, the sooner the onset, the more rapidly evolving and severe the anaphylactic reaction.

The normal respiratory rate varies by age (approximate):

- <1 year 30-40 min
- >1 to 2 years 26-34 min
- >2 to 5 years 24-30 min
- >5 to 12 years 20-24 min
- **>12 years 12-20 min**

Normal heart rate by age (approximate)

- Newborn to 3 months 140 min
- >3 months to 2 years 130 min
- >2 to 10 years 80 min
- >10 years 75 min
- **Adults 60-100 min**

Lower Limit of SBP by Age

- 0 to 1 month 50-60 mmHg
- >1 to 12 months 70 mmHg
- >1 to 10 years 70 + (age in years x 2) mmHg
- >10 years 90 mmHg
- **Adults: aim to keep at usual BP or if not known aim for >100 mmHg**

EPI Record No: HPA-EPI-0011

National Immunization Program

Cold Chain Incident Reporting Process

1. NIP FP receives notification regarding a break in cold chain in an atoll/island by phone.

2. NIP FP advice the health facility FP reporting the cold chain incident that:

- Vaccines must be bagged, dated and labeled Do not use: Quarantined,

- Vaccines are to be kept refrigerated between 2 to8 °C until it is determined which vaccines can or cannot be used.

3. Send a copy of the Incident Report: Vaccine Cold Chain Failure: Parts 1 and 2 to NIP via email immunization495@health.gov.mv.

4. After receiving completed document, NIP focal point (designated person) discusses the issue with concerned person/HPA heads for a decision regarding further use of the vaccine. After that NIP FP will forward the final recommendations via email or Viber to the HF reporting the cold chain break.

5. The NIP will provide the information to the person initially reporting the cold chain break, detailing how each of the vaccines should be handled (including disposal of the vaccines).

EPI Record No: HPA-EPI-0011

National Immunization Program

INCIDENT REPORT: VACCINE COLD CHAIN FAILURE

Location (HF- Atoll/Island):	
Focal Point Name and Designation:	
Phone Number:	
Incident notifying date and time:	
Incident happened date and time:	
Notified person name and contact number (HPA staff):	

Part 1 – Vaccine Fridge

STEP 1: Circle one box (under either a, b, c, or d) that best describes the problem:

A. Power Interruption	a.1 Power Outage	a.2 Power Interruption to Equipment
B. Equipment Problem	b.1 Equipment Breakdown	b. 2 Other Temperature Problem
C. Handling Error	C. 1 Vaccine Left Out	C.2 Refrigerator Door Left Open
D. Shipment Problem	D.1 Temp Reading	D.2 Product Damaged in Transit
E. Exposed Temperature °C	Highest: -------- °C ↑ Duration:	Lowest: -------- °C ↓ Duration:

STEP 2: Answer each question below:

E. Was a min/max thermometer in the fridge? Yes No

F. Was there a temperature log maintained for this fridge? Yes No

G. What was the air temperature of the room where vaccines were stored? .....^{0}C

H. What actions have been taken to correct the problem? (Details)

……..

EPI Record No: HPA-EPI-0011

National Immunization Program

Part 2: Vaccine details

Vaccine Name	# of doses/ Vials	Lot /Batch Number	Expiry Date	# of Previous Exposures and Duration	Type of vaccine fridge (ILR/Domestic)	VVM stage	Remarks

Completed by (Name): ---------- Date:
Contact Number:

With the complete form, please email (immunization495@health.gov.mv) detailed message of the incident in Dhivehi (in HF letter head), including the persons involved / responsible for the incident and the temperature sheet.

Immediate advice to Person Reporting (check as completed)

- Isolate vaccine in question in a bag/container and keep within 2°-8°C
- Clearly mark the bag/container "Do Not Use: Quarantined"
- Mark exposed vaccines with a permanent marker indicating the cumulative length of time exposed to a cold chain break

For HPA use:
Date Reported to NIP:_____ Advice / corrective actions given to health facility:
Total value of vaccines lost due to cold chain break: Name and Signature (given the advice from HPA):

SPG-1

Electronic Immunization Registry

Single-Page Guide

Login to the System

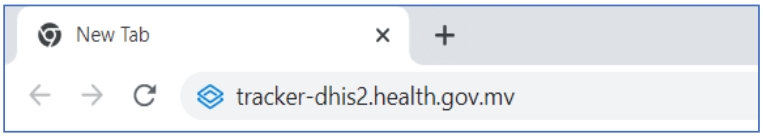
STEP 1

Open a web browser.
We recommend the latest version of Google Chrome®.

Google Chrome

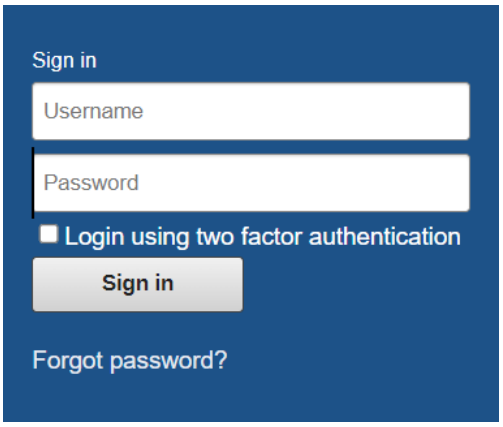
STEP 2

Type the URL/ Web address (https://tracker-dhis2.health.gov.mv/) in the address bar and press "Enter" key.



STEP 3

Enter the username and the password provided
Click on Sign in button.



Now, you should be able to login to the system and see dashboards.

World Health Organization Maldives
Ministry of Health Republic of Maldives
Health Protection Agency

Electronic Immunization Registry

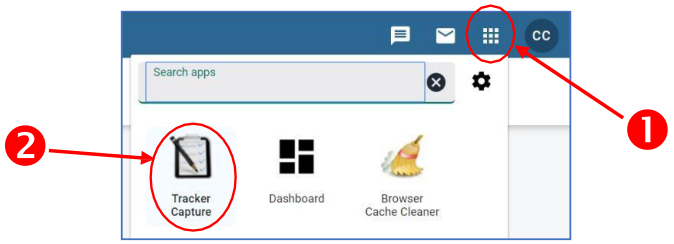
SPG-2

Single-Page Guide

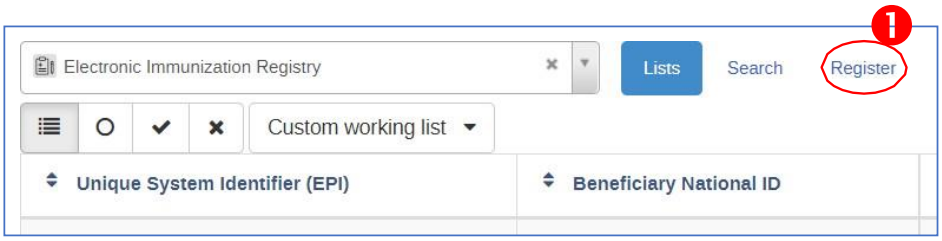
Registering a New Child

STEP 1 Login to the system with your username & password

STEP 2 Open "Tracker Capture" app

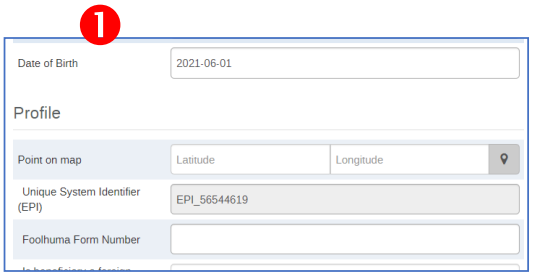


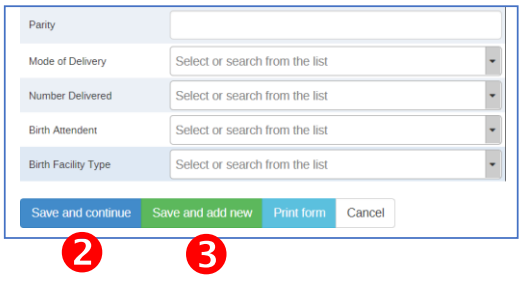
STEP 3 Click "Register"



STEP 4

(1) Fill all necessary details (Check the Date of Birth)
(2) To add vaccine data to this child - Click "Save and continue"
(3) To register a new child – Click "Save and add new"





World Health Organization Maldives
Ministry of Health Republic of Maldives

Electronic Immunization Registry

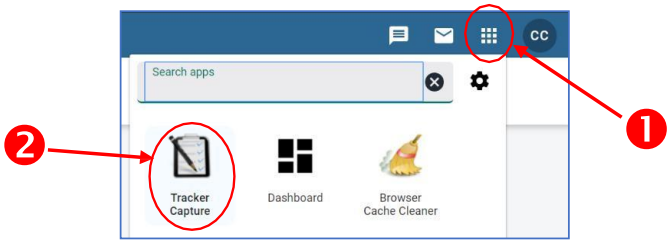
SPG-3

Single-Page Guide

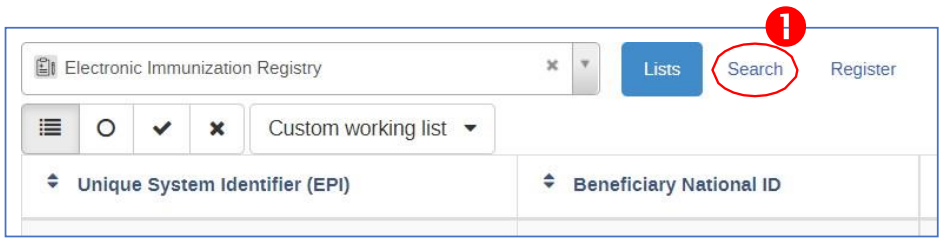
Searching a Child

STEP 1 Login to the system with your username & password

STEP 2 Open "Tracker Capture" app

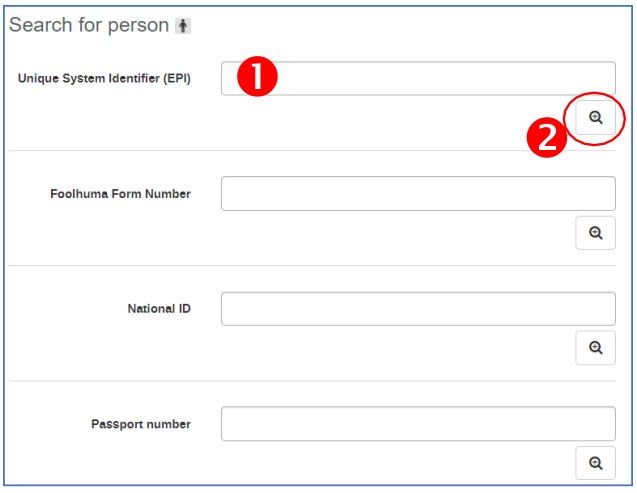


STEP 3 Click "Search"



STEP 4

(1) Enter one or more data to the search criteria
(2) Click on the search button



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Health Protection Agency

Electronic Immunization Registry

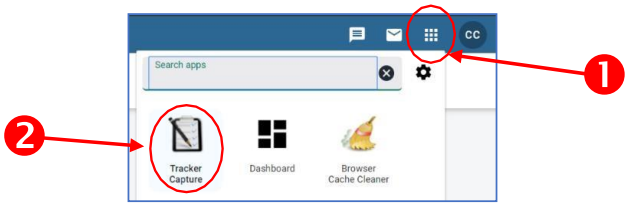
SPG-4

Single-Page Guide

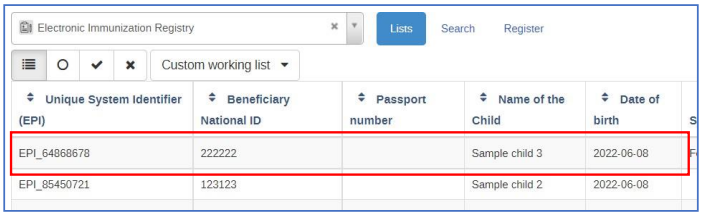
Entering Vaccines

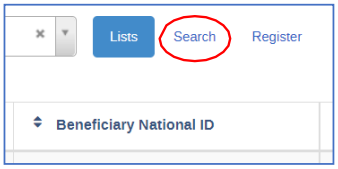
Note: If you have already opened the child's record, you can start from Step 3

STEP 1 Login to the system and open the "Tracker Capture" app



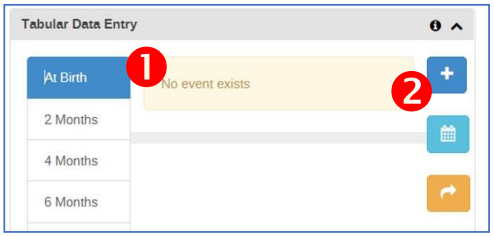
STEP 2 If you can see the child on the list, click on the record
If not click "Search" & search for the child using search parameters

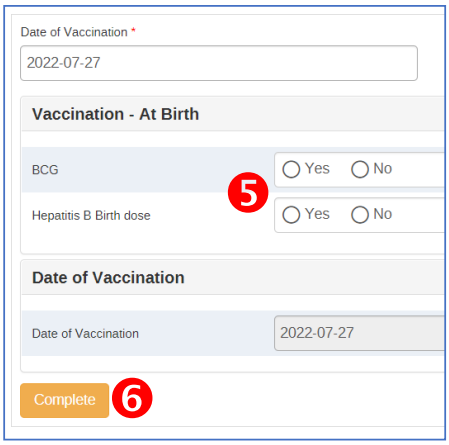


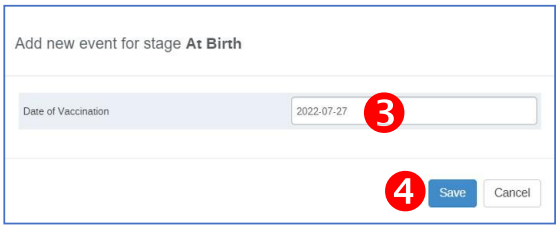


STEP 3

(1) Select the vaccination stage
(2) Click on Add new event button
(3) Select the correct vaccination date
(4) Click on Save button
(5) Enter the relevant data
(6) Click "Complete"







STEP 4 Click on "Back" to go to the main page

World Health Organization Maldives
Ministry of Health Republic of Maldives
Health Protection Agency

SPG-5

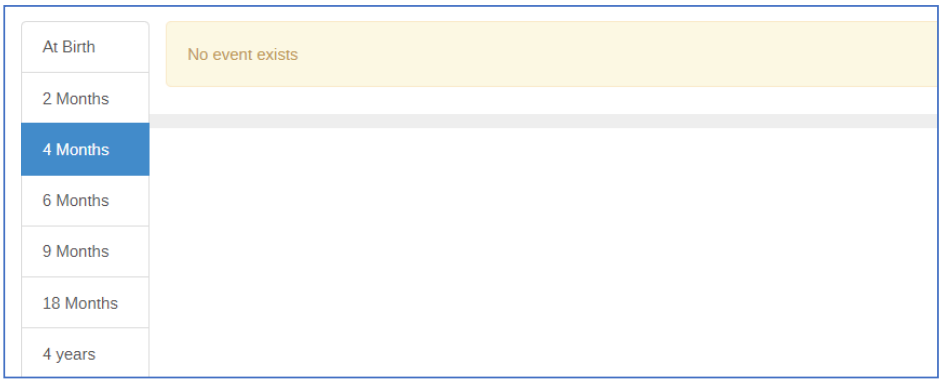
Electronic Immunization Registry

Single-Page Guide

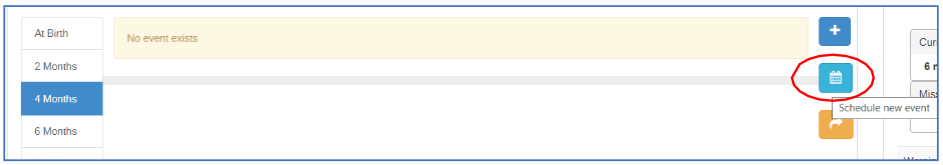
Scheduling Next Visit

STEP 1 Open child's record in the Tracker Dashboard (Please refer single-page guide on "Searching a Child")

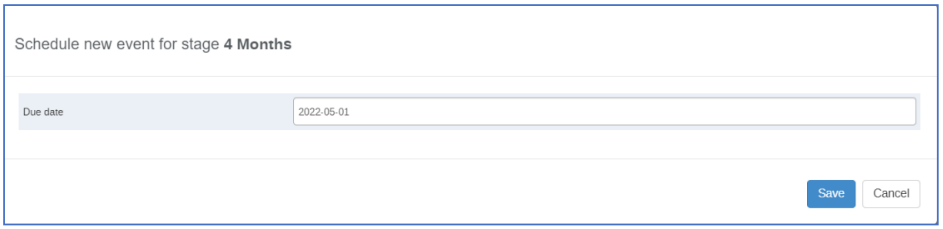
STEP 2 select the vaccination stage for which you need to add a schedule



STEP 3 Click "Schedule new event"



STEP 4 (1) Select the date for the next visit
(2) Click on "Save"



World Health Organization Maldives

Ministry of Health Republic of Maldives

Health Protection Agency

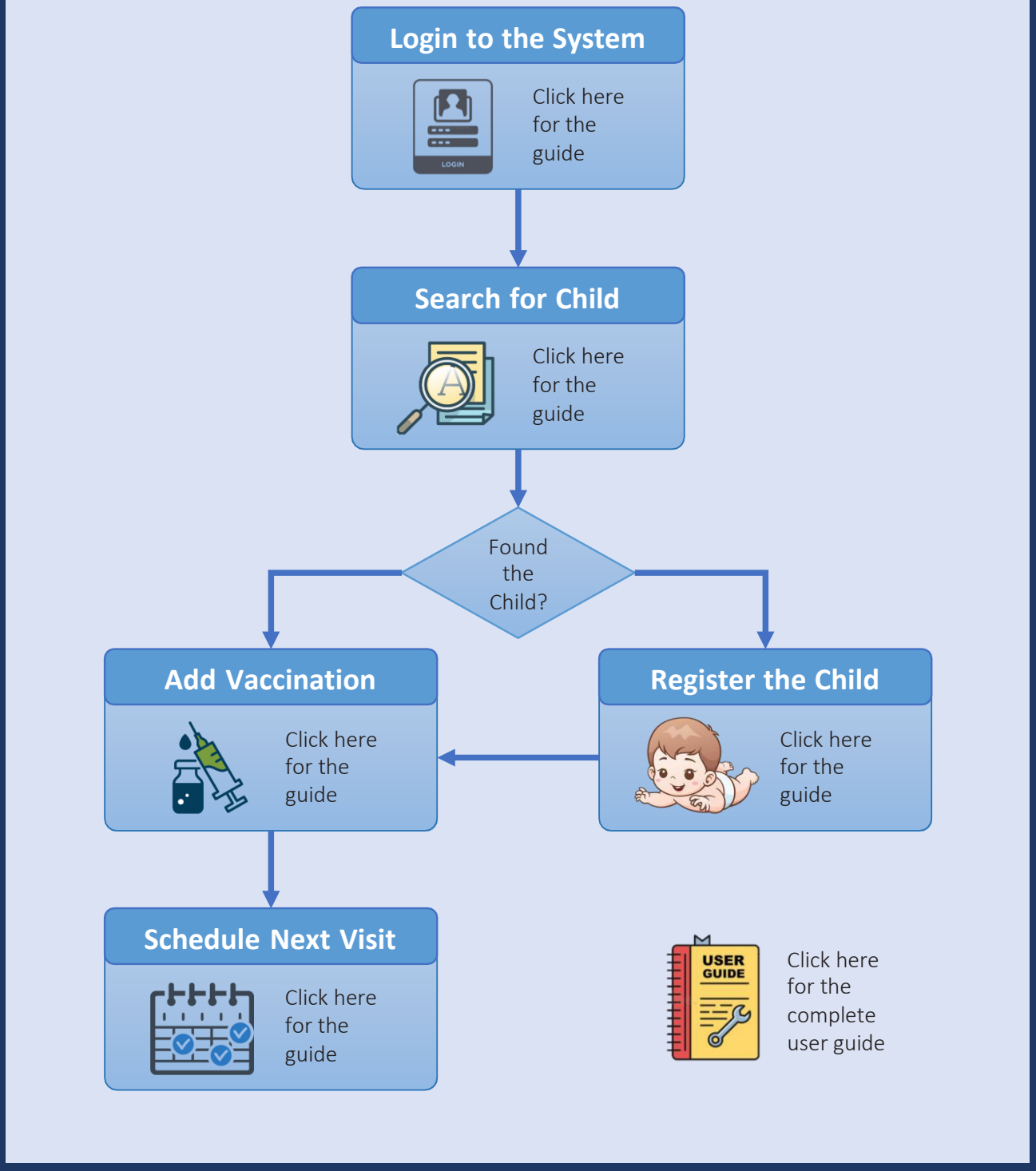
World Health Organization Maldives

Ministry of Health Republic of Maldives

Health Protection Agency

Electronic Immunization Registry

Data Entry Guide



VACCINE INCIDENT REPORT

National Program on Immunization
Health Protection Agency
Male', Republic of Maldives

1.Reporting Facility:

2. Client Information (Vaccinee)

Name:
Address:
Island:
Date of Birth:
Parent Name:
Address:
Contact Number:
Email address:

3. Vaccine Providers Information

Names of the involved Practioners: **Designation:**
1.
2.
3.
4.

4. Incident Detail

Incident Date: **Incident Time:**

Incident repoted to HPA via Telephone
Name of the person imformed from HPA :
Name of the reporter:
Date:
Time:

Describe the Incident (Dhivehi) ދަތުރުވެ ދިޔައީ ކިހާ ދުވަހަކަށް ހެދި ތަކެއް ހުންނަ ބޭނުންވާ ތަކެއް (ތަކެތި) ލިޔުއްވާ ދެއްވާ

Reporter Information

Name of the repoter:
Designation:
Contact Number:
Email Address:
Repoting date to HPA :

Note: Please attach all related documents(eg, Prescription)

FORM 2

National Immunization Program

Adverse Events Following Vaccination-Investigation Form

(only for Serious Events Following Immunization -Death/Disability/Hospitalization/Cluster)

SECTION A Basic Details

Atoll and Island: Case ID:

Place of vaccination (P): ☐ Gov. Health Facility Private Health Facility ☐ Other_____
Vaccination in (P): ☐ Campaign ☐ Routine ☐ Other (Specify): _____

Address of Vaccination Site:

Name of Reporting Officer:
Designation/Position:
Phone Number:
Email Address:

Date of Investigation: _ _ /_ _ /_ _
Date of filling this form: _ _ /_ _ /_ _
This report is ☐ First ☐ interim ☐ Final

Patient Name:
(use a separate form for each case in a cluster)
Date of Birth (DD/MM/YY): _ _ /_ _ /_ _
OR Age at onset: _ _ *years* _ _ *months* _ _ *days*
OR Age group: ☐ *< 1year* ☐ *1-5 years* ☐ *> 5 years-18 years* ☐ *>18years- 60 years* ☐ *> 60 years*
Patients full address with landmarks (street name, house name, locality, phone number etc.):

Brand name of vaccines (including manufacturer / diluent received by the patient)	Date of vaccination	Time of vaccination	Dose (e.g.: 1st, 2nd 3rd)	Batch number	Expiry date
				Vaccine Diluent	Vaccine Diluent
				Vaccine Diluent	Vaccine Diluent
				Vaccine Diluent	Vaccine Diluent
				Vaccine Diluent	Vaccine Diluent
				Vaccine Diluent	Vaccine Diluent

Type of site (P): ☐ Fixed ☐ Mobile ☐ Outreach ☐ Other _____

Date of first key symptom *(DD/MM/YY):* _ _ /_ _ / _____ Time of first symptoms *(hh/mm):* _ _ /_ _
Date of hospitalization *(DD/MM/YY):* _ _ /_ _ /_ _ _ _
Date first reported to health facility *(DD/MM/YY)*: _ _ /_ _ /_ _ _ _

Status on the date of investigation (P): ☐Died ☐Disabled ☐Recovering ☐Recovered Completely ☐ Unknown

If died, date and time of death *(DD/MM/YY):* _ _ /_ _ /_ _ _ _ (*hh/mm):* _ _ /_ _
Autopsy done?(P): ☐Yes (date):_____No, Planned on (date):_____Time:_____
Attach report (if available)

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SECTION B- Relevant Patient Information Prior to Immunization		
Criteria	**Finding**	**Remarks (if yes Provide details)**
Past history of similar event?	Yes/No/Unkn	
Adverse event after any previous vaccinations?	Yes/No/Unkn	
History of allergy to vaccine, drug or food?	Yes/No/Unkn	
Pre-existing comorbidity/ congenital disorder?	Yes/No/Unkn	
Pre-existing acute illness (30days) prior to vaccination?	Yes/No/Unkn	
Has the patient tested positive COVID19 prior to vaccination?	Yes/No/Unkn	
History of hospitalization in last 30 days, with cause?	Yes/No/Unkn	
Was the patient receiving any concomitant medication? (if yes, name the drug, indication, doses and treatment dates)	Yes/No/Unkn	
Family history of any disease (relative to AEFI) or allergy?	Yes/No/Unkn	

For adult women

- Currently pregnant? Yes (Weeks) _____ / No / Unknown
- Currently Breast feeding? Yes/No

For infants

The birth was ☐ full term ☐pre-term ☐ Post-term Birth weight: _____

Delivery procedure was ☐ Normal ☐Cesarian ☐Assisted (forced, vacuumed etc.) ☐with complications specify

SECTION C- Details of First Examination** of Serious AEFI case		
Source of information (Pall that apply): ☐Examination by the investigator ☐Documents ☐Verbal autopsy other_____*if from verbal autopsy, please mention the source* _____		
Name of the person who first exmined/ treated the patient: Name of the person treating the patient: Other sources who provided the information (specify):		
Name and contact information of the person completing these clinical trials:	Designation:	Date/ Time:

Instructions- Attach copies of ALL available documents (including case sheets, discharge summary, case notes, laboratory reports and autopsy reports, prescription for concomitant medications) and then complete addtitional information NOT AVAILABLE in existing documents, i.e,

- **If patient has received medical care-** attach copies of all available documents (including case sheet, discharge summary, laboratory reports and autopsy reports, if available) and write the only information that is not available in the attached document below.
- **If the patient has not received medical care-** obtain history, examine the patient and write down your findings below. (add additional sheets if necessary).

Provisional/ Final Diagnosis:

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SECTION D- Details of vaccine provided at the site linked to AEFI on corresponding day										
Number immunized for each antigen at session site. Attach record.	Vaccine name									
	Number of doses									

a) When was the patient immunized? (P) tick the box below and respond to all questions ☐ within the first vaccination of the session ☐ within the last vaccination of the session ☐ Unknown	
In case of multidose vials, was the vaccination given ☐ within the first few doses of the vial administered ☐ Within the last doses of the vial administered ☐ Unknown?	
b) Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?	Yes* / No
c) Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	Yes*/ No/ Unable to access
d) Based on your investigation, do you feel that the vaccine's physical condition (eg. colour, turbidity, foreign substance etc.) was abnormal at the time of administration?	Yes*/ No/ Unable to access
e) Based on your investigation, do you feel that there was an error in vaccine reconstitution/ preperation by the vaccinator (eg. Wrong product, wrong diluent, improper mixing, improper syringe filling etc.)	Yes*/ No/ Unable to access
f) Based on your investigation, do you feel that there was an error in vaccine handling (eg. Break in cold chain during transport, storage and/or immunization session etc.)?	Yes*/ No/ Unable to access
g) Based on your investigation, do you feel that the vaccine was administered incorrectly (eg. Wrong dose, site or route of administration, wrong needle size, not following injection practice etc.)	Yes*/ No/ Unable to access
h) Number immunized from the concerned vaccine vial/ampoul	
i) Number immunized with the concerned vaccine in the same session	
j) Number immunized with the concerned vaccine having same batch number at other location. Specify locations:	
k) Could the vaccine given to this patient have a quality defect or is substandard or falsified?	Yes*/ No/ Unable to access
l) Could this event be a stress response related to immunization(eg. Acute stress response, vasovagal reaction, hyperventilation, dissociative neurological symptom reaction etc.)?	Yes*/ No/ Unable to access
m) Is this case a part of a cluster?	
i. If yes, how many other cases have been detected in the cluster?	
a. Did all the cases in the cluster receive vaccine from same vial?	Yes*/ No/ Unable to access
b. If no, number of vials used in the cluster?	

it is compulsory for you to provide explanations for these answers separately

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SECTION E- Immunization practices <u>at the place(s) where concerned vaccine was used</u> (Complete this section by asking and/or observing practice)			
Syringes and needles used:			
• Are AD syringes used for immunization?			
If no, specify the type of syringe used ☐ Glass ☐ Disposable ☐ Recycled disposable ☐ Other_____			
Specific key findings/additional observations and comments:			
Reconstitution: (complete only if applicable, P NA if not applicable			
Reconstitution procedure (P)	Status		
• Same reconstitution syringe used for multiple vials of same vaccine?	Yes	No	NA
• Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
• Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
• Separate reconstitution syringe for each vaccination?	Yes	No	NA
Are the vaccines and diluents used the same as those recommended by the manufacturer	Yes	No	NA
Specific key findings/additional observations and comments:			
Injection techniques in vaccinator(s): (Observe another session in same locality- same or different place)			
• Correct dose and route?	Yes/ No		
• Time of reconstitution mentioned on the vial?(in case of freeze dried vaccine)	Yes/ No		
• Non-touch technique followed?	Yes/ No		
• Contraindications screened prior to vaccination?	Yes/ No		
• How many AEFI reported from the centre that distributed the vaccine in last 30 days?			
• Training received by the vaccinator? (if yes, specify the date of last training_____)	Yes/ No		
Specific key findings/additional observations and comments:			

SECTION F-Cold Chain and Transport (Complete this section by asking and /or observing practice)	
Last vaccine storage point:	
• Is the temperature of the vaccine storage refrigerator monitored?	Yes/ No/ Unkn
○ If 'yes', was there any deviation out side of 2-8degrees after the vaccine was placed inside?	Yes/ No/ Unkn
○ If 'yes', provide the details of monitoring separately.	
• Was the correct procedure for storing vaccines, diluent and syringes followed?	Yes/ No/ Unkn
• Was any other item (other than EPI vaccines and diluents) in the refrigerator or freezer?	Yes/ No/ Unkn
• Was any partially used reconstituted vaccine in the refrigerator?	Yes/ No/ Unkn
• Were any unusable vaccines (expired, no label, VVM at stages 3 or 4, frozen)in	Yes/ No/ Unkn

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the store?	
• Were any unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store?	Yes/ No/ Unkn
Specific key findings/additional observations and comments:	
Vaccine Transportation	
• Type of vaccine carrier used?	
• Was the vaccine carrier sent to the site on the same day as vaccination?	Yes/ No/ Unkn
• Was the vaccine carrier returned from the site on the same as vaccination?	Yes/ No/ Unkn
• Was a conditioned ice pack used?	Yes/ No/ Unkn
Specific key findings/additional observations and comments:	

SECTION G- Community Investigation (Please visit locality and interview parents /others)
Were any similar events reported within the time period similar to when the adverse event occurred and in the same locality? Yes/ No/ unknown. If yes, describe.
If yes, how many events/ episodes?
Of those effected, how many are • Vaccinated _____ • Not vaccinated _____ • Unknown _____
Other comments:

SECTION H- Other findings/Observations/Comments

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Patient Summary Report

Name:	**NID:**	**Age:**
Date and Time of Vaccination:		
Date of Presenting Complaints:		
Presenting Complaints:		
Underlying conditions and Medications: **Previous Allergies:** **Significant Past History:**		
If it's a sudden death, please write the patient's condition from the time of vaccination		
Working diagnosis:		
Treatments given:		
Progression:		
Final diagnosis:		
Plan:		

Treating Doctor:
Signature:

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Vaccine Errors Reporting Form

National Program on Immunization
Health Protection Agency
Male', Republic of Maldives

Reporting Facility:

1.Event Detail Questions

Report submission type (select one)

- ☐ Error occurred and reached the patient
- ☐ Error occurred but did NOT reach the patient
- ☐ Hazardous condition (no error, but situation warrants concern)

Event Date:	**Name of the Vaccine(s)involved in the event:**

2.Vaccine product information

Brand Name:	Generic Name:
Manufacturer:	Lot #:
Dosage (Optional):	Expiry Date (Optional):

3. Describe the event. (Please do NOT submit any provider or patient identifiable information when submitting reports to HPA. For the patient Identification, separate report (Incident report) should be submitted to HPA).

4. Type of event / Contributing factors (select all that apply)

- ☐ Wrong Vaccine
- ☐ Wrong timing/interval (e.g., interval too short)
- ☐ Wrong route of administration (e.g., IM vs. subcutaneous)
- ☐ Wrong patient
- ☐ Wrong dose - over dosage
- ☐ Wrong dose - under dosage
- ☐ Wrong age (patient not correct age for vaccine given)
- ☐ Wrong administration site (e.g., gluteus maximus rather than the deltoid)
- ☐ Extra dose (Repeated Dose)
- ☐ Expired vaccine
- ☐ Contaminated or deteriorated vaccine
- ☐ Vaccine/component omission - Diluent given without the vaccine
- ☐ Vaccine/component omission - Only one component of multi-component vaccine administered

Event type not listed (please specify) …….

5. Age of Child / Client at the time of the event:

☐ Years and /or ☐ Months and /or ☐ Days.

6. Type of practitioner(s) involved in the event (select all that apply)

☐ Medical Doctor ☐ Health Worker ☐ Nurse (RN, EN)

☐ Student (e.g., medicine, nursing, pharmacy) If "Other" then please specify:.....

Name:
Email:
Contact Number:
Signature:

Is reporter same as person involved in the event?

☐ Yes ☐ No ☐ Not applicable

Further Corrective Action and Advice:

Name: **Date:** **Signature:**

For further information or inquiries, please contact:

Health Protection Agency, Ministry of Health,
Roshanee Building, Sosun Magu, Male'
Telephone: +960- 3014333 , Fax: +960-3014 484 **Mobile: +960-7903118, +960-9752299,**
Email: immunization495@health.gov.mv, hpa@health.gov.mv

- **Any errors/incident related to vaccine, please notify immediately to National Program and completed "Vaccine Errors Reporting Form" to be submitted to HPA within 24 hours of the incident.**

NATIONAL IMMUNIZATION PROGRAM

AEFI MONTHLY COMPILATION FORM

								Source
								S.No
								Name/ID
								AEFI Reporting ID Number
								Patient Location (Island)
								Sex (M/F)
								Pregnant (Y/N)
								Lactating (Y/N)
								Age
								Vaccine Brand
								Manufacturer
								Dose
								Vaccine Batch Number
								Diluent Batch Number
								Adverse Event
								Place of Vaccination
								Date of vaccination
								Date of onset
								Date of Notification
								Date of Reporting
								Serious(Y/N)
								Reason for serious
								Outcome
								Autopsy Conducted (Y/N/NA)
								Reported by
								Reporter Location
								Investigation planned Y/N)
								Date report recorded at National level

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CHECKLIST FOR SUPERVISION VISITS TO SERVICE DELIVERY POINTS

(Expanded Program on Immunization)

Name of the supervisor (s):

……

Supervision Trip from ……..……..…… To ……..…..

Name of Facility: _____

Level of the facility: _____

	Number	Remarks
Total Population		
No. of Children under 2 years		
No. of CBAW		
No. of Pregnant women		

Observing the health facility environment and immunization area

(Tick in the box yes / No and provide details in the comment box. Note any corrective action taken in the adjoining box.)

#	Category and aspect to be verified	Yes	No	Comment or Problem Observed	On-Site Corrective action taken
Vaccine Storage					
1	Is there a thermometer in the fridge				
2	Is there a freeze watch indicator				
3	Refrigerator temperature monitoring charts available and recorded twice daily				
4	Are the vaccines kept properly inside the refrigerator				
5	Are open vials kept in front (how it is kept, opened date properly labeled and followed)				
6	Has there been any incidents of vaccine shortage during the last 6 months (add in remarks from when, till when and which vaccine)				
7	Are there any vaccines with VVM reaching the discard point				

#	Category and aspect to be verified	Yes	No	Comment or Problem Observed	On-Site Corrective action taken
8	Are there frozen vaccines				
9	Are there any expired vaccines inside the refrigerator				
10	Any incidents of cold chain failure during transport and/or storage within the last 6 months				
11	Has proper action been taken whenever temperature requirements are not met. (add in remarks - what action was taken)				
12	Is there any register recording vaccines discarded (Qty, Name, reason)				
13	Are vaccines with short expiry dates used first				

Immunization Related					
14	Is Vit A supplementation integrated with routine vaccination				
15	Are parents advised on vaccine reactions (AEFI) before vaccination				
16	Are parents advised on when to return for next vaccination				
17	Is there an adequate stock of AD syringes				
18	Are AD syringes used for every immunization session				
19	Is safety boxes used for each AD syringes and needles				
20	Are there any syringes or open safety boxes lying around that could pose a threat to the community				

21	Are doctors aware of AEFI report forms				
#	**Category and aspect to be verified**	**Yes**	**No**	**Comment or Problem Observed**	**On-Site Corrective action taken**
22 23 24 25 26	How are sharp wastes disposed? Open Pit burning Incinerator Under ground burying Others				
Advocacy & Supervision					
27	Are IEC materials displayed				
28	Immunization coverage monitoring charts displayed				
29	Health education conducted (how often, target group, topics)				
30	Cold chain supervision of pharmacies conducted periodically				
Data records					
31	Is Immunization register available				
32	Are monthly immunization reports prepared and sent regularly (child vaccine and TT vaccine report, AEFI, sentinel surveillance, vaccine refusal, ORS report)				
33	Vaccine and vaccine consumables stock records maintained				

#	**Category and aspect to be verified**	**Yes**	**No**	**Comment or Problem Observed**	**On-Site Corrective action taken**
34	Does the stock records show adequate vaccines and diluents and their periodic supplies				
35	Does the actual physical stock of any vaccine and diluents match with what is marked in the register				
36	Is drop-out cases recorded and the records maintained				
37	Vaccines data's collected from islands and maintained				
38	Island level supervision conducted (how frequently, areas covered)				
39	Is in-service training for staff undertaken				
Human Resource					
40	Is a focal point appointed for EPI activities (if YES name)				
41	Is there a responsible person for cold chain management				
42	Is there a person designated for AEFI Management				

Any other comments:

Availability of Basic Item and Quality Check

Items	***Available Number***	***Functional***		
		Yes	**No**	**Remarks**
Equipment				
Refrigerators				

Items	*Available Number*	*Functional*		
		Yes	No	Remarks
Deep Freezers				
Vaccine Thermometers				
Cold Boxes				
Vaccine Carriers				
Oxygen Concentrators(in Health Facility)				
Syringes & Safety box				
One shot syringes				
BCG syringes				
vaccine reconstitution syringes				
Safety box.				
Vaccines and other drugs				
BCG Vaccine with Diluents				
IPV Vaccines				
Hep. B Vaccines				
Measles Vaccines with Diluents				
Oral Polio Vaccines				
Td Vaccines				
MMR Vaccines				
Pentavalent Vaccine				
Other Vaccines & Drugs				

Items	*Available Number*	*Functional*		
		Yes	No	Remarks

Guidelines and other relevant documents (reply in Yes / No)

Description	Unit	Is it Available ?	Is it used?	Is staff well familiar?	Remarks
Immunization in Practice	EPI				
Essential Immunization	EPI				
MMR guideline	EPI				
Poster on How to store vaccine in a refrigerator	EPI				
Vaccination posters	EPI				
Hand Book for Health Care Providers (Hospital)	EPI				
Vaccine folders (leaflets on vaccines)	EPI				

Date of Last Refresher for Health Providers

#	*Health Personnel*	*Duration and date*	*Which area*

Perceived Quality of EPI/IMCI Counseling

.....

DISCUSSION BY SUPERVISORY TEAM

a) Topics discussed

_____

_____

_____

b) Strengths Highlighted: ……

c) Weaknesses highlighted : ……..

#	Are of weakness	Suggested recommendation	Remarks

e) Additional Areas on which support is needed from HPA

Recommendation:

Thank You