EXPANDED PROGRAMME ON IMMUNIZATION (EPI) MANUAL FOR HEALTH STAFF

6th Edition, 2022

Vaccine Preventable Disease Program
Department of Public Health
Ministry of Health
Royal Government of Bhutan

PREFACE

With the overarching aim to sustain high immunization coverage in Bhutan, the 2022 edition of the EPI manual addresses the change in need surrounding immunization services that have emerged in the past two years. Over the past three years, COVID-19 vaccines have been developed and introduced to prevent or reduce disease severity in response to the pandemic that has affected and taken millions of lives globally. Vaccines such as the Pfizer, Moderna, AstraZeneca, CoviShield and Sinopharm are well covered in this manual to assist service providers in contributing towards the battle against COVID-19.

In this edition, the chapter dedicated to managing vaccines and cold chain has been revised and elaborated into two distinct chapters namely Vaccine Management and Maintenance of Cold Chain Equipment. A distinct feature of this edition is the emphasis that has been placed not only on vaccine management but also on the maintenance and repair of cold chain equipment which is of equal significance for ensuring vaccine potency and sustaining optimum quality service delivery in the field of immunization. In the 2022 edition, the chapter on Ensuring Safe Injection also prioritizes waste management resulting from vaccines to ensure proper disposal of immunization wastes.

This manual aims to provide the service providers with adequate and accurate knowledge on the use of cold chain equipment and temperature monitoring devices. Hence, the chapter on Cold Chain Equipment consists of the detailed types of cold chain equipment and description of its components. To ease the monitoring and maintenance process, a chapter on Documentation and Reporting has been included. The standard format for documentation, budgeting and reporting included in this chapter would not only ensure uniformity in the data given by service providers residing in different parts of the country but would also ease the process of indent and management of the vaccines and equipment thereby easing the process of service delivery of immunization as a whole.

To make the content of this manual less complex for the service providers who will be using it, the manual has been made more pictorial and illustrative. With the inclusion of the newer vaccines and technological changes in the immunization program, the manual is revised to update the knowledge of the health workers on these new vaccines and enhance their skills so as to deliver quality immunization services in the country.

First Edition	:	2002
Second Edition	:	2007
Third Edition	:	2010
Fourth Edition	:	2014
Fifth Edition	:	2020
Sixth Edition	:	2022

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Authored by:

1. Dr. Dhrupthob Sonam Specialist in General Practice, JDWNRH
2. Mr. Tashi Dawa, Dy. Chief Programme Officer, VPDP, DoPH, Ministry of Health
3. Ms. Cheten Zangmo, Assistant Programme Officer, VPDP, DoPH, Ministry of Health
4. Dr. Indrani Chakma, Health and Nutrition Specialist, UNICEF Bhutan
5. Dr. Anshu Kumar, Cold Chain Specialist, UNICEF Bhutan
6. Dr. Chandralal Mongar, Health and Nutrition Officer, UNICEF Bhutan
7. Mr. Tshewang Dorji Tamang, National Consultant, UNICEF Bhutan
8. Mr. Sonam Wangdi, WHO Bhutan

Advisor:

1. Rixin Jamtsho, Chief Programme Officer, CDD, DoPH, Ministry of Health
2. Dr. Sonam Wangchuk, Head/Specialist, RCDC
3. Dr. Mimi Lhamu Mynak, Paediatrician, JDWNRH

Contributors

1. Teaching Faculty, FNPH
2. Health Staff, Bhutan

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Pemba Wangchuk,
Acting Secretary
Ministry of Health

ABBREVIATIONS

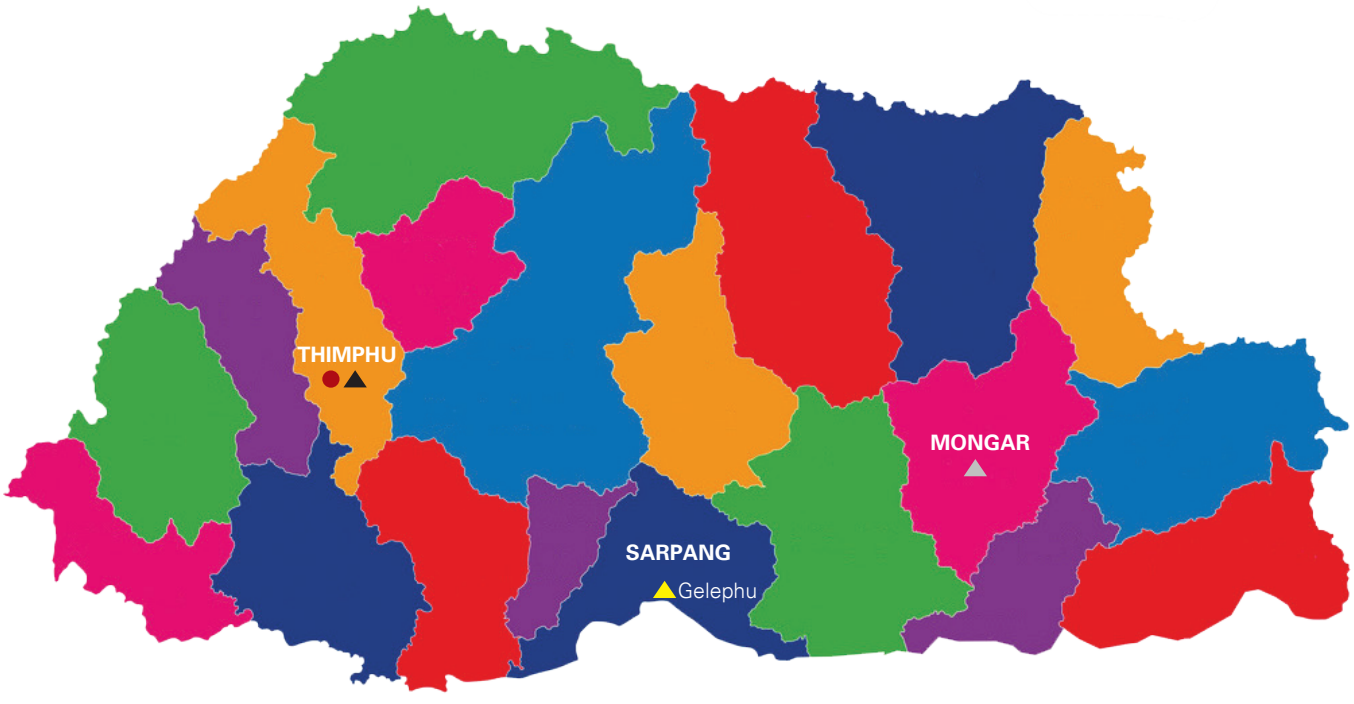
AD	Auto Disable (syringe)
ADB	Asian Development Bank
AEFI	Adverse Events Following Immunization
AFP	Acute Flaccid Paralysis
AMC	Average Monthly Consumption
AMF	Auto Mains Failure
ANC	Antenatal Care
BCG	Bacillus Calmette-Guerin (tuberculosis vaccine)
bOPV	Bivalent Oral Poliomyelitis Vaccine
COVID-19	Coronavirus Disease - 19
CCE	Cold Chain Equipment
CCH	Cold Chain handler
CCP	Cold Chain Point
CCT	Cold Chain Technician
CMO	Chief Medical Officer
Combo	Combination of ice-lined refrigerator and freezer
30 DTR	30 Days Temperature Recorder
DHO	District Health Officer
DF	Deep Freezer
DG	Diesel Generator
DTP	Diphtheria-Tetanus-Pertussis
EEFO	Early Expiry First Out
EPI	Expanded Program on Immunization
EVM	Effective Vaccine Management
FEFO	First Expiry First Out
HF	Health Facility
Hep B	Hepatitis B vaccine
Hib	Haemophilus influenzae type b
HIMS	Health Information Management System
HPV	Human Papillomavirus vaccine
HW	Health Worker
ILR	Ice Lined Refrigerator
IPV	Inactivated Polio Vaccine
LF	Limes flocculation
MCH	Maternal Child Health
MIS	Management Information System
MMR	Measles Mumps and Rubella

MOI	Medical Officer In charge
MO	Medical Officer
MoH	Ministry of Health
NEPIS	National EPI Store
OPV	Oral Polio Vaccine
ORC	Outreach Clinic
PCV	Pneumococcal Conjugate Vaccine
Penta	Diphtheria-Pertussis-Tetanus-Hepatitis B and Hib
PHC	Primary Health Center
PUF	Polyurethane Foam
RI	Routine Immunization
RCDC	Royal Center for Disease Control
REPIS	Regional EPI Store
SC	Satellite Clinic
SDD	Solar Direct Drive Refrigerator
TB	Tuberculosis
Td	Tetanus diphtheria
Td	Tetanus diptheria
UIP	Universal Immunization Programme
UNICEF	United Nations Children's Fund
VCCH	Vaccine and Cold Chain handler
VHW	Village Health Worker
VPDP	Vaccine Preventable Disease Program
VVM	Vaccine Vial Monitor
WHO	World Health Organization
WIC	Walk in Cooler
WIF	Walk in Freezer

Contents

CHAPTER 1:
INTRODUCTION

EPI STORES IN BHUTAN



- National EPI Store
- Western EPI Store
- Central EPI Store
- Eastern EPI Store

1.1 BACKGROUND

Immunization is one of the most effective interventions against preventing infectious diseases. With the implementation of Universal Immunization Program (UIP), Bhutan has made significant achievements in preventing and controlling Vaccine Preventable Diseases (VPDs). Immunization needs to be sustained as a high priority in order to reduce the incidence of all VPDs, sustain the eradication status of Polio, the elimination status of Measles and neonatal tetanus, while also gearing towards eliminating rubella.

Under UIP, all the children in Bhutan are protected against the following Vaccine Preventable Diseases (VPD) namely Tuberculosis, Polio, Hepatitis B, Diphtheria, Pertussis, Tetanus, Haemophilus influenzae (type b) Meningitis, Pneumonia and Human papillomavirus. The Expanded Program on Immunization (EPI) was launched in Bhutan on 15th November 1979 with the objectives to reduce morbidity, disability and mortality from the vaccine preventable diseases to a level where these diseases cease to be a public health problem. The national Immunization policy is to provide immunization to all children and to complete the primary series of vaccination before the age of one year.

Immunization program was initially started with only 6 antigens (BCG, DTP, bOPV and Measles). Subsequently, more antigens (Hepatitis B in 1996, Rubella in 2006, Haemophilus influenza B in 2009 and Human Papilloma Virus (HPV) in 2010 for girls and in 2020 for boys, IPV in 2015, Mumps in 2016, PCV and seasonal influenza vaccine in 2019) were added in the immunization schedule keeping in view of the disease burden, financial implications and health infrastructure in the country. During the COVID-19 pandemic, COVID-19 vaccines were administered to the various category of eligible population in 2021 and 2022 based on available vaccine efficacy evidence. In the event of disease outbreak, relevant vaccines will be introduced based on disease burden and cost effectiveness.

In February 1988, the 66th National Assembly passed a resolution calling for all children and pregnant mothers to have access to immunization and to be fully vaccinated. In the next few years, immunization services were given high priority and in addition, the requirement of producing the vaccination card for school admission, encouraged the people to bring their children for immunization. In 1991, Bhutan achieved the certificate of Universal Child Immunization (UCI).

The last case of clinical compatible polio was reported in 1986 and since then Bhutan has maintained zero polio status. Bhutan received polio free certification from WHO as part of SEARO countries polio free certification in 2014, measles elimination certificate in 2017 and hepatitis B control certificate in 2018 for under five. Bhutan has also maintained the neonatal tetanus elimination criteria ever since 1994. Bhutan has also been able to sustain high (>95%) immunization coverage for the past several years (2002 and 2008 EPI coverage survey and 2012, NHS). However, the challenge to the immunization program is to sustain high immunization coverage especially with the hard-to-reach population and migrating population in the country. Maintaining injection safety and to manage Adverse Events Following Immunization (AEFI) is also a concern for the program. Further, strengthening of the cold chain system and replacement, vaccine management, monitoring and supervision, advocacy and social mobilization for immunization are some of the challenges faced by the program.

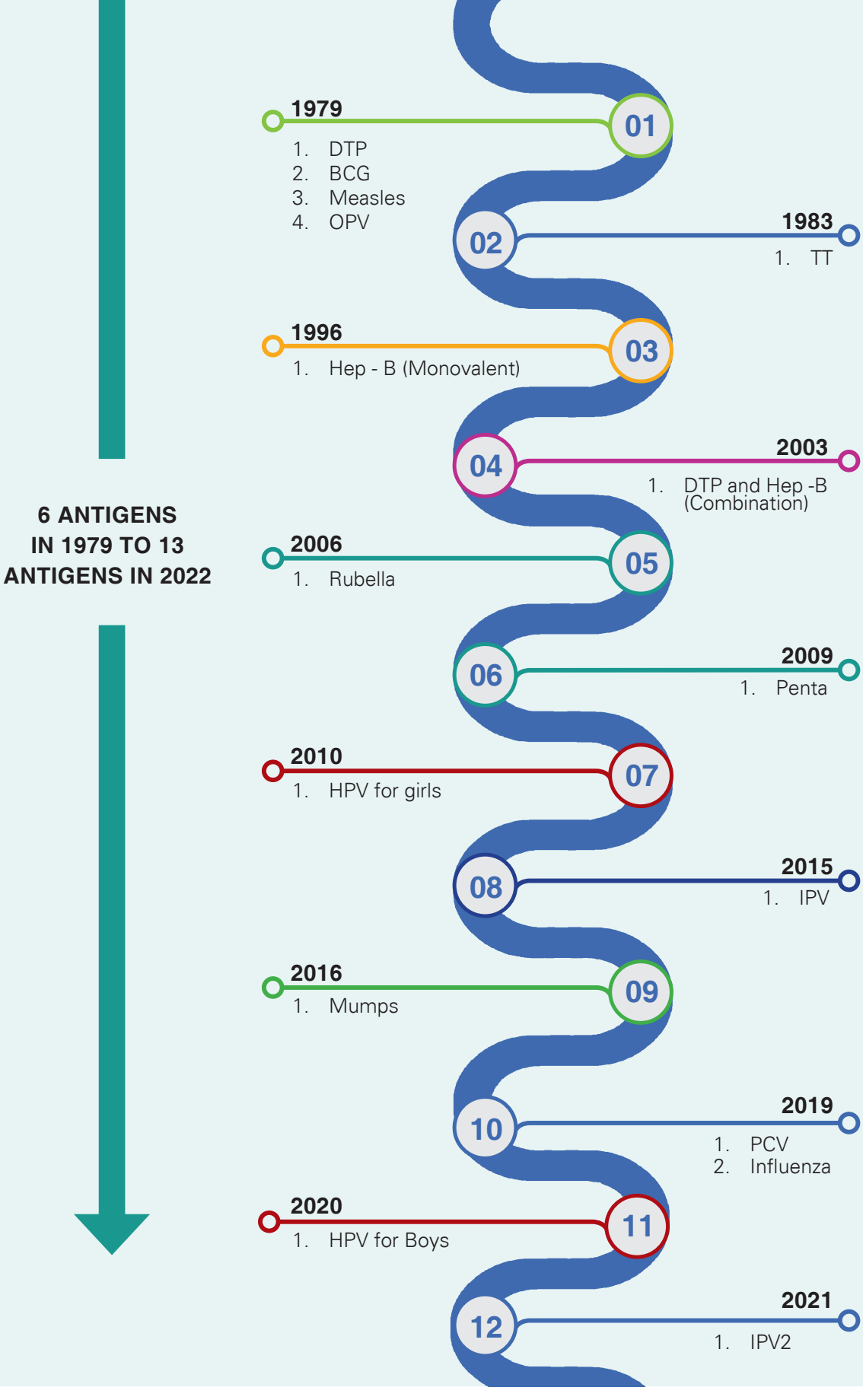


Figure 1:The journey from 1979 to 2022

The EPI programme was renamed as Vaccine Preventable Disease Program (VPDP) in 2005, not to look only for immunization but to cover broader aspects for vaccine preventable disease. The goal of the VPD program is to reduce morbidity, disability and mortality due to vaccine preventable diseases.

The first National EPI Services Manual was developed as a field guide, training, and reference material in 2002. The 2nd edition was published in 2007, 3rd in 2011, 4th in 2014, 5th edition of the EPI manual in 2020 and now 6th edition in 2022. The revision of the manual is based on the need like introduction of new vaccines and cold chain equipment.

Figure 2: Immunization for the safe lives of children and women

1.2 IMMUNIZATION SUPPLY CHAIN LEVELS IN BHUTAN

Cold chain network in the country is the backbone to ensure the delivery of quality and potent vaccines. Since the inception of UIP, the Immunization services are provided through a vast health care infrastructure in two major ways –

a. **Through fixed sites/facility level:** consisting of District Hospitals, Primary Health Centres (PHC), Sub-Post.

b. **Outreach sessions:** in Bhutan, planned routine immunization (RI) outreach sessions are held at least once a month.

1.3 SUPPLY CHAIN SYSTEM

The National EPI Store receives vaccines from manufacturers across the globe. These vaccines are then distributed to the three regional stores known as Western EPI Store in Thimphu, Eastern EPI Store in Mongar and Central EPI Store in Gelephu to meet the country's demand. The delivery of vaccines from National Store to Local Distribution (LD) till District level is represented in the figure below:

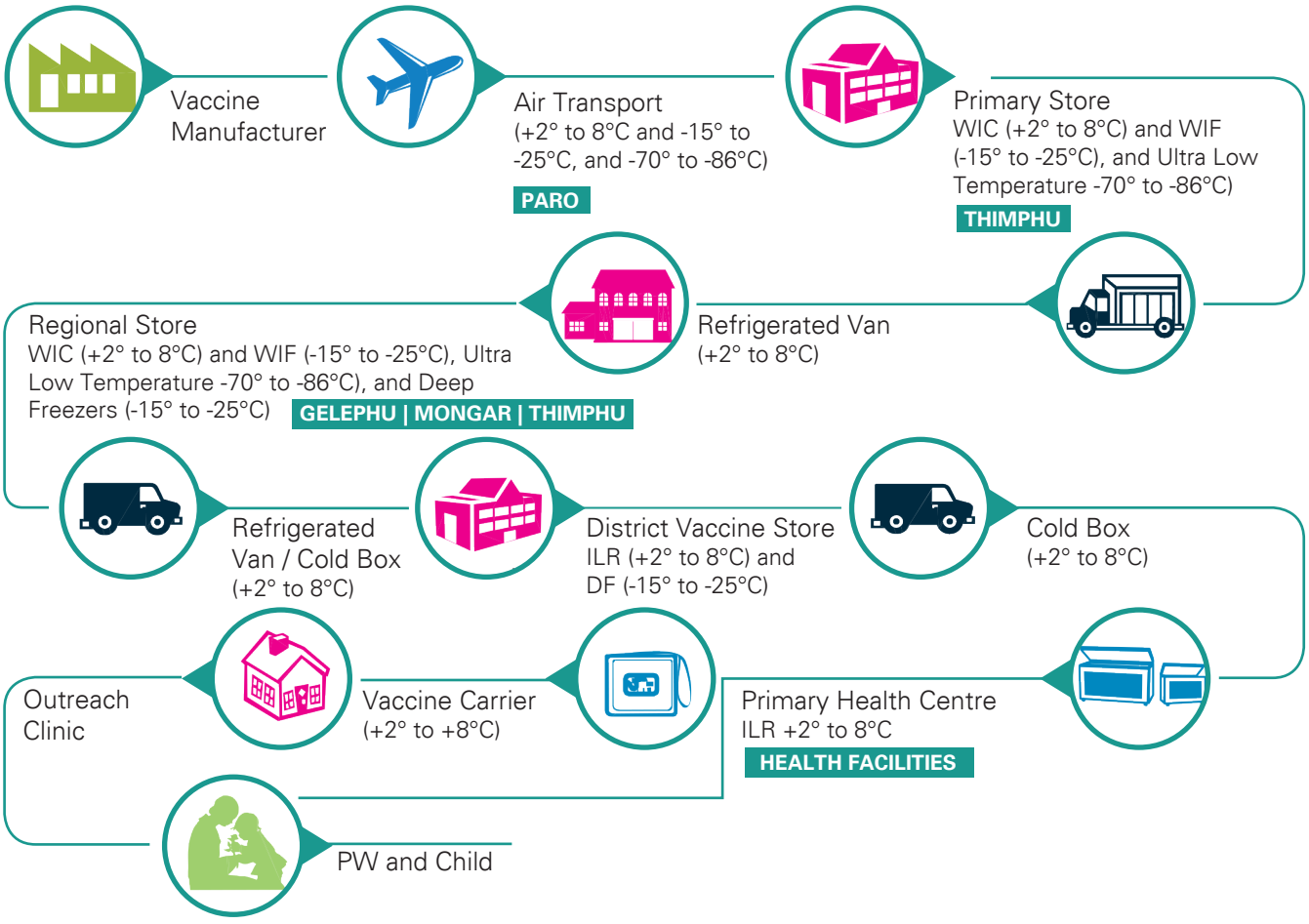


Figure 3: The immunization supply chain system of Bhutan

From District hospitals the vaccines are distributed to PHCs and Sub-posts, where routine immunizations are provided via fixed session or as outreach clinic (ORC).

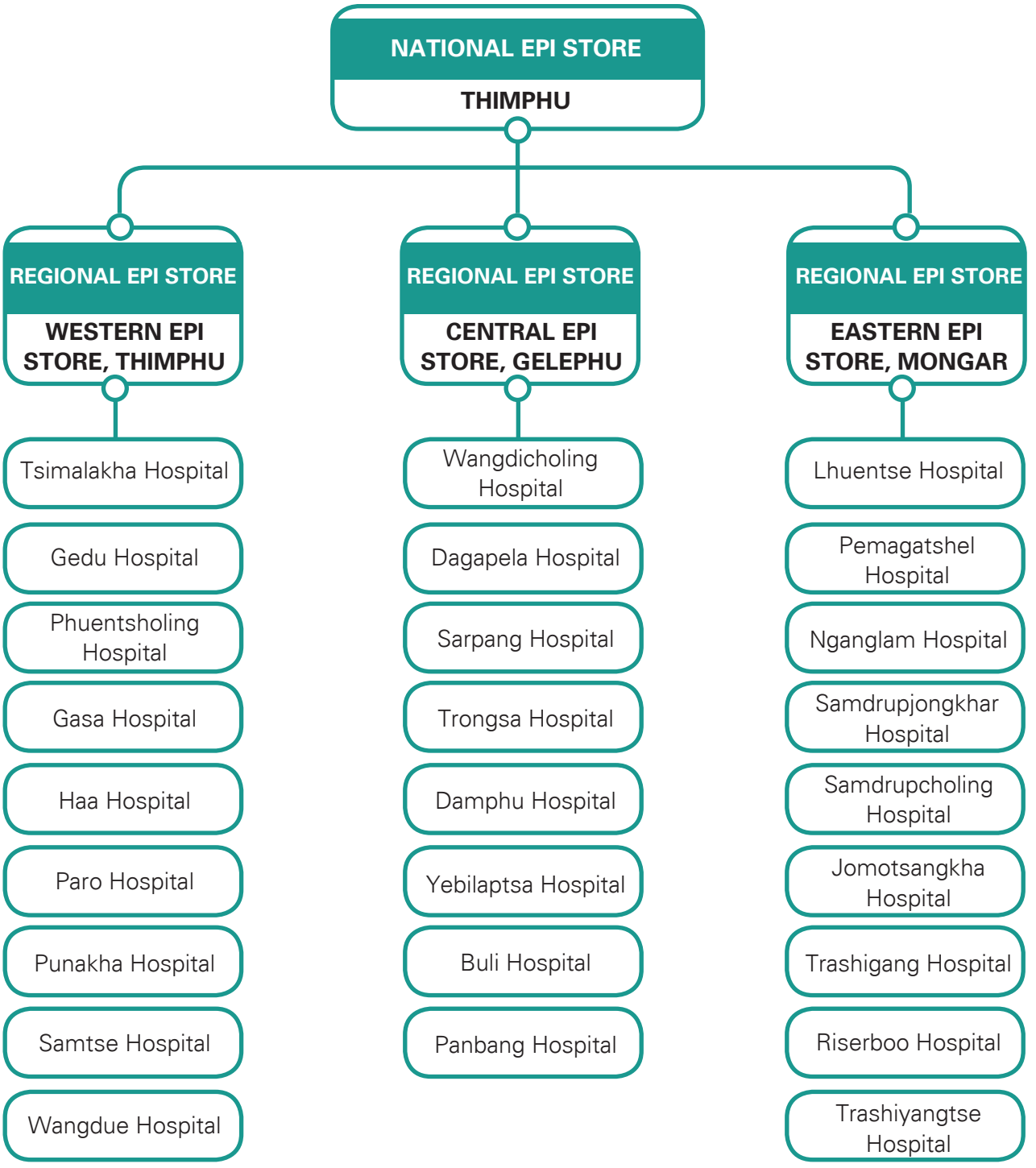


Figure 4: Vaccines flow from National EPI Store, Thimphu

1.4 IMPORTANCE OF IMMUNIZATION SUPPLY CHAIN SYSTEM (ISCS)

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 the immunization programme and plays a vital role in improving the immunization coverage with quality by timely supply of safe and potent vaccines along with necessary logistics.

This EPI manual has been written for the Vaccine and Cold Chain Handlers serving at all levels of Cold Chain Points i.e., National, Regional, District, PHC and Sub-posts. The Vaccine and Cold Chain Handler is a key person for the management of cold chain, vaccine logistics and responsible for safe storage of vaccines under UIP. The ISCS has evolved significantly over the decades with evolving technology. This includes advances in cold chain equipment and refrigerant technology, establishing equipment inventories, and continuous real-time temperature monitoring. The increasing focus on quality of immunization along with coverage, efficient management of cold chain space and the increasing cost of immunization requires a coordinated and comprehensive approach to the capacity building of vaccine and cold chain handlers.

CHAPTER 2:

COMMON DISEASES PREVENTED BY VACCINATION

On-time vaccination throughout childhood is essential because it helps provide immunity before children are exposed to potentially life-threatening diseases. Vaccines are tested to ensure that they are safe and effective for children to receive at the recommended ages. The common diseases prevented by vaccination are narrated in this chapter.

2.1 TUBERCULOSIS (BAYKEY NEY)

Tuberculosis (TB) is caused by bacteria (*Mycobacterium tuberculosis*). It is a highly contagious disease that affects the lungs but can also affect the intestines, bones and joints, lymph glands, meninges (membranes of the brain), and other organs of the body. TB can cause serious illness and even death .

How to suspect the disease?

- An ill child with a history of contact with a suspected or confirmed case of pulmonary tuberculosis
- An ill child with one of the following: weight loss, cough and wheeze, which does not respond to antibiotic therapy for acute respiratory infection

Any child suspected to be suffering from TB, please refer to the National TB guideline for management and treatment.

How is it spread?

TB is spread through droplets of sneezing or coughing by active pulmonary TB patients. A variety of tuberculosis called bovine tuberculosis occurs when milk of infected cattle is consumed without boiling.

How is the disease prevented?

Vaccination with Bacillus Calmette-Guerin (BCG) at birth or as soon as possible after birth will prevent severe forms of childhood tuberculosis.

2.2 POLIO (TSA KAM NEY)

Polio is a viral infection that affects the nervous system and can cause severe illness, paralysis, and even death.

How to recognize the disease?

History of sudden onset of weakness and paralysis of the leg(s), and /or arm(s) and/or trunk. The paralysis was not present at birth or associated with serious injury or mental retardation.

How is it spread?

Polio is transmitted by contact with fecal matter, usually as a result of poor hygiene, or indirectly through contaminated water, milk, or food. More than 50 percent of all cases involve children less than three years of age.

How is the disease prevented?

Immunization with the Oral Polio Vaccine (OPV) and with the Inactivated Polio Vaccine (IPV) is the way to effectively prevent infection apart from hygiene. Oral polio vaccine (OPV) should be routinely administered as per the immunization schedule and during Supplementary Immunization Activities (SIAs) until 5 years of age, if needed, good hygiene and sanitation practices can prevent transmission of polio. Travelers to polio endemic countries need to take one dose of OPV one month prior to travel.

2.3 DIPHTHERIA (KYEM NEY)

Diphtheria is caused by bacteria (*Corynebacterium diphtheriae*). Diphtheria is an infectious disease that commonly infects the tonsils and pharynx, commonly presenting as a bluish-white membrane in the back of the throat often causing difficulty in breathing and even death.

How to recognize the disease?

Any case with sore throat with gray patch or patches in the throat should be suspected to have diphtheria.

How is it spread?

The bacteria causing diphtheria inhabit the mouth, nose and throat of an infected person. It spreads from person to person through droplets by coughing and sneezing.

How is the disease prevented?

The most effective method of prevention is immunization with diphtheria vaccine in DTP- Hep B- Hib vaccine (pentavalent) in early childhood and followed by booster dose.

2.4 PERTUSSIS (WHOOPING COUGH) (LOU KHOK NEY)

Pertussis commonly known as whooping cough is caused by bacteria (*Bordetella pertussis*). Pertussis is a highly contagious bacterial disease, involving the respiratory tract. It is characterized by repeated coughing that may lead to aspiration and possible death in some cases.

How to recognize the disease?

A history of repeated and violent coughing, with any one of the following: cough persisting for two or more weeks, fits of coughing, cough followed by vomiting and typical whoop in older infants.

How is it spread?

Pertussis bacteria live in the mouth and nose of the patients and spread easily through the air usually by coughing or sneezing.

How is the disease prevented?

Pentavalent vaccine contains pertussis component which is given according to the immunization schedule will prevent pertussis.

2.5 TETANUS (TSAKUM NEY)

Tetanus is caused by bacteria (*Clostridium tetani*). People of all ages can become infected with tetanus.

How to recognize the disease?

Neonatal tetanus presents after 2 days of life with inability to suck followed by stiffness of neck and body and/or jerking of muscles. The child will have normal suck and cry during the first two days of life.

Tetanus in age groups other than in the neonatal period presents with local spasms around a wound, generalized convulsion and stiffness of the whole body, abnormal postures, lockjaw and often death.

How is it spread?

Tetanus bacteria are present in dirt, intestines and feces of animals. It enters the body through cuts, punctures or other wounds/infections (like ear infection) and occurs when bacteria come in contact with broken skin or injuries, and also unclean cutting and dressing of the umbilical cord. Neonatal Tetanus (NNT) affects newborn babies and can lead to death, if not treated. It generally occurs during the first few days of life, often as a consequence of delivery in unhygienic conditions.

How is the disease prevented?

Immunizing pregnant women with Td and children with DTP-HepB- Hib (pentavalent) vaccine is an effective method of preventing both neonatal as well as tetanus in other age groups. Ensuring clean birth surface, clean delivery and cutting umbilical cord with clean instruments or blades are considered as essential factors in preventing neonatal tetanus.

2.6 HEPATITIS B (CHHIM NEY B)

Hepatitis B is a highly infectious viral disease (40-100 times more infectious than HIV) and is the leading cause of jaundice, fulminant liver disease, cirrhosis and liver cancer. It is established that the younger the age at infection, the more the chance of getting the complications from hepatitis B infection like chronic active hepatitis, cirrhosis and carcinoma at later stages of life. That is why it is important to provide three doses of hepatitis B vaccine to all children before they reach the age of one.

How to recognize the disease?

Clinical signs and symptoms include fever, headache, nausea, vomiting and jaundice (yellowish eyes). Final confirmation is done by laboratory tests.

How is it spread?

The disease spreads through transfusion of infected blood, contact with infected blood or body fluids. It can be acquired during childbirth, through unprotected sex, use of unsterilized needles and sharing of needles and razors by intravenous drug users.

How is the disease prevented?

By immunizing children, we can prevent the infection and its complications. Hepatitis B vaccine is given within 24 hours of birth and DTP-HepB- Hib (pentavalent) vaccine at 6, 10 and 14 weeks of age.

2.7 HAEMOPHILUS INFLUENZAE TYPE B (HIB) INFECTION

Haemophilus influenzae type b (Hib) is a bacterium associated with a number of severe childhood diseases namely infection of the meninges (pyogenic meningitis), pneumonia, sepsis and infection of other internal organs and bones. Hib accounts for roughly half of the pyogenic meningitis cases in the age group of 6 months to 2 years and is also estimated to be responsible for 20% of pneumonia cases in this age group.

How is it spread?

Hib is spread from person to person through droplets released during coughing or sneezing by an infected person.

How is the disease prevented?

Hib disease has been eliminated in developed countries through immunization with Hib vaccine (DTP-HepB-Hib) for children at the age of 6, 10 and 14 weeks. When infected by Hib, the child can be treated with antibiotics, the resistance to antibiotics is common. Often the child may die even after appropriate treatment or survive with neurological deficits.

2.8 PNEUMOCOCCAL DISEASE

Pneumococcal disease is a group of diseases caused by a bacterium called *Streptococcus pneumoniae*, (also known as pneumococcus). Diseases caused by pneumococcus include

- severe diseases such as pneumonia, meningitis and bacteremia (presence of bacteria in the blood), and
- milder diseases such as middle ear infection (otitis media), sinusitis and bronchitis.

How to recognize the disease?

Although it is difficult to establish diagnosis, pneumococcal infections are normally diagnosed through laboratory testing of the blood (for bacteraemia and bacteraemic pneumonias) or suspected meningitis by performing a lumbar puncture.

How is it spread?

Pneumococcus is transmitted by respiratory secretions of people carrying pneumococcus in their nose or throat.

How is the disease prevented?

Pneumococcal vaccination can prevent substantial mortality and morbidity.

2.9 MEASLES, MUMPS AND RUBELLA (MACHHEM NEY/ZATAP BONEY)

Measles is a highly infectious illness caused by a virus that can be found in the nose, mouth or throat of an infected person. Infection is characterized by fever, cough and spreading rash that may lead to death due to secondary infections like diarrhea and pneumonia.

Rubella is also called German measles, a viral disease with similar features as measles and may not be possible to distinguish between the two diseases unless appropriate samples are tested at specialized measles and rubella laboratories.

Mumps is an infection caused by a virus, sometimes called infectious parotitis, and it primarily affects the salivary glands. Mumps is mostly a mild childhood disease, and most often affects children between five and nine years of age. But the mumps virus can infect adults as well. When it does, complications are more likely to be serious.

How to recognize measles?

A history of fever with rash with any of the following

- Cough or
- Running nose (coryza) or
- Red eyes (conjunctivitis)

How to suspect rubella?

Maculopapular rash with low grade fever that lasts for or up to 24 hours, associated with appearance of rash on face and neck that may spread to the body. There is presence of post auricular or suboccipital lymph nodes.

How to recognize mumps?

Mumps is an infection caused by a virus and sometimes called infectious parotitis, and it primarily affects the salivary glands. Initial symptoms are typically non-specific, such as headache, malaise and fever, followed within a day by the swelling of the parotid (salivary) glands.

How are diseases spread?

The viruses are transmitted through the air via direct contact or by airborne droplets expelled by infected individuals during coughing and sneezing. Rubella can also be transmitted to newborn through the infected mother causing Congenital Rubella Syndrome (CRS).

How are diseases prevented?

The measles, mumps and rubella vaccines are effective in preventing measles, mumps and rubella; and should be given according to the immunization schedule. However, the Rubella vaccine should not be given to pregnant women, which could lead to Congenital Rubella Syndrome.

Rubella vaccine should not be given to pregnant women, which could lead to Congenital Rubella Syndrome.

2.10 HUMAN PAPILLOMA VIRUS (HPV) INFECTION

In Bhutan, cervical cancer is one of the most prevalent cancers and a leading cause of death in women. About 100 types of HPV are known to infect human beings and among which 40 are known to cause anogenital warts. HPV types that cause anogenital warts are low risk types that are 6 and 11 and high-risk types 16 and 18 which are associated with more than 99% of all cervical cancers. HPV also causes cancer of vagina, vulva, anus and penis. It also causes diseases at other sites often associated with esophageal and oropharyngeal cancer and respiratory papillomas.

How does HPV spread?

HPV is mainly transmitted by sexual route, but there is also a vertical transmission from mother to child during birth. It can also be transmitted by fomites.

How to prevent cervical and other cancers due to HPV?

The HPV vaccination will reduce the risk of developing cervical cancer. Abstaining or safe sexual practices e.g. use of condoms and being faithful to partners prevent all STIs including HPV. Routine screening like PAP smear and VIA combined with HPV vaccination programs reduce incidences of cervical and anogenital cancers significantly.

2.11 INFLUENZA.

Influenza viruses (family Orthomyxoviridae) is the causative organism. The influenza viruses are classified into types A, B and C on the basis of their nucleoprotein, whereas the subtypes of influenza A viruses are determined by envelope glycoproteins possessing either haemagglutinin (HA) or neuraminidase (NA) activity.

How to recognize the disease?

The disease can present with fever, cough, sore throat, runny nose, headache, muscle and joint pain and severe malaise. The fever and body ache may last 3–5 days and the cough for 2 or more weeks. In children, signs of severe disease include apnoea, tachypnea, dyspnea, cyanosis, poor feeding, dehydration, altered mental status, and extreme irritability.

How is it spread?

Influenza A and B viruses transmitted mainly by droplets and aerosols originating from the respiratory secretions of infected people, but occasionally also through contact with virus contaminated fomites.

How is the disease prevented?

Vaccination with Influenza vaccine can prevent the disease which has varying efficacies depending on the types.

CHAPTER 3:

ABOUT THE VACCINES

3.1 WHAT IS A VACCINE?

Vaccines are biological preparation that is used to stimulate the body immune response against infectious diseases.

The types of vaccines that act in different way are.

- **live-attenuated:** BCG, bOPV, MMR vaccines
- **Inactivated Vaccines:** IPV, Influenza
- **Messenger RNA (mRNA) vaccines:** Pfizer
- **Viral vector vaccines:** AstraZeneca
- **Sub-unit, Recombinant, Polysaccharide and Conjugate vaccines:** HepB, PCV
- **Toxoid:** Td, DTP

Vaccines are being provided to infants, children and pregnant women to prevent certain diseases. The vaccine preventable diseases against which vaccines are currently available under UIP are:

Sl. No.	Name of the vaccine	Disease Prevented
1	Pfizer, Moderna, CoviShield, AstraZeneca, Sinopharm	COVID-19
2	IPV	Polio
3	bOPV	Polio
4	BCG	Tuberculosis
5	Hep-B	Hepatitis – B
6	Influenza	Seasonal Flu
7	HPV (Boys and Girls)	Cervical Cancer
8	PCV	Pneumococcal Infection
9	MMR	Measles, Mumps, and Rubella
10	Td (Tetanus diptheria)	Maternal and Neonatal Tetanus
11	DTP	Diphtheria, Tetanus and Pertussis (Whooping Cough)
12	Pentavalent	Diphtheria, Pertussis, Tetanus, Hepatitis B, Haemophilus influenzae B, Meningitis and Pneumonia

Figure 5: Vaccine preventable diseases against each vaccines under UIP

Table 1: Vaccine, Storage, Side effects and Efficacy

Vaccine	Storage	Side effects	Efficacy
BCG (Bacillus of Calmette and Guerin) vaccine First vaccine to be used in the country to prevent an endemic infectious disease, it contains live attenuated bovine strain of tubercle bacilli, (bacillus Calmette and Guerin). It is provided with diluents.	- Freezing does not damage BCG - Should be stored at +2 to +8 °C	Local reaction: - Minor:- Redness, soreness, pain at the site of injection - Major:- Hypertrophy/ swelling of the lymph glands in axilla - Abscess in the injection area	0-90% in preventing child hood tuberculosis. Best prevents tuberculosis meningitis and miliary tuberculosis
Oral Polio Vaccine (bOPV) Oral Polio vaccine contains live attenuated Poliomyelitis virus strains; type 1 and 3.	- +2 to +8° C - Can be stored at –15 to –20° C	- Normally no side effects - Rarely Vaccine Associated Paralytic Poliomyelitis (VAPP) may be noted	For more than 95% of recipients, three doses of OPV produce immunity for all three of the poliovirus types in the vaccine
Inactivated Polio Vaccine (IPV) Inactivated Polio Vaccine (IPV) is produced from wild-type poliovirus strains of serotypes 1, 2 and 3, that have been inactivated (killed) with formalin. It is an injectable vaccine.	- +2 to +8° C - Not to be frozen	Adverse events following administration of IPV are very mild and transient. - Redness and tenderness are common side effects - Minor side effects include induration, erythema, fever, hypersensitivity reactions to trace antibiotics	More than 95% of recipients, three doses of IPV produce immunity for all three of the poliovirus types in the vaccine.
IPneumococcal Conjugate Vaccine (PCV) PCV consists of sugars (polysaccharides) from the capsule of the bacterium *Streptococcus pneumoniae* that are conjugated to a carrier protein, and it is a killed vaccine.	- +2 to +8° C - Heat and freezing damages PCV	Mild side effects such as soreness at the injection site, and transient fever has been reported in less than 5% of vaccinees. Severe adverse reactions attributable to the vaccine are extremely rare.	
Diphtheria-Pertussis-Tetanus Vaccine (DTP Vaccine) It is manufactured from: Purified Diphtheria toxoid, Inactivated pertussis organism and Purified tetanus toxoid	- +2 to +8° C - Freezing damages Diphtheria and Tetanus toxoid part of the vaccine - Heat damages pertussis vaccine	- Mild: - pain, redness, swelling at the site of injection Fever- disappear in 1-2 days **Severe /Rare:-** - Abscess – because of unsterile syringe/needle or wrong technique - Persistent inconsolable crying - Fever, Temperature in excess of 40.5° C - Unusual screams - Convulsion - Hypotonic/Hypo responsive episode. - Anaphylactic Reactions	
Measles Mumps and Rubella Vaccine (MMR Vaccine) - Measles, Mumps and Rubella Vaccines are live, attenuated strains of measles (Edmonston-Zagreb) and Rubella (Wistar RA 27/3) virus, Mumps L-Zagreb - It is lyophilized and is provided with diluent	- Store at +2 to +8° C - Freezing does not damage undiluted MMR vaccine. Keep diluents cool -Protect from light	- Local reaction: - redness, urticaria. - Generalised Rash - Fever> 38° C - Febrile seizure - Thrombocytopenia (bleeding disorder) - Anaphylactoid reaction - Anaphylaxis	Lifelong immunity for 90-95% of immunized persons

Vaccine	Storage	Side effects	Efficacy
Tetanus diphtheria (Td) -Td is prepared by combining purified diphtheria toxoid and tetanus toxoid. -Smaller "d" indicates reduced diphtheria antigen units (Lf) and capital "T" indicates regular Tetanus components - Protects against tetanus including neonatal tetanus, if mother is immunized.	- Store at +2 to +8°C - Do not freeze	- Local reactions:- mild pain, redness, warmth and swelling - The severity and frequency of local reaction are more common in hyper immunized persons, - Systemic reaction: - fever, malaise, shivering, general aches/headache. - Adverse events like urticaria, anaphylaxis, brachial neuritis and GBS are rare	- 1 dose: minimal protection - 2 valid doses: 3 years protection - 3 valid doses: 5 years protection - 4 valid doses: 10 years protection - 5 valid doses: all adult age protection (child bearing age)
Haemophilus Influenza Type -B (Hib) Vaccine Prevents meningitis, pneumonia and other serious infection, caused by Haemophilus influenza type-B bacteria). Available in monovalent or in combination with other vaccines:- - Pentavalent - DTP-HepB-Hib	Store at +2 to +8°C Liquid vaccine, if frozen should be discarded.	Local: - redness - swelling - pain General: - fever, irritability	3 doses provide 95% immunity against Haemophilus influenza Type-B
Hepatitis B Vaccine Hepatitis B vaccine may be in mono-valent form or in combination with DTP-HepB (Tetravalent) or with DTP-HepB and Hib (DTP-HepB-Hib) vaccine as pentavalent	- Store at +2 to +8°C -Both heat and freezing damages HepB vaccine	- pain/swelling in the injection site - mild fever - muscle pain - Very rarely anaphylactic reaction	95% of children immunized with 3 doses of Hepatitis vaccine develop lifelong immunity
Human Papilloma Virus Vaccine (HPV Vaccine) Inactivated viral particles of HPV types 6, 11, 16 and 18	- Store at +2 to +8°C - Not to be frozen	Local reaction:- soreness, swelling and redness Systemic reaction:- Fever, headache, muscle or joint aches Fainting attack, life threatening allergic reactions are rare. Local and systemic reactions are mild and last about one to two days.	3 doses of HPV vaccine produces high level of serum antibodies (98-100% protection against CIN II and CIN III and genital warts for up to 5 years after vaccination) - Does not eliminate all risks of cervical cancer

3.2 MINIMIZING PAIN DURING MULTIPLE INJECTIONS

There are ways that healthcare providers can do when providing multiple injections to minimize pain. Studies have found that pain during immunization can be decreased by:

1. Encouraging breastfeeding mothers to breastfeed their infants after the vaccination
2. Securing the child before the vaccination by caregiver
3. Stroking the skin or applying pressure close to the injection site before and during injection and not after the vaccination
4. Injecting the least painful vaccine (IPV) first when two or more vaccines are being administered sequentially during a single visit
5. For intramuscular injections (IM), gently stretch and support the skin between thumb and forefinger. Push the entire needle in at a 90 degree angle with a quick, smooth action. For all injections, depress the plunger slowly and smoothly, taking care not to move the syringe around. Pull the needle out quickly and smoothly at the same angle that it went in.
6. The caregiver may hold a clean swab gently over the site if it is bleeding after injection

Figure 6: Steps to hold the baby correctly for vaccination

CHAPTER 4:

ROUTINE IMMUNIZATION SCHEDULE FOR CHILDREN AND ADOLESCENTS

The recommended National routine immunization schedule is provided below:

Table 2: Routine vaccination schedule

Vaccines	Number of doses	Schedule and age for vaccination	Minimum interval between doses	Dosage	Route/site
BCG (Bacille Calmette Guerin)	1	At birth or at first contact	NA	0.05ML	Intradermal, right upper arm
Hepatitis B (Pediatric)	1	Hep. B at birth (Within 24 hours as "Zero" dose)	NA	0.5 ML	Intramuscular (IM) antero-lateral aspect of mid-thigh
Pentavalent (DTP-Hep,B-Hib)	3	At 6, 10, and 14 weeks	4 Weeks	0.5 ML	Intramuscular (IM) antero-lateral aspect of mid thigh
Inactivated Polio Vaccine (IPV)	2	At 14 weeks At 8 Months	4 months	0.5 ML	antero-lateral aspect of mid thigh
Oral Polio Vaccine (bOPV)	4	At 0 (within 14 days), 6, 10, and 14 weeks *if the 0 dose is missed it should be given at 9 months	4 weeks	2 drops	Oral
Pneumococcal conjugate Vaccine (PCV)	3	at 6, 10 weeks and 9 months	4 weeks between the 1st and 2nd dose and 6 months from 2nd to 3rd dose	0.5 ML	antero-lateral aspect of mid-thigh
Measles, Mumps and Rubella (MMR)	2	MMR 1 at 9 Months MMR 2 at 24 Months	15 months	0.5 ML	Subcutaneous-left upper arm
Diphtheria, Tetanus and Pertussis (DTP)	1	DTP booster at 24 Months	NA	0.5 ML	Intramuscular (IM) antero-lateral aspect of mid-thigh
Tetanus diphtheria (Td)	2	Td 1 at PP Class student Td 2 at Class seven students Out of school 6 years and 13 years old	6 years	0.5 ML	Intramuscular (IM) upper arm
Human Papillomavirus (HPV) vaccine	2 doses girls and boys below 15 years of age	• Class six girls and boys • Out of schoolgirls and boys at 12 years of age • For 15 years and above 3 doses	6 Months	<15 yrs 1st dose- 0 2nd dose – 6 months >=15 yrs 1st dose- 0 2nd dose- 2months 3rd dose- 6 months	Intramuscular (IM) upper arm
Hepatitis B (Adult)	3	at 0, 1 and 6 months	NA	1.0 ML	Upper arm

Note: Children brought late (less than 5 years) for subsequent doses should continue from the missed dose for all routine antigens.

Table 3: Influenza vaccination doses for high risk group

Vaccine	Number of doses	High Risk Groups
Seasonal Influenza Vaccine	1	• Pregnant women • Health Workers • People with Existing Medical Conditions (heart disease, cancer, lung disease, active pulmonary TB, liver disease, kidney disease, diabetics patients on medication, HIV) • Elderly Population 65 Years and above • Others as defined by MoH
Seasonal Influenza Vaccine	2 doses with an interval of four weeks	• Children 6 to <24 Months – 0.25ml • Children 2- <3 years if they have existing medical condition)- 0.3ml • 3-8 years (if they have existing medical condition) -0.5ml Note: all the above age groups will receive two doses or only one dose if received earlier.

Table 4: Pregnant women with no previous record of Tetanus diptheria Vaccination

Vaccine	Frequency/time	Dosage	Route/site
Td1	***As soon as possible***	0.5 ml	Intramuscular (IM) left upper arm
Td2	***4 weeks after 1st dose***		
Td3	***6 months after 2nd dose***		
Td4	***1 year after 3rd dose***		
Td5	***1 year after 4th dose***		

Table 5: Pregnant women having record of Tetanus diptheria Vaccination

Number of prior Td received	Td dose	Frequency /Time	Dose	Rout/Site
Pregnant women who have received 1st dose of Td vaccine	- 2nd dose - 3rd dose - 4th dose - 5th dose - 6th dose	- As soon as possible - 4 weeks after 2nd dose - 6 months after 3rd dose - 1 year after 4th dose - 1 year after 5th dose	0.5ML	Intramuscular (IM) left upper arm
Pregnant women who have received 2nd dose of Td vaccine	- 3rd dose - 4th dose - 5th dose - 6th dose	- As soon as possible - 4 weeks after 3rd dose - 6 Months after 4th dose - 1 year after 5th dose		
Pregnant women who have received 3rd dose of Td vaccine	- 4th dose - 5th dose - 6th dose	- As soon as possible - 4 weeks after 4th dose - 1year after 5th dose		
Pregnant women who have received 4th dose of Td vaccine	- 5th dose - 6th dose	- As soon as possible - 1 year after 5th dose		
Pregnant women who have received 5th dose of Td vaccine	- 6th dose	As soon as possible		

4.1 VACCINE SAFETY

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 vaccine 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.), 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.

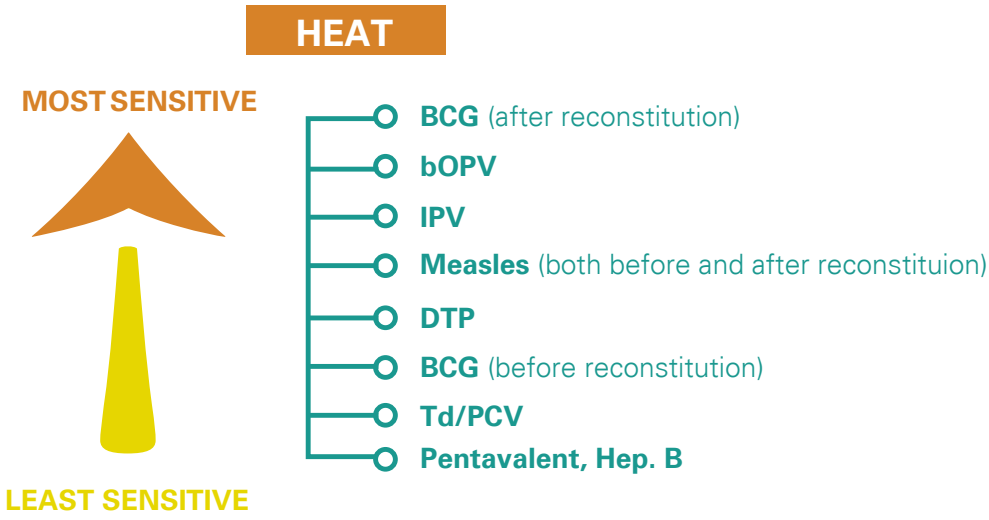


Figure 7: Vaccine sensitivity to heat

4.5 CONTRA-INDICATIONS TO IMMUNIZATION

Table 6: Frequently asked questions and responses

BCG vaccine	**bOPV**
Why is the BCG vaccine given on the right upper arm? BCG is given on the right upper arm to maintain uniformity and for helping surveyors in verifying the receipt of the vaccine. **If not given at birth, when should BCG be given?** If not given at birth or along with DTP HepB1, it can be given at any time up to 2 years; the dose should be increased to 0.1ml, if given after the age of one year. **If no scar appears after administering BCG, should health staff re-vaccinate the child?** There is no need to revaccinate the child if there is no scar but vaccinated evidence. However, if you are not sure about the vaccination history or documentation, repeat the vaccination.	**Till what age can a child be given OPV. If a child misses the dose in RI?** OPV can be given to children up to 5 years of age. **IPV** What is the upper limit age for IPV vaccination if the child does not receive IPV at 14 weeks? **Ans:** If the child misses IPV first dose at 14 weeks, the child can be vaccinated at the next visit and the 2nd dose should be given after 5 months interval.

Pentavalent (DTP-HepB –Hib vaccine)

If a child could not receive Pentavalent 1, 2, 3 till what age can the vaccine be given?

If a child misses one or more doses of Pentavalent vaccination, subsequent doses can be given up to 4 years of age with a minimum gap of 4 weeks between the doses to complete the immunization schedule.

Why Pentavalent is given on the outer mid-thigh and not in the gluteal region (buttocks)?

Pentavalent is given in the outer mid-thigh to prevent damage to the sciatic nerve. Moreover, the vaccine deposited in the fat of the gluteal region may not develop immunity.

If a child comes after completing 5 years of age without any vaccination, which vaccines should be given?

Ans: bOPV (2 doses), IPV (2 doses), MMR (2 doses) with an interval of at least 1 month between the doses. Give 2 doses of Td after completing 2nd doses of MMR and IPV.

If a child who has never been vaccinated but brought at 9 months of age, can all the vaccines be given to a child on the same day?

Yes, all the vaccines can be given at the same session but at different injection sites using separate sterile syringes and needles. It is safe and effective to give BCG, Pentavalent, bOPV and MMR vaccines and Vitamin A at the same time to a 9 month old child who has never been vaccinated.

If a child who has never been vaccinated is brought between 1 and 4 years of age, which vaccines can be given to the child?

All childhood vaccines can be given except BCG if the child is 2years or older.

Should one re-start with the first dose of a vaccine if a child is brought late for subsequent doses?

Do not start the schedule all over again even if the child is brought late for a dose. Continue from the missed schedule and ensure to complete it.

CHAPTER 5:
COLD CHAIN EQUIPMENT

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

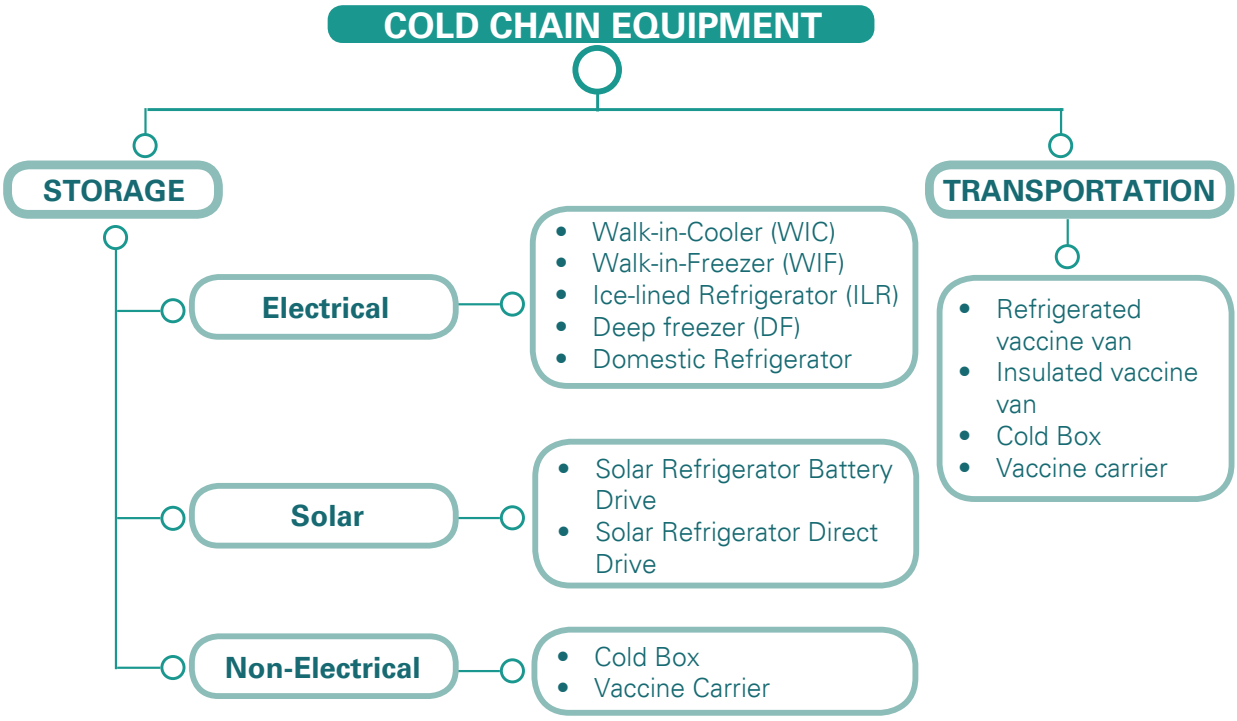


Figure 8: Classification of cold chain equipment

5.1 ELECTRICAL COLD CHAIN EQUIPMENT

There are different equipment for storage of vaccines at different levels, which are dependent on electric supply to maintain the recommended temperature. The cold chain equipment which runs on electricity is described below:

5.1.1 Walk-in-Cooler (WIC)

Figure 9: Walk-in-Cooler to store large volume of vaccines at positive temperature

Walk-in-Cooler is a prefabricated modular CFC free Polyurethane (PUF) insulated panels assembled as a cold room with two identical refrigeration units. They maintain a temperature of +2°C to +8°C. In Bhutan, under UIP WICs with capacity of 40m3 and 30m3 are in use. These are used for storage of large quantities of all UIP vaccines like, BCG, Hepatitis B, DTP, Pentavalent, IPV, Measles and Td. These Walk-in-Coolers are installed at National EPI Store and three Regional EPI Vaccine Stores. WICs and WIFs installed in Bhutan are fitted with real time temperature monitoring devices (RTMD) and alarm systems. Once the temperature of WIC/WIF exceeds or go below set limits the alarm system gives an alarm loudly and sends sms to the cold chain handler. Similarly, in case of power failure, it gives immediate alarm. A standby generator with automatic start and stop function is provided at National and Regional Stores.

5.1.2 Walk-in-Freezer (WIF)

Walk-in-Freezer is a prefabricated modular CFC free Polyurethane (PUF) insulated panels assembled as a cold room with two identical refrigeration units. They maintain a temperature of -15°C to -25°C. In Bhutan, all the WIFs are 20m^3. These WIFs are installed at National EPI Store and two Regional EPI Stores at Mongar and Gelephu. An alarm or hooter system is also provided to alert in case of any temperature excursion and sms goes to the cold chain handler. A standby generator with automatic start and stop function is provided at National and Regional Stores.

Figure 10: Walk in Freezer to store large volume of vaccines at minus temperature

WICs/WIFs are equipped with following Temperature Monitoring Devices/components:

5.1.2.1 Graphic chart temperature recorder: A Temperature recorder measures cold/freezer room temperature continuously on a circular chart. Normally the chart completes one cycle in seven days. So, the charts need to be changed every week. After one cycle the chart needs to be reviewed and signed by the supervisor. All temperature records should be kept for three years.

5.1.2.2 Real-time Temperature Monitoring Device: WICs/WIFs are installed with RTMDs. These RTMDs are installed with a Lithium-ion battery and sim card, four temperature sensors, one door opening sensor and one power failure sensor. RTMD of WIC and WIF are using internet/ GSM services. More details are provided in cold chain Temperature Monitoring Devices.

5.1.2.3 Alarm systems: An alarm or hooter system is provided to give alert in case of any temperature excursion. As soon as the temperature crosses the safe range a hooter gives a loud alarm.

5.1.2.4 Servo Controlled Voltage Stabilizer: The main power to WIC/WIF is connected through a Servo Controlled Voltage Stabilizer to safeguard the WIC/WIF from voltage fluctuations by providing a constant voltage. All the stabilizers are equipped with a human-machine-interface (HMI) touch screen.

5.1.2.5 Diesel generator (DG): WICs/WIFs are meant for continuous operation. Hence in the event of mains' power failure, DG set is used to provide the standby power supply. The DG set is equipped with Auto Mains Failure (AMF) panel for providing automatic start and stop facilities. AMF panel enables DG set to automatically start as soon as the power goes off and stops when main power returns.

5.1.3 Ice Lined Refrigerator (ILR)

Figure 11: ILR to maintain the set temperature

An ILR is known as an ice-lined vaccine refrigerator. It is a device that maintains the temperature between +2°C to +8°C. It is used to store all Universal Immunization Program vaccines at the Health Facilities. The ILR is used because the power supply at health facilities may be unreliable. An ILR can maintain a temperature from +2°C to +8°C with as little as 8 hours of power supply in 24 hours. If the electricity supply fails, then the ice lining maintains the inside temperature of the refrigerator at a safe level for vaccines. Also, an ILR has a top-opening lid which prevents loss of cold air during door opening. Therefore, the temperature is maintained in ILR for a much longer duration. ILRs are available in two sizes – large (for districts) and small (for PHCs). The bottom of the ILR is its coldest part and the vaccines are arranged according to their freeze sensitivity; the least freeze-sensitive vaccines are placed at the bottom of the basket and the most freeze-sensitive vaccines are placed at the top. In ILR leave a space of 2 cm between the vaccine boxes and ILR wall for better circulation of cold air. Place a 30 DTR among the vaccines in the basket.

5.1.3.1 Hold Over Time: In the event of power failure, "holdover time" for any cold-chain equipment is defined as "the time taken by the equipment to raise the inside cabinet temperature from its cut-off temperature to the maximum temperature limit of its recommended range", e.g. in the case of ILR, if the temperature is 4°C, then the time taken to reach 8°C from 4°C will be the holdover time for that ILR. Hold over time depends on the following factors:

- Ambient temperature—A higher ambient temperature will result in short hold over time
- Number of frozen ice packs inside
- Frequency of opening of lid
- Quantity of vaccines kept inside with adequate space between the containers
- Condition of ice packs inside nonelectric equipment (frozen/partially frozen/melted)

e.g. the holdover time for an ILR is minimum of 20 hours at 43°C.

Note: Unlike ILR, a 'Deep Freezer' does not have holdover time, as it does not have an ice lining inside its wall. It is dependent only on the number of frozen ice packs kept inside it, if any.

5.1.4 Deep Freezer (DF)

Figure 12: Deep Freezer to make frozen ice packs and to store OPV vaccine

The Deep Freezer is an equipment, which operates on a vapour compression system similar to any conventional type of refrigerator operating on 220 volts A.C. mains supply. However, DF has a top opening lid to prevent loss of cold air during door opening. DFs have been supplied under the immunization program for storage of vaccines at

appropriate level and preparation of Ice Packs. The cabinet temperature is maintained between -15°C to -25°C. This is used for storing of OPV vaccine (district level and above only) and also for freezing of ice packs. At PHC level it is used for freezing 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. These are available in different sizes- large and small.

5.1.5 Combo

A combo is known as a combination of refrigerator (+2°C to +8°C) and deep freezer (-15°C to -25°C). This combo is very useful where the target population is small. Its storage capacity varies from model to model and brand to brand. Bhutan has a maximum quantity of VLS 064A RF. It is the most energy efficient ice lined refrigerator available in the global market. Its ambient working range is +5C to +43C. In the new models of Combo, the stabilizer is built in. There is no need to provide extra stabilizer.

Figure 13: To store vaccines at positive temperature and make ice packs

5.1.6 Ultralow Temperature Freezer (ULTF)

ULTF works at a temperature of -60°C to -86°C. It is meant for COVID-19 Pfizer vaccines storage, in general. It has a cascade refrigeration system to maintain the minus temperature. The handlers of this ULTF need to understand that while loading or unloading the vaccines to this ULTF have to wear the cryogenic gloves, otherwise frostbite can happen. ULTF has electronic temperature monitoring devices, which can store the data for five years. In case of temperature excursion, it has audio and visual alarms.

Figure 14: To store vaccines at -86^{0}C temperature

5.1.7 Kerosene and Electric Refrigerator (SIBIR)

The popular name of this refrigerator is SIBIR. It runs with Kerosene-Electric, Gas-Electric. This refrigerator do no have any compressor like mechanical refrigeration system, however generator and heater are there. In case of no power, it runs on kerosene or gas, based on the design. In Bhutan it is available in two models V110KE and V170KE. VK110KE is single door refrigerator with a vaccine storage capacity of 17 liters whereas VK170KE/GE is double door with 55 liters of vaccines storage capacity and 36 liters of freezing capacity.

Figure 15: To store vaccines at positive temperature and make ice packs

5.1.8 Cold Chain Equipment-make, model number, gross storage-vaccine storage-freezer storage capacity

Bhutan has a variety of cold chain equipment like ILR, Deep Freezer, Combo and ULTF. A few of them are mentioned below to support the health staff in understanding the model no., gross storage capacity, and vaccines storage capacity apart from freezer capacity.

MAKE	MODEL	STORAGE CAPACITY (GROSS) LITERS	VACCINE STORAGE CAPACITY	STORAGE CAP FREEZER
Vestfrost	MF 214	171	138	
Vestfrost	MF 114	105	98	
Vestfrost	MK 144	64	48	
Vestfrost	MK 204	218	105	
Vestfrost	MK 304	296	200	
Vestfrost	MK 404	240	135	
Vestfrost	MKF 074	54	16	9
Vestfrost	VLS 064A RF	75	52.5	5.1
Vestfrost	VLS 200A	113	60	
Vestfrost	VLS 504A	314	242	
Vestfrost	VLS 404A	235	145	
Vestfrost	VLS 204A	113	60	
Vestfrost	VLS 026 RF SDD	69.3	20	1.8
Vestfrost	VLS 056 RF SDD	60	36	
Vestfrost	SB 202	198	189	
SIBIR	V110KE	110	17	
SIBIR	V170GE	170	55	36
SIBIR	V170KE	170	55	36
Electrolux	TCW1151	290		
BM System	TFW800	290		

5.2 SOLAR COLD CHAIN EQUIPMENT

Accurate and uniform temperature in a refrigerator plays a key role in ensuring the life of vaccines, reagents and other biologicals. Keeping heat-sensitive vaccines at the right temperature is crucial yet often in difficult areas with limited or no electrical power or frequent or long-duration power outages that makes the use of grid-powered cooling impractical for vaccine storage.

Figure 16: Solar ILR and DF

In recent years a new approach to solar refrigerator design has emerged that eliminates the expensive (and problematic) energy storage batteries. "Direct-drive" technology uses the sun's energy to freeze water or other phase change material and then uses the cooling from that "ice bank" to keep the refrigerator cold during the night and cloudy days. These refrigerators are called "Solar direct-drive refrigerators" because they are wired directly to the photovoltaic generators. In Bhutan, during the summer, the electricity grid often does not reach rural areas, and is not always reliable. As keeping vaccines at the appropriate temperature is vital, solar powered refrigerators are a cost-effective alternative that can be highly reliable. A typical system will use a solar photovoltaic panel to generate electricity from sunlight. The compressor runs at very low volage as compared to the conventional refrigerator. It is a

refrigerator cum freezer having basket for storing of vaccine and freezing of icepacks. It has two separate compartments.

1. Vaccine storage compartment maintains temperature range of +2°C to +8°C (Refrigerator).
2. Freezer compartment is for storing frozen icepack maintaining temperature up to -15°C (Freezer).

5.2.1 Solar Panel and Array

Figure 17: Solar Panel and array

Solar panels, commonly called solar modules, are the key components used to convert sunlight into electricity. The solar array (two or more solar panels connected together) must be permanently positioned where the modules will receive the maximum amount of sunshine. However, they are very fragile and should not be located where they may be damaged. A suitable position must be found away from trees and tall objects, to avoid shading the array, as this will impair the performance of the modules. Array structures are designed to withstand wind loads of +200 kg per square meter and are supplied with fixings for either ground or roof mounting.

5.3 TEMPERATURE MONITORING DEVICES AND STABILIZER WITH COLD CHAIN EQUIPMENT

Temperature of ILRs/Deep Freezers used for storage of vaccines must be recorded twice daily. These records should be checked during supervisory visits. A break-down in the cold chain is indicated if temperature rises above +8°C or falls below +2°C in the ILR; and above -15°C in the Deep Freezer. ILR and Deep freezers should have separate thermometers and comprehensive logbooks. The serial numbers of ILR and Deep Freezers should be indicated in the designated space provided in the temperature record book and should be available near the equipment. Every supervisory and preventive maintenance visit should be documented in the logbook. The repair maintenance work done for the equipment should also be recorded in the respective logbook. The storage temperature and excursion devices are as follow:

5.3.1: 30 DTR

Figure 18: 30 DTR to monitor the temperature

Electronic data loggers are also being introduced to monitor the temperature of ILR. It is an electronic device placed with the vaccine which records the vaccine temperature for 60 days, even though the device is called 30DTR. It has an alarm system and as soon as the temperature of the equipment storing the vaccine crosses the safe range visual alarm alerts the handlers.

This device assists in temperature monitoring through following features.

- It shows the temperature of ILR in digital LCD screen all the time.
- It indicates if there was any alarm situation during the past 60 days.
- It shows the duration of temperature excursion for every alarm situation happened in past 60 days. To see the duration of temperature excursion, device is equipped with a "Read" button which guides the user through the history of past 60 days starting from "today" till "last 60 days".
- It shows an "OK" sign if there has been no excursion of temperature in past 60 days.
- It has a shelf life of two to six years from the date of activation of device.
- The device once activated, cannot be stopped throughout its operational life. Hence, it provides round the clock monitoring of ILRs without any need of intervention of users for two to six years of time.
- It has been specifically designed to be used with ILRs, Combo (Refrigerator compartment), and Walk-in-Coolers that are required to maintain the temperature between +2°C to +8°C.
- If the cross sign appears on the device does not mean that the devices has gone faulty. After 30 days the cross will automatically go off, if the temperature for the next 30 days is within set limits.

At all Health facilities two 30DTRs are required. One should be marked as ONLY FOR ILR and other for ORC/VACCINE COLLECTION.

5.3.2: Eye Sensor with GPS (Temperature excursion device)

This eye sensor comes with GPS system in compact size to record and transmit temperature and humidity. The eye sensor senses the temperature and humidity and pass it through Bluetooth to GPS device. GPS device passes the data to central server. It can operate from -25°C to +55°C. In case of any temperature excursion (pre-set temperature) it provides alert to the health staff through sms. If the health staff does not attend to the call, the message will pass to ADHO/DHO, the Regional EPI Stores and National Store to take the corrective action followed by the program.

Eye Sensor

GPS System

These devices are Low Energy ID beacon and sensor models with robust casing and long life-time battery. They are designed for a low-cost fast and easy configuration and integration to save precious time, resources, and improve vaccine efficacy. Battery lifetime is up to 10 years reducing the financial and environmental cost. It comes in robust and waterproof IP67 casing enhancing longevity. All the android and iOS compatible apps are available for fast and easy configuration. These devices are fitted with local sim card and installed in all the health facilities of Bhutan for keeping the vaccine safe.

Figure 19: Temperature excursion flow message hierarchy

The functioning of this device is as:

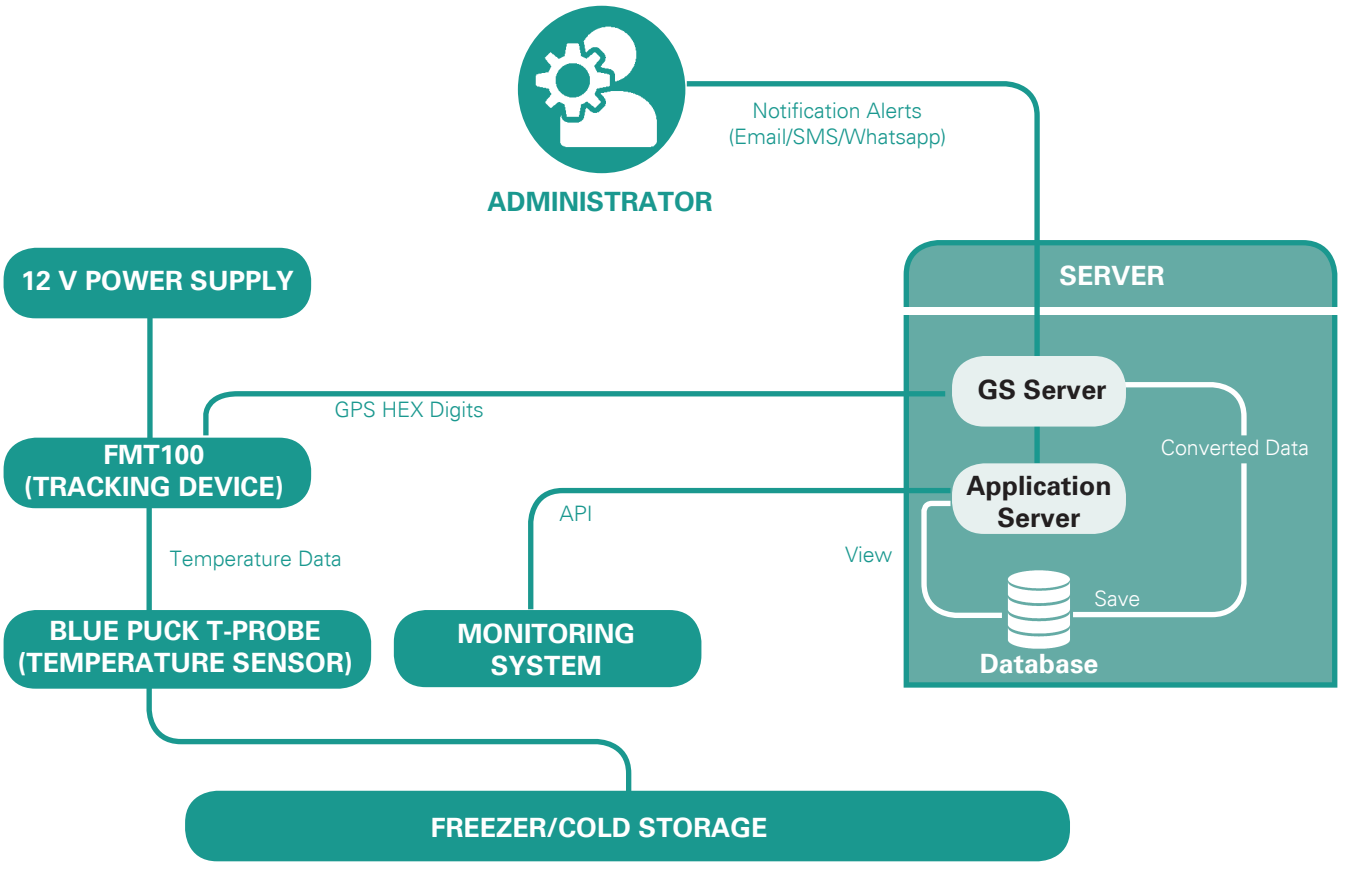


Figure 20: Temperature excursion flow system

5.3.3: Realtime Temperature Monitoring Devices (RTMD)

Figure 21: RTMD to remotely monitor the temperature of vaccine in the refrigerator

The Realtime Temperature Monitoring Devices are the preferred temperature monitoring devices across globe. It can operate from -25°C to +55°C. These kinds of devices run on single or dual-SIM design with a global or local SIM card. It gives complete network redundancy anywhere in the world without the need for physical network infrastructure. The off-grid and on-grid design makes it completely immune to damage from spikes, surges, brownouts and blackouts. This device has a major advantage in parts of the world where power supply is unreliable. The device is easy to install, requiring no tools and no special training. A typical installation takes less than 10 minutes. It has a run time of up to 10 years without the need to recharge or replace the batteries offering the lowest possible maintenance cost. It can simultaneously monitor up to 2 to 4 temperature sensors as well as the mains power status, and door position. It also monitors both the ambient temperature and humidity. It also offers real-time GPS tracking when monitoring the cold chain in mobile assets like trucks, containers and cooler boxes when installed in the specific equipment.

5.3.4: Freeze Alert

It is also an electronic device to monitor vaccines exposed to less than 0°C. It contains an electronic temperature measuring circuit with associated LCD display. If the indicator is exposed to a temperature below 0°C for more than 60 minutes the display will change from "good" (√) status in to the "alarm" status (X). The freeze indicator is placed in between freeze sensitive vaccine (Hepatitis B, DTP, TT, IPV, Pentavalent etc.) Once it changes to cross (X), it cannot be re-used or reset and will be discarded. The vaccines should never be used without shake test when freeze tag shows the cross mark (X). Its shelf life is five years.

Figure 22: Temperature indicator shows if a vaccine has been exposed to freezing

5.3.5: Temperature Monitoring Thermometer

Measuring temperature of cold chain equipment is helpful in:

a. Ensuring vaccine safety

b. Monitoring the functionality of the cold chain equipment

Hence temperature should be monitored for all the cold chain equipment available in the health facility (Cold Chain Point) twice every day on all days of the week irrespective of Sundays and holidays. Temperature should also be monitored and recorded for the Deep Freezers meant for freezing icepacks. Only situations, where the temperature is not recorded are

1. Equipment is non-functional and
2. Equipment is not put to use due to various reasons.

To measure the temperature during storage/transport, different type of thermometers and temperature measuring instruments are used.

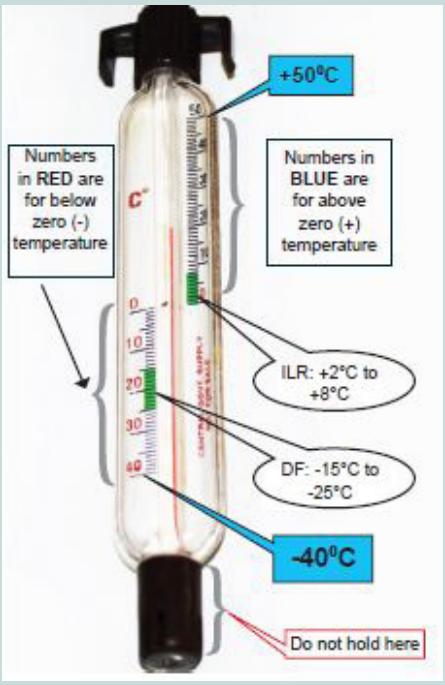


Figure 23: To measure the temperature of vaccine

Alcohol Stem Thermometers are much more sensitive and accurate than dial thermometers. They can record temperatures from -40°C to +50°C and can be used for ILRs and Deep Freezers.

5.3.6: Voltage Stabilizer

The function of the voltage stabilizer is to monitor the range of fluctuations in the main incoming voltage and to safeguard equipment from excessive voltage variation. Voltage stabilizers provide constant stabilized voltage to CCEs (ILRs, Combos, and DFs) for its desired optimum operation and in turn protect vaccines.

Figure 24: Single phase voltage stabilizer

Types of voltage stabilizers

Voltage stabilizers can be classified as follows:

i. Normal Voltage stabilizers: The voltage range: 150 – 280 V.
ii. Low range voltage stabilizers: voltage range: 110 – 280 V.
iii. Low range stabilizers for specific areas: 90 – 280 V.

Stabilizers should be selected and installed as per the input voltage available.

Low input voltage range (90V – 280V) voltage stabilizers are recommended in the areas with low voltage supply.

Instructions to User:

- Every refrigeration unit must be connected to an individual stabilizer.
- Bypassing of Stabilizer is not recommended, as such practice may lead to damage of the CCE and in turn safety of vaccines and hence must be avoided.
- Proper earthing should be available and connected.
- Emphasize on repairing stabilizers immediately. Local help can be sought. Identify authorized and qualified service provider.
- Include status of stabilizer in monthly report, it is an integral and important part of cold chain equipment.

5.4 NON-ELECTRICAL COLD CHAIN EQUIPMENT

5.4.1 Vaccine carriers

Vaccine carriers are used for carrying vaccines (16-20 vials) to out-reach sites. They maintain the cold chain during transport from the Health Centers to immunization sites. Vaccine carriers have thick walls and lids are made of a special material that prevents heat from passing through and maintain

Figure 25: Vaccine Carrier to store and transport vaccines

the required temperature for the vaccines. The vaccine carrier is filled with polyurethane foam. The inside temperature of a vaccine carrier is maintained between +2 to +8°C with 4 conditioned ice packs for 4 -10 hrs (cool life at +43°C, it depends on frequency of opening and other factors). The vaccine carrier comes in the following:

a. Short range vaccine carrier
b. Long range vaccine carrier
c. Freeze free vaccine carrier

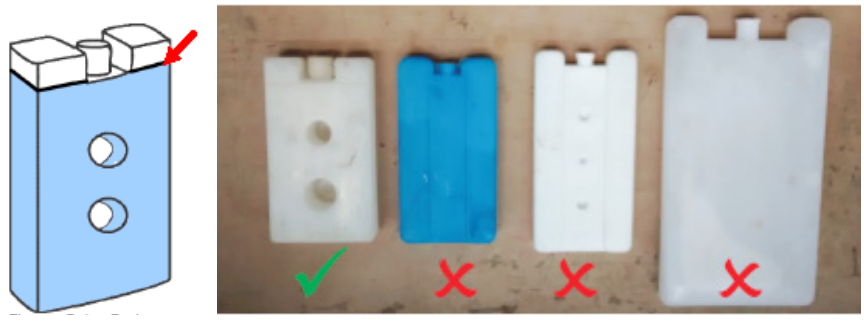
Bhutan has only two types of vaccine carriers:

a. Short range vaccine carrier: It requires the ice pack conditioning prior to loading of vaccines
b. Freeze free vaccine carrier: This vaccine carrier can be directly loaded with ice packs without conditioning

How to pack the vaccine carrier:

5.4.1.1 Ice packs for vaccine carrier

- Ice packs are plastic containers filled with water. These are frozen in the deep freezer.
- Ice packs can be filled with tap water up to the mark as shown in the picture and the cap tightly closed, so that there is enough ice and the water does not leak when the ice melts.



Unconditioned ice-packs may damage freeze sensitive vaccines

Figure 26: Ice pack and its proper ice-pack conditioning

- Excess water filled in ice pack will swallow the ice pack and less water in ice pack will squeeze the ice pack, so fill proper water upto the marked level
- Only conditioned ice packs to be used in vaccine carriers
- Conditioned Ice packs are kept along the walls of the vaccine carrier.
- The outer surfaces of the ice packs should be cleaned with dry cloth before putting these in the deep freezer for freezing cold boxes
- In the cold box icepacks are to be kept along the walls, on the floor and on top of the vaccines.

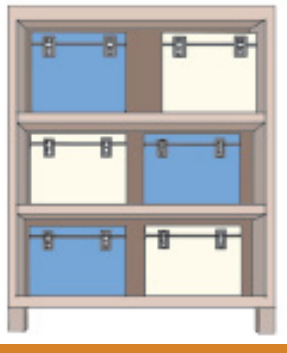
5.4.2 Cold Boxes

Figure 27: Cold Box for storage of vaccines / ice packs

Cold boxes are used to collect and transport vaccines from EPI stores to the hospitals, and hospital to PHC/sub-posts. They are also used to store vaccines when the ILR and refrigerators are out of order and when defrosting the freezer to keep vaccines at correct temperatures. Before the vaccines are placed in the cold box, conditioned ice packs should be placed at the bottom and sides of the cold box. Thereafter, vaccines should be placed in cartons or polythene bags and placed in the cold box. The vaccines should be covered with a layer of conditioned ice packs before the cold box is closed. The vials of DTP-HepB-Hib, HPV, DTP, Td and Hepatitis B should be wrapped in thick paper to prevent the vaccine from freezing. Vaccines should be transported or stored in cold boxes only with sufficient number of conditioned ice packs. In such a situation, vaccines can be stored for 12 - 52 hrs cool life at 43°C in cold box, depending upon the openings and atmospheric temperature. The temperature of the cold box should be monitored by keeping a freeze tag or 30 DTR inside the cold box.

5.4.2.1 Ice packs for Cold box

- Please read the instructions mentioned inside the lid for loading the cold box
- Ice packs are plastic containers filled with water. These are frozen in the deep freezer.
- Ice packs can be filled with tap water up to the mark as shown in the picture and the cap tightly closed, so that there is enough ice, and the water does not leak when the ice melts.
- Excess water filled in ice pack will swallow the ice pack and less water in ice pack will squeeze the ice pack, so fill proper water up to the marked level
- Only conditioned ice packs to be used in vaccine carriers
- In the cold box icepacks are to be kept along the walls, on the floor and on top of the vaccines.
- The outer surfaces of the ice packs should be cleaned with dry cloth before putting these in the deep freezer for freezing



When Cold Box is not in use, place properly, do not close lid with lock.

5.5 VEHICLE USED FOR TRANSPORTATION

Refrigerated Vaccine Van

Transportation equipment forms an important link in the entire cold chain system. It can be used for transportation of vaccines in bulk quantity. This can be used to provide transportation solution from National Store to Regional Stores and from Regional Stores to District Hospitals. Apart from it, it is used to collect the vaccines when vaccines land at airport. The refrigerated vaccine van can provide temperature range as per the specific requirement of vaccine like +2°C to +8°C. At present Bhutan is using only +2°C to +8°C. The use of Refrigerated vaccine van does not require the cold boxes or ice packs for vaccine transportation. The refrigeration system in the vaccine refrigerated van should be started to get the required temperature before loading the vaccine.

Figure 28: Safe transportation of vaccines through refrigerated van

CHAPTER 6:

MAINTENANCE OF COLD CHAIN EQUIPMENT

The fact of life is that every piece of equipment needs maintenance. It may be routine maintenance, such as changing the oil in your car to prevent problems from occurring later on, or it may be the larger actions to repair or replace damaged parts. Sometimes you may even have to replace your car's entire engine. Both types of maintenance, preventive and curative, are important to keep your car running as best as it can. Similarly, cold chain equipment (CCE) used to keep vaccines at an optimum temperature range of +2°C to +8°C, -5°C to -25°C and -60°C to -86°C needs regular preventive maintenance. This is necessary to keep the equipment functioning optimally, to maintain the vaccine's quality and effectiveness against disease, and to save lives. Maintenance plans need to be realistic and backed-up with a HR, technical capacity and available funds.

For immunization programs in Bhutan, ensuring CCE is continuously working properly has been an ongoing challenge, because often equipment was installed decades ago (Domestic and SIBIR refrigerators) and it's easy to understand the challenge. The scope is huge – each program like EPI and Health has thousands of pieces of equipment installed across the country, many in very hard-to-reach areas. The electrical grid that runs much of this equipment can be unreliable, which can put a strain on the CCE. Spare parts for the equipment are often not available locally, which complicates a quick response to a maintenance issue. And there are never enough technicians when and where they are needed, or inadequate financial resources to deploy them.

Bhutan is in process of development of maintenance plan into the country plan that details the on-going preventive maintenance for CCE, such as keeping it clean, not overloading the equipment, and defrosting when needed. The plans should also provide the details of what to do when a piece of equipment breaks down – who is responsible to fix it; expected quantity of spare parts needed and where they should be stored; estimated costs of corrective maintenance; and who authorizes decommissioning of equipment that can't be repaired, among many other details. Also, annual maintenance contract (AMC) can also be designed to improve the regular maintenance of cold chain equipment. Models that are ten or more years old are still being used, some with no problems and some that should be retired/replaced and will still require maintenance. The maintenance system must be available for all equipment, not just those recently procured. Older equipment will naturally need more care and attention to maintain the optimum temperature range.

That maintenance plans need to be realistic and backed-up with a budget and available funds. Even if a cold chain technician can create the most accurate budget for maintenance of all equipment, if the funds are not available when the technician needs to buy fuel for the vehicle to go out to a health facility to fix a piece of equipment, the problem will persist. On the other hand, if the needed spare part is stored at the national level, regional level, and the district level, it can avoid delay in maintenance. These are the "nuts and bolts" of a maintenance system that still need to be addressed. At the country level as well, immunization program managers, logisticians, and cold chain technicians should continue to advocate for the funds and attention necessary to establish strong and reliable maintenance systems to protect the investment in equipment and in children's lives.

Maintenance of the Ice Lined Refrigerator, Deep freezer, Walk-in-Cooler, Walk-in-Freezer and Ultralow Temperature Freezer.

6.1 MAINTENANCE SCHEDULE REFRIGERATOR/ILR/COMBO

IMPORTANT REFRIGERATOR CARE

Daily Tasks:
1. Check and record temperature daily morning and evening.
2. If the temperature is >8°C or <2°C, take corrective action.

Weekly Tasks:
1. Remove any water at the bottom of the refrigerator with a cloth or through the drainage hole
2. Wipe of water droplets on the inside wall
3. Check if lid gasket is sealing properly when the lid is closed

Monthly Tasks:
1. Defrost the equipment
2. Clean refrigerator with lukewarm water and mild detergent from inside and outside
3. Clean the grill on the right side of the refrigerator

HOW TO DEFROST A VACCINE REFRIGERATOR

1. Transfer vaccines to a working refrigerator or cold box with conditioned icepacks
2. Turn off the power supply to the refrigerator
3. Leave the lid or door open and wait for the ice to melt. Do not try to remove the ice with a knife or other sharp object. Doing this can permanently damage the lining. Clean and dry the inside of the appliance
4. Turn the power supply ON

When the temperature falls below to +8°C or lower (but not less than +2°C), return the vaccines, diluents, and/or cool water packs back to the refrigerator.

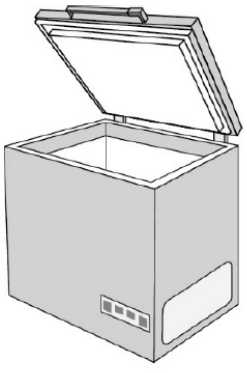
SERVICE TECHNICIAN TO CHECK

- ☐ Is the green diode in the control panel ON (power check)
- ☐ Is the internal temperature inside the acceptable range of +2° to +8°
- ☐ Is the vaccine compartment clean and without condensation (water)
- ☐ Is the Compressor running
- ☐ Are baskets used and in place
- ☐ Is the appliance placed according to the instruction in the manual
- ☐ Does the lid close tight to cabinet and is the lid gasket in good condition
- ☐ Is the grill for compressor compartment clean
- ☐ Is the condenser coils on the backside clean
- ☐ Are all electrical components working properly
- ☐ Is there condensation on electric parts (water condensation)?
- ☐ Over all condition of the cabinet - internal and external: any corrosion, rusting, cracks?
- ☐ Inspection of the refrigeration line (the condenser, evaporator, the whole refrigeration circuit/line)

HOW TO MAINTAIN YOUR VACCINE REFRIGERATOR

1 Check Installation

Refrigerator is:



- Outside of direct sunlight
- In a well ventilated area
- Clear of any heat source
- On a level floor
- Has enough space for air circulation
  - More than 50 mm between the back and the wall
  - More than 100 mm from the right side of the refrigerator (grille) and the wall
  - More than 200 mm between vaccine refrigerators.

2 Protect the power supply

Refrigerator power supply is protected with:

- "Do Not Unplug" sign by the outlet
- "Do Not Interrupt Power" warning label by the circuit breaker
- Signs including current emergency contact information and notification of emergency plan
- A voltage regulator

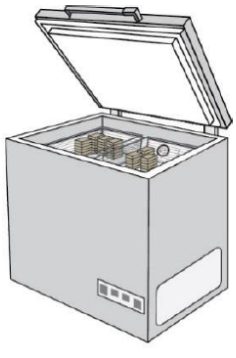
3 Store vaccines properly

The vaccine compartment includes;

- An alcohol stem thermometer or an electronic freeze indicator in the coldest area.
- No food or drink inside the equipment
- Vaccines with earliest expiration date are easiest to access
- Notice of emergency plan for vaccine storage if equipment failure or power cut

4 Arrange packaged vaccines

Vaccine cartons and vials are:



- Stored in baskets or in uncovered containers with slotted sides placed inside these baskets
- Stored with vertical space between stacks of cartons to allow air to circulation
- Not in contact with the walls of the refrigerator or freezer
- Not stored directly in of fan or outlet from freezer compartment

- Report breakdowns immediately so that repairs can be carried out immediately or as soon as possible
- Regularly check ILR/Deep Freezer/Combo seals to ensure that cold air does not leak out. If they are brittle or torn arrange for replacement
- Defrost ILR/Deep Freezer/Combo to prevent ice building up which reduces efficiency.
- Ensure the area around (including behind and under) the ILR/Deep Freezer/Combo is clean and dust free
- Arrange for regular maintenance inspections by EPI/BMED technicians. Inspections may need to be more frequent as the refrigerator ages

Defrosting or Cleaning

When there is solid ice in and around the freezer compartments of refrigerators or the sides of ILRs or deep freezer (5 mm), it is time to defrost to remove the ice. When defrosting or cleaning the refrigerator, move the vaccines to any refrigerator. This temporary storage refrigerator must also be monitored to ensure the correct temperature +2°C to +8°C is maintained. If there is no other refrigerator, store the vaccines in a cold box with conditioned icepacks. Continue to monitor the temperature inside the cold box till vaccine refrigerator is ready for use again. Refrigerator should be kept clean. Put back the vaccines in the ILR once the ILR temperature reaches +2°C to +8°C.

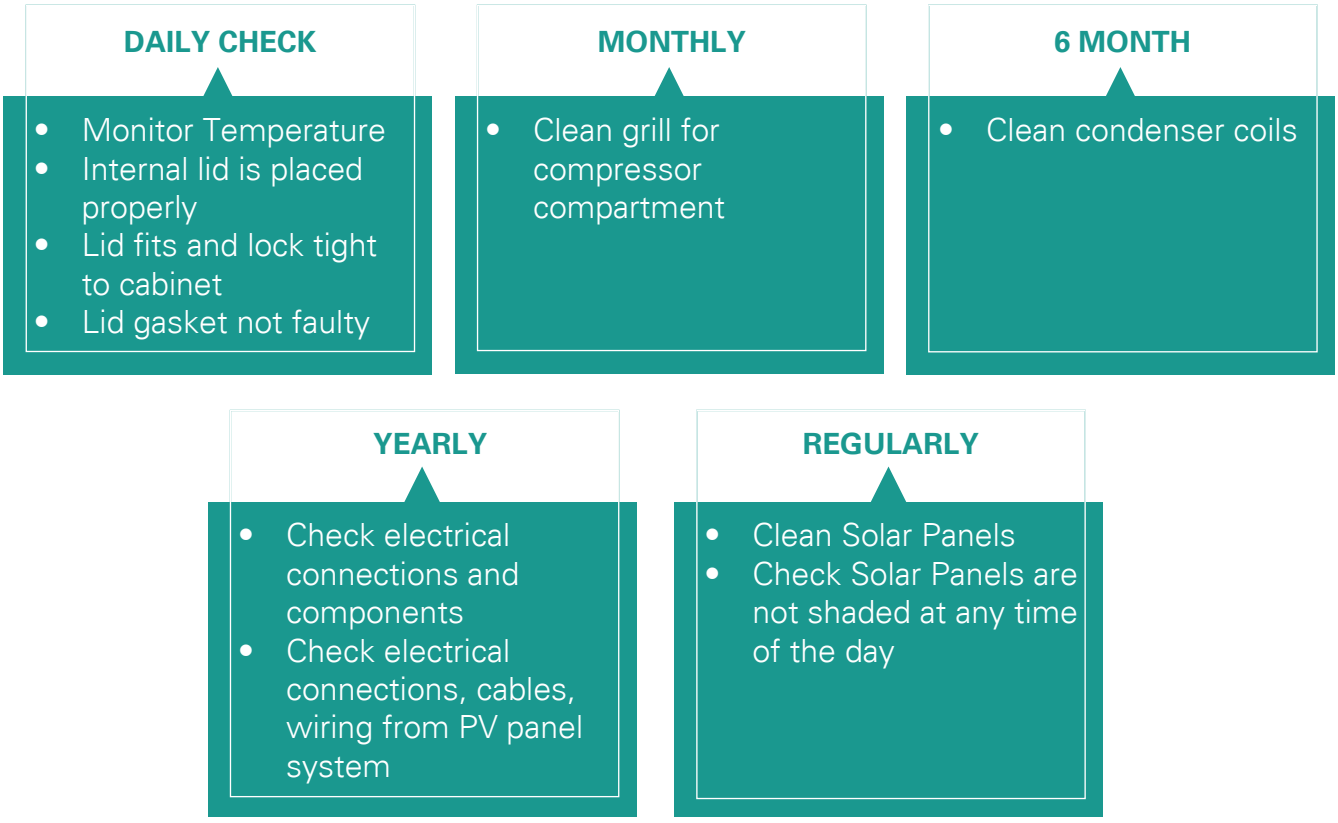


Figure 29: Maintenance of Solar refrigerator

6.2 SOLAR REFRIGERATOR

6.3 WALK-IN-COOLER/WALK-IN-FREEZER

ROUTINE MAINTENANCE INSTRUCTIONS

1. Regularly check the surface of the condenser and clean foreign objects to keep the condenser clean
2. Regularly check the operation condition of the condenser, and ensure that each fan operates normally
3. Regularly check the time required for each unit to run the refrigerating cycle, and analyze and eliminate the potential problems
4. Regularly check the inner door lock to protect the personnel from being trapped due to broken lock
5. Regularly check whether the door frame heater is normal to avoid condensation due to damages of the heater

CHAPTER 7:
VACCINE MANAGEMENT

7.1 HOW TO MAINTAIN THE CORRECT TEMPERATURE OF VACCINES?

As some vaccines are sensitive to heat and light and some vaccines are sensitive to cold, a proper care must be taken when packing vaccines and transporting them from the EPI Vaccine store and Health Centers to the immunization sessions and using them during the sessions. This involves people, equipment, and procedures.

Vaccines require to be stored at the recommended temperature during their entire shelf life to retain its potency. Various cold chain equipment are used to ensure that the vaccines are stored at the recommended temperature right from the manufacturer to the time of administration. Below table explains the right temperature at all levels. It is essential to store adequate stock of vaccines at every level of the immunization supply chain. If it is less than the required quantity the immunization programme may suffer and in the case of excess quantity, there are chances of losing vaccine potency. 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 30DTR/thermometer among the vaccines to ascertain the actual vaccine temperature.
- Store Freeze sensitive vaccines (DTP, Td, IPV, PCV, Penta and Hep. B) away from the bottom of the ILR to avoid any temperature excursion.
- Always keep the vaccines in the basket provided in the ILR. bOPV, BCG, and MMR vaccine to be stored at bottom of 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.
- Vaccine should be stored as per their heat and cold sensitivity.

Table 7: Vaccine storage specifications at different levels

	At National Level	At Regional Level	At District Level	At PHC, sub-post Level	During Transportation
Name of vaccines	**All vaccines under UIP except OPV**			**All vaccines**	
Storage Equipment	WIC	WIC	ILR (L)	ILR (S)	In Cold Box with Conditioned ice packs
Storage Temperature	+2° to +8° C	+2° to +8° C	+2° to +8° C	+2° to +8° C	
Maximum Stock (months)	6	6	3	2	
Minimum Stock (months)	3	1	1	1	
OPV					
Storage Equipment	WIF	WIF	DF (L)	ILR (S)	In Cold Box with hard frozen ice packs
Storage Temperature	-15° to -25° C	-15° to -25° C	-15° to -25° C	+2° to +8° C	
Maximum Stock (months)	6	6	3	2	
Minimum Stock (months)	3	1	1	1	

7.2 VACCINE SENSITIVITIES

As indicated in the chart below, DTP-HepB-Hib, DTP, Td, IPV, PCV and HPV vaccines will lose their potency if frozen. Reconstituted BCG and MMR vaccines are the most heat and light sensitive vaccines and should not be used after 6 hours of reconstitution.

Table 8: Summary of Vaccine Sensitivities

Vaccine	Exposure to heat/light	Exposure to cold	Temperature of refrigerators
Heat and light sensitive vaccines			
BCG	Relatively heat stable, but sensitive to light	Not damaged by freezing	+2° to +8°C
bOPV	Sensitive to heat and light	Not damaged by freezing	+2° to +8°C (PHC and sub-posts) 15-25 °C (EPI stores and hospitals)
IPV	Relatively heat stable	Damage by freezing	+2° to +8°C
MMR	Sensitive to heat and light	Not damaged by freezing	+2° to +8°C
Hib	Sensitive to heat and light	If lyophilized, it is not damaged by freezing, but liquid formulations can be damaged by freezing. Once reconstituted, freeze-dried or lyophilized vaccine also should not be frozen	+2° to +8°C
COVID-19 (Pfizer)			-86° to -60°C at National and Regional EPI Stores till date of expiry
COVID-19 (Moderna)			-20°C at the national and regional levels
COVID-19 (Others)			+2° to +8°C at all levels
Freeze sensitive vaccines			
Hepatitis B	Relatively heat stable	Freezes at –0.5°C. Should not be frozen	+2° to +8°C
Pentavalent (DTP-HepB-Hib)	Relatively heat stable	Should not be frozen	+2° to +8°C
PCV	Relatively heat stable	Should not be frozen	+2° to +8°C
DTP	Relatively heat stable	Should not be frozen as it is freeze sensitive	+2° to +8°C
Td	Relatively heat stable	Should not be frozen	+2° to +8°C
HPV	Relatively heat stable	Should not be frozen	+2 to +8°C
Influenza vaccine	Relatively heat stable	Should not be frozen	+2 to +8°C
At PHC level all vaccines are kept at +2° to +8°C			

7.3 PROCEDURES

7.3.1 How to load vaccines in Vaccine Carrier

The vaccines should be collected on the day of immunization as per schedule.

1. Check the vaccine carrier and make sure the lid fits tightly. Check the insulation for cracks.
2. Conditioning of ice packs-Remove the ice packs from the freezer and keep them outside till you see water droplets on the surface of the ice packs. You will hear the crackling sound from inside the icepack when the ice pack is shaken. This means that there is water in the ice pack and not just ice. The time taken for conditioning ice packs depends on the outside temperature. Use of conditioned ice packs prevents freezing of vaccines that may come in contact with the ice packs.
3. Pack four conditioned ice packs into the vaccine carrier along the four sides.
4. Take the required quantities of MMR, bOPV, BCG, Td, DTP-HepB-Hib, DTP, HPV, IPV, PCV and Hepatitis B vaccine, plus one vial of diluents for every BCG and MMR vials and place inside a plastic bag. Place this bag in the centre of the vaccine carrier, away from the ice packs. This will prevent labels from peeling off from the vaccine vials. The vials of DTP-HepB-Hib, HPV, DTP, Td, IPV and Hepatitis B vaccine should not be placed in direct contact with ice packs. The dropper for bOPV should also be placed inside the vaccine carrier in the plastic bag.
5. Put 30 DTR/freeze tag/freeze alert/dial thermometer with the vaccine.
6. Close the lid securely after putting the foam
7. Use freeze tag/alert and/or 30 DTR and thermometer during transportation of vaccines in all levels.
8. Print 30 DTR records after reaching the destination and after return from outreach clinics.
9. The 30 DTR should be marked as ORC/Vaccine Collection

7.4 HOW LONG CAN VACCINES BE KEPT IN THE VACCINE CARRIER?

Usually, vaccines can be stored in a vaccine carrier for one to two working days only. However, this depends on the condition of the ice packs and the ambient temperature. Vaccines can be kept safely in a vaccine carrier only till the ice packs remain at least partially frozen.

- Only the diluents provided by the manufacturer should be used and SHOULD NOT BE INTERCHANGED.
- Diluents should be stored with the vaccine in the vaccine carrier during transportation (temperature of diluents and vaccine should be same at the time of reconstitution). Diluents need to be cooled before use but should not be frozen. So, it should not come in direct contact with the ice pack.
- Do not drop or sit on the vaccine carrier: this can damage the carrier.
- Do not carry vaccines in handbag as this can spoil vaccines that are sensitive to heat
- Do not empty the ice packs even when ice has melted when vaccines are still in the carrier

7.5 PLACING VACCINES IN THE REFRIGERATOR

- Store bOPV, MMR, BCG on the bottom shelf of ILR/Combo
- Diluents of MMR and BCG vaccines must be stored at room temperature. However, the diluents must be stored at 2°-8°C for 24 hours at the upper self of ILR/Combo before the immunization session.
- During the immunization sessions at the ORCs, the diluents should be packed and transported along with the vaccines.
- All freeze sensitive vaccines (DTP-HepB-Hib, DTP, HPV, IPV, PCV and Td) should be stored on the upper shelf
- The freeze alert/freeze tag or 30 DTR should be kept along with the freeze sensitive vaccines

7.6 HOW TO KEEP VACCINES COLD DURING THE IMMUNIZATION SESSION?

Vaccine carrier comes with a foam pad that has slits/holes in it for keeping vaccine vials. During the immunization session, the vaccine in use should be kept in the slits in the foam pad which is kept on top of the ice packs in the carrier as shown in the figure.

Figure 30: To keep open vaccine vial cold

If the vaccine carriers do not have foam pads, in such cases during immunization session take out only one ice pack for keeping bOPV and reconstituted BCG and MMR vaccines. The ice pack, once taken out, should not be put inside the carrier till the end of the session. DTP-HepB-Hib, PCV, Td, DTP, HPV, IPV and Hepatitis B vaccines should never be kept directly on the ice pack.

In most areas, the temperature in a vaccine carrier will stay below +8°C for one day. In order to achieve this:

- Keep the carrier in the shade and in a cool place
- Reconstituted BCG and MMR vaccine should be used within 6 hours of reconstitution.
- Write the time of reconstitution on the label of the vaccine vial and discard after six hours or at the end of the session, whichever comes first.

7.7 HOW TO ENSURE THAT THE VACCINE WAS KEPT IN THE CORRECT TEMPERATURE

- Vaccine can lose its potency due to excessive heat and freezing.
- You can check whether vaccine is exposed to excessive heat or freezing by checking VVM and Shake Test respectively.

7.8 HOW TO CHECK FOR HEAT DAMAGED VACCINES?

7.8.1 Vaccine Vial Monitor (VVM)

Reading VVM: VVMs are labels on vaccine vials that have a small white square inside a blue circle. As the vial is exposed to cumulative high temperature, the color of the white square will change. Read the VVM (see below) and determine whether the vaccines have been damaged by heat. If the vaccine vials show change in colour to the discard point, then discard the vaccines. Remove vaccines that have reached discard point from the vaccine carrier.

VACCINE VIAL MONITOR (VVM)

Inner square is lighter than outer ring **= USE** — **= Good**

Inner square is still lighter than outer ring **= USE** — **= Good**

Discard point - Inner square matches colour of outer ring **= DO NOT USE** — **= Bad**

Beyond discard point - Inner square is darker than outer ring **= DO NOT USE** — **= Bad**

7.9 VACCINE VIAL MONITOR AND REACTION RATES

There are four types of VVM, which are assigned based on the different stability characteristic of the product. The table below summarizes different levels of VVM reaction rates by category of heat stability

Figure 9: VVM stages of vaccines

Category (vaccines)	No. of days to end point at +37°C	No. of days to end point at + 25°C	Time to end point at +5°C
VVM 30: High stability	30	193	>4 years
VVM 14: Medium stability	14	90	>3 years
VVM7: Moderate rate stability	7	45	>2 years
VVM 2: Least stable	2	NA	225 days

7.10 HOW TO CHECK THE VACCINES FOR DAMAGE BY FREEZING

Hepatitis B, DTP-HepB-Hib, PCV, DTP, HPV, IPV, PCV and Td vaccines should not be frozen. If suspected to be frozen, perform Shake test. Discard the vial if it has a slower or same sedimentation rate as the control vial and/or contains flakes.

DO NOT USE T-SERIES VACCINES, HPV, IPV, PCV AND HEPATITIS B IF:

- Frozen: There is no need to carry out the shake test if the vaccine is obviously frozen or

- If not frozen then only perform the shake test

7.11 HOW TO PERFORM A SHAKE TEST?

The SHAKE TEST is designed to determine whether freeze sensitive vaccines were frozen. Sedimentation occurs faster in a vaccine vial which has been frozen than in a vaccine vial from the same manufacturer which has never been frozen.

Note that individual batches of vaccine may behave differently from one another. Therefore, the test procedure described below should be repeated with all suspect batches.

Test procedure:

1. Prepare a frozen control sample: Take a vial of vaccine of the same type and batch number, from the same manufacturer as the vaccine you want to test. Freeze the vial until the contents are solid, and then let it thaw. This vial is the control vial. Clearly mark the vial "FROZEN" so that it cannot later be used by mistake.
2. Choose a test sample: Take a vial of vaccine from the batch that is suspected to been frozen. This is the test vial.
3. Shake the control and test vials simultaneously:
   Hold the control vial and the test vial together in one hand and shake vigorously for 10–15 seconds.
4. Allow the vials to rest: Leave both vials to rest for 15 minutes
5. Compare the vials: View both vials against the light to compare the sedimentation rate

7.12 RESULTS OF THE SHAKE TEST

1. If the test vial shows a much slower sedimentation rate than the control vial, the vaccine is not frozen and can be used.
2. If the sedimentation rate is similar or faster and the test vial contains flakes, the vial under test has probably been frozen and considered as ***positive***. The vaccine should not be used.

Note that some vials have large labels which conceal the vial contents. This makes it difficult to see the sedimentation process. In such cases, turn the test and control vials upside down and observe sedimentation taking place in the neck of the vial.

DO NOT USE THE VACCINE WITH POSITIVE SHAKE TEST.
RECORD AND DISCARD THE VACCINE.

Power Failures

During power failure of 4 hours or less, the refrigerator door should be kept closed. If the power failure continues for more than 4 hours, store vaccines in a cold box with conditioned ice packs. If power failures are a common occurrence, consider purchasing a power generator or solar freezers.

Unpacking Vaccines after Transport

On receiving the vaccines, store them in their packaging regardless of their bulkiness. Removing the vaccines from the original packaging exposes vaccines to room temperature and light. Check the temperature, freeze tag/alert and VVM status to ascertain the vaccines have not been exposed to temperatures above +8°C or below +2°C.

Placing vaccines in Ice-Lined Refrigerators:

ILR has got two sections- the top and the bottom. The bottom of the refrigerator is the coldest place. ILR maintains the temperature of +2° to +8°C. DTP-HepB-Hib, PCV, influenza vaccine, DTP, IPV and Td vaccines are kept in this section in the baskets provided with the refrigerator. At the PHC level, bOPV, MMR and BCG vaccines are stored at the bottom section.

7.13: ROUTINE MONITORING

7.13.1 Temperature monitoring

Temperature monitoring is a simple but very useful tool for checking the freeze or heat damage to the vaccines. The following tools are usually used for temperature monitoring.

- Thermometers
  - Mercury thermometers
  - 30 DTR (daily temperature recording)
- Temperature record sheet is the uniform temperature monitoring chart used at various levels. The temperature shown by the thermometer/30 DTR is recorded twice a day by the health workers even on weekends and holidays.

  Temperature records of 30 DTR should be printed monthly and kept for minimum of 3 years. 30 DTR should be used during transportation of the vaccines from national EPI store to the regional EPI stores and from regional EPI store to the district hospital. The vaccine receiver should print the record after reaching the destination. When 30 DTR is used for transporting to ORCs, the staff responsible for immunization session should print the record after returning from ORCs. In case of temperature excursion, necessary action should be taken and documented. (Include flow chart of vaccine flow).

- Freeze tag

  Freeze tag/alert is used for monitoring of vaccines that are at risk of being damaged by freezing temperatures during shipment and storage. Freeze tag/alert should be put beside freeze sensitive vaccines. It should be checked every morning whether the freeze tag/alert shows (tick:☑) or (Cross: X). If the tag shows cross X, the vaccines were exposed to freezing temperature at certain point of time. Perform Shake test.

- Temperature excursion monitoring and alarm device

  The temperature excursion devices are meant to manage the data remotely and centrally. In case of the temperature goes beyond set temperatures, a sms will go to health staff that temperature has gone plus/minus, kindly check cold chain. If health staff is unable to take the call due to any unforeseen reason, then a sms will flash to senior authorities of the district and further regional stores. This will keep the vaccine safe with full efficacy.

- Realtime Temperature Monitoring Devices

  These devices are expensive devices to monitor the real time temperature and provide alarm through different ways i.e. audio, visual and through sms.

7.13.2 Action points guided by Temperature monitoring

- Temperature between +2°C and +8°C. Situation normal, no action necessary.
- Temperature at or below 0°C. **VACCINE AT RISK**. Take immediate action to correct the low temperature and ensure that the problem does not arise again. Inspect the freeze-sensitive vaccines and carry out a shake test if the vaccine is suspected to be frozen.
- Temperature between +8°C and +10°C. If there has been a temporary power failure, no further action is necessary. Check that the refrigeration unit is working, monitor the situation closely and take appropriate action if temperature is not within the normal range at the time of the next inspection.
- Temperature above +10°C. **VACCINE AT RISK**. Take immediate action to implement the agreed contingency plan, and make a report.
- In the event of alarm, attend the cold chain equipment immediately.

Identify a range of contingency options

- Move the vaccine to another cold store in cold boxes maintaining appropriate cold chain
- Move the vaccines to cold boxes, report to your supervisor and regional cold chain in-charges to fix the problems

7.14 LOGISTICS MANAGEMENT OF EPI VACCINES AND CONSUMABLES

Ensure adequate quantity of vaccines and injection devices are in place for providing timely immunization services.

7.14.1 Setting of maximum and minimum stock levels

1. **Annual consumption** is calculated based on:

   - Previous year consumption (from Stock Ledger) for each vaccine or
   - Target population for each Vaccine and wastage factor of particular Vaccine

2. **Average Monthly consumption (AMC)** for each vaccine is calculated by dividing annual consumption by 12.

3. **Months of Stock** (see table below) is converted to vials by following formula:

Maximum Stock (vials) = [AMC for each vaccine] X [Month of Stock for Maximum]

Minimum Stock (vials) = [AMC for each vaccine] X [Month of Stock for Minimum]

Recommended Month of Stock	Maximum	Minimum
Regional Stores	6 months	3 months
District Hospitals	4 months	1 month
Hospitals and PHCs	2 months	1 month
PHC (remote and difficult to access)	3 months	1 month

Example-1 (calculation with annual consumption based on District Hospital)

A hospital issue/use 960 vials of BCG vaccine in previous year
AMC=960 / 12 = 80 (vials).
Maximum Stock for BCG is 80 X 4 = 320 (vials) and
Minimum Stock for BCG is 80 X 1 = 80 (vials).

Example-2 (calculation with target population based on Hospital and PHCs)

bOPV
Target Population :100
No. of doses required= 4 doses
Wastage factor: 1.67
Total Annual OPV doses required= 100 x 4 x 1.67 = 668 doses or 67 vials (10 dose vials)
Monthly Requirement = 67/12 = 6 vials (Approx.)
Maximum stock = 12 vials (2 months)
Minimum stock = 6 vials (1 month)

4. A table indicating maximum and minimum stock level needs to be pasted on the refrigerator or on the wall nearby.

5. The Maximum and Minimum stocks are revised annually based on consumption of previous year.

7.14.2: Vaccine Storage procedure

1. All vaccines should be kept in the WHO prequalified refrigerator/deep freezer.
2. Do not keep vaccines in door pockets. If refrigerator has door pockets, keep water bottles to prevent rapid temperature rise in case of electricity failure.
3. In order to avoid frequent door opening/closing and thus temperature rise, do not keep other items in the refrigerator.

7.14.3: Arrangement and labeling inside refrigerator

1. Label the trays in the refrigerator clearly, with type of vaccine and expiry date
2. Vaccine should be arranged according to FEFO, which means that the shortest expiry vials are put in front or in the most accessible place.
3. Open vial vaccines should be labelled and kept in a separate tray with date of opening written on the vaccine vial.

7.14.4: Contingency plan for emergency vaccine management

All CHUs, PHCs, and sub-posts should have a written contingency plan for vaccine management (storage and handling) during planned power cut or electricity power failure or other disasters. Too much exposure to heat, cold, or light at any time will lead to cold chain failure and damage vaccines, resulting in loss of vaccine potency. Once lost, vaccine potency cannot be restored. Eventually, if the cold chain is not properly maintained, potency will be lost completely, and vaccines will be useless.

Preparations for vaccine management during power failure:

1. All Health workers handling vaccines are responsible for vaccine management during power failure and other disasters.
2. Cold boxes and vaccine carriers should be available and accessible at all times to vaccine handlers.
3. Prepare and keep sufficient ice packs at any time.
4. Vaccine refrigerator should be connected to generator, if available, which may have auto switch system.
5. Avoid frequent opening of refrigerator/deep freezer doors.
6. Plug in only one cold chain equipment per power socket/electrical outlet.
7. Any switch used to connect cold chain equipment to the power supply should be clearly identified 'Refrigerator– Do Not Switch Off' or 'Deep freezer – Do Not Switch Off'

In the event of power failure, do the following as soon as possible:

a. Temperature of the refrigerator should be monitored until either the supply is reinstated or alternative arrangements for storage can be made.

b. Enquired BPCL (Bhutan Power Corporation Limited) regarding electricity failure.

c. Arrange transfer of vaccines from the refrigerator to cold box before temperature reaches $+8^0$C or when power failure is known to exceed 24 hours.

d. Transfer vaccines to the nearest health facility if needed.

e. Use temperature monitoring devices when vaccines are stored in cold boxes or transferred to the health facility.

CHAPTER 8:
MANAGING DRY STORE FOR EPI

1. AD syringes and vaccine carriers should always be stored in a clean, dry place free of insects with proper ventilation preferably in standard metal/wooden racks.
2. Syringes should not be exposed to excessive heat or direct sunlight. Such exposure will result in discoloration of the polythene and paper cover and destruction of portions sensitive to heat. There should be good air circulation around the outside of the storage unit. Store must have well ventilated facilities such as open windows with curtains, fan and AC.
3. Dry stores must have a thermometer to monitor and maintain records of room temperature.
4. Boxes containing syringes should not be placed directly on the floor, but on wooden or metal racks to avoid collection of moisture, to prevent infestation with fungi. Further, the insects may enter the boxes and damage the covers, which will affect the sterility.
5. Syringes should not be stored close to acids or corrosive chemicals, which may result in corrosion and decaying of the metal parts of the syringes.
6. When stacking boxes of syringes on racks, a space of at least six inches should be provided in between the wall and the cases to prevent insects coming into contact and to provide air circulation.
7. In order to facilitate easy handling and regular inspection, the cases should be stored on top of one another at a convenient height (maximum 4 feet) and a narrow space should be provided in between stacks of syringe cases.
8. No hooks or other equipment with sharp points should be used when lifting or handling boxes which will tend to affect sterility of the covers.
9. When storing boxes of syringes different brands of boxes should not be stacked together. Stocks of syringes should be used in order of receipt. To facilitate this, cases should be stacked in separate rows, according to the date of manufacture, expiry and lot number.
10. Frequent checks should be done to ascertain whether any available stocks of syringes are close to expiry and such stocks should be used before expiry. Follow the first expired first out (FEFO) strategy.
11. Opened or half-used boxes should be stored separately, and the syringes therein should be completely used before opening new cases.
12. The rooms, stores and racks where these syringes are stored should be cleaned every week and careful inspection should be done as regards to collection of moisture, fungi, discoloration, damages to cover, and insect attacks. Necessary steps should always be taken accordingly.
13. For proper recording and reporting, stock ledgers and issue registers should be properly maintained indicating dates of receipts, dates of issues, lot numbers, dates of manufacture and dates of expiry.
14. Vaccine carriers and cold boxes must be cleaned and dried well after use. Keep their lids open until fully dried. If they are left wet with their lids closed, there will be growth of fungus which will spoil the equipment, If possible, store cold boxes and vaccine carriers with the lids open.

15 Knocks and sunlight can cause cracks in the walls and lids of cold boxes and vaccine carriers. This exposes the insulation and increases the risk of heat exposure to the vaccines inside. If a cold box or vaccine carrier wall has a small crack, use adhesive tape to cover it until an undamaged container becomes available.

16 Condemnation: The process of disposing all non-repairable cold chain equipment. A large number of condemned equipment often clutters valuable space in dry storerooms. Concerned health workers should understand the current procedures for condemnation of equipment and help in clearing off condemned materials. Contact respective procurement sections for guidance.

17 Always maintain 5s (sort, set, shine, standardize and sustain) in the dry store.

8.1 DRY STORE DO'S AND DON'TS.

Table 10: Do's and Don'ts for dry stock

SL. NO.	CRITERIA	DO'S	DON'TS
1	Location	Within the health facility campus, in a room with no direct exposure to sunlight, covered from all sides with a secure door which can be closed if required.	Separate from the health facility campus. In a room exposed to direct sunlight. Open and exposed on one or multiple sides.
2	Size	Large enough to accommodate all dry storage space and also adequate space for loading and distribution	Small areas between rooms or verandahs, or scattered areas where different equipment, dry commodities and staff areas are placed.
3	Electrical Fittings	All wirings carried out by a qualified electrician All circuits having sufficient earth protection Refrigerators and freezers should be wired directly to stabilizers which in turn should have direct wiring into wall units	• Poor quality wiring using plugs and sockets of improper quality • Circuits having inadequate or lack of earth protection coiled or loose cables/wires • No connection of stabilizers with equipment • Loose wires put into electrical sockets.
4	Space between equipment and walls	ILRs and deep freezers should be spaced 10 cms. from walls and 10 cms. away from other equipment. ILRs and freezers should be mounted about 10 cm clear of the floor on their own wooden pallets, stands or blocks. This prevents corrosion when water is swept under units during floor cleaning	Equipment too close to or touching walls /each other. Direct placement of electrical cold chain equipment on the floors
5	Flooring	Level floors preferably with a concrete slab beneath	Broken or unlabeled floors.

CHAPTER 9:
ENSURING SAFE INJECTIONS AND WASTE MANAGEMENT

9.1 WHAT IS A SAFE INJECTION?

A safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community. Health workers should assume that all used injection equipment are contaminated and should not be reused. They should take precautions to ensure that no person is potentially exposed to infection or accidental needle-stick injuries.

9.2 WHAT ARE THE RISKS ASSOCIATED WITH UNSAFE INJECTIONS?

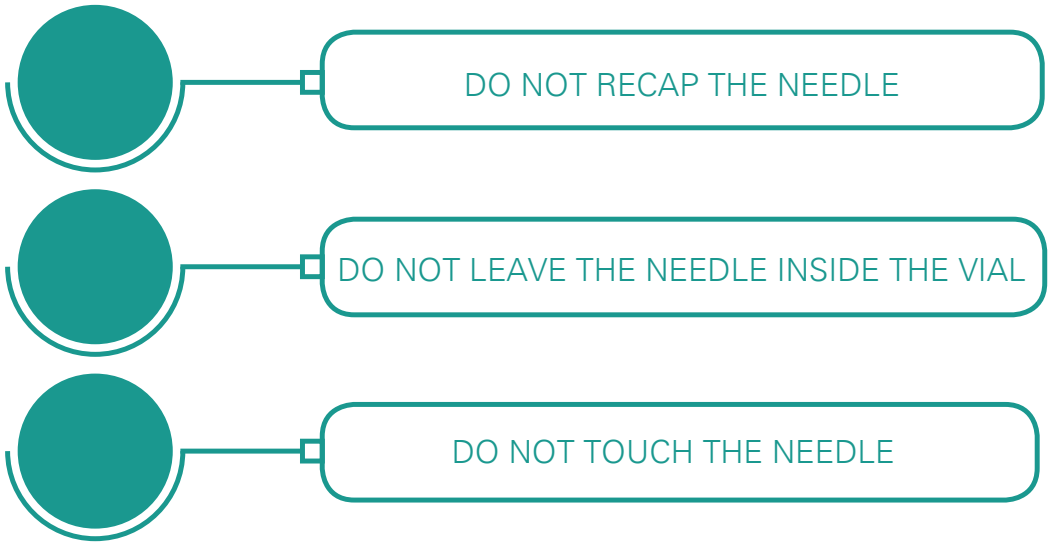
Health workers reusing syringes and needles can cause cross-infection and put people at risk. The most common, serious infections transmitted by unsafe injections are hepatitis B, hepatitis C, and HIV/AIDS among others. Poorly administered injections can also cause injuries or drug toxicity with the wrong injection site, wrong vaccines, wrong diluents, or wrong dose is used. It is important to understand the risks of accidental needle-stick injury, and the importance of safely disposing injection equipment to prevent risks to the community at large.

9.3 SIMPLE WAYS TO IMPROVE INJECTION SAFETY

- Keep hands clean before giving injections
- Wash or disinfect hands prior to preparing injection material.
- Avoid giving injections if the skin of the recipient is infected or
- Avoid local infections (such as a skin lesion, cut, or weeping dermatitis), select alternative site for the injection.
- Cover any small cuts on the service provider's skin
- Use sterile injection equipment, every time
- Prevent the contamination of vaccine and injection equipment
- Prepare each injection in a designated clean area
- Avoid contamination from blood or body fluid.
- If the injection site is dirty, wash with clean water.
- Always pierce the rubber cap of the vial with a sterile needle.
- Do not leave the needle in the stopper of the vial.
- Follow product-specific recommendations for use, storage, and handling of a vaccine.
- Discard any needle that has touched any non-sterile surface.
- Assume all used equipment are contaminated
- Practice safe disposal of all medical sharps waste
- Fill the safety box up to about 75% full (Do not over fill the box) and then carry to the PHCs for safe disposal.
- Prevent needle-stick injuries, put syringe and needle into safety box immediately after use without recapping.
- Anticipate sudden movement of the child.

Discard the used syringe and its parts into the safety box; DO NOT recap the needle.

UNSAFE IMMUNIZATION PRACTICES



Use disposable syringes and needles for reconstitution of BCG and MMR vaccines. One syringe and needle should be used for each vial. All syringes used for vaccination should be auto-disable.

9.4 ADVANTAGES OF USING AD SYRINGES

- AD syringes are designed to prevent the re-use of non-sterile syringes.
- The fixed-needle design reduces the dead space in the syringe that wastes vaccine. It eliminates chances of entry of air bubbles into the syringe caused by loose fitting of the needle.
- AD syringes are dose-specific (0.05ml, 0.1ml, 0.25ml and 0.5ml) and hence, drawing the plunger to the full length to the specified marking ensures the correct dose. No further adjustment is required.

If you touch any part of the needle, discard the syringe and vaccine in the syringe. Use a new AD syringe.

- In AD syringes the plunger can go back and forward only once. The plunger gets locked after the complete dose of vaccine is pushed in.

9.5 INJECTION TECHNIQUE

- Select the correct syringe for the vaccine to be administered. BCG 0.05 ml and all others 0.5ml can be put on the table.
- Check the packaging. Don't use if the package is damaged, opened, or expired.
- Peel open or tear the packet from the plunger side and remove the syringe by holding the barrel. Discard the packaging into a waste bin.
- Remove the needle cover/cap and discard it into the waste bin. Do not move the plunger until you are ready to fill the syringe with the vaccine and **do not inject air into the vial as this will lock the syringe**

- Take the appropriate vaccine vial and insert the needle such that the tip is within the level of the vaccine. If inserted beyond you may draw air bubble which is difficult to expel. **Do not touch the needle or rubber cap (septum) of the vial.**
- Pull the plunger back slowly to fill the syringe. The plunger will automatically stop when the necessary dose of vaccine has been drawn (0.05 or 0.5ml). **Do not draw air into the syringe.** In case air accidentally enters the syringe, follow these steps to remove the air bubble: Remove the needle from the vial. Hold the syringe upright, tap the barrel to bring the bubbles towards the tip of the syringe. Then carefully push the plunger to the dose mark (0.1 or 0.5 ml) thus expelling the air bubble.
- If the injection site is dirty, then clean it with clean water swab and allow it to dry, and administer the vaccine. (BCG: right upper arm, DTP-HepB-Hib and Td: anterolateral aspect (outer side) of mid thigh, MR: left upper arm, TT and HPV: Upper arm. Push the plunger completely to deliver the dose. **Do not rub the injection site after the vaccine is given**
- Discard the syringe with needle into the safety box; **DO NOT RECAP**. Fill the Safety Box up to about 75% of its capacity and carry to designated place for waste disposal according to procedure.

9.6 GUIDELINES FOR WASTE DISPOSAL

Safety Boxes

All used syringes and needles must be disposed of immediately after use by dropping them into the safety boxes. Tape the nearly (approximately 3/4) full box securely shut and store the box in a safe place until it can be properly disposed-off. Safety boxes should not be over-filled (not more than ¾) or reused.

One box can hold 100 syringes and needles. If for any reason the safety boxes run out at health centers, used injection equipment can be disposed of in a puncture-resistant container with a lid, such as bucket/ plastic container.

Figure 31: Safety Box

NOTE:

- The safety boxes should be properly assembled according to instruction printed on the boxes.
- Do no open the safety boxes after use, this may be DANGEROUS
- A cardboard box is NOT puncture-resistant, BE CAREFUL

9.6.1 Collection of syringes with needle attached

The used syringes and needles should be put directly into the safety boxes.

9.6.2 Transportation and Disposal of Contaminated Sharps

Filled safety boxes should be collected on a regular basis and sent to the health facility/ designated area for treatment (autoclaving) or for onsite burial. Detailed logistical plan must be put in place for movement of safety boxes from the facility/ outreach to the disposal point.

Please refer to the infection control guidelines go online to download https://www.moh.gov.bt/wp-content/uploads/afd-files/2014/11/ICMWM-guideline.pdf

9.6.3 Handling of safety boxes

Contaminated sharps should not be transferred from container to container and must not be left in a public area or health facility. Care should be taken to avoid spillage from filled containers. The vehicles used to transport the filled containers must be disinfected if spillage occurs.

9.6.4 Methods for disposal of all leftover/expired/unusable vaccines

All used/expired vials, caps are to be deactivated before disposal. The safest method of disposal would be incineration which is not available in our health centers. So the only options are heat sterilization and chemical disinfection as the primary treatment followed by disposal into deep burial pits or municipal waste disposal. The following options are to be followed:

1. For health center with separate autoclave for wastes

- Collect the vials in the red/infectious bags from MCH and ORCs
- Autoclave every week with other wastes

2. For health centers without autoclave

- Use chemical disinfection method
- Collect the vials in the red/infectious bag or any leak proof containers
- Freshly prepare 0.5% bleaching solution (mix 16.7 grams of 30% chlorine powder with one liter of water) or as per the infection control procedures.
- Open the used/expired OPV vials and immerse all the vials caps and droppers (collected for the week), into this solution and keep for 30 minutes (all vials should be immersed in the solution)
- After 30 minutes – drain the solution as per the infection control protocol like other wastes.
- If the chlorine tablet (1000mg = 0.1%) is supplied to prepare a chlorine solution:

  Strength: 0.1% (cleaning purposes)

  Dissolve 1 tablet in 1 liter water

  Strength: 0.5% (decontamination purposes)

  Dissolve 5 tablets in 1 liter water

After treating the used vials with one of the above methods, dispose-of by ONE of the following methods convenient to the individual centers:

1. Disposal with other wastes into municipal wastes

Any infectious wastes treated properly with one of the above methods are safe for disposal with other non-infectious wastes. This can be disposed of with other wastes into municipal wastes. This can even be sent for recycling if facilities are available, but the treatment should have been properly done.

2. Disposal into the deep burial pit

If the health center has no municipal wastes collection facility, the treated vials can be disposed into the deep burial pits in the health facility. Ensure that the burial pit has cover and a sign board.

9.6.5 Autoclave procedure

- Collect all expired and unused vaccines in a biohazard bag and seal it.
- Put on autoclave machine and place the biohazard bag in autoclave
- Allow it to heat till the temperature reaches 121°C.
- Keep heating for 15 minutes at 121°C
- After 15 minutes of heating at 121°C, switch off the autoclave and allow it to cool.
- Take out the autoclaved biohazard bag and dispose with other hospital waste for land fill or sewerage

9.6.6. Handling of leftover/expired/unusable vaccines

- Wear gloves
- Open all the vials to be disposed
- Empty all the contents into a small bucket
- Prepare 0.5% bleaching solution as above (fresh preparation, not more than 24 hrs)
- To the known volume of vaccine put at least equal or more of 0.5% Chlorine solution and keep for at least 30 minutes.
- After 30 min, dilute with lots of water and dispose the mixture into drainage system. Refer infection control guideline
- Treat empty vials as in used vials and dispose by one of the above methods

SAFE DISPOSAL OF SHARPS, NOT TO HARM COMMUNITY

Dos

- DO immediately place used needles and other sharps in a sharps disposal container to reduce the risk of needle sticks, cuts or punctures from loose sharps.
- DO use an FDA-cleared sharps disposal container or safety boxes provided by the department.
- DO carry a portable sharps disposal container for outreach clinics.
- DO follow your community guidelines for getting rid of your sharps' disposal container.
- DO call your local trash or public health department to find out about sharps disposal programs in your area.
- DO keep all sharps and sharps disposal containers out of reach of children and pets.
- DO seal sharps disposal containers when disposing of them, label them properly and refer infection control guideline on how to properly dispose of them.
- DO report a problem associated with sharps and disposal containers.

Don'ts

- DON'T throw loose needles and other sharps into the trash.
- DON'T flush needles and other sharps down the toilet.
- DON'T put needles and other sharps in your recycling bin -- they are not recyclable
- DON'T try to remove, bend, break, or recap needles used by another person. This can lead to accidental needle sticks, which may cause serious infections.
- DON'T attempt to remove the needle without a needle clipper because the needle could fall, fly off, or get lost and injure someone.

Figure 32: Do's and Don'ts for safe disposal

CHAPTER 10:

PLANNING AND CONDUCTING IMMUNIZATION

10.1 WHAT IS THE MICRO PLAN FOR IMMUNIZATION?

In terms of immunization, the micro plan for a PHC/Hospital includes:

- Total population
- Target population (infants, under 5, 6 years old, 12 years old, 13 years old, pregnant women, elderly population, population with existing medical conditions)
- Number of sessions in a month
- Human resource availabilities and responsibilities
- Session sites with dates
- Availability of vaccines, logistics, finance and other resources
- Approximate travel distance and time for each ORC in the catchment area- by vehicle or on foot

10.1.1 Beneficiaries and yearly target

- Infants (0-11months): Number of children born in the past year can be obtained from different sources depending upon the type and size of the catchment area like birth registers, household survey of the previous year, or estimation based on National Crude Birth Rate of 17.9 (NHS 2012) of total population.
- Children 12-23 months for all practical purposes can be safely estimated to be equal to the number of infants
- Children under-5 years of age can be best estimated from the household survey, alternate source could be calculation of 15% of total population in the catchment area
- Pregnant women: approximately 110% of the number of infants
- School going children: the information can be obtained from household survey or school admission register
- BVS can be also used to gather information for some cohorts

If annual household survey is not accurate or not conducted, Dzongkhag population projection is used for the estimation of target population (Ref. PHCB 2017, NSB).

Example

Population of PHC	= 5500
Infant population for the year	= (Total population) X (National Crude Birth Rate)
	= 5500 X 1.2/100 = 66 Children
12-23 months of age	= same as infants = 66
Children under 5 years	= (Total Population) X 15%
	= 5500 X 15/100 = 825
Pregnant women	= 110% of infant
	= 66 X 110/100 = 73

10.1.2 Estimation of monthly targets and contacts

- Once we have estimated the yearly target in the catchment area for each group of beneficiaries we can safely reduce the average monthly target by dividing the annual target by 12.
- Number of doses required is obtained by multiplying number of target as shown below.

Infants BCG: 1 dose
OPV: 4 doses
DTP-HepB-Hib: 3 doses
IPV: 2 doses
MMR:1 dose
PCV: 3 doses

Under 5 years: MMR: 1 dose
DTP: 1 dose

Class VI/12 year boys and girls
HPV: 2 or 3 doses

Class PP and 7:
Td: 2 doses

Pregnant women Td: as per the new schedule

5 high risk groups: Influenza: 1 dose each except for children less than 24 months (follow the schedule)

10.1.3. Guidelines for estimation of the number of sessions for each CHU/PHC

- The number of sessions at PHC will depend upon monthly targets for different groups of beneficiaries, especially considering the population of the adjoining community.
- Organization and frequency of ORC will depend upon accessibility, number of beneficiaries in the targeted ORC, number of available health personnel, availability of transport and other logistic support
- Health facilities can conduct vaccination sessions more than once a month depending upon their target population. In the ORCs, sessions should be organized at least once a month. In remote and difficult to access areas, sessions can be planned and conducted as per the need.
- In any case, plan of immunization session whether at Fixed Site or at any ORC should be shared with all stake holders and all measures should be taken to adhere to the plan.
- Health staff should inform the Village Health Worker, Community Leaders, Caregivers and Parents on:
  - Where and when the next session is
  - Children due for vaccination, to ensure that they bring all children to the session

10.1.4 Steps in preparation of a CHU/PHC/ORC micro plan

STEP 1: List all villages and settlements in the area

STEP 2: Write the population of each village/ settlement

STEP 3: Write estimated number of beneficiaries (children and pregnant mothers).

STEP 4: Prepare a map of PHC showing;

- All villages and settlements with their population and expected beneficiaries.
- The location of the PHC, ORCs
- All-important landmarks
- Distance of villages from the PHC and the mode of transport
- Important road networks etc.

STEP 5: Prepare the PHC Session Plan and Work Plan

10.2 LISTING EQUIPMENT AND SUPPLIES REQUIRED FOR FIXED IMMUNIZATION SESSIONS

Opened, Un-Opened Vaccines & Syringes													
Item		Issued (In Doses)					No. of doses administered	Returned (In Doses)					
Sl. No.	Name of the Item	Quantity	Manufacturer	Batch No.	Exp. Date	VVM Stage		Quantity	Opened No. of doses	Un-opened No. of doses	Doses discarded	Vaccine wastage in %	VVM Stage
1	BCG												
2	Diluent BCG												
3	OPV												
4	Dropper												
5	DTP												
6	HepB (Birth Dose)												
7	HPV (GIRLS)												
8	HPV (BOYS)												
9	Influenza												
10	IPV												
11	MMR												
12	Diluent MMR												
13	PCV												
14	Penta												
15	Td												
1	Syringe 0.05 ml												
2	Syringe 0.25 ml												
3	Syringe 0.5 ml												
4	Syringe 2 ml												
5	Syringe 5 ml												
1	Safety Box												

Sl. No.	Item	Sl. No.	Item
1	Clean water	11	MCH handbook
2	Vaccines and diluents	12	Tally sheets
3	AD Syringes	13	MCH Register
4	Reconstitution syringes	14	Table, stools and chair
5	Safety Box	15	Cotton swabs
6	Paracetamol	16	Vitamin A capsules
7	AEFI emergency kit	17	Albendazole tablet
8	Soap/Hand Sanitizer	18	Scissors
9	Metal file to open ampoules	19	Height and Weight measuring instruments
10	BP Instrument	20	Vaccinator's Logistic Diary

In addition to immunization PHC workers are reminded to include the following equipment and supplies required for outreach (ORC)immunization sessions:

10.3 LISTING EQUIPMENT AND SUPPLIES REQUIRED FOR OUTREACH CLINIC SESSIONS

Sl. No.	Item	Sl. No.	Item
1	Clean water	13	MCH handbook
2	Vaccines and diluents	14	Tally sheets
3	AD Syringes	15	MCH Register
4	Reconstitution syringes	16	Height and Weight measuring instruments
5	Safety Box	17	Cotton swabs
6	Paracetamol	18	MCH Bag
7	AEFI emergency kit	19	Albendazole tablet
8	Soap/Hand Sanitizer	20	Scissors
9	Metal file to open ampoules	21	Conditioned Ice packs
10	Vaccine carrier with foam pad	22	Vitamin A capsules
11	Disposable syringes	23	BP instrument
12	30 DTR or freeze alert	24	Vaccinator's Logistic Diary

10.4 ARRANGING THE IMMUNIZATION SESSION

Ideally, the immunization session sites should have;

- A clean area not directly exposed to sunlight, rain or dust
- Adequate space to accommodate beneficiaries before and after being immunized, space for registration, immunization and recording
- A table for vaccines and injection equipment
- A seat on which a parent can sit while holding a child for immunization
- A seat for the health worker

Place everything you need within reach

A table is required to hold the equipment and stationery used while giving immunization. On the table you should put:

- Vaccine carrier
- Safety box
- MCH handbook and records
- MCH register
- Cotton swabs
- Clean water for cleaning the injection site
- AEFI Kit

Also keep a bowl, water and soap for scrubbing your hands clean before beginning the immunization session and every time your hands come in contact with any un-sterile surface.

If needed, use only wet cotton swab for cleaning the injection site.

10.5 CONDUCTING IMMUNIZATION SESSION

10.5.1 Steps in conducting the immunization session

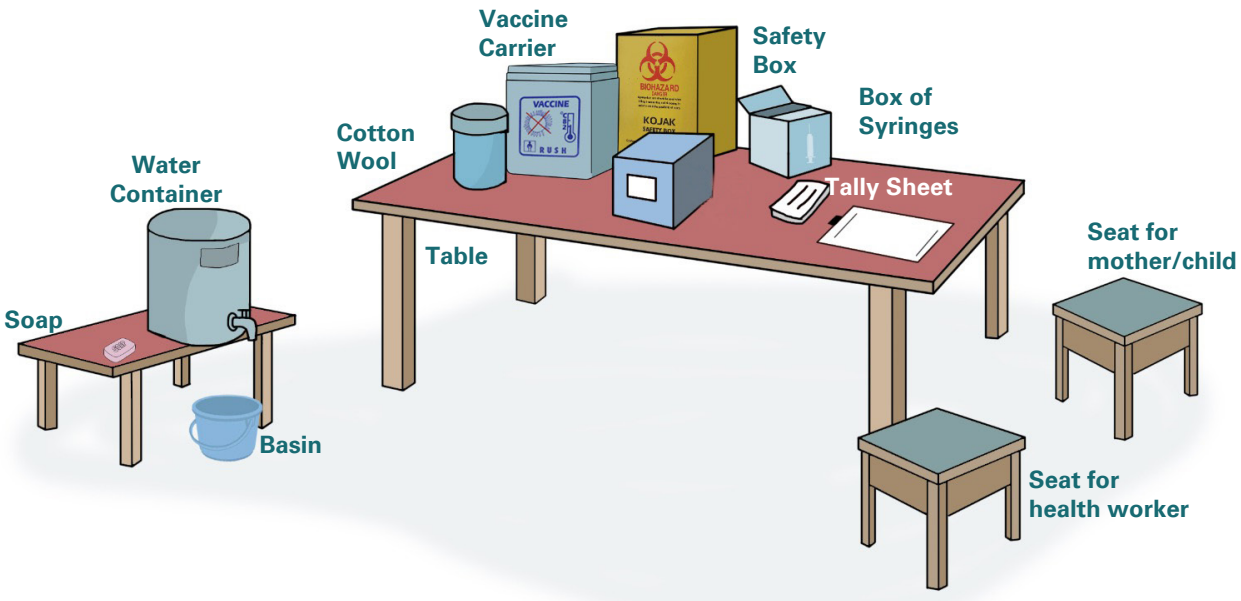


Figure 33: Layout of an Immunization Site

You should follow the steps given below while conducting an immunization session:

1. Welcome the beneficiaries
2. Verify beneficiaries' record and age and check if the beneficiary is due for vaccination
3. Explain what vaccine(s) will be given and route of administration
4. Screen for eligibility of vaccine(s) and for the contraindications
5. Check vial expiry date and double check vial label. Do not use if there is no label on vaccine vial
6. Check VVM for all vaccines; If VVM is in Stage 3 or 4 do not use; If any vaccine vials are suspected to be frozen, do SHAKE TEST if possible and if not DO NOT USE.
7. Wash hands before reconstituting vaccine and conducting the session. Write the time of reconstitution on the vial (BCG, MMR). Reconstitute vaccine making sure that at least one recipient is present; do not reconstitute before the session.
8. Maintain aseptic technique throughout.
9. For T-Series vaccines lightly shake the vials before withdrawing the dose.
10. Use only diluents supplied with the vaccine from the same manufacturer; do NOT use diluents of one vaccine for the other.
11. Inject the right vaccine at the correct site to the correct recipient, with correct technique and correct route. e.g. intra dermal; subcutaneous; intramuscular
12. Inject the vaccine using steady pressure
13. Withdraw the needle at the angle of insertion

Do not massage the injection site after the injection.

14. Discard the syringe and needle without recapping into the safety box.
15. Explain potential minor side-effects/ problems that may occur due to the vaccine and how to deal with them.
16. Ask beneficiaries to wait for at least 30 minutes after immunization
17. Fully document each immunization in MCH handbook, tally sheets and MCH register
18. Remind beneficiaries /parents about the next visit and ask them to bring the hand book on next visit.
19. Disposal of syringes and needles in the safety boxes should be done as per guidelines.
20. At the end of the session return all unopened vials in the vaccine carrier to the PHC and return them into refrigerator after checking VVM. If the immunization session is taking place at a fixed site, partially used vials can be used on the next session if all the criteria of WHO Recommended Open Vial Policy are met. However, all vaccines that are reconstituted should be discarded at the end of the session.

10.5.2 WHO Recommendations concerning Open Vials (Multi-dose, opened vial policy)

The term "Open Vial" means a vial from which one or more doses of vaccine have been taken, following the universal rules of asepsis.

The WHO Multi dose open vial policy states that liquid vaccines (OPV, DTP-HepB-Hib, DTP, Td, and HepB) may be used up to 28 days after opening of the vial provided the following conditions are met:

- Their expiry date is not passed
- Their VVM is not in the discard stage
- They are properly stored, between +2°C and +8° C
- It be practiced only in fixed clinics (Hospitals and PHCs)
- The vial septum was not submerged into water or into any other liquid

They must be discarded in the following cases:

- The procedures of asepsis were not followed
- The open vial is suspected to be contaminated
- There are evident signs of contamination (change of appearance, particles in suspension)

Reconstituted Freeze-dried vaccines (BCG and MMR) must be discarded at the end of the immunization session or after 6 hours of reconstitution or whichever is earlier. These vaccines do not qualify to be considered in open vial policy.

10.5.3 Selecting safe and potent vaccines

Before beginning your immunization session, and before giving each vaccine, follow these steps to ensure that every dose that you are going to give is safe and effective

- **All vaccines including BCG and MMR vials should be opened even for one beneficiary on clinic day. Spend sufficient time for each child for immunizing, recording and communicating.**
- Check label: Make sure the label on the vaccine vial is attached and clear enough to read. If you find that the label is not clear enough to read or has come off, **discard the vial.**
- Check vaccine: Check that the vaccine being given is the **correct one**.
- Check expiry: Look for the expiry date on the vial. If the expiry date has passed, do not use the vial; **Discard it.**
- Check the vaccine vial monitor (VVM) to make sure that the vaccine is in the **usable stage**.

10.5.4 Reconstituting vaccines

BCG and MMR vaccines are freeze-dried and must be reconstituted with diluents before use. Do not freeze the diluents because the ampoules can break when frozen. Keep diluent in the refrigerator for 24 hours to ensure that the temperature of the diluent is same as of the vaccine during immunization.

When reconstituting vaccines, follow these steps carefully:

- Double check that you have chosen the correct diluents, which has been supplied by the manufacturer for the specific freeze-dried vaccine you are going to reconstitute.
- Reconstitute the vaccine even when only one eligible child is present. Vaccination is more important than wastage.
- Use a separate syringe for reconstitution for each vaccine vial. Do not use the reconstitution syringe for injection.
- Open the vaccine vial and open an ampule of diluent.
- Draw the required quantity of the diluents into the reconstitution syringe. Tap the vaccine vial or ampoule before opening and then shake till all the vaccine powder has settled to the bottom.
- Insert the reconstitution needle into the vaccine vial, inject the diluents into the vial and remove the needle.
- Do not leave the needle in the septum of the vial.
- To reconstitute the vaccine and diluents, shake the vial gently between your thumb and forefinger.
- Write the time of reconstitution on the vials.
- Use the reconstituted vaccine, within 6 hours after reconstitution. After 6 hours discard the vaccine and reconstitute a new one.

10.5.5 Positioning the child for immunization

The correct positioning of a child for immunization is to ask the mother (or caregiver) to sit with the baby on her lap with one arm around the back of the baby, holding the baby's hand and leg steadily. The baby's other arm should be wrapped around the mother's side.

10.5.6 Giving the injection

Vaccine administration is the key to the successful outcome of any immunization program. The ease and efficiency with which vaccine administration is done goes a long way towards establishing confidence in the minds of beneficiaries and helping to achieve the goal of full coverage. The following are critical to delivery of safe and effective immunization services.

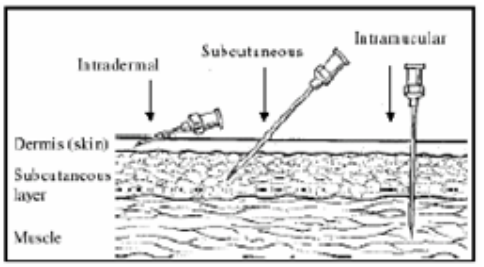


Figure 34: Various needle positions

10.5.6.1: Intra-dermal injection (BCG)

An Intra-dermal injection is one given into the dermis (skin) layer. Carry out the following steps when giving an intra-dermal injection:

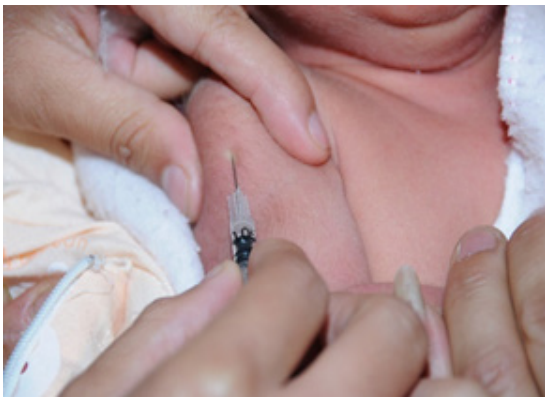


Figure 35: How to give Intra-dermal injection (BCG)

1. Position the baby and load the reconstituted BCG vaccine 0.05ml for infants under one year and 0.1ml for children older than one year.
2. Position your left hand under the child's right arm and gently pull the skin under the arm to stretch the skin at the injection site.
3. Hold the syringe in your right hand with the beveled edge of the needle pointing up towards you.
4. Insert the tip of the needle into skin a little bit at an angle of 15°.
5. Do not push too far, and do not point downward (This way, the needle will go under the skin and will make the injection subcutaneous, instead of intra dermal)
6. Put your left thumb over the needle-end of the syringe (not on the needle itself) to hold it in position.
7. Hold the plunger end of the syringe between the index and middle fingers of your right hand and press the plunger in with your right thumb.
8. Inject vaccine (0.05/0.1 ml as required) and withdraw the needle.
9. Discard the syringe and needle into the safety box.
10. If the technique is correctly followed, there will be a clear, flat-topped swelling in the skin. The swelling may look pale, with very small pits (like an orange peel).

After 2-3 weeks of a correct injection, a papule develops which increases slowly in size up to 5 weeks (4-8mm). It then subsides and breaks into a shallow ulcer. Healing occurs spontaneously within 6-12 weeks, leaving a permanent tiny round scar, 4-8 mm diameter. This is a normal reaction. When the technique is incorrect (the vaccine will go in easily and no swelling will be visible).

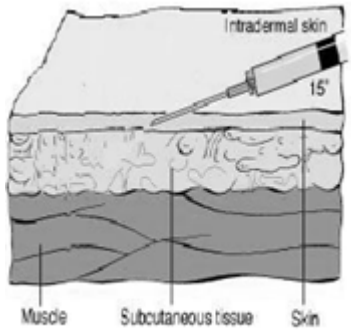


Figure 36: Intra-dermal Needle Position

1. If the whole dose has been delivered under the skin, consider the child vaccinated. Do not repeat the injection.
2. If the whole dose has **not** been administered, reposition the needle and give the remaining dose.
3. Follow-up for side effects such as abscess and enlargement of the glands.

10.5.6.2: Intra-muscular injection (DTP-HepB-Hib, HepB, Td, IPV, DTP, HPV)

Intra-muscular injections are injections given into the muscle tissue. All intramuscular injections should be given in the antero-lateral aspect of mid-thigh. In pregnant women injection should be on the outer aspect of the upper arm. Carry out the following steps when giving an intra-muscular injection:

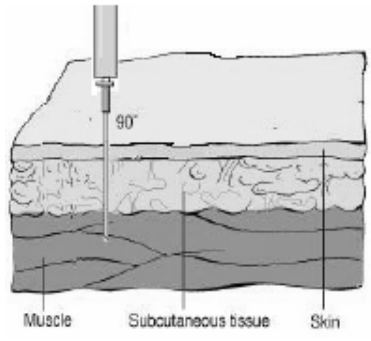


Figure 37: Inter-muscular Needle Position

1. Check the vaccine vial.
2. Position the child on the mother's lap.
3. Shake the liquid vaccine well before use to maintain uniform suspension of vaccine.
4. Load the vaccine into a 0.5 ml AD syringe (throw the AD syringe wrapper or plastic caps in the plastic bag).
5. If necessary, expel excess air from the syringe by tapping the syringe.
6. Make sure you have exactly 0.5 ml of vaccine in the syringe (no more, no less).
7. Put your finger and thumb of your hand on either side of the injection site.
8. Stretch the skin flat between finger and thumb.
9. Hold the syringe like a pen in the hand and push the needle straight down at 90° (as it will traumatize fewer muscle fibers) through the skin between finger and thumb. Penetrate deep into the muscle, but not all the way to the bone.
10. Press the top of the plunger with the thumb to inject the vaccine.
11. Withdraw the needle and press the site of injection with a dry cotton swab.
12. Discard the syringe and needle into the safety box,
13. Do not massage the injection site after vaccination

CAUTION

Infants should never be given injections in the buttock as evidence indicates that there is risk of damaging the nerves in the area. The vaccine will also be less effective if injected deep into fatty tissues.

10.5.6.3: Subcutaneous injection (MMR)

A subcutaneous injection is one that is given into the thin layer of tissue between the dermis (skin) and the muscle. The injection should be given in the left arm in the deltoid site of the skin. Carry out the following steps when giving a subcutaneous injection:

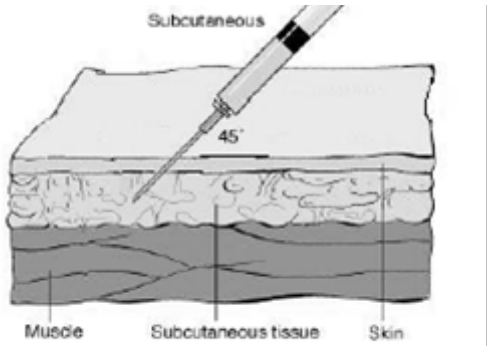


Figure 38: Subcutaneous Needle position

1. Make sure the reconstituted vaccine has not expired.
2. Position the child on the mother's lap.
3. Load the vaccine into a 0.5ml AD syringe (put the AD syringe wrapper or plastic caps in the bucket)
4. If necessary, expel excess air from the syringe by tapping the syringe.
5. Make sure you have exactly 0.5ml vaccine in the syringe (no more, no less).
6. Pinch the skin of the left upper arm between index finger and thumb.
7. Push the needle in a slanting position at 45° angle into the pinched-up skin. Do not push the needle too far in.
8. Press the plunger with your thumb to inject the vaccine.
9. Withdraw the needle and press the site of injection with a dry cotton swab.
10. Discard the syringe and needle into the safety box.

10.5.6.4: Oral administration (bOPV)

The Oral Polio Vaccine (bOPV) comes in a glass/plastic vial with a sterile dropper. The vaccine is given orally; two drops in the child's mouth

1. Check VVM on the vial before use
2. Remove the metal or rubber cap on the vaccine vial
3. Fit the dropper on the vial
4. Put two drops directly in the mouth of the child. Take care that the dropper does not touch the mouth
5. Make sure the child swallows the vaccine. If it is spitted out, repeat the dose

10.6 IMMUNIZATION SERVICES AT OUTREACH CLINIC:

Outreach Clinic facility is one of the nearest and easily accessible health care services in the community and it is provided monthly by the health workers from the primary Health Centres, Hospitals and sub-posts. Therefore, it is crucial to have guidelines for the programme to reach immunization and other health services in the communities for prevention of vaccine preventable diseases.

10.6.1 Services provided at ORC.

1. Immunization services
2. Growth monitoring for under 5 years children
3. Care for Child Development (C4CD plus) services and referral
4. Reproductive, maternal and neonatal health care services- ANC, PNC, family planning
5. health education
6. first aid treatment, and management and referral.
7. Recording and reporting of the health, nutrition, water and sanitation activities

Target Population at the ORC includes pregnant and lactating mothers, children, adolescents and sick people.

10.6.2 Micro plan of the ORC Should include

1. Target population of children, adolescents, pregnant and lactating women
2. Frequency of ORC sessions with dates
3. Line listing of elderly persons (65 years and above)
4. Display in a board at the PHC/CHU/Subpost.

10.6.3 Infrastructure -a standard place to conduct immunization

ORC sessions should not be conducted in an open space and under direct sunlight. Proper shade and privacy is required for immunization to maintain the quality of vaccine and for ANC.

10.6.4 Transportation of Vaccines to ORC:

Vaccines should be packed and loaded by health workers and may be transported by caretaker/ VHW or health workers.

Care must be taken to avoid exposure of vaccines to direct sunlight or rain during transportation.

10.6.5 What to do with the leftover vaccines at ORCs

- Opened vials should be brought back to PHC for disposal (refer guideline for waste disposal)
- The unopened vials which are cold chain maintained should be marked, brought back to the health facility and used in the subsequent immunization session.
- Used AD syringes and other syringes which are put in the safety boxes should be returned to the health center
- Unused AD syringes and other syringes should be used in the next session.

CHAPTER 11:
ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) MONITORING DEFINITION

11.1 WHAT IS AEFI?

An adverse Events Following Immunization (AEFI) is any untoward medical occurrence which:

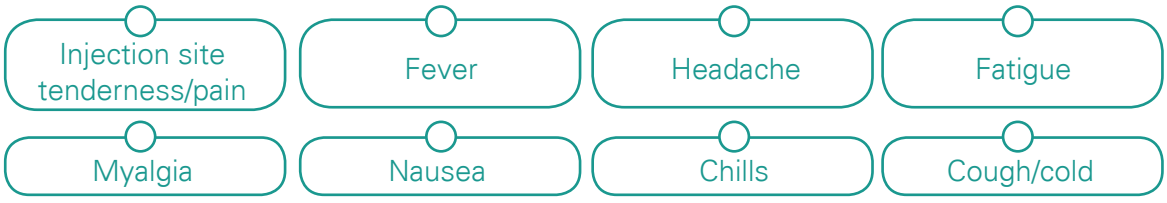
- Occurs after immunization;
- Does not necessarily have a causal relationship with vaccine usage;
- May be an unfavorable symptom about which a vaccine recipient complains; and may be abnormal laboratory findings, signs or disease found by medical staffs

11.2 CATEGORIES OF AEFI

1. Vaccine product-related reaction: caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product
2. Vaccine quality defect-related reaction: cause 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.
3. Immunization error-related reaction: caused by inappropriate handling, prescribing or administration of vaccines
4. Immunization anxiety-related reaction: arising from anxiety about the immunization and fear of injection.
5. Coincidental event: event that happens after vaccination but is not caused by vaccine or vaccination process

11.3 LIST OF MINOR AEFIS

The list of common minor AEFIs:



11.4 LIST OF SERIOUS AEFIS

1. Death
2. Life threatening; Anaphylaxis, severe allergic reactions,
3. Requiring hospitalization,
4. Causing disability and congenital anomaly

11.5 AEFI RECORD AND REPORTING SYSTEM

All the health centers will monitor AEFI of vaccines, record and report to DHO during the campaign and routine immunization services

- All minor AEFIs will be recorded and reported along with monthly AFP Zero report to DHO
- All serious AEFIs should be reported to the CMO/MOI immediately for clinical management and treatment (Annexure III). Then, CMO/MOI will submit the report to DHO

- The District AEFI committee coordinated by the DPHO will initiate the investigation immediately upon receipt of AEFI report from CMO/MOI and submit the report within 72 hours to the VPDP
- All serious AEFI cases should be investigated by the AEFI committee, as per the AEFI investigation Form (Annexure IV)
- Designated National AEFI committee members will review the case details immediately
- National AEFI committee will do the causality assessment immediately
- Final AEFI causality assessment report should be submitted to the MoH, NITAG and BFDA.

11.6 MANAGEMENT OF AEFIs

Signs and symptoms of Anaphylaxis.

1 or more signs and symptoms of any of the two systems (respiratory, cardiovascular and dermatological):

1. Respiratory: Noisy breathing, wheeze or stridor; persistent cough; swelling of tongue and lip; cyanosis
2. Cardiovascular: Fast pulse, hypotension; decreased level/loss of consciousness
3. Dermatological: Red, raised itchy rash; swollen eyes and face; generalized rash
4. Others: Anxiety; diarrhea, nausea and vomiting; sneezing and rhinorhhea

11.7 DISTINGUISHING ACUTE STRESS RESPONSE AND ANAPHYLAXIS

Figure 11: Acute stress responses and anaphylaxis

	Acute stress response		Anaphylaxis
	General acute stress response	Vasovagal syncope - VVS	
At onset	Suddenly, before, at time of or soon after injection (<5 min)	Suddenly, before, at time of or soon after injection (<5 min) May present after 5 mins if the individual suddenly stands up	Usually 5 min after exposures, almost all cases within 1 hour
Skin	Pale, cold, sweaty/clammy	Pale, cold, sweaty/ clammy	Red, raised itchy rash, swollen eyes and face, generalized rash
Respiratory	Rapid deep breathing	Normal to deep breaths	Nosiy breathing, wheeze or stridor, persistent cough
Heart	Normal or fast pulse or hypertension	Slow pulse, transient hypotension	Fast pulse, hypotension
Gastro-intestinal	Nausea	Nausea, vomiting	Abdominal cramps, vomiting, nausea
Neurologic	Fearfulness, dizziness, numbness, weakness, tingling around lips, spasms in hands and feet	Transient loss of consciousness reversed by supine position	May develope loss of consciousness not relieved by supine position

11.8 AEFI KIT

AEFI kit should have the following essential items:

Mandatory list

1. Injection Adrenaline (1:1000)
2. Injection Promethazine
3. Injection Hydrocortisone acetate
4. Promethazine tablet
5. Intravenous Fluid – Ringer lactate/normal saline
6. IV cannula
7. IV drip set
8. 1ml syringe with needle
9. Disposable Syringes with needle- 2ml, 5ml, 10ml
10. Adhesive tape
11. Stethoscope
12. Alcohol/spirit swab
13. BP instrument

Optional

1. Tab. Cetirizine
2. SPO_2 Monitor

11.9 STEP WISE MANAGEMENT OF ANAPHYLACTIC SHOCK:

In the event of any anaphylaxis, follow the following procedure immediately:

1. Put patient in recovery position, if required
2. Check for airway, breathing and circulation
3. Check for pulse and BP
4. Administer adrenaline injection 1:1000 as follows:
   - 0 months to < 12 months – 0.05mg (0.05ml)
   - 12months to <6 years – 0.1mg (0.1ml)
   - 6 years to < 12 years - 0.2mg (0.2ml)
   - 12 years and above - 0.3mg -0.5mg (0.3ml-0.5ml)
   - The route is IM at the anterolateral aspect of the thigh and can be given through the clothing.

Note: Dose of the adrenaline should not be changed even in the child with obesity or wasting.

- Give oxygen by face mask, if available

- Call for professional assistance but **never leave the patient alone.**
- Call ambulance (or arrange other means of transportation) and a medical officer, if necessary, after the first injection of adrenaline, or sooner if there are sufficient people available to help you.

5. If no improvement after 5 minutes, repeat the dose for two times, if required
6. Start an IV line.
7. Stabilize the patient and admit to the health center for further management

**In the event of any Anaphylaxis, the Inj. Adrenaline is the most important drug to be given. For other AEFIs, manage as per their symptoms*

8. Inj. Promethazine 25mg(stat dose) if required
9. Inj. Ranitidine 150mg (state dose) If required
10. Give inj. Hydrocortisone 5mg/kg body weight (stat dose) If required

****Follow anaphylactic shock management protocol***

Table 12: Frequency and nature of serious vaccine reactions

Vaccine	Reaction	Interval between vaccination and onset	Number of events per million doses
BCG	Suppurative adenitis	2-6 months	100-1000
	BCG Osteitis	Up to several years	-
	Disseminated BCG infection	1-12 months	-
Hep B	Anaphylaxis	0-1 hour	1-2
MMR[a]	Febrile seizures	5-12 days	330
	Thrombocytopenia (low platelets)	60 days	30
	Anaphylaxis	0-1 hour	1
bOPV	Vaccine-Associated Paralytic Poliomyelitis	4-30 days	Up to 0.4[b]
Tetanus diphtheria (Td)	Brachial Neuritis	2-28 days	5-10
	Anaphylaxis	0-1 hour	1-6
	Sterile abscess	1-6 weeks	6-10
DTP	Persistent (>3hours) inconsolable screaming	0-48 hours	1,000-60,000
	Seizures	0-3 days	600[c]
	Hypotonic Hypo Responsive Episode (HHE)	0-24 hours	30 - 990
	Anaphylaxis/Shock	0-1 hour	1 -6
Influenza vaccine	fever, general discomfort and muscle pain	6–12 hours	12 per 100 children aged 1 – 5 years, 5 per 100 aged 6 - 15 years

a. Reactions (except anaphylaxis) do not occur if already immune (~ 90% of those receiving a second dose): children over six years are unlikely to have febrile seizures

b. Seizures are mostly febrile in origin, and the rate depends on past history, family history and age, with a much lower risk in infants under the age of 4 months

CHAPTER 12:

RECORDING, REPORTING AND USE OF VACCINATION DATA FOR ACTION

12.1 IMPORTANCE OF RECORD-KEEPING

Accurate, reliable and timely information is critical to the success of any activity. The following records are the foundation of all the health information generated at the health centers:

- MCH handbook
- Tally sheet
- Mother and child health register
- Monitoring chart (for coverage, dropout and left out)
- Monthly activity report
- Bhutan Vaccine System

The records should not be seen only as a source of information for your supervisors, but these should be viewed as important tools for self-monitoring and guidance. Store all immunization records in a safe place

12.2 MCH HANDBOOK

MCH Handbook is used to record child immunization, maternal immunization and care. This MCH handbook is important for the following reasons:

- It serves as a reminder for parents to return to the clinic on the scheduled date until the child has achieved full immunization.
- It helps the health worker to determine a child's immunization status
- It helps the health system to track coverage, dropouts and performance

To properly use the handbook:

For Beneficiaries coming for the first time:

- If the mother is not issued an MCH handbook before delivery, she should then be issued a handbook to record the child immunization at first contact (just after birth or as soon as possible). In case of twins, issue another MCH handbook to the second baby.
- Inform the mother that the handbook is an important document; as it records all the necessary information about the child; is necessary for future follow up; for growth monitoring and immunization and to record medical problems of the child.
- Record the date, month and year of all entries clearly
- Write the date of birth of the infant and not the age in months.
- If the beneficiary cannot give the exact date, try to get the exact dates using local calendar/ fairs and festivals.

If the MCH handbook is lost, issue a duplicate booklet and record previous dates

For the beneficiaries coming subsequently:

Check the child's immunization record before giving immunization and identify missed doses (if any) and complete according to the schedule.

- After every dose, ensure that the parent is informed of the next immunization date.
- Give back the booklet to mother/parent of the child following immunization
- Tell the mother that the handbook must be kept in a good condition. She must bring the handbook whenever the child is brought to the health center or out-reach clinic for immunization.

12.3 MOTHER AND CHILD REGISTER

The mother and child register should be used by the Health Worker in planning immunization sessions, recording the work during the session and for following up and tracking of the defaulters after the session. It is used before, during and after the immunization session. Follow the MCH guidebook.

12.4 TALLY SHEETS (REPORTING FORM OF IMMUNIZATION SESSION SITE)

Tally sheets are forms on which health workers make a mark every time they administer a dose of vaccine. These are used as a basis for monitoring and reporting. Use a new tally sheet for each session. The same tally sheet can be used to mark both vaccines given to children and mothers. Use separate tally sheet for separate immunization sessions

12.5 BHUTAN VACCINE SYSTEM (BVS)

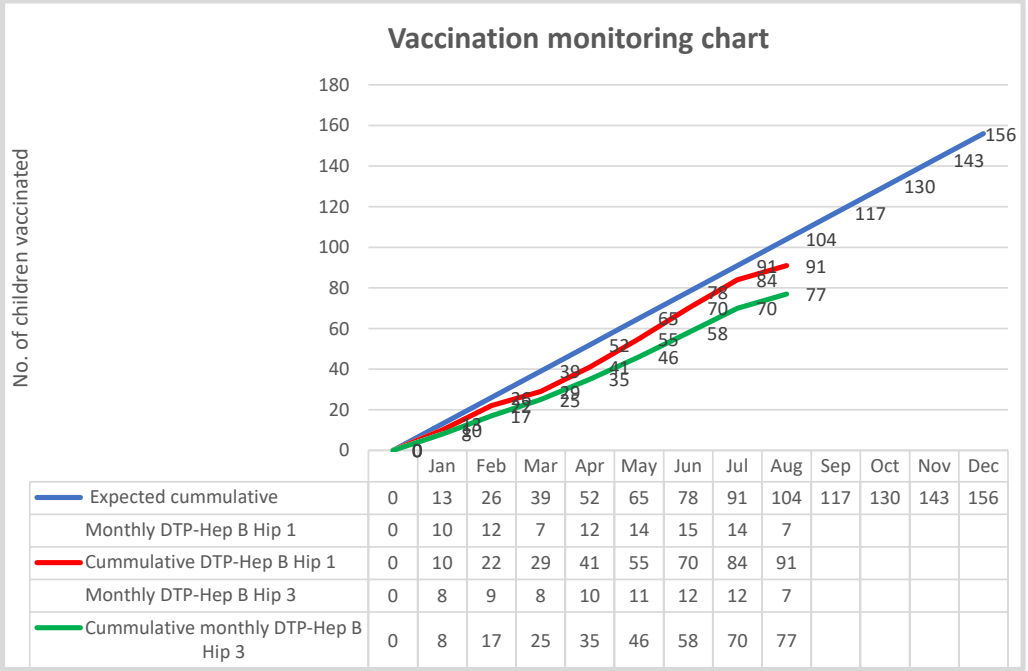
During the Covid-19 pandemic, the Ministry of Health has developed the Bhutan Vaccine System (BVS) for the nationwide Covid-19 vaccination. This is a web-based portal aimed for ensuring quality data collection, proper planning and management of Covid-19 vaccination program. The BVS is used for real time monitoring of vaccines distribution, coverage, vaccines inventory and monitoring of AEFI. The BVS has also opportunities to incorporate other EPI vaccines in the system. Currently the reporting of HPV and influenza vaccination have been incorporated into the BVS.

12.6 MONTHLY REPORT FORM

Every health facility including PHC should submit a consolidated monthly immunization report to the district using the monthly activity report form. The consolidated monthly report from districts should reach the HMIS. Data should be analyzed and reviewed at every level to improve the quality of EPI services.

12.7 VACCINATION MONITORING CHART

The monitoring chart is a tool showing the annual total target children in the catchment area to monitor vaccination coverage. At-a-glance, it provides information on target figures and trends in immunization coverage, particularly in terms of dropouts. It should include the children vaccinated from the catchment area of the home health center only. Do not include the vaccinated children who belong to other catchment areas but give feedback or report to the concerned catchment areas. It should be updated every month by the health workers after completing the immunization session. Here is an example for calculating coverage dropouts for DTP-HepB-Hib1 and DTP-HepB-Hib3. A similar chart can be prepared for other vaccines.



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Expected cummulative	0	13	26	39	52	65	78	91	104	117	130	143	156
Monthly DTP-Hep B Hip 1	0	10	12	7	12	14	15	14	7				
Cummulative DTP-Hep B Hip 1	0	10	22	29	41	55	70	84	91				
Monthly DTP-Hep B Hip 3	0	8	9	8	10	11	12	12	7				
Cummulative monthly DTP-Hep B Hip 3	0	8	17	25	35	46	58	70	77				

Figure 39: Example of vaccination monitoring chart

For example: If the yearly target for DTP-HepB-Hib1 is 156 children in a PHC with a population of 12,000, then the monthly target is 156/12 = 13 children. On the chart, the months of the year are given on the horizontal axis starting from January to December. On the vertical axis, the line is divided into 12 equal parts each representing the monthly target (in this case, 13 children). Plot above on the graph is the cumulative total of monthly DTP-HepB-Hib1. Similarly, plot DTP-HepB-Hib3 in a different color in the same column.

You can also calculate dropout rate by using the formula:

$$\frac{\textbf{(DTP-HepB-Hib1- DTP-HepB-Hib3) x100}}{\textbf{DTP-HepB-Hib1}}$$

This will give you the dropout rate in percentage.

Similar monitoring charts with dropout rates can be calculated for other antigens like bOPV1, bOPV3, BCG, MMR, etc. When Hib-vaccine is introduced as DTP-HepB-Hib vaccine, DTP-HepB-Hib1-DTP-HepB-Hib3 monitoring chart should be ideally used.

You can calculate the coverage percentage by using the formula:

$$\textbf{Percentage Coverage} = \frac{\textbf{No. of doses administered X 100}}{\textbf{Target population}}$$

12.8 VACCINE WASTAGE

The wastage rate is the percentage of vaccine doses that are wasted.

12.8.1 What are some of the reasons for vaccine wastage?

Some unused doses may have to be thrown away, for example they have passed their expiry date or lost their labels

Some doses may be spoilt for one reason or another - vaccines damaged by storage at the wrong temperature or some vials or ampoules may be broken during transport and handling

12.8.2 Acceptable vaccine wastage rates:

For liquid vaccines supplied in single or two-dose vials (e.g. PCV and pentavalent vaccines) a wastage rate of 5% is acceptable

For bOPV, a wastage rate of 10% is considered acceptable

For liquid vaccines supplied in multi-dose vials of 10 or more doses, a wastage rate of 15% is acceptable

For reconstituted vaccines, wastage rates of 50% for BCG and 25% for measles vaccines are considered acceptable

12.8.3 How to calculate the wastage rate

To calculate Wastage Rate (WR) = (No. of doses used - No. of Children vaccinated) X 100/No. of doses used.

Eg. No. of doses used = 20

No. of children vaccinated = 2

WR = (20-2)/20 X 100

WR = 18/20 X 100

WR: 90%

12.8.4 Calculating the wastage factor

The wastage factor (wf) is the number by which estimated vaccine needs is multiplied to allow for some doses being wasted.

Wastage factor (wf) = 100 ÷ (100 minus % wastage rate), where wastage rate is the number of doses wasted, expressed as a percentage.

Example

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

= 100 ÷ (100 – 30)
= 100 ÷ 70
= 1.43

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

12.9 WASTAGE FACTORS

VACCINES	NO. OF DOSES PER VIAL	WASTAGE RATE (%)	WASTAGE FACTORS
BCG	20	90	10
MMR	5	50	2
bOPV	10	40	1.67
DTP-HepB-Hib	1	5	1.05
Td	10	15	1.18
PCV	4	5	
IPV	-	-	-
DTP	10	-	-

Figure 40: How to calculate wastage factor

CHAPTER 13:
INCREASING IMMUNIZATION COVERAGE

13.1 INTRODUCTION

As a health worker you are responsible for immunization services at your PHC/hospitals. Your goal is to ensure that all children in your area are fully immunized before their first birthday. This also means that children should be protected against neonatal tetanus through the immunization of their mothers. In terms of immunization, the community where you work can typically be divided into four groups.

The four groups can be represented as:

Your aim is to expand the inner circle to cover the entire universe of eligible children. Since there are varied reasons for each of the above behavior groups, they also require different interventions.

13.2 DROPOUTS

Dropouts are children who receive one or more vaccination, but do not return for subsequent immunization. Common reasons for Dropout are:

- Parents are not told or forget when to return
- Parents are not aware of the reason of following an immunization schedule
- Parents do not know that immunization is important
- Parents develop misconceptions about immunization
- Families move to a new village or place.
- Attitude of health workers
- No proper plan of follow up
- Long distance/hard to reach areas
- Fear of AEFI

13.2.1: Why bother about dropouts?

Parents of children who "drop-out" of the immunization system are the easiest to reach and convince to return for full immunization. If you focus your efforts on reducing dropouts, you can increase coverage significantly in your area.

13.2.2: Actions to be taken to minimize dropouts:

- Immunization Schedule should be carried out in fixed date irrespective of Government holidays
- Maintain a list of children who have not completed full immunization
- Fill in correctly and completely in the MCH handbook and record in mother and child register
- Inform the parents about next date for immunization and advise them to come again on that date
- Visit dropouts before the next session to find out the reasons why they missed the session. Often, people have misconceptions about immunization. Talk to them, answer their questions and doubts and provide advice accordingly.
- Sometimes parents refrain from subsequent visits to immunization sessions due to minor AEFIs like fever, pain after the previous session, or even sometimes due to major AEFIs, which were not reported (like abscess, high fever or lymphadenitis) or due to fear of AEFI. During your visits to the dropouts, if such situations are revealed, talk to them and try to provide answers to their questions as much as possible. If some questions are beyond your knowledge, report to your supervisor.
- Take the help of your community teams (VHW, Community leaders, NGOs etc.) and share with them the list of dropouts so that they can remind parents about the importance of full immunization and inform them about the date and time of the next session.
- Provide immunization services to children from outside the area, if they are brought to the session and provide their parents with a follow-up schedule
- Develop your own solutions based on the responses of parents who have dropped out of the immunization program. For example, if most parents complete the full immunization schedule except MMR vaccine, give a talk in the village about the MMR vaccine to answer questions and clear doubts.
- IEC and IPC on immunization

13.3 MISSED OPPORTUNITIES

A missed opportunity occurs when an eligible child or a woman come to outreach site, PHC or any other health facility (along with a sibling or parent or child, who is getting a service or receiving a service) and the immunization status of the child or woman is not enquired about and immunization service is not provided in spite of eligibility.

13.3.1: How to minimize missed opportunities?

- Whenever mothers or children visit PHC/CHU or at outreach clinics for any service including growth monitoring, ask whether the child has been fully immunized. Ask to see the MCH Handbook or check the register.

- If the child is eligible for any of the vaccines, provide it, although the mother or the caregiver is not asking for it after explaining the need.
- Ask any woman 15-49 years of age coming to the PHC or ORC for any service about her Td immunization status. Check Td card, if available, and/or MCH register. If the woman is eligible for the next dose of Td, administer it to her after explaining the need.
- Put a reminder about immunization in the waiting area of the PHC, ORC or hospital
- In the hospitals reorient the doctors, nurses and other service providers about immunization schedule and remind them to refer any eligible woman or child to CHU unit of the hospital
- Keep sufficient stock of vaccines available in order to provide services to beneficiaries

13.4 EVERY OPPORTUNITY SHOULD BE USED FOR VACCINATION

13.4.1: Left-outs/Un-reached population

Left outs/un-reached population is children and women who do not utilize the immunization services or zero dose vaccination for reasons due to difficult geographical access and migration/ mobile population or other social factors.

13.4.2: Actions to be taken to reach the unreached:

- Develop a list of children who have never accessed immunization services in the area
- Look for migrant populations traveling through your service delivery area and reach out to them. Tell them about immunization and give them the date, time and place of the nearest session or get it from any health facilities nearby.
- Visit several of these households to find out the reasons why they have never accessed immunization services. Use the opportunity to clear up any doubts expressed by the families. Help them find ways to overcome any barriers that prevent them from bringing their child to the next session.
- During planning of immunization session think of setting up of Seasonal/Mobile clinic in these areas
- Take the help of the community (Community leaders, teachers, religious leaders, Village Health Workers and NGOs) to talk to parents about the importance of full immunization and give them the date and time of the next session.

13.4.3: How can you deal with difficult geographical access?

You can bring the issue to the attention of your supervisors and request them to reorganize your catchment area in order to provide immunization services to unreached populations. Sometimes, the best solution will be to visit the remote site once every two or three months and conduct at least 4 immunization sessions in a year.

13.5 USE INTERPERSONAL COMMUNICATION TO INCREASE DEMAND

As a health worker you are in direct contact with parents and caregivers. Perhaps the most important contribution you can make towards increasing demand is by being a friendly, efficient, interested person, who sincerely cares. Smile, be friendly, and reassure both parents

and children. This ensures that parents will listen to your advice, change their behavior and return for a full course of immunization for their children.

13.5.1: Tips for effective communication with parents at the facility or outreach session

- Act respectfully towards the mother/parent
- Praise parents/caregivers for bringing their children for immunization.
- Give clear information on side effects and the date for next immunization.
- Encourage them to continue bringing their child to the immunization session and bring the handbook until fully vaccinated and keep the handbook for future reference.
- Keep information simple and clear and be sure to remind the parent on the date of next vaccination.
- Encourage parents to ask questions

13.5.2: Give basic information to all parents on immunization

Besides understanding the value of immunization, parents need to know:

- When and where they should bring their child for the next immunization.
- The number of additional contacts needed for the child to complete its vaccination schedule.
- Explain common side effects that may occur after immunization.
- Discuss what they should do if side effects do occur.
- The importance of bringing the MCH Handbook each time the child comes for healthcare.

13.5.3: Use the MCH Handbook to remind parents when to return with their child

MCH Handbooks for each child are important communication tools. Educated parents can determine from the handbooks, the type of vaccine and dosage given and the due dates. For those less educated, recognizing a vaccine by how it is delivered is one way of keeping abreast of their child's schedule.

- Information on immunization is easier to understand when one vaccine at a time is discussed.
- In addition to being a healthcare provider, you are also a health educator.
- In most situations, one-to-one, interpersonal communication is the best when providing specific information.

13.6 DIFFERENT METHODS FOR GIVING INFORMATION TO PARENTS

13.6.1: Call upon other trusted sources of information

Involve formal and informal leaders and other community resource persons like the village heads, political leaders, teachers, religious leaders and village health workers in the program and then conduct immunization orientation training.

13.6.2: Identify locations to communicate with parents

Identify places where people frequently gather, such as markets, bus stops, temples and monasteries, and display information related to the session site, date, and program details.

13.6.3: Make use of community-based organizations

Build a rapport with community-based organizations and NGOs in your area. Conduct health talks on the vaccine preventable diseases, the immunization and common side effects.

13.6.4: Use schools

Teachers and students may be important players in creating awareness in the community about immunization. Visit the schools and give talks to the teachers and students about immunization programs explaining the need and schedule of immunization. Explain how they can help by bringing their own relatives, siblings or children to the immunization session.

CHAPTER 14:
SURVEILLANCE OF VACCINE PREVENTABLE DISEASES

14.1 DEFINITION OF SURVEILLANCE

An ongoing, systematic collection, analysis, and interpretation of health-related data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those responsible for prevention and control.

VPD surveillance is disease specific surveillance system and all health centers are reporting centers. AFP, measles and rubella are case based surveillance while Diphtheria, Pertussis, and Tetanus are reported as aggregate on monthly basis including zero-reporting by health centers to district health office and to VPDP. CRS and AES/JE are sentinel-based surveillance.

All suspected cases of Vaccine Preventable Diseases (Poliomyelitis, Diphtheria, Pertussis, Neonatal Tetanus, Measles/Rubella) are immediately notifiable diseases and should be reported to RCDC in NEWARS. A single lab confirmed case of Measles, Rubella and AFP should be considered as an outbreak and active case investigation should be carried within 72 hours using standard investigation norms (refer Integrated Surveillance Guideline for selected Vaccine Preventable Diseases, 2018)

14.2 GOALS OF VACCINE PREVENTABLE DISEASE SURVEILLANCE

1. Early detection and notification of suspected cases
2. Monitoring trends of VPD's over the period of time
3. Ensuring adequate and timely response to cases/outbreak notified
4. Identifying risk population for institution of appropriate prevention measures
5. Monitoring and evaluation of vaccine preventable Disease Program performance
6. Resource prioritization and mobilization for implementing preventive and control measures based on the information obtained through the surveillance
7. To determine the effectiveness and impact of Vaccination Program.

14.3 HOW TO REPORT SUSPECTED CASES OF VACCINE PREVENTABLE DISEASES

1. If any clinicians including specialists, nurses and health workers suspect any Vaccine Preventable Diseases, they should immediately report it in the NEWARS online system.
2. If the suspected case is in the PHCs/Sub-post, complete the Case Investigation Form (refer Integrated Surveillance Guideline for selected Vaccine Preventable Diseases, 2018) and send the patient to the nearest hospital for sample collection (inform the laboratory in-charge through a call and confirm).
3. If the suspected case is in the hospitals, the clinicians/health workers/nurses should complete the Case Investigation Form and direct the patient to the laboratory unit for sample collection.
4. While waiting for the report, search for similar cases in the locality and provide necessary health advice. If necessary, activate the Dzongkhag Health Rapid Response Team (DHRRT) before the arrival of the report from RCDC.

5. If the report is positive, then the DHO will activate the DHRRT immediately for active case investigation.
6. The investigation team should submit the preliminary investigation report to RCDC and VPDP.
7. Upon completion of the investigation by the DHRRT, the final report should be submitted to RCDC and VPDP.

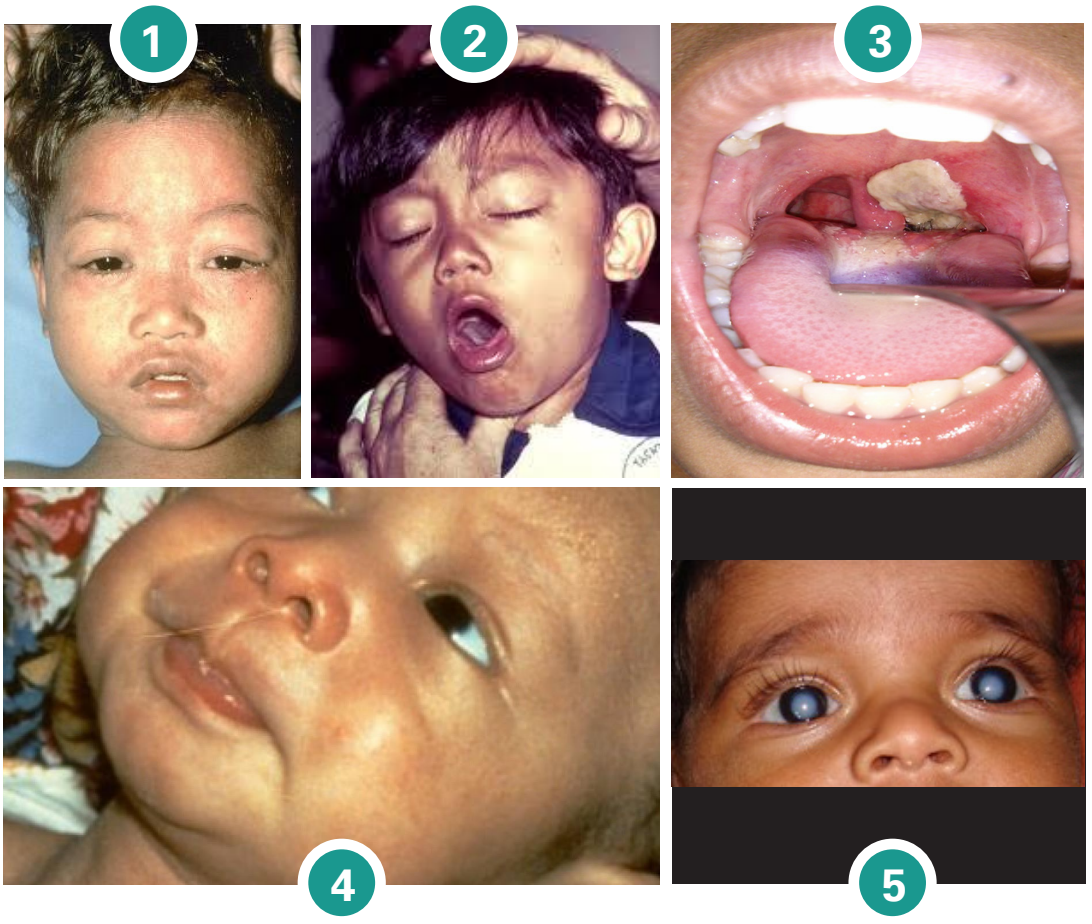


Image 1: Measles Rash
Image 2: Pertussis (Whopping Cough)
Image 3: Diptheria
Image 4: Neonatal Tetanus
Image 5: CRS

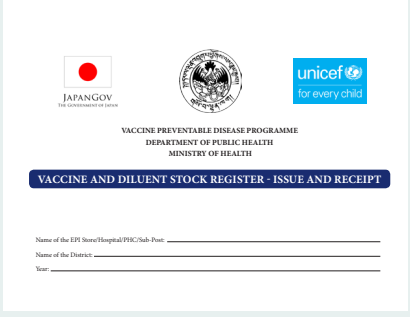
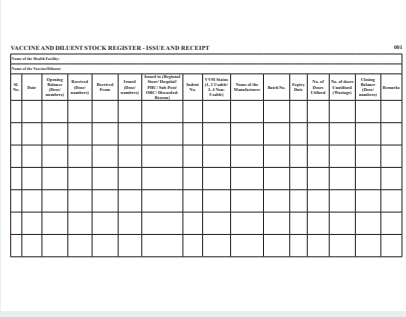
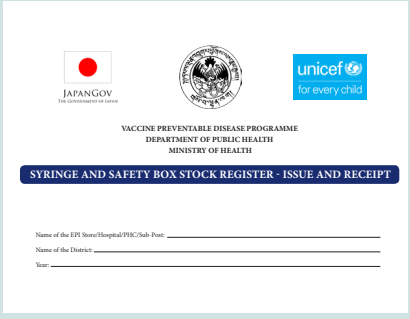
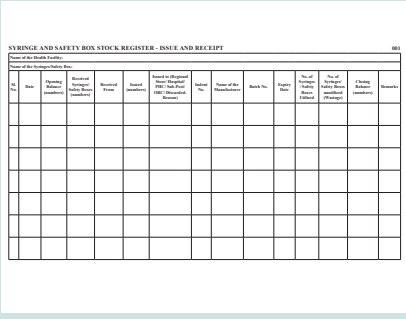
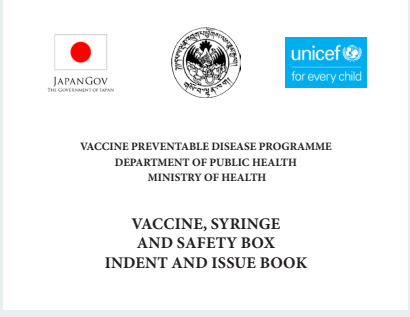
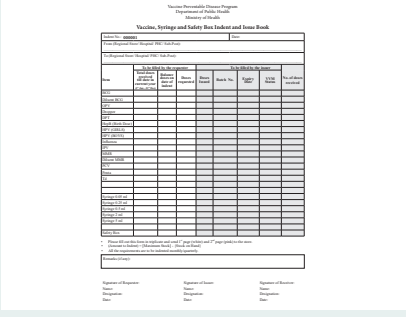
CHAPTER 15:
VACCINE AND COLD CHAIN EQUIPMENT INVENTORY, DISTRIBUTION DOCUMENTATION, AND REPORTING

15.1 DOCUMENTATION

The Department of Public Health, Ministry of Health has developed certain formats for recording and reporting of information related to UIP at all the cold chain points. These are as follows:

- Vaccine Stock Ledger
- Syringes/ Safety box stock register
- Vaccine and Logistics indent and issue book
- Vaccinator logistics diary
- Cold chain equipment – repair and maintenance logbook
- Cold chain equipment – indent and issue form
- Cold chain equipment inventory ledger
- Temperature monitoring logbook

The sample of each format is provided here:

Description	Title Page	Inner Page
Vaccine Stock Ledger		
Syringes/ Safety box stock register		
Vaccine and Logistics indent and issue book		

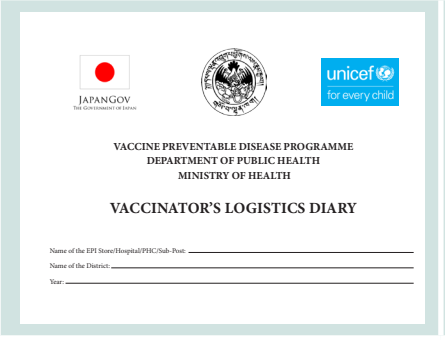
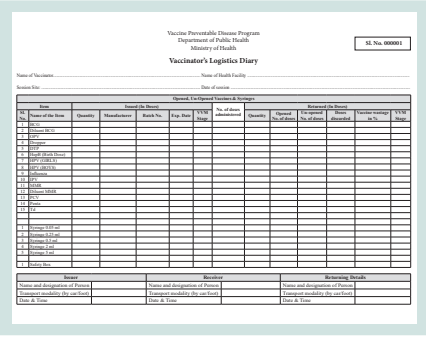
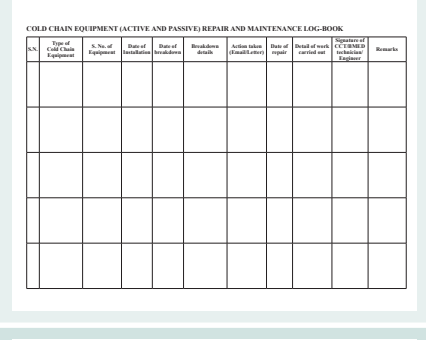
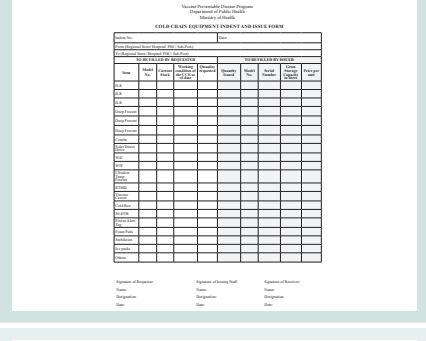
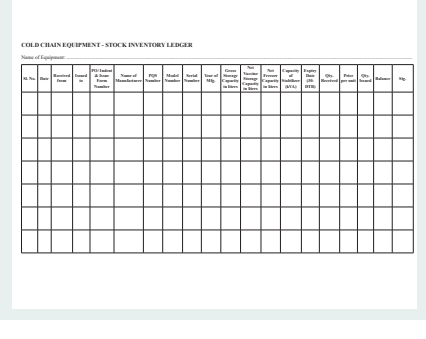
Vaccinator logistics diary		
Cold chain equipment – repair and maintenance logbook		
Cold chain equipment – indent and issue form		
Cold chain equipment inventory ledger		

Figure 41: Sample of recording formats

15.2 REPORTING

All the health facilities should report the vaccine and dry stock on monthly basis as per the below format:

Routine Vaccine Stocks																		Campaign Vaccine - move next to RI								
Report date	Country name	Select ISC Level	Stock levels	BCG	HepB	bOPV	DTP-HepB-Hib (Penta)	PCV	Rota	IPV	MCV/ MR/M MR	YF/FJ	MenA	HPV	TT/Td	DTP	Other 2 (Please write vaccine name here)	bOPV	mOPV 2	nOPV 2	tOPV	IPV	MCV/ MR	YF	MenA	TT / Td
1-Jan-23	Bhutan	Central Store	Opening Stock																							
1-Jan-23	Bhutan	Central Store	Stocks received during the month																							
1-Jan-23	Bhutan	Central Store	Stocks issued during the month																							
1-Jan-23	Bhutan	Central Store	Closed Vail Wastage																							
1-Jan-23	Bhutan	Central Store	Closing Stock - National																							
1-Jan-23	Bhutan	Central Store	Average monthly consumption / Distribution																							
1-Jan-23	Bhutan	Regional Store	Gelephu																							
1-Jan-23	Bhutan	Regional Store	Mongar																							
1-Jan-23	Bhutan	Regional Store	Thimphu																							
1-Jan-23	Bhutan	District Store	Buli Hospital																							
1-Jan-23	Bhutan	District Store	Dagapela Hospital																							
1-Jan-23	Bhutan	District Store	Damphu Hospital																							
1-Jan-23	Bhutan	District Store	Gasa																							
1-Jan-23	Bhutan	District Store	Gedu Hospital																							
1-Jan-23	Bhutan	District Store	Haa Hospital																							
1-Jan-23	Bhutan	District Store	Jomotsangkha Hospital																							
1-Jan-23	Bhutan	District Store	Lhuentse Hospital																							
1-Jan-23	Bhutan	District Store	Nganglam Hospital																							
1-Jan-23	Bhutan	District Store	Panbang Hospital																							
1-Jan-23	Bhutan	District Store	Paro Hospital																							
1-Jan-23	Bhutan	District Store	Pemagatshel Hospital																							
1-Jan-23	Bhutan	District Store	Phuntsholing Hospital																							
1-Jan-23	Bhutan	District Store	Punakha Hospital																							
1-Jan-23	Bhutan	District Store	Riserboo Hospital																							
1-Jan-23	Bhutan	District Store	Samdrupcholing Hospital																							
1-Jan-23	Bhutan	District Store	Samdrupjongkhar Hospital																							
1-Jan-23	Bhutan	District Store	Samtse Hospital																							
1-Jan-23	Bhutan	District Store	Sarpang Hospital																							
1-Jan-23	Bhutan	District Store	Trashigang Hospital																							
1-Jan-23	Bhutan	District Store	Trashiyangtse Hospital																							
1-Jan-23	Bhutan	District Store	Trongsa Hospital																							
1-Jan-23	Bhutan	District Store	Tsimalakha Hospital																							
1-Jan-23	Bhutan	District Store	Wangdicholing Hospital																							
1-Jan-23	Bhutan	District Store	Wangdue Hospital																							
1-Jan-23	Bhutan	District Store	Yebilaptsa Hospital																							

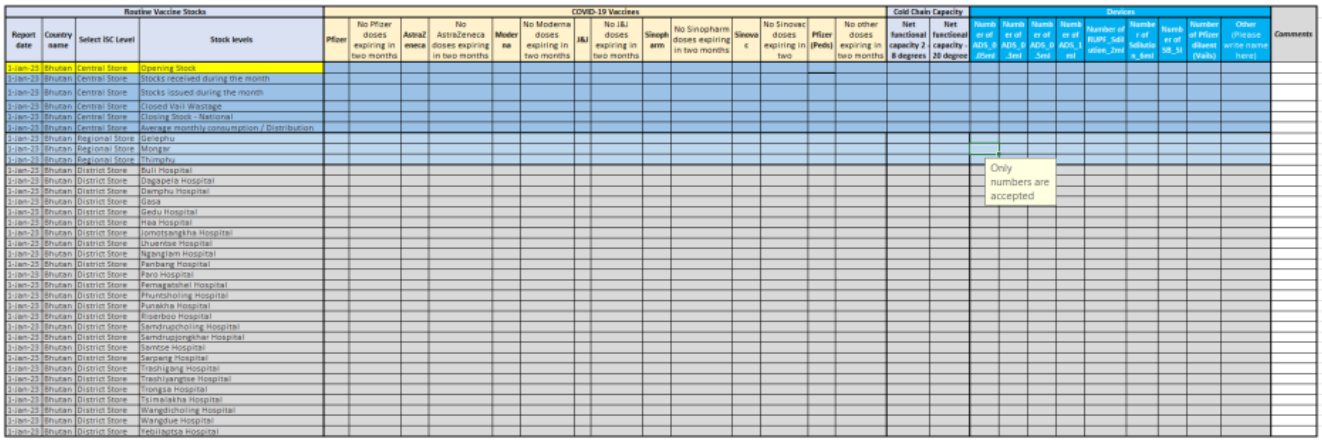


Figure 42: Vaccine and dry stock recording format

Only numerical values are accepted in this format.

For any support on stock ledgers, indent book etc., kindly contact National EPI Store, Thimphu or Regional Stores at Thimphu, Gelephu and Mongar.

Every health facility must maintain the records of 30 DTR every month on the first day of the month. Always take only one month to print from 1st to 30th or 31st in one page.

15.3 SUPPORTIVE SUPERVISION AND MONITORING:

The supportive supervision and monitoring are important; this will include observation, use of data and problem solving. The supervision and monitoring has to be performed by the Program, DHOs and EPI regional staff in their own respective health centers using standard checklist and feedback has to be provided in writing for further improvement and it should be properly documented at least 2-3 years. The supervisor should visit at least once in year and to follow up on the implementation status of previous visit recommendation. The supervision also enhances the knowledge of the health staff in their respective fields.

15.4 BHUTAN VACCINE SYSTEM (BVS)

During the Covid-19 pandemic, the Ministry of Health has developed the Bhutan Vaccine System (BVS) for the nationwide Covid-19 vaccination. This is a web-based portal aimed for ensuring quality data collection, proper planning and management of Covid-19 vaccination program. The BVS is used for real time monitoring of vaccines distribution, coverage, vaccines inventory and monitoring of AEFI. The BVS has also opportunities to incorporate other EPI vaccines in the system. Currently the reporting of HPV and influenza vaccination have been incorporated into the BVS.

15.5 WORK PLAN/BUDGET

The annual work plan should be developed as per the goal and program strategies. This will guide the program for allocation of resources to achieve the plan. The work plan should have a budget allocation for each activity. The implementation status of budget/expenditure should be monitored. In the hospital/PHC if the budget is managed by the District level atleast essential activities budget should be included in the hospital/PHC example annual budget for conducting out-reach-clinic (ORC) etc.

15.6 INDENT

Vaccines should be indented timely by the staff responsible to ensure that vaccines are available for all immunization sessions. Before the indent, stock taking should be conducted for all vaccines and consumables.

15.6.1 Schedule for vaccine indent

Table 13: Time schedule for vaccnie indenting

Name of vaccine store level	Frequency/Dates	Mode of Transport
For collection of vaccines by Regional EPI Stores from National EPI Store	Bi-annually January, and July (preferred first week of the month)	Refrigerated Van
Vaccine distribution by regional EPI stores to District Hospitals	January, April, July and October (preferred second week of the month)	Refrigerated Van
Vaccine distribution by District Hospitals to PHCs	preferred first week of every month	Cold Box and/or vaccine Carrier
For remote and difficult to access PHCs regular indent placed	Once in two months	Cold Box and/or vaccine Carrier or in emergency Chopper Services

15.5.2 Amount to Indent is [Maximum stock] – [Current Stock]

- Fill up the Indent/Issue Form in triplicate and send 1st and 2nd page to the vaccine provider.
- Fill the total doses received in current year (1st January – 31st December)
- Fill balance doses in your stock on the day of indent

- As per the target population, request the balance number of doses as required
- When indenting a vaccine, all other vaccines are to be indented up to maximum.
- Whenever stock of any vaccine goes below minimum, urgent indent is placed immediately.
- Consumables are indented in the same procedure.

15.6.3: Receipt

1. When you receive the vaccine, confirm the type, amount and expiry date of the vaccine, referring Indent/Issue Form, as well as check VVM, freeze tag/alert status and temperature and record it.
2. After checking the vaccines, put the vaccine inside the refrigerator according to "First Expiry, First Out (FEFO)."
3. Update Stock Ledger.

15.6.4: Issue

- Vaccines should be indented within the prescribed period as recommended in table #---)
- Issuing staff checks the indent;
  - All necessary columns are filled out
  - Amount indented is reasonable
  - All vaccines are indented
- Considering the current stock, the staff decides the amount of vaccine to be issued.
- Following FEFO, the shortest expiry vaccine is issued.
- To far remote PHCs, longer expiry vaccines should be issued.
- Short expiry vaccines can be issued only to nearby immunization sites (PHCs or hospitals) with prior information.
- Issuing staff fills up "quantity issued, Expiry date, batch #, VVM status in Indent/Issue Form in duplicate,
- The 3rd page of the form is returned to the requester with the indented vaccines
- Issuing staff ensures the vaccines are properly packed.
- Issuing staff updates stock register

15.6.5: Transportation

During the transportation, the vaccine carrier or cold box should not be kept under direct sunlight. Vaccines are transported from National EPI Store to Regional EPI store bi-annual, and from regional EPI store to district hospitals quarterly by refrigerated vans. From the district hospitals to other hospitals and PHCs and sub-posts monthly or hard-to-reach PHCs and sub-posts once in two months.

15.7 MAINTAINING STOCK REGISTER AND STOCK-TAKING

- Stock register is a record of stock in which all transactions of vaccine and consumables are recorded.
- Whenever vaccines are taken out or put into the stock, update the records promptly.
- Stock-taking should be conducted at least once a month for vaccines and consumables.
- For vaccines, take out the stock of vaccine from the refrigerator and count physically by type and by expiry date, with checking VVM. Then compare the figure to its record.
- If there is discrepancy between physical quantity and its record at stock–taking, staff updates the figure of the physical quantity.

15.8 VERIFICATION OF IMMUNIZATION STATUS

The respective DHOs, Thromdey Health Officers, Hospitals and PHC in charge should coordinate with the respective DEOs, and School principal in every academic year to verify the immunization status during the admission of children at primary level both in government and private schools, as per the format. The children who are not fully immunized should be vaccinated accordingly. The report should be submitted to DHOs/Thromdey Health Officers and further DHOs and Thromde Health Officers will submit the school wise report to VPD Program, DoPH by 20th March annually.

Format for verification of Immunization status during school Admission at Primary Level is as below:

Name of Dzongkhag					
Name of School/ Government/Private					
Date of Verification					
		Fully Immunized		If no, which vaccine	MCH Handbook No.
Sl. No.	Name	Yes	No		
Definition of Fully Immunized					
1. One dose of BCG 2. Three doses of OPV 3. Three doses of Pentavalent 4. One doses of Measles Rubella (MR or Measles Rubella Mumps (MMR) 5. Three doses of PCV from 2025 onwards					

ANNEXURES

ANNEXURE I: FORMAT FOR INVESTIGATION OF DEATHS FOLLOWING IMMUNIZATION

Name of child: ..... Date of death: .....
Name of investigator: ..... Contact no: .....
Hospital Registration No: .....

1). Investigation of sequelae leading to death and past history

Identification and related basic information	
Name, address and contact number of the parent	
Date of birth	
Age on the date of immunization	
Sex	
Birth weight	
Weight on the date of immunization	
Responsible vaccine (if known)	
Date and time of vaccination	
Time interval between immunization and death	

2). Clinical description of the event as described by the mother

2.1 Assessment of the child before the immunization

- Feeding .....
- Activity .....
- Features of any acute illness prior to immunization (specify) .....
  .....
- Any medication in last 24 hours prior to immunization. Yes or No. If yes , please specify

Drug	Dose	Time of last dose

3). Assessment of the child during immunization

- Incriminated Vaccine ..... Date and time of vaccination .....
- Medications given with vaccination .....
- Description of significant adverse event noted by mother .....
  .....

3.1. Measures taken by mother / guardian to overcome the adverse event

1. Treatment at another health centre .....
2. When was the child taken to the hospital? .....
3. Diagnosis made at this health centre .....
4. Medicines prescribed, dose frequency and time of last dose .....

.....

5. Traditional medicine, specify (if applicable) .....
6. Any other measures/treatments .....
7. Outcome of the above measures on the observed adverse event .....
.....

3.2. Was the child hospitalized? YES/NO

If yes, give details as per mother/attendant .....

.....

3.3 Description of final event as per mother .....

.....

3.4 Was the child sleeping at the time of death? If yes, give details. Sleeping place, sleeping position, other people sleeping in the same place .....

.....

4). Antenatal and birth history

- Antenatal complications:
- Place of birth:
- Mode of deliver:
- APGAR score:
- Significant finding in neonatal examination:

5) Developmental history .....

.....

6) Past medical history .....

.....

7). Congenital or acquired disease for which the child is on treatment .....

.....

8). Previous immunization

Vaccine	Date	Batch	Adverse event

9). Family and social history

- Smoking and alcohol use:
- Neonatal or infant death in family:
- Details of siblings:
- Medical history of siblings:

10). Details of management of the case at the hospital

- Name of the hospital:
- Date and time of admission:
- Name of doctor taking care of the patient:

Clinical description and clinical findings as per admitting doctor

.....

.....

Details of subsequent management as per records

.....

.....

Investigations

	Investigation	Interpretation
Hematological		
Biochemistry		
Radiological		
Others		

Management

- Pharmacological:
- Non-pharmacological:
- Probable diagnosis:

ANNEX II

Vaccine Preventable Disease Program
Department of Public Health
Ministry of Health

ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) Reporting Forms

<table>
<tr><td colspan="7">Patient Information: Name: Date of birth: Sex:</td></tr>
<tr><td colspan="7">Name and Address of the Parent/Guardian : Mobile No:</td></tr>
<tr><td colspan="7">Information on the vaccine</td></tr>
<tr><td>Name of Vaccine Received</td><td>Date of vaccination</td><td>Time of vaccination</td><td>Dose (0,1st, 2nd, 3rd, 4th)</td><td>Batch/Lot Number</td><td>Expiry date</td><td>VVM Status (I, II, III, IV)</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="7">Diluent Used: ☐ No ☐ if ‘yes’, Diluent batch lot number Expiry date of Diluent :</td></tr>
<tr><td colspan="7">Place of vaccination: _____</td></tr>
<tr><td colspan="7">Adverse Events: Date of AEFI reported: _____ Time of AEFI started: _____</td></tr>
<tr><td colspan="7">Adverse event(s):
☐ Severe local reaction ☐ Seizures ☐ Abscess ☐ Sepsis
☐ Encephalopathy ☐ Toxic Shock Syndrome ☐ Thrombocytopenia ☐ Anaphylaxis
☐ Fever ≥38°C ☐ Others (specify)……</td></tr>
<tr><td colspan="7">Describe AEFI (Signs and Symptoms)</td></tr>
<tr><td colspan="7">Date and Time referring to higher center</td></tr>
<tr><td colspan="2">Medical History/other</td><td colspan="5">Outcome:</td></tr>
<tr><td colspan="2" rowspan="2"></td><td colspan="5">Hospitalized: Yes /No if ‘Yes’, Hospital Registration No: _____
Still in the hospital ☐ Discharged ☐</td></tr>
<tr><td colspan="5">Outcome Recovered completely ☐ Partially recovered ☐
Death ☐</td></tr>
<tr><td colspan="7">Name of Health Centres:</td></tr>
<tr><td colspan="7">Date of the notification: Name of Health Centers:
Name and Signature of the notifying officer:
Mobile No:</td></tr>
</table>

ANNEX III: AEFI CASE INVESTIGATION FORM

A. PATIENT INFROMATION

A.1. Name of the patient: Hospital registration No.:

A.2. Address:

A.3 Date of birth: Gender: Male/Female

B1. PRESENT ILLNESS:

B1. What is the AEFI reported?	B4. Was patient admitted to hospital?	B7. Outcome of the case
.....	Yes ☐ . No. ☐ Unknown ☐	Recovered ☐ Died ☐
B2. Date of onset	B5. If yes, date of admission:	Unknown ☐
.....	.....	B8. Date of discharge, Refer or death: .....
B3. Where was the patient treated?	B6. Name of the health facility	B9. If referred name of hospital .....
.....	.....	

C. CLINICAL DATA

C1. Symptoms and signs	C2. Date of onset	C3. Laboratory investigation	C4. Treatment
☐ Fever ☐ Inconsolable cry ☐ Painful swelling at the injection site ☐ Enlarged tender axillary lymph nodes ☐ Convulsions ☐ Altered sensorium Any other symptoms and signs:	....		

D. PAST MEDICAL AND FAMILY HISTORY

		Yes	No	Unknown	if yes (specify) No and Place
D1.	Existing congenital disease	☐	☐	☐	……..…
D2.	Persisting underlying disease	☐	☐	☐	……..……
D3.	Previous history of significant illness	☐	☐	☐	……..……
D4.	Family history of similar event	☐	☐	☐	……
D5.	Previous history of similar event	☐	☐	☐	……

E. OTHER RELEVANT HISTORY

		Yes	No	Specify
E1	Delays in taking patient to the hospital	☐	☐	.....
E2	Delays in transferring patient to the hospital for specialized hospital	☐	☐	.....
E3	Delays in receiving treatment	☐	☐	.....

F. IMMUNIZATION HISTORY

F1. Date of immunization: Time of immunization:

F2. Place of immunization: Hospital/PHC/ORC

F3. Type of vaccine (please √ appropriate box)	F4. Dose	F5. Expiry Date	F6. Batch No.	F7. Manufacture	F8. Diluents Batch No. and Expiry date
☐BCG ☐bOPV ☐Penta ☐MMR ☐DTP ☐PCV ☐IPV ☐Td ☐Hep.B ☐ Others	☐ 1st ☐ 2nd ☐ 3rd ☐ 4th	.....			

G. INFORMATION ON COLD CHAIN /STORAGE / VACCINATION TECHNIQUE

G1. Vaccines and diluents stored in the:	**G2. Vaccine transported in a:**	**G3. Status of the data logger for 1 month period prior to the date of the immunization:**
☐ Refrigerator ☐Others (Specify)	☐ Vaccine carrier ☐ Cold box ☐ Others (specify)	Maximum temperature ..... Minimum temperature ..... Duration of temperature excursion .....

At the time of the observation of the immunization	Satisfactory	Unsatisfactory	Not observed
G5. Maintenance of cold chain 1. Packing of vaccine 2. Maintenance of cold chain in unopened/opened vials during immunization G6. Vaccination procedure 1. Reconstitution 2. Drawing of vaccine 3. Injection technique	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐
G7. Types of Syringes used:			

H. AEFI IN THE CLINIC CENTRE / FIELD

Any history of similar events reported among those vaccinated	No	Yes	Unknown
H1. At the same clinic session	☐	☐	☐
H2. Using same vaccine at previous clinic session at the same clinic center	☐	☐	☐
H3. Using same vaccine at the other clinic centre	☐	☐	☐
H4. History of similar events reported among those unimmunized	☐	☐	☐

I. CONCLUSION AS TO THE CAUSE OF AEFI

Immunization errors related reaction Event caused by an error in vaccine preparation handling or administration	Vaccine product related reaction Event caused by the inherent properties of the vaccine	Vaccine quality defect of the related reaction Event caused due to quality defects of the vaccine product	Immunization anxiety related reaction Event from anxiety about or pain from the injection itself rather than the vaccine	Coincidental events Event that happens after immunization but not caused by the vaccine- a chance association	Unknown
If possible, describe the cause in below given area					

Others information: Type of delivery: Birth weight during delivery:
Place of delivery:
Nos. of children immunized same day with same vaccine:

Corrective action taken .....

Remarks .....

Signature of the investigation team (member 1) .....
Name .....
Designation .....
Date .....

Signature of the investigation team (member 2).....
Name .....
Designation .....
Date .....

Signature of the investigation team (member 3).....
Name .....
Designation .....
Date .....

Signature of the investigation team (Team leader).....
Name .....
Designation .....
Date .....

REFERENCES:

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