Immunization Handbook for Health Care Professionals

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National Program on Immunization
Health Protection Agency
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AD</td>
<td>Auto Disable (syringe)</td>
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<tr>
<td>AEFI</td>
<td>Adverse events following immunization</td>
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<tr>
<td>AFP</td>
<td>Acute flaccid paralysis</td>
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<tr>
<td>AIDS</td>
<td>Acquired immunodeficiency syndrome</td>
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<tr>
<td>BCG</td>
<td>Bacilli Calmette Guerin</td>
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<td>CBA</td>
<td>Child bearing age</td>
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<tr>
<td>CHW</td>
<td>Community health worker</td>
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<tr>
<td>DPT</td>
<td>Diphtheria- Pertussis- Tetanus</td>
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<tr>
<td>DPT +Hep+B+Hib</td>
<td>A combination vaccine containing DTP, Hepatitis B vaccine and haemophilus Influenzae Type b vaccine</td>
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<tr>
<td>DSFP</td>
<td>Disease surveillance focal person</td>
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<td>DT</td>
<td>Diphtheria-tetanus</td>
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<td>EPI</td>
<td>Expanded Programme on Immunization</td>
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<td>FHW</td>
<td>Family health worker</td>
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<td>HepB</td>
<td>Hepatitis B</td>
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<td>Hib</td>
<td>Haemophilus Influenzae type b</td>
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<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<td>IU</td>
<td>International unit</td>
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<td>LSO</td>
<td>Local surveillance officer</td>
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<td>MMR</td>
<td>Measles-mumps-rubella</td>
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<td>MOH</td>
<td>Ministry of health</td>
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<td>MO</td>
<td>Medical Officer</td>
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<td>MR</td>
<td>Measles-rubella</td>
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<td>NGO</td>
<td>Non Governmental Organization</td>
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<td>NID</td>
<td>National Immunization Day</td>
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<td>NT</td>
<td>Neonatal tetanus</td>
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<td>OPD</td>
<td>Out patient department</td>
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<tr>
<td>OPV, IPV</td>
<td>Oral polio vaccine, Inactivated Polio Vaccine</td>
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<td>ORI</td>
<td>Out break response immunization</td>
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<tr>
<td>Penta</td>
<td>Pantavalent Vaccine (DTP=HepB+Hib)</td>
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<tr>
<td>RED</td>
<td>Reaching Every District</td>
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<td>SIAs</td>
<td>Supplementary immunization activities</td>
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<td>Sub National Immunization Day</td>
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<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>TT / Td</td>
<td>Tetanus Toxoid / Tetanus diphtheria</td>
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<tr>
<td>UNICEF</td>
<td>United Nation Children's Fund</td>
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<tr>
<td>VAPP</td>
<td>Vaccine Associated Paralytic Poliomyelitis</td>
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<td>VVM</td>
<td>Vaccine vial monitor</td>
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<tr>
<td>VPDs</td>
<td>Vaccine Preventable Diseases</td>
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<td>WHO</td>
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<td>YF</td>
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Chapter 1

1. Immunization Programme in Maldives

Introduction
The Republic of Maldives is highly committed to provide basic health services to all with
special emphasis on children and women. The National Program on Immunization and Travel
Health (NPITH) is considered a success story in Maldives because of its remarkable progress
made during the past 25 years. The NPITH is a universal programme and its goal is to protect the
life of thousands of children from premature death and disability from vaccine preventable
infectious diseases.

The NPITH was launched in 1976 as the National Expanded Program on Immunization (EPI)
with financial support from Danish Scout Aid DENMARK and technical support from WHO.
Accordingly, in 1976 government took the initiatives for implementing vaccination program to
combat six vaccine preventable diseases - Diphtheria, Whooping cough, Tetanus, Poliomyelitis,
Tuberculosis and Measles.

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

Thereafter, Hepatitis B vaccine has been introduced in 1993, MR vaccine in 2006 and followed by
MMR vaccine in 2007 in EPI programme. In view of enhancing the injection safety AD syringes
were introduced into the programme from 1997.

The Republic of Maldives has decided to incorporate Haemophilus Influenzae type- b vaccine
in National EPI in 2012 in addition to current 9 infectious diseases. And this has been included
in the Pentavalent Vaccine which was introduced in 2013.

Maldives Technical Advisory Group on Immunization (MTAGI) in its meeting in January 2014
decided to introduce IPV vaccine into Routine Immunization Schedule in Maldives align with the
global and regional recommendations. Therefore, following the recommendations, government of
Maldives introduced one dose of IPV into routine immunization schedule on April 2015. The
global switch from trivalent oral polio vaccine (topv), containing antigens for poliovirus types 1,2,
and 3 to bivalent oral polio vaccine (bopv), containing only types 1 and 3, is expected to occur in
April 2016 in Phase manner.
1.1. Goals of Immunization Programme in Maldives
National Immunization Program aims to reduce mortality and morbidity by protecting children from the vaccine preventable diseases.

1.2. Target Population
- 0-18 Months Children
- 15-49 Years Women

1.3. Vaccine Preventable Diseases
1) Tuberculosis
2) Diphtheria
3) Pertussis (Whopping Cough)
4) Tetanus
5) Poliomyelitis
6) Measles
7) Hepatitis-B
8) Mumps
9) Rubella
10) Haemophilus Influenzae type-b

1.4. Objectives of National Program on Immunization (EPI)

a) Objective of Immunization Achievement:
   - Strengthen routine immunization services to achieve 100% coverage for all EPI antigens at National level.
   - Target to achieve 100% TT coverage among women of child bearing age group

b) Objectives of Disease Reduction:
   - Maintain Polio free status
   - Sustain MNT elimination Status
   - Achieve and sustain Measles elimination status
   - Achieve Rubella elimination status

c) Strategies for Achieving Objectives:
   - Development of EPI Micro-plan in all Atolls and its implementation
     - Organization of EPI sessions maintaining quality
     - Planning for supportive supervision
     - Involvement of Community to implement EPI work plan
     - Planning and Implementation based on monitoring and data analysis
     - Planning and management for utilization of human and other resources
   - Safe Injection and sharp waste disposal, expired and unused vaccine disposal to be introduced such as incinerators
   - Management of Adverse Events Following Immunization (AEFI)
   - Disease Surveillance
   - Special Immunization Activities like SNID / NID, Measles Campaign etc as and when necessary.
2. Vaccine Preventable Diseases in National Programme on Immunization and Travel Health

The national EPI programme of Maldives preventing diseases - Diphtheria, Whooping cough, Tetanus, Haemophilus Influenzae type b, Hepatitis-B, Poliomyelitis, Tuberculosis, Measles, Mumps and Rubella by providing immunization to all children and TT for women of childbearing age. These diseases are infectious and can be prevented by immunization. The children below one year of age have more chance of getting infection and risk of death from these diseases.

The burden of the Haemophilus Influenzae type b (Hib) diseases is well recognized in Maldives. The bacterium Haemophilus Influenzae type b (Hib) is an important cause of bacterial meningitis and severe pneumonia in infants and young children.

The disease burden is highest among those aged between 4 to 18 months. A study in 2003 showed that the annual incidence of Hib meningitis is estimated at 13-27 and pneumonia is 4-8 per 100,000 under 5 years children and death due to Hib is about 3-6. (Ref: Dr. Fiona – Hib Disease burden study).

2.1. Childhood Tuberculosis

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

2.1.2. Mode of Transmission
Infection with *M. tuberculosis* usually results from inhalation into the lungs of infected droplets produced by someone who has pulmonary TB and who is coughing. The source of infection of most children is an infectious adult in their close environment (usually the household).

2.1.3. Sign/Symptom
In most cases, children with symptomatic TB develop chronic symptoms. The commonest are:

1. Moderate fever and persistent cough
2. Night sweat
3. Reduced appetite and fatigue
4. Non-painful enlarged cervical and axillary lymphadenopathy with fistula formation
5. Gradual weight loss
6. In case of bone infection -non-Painful joint swelling and difficult to move
7. In case of Vertebrae infection –painful swelling and bending

*Pic: A Case of Tuberculosis*
2.1.4. Complications
Tuberculosis may affect any part of the body and if untreated miliary Tuberculosis and TB meningitis may lead to death.

2.1.5. Prevention
One dose of BCG vaccine just after birth protects children against invasive Tuberculosis.

2.2. Diphtheria

2.2.1. What is diphtheria?
Diphtheria is a potentially acute disease caused by Corynebacterium Diphtheriae. The bacteria produces toxin that may cause obstructive pseudo-membrane in the upper respiratory tract or damage to myocardium or other body tissues or organ. Diphtheria affects people of all ages but most common in children under 15 years.

2.2.2. How Diphtheria Spreads
Diphtheria is transmitted from infected to susceptible individuals through droplets infection (sneezing & cough). The bacteria are also transmitted from person to person through close physical contact and contaminated usable articles like toys, towel of infected persons.

2.2.3. Sign/symptom

1-3 Days
When diphtheria affects the throat and tonsils early signs and symptoms are
1. Weakness and tiredness
2. Sore throat, pharyngitis
3. Loss of appetite and
4. Moderate Fever, cough and coryza
5. After two or three days typical asymmetric grayish- white pseudo-membranes gradually form in the throat or tonsils. Contaminated skin lesions may result in cutaneous Diphtheria.

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

2.2.4. Complications
Diphtheria can lead to potentially life-threatening complications: It affects respiratory tract and cause serious breathing difficulties. The bacteria can infects heart muscle and cause myocarditis and also affects the nervous system which leads to death.

2.2.5. Prevention
Three doses of Pentavalent vaccine protect children from Diphtheria. Pentavalent vaccines are conjugate liquid vaccines in combination with five vaccines DTP, Hepatitis B and Hib vaccine. This vaccine is included in national immunization programme as routine vaccine.
2.3. Pertussis

2.3.1. What is Pertussis?
Pertussis or whooping cough is a disease of respiratory tract caused by the bacterium Bordetella Pertussis. The germ usually lives in the mouth, nose and throat. The disease is common in un-immunized children and most dangerous in children aged less than one year.

2.3.2. Mode of Transmission
Pertussis is transmitted from infected to susceptible individuals through droplets. The virus is also by direct contact with the nasal and throat secretions of an infected person or by indirect contact with freshly contaminated articles.

2.3.3. Sign/symptoms

1. Fever
2. Common cold with runny nose
3. Watery eyes
4. Sneezing
5. A mild cough

2nd week
1. Cough worsen
2. Child has numerous bouts of rapid coughing and at the end of bouts the child takes in air with a high pitched whoop. The child may turn blue because of lack of oxygen.
3. Vomiting often follow the coughing attacks.

3rd - 6th Week
1. Recovery from Pertussis happens slowly. The cough gradually becomes less.

2.3.4. Complication
Pertussis can cause serious and sometimes life-threatening complications in infants and young children, especially those who are not fully vaccinated. More commonly:-
1. Pneumonia
2. Convulsions
3. Apnea (slow or stopped breathing)
4. Encephalopathy (Disease of brain)

---

2.4. Tetanus

2.4.1. What is tetanus?
Maternal and Neonatal tetanus (NT) is a non-communicable, fatal disease caused by the spore-forming bacterium, Clostridium tetani. C. tetani spores (the dormant form of the organism) are found in soil of warm and moist areas and in animal and human feces. Neonatal tetanus is a form of generalized tetanus that occurs in newborn. Maternal tetanus is consequence of un-cleaned delivery or abortion practices and neo-natal tetanus occurs when un-clean instruments are used to cut the umbilical cord or when contaminated materials are used to cover umbilical stamp.
2.4.2. Mode of Transmission
*C. tetani* usually enters the body through a wound and in neonate through unhealed umbilical stump, particularly when the stump is cut with an unsterile instrument.

2.4.3. Clinical Symptoms

**Neonatal Tetanus:**
Neo-natal tetanus is an illness occurring in a child in the first 2 days of life and

1. who, between 3 - 28 days of life, cannot suck normally and
2. becomes stiff or has spasms (i.e. jerking of the muscles)
3. spasm of the jaw muscles, afterwards, the baby develops stiffness of the neck and then the entire body
4. contraction of the spinal muscles causing the baby to arch its back

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

2.4.5. Complications
The baby’s breathing becomes difficult and spasms and convulsive fits become more frequent, usually resulting in death.

2.4.6. Prevention
Neonatal tetanus can be prevented by ensuring clean delivery practices and clean care of the umbilical stump after birth and by immunizing mothers with tetanus toxoid (TT) vaccine before or during pregnancy.

2.5. Poliomyelitis

2.5.1. What is poliomyelitis?
Polio is highly communicable disease caused by poliovirus infection of the anterior horn cells of the spinal cord. The polioviruses are three related RNA enteroviruses: type 1, 2, and 3 and all three types cause paralysis.

2.5.2. Mode of Transmission
Transmission is primarily person-to-person via the fecal-oral route: poliovirus multiplies in the intestines and is spread through the feces. The virus spreads rapidly to non-immune persons; transmission is usually widespread by the time of paralysis onset.
2.5.3. Sign/Symptom

Three symptoms are observed with this form of poliovirus infection:

1. Upper respiratory tract infection (sore throat and fever),
2. Gastrointestinal disturbances (nausea, vomiting, abdominal pain, constipation or rarely diarrhoea) and
3. Influenza like illness. These syndromes are indistinguishable from other viral illnesses.

In 1%–2% of polio infections symptoms of stiffness of the neck, back and/or legs occur usually following several days after a prodrome similar to that of minor illness.

Less than 1% of all poliovirus infections result in flaccid type paralysis mainly in lower limbs which is asymmetric and sensation remain intact. Muscle spasm occurs in the affected limb and as a result the child feels pain and cannot stand. The affected limb gradually become weak and paralysis may be permanent.

2.5.4. Complications

The paralysis of the affected limb gradually turns to permanent disability if untreated. In case of lungs, heart and nervous system infection the child may die.

2.5.5. Prevention

Oral Polio Vaccine (OPV) protects children from poliomyelitis. Three OPV doses given at 2, 4, 6 months and 1 dose of IPV at 6months with last dose of OPV.

2.6. Hepatitis B

2.6.1. What is Hepatitis B?

Hepatitis B is disease caused by hepatitis B virus which affects the liver. People infected by this virus usually recover but some continue to carry the virus for many years and can spread the disease to others.

2.6.2. Mode of Transmission

Currently, there are four recognized modes of transmission:

1. Hep B virus is most commonly spreads from infected mother to child at birth (perinatal)
2. Sexual transmission and by parenteral – (blood to blood) exposure to unsafe blood transmission, use of contaminated needles, especially among injecting drug users.

2.6.3. Sign/symptom

The acute form of the disease often resolves spontaneously after a 4-8 week illness. Most patients recover without significant consequences and without recurrence. Young children rarely develop acute clinical disease, but many of those infected in the early age and become chronic carriers. The initial symptoms are with the appearance of dark urine followed by pale stools and yellowish discoloration of the mucous membranes, conjunctivae, sclera, and skin. In patients with clinical illness, the onset is usually insidious with:
1. Tiredness, anorexia
2. Vague abdominal discomfort, nausea and vomiting
3. Sometimes arthralgias and rash,
4. Often progressing to jaundice.
5. Fever may be absent or mild.

It is important to mention here that persons infected with any hepatitis virus manifest Jaundice. Hepatitis B vaccine only protects from Hepatitis-B infection.

2.6.4. Complications
Many infected children become chronic carriers. Therefore, most carriers are contagious. The chronic Hepatitis disease which leads to cirrhosis of liver and/or hepatocellular carcinoma.

2.6.5. Prevention
Hepatitis B vaccine at birth and with Pentavalent vaccine at 2, 4,6months.

2.7. Measles

2.7.1. What is Measles?
Measles virus is highly infectious and infects all unvaccinated individuals rapidly. Measles occurs only in humans. It kills more children than any other vaccine preventable diseases in the world. Measles sometimes occur as epidemics. In conditions of crowding and poverty where large numbers of non-immunized people are living in close contact the stage is set for measles epidemics.

2.7.2. How Measles Spreads
The virus is transmitted easily by respiratory droplets (sneezing, coughing) or by direct contact with the nasal and throat secretions of an infected person.

2.7.3. Sign/Symptom
1-3 Days
1. High fever,
2. cough
3. coryza
4. Conjunctivitis

4 days
1. Low grade fever
2. Maculopapular rash spreads from the face and neck to the trunk and extremities
3. Bluish-white Koplik’s spots, which are pathognomonic of Measles, may be seen in the oral mucosa.

3-4 days after eruption of rash:
Rash fading after about 3 days, becomes blackish and desquamated and normally improve by the third day of rash, and are full recovery occurs 7–10 days from the onset of disease.
### Criteria for Diagnosing Measles

Any person with:
Fever and Maculopapular (i.e. non-vesicular) rash and at least one of the following: Cough, coryza (i.e., runny nose) or conjunctivitis (i.e. red eyes)

### 2.7.4. Complications

Most persons recover from Measles without sequelae. Among children less than 5 years of age, relatively common complications of Measles include otitis media (5–15%), laryngotracheobronchitis and pneumonia (5–10%). In developing countries persistent diarrhoea with protein-losing enteropathy may ensue, particularly in young infants. Post infectious Measles encephalitis occurs in about 1/1000 cases. Measles occurring in vitamin A deficiency has a high mortality.

### 2.7.5. Prevention of the disease and its complications

One dose of Measles vaccine with another dose of MMR protects children from getting this disease. Administration of vitamin A to children with measles has shown to decrease both the severity of disease and the case fatality rate. Vitamin A is important to support intestinal and respiratory epithelial integrity and prevent post measles pneumonia, severe diarrhoea and blindness. Vitamin A should always be supplemented to Measles patient for 2 consecutive days.

### 2.8. Mumps

#### 2.8.1. What is Mumps?

Mumps is an acute viral infection caused by a paravyxovirus which affects mainly school age children (five to nine years) and young adults.

#### 2.8.2. Mode of Transmission

Mumps virus spreads via direct contact or by air borne droplets from the upper respiratory tracts of infected individuals.

#### 2.8.3. Sign/Symptom

1. Mumps typically begins with non-specific symptoms such as myalgia, headache, malaise and low grade fever. Within a day these are followed by the characteristic unilateral or bilateral swelling of the parotid glands.
2. Malaise, Trismus and pain near the angle of jaw

#### 2.8.4. Complications

Meningitis, paralysis, seizures, cranial nerve palsies, and hydrocephalus may occur. Deafness, Orchitis and Spontaneous abortion

#### 2.8.5. Prevention

One dose of MMR vaccine protects children against Mumps.
2.9. Rubella

2.9.1. What is Rubella?
Rubella or German measles is an acute viral infection caused by virus which presents with short prodromal symptom. When a woman is infected with rubella virus especially in early pregnancy, there is more chance to pass this virus on to her fetus resulting congenital rubella syndrome. Congenital rubella syndrome is one of the major causes of birth defects in infants.

2.9.2. Mode of Transmission
Rubella virus is transmitted by the respiratory route and the virus initially replicates in the nasopharyngeal mucosa and local lymph nodes. In pregnant women the virus infects the placenta and developing fetus

2.9.3. Sign/symptoms
For rubella sometimes affected person does not notice any symptom at all but usually comes with features like
- Fever
- Malaise
- Mild conjunctivitis
- Post auricular, occipital and posterior cervical lymphadenopathy which is very characteristic
- Maculopapular often pruritic rash starts on the face and neck and spread down the body.

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

2.9.5. Prevention
MMR at 18 months of age protects Children from Rubella Disease and Congenital rubella Syndrome (CRS).

2.10. Haemophilus Influenzae type b (Hib)

2.10.1. What is Hib?
There are six types of Haemophilus Influenzae. Haemophilus Influenzae type b (Hib) is one of six related types of bacterium and type b is responsible for more than 90% of systemic infections in children. The disease burden is highest among those aged between 4 months and 18 months. This type b (Hib) cause serious infections/diseases in children every year. The most important manifestations of Hib infection are;
1) Pneumonia
2) Meningitis
Other important but less frequent manifestations of Hib infection include septicemia, septic arthritis, osteomyelitis, pericarditis and cellulitis.
2.10.2. How the disease spreads
The Hib bacteria usually present in the nose and throat. The Hib is primarily transmitted by droplets (sneezing, coughing) from nasopharyngeal secretions. The bacteria are also transmitted from person to person through usable articles like toys and towel of infected persons.

2.10.3. Bacterial Meningitis
Clinical Symptoms:
- Headache, fever, vomiting and stiffness of neck
- sensitive to light
- breathing difficulty
- cyanosis
- Joint pain
- Neck stiffness
- Hypothermia
- Loss of consciousness

2.10.4. Severe Pneumonia
Clinical Symptoms:
- Inability to drink and or inability to suck nipple or vomiting after feeding
- Retractions or pulling-in (In drawing) of lower part of ribcage
- Rapid breathing

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

2.10.6. Prevention
Hib conjugate vaccines are effective when given in early infancy, and have virtually no side effects except occasional temporary redness or swelling at the injection site. In Maldives, Hib vaccine is given in combination vaccines, DTP-HepB+Hib as pentavalent in routine National Schedule.
3. Vaccines, Protection against Diseases (immunity), Vaccination Schedule

3.1. Immunity, Use of Vaccines, Side effects and Actions
Immunity is the protection against infectious disease conferred mostly by the immune response generated by immunization or previous infection. After vaccination of a child, the vaccines develop the capability of the child’s body to resist harmful microbes causing the disease. The specific vaccine is able to generate pathogen-specific immunity in the body after immunization.

Vaccines are biological product prepared from killed or attenuated (weakened) virus or bacteria or their toxins, used for vaccinating people to induce specific immunity against an infectious diseases. Vaccines are heat sensitive and must be stored and transported in a cold chain. Certain vaccines also are damaged by freezing and light. Even under the most favorable conditions, vaccines have a very limited shelf life. When vaccine is introduced in human body it develops immunity in the body and protects from diseases.

The quality and efficacy of the vaccine should be maintained throughout its production, arrival, transportation, storage and use. Protection for diseases only comes from effective and quality vaccines that are maintained with proper techniques. A vaccine that has deteriorated before administration is not only useless in terms of protecting against disease but it may also cause adverse events.

3.2. Vaccines Used in National EPI Programme

<table>
<thead>
<tr>
<th>Name of Vaccines</th>
<th>Name of Diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>• BCG Vaccine</td>
<td>✓ Tuberculosis</td>
</tr>
<tr>
<td>• Hepatitis-B Vaccine</td>
<td>✓ Hepatitis-B</td>
</tr>
<tr>
<td>• OPV (Oral Polio Vaccine) Vaccine</td>
<td>✓ Poliomyelitis</td>
</tr>
<tr>
<td>• Pentavalent Vaccine (DPT+Hep-B+ Hib)</td>
<td>✓ Diphtheria, Whooping cough, Hepatitis-B and Haemophilus Influenzae-b diseases.</td>
</tr>
<tr>
<td>• Measles Vaccine</td>
<td>✓ Measles</td>
</tr>
<tr>
<td>• MMR Vaccine</td>
<td>✓ Measles, Mumps and Rubella</td>
</tr>
<tr>
<td>• TT / Td</td>
<td>✓ Tetanus</td>
</tr>
<tr>
<td>• IPV (Inactivated Polio)</td>
<td>✓ Poliomyelitis</td>
</tr>
</tbody>
</table>
**BCG Vaccine**

- BCG vaccine protects against Tuberculosis
- BCG is freeze dried powdered vaccine, diluents are used to reconstitute BCG vaccine
- BCG Vaccine and Diluents should come from same manufacturer. Diluents from other types of vaccine or from other manufacturers must **NOT** be used
- The reconstituted vaccine must not be kept longer than **SIX** hours. Reconstituted vaccine looses its potency rapidly and if used there might be severe side effects.
- BCG vaccines are light sensitive and loose its potency rapidly hence the BCG vials are brown in color.
- Both the BCG vaccine and diluents are stored under appropriate cold chain conditions at +2°C to +8°C.
- BCG vaccines are recommended just after birth; single dose of BCG injection is given in left upper arm in intra-dermal route with 0.05 ml reconstitute vaccine
- BCG often causes a local reaction, which starts two or more weeks after immunization as a papule (lump). It becomes ulcerated and heals after several months, leaving a scar
- Deep seated BCG vaccine may cause large deep seated abscess
- BCG vaccines are in 20 doses Vials

---

**OPV Vaccine**

- OPV vaccines protect against Poliomyelitis. These vaccines contain live attenuated organisms and loose its potency on exposure to heat
- OPV vaccines are stored at central level for a maximum period of 6 months at -15°C to - 25°C and at atoll level for 3 months. This vaccine is also preserved at island level at +2°C to +8°C for 1 month
- Dose of OPV is 2 drops. 1st dose with Penta 1st dose (at 2 months), 2nd dose with Penta 2nd dose (at 4 months) and 3rd dose with Penta 3rd dose (at 6 months).
  - Even if a child has vomiting and diarrhea on the date of OPV, it must be administered. An additional dose should be given after 28 days from this dose. If any dose of OPV remains to be given should be given on the scheduled date. These all should be stamped on the vaccine chart (Reference).
- There is hardly any side effects of OPV vaccines
- Ten doses vials with VVM are used in routine EPI sessions
**IPV Vaccine**

- Inactivated poliovirus vaccine (IPV) is liquid suspension providing protection against all 3 types of poliovirus
- IPV does not cause any paralysis and is a very safe vaccine
- Store IPV in a refrigerator, between +2°C and +8°C
- Does not require reconstitution
- Multi-dose vials of this vaccine must be discarded at the end of the immunization session or within 6 hours after opening, whichever comes first
- IPV is administered as a 0.5 ml dose into the muscle in the outer part of the thigh at a 90° angle by the health care provider

**Hepatitis-B Vaccine**

- Hepatitis-B vaccine is viral vaccine containing highly purified, noninfectious particles of Hepatitis-B surface antigen (HBsAg)
- The vaccine is about 95% effective in preventing Hepatitis-B disease; Hepatitis-B vaccine protects children against acute Hepatitis-B, as well as against liver cirrhosis and liver cancer
- Hepatitis-B vaccines are recommended just after birth and subsequent 3 doses are given as pentavalent combination vaccine
- The storage temperature of Hepatitis-B vaccine is +2°C to +8°C
- Hepatitis-B vaccine is cold sensitive and should **never be frozen**, discarded vaccine if ever frozen
- This vaccine is given intramuscularly in outer aspect of medial thigh.
- The recommended standard single dose volume is 0.5 ml.

**Pentavalent Vaccines**

- The Pentavalent are five-component DPT + HepB + Hib formulation vaccine protects against Diphtheria, Tetanus, Pertussis, Hepatitis-B and Haemophilus Influenzae -b.
- This vaccine loose its potency on frozen
- These vaccines are stored at +2°C to +8°C.
- First dose Pentavalent vaccine is given at 2 months, 2nd dose at 4 months and 3rd dose at 6 months.
- This vaccine is given by injection with an amount of 0.5ml
• This vaccine is given intramuscularly in outer aspect of medial thigh. First dose is given in left thigh, second dose in right thigh and third dose in left thigh is advisable.

• The parents are to be informed that most of the rare vaccine reactions are moderate fever, redness, swelling and pain at the site of injections. These are self-limiting by 1-3 days.

• Severe side effects of this pentavalent vaccine are rare. But there may be sudden convulsion due to Pertussis component. If convulsion occurs remaining doses of Pentavalent vaccine cannot be given. Instead after 28 days vaccination will be completed with one dose TD vaccine, hep B and Hib (OR if available, can give Infanrix hexa).

• Single dose liquid pentavalent vaccine vial are used in Maldives national EPI programme.

<table>
<thead>
<tr>
<th>Measles Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Measles vaccines protect children against Measles. It is a freeze dried powdered vaccine, with diluents are used to reconstitute this vaccine. This contains live organisms and loses its potency on exposure to heat.</td>
</tr>
<tr>
<td>• Once they are reconstituted, vials of these vaccines must be discarded at the end of the session or SIX hours after reconstitution and these reconstituted vials should be kept in +2°C to +8°C with clear label (ie: Date &amp; Time of Opening). Reconstituted vaccine loses its potency rapidly and if used there might be severe side effects leading to death.</td>
</tr>
<tr>
<td>• Draw and use the contents of the diluent for reconstituting measles vaccine according to Manufacturer’s advice.</td>
</tr>
<tr>
<td>• One dose of Measles vaccines must be given after 9 months of age or after 270 days of age and vaccination should be completed before one year of age. A second dose of Measles will be given at 18 months with Mumps and Rubella (MMR).</td>
</tr>
<tr>
<td>• This vaccine is to be given subcutaneously at the outer part of middle right thigh. The dose of Measles is 0.5ml</td>
</tr>
<tr>
<td>• Measles Vaccines and Diluents should be from same manufacturer. Diluents from other types of vaccine or from other manufacturers must NOT be used</td>
</tr>
<tr>
<td>• One Measles vial should be OPENED even if only one child arrives at session. Remember child’s life is more precious than wastage of vaccine</td>
</tr>
<tr>
<td>• The parents are to be informed that in some cases vaccine side effects /reactions are moderate fever and mild rash. In this case the child should be given more breast feed and fluids. These usually last 1-3 days.</td>
</tr>
</tbody>
</table>
MMR Vaccine

- MMR vaccines protect children against Measles, Rubella and Mumps
- MMR live virus vaccines are supplied in lyophilized form and diluents are used to reconstitute this vaccine
- This vaccine contains live organisms and loose its potency on exposure to heat
- These vaccines are stored at +2°C to +8°C.
- The vaccine must be protected from sun light which may inactivate the vaccine viruses
- Vaccines and Diluents should be from same manufacturer. Diluents from other types of vaccine or from other manufacturers must NOT be used
- Once reconstituted, vials of these vaccines must be discarded at the end of the session or SIX hours after reconstitution and these reconstituted vials should be kept in +2°C to +8°C with clear label (ie: Date & Time of Opening). Reconstituted vaccine loses its potency rapidly and if it is used after recommended time frame, there might be severe side effects leading to death.
- MMR vaccine should be administered subcutaneously in outer aspect of mid-thigh
- The dose of MMR is 0.5ml

3.3. Routine Vaccination Schedule

i. Vaccination Schedule for 0-18 months Children

<table>
<thead>
<tr>
<th>EARLIEST ELIGIBLE AGE</th>
<th>VACCINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>At Birth</td>
<td>BCG, Hepatitis B</td>
</tr>
<tr>
<td>2 months</td>
<td>OPV1, Pentavalent 1</td>
</tr>
<tr>
<td>4 months</td>
<td>OPV2, Pentavalent 2</td>
</tr>
<tr>
<td>6 months</td>
<td>OPV3, Pentavalent 3, IPV</td>
</tr>
<tr>
<td>9 Months*</td>
<td>Measles,</td>
</tr>
<tr>
<td>18 Months*</td>
<td>Measles-Mumps-Rubella (MMR),</td>
</tr>
</tbody>
</table>

At 9 months child also be given vitamin A 100,000 IU orally and at 18 months 200,000 IU orally
### ii. Vaccination Schedule for 0-18months Children

<table>
<thead>
<tr>
<th>Name of Disease</th>
<th>Name of Vaccine</th>
<th>Dosage</th>
<th>Number of Doses</th>
<th>Interval between dosage</th>
<th>Earliest age of Vaccination</th>
<th>Vaccination site</th>
<th>Route of Injection/Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis-B</td>
<td>Hep-B</td>
<td>0.5 ml</td>
<td>1</td>
<td>---</td>
<td>Birth</td>
<td>Outer Mid-thigh</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>BCG</td>
<td>0.05 ml</td>
<td>1</td>
<td>Birth</td>
<td>Outer upper left arm</td>
<td>Intradermal</td>
<td></td>
</tr>
<tr>
<td>Diphtheria, Whooping cough,</td>
<td>Pentavalent (Hib)</td>
<td>0.5 ml</td>
<td>3</td>
<td>8 Weeks</td>
<td>2 Months 4 Months 6 Months</td>
<td>Outer Mid-thigh</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Tetanus, Hepatitis-B,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemophilus Influenzae-b</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poliomyelitis</td>
<td>OPV</td>
<td>2drops; as instruction on vials</td>
<td>3</td>
<td>8 Weeks</td>
<td>2 Months 4 Months 6 Months</td>
<td>Oral</td>
<td>Mouth</td>
</tr>
<tr>
<td>Poliomyelitis</td>
<td>IPV</td>
<td>0.5 ml</td>
<td>1</td>
<td>---</td>
<td>6 month (with OPV3 and Penta3)</td>
<td>Outer Mid-thigh</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>Measles</td>
<td>Measles</td>
<td>0.5 ml</td>
<td>1**</td>
<td>---</td>
<td>9 months</td>
<td>Outer Mid-thigh</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Measles, Mumps &amp; Rubella</td>
<td>MMR</td>
<td>0.5 ml</td>
<td>1**</td>
<td>---</td>
<td>18 months</td>
<td>Outer Mid-thigh</td>
<td>Subcutaneous</td>
</tr>
</tbody>
</table>

* OPV vaccine will be given 3 times with every dose of Pentavalent vaccine
** Vitamin A capsule (100,000 I.U) will be given with Measles after 9 months and Vitamin A capsule (200,000 I.U) will be given with MMR at 18 months.

**Valid Dose**
When Vaccination is given as indicated in immunization schedule and after recommended minimum interval, it is called a valid dose.

**Invalid Dose**
When vaccination is done without following immunization schedule and before minimum interval, it is called invalid dose. E.g. Measles is given before 9 months of age.
Tetanus diphtheria (Td) vaccine used to protect adolescents and adults (women of child bearing age 15-49 years) from both of these diseases (tetanus and diphtheria).

The vaccine contains purified tetanus and diphtheria toxoids, with a reduced dose of the diphtheria component. One dose of 0.5ml has a potency of 2.0 International Units of diphtheria toxoid, and 40 International Units of tetanus toxoids.

Tetanus toxoid should be stored between +2ºC to +8ºC

The dose of Td is 0.5ml with recommended interval. At least 5 shots are recommended to complete vaccination schedule

This vaccine is to be given intramuscularly at outer upper arm and the dose is 0.5ml

There are mild reactions to Td vaccines include: Mild pain, redness, warmth and swelling at the injection site and usually last 1-3 days. 3.3.1. TT/Td vaccination schedule for women of child bearing age (15-49yrs)

<table>
<thead>
<tr>
<th>Recommened Schedule</th>
<th>Immunization with diphtheria–tetanus-pertussis(DPT)and diphtheria toxide (Td) vaccine required to obtain long term protection against tetanus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Doses</td>
<td>Interval between doses</td>
</tr>
<tr>
<td>Td / TT1</td>
<td>15 Years</td>
</tr>
<tr>
<td>Td / TT2</td>
<td>Minimum 28 days after TT1</td>
</tr>
<tr>
<td>Td / TT3</td>
<td>Minimum 6 months after TT2</td>
</tr>
<tr>
<td>Td / TT4</td>
<td>Minimum 1 year after TT3</td>
</tr>
<tr>
<td>Td / TT5</td>
<td>Minimum 1 year after TT4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3Doses of DPT/ Penta Completed</th>
<th>Immunization with diphtheria–tetanus-pertussis(DPT)and diphtheria toxide (Td) vaccine required to obtain long term protection against tetanus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Doses</td>
<td>Interval between doses</td>
</tr>
<tr>
<td>Td / TT3</td>
<td>At age of 15 years or first pregnancy</td>
</tr>
<tr>
<td>Td / TT4</td>
<td>At least 4 weeks after previous dose</td>
</tr>
<tr>
<td>Td / TT5</td>
<td>Minimum 1 year after TT4 or next pregnancy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adolescents and Pregnant women with 4 doses of childhood DPT/Penta</th>
<th>Immunization with diphtheria–tetanus-pertussis(DPT)and diphtheria toxide (Td) vaccine required to obtain long term protection against tetanus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Doses</td>
<td>Interval between doses</td>
</tr>
<tr>
<td>Td / TT4</td>
<td>At age of 15 years or first pregnancy</td>
</tr>
<tr>
<td>Td / TT5</td>
<td>Minimum 1 year after TT4 or next pregnancy</td>
</tr>
</tbody>
</table>

Note: DT should be used for children less than 7 years, who had sever reaction due to pentavalent (mostly due to pertussis component), whereas for older age group dT/Td should be used.

http://www.who.int/wer/2006/wer8120.pdf?ua=1

1Other Tetanus containing combination vaccines can be used as per national Schedule
3.3.2. Principles of Immunization

1. Child vaccination to be completed with all vaccines by one and half year of age as per schedule.

2. Routine vaccines can be given one week before or after the minimum interval.

3. There is no maximum interval between Pentavalent, OPV and TT doses. The minimum duration between two doses is 28 days. Even if a child come for next dose after a long period the child should be vaccinated with the missing doses.

4. All the children must have the documentation that a BCG is given. If a child is less than one year, and there is no scar and no documentation that a BCG was given, administer BCG and document it. If the child is more than one year, then there is no need to vaccinate for BCG.

5. OPV will be given to the child with 3 doses of pentavalent vaccine as per National Vaccine Schedule.

6. Severe side effect is rare after pentavalent vaccination. But there may be sudden convulsion due to Pertussis component. If convulsion occurs, rest of the doses to be completed with DT, Hib and Hepatitis B vaccine instead of Penta at an interval of 28 days.

7. Even if there is history of rash in the body or suffers from measles in the past, the child should be vaccinated with measles after 270 days or at 9 months of age.

8. In routine EPI programme 1st dose of Pentavalent vaccine in left thigh, 2nd dose in right thigh and 3rd dose in left thigh is recommended.

9. Many vaccines can be given at a time. This does not hamper to develop vaccines ability to protect from the diseases. If 2 vaccines have to be given on the same thigh it should be given 1-2 inches (2.5-5 cm) apart.

3.3.3. Following are not contraindications to Immunization

1. Minor illnesses such as upper respiratory infections or diarrhoea, with fever < 38.5ºC

2. Allergy, asthma, hay fever or sniffles (breathe audibly through a runny or congested nose).

3. Malnutrition, it is important to immunize children suffering from malnutrition.

4. Treatment with antibiotics, low-dose corticosteroids or locally acting steroids (e.g. topical or inhaled)

5. Dermatoses, eczema or localized skin infections

6. Chronic diseases of the heart, lung, kidney and liver

7. Premature babies should be vaccinated once the weight is appropriate. 1.8 kg for BCG and 2 kg for Hepatitis B
### 3.3.4. Contraindications to Immunization

1. Serious illness or high fever (>101° F), where a child needs hospitalization. They should be vaccinated as soon as their general condition improves and at least before discharge from hospital.

2. Persons with a history of anaphylactic reactions (difficulty in breathing, swelling of the mouth and throat, hypotension or shock) following egg ingestion should not receive vaccines prepared on hen’s egg tissues (e.g. yellow fever vaccine and influenza vaccine).

3. Children with symptomatic HIV (AIDS) should not be immunized with BCG and Yellow Fever vaccines.

4. Anaphylactic reaction and convulsion following a dose of DPT or Penta vaccine is a contraindication to subsequent doses. Another dose of same vaccine DTP/Penta should not be given to the child instead TT/DT or acellular pertussis vaccine must be given.

### 3.3.5. Managing Side effects after Vaccination

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>Possible Side effects</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>Redness and local reaction at the site of injection after 2 weeks as a papule (lump).</td>
<td>Keep dry and clean. Usually heals leaving a scar</td>
</tr>
<tr>
<td></td>
<td>It becomes ulcerated and heals after several months, leaving a scar</td>
<td></td>
</tr>
<tr>
<td>Measles</td>
<td>Redness, swelling and pain at the site of injection</td>
<td>Usually last 1-3 days</td>
</tr>
<tr>
<td></td>
<td>Moderate temperature and mild rash</td>
<td>Plenty of fluid and breast feed</td>
</tr>
<tr>
<td>TT</td>
<td>Redness, swelling</td>
<td>Usually self-limiting</td>
</tr>
<tr>
<td>OPV</td>
<td>No</td>
<td>Nothing</td>
</tr>
<tr>
<td>MMR</td>
<td>Redness, swelling and pain at the site of injection</td>
<td>Self-limiting by 1-3 days</td>
</tr>
<tr>
<td></td>
<td>Moderate temperature and mild rash</td>
<td>Plenty of fluid and breast feed</td>
</tr>
<tr>
<td>Pentavalent (DPT+HepB+Hib)</td>
<td>Mild redness, pain, swelling at injection site, Mild temperature 2-3 days</td>
<td>Self-limiting by 1-3 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Plenty fluid and breast feed</td>
</tr>
<tr>
<td>IPV</td>
<td>Redness and pain at the site of injection</td>
<td>Usually self-limiting</td>
</tr>
</tbody>
</table>

* Any AEFI that is of concern to the parents should be reported immediately.
Chapter 4

4. Cold Chain

4.1. What is cold chain?

Cold chain is a system for maintaining the potency of the vaccines in every stage at specific temperature during storage and transportation vaccines from the manufacturer to the beneficiaries at vaccination site.

The vaccines which are used in Maldives National Vaccine Program are imported from foreign countries. These vaccines are imported in Maldives in insulated shipping cartoon maintaining the right temperature. These vaccines are stored at central EPI cold room at Male’.

![Diagram of Cold Chain]

*Figure 1: Cold chain*

These vaccines are sent from central store to Atolls store and from atolls to islands with Cold Boxes. These vaccines are also sent to vaccinating centres with vaccine carriers on the day of EPI session.
4.2. Importance to maintain the cold chain
If a vaccine loses its potency then it will not produce immunity against particular disease. As a result programme will be under threat of failure i.e. infant morbidity and mortality will not be reduced.

4.3. The sensitivity of different vaccines to heat and freezing

<table>
<thead>
<tr>
<th>Heat Sensitive Vaccine</th>
<th>Cold sensitive Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Most Sensitive</strong></td>
<td><strong>Most Sensitive</strong></td>
</tr>
<tr>
<td>OPV</td>
<td>Pentavalent vaccine</td>
</tr>
<tr>
<td>Measles, MMR</td>
<td>Hepatitis-B</td>
</tr>
<tr>
<td>Pentavalent</td>
<td>IPV</td>
</tr>
<tr>
<td>BCG</td>
<td>TT vaccine</td>
</tr>
<tr>
<td>TT Vaccine</td>
<td></td>
</tr>
<tr>
<td><strong>Least Sensitive</strong></td>
<td><strong>Least Sensitive</strong></td>
</tr>
</tbody>
</table>

Vaccines must be storing and distributing at right temperature. Otherwise its potency will be lost.

4.4. Conditions that loses potency of vaccines
1. Freezing of vaccines (Pentavalent, Hep-B and TT/Td)
2. If the inner square of VVM (Vaccine Vial Monitor) becomes darker than the outer circle.
3. Exposed to heat
4. Exposed directly to sun light
5. After Date of expiry
6. Keeping beyond the range $+2^\circ$C to $+8^\circ$C
### 4.5. EPI Vaccine storing duration and correct temperature maintenance at different stages

<table>
<thead>
<tr>
<th>Place</th>
<th>Duration of Storing</th>
<th>Temperature</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Cold Room, Male'</td>
<td>6 Months</td>
<td>-15°C to -25°C</td>
<td>+2°C to +8°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OPV Measles vaccine</td>
<td>BCG, Pentavalent, Hep-B and TT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+2°C to +8°C</td>
<td>+2°C to +8°C</td>
</tr>
<tr>
<td>Atolls</td>
<td>3 Months</td>
<td>-15°C to -25°C</td>
<td>+2°C to +8°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OPV Measles vaccine</td>
<td>BCG, Pentavalent, Hep-B and TT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+2°C to +8°C</td>
<td>+2°C to +8°C</td>
</tr>
<tr>
<td>Island</td>
<td>1 Month</td>
<td>+2°C to +8°C</td>
<td>+2°C to +8°C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OPV Measles vaccine</td>
<td>BCG, Pentavalent, Hep-B and TT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+2°C to +8°C</td>
<td>+2°C to +8°C</td>
</tr>
<tr>
<td>During transportation</td>
<td>4 Days</td>
<td>+2°C to +8°C</td>
<td>+2°C to +8°C</td>
</tr>
<tr>
<td>Cold box</td>
<td>1 Day</td>
<td>OPV Measles vaccine</td>
<td>BCG, Pentavalent, Hep-B and TT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+2°C to +8°C</td>
<td>+2°C to +8°C</td>
</tr>
</tbody>
</table>

** Diluents of MMR, Measles and BCG should be made cool before mixing with the vaccine. This can be made by keeping the diluent at +2°C to +8 °C temperatures, 12 hours before use. **

**Remember:** Please check VVM status and expiry date before use of every vaccine. Never use vaccine when the expiry date has passed even if the VVM shows no heat damage. In general, always apply the earliest-expiry-first-out (EEFO) principle. Exceptionally if the VVM is in second stage then this vaccine can be supplied first without considering the EEFO principle.

**Diluents:**

Diluents can be stored outside the cold chain. Diluent must be cooled before use, preferably for a day or for a period of time sufficient to ensure that the vaccine and diluent are both at temperatures between +2°C to +8°C when they are reconstituted. Never freeze diluent.

**Vaccines and Diluents should not be used under following conditions:**

- IPV, Pentavalent and TT/Td vaccines are frozen
- Expired vaccines
- VVM not in acceptable stage, i.e. inner square matches colour of outer circle or inner square darker than outer circle
- Diluents of Measles and BCG were not stored at +2°C to +8°C temperature 12 hours before use or frozen diluents
4.6. Safety of the Cold chain
Vaccines must be stored at the proper temperature in order to keep potent before use. A vaccine that has deteriorated before administration is not only useless in terms of protecting against disease it may also cause unnecessary reactions. All vaccines are heat sensitive and need to be stored in cold conditions. All programme managers should put high priority to the maintenance of the cold chain including the main equipment’s and cold rooms. Storekeepers and repair technicians should receive proper training to manage this important component of the EPI.

The following are the cold chain equipment’s

- Cold room/freezer room
- Ice lining refrigerator
- Deep freezer
- Other refrigerator equipments like simple refrigerators, first freezers, cold boxes, vaccine carrier, Icepacks, foam pad, etc

Supplementary equipments for cold chain

- Voltage stabilizer
- Thermometer, vaccine vial monitor (VVM), freeze watch, vaccine cold chain monitor etc
- Back-up generators

4.7. Shake test
Freezing damages the potency of some vaccines such as Pentavalent, DPT, Hep B and TT. Regularly inspect your vaccine refrigerator for any signs of freezing. So if there any doubts whether vaccine have been damaged or not, do the shake test.

The “Shake test” can help to give an idea whether adsorbed vaccines such as Pentavalent, Hep-B and TT have been subjected to freezing temperatures likely to have damaged them. After freezing, the vaccine no longer has the appearance of a homogenous cloudy liquid, but tends to form flakes which settle at the bottom quickly of the vial after shaking. Sedimentation is faster in a vial which has been frozen than in a vial, from the same manufacturer which has not been frozen
Steps to follow perform shake test:

![Diagram of shake test](image)

Figure 9: Demonstrating the shake test

a) Gather the potentially “frozen” suspect vial that you want test. Take a vial and label it as **test sample**.

b) Take a vial of vaccine of the same type and batch number as the vaccines you want to test and from the same manufacturer. Intentionally freeze the vial until the contents are solid (at least 10 hours at -10ºC), label it as a **control sample**. Then let it thaw.

c) Shake the test sample (suspected) and control sample (frozen) together in one hand and shake vigorously for 10-15 minutes.

d) Allow both vials to rest in flat table and not moving them further.

e) Observe the two vials against the light and compare the sedimentation rate. If test sample (suspected) shows a much slower sedimentation rate than the control (frozen) sample, then the test sample has most probably **not been frozen** and can be used. If the sedimentation rate is similar, the vial has probably been damaged by freezing and **should not be used**.

f) **This test is not applicable to IPV.** Even if IPV vaccine is frozen it does not show positive result. If there is a doubt about whether the IPV vaccine is frozen, it has to be discarded.

If the vials have large labels, which conceal the vial contents, turn both vials upside down and observe sedimentation in the neck of vials.
4.8. Thermometer

There are different types of thermometer are used in the refrigerator to monitor the temperature.

![Thermometer images]

Figure 7: vaccine thermometer

4.9. Vaccine vial monitor (VVM)

Vaccine vial monitor (VVM) is a heat sensitive label on a vaccine vial which gradually and irreversibly changes color when the vial has been exposed to heat over a period of time. It warns the health workers before opening a vial, the status of VVM must be checked to whether the vaccine has been damaged by heat. The VVM is printed on the vial level or cap. It looks like a white square inside a violet circle. As the vaccine vial is exposed to more heat, the square becomes darker. Use only vials with inner squares are lighter in color than the outside circle. Vials with VVM in which the inner square has begun to darken but is still lighter than the outer circle should be used before the vials with a lighter inner square.

More time with more heat VVM with vaccine will change also so fast. Please note that if vaccine vial monitor (VVM) is okay but vaccine date expires then vaccine must not use. The VVM changes its color in 4 stages and only stage 1 and stage 2 is recommended for use.

**Vaccine Vial Monitor Manual**

<table>
<thead>
<tr>
<th>The vaccine vial monitor says...</th>
</tr>
</thead>
<tbody>
<tr>
<td>![VVM stages images]</td>
</tr>
<tr>
<td>The inner square is lighter than the outer circle. If the expiry date has not passed, USE the vaccine.</td>
</tr>
<tr>
<td>At a later time the inner square is still lighter than the outer circle. If the expiry date has not passed, USE the vaccine.</td>
</tr>
<tr>
<td>Discard point: the colour of the inner square matches that of the outer circle. DO NOT use the vaccine.</td>
</tr>
<tr>
<td>Beyond the discard point: the inner square is darker than the outer circle. DO NOT use the vaccine.</td>
</tr>
</tbody>
</table>

Figure 10: Vaccine vial monitor

VVM for liquid vaccine are attached to label while for freeze dried vaccine to the cap. Remember that VVM do not measure the exposure to freezing temperature.
4.10. Multi-dose vial policy
This applies to liquid vaccines i.e. Pentavalent, OPV, Hepatitis-B and Td. In routine immunization by this multi dose vials policy any open vial of above vaccines can be used in subsequent sessions provided that all the following conditions are met:
1. The expiration date has not passed
2. The vaccines are stored under appropriate cold chain
3. The vaccine vial septum has not been submerged
4. Aseptic technique has been used to withdraw all doses
5. The VVM, if attached had not reach the discard point

This open vial policy is applied only in fixed EPI sites where refrigerator is available. All opened vials returned to the refrigerator, should be clearly marked with the date of opened and can be used maximum for a month (28 days).

4.11. Cold Boxes
A cold box is an insulated container that is lined with frozen icepacks to keep vaccines and diluents cold. Cold boxes are mainly used for transportation of vaccine from national level to atolls and atolls to Islands.

![Figure 3: Cold box](image)

4.11.1. Loading cold box
Cold boxes are insulated box are used for transportation of vaccines from one point to another. Vaccines can be stored 3-4 days in cold box if it is well packed with conditioned icepacks and not opened. Quickly take all the frozen ice packs you require (24 for RCW 25) from the freezers and close the door
1. Put ice pack against each four sides and surface of the cold box.
2. Quickly take all the vaccines and diluents you need from the refrigerator and close the door.
3. Put the vaccines and diluents in the cold box, arrange such a way that air can move
4. Freeze sensitive vaccine can be packed with plastics bag
5. Close tightly the cold box
4.11.2. Vaccine Carriers
Like cold box vaccine carrier is insulated container that are lines with frozen ice packs to keep the vaccines and diluents cold. Vaccine carrier is smaller than cold box and easier to carry if you are walking but they do not stay cold for long.

Figure 4: vaccine carrier
They usually stay cold only for 24 to 72 hours. Vaccine carrier is mainly used to transport vaccines and diluents for outreach and for temporary storage during immunization sessions. Vaccine carriers are also used to carry laboratory sample for AFP and other EPI disease but should be designated and kept separately.

4.11.3. Loading vaccine carrier
- Check vaccine carrier for cleanliness, intact body, good handle and lid
- Quickly take all the frozen ice packs you require (usually 4) from freezers and close the door
- Keep the vaccine carrier in the shade
- Put conditioned ice pack against each four sides of the vaccine carrier
- Quickly take all the vaccines and diluents you need from the refrigerator and close the door.
- Place Measles, MMR and Polio vaccines first inside the vaccine carrier
- Wrap Penta, Hep-B, TT IPV and BCG vaccines and diluents in thick paper or thick plastic bag and then put inside the vaccine carrier.
- Put dial thermometer inside the vaccine carrier in such a way that it does not come in contact with ice packs
- Place a foam pad at the top of vaccine carrier.
- Close the vaccine carrier lid tightly

Figure 12: Showing how to load a vaccine carrier
When moving freeze sensitive vaccine/liquid vaccines like DPT, Hep B, TT, DT IPV and pentavalent vaccines use conditioned/chilled ice packs
4.11.4. Making ice packs

The proper freezing and use of ice packs is essential for good quality of the vaccines. To make an ice pack it takes 24-48 hours to completely freeze. Make ice pack as follow
1. Fill ice pack with clean water leaving a little space at the top and put the cap on tightly
2. Hold ice pack upside down and squeeze it to make sure that there is no leakage.
3. Put the ice packs upright or on their side in the freezer part of refrigerator and close the door
4. Leave the ice pack in the freezer part for 48 hours to freeze solid
5. Keep ice packs that do not fit in the freezer part, on the bottom shelf of the main part of refrigerator in order to keep them cold.

When you need urgent icepacks, then you may fill the icepack with cold water and put it in freezers which will facilitate it to be frozen quickly. You do not need to refill ice packs every time you use them.

4.11.5. What is conditioned ice packs?
These are similar ice packs in every aspect, the only difference being that water is not allowed to freeze before being used for vaccine transportation. If there is already frozen ice packs, allow the ice packs to sit at room temperature until it begins to melt and liquefies. To make sure the icepacks has been conditioned already, shake it and listen the movement of water.
Conditioned ice packs are used for the transportation of freeze sensitive vaccine from freezing such as DPT, HepB, Td IPV and DT.

1. Do not place ice on the top of vaccine
2. For keeping the freeze sensitive vaccines may use plastic bag
3. Do not open unnecessary the lid which reduce the cold life
4. May put the thermometer in vaccine carrier or cold box for long distance
Chapter 5

5. Injection Safety

Maldives has decided to provide all vaccinations with AD Syringes to maintain injection safety. At the same time the government has also decided to use safe, potent vaccine and collect used Syringes and other wastes for safe disposal.

5.1. What is safe injection?

An injection is safe when
1) It doesn’t harm recipients where a sterile syringes and needle and an appropriate injection techniques are used for a client.
2) It doesn’t expose the providers to any avoidable risks where health workers avoid needle stick injuries.
3) It doesn’t result in any waste that is dangerous to other people or environment where used injection equipment is disposed correctly.
Safe injections not only include safe administration, but also proper vaccine handling and reconstitution as well as safe collection and disposal of used syringes and needles.

5.2. Consequences of unsafe injections

1. Development of bacterial abscess at the injection sites
2. The most common serious infections transmitted by unsafe injections are hepatitis B, hepatitis C and HIV. World Health Organization has estimated that unsafe injections transmit 8-16 million hepatitis B virus infections, 2.3 - 4.7 million hepatitis C virus infections and between 80,000 to 160,000 HIV/AIDS infections each year.
3. Poorly administered injections can also cause injuries or drug toxicities when the wrong injection site, drug, diluents or dose are used.
4. Health workers may acquire needle stick injuries due to mishandling of used syringes and needles

Auto-Disable (AD) Syringes virtually eliminate the risk of patient-to-people (or carrier-to-people) transmission of blood-borne pathogens (such as hepatitis B or HIV) because they cannot be re-used.

Steps of Injection Safety:
To ensure injection safety following steps should be taken at regional, atoll hospital and health Centre as well as in outreach session.
1. Wash or disinfect hands before preparing vaccines and giving injections
2. Use AD syringes during immunization session for each client for injectable vaccines
3. Apply the appropriate injection techniques and correct dose
4. Clean injection sites
5. Do not recap used needles
6. Handle used needles carefully to avoid wounds caused by needles
7. Discard a needle that has touched any non-sterile surface (hands, environmental surfaces)
8. Use safety boxes for disposing the used syringes. Safety boxes and containers needs to be disposed according to guidelines.
5.3. Needle sticks Injuries
Needles frequently injure health workers and can inject small but dangerous amounts of blood infected with hepatitis-B, hepatitis-C, HIV or other germs. Needle sticks may occur through recapping or carrying used syringes and needles, through insecure positioning of the patient, particularly children, and through disposal practices that leave syringes and needles accessible to the public.

Precautions from getting needle prick:
1. Use safety box in each session
2. After giving injection put used syringes in to the safety box.
3. Don’t do any other work at EPI session holding the Syringe in hand
4. Don’t recap the used syringes
5. Put cap of needle in to the safety box immediately
6. Don’t put pressure on safety box filled with used syringes

5.4. Injection Equipment
A sterile needle and a sterile syringe must be used for each injection. If the sterility of equipment is in doubt, do not use them. A sufficient supply of needles, syringes and disposal safety boxes is as important as an adequate supply of vaccines. At present, auto-disable (AD) syringes are the safest injection equipment available and preferred to standard, single use disposable syringes.

5.5. Sharp Waste Disposal
Safety Box:
Safety Boxes are puncture proof, impermeable container made up of special cardboard for the safe collection and disposal of used Syringes and needles at EPI sessions. Needles can not easily pierce them. Safety boxes require proper assemble before use. All used AD and reconstituted syringes should be placed in safety box and once filled, safety boxes should be destroyed safely.

How to use safety boxes?
For each immunization post there must be one safety box. Safety box is a special type of box for dropping the used AD Syringes after use. To destroy the syringes with safety boxes is an important element of injection safety.

1) After giving the injection, used syringe put immediately in to the safety box. In this box maximum 100 syringes can be kept.
2) Don’t handle or shake the safety box unnecessary. Never squeeze, sit or stand on safety box.
3) Keep safety box in a dry, safe place out of the reach of the children and general people until safe disposal.
4) When the safety box is not in use, close the opening on the top
5) If box became 3/4 full then close the box securely and send it for burning in incineration. Do not fill the safety box until completely full.
6) Destroy the safety box carefully and completely
7) At least one CHW should be in charge for handling the issue.
5.6. Auto Disable (AD) Syringes

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

Main parts of AD syringes:

- Barrel
- Plunger
- Needle
- Needle cap

WHO and UNICEF recommended EPI programme to use Auto Disable Syringes for providing injections through safe injection practice. Two types of Syringes are used in Maldives.

1) Disposable syringes for reconstitution of vaccines, (2/3 ml and 5/6 ml reconstitution syringe)
2) Auto Disable Syringes for injections of vaccines; (0.05 ml for BCG and 0.5 ml for other injections)

AD Syringes used in EPI

- 0.05 ml AD syringe for BCG vaccine
- 0.5 ml AD syringe for all other vaccine
5.6.1. How to use Auto disables (AD) syringes
After giving injection to a client, piston inside the syringe will lock automatically. So there is no way to use it for second time.

1. wash hands well before use
2. Peel open the syringe needle at the back of auto disable syringe package and remove syringes
3. Remove the cap of needle and immediately put it in to safety box. Do not recap it and do not touch the needle.
4. Take the vaccine vial and insert the needle to vial up to liquid to avoid air into the syringe.
5. Then take the vaccine from vial by pulling the plunger slowly until the limit. After taking the vaccine into syringe then remove the needle from vial. Always keep in mind that needle must not be touched.
6. If there is air in syringe, put the syringe in vertical position and flick/tap by figure so that air will push to top. Then push the plunger slowly and air will come out from syringe but remember don’t pushes hard or fast or force fully otherwise plunger will be locked or injection device automatically destroyed. (Note that vaccine inside the syringe should not be less than 0.5 ml).
7. Now clean the place where injection will be given by cotton. Then give injection. After use of syringe, drop it to safety box.

5.6.2. How to give an injection using AD syringes
1. Wash skin that looks dirty with water. It is not necessary to swab clean skin.
2. Hold syringe barrel between thumb, index and middle fingers. Do not touch the needle. The plunger can go back and forth only once, so health workers should not draw up air to inject into the vial as this will disable the syringe.
3. Insert needle with a smooth action.
4. It is not necessary to aspirate first.
5. Use thumb to push the plunger without moving the syringe around.
6. Pull needle out quickly and smoothly (less painful than doing it slowly).
7. Ask the parent to press the site gently with a clean swab for a few seconds (to stop bleeding and relieve pain).
8. Do not rub the area where the injection was given.

Advantages of AD syringes:
1. They can only be used once
2. The eliminate the patient-to-patient disease transmission caused by the use of contaminated needles and syringes
3. They save time for health workers from the heavy work of sterilization.
5.7. Key Messages for Safe Injection
1. Use AD syringe for vaccination
2. Put AD syringe in to the safety box immediately after injection for safe disposal
3. Keep vaccine and injection equipments sterile and prepare injections in a clean dry designated area. Prepare each dose immediately before administering.
4. Take off the needle cap without touching the needle
5. If you touch any of the parts of the AD syringe, discard the syringe and needle and get new sterile one.
6. Don’t recap the needle
7. Never leave the needle in the top of the vaccine vial.
8. Follow safe procedures to reconstitute vaccines.
10. Keep filled safety box in a dry, safe place out of the reach of the children and general people until safe disposal.
11. Don’t put plastic or paper packets of AD syringes, broken ampoules, used vials, cotton etc in to the safety box.
12. Ensure safe disposal of sharp wastes to prevent environmental hazards.

5.8. Procedures for disposing Safety Boxes
The proper disposal of used safety boxes is one of the most important issues in assuring immunization safety.

1) Following the immunization session or when the safety boxes is three quarters full, close the container
2) Keep the safety boxes in safe place and out of reach of public
3) Collect all safety boxes at Atolls and dispose of under the supervision of EPI focal person.

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

If Incinerator is not available:

Pit burn:
Safety boxes may be burned and buried on premises in a controlled manner. A fence should restrict access to the pit. In unstable soils, the sides of the pit should be lined with brick or concrete to prevent collapse. A 10–15 cm layer of earth should be placed on each layer of waste, and the pit should be filled with soil or concrete when the contents reach 50 cm of the surface of the hole. Once closed, the site should be marked to prevent any future digging. Open dumping of safety boxes should be prohibited.
Chapter 6

6. Adverse Events Following Immunization (AEFI)

6.1. Introduction

The goal of immunization is to protect children and women of childbearing age from vaccine-preventable diseases. Although modern vaccines are safe but no vaccine is entirely without risk. Some people experience events after immunization ranging from mild side effects to rare serious illnesses. In some cases these reactions are caused by the inherent properties of vaccine; in others, they are caused by an error in transportation, storage, preparation and administration of vaccine; and in majority of cases, there is no relationship. Whatever the cause, when an adverse event following an immunization upsets people to the extent that they refuse further immunizations for their children, the children are much more likely to get a vaccine-preventable disease, become seriously ill, disabled, and even die. To increase immunization acceptance and improve the quality of services, surveillance of AEFIs must become an integral part of national immunization programme.

6.1.1. What is an AEFI?

*Adverse event following immunization (AEFI):* any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

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

Table 1: AEFI can be classified into 4 types, depending on the suspected cause of the reaction

<table>
<thead>
<tr>
<th>Types of AEFI</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Vaccine Reaction</td>
<td>An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties or due to one or more quality defects of the vaccine product.</td>
<td>Anaphylaxis due to Measles vaccine</td>
</tr>
<tr>
<td>2. Immunization Error</td>
<td>An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.</td>
<td>Abscess at the site of injection due to un-sterile injection or wrong technique</td>
</tr>
<tr>
<td>3. Coincidental</td>
<td>An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.</td>
<td>Pneumonia after administration of Oral Polio Vaccine</td>
</tr>
<tr>
<td>4. Immunization anxiety related reaction</td>
<td>An AEFI arising from anxiety about the immunization.</td>
<td>Fainting spell after vaccination</td>
</tr>
</tbody>
</table>

6.1.3. Vaccine Reaction

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

*Common minor reactions:*

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

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

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

It should be mentioned that these minor reactions are common and usually expected, which don’t need to be reported as AEFI.
<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Local reaction (pain, swelling, redness)</th>
<th>Fever</th>
<th>Irritability, malaise and non-specific symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>Common</td>
<td>Rare</td>
<td>Rare</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Children up to 5%</td>
<td>1-6%</td>
<td>Rare</td>
</tr>
<tr>
<td>Penta Hib</td>
<td>5% - 15%</td>
<td>2-10%</td>
<td>Rare</td>
</tr>
<tr>
<td>Measles</td>
<td>~10%</td>
<td>5-15%</td>
<td>5% rash</td>
</tr>
<tr>
<td>OPV</td>
<td>None</td>
<td>Less than 1%</td>
<td>Less than 1%</td>
</tr>
<tr>
<td>TT</td>
<td>~10%</td>
<td>~10%</td>
<td>~ 25%</td>
</tr>
<tr>
<td>DPT ¹</td>
<td>Up to 50%</td>
<td>Up to 50%</td>
<td>Up to 60%</td>
</tr>
</tbody>
</table>

**IPV**

- Cold cloth at injection site  
- Paracetamol ²  
- Give extra fluids  
- Wear cool clothing  
- Tepid sponge or bath  
- Paracetamol  
Symptomatic

¹ With whole cell Pertussis vaccine; A cellular Pertussis vaccines rate are lower.  
² Paracetamol dose: up to 15 mg/kg every 4 hours, maximum of 4 doses in 24 hours

**Serious vaccine reactions**

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

All serious vaccine reactions need to be reported as AEFI and require investigation
Table-3: Summary of rare serious vaccine reactions, onset interval and rate by antigen

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

6.1.4. Immunization Errors

Immunization errors are the most commonly reported adverse events. These occur as a result of inappropriate storage, transportation, reconstitution, preparation and administration of vaccines. It is extremely important that these AEFI are reported and addressed for early correction. Table-4 provides a list of some programme errors and types of AEFI.

An immunization error may lead to a cluster of events associated with immunization. These clusters are usually associated with a particular provider or health facility or even a single vial of vaccine that has been inappropriately prepared or contaminated.
### Table 4: Immunization Error-related reactions/adverse events

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

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

**BASIC RULES TO AVOID IMMUNIZATION ERRORS**

1. Reconstitute your vaccine only with the diluent supplied by the manufacturer
2. Discard reconstituted vaccines at the end of each immunization session and never retain them. (Remember, opened vial policy applies only to liquid formulation of vaccines!)
3. Do not keep drugs or other substances in the vaccine refrigerator
4. Use sterile needle and sterile syringe for each injection
5. Full investigation of an AEFI is needed to pinpoint the cause and to correct inappropriate immunization practices

6.1.6. **Coincidental Events**

Children are usually given vaccines at an age when they are susceptible to many diseases. So when a medical event occurs after vaccination, it is usually believed that the event occurred due to vaccination. In fact this event is not linked with vaccination except in time so it is termed as coincidental. In other words a chance temporal association (ie, event happens after immunization) is falsely considered to be caused by immunization. These purely temporal associations are expected and common when a large number of vaccine doses administered, especially in a mass campaign.

6.1.7. **Immunization anxiety related reaction**

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

The objective of AEFI surveillance is to:

1. To detect and manage serious AEFI cases
2. To report AEFI using standard case definition
3. To take appropriate regulatory actions when serious and unexpected AEFIs detected
4. Identify unusual high rates of AEFI with specific vaccine lots and brands
5. Promptly address programmatic errors through implementation of corrective measures
6. Ensure that if any coincidental events are falsely blamed on immunization, to disseminate correct information to concerned authorities and public
7. Maintain confidence in the immunization programme by properly responding to concerns
8. Estimates AEFI rates in the population compared with local and global data

6.3. Reporting AEFIs

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

6.3.1. Reportable AEFI

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

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

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

1. Abscess at injection site
2. Fever as an adverse event following immunization
3. Hypotonic-hyporesponsive episode (HHE) as an adverse event
4. Induration at or near injection site:
5. A local reaction at or near injection site:
6. Nodule at injection site as an adverse event following immunization
7. Allergic reactions; rash
8. Seizures (febrile seizures or afebrile seizures)
9. Acute onset of flaccid paralysis (occurs extremely rare with OPV)
If the AEFI does not occur within the time frame specified, but there is a suspicion that the event may be related to vaccine, then these should also be reported. If the adverse event occurs outside of this time frame, the event is less likely to be due to vaccination.

6.4. AEFI Reporting System

AEFI surveillance will be carried out in both facility and community. Facility based AEFI surveillance refers to collection of data from designated facilities. Community based AEFI surveillance refers to collection of data from community by the field health staff and other individuals.

When, Whom and How to Report

Information on AEFI is reported from following sources:

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

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

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

6.4.1. Encouraging Health Workers Reporting

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

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

1. Train staff on AEFI and its reporting
2. Increase awareness of health staff on importance of reporting
3. Give positive feedback and appreciation for reporting. It is essential that health workers be given feedback about the results of investigations and any actions taken as a result of the report

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

Community
Community Health workers who detect or get information of an AEFI from the community should report to their supervisor within 3 days using AEFI report form (Appendix-1). The supervisor will send this report to the focal person of Health Centers/Atolls Hospital on weekly basis. In the event that Health workers cannot contact their supervisors they will report to focal person of Health Centers/Atolls Hospital directly.

Health Facility/Hospital
Service providers of health facility or hospital detecting AEFI should report to respective focal person within 24 hours using AEFI report form. The focal person will submit these reports to focal person of Atolls at the end of every epidemiological week. The Chief of Atolls will submit all AEFIs reported in each Epidemiological Week in AEFI compilation form to National EPI. The report should reach national EPI by following Tuesday.

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

1. To confirm diagnosis of a reported AEFI and determine the outcome
2. To investigate link between the vaccine administered and the AEFI
3. To determine contribution of the operational aspects of the programme to the reported AEFI
4. To determine whether a reported event was isolated or part of a cluster
5. To determine cause of the AEFI so as to provide the best intervention/medical care and take any further action deemed necessary
6. To determine whether un-immunized persons are experiencing the same medical event(s)

If the cause is determined to be a programme error, problem should be corrected quickly. If an AEFI is found to be coincidental, then the community can be reassured about the safety of the vaccine and the immunization programme. The act of investigating AEFI increases the confidence of the community in the health care system and the immunization programme in particular.
6.5.2. What AEFI to report and investigate immediately
Managers should ensure that their staff monitor and report an agreed list of adverse events. Health workers should know to monitor and report at least the following AEFI immediately.

The following AEFIs must be reported and investigated immediately
Managers should ensure that their staff monitor and report an agreed list of adverse events. Health workers should know to monitor and report at least the following “triggers” events immediately.

The following AEFIs must be reported and investigated:
1. All clustering of any AEFI
2. All deaths that are believed by health workers, or the public, to be related to immunization.
3. All cases requiring hospitalizations that are believed by health workers, or the public, to be related to immunization.
4. All severe or unusual medical events about which health workers, or the public are concerned to be related to immunization.

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

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

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

6.5.4. Who should investigate?
In case of death, hospitalization, cluster event, and event causing significant parental/community concern, Hospital focal person will initiate investigation and notify to the Chief of Atolls. The detail investigation will be carried out by a team.
6.5.5. Immediate Reporting and Investigation

In case of death, hospitalization, cluster or any event causing significant parental /community concern the AEFI must be reported immediately to Focal person of Hospitals. Once Focal person is notified of the above events he will immediately notify to National EPI through Chief of Atolls and will initiate an investigation. If these events occur in a facility other than Hospital, respective Focal person of Hospital will immediately notify to Chief of Atolls who will initiate an investigation and notify to National EPI.

During line listing if any cluster is identified Focal person of Health Center or Hospital will initiate investigation and take necessary actions to prevent further occurrence of similar event. If such cluster is identified during compilation at Atoll level then Chief of Atoll will inform respective Focal person to initiate an investigation.

Flow Chart of AEFI Reporting from community, Health Facilities and Hospitals

6.5.6. How to Handle Parents/Patient

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

1. Communication with parents/patient is a crucial part of managing an AEFI
2. Listen sympathetically to parents and their concerns
3. Reassure the parents and patient but do not make false promises
4. Assist the parent/caregiver to take patient to hospital/Health facilities
5. Keep the parent routinely informed of the progress of the patient.
Chapter 7

7. Vaccine reconstitution, vaccination schedule, organization of EPI session and Management

7.1. Giving Injection

7.1.1. Consider 5 key principles for giving injection

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

7.1.2. Sites and route of Vaccination

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>Intradermal – Left upper arm</td>
</tr>
<tr>
<td>Hepatitis-B</td>
<td>Intramuscular – Outer aspect of middle thigh</td>
</tr>
<tr>
<td>Pentavalent</td>
<td>Intramuscular – Outer aspect of the middle thigh</td>
</tr>
<tr>
<td>Measles</td>
<td>Subcutaneous – Outer aspect of middle thigh</td>
</tr>
<tr>
<td>MMR</td>
<td>Subcutaneous – Outer aspect of middle thigh</td>
</tr>
<tr>
<td>TT/Td</td>
<td>Intramuscular – Outer part of the upper arm</td>
</tr>
<tr>
<td>OPV</td>
<td>Oral – OPV is given in mouth</td>
</tr>
<tr>
<td>IPV</td>
<td>Intramuscular – Outer aspect of the middle thigh</td>
</tr>
</tbody>
</table>

7.1.3. Different route and needle position

- **Intramuscular injection:**
  Insert needle in to the muscle at 90° angle

- **Subcutaneous injection:**
  Insert needle in to the pinched up skin almost at 45° angle – the needle should point towards the shoulder

- **Intradermal injection:**
  Keep the needle flat along the skin and insert the tip of the needle just under the surface, keeping the bevel of the needle facing up.
7.1.4. Types of Syringe used in Vaccination

1. 0.05 ml AD Syringe for BCG
2. 0.5 ml AD Syringe for Pentavalent, DPT, Td, HepB, Measles IPV and MMR Vaccine
3. 2 ml / 5 ml Reconstitution/mixing syringe (2ml for BCG and 5 ml for Measles and MMR)

7.1.5. Non - touch Technique

1. Don’t touch needle of the syringes
2. Don’t swab needle with cotton
3. Don’t touch top of the rubber cap of the vaccine vials
4. Needle of AD syringes and Mixing syringes should not get in touch with others except top of rubber cap and site of injection.

7.2. Reconstituting Vaccines

Reconstituting vaccines means mixing a powdered form of a vaccine with a fluid called a diluent so that the vaccine can be injected.

*You must reconstitute BCG, Measles and MMR vaccines before the vaccine can be injected.*

*Follow the steps indicated below to mix BCG, Measles and MMR powder vaccines with a fluid so that the vaccine can be used.*

7.2.1. Steps to reconstitute vaccines safely

1. Read the label on the diluent to be sure that it is the diluent provided by the manufacturer for that specific vaccine and vial size.
2. Check to make sure the expiry date has not passed.
3. Cool the diluent to 2-8°C prior to use to avoid heating the vaccine.
4. Draw the entire contents of the diluent vial into the mixing syringe.
5. Empty the entire contents of diluent into the vaccine vial.
6. Discard the used mixing syringe and needle safely into safe box.
7. Do not leave the mixing needle in the vial; this is a common mistake that leaves the vial open to contamination.
8. Hold the neck of the vial between your fingers and shake gently to mix the contents until all of the vaccine powder has dissolved. If necessary, note the date and time the vial was mixed.
9. Keep the reconstituted vaccine cool by placing the vaccine inside slits cut in the top of a foam pad that has been cut to fit a vaccine carrier. WHO recommends this technique to keep vaccine cold and protected from sunlight, however Vials should not be placed in a cup of ice as it can damage or remove the vaccine vial label.
10. Discard all reconstituted vaccine 6 hours after reconstitution
11. Use the same syringe that is used to withdraw the vaccine from the vial to inject the vaccine.
Key Points

- Using the wrong diluent or another medication to reconstitute a vaccine can make the vaccine ineffective or dangerous.
- Use ONLY the diluent approved by the manufacturer to reconstitute the specific type of freeze-dried vaccine.
- Diluents should be cooled before being mixed with the vaccine.
- Do not reconstitute the vaccine until the person needing a particular vaccine is present.
- **Discard reconstituted vaccines after 6 hours of reconstitution or at the end of the immunization session, whichever comes first.**
- Use a sterile syringe and needle to mix each vial of freeze-dried vaccine.
- Do not leave a needle in the top of the vial.
- Use the same syringe and needle to draw up the dose and to inject.

### 7.2.2. Reconstitution of BCG Vaccine

- Wash your hand with clean water and soap before reconstituting vaccines.
- Make sure that all of the vaccine powder is at the bottom of the ample. Flick or tap the ample with your finger.
- Use a new disposable mixing syringe and draw all the diluents from the ample in to the syringe.
- Insert the mixing syringe in to the ample and push the plunger to mix diluent with powder.
- Put the mixing syringe and needle in a safety box after use.
- Put the reconstituted vaccine on the foam pad of your vaccine carrier.

### 7.2.3. Reconstitution of Measles Vaccine

The procedure of reconstitution of Measles vaccine is almost same as BCG.

- Use a new disposable mixing syringe (5 ml) and draw all the diluents from the vial in to the syringe.
- Make sure that all of the vaccine powder is at the bottom of the vial. Flick or tap the vial with your finger.
- Insert the mixing syringe in to the vial and push the plunger to mix diluent with powder.
- To mix the diluent and vaccine, draw them up slowly into the syringe and inject them slowly back into the vial or ampoule. Repeat several times. Or hold the neck of the vial between your fingers and shake gently to mix the contents until all of the vaccine powder has dissolved. If necessary, note the date and time the vial was mixed.
- Put the mixing syringe and needle in a safety box after use.
- Put the reconstituted vaccine vial on the foam pad of your vaccine carrier.
7.3. **Positioning children correctly for injections**

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

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

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

- The mother may tuck the child’s legs between her own to secure them, or she may hold the child’s legs.

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

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

---

**Route of Injection and technique**

**For Pentavalent/IPV/Hepatitis-B injection:**

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

**For Td injection:**

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

**For Measles / MMR injection:**

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

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

Oral Polio Vaccine (OPV):

- Ask the parent to hold the infant with the head supported and tilted slightly back.
- Open the infant’s mouth gently, either with your thumb on the chin or by squeezing the infant’s cheeks gently between your fingers.
- Let 2 drops of vaccine fall from the dropper on to the tongue. Don’t let the dropper touch the infant’s mouth.
Chapter 8

8. Organization EPI Session and Management

8.1. Organizing outreach sessions at health centre/house/School/Islands office

As per the target, session and geographical terrain of catchment area of health facility, outreach site will be determined consulting with the islands leader and other community people. After agreeing date, time and place for outreach session, broadcast well to the people in the community so that they can attend as per schedule for immunization and other service including curatives.

If the outreach site place is other than health centre then make sure that it is well located and middle of islands. Site should be cleaned, well ventilated and enough space for comfortable works of health care providers and for movement of clients. If the outreach services are combined with curatives side and if they are not able to go, you must have to arrange to go for immunization service only in the schedule day.

Importance of a Well-organized EPI session:

A well-organized EPI session facilitates health workers to perform important activities before session, during session and after session as because well-organized session-

1. creates opportunities for health education

2. Cold chain is well maintained

3. Non-touch technique can be followed

4. Possible to provide the correct dose and right injections to the target children and women

5. it satisfies parents and inspires them to come for next doses

Before session:

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

1. Easily accessible to women, children and infants. Arranged such a way so that they are not crowding the immunization area;

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

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

4. Convenient space for the vaccinators for preparing injections

5. A table for vaccines, injection equipment and for the vaccinator who will immunize the children

6. A table for the recorder for recording the information for the client in child vaccination card and child growth development

7. A chair on which a client’s/parents can sit while holding a child for immunization

8. Quiet enough for you to be able to explain what you are doing and to give advice

9. Preparation for session is same like fixed facility

10. As outreach site will not be like health facility, make sure vaccine carrier is in shade
B. Supplies and equipments needed for a session
For a session following are the items are needed:
1. Vaccines, diluents and other supplies
2. Vaccine carrier, icepack, foam pad
3. AD syringes for injection, disposable syringes for reconstitution
4. Safety boxes
5. Cotton
6. Water Bucket, plastics bags, soap/hand sterilizer, towel
7. Child vaccination record forms, child growth development card
8. Women card
9. Pencil, pen, scissors

C. Assessing/ Screening the client in the session
The purpose of assessing a client is to find out what vaccines he or she is eligible for and whether there is any reason not to give them.
1. You should know the standard immunization schedules for the children and women and how to recognize contraindications on which to base your decision.
2. If the client has come to health facility or outreach for reasons other than immunization, such as treatment or antenatal care, screen them and if needed give the appropriate vaccine.
3. If a client is ill, you can give treatment but make sure you are immunizing them

During session:
Preparing vaccine for use
Aseptic preparation for vaccine handling or administration is essential part of injection safety and very much important for the success of EPI programme.

1. Washing / disinfecting hands
By washing hands with soap and water or using sterilizer you remove the germs from them and help to prevent contamination. Some germs remain in your hands even after thorough washing. So therefore you can wash also by antiseptics if possible.

2. Checking the vaccines and diluents
Before you use any vaccines and diluents for reconstitution and administration check-
   a) Is the label still attached to the vial?
   b) Is it right vaccine or diluents?
   c) What is expiry date? Is it passed expiry date?
   d) Is VVM Ok? Check the color change in square.

3. Reconstitute BCG, Measles and MMR Vaccines:
   Go to chapter 7 for details.
4. **Vaccine storing at EPI session and use of Vaccine:**

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

a) Conduct session and keep the vaccine carrier in the shade
b) Don’t open vials until target child and woman arrive at the session
c) Use only one vial of a vaccine at a time, don’t bring more vials of same vaccine
d) Reconstituted BCG and Measles vials and OPV vial should be kept on Ice packs/ in the slit of foam pad.
e) Pentavalent and TT vials should be kept on table besides icepack in such a way that vials are not in close contact of icepacks.
f) The vials should be shaken gently before taking vaccine in the syringe every time. As because sediment may deposit at the bottom of vials during storing.
g) Frozen Pentavalent (DTP + Hep-B +Hib) and TT vaccine and frozen diluents of BCG and Measles must not be used in any way.
h) Once BCG and Measles are reconstituted should not be used more than six hours.
i) Date and time of reconstitution should be written on the levels of vials at the time of reconstitution of BCG, Measles and MMR
j) Reconstituted vaccine loses its potency rapidly and if used there might be severe side effects.
k) If the icepacks on the table were melting, it should be changed to keep vaccine potent. Melted ice pack should not be kept inside the vaccine carrier.

5. **Immunization card should be checked or registration should be completed,**

6. **Needle cap should be kept in to the safety box**

7. **Used AD syringes should be put in to the safety box immediately after use.**

8. **Right vaccine should be drawn in right syringe**

9. **Vitamin A should be given with Measles and MMR vaccines**

10. **Td vaccine should be given to women on the basis of eligibility**

11. **Daily tally report should be prepared**

12. **Parents should be informed when to come for the next dose with thanks**

Before giving any vaccine to a child, the above points to be followed.
**Key messages for parents:**

1. Bring the child on the right date to complete the vaccination by one year.
2. Vaccination can be given if child suffers from mild fever, mild cough and diarrhoea.
3. After vaccination the child may develop mild fever, pain or ulcer at the site of BCG injection, these are self-limiting and nothing to be worried.
4. Preserve vaccination card for future need.
5. Ask the parents about any paralysis case, Measles case and Neonatal tetanus case they have seen in their community. Request them to report these cases to nearby health worker or health centers.

**8.2. Vitamin A supplementation**

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

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

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

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

---

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

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

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

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

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**After Session:**
A. Care of Equipments and space:
1. Close the opening on the top of safety box
2. Keep the safety box in secure place and out of reach of the children and public. If box became 3/4 full then close the box securely and send it for burning in incineration.
3. Take care of the vaccines after the immunization session- Liquid vaccines like OPV, TT can be used in subsequent session (if multi dose vial criteria permits), put in return box in refrigerator.
4. Care of the other supplies (injection material) and equipments (vaccine carrier), clean the equipments.
5. Clean the space
6. Filling the records in the office
7. Prevent injuries and infection from unsafe injection practices

B. Clean waste of Vaccination center:
1. Do not leave anything behind that might be a health threat to the community.
2. Do not leave empty or opened vials at the site.
3. Do not leave any syringes or needles at the site.
4. Return tables, chairs, and other equipment to their owners.
5. Thank the local people who have helped to organize the session and remind them when you will return.

Caution: All AD syringes and Reconstituted syringes should be put in to the safety box immediately after use.
Disease Surveillance: National EPI started its journey in Maldives with a view to reduce child mortality and morbidity against nine vaccine preventable diseases (Tuberculosis, Diphtheria, Pertussis, Tetanus, Measles, Rubella, Mumps, Polio and Hepatitis-B) through vaccinating the target group with antigens. EPI disease reduction goals were set in 41 World Health Assembly in 1988. Maldives also continue extreme efforts to achieve these goals with other countries of the world.

9.1. Disease Reduction Goals in National EPI

a) Objective of Immunization Achievement:
   - Strengthen routine immunization services to achieve 100% coverage for all EPI antigens at Atoll level

b) Objectives of Disease Reduction:
   - Maintain Polio free status
   - Sustain MNT elimination Status
   - Achieve and sustain Measles elimination status
   - Achieve Rubella and CRS elimination status
   - Achieve Haemophilus Influenzae-b elimination status

Control:
Control of diseases is defined as a reduction in the incidence, prevalence, morbidity or mortality of an infectious disease to a locally acceptable level; E.g. Measles has been reduced to status of control in Maldives.

Elimination:
Elimination as reduction to zero of the incidence of disease or infection in a defined geographical area; cessation of transmission of the causative disease agent in human being and may present in environment. E.g. Neo-natal Tetanus has been eliminated in Maldives.

Eradication:
Eradication is from permanent reduction to zero of the worldwide incidence of infection. i.e. complete extinct of the causative disease agent from human being as well as from the environment. E.g. Small Pox has been eradicated in the whole world.

9.2. Strategies for Disease Reduction
EPI is playing significant role in saving thousands of children’s life of Maldives through vaccination against vaccine preventable diseases. Finally, eradication of Polio, elimination of Neo-natal Tetanus and control of Measles is not possible only through vaccination. To achieve these goals an effective and reliable Disease Surveillance should be strengthened and continued in addition to strengthening routine immunization. Furthermore, these goals may be attained by organizing Supplementary Immunization Activities like National Immunization Days (NIDs), Sub-National Immunization Days (SNIDs), Measles campaign, Maternal and Neonatal Tetanus (MNT) campaign.
Disease Surveillance

Disease surveillance is defined as ongoing collection and analysis of information about cases of a disease as a basis for planning, implementing and evaluating disease prevention and control activities. The type of information collected by disease surveillance consists of descriptive epidemiologic categories of time (date of symptom onset), place (where infected) and person (age, sex, vaccination status, mortality etc.).

Disease surveillance may be facility-based or community-based. Facility-based disease surveillance refers to the collection of data (actively or passively) from fixed sites. Community-based disease surveillance refers to collection of data from individuals in the community rather than from the fixed facilities.

Vaccination can prevent diseases but surveillance detects the diseases and collects information/data of disease incidence rate for action. In case of disease surveillance, it is important to know the case definition of diseases.

9.3. Reportable Diseases in EPI

1. Acute Flaccid Paralysis -AFP (below 15 years of Children)
2. Neo Natal Tetanus ( birth to 28 days infants)
3. Measles (at any age)
4. Mumps (at any age)
5. Tuberculosis (below 5 years)
6. Diphtheria (at any age)
7. Whooping cough (at any age)
8. Rubella (at any age)
9. Tetanus (after neonate to any age)
10. H. Influenza disease of any type (below 5 years)

Aggregated data of Vaccine Preventable Disease must be reported in Daily Surveillance Form by Public Health Staff to HPA. Any suspected Vaccine Preventable Disease must be reported immediately to the public health unit and Health Protection Agency. For more information please refer Communicable Disease Reporting Guide for Health Professionals available from Ministry of Health Website (www.health.gov.mv) or Health Protection Agency website (www.hpa.gov.mv).
9.4. Stages of Disease Surveillance

9.5. AFP Disease Surveillance

Acute Flaccid Paralysis (AFP) surveillance is one of the most vital strategies of polio eradication. AFP is not a disease but it is symptom. There are other diseases including Polio that develop AFP. It is imperative to identify all the Polio cases for eradication.

9.5.1. Case Definition of Acute Flaccid Paralysis (AFP)

Use of Standard case definition of Acute Flaccid Paralysis is crucial to monitor the ability of the surveillance system of Polio Eradication Program to detect Polio case.

Any child less than 15 years old with:

- **Acute**: Rapid progression from weakness to paralysis (Sudden onset- as opposed to chronic)
- **Flaccid**: Loss of muscle tone, “floppy” (as opposed to spastic or rigid)
- **Paralysis**: Inability to move the affected part (Weakness, loss of voluntary movement)

AND the paralysis is **not** from birth or is **not** a result of an injury **OR**

Paralysis of any age diagnosed as Polio by Clinician

9.5.2. Steps for AFP Investigation

1) All cases of AFP at the outpatient department, emergency room and inpatient ward in health care facilities should be identified by clinicians; Community Health Workers (CHW)/Nurses should identify and immediately notify any suspected AFP case to Atoll Public Health Unit and Health Protection Agency Surveillance Focal Point.

2) The Health Protection Agency Surveillance will coordinate with the Atoll/Island PHU to investigate the case within 48 hours of notification and take appropriate actions.
3) If a case is identified in the home visit, immediately refer the case to the Health facility. The confirmed AFP case should be admitted in nearby Health facility or Hospital for easy collection of stool specimens. **It is advisable that all cases from Atoll/Island to be referred to IGMH, after consulting IGMH Pediatric department.**

4) Collect two adequate stool specimens 24 – 48 hours apart and send to IGMH Laboratory, with filled up *Investigation Form for Acute Flaccid Paralysis.*

*Adequate stool* means that 2 stool specimens are collected at least 24 hours apart and within 14 days of onset of paralysis and fulfill all of the following criteria:

- Stool specimens are sufficient in amount (at least 8 grams- *half of the adult thumb size*).
- Stool specimens are preserved and transported maintaining cold chain (it is critical that the temperature maintained between +2°C to +8°C Celsius, so that virus does not die).
- There is no leakage from the containers with stool specimens and
- Both stool specimens arrive to IGMH within 72 hours of collection.

5) The community health workers should conduct home visiting searching for additional cases.

6) Conduct follow-up examination 60 days after paralysis onset and submit completed 60 Days Follow up Examination Form to HPA.

7) For cases without adequate stool sample and 60 days follow-up with residual paralysis or follow-up not done due to death or lost to follow-up – additional information form along with all medical record should be sent to HPA for Expert Review Committee (ERC) to classify the case. The CHW will assist physician in conducting 60 days follow-up by visiting the case’s house.

8) Attending doctor at health facility should demonstrate how to do exercise of the affected parts of the child and advice the parents to continue physical exercise. The CHW should follow-up the case regularly.

**9.5.3. Differential Diagnosis of AFP**

The most common differential diagnosis of acute flaccid paralysis includes paralytic poliomyelitis, Guillain-Barré syndrome, Transverse myelitis and Traumatic neuritis. These diseases **always** presented with AFP. Non Polio Enteroviruses (like Coxsackieviruses A and B, echovirus, enterovirus 70 and enterovirus 71) infections have been implicated in polio-like paralytic disease and thus has been associated with AFP.

![Differential Diagnosis of AFP](image-url)
However, any disease that presents as AFP, even if diagnosed as a disease other than polio by the physician, must be immediately reported.

9.5.4. Classification of AFP cases

Final classification of AFP cases includes three possibilities:

1. Confirmed Polio,
2. Non Polio AFP (Discarded polio case) and
3. Case compatible with Polio

An AFP case is confirmed as Polio only by the isolation of Wild Polio Virus from any stool specimen.

A non-polio AFP case (Discarded polio case) is an AFP case with no wild poliovirus isolated from any of the two stool samples by any WHO reference laboratory and fulfills any of the following criteria:

1. The two specimens collected were adequate; or
2. Inadequate stools but absence of residual paralysis during the 60+ days follow-up
3. Inadequate stools, but absence of residual paralysis during the 60+ days follow-up or 60+ follow-up investigation could not be done (either due to death or loss to follow-up); but after reviewing the history, clinical features and necessary investigation reports, NCIP/ERC is convinced that this case is not compatible with polio.

A case compatible with polio is an AFP case from whom adequate stool samples could not be collected and there was either residual paralysis on 60+ days follow-up or 60+ follow up could not be done (either due to death or loss to follow-up); and after reviewing history, clinical features and necessary investigation reports, the National Expert Review Committee (ERC) could not rule out possibility of poliomyelitis
### Table 2: AFP Surveillance Performance Indicators

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Annual Non-Polio AFP rate in children &lt; 15 years old</td>
<td>&gt;2/1 00000</td>
</tr>
<tr>
<td>2 Completeness of passive reporting from facilities</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>3 Timeliness of passive reporting from facilities</td>
<td>&gt;80%</td>
</tr>
<tr>
<td>4 Suspected AFP cases investigated within 48 hours of notification</td>
<td>&gt;80%</td>
</tr>
<tr>
<td>5 Confirmed AFP cases with 2 stool specimens collected within 14 days after paralysis onset</td>
<td>&gt;80%</td>
</tr>
<tr>
<td>6 Stool specimens arriving at laboratory within 3 days after collection</td>
<td>&gt;80%</td>
</tr>
<tr>
<td>7 Stool specimens arriving at laboratory in “good” condition “good” =</td>
<td></td>
</tr>
<tr>
<td>1. Presence of un-melted ice or temperature &lt;8°C</td>
<td></td>
</tr>
<tr>
<td>2. Adequate volume (8 grams)</td>
<td></td>
</tr>
<tr>
<td>3. No evidence of leakage</td>
<td></td>
</tr>
<tr>
<td>4. No evidence of desiccation (drying)</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>8 60+ follow up rate (Percentage of AFP cases with a follow-up investigation at least 60 days after onset of paralysis among the cases that need 60+ follow-up)</td>
<td>&gt;80%</td>
</tr>
<tr>
<td>9 Stool specimens with laboratory results within 14 days after specimen receipt</td>
<td>&gt;80%</td>
</tr>
<tr>
<td>10 Stool specimens from which non-polio enterovirus (NPEV) was isolated</td>
<td>&gt;10%</td>
</tr>
</tbody>
</table>

### 9.6. Measles surveillance

#### 9.6.1. Case Definitions of Measles in Surveillance

Use of standard case definition of Measles is crucial to monitor the ability of the surveillance system to detect measles and measles-like cases.
9.6.2. Clinical case definition of suspected measles

Any person in whom a clinician suspects measles infection, or

Any person with:
- fever and
- generalized maculopapular (i.e. non-vesicular) rash and any one of the following:
  - cough
  - coryza (runny nose)
  - conjunctivitis (red eyes)

9.6.3. Measles Case Identification and Investigation

All cases of measles who meet the surveillance case definition of measles when present to the outpatient clinic, emergency room and inpatient ward in health care facilities should be identified and investigated by attending physician. The clinicians (Resident Medical Officers, Medical Officers, Pediatricians and other Physicians) of the health care facility collect information from cases at the time they see the patients. They record information on AFP & EPI disease report form and drop them in the surveillance Box or hand over to HSO at the end of their duty. Measles case based surveillance

9.6.4. Measles case based surveillance

Measles surveillance is now case based surveillance in Maldives. An investigation form was developed by the Health Protection Agency and distributed to the field. Any single suspected case of measles should be reported and investigated by team and Laboratory specimen should be collected from every case.

Objectives of measles case based surveillance:

1. To determine the disease burden and characterize the pattern in time, place and person
2. To detect cases and investigate outbreaks
3. To identify areas and populations at risk
4. To monitor the impact of measles vaccination on disease incidence and to direct the vaccination program
9.6.5. Measles Case Based Surveillance Summary

9.6.6. Treatment
Although there is no specific treatment for Measles, limited studies have demonstrated some clinical benefit of the antiviral drug ribavirin. Administration of vitamin A to children with measles has shown to decrease both the severity of disease and the case fatality rate.
Table 4: WHO Recommended Vitamin A Schedule for measles treatment

<table>
<thead>
<tr>
<th>Age</th>
<th>Immediately On Diagnosis</th>
<th>Next Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;6 months</td>
<td>50 000 IU</td>
<td>50 000 IU</td>
</tr>
<tr>
<td>6-11 months</td>
<td>100 000 IU</td>
<td>100 000 IU</td>
</tr>
<tr>
<td>&gt; 12 months</td>
<td>200 000 IU</td>
<td>200 000 IU</td>
</tr>
</tbody>
</table>

9.7. Neonatal Tetanus Surveillance

9.7.1. Strategies for NT Elimination

- Provision of Td 5-dose to all 15-49 years child bearing age women (CBAW)
- Provision of clean delivery services to all pregnant women
  - Clean surface/ bed
  - Clean hand
  - Clean cord with sterile instrument and thread
- SIA in high risk areas
- Effective surveillance for MNT

9.7.2. Rationale for NT Surveillance

Neonatal tetanus (NT) is targeted for elimination since it is a major public health problem along with maternal tetanus. High coverage with Tetanus Toxoid (Td) among pregnant women and in high-risk areas for all child bearing aged women (15-49 years), including improved access to clean delivery services are primary strategies for achieving this goal and sustaining the achievement. NT elimination is targeted along with maternal tetanus. Effective surveillance is critical for identifying areas or populations at high risk for NT and for monitoring the impact of interventions.

9.7.3. Case Definition of Neonatal Tetanus

Suspected case:

- Any neonatal death between 3-28 days of age in which the cause of death is unknown; or
- Any neonate reported as having suffered from neonatal tetanus between 3-28 days of age and not investigated.

Any neonate with normal ability to suck and cry during the first 2 days of life and

- who, between 3-28 days of age, cannot suck normally and
- becomes stiff or has spasms (i.e. jerking of the muscles)
Confirmed NT case / Case definition of NT:

Note: The basis for case classification is entirely clinical and does not depend on laboratory confirmation. NT cases reported by physicians are considered to be confirmed.

9.7.4. Neonatal Tetanus case notification

All Neonatal tetanus cases should be immediately notified to DSFP. All health facilities, private practitioners and other health care providers must immediately report any case of NT (either living or dead) to the respective DSFP. The mother of the NT case should be vaccinated with TT as soon as possible once the diagnosis is made regardless of her prior immunization status. The DSFP will send the LSO to investigate the case and take appropriate actions.

9.7.5. NT case reporting from community

All Community health workers/Nurses and NGO health workers should immediately bring the suspected NT case to the health facility to report and for treatment. All neonatal death should be reported to immediate supervisor and should be investigated by Medical Officer to identify NT. Any neonatal death between 3-28 days of age in which the cause of death is unknown will be considered as a suspected NT Case.

9.7.6. NT case investigation and response

Investigation and response to NT case confirmed at facilities or reported by field workers should follow a stepwise approach:

Step 1: Interview the mother, examine the infant (if living) and complete the “Neonatal Tetanus Case Investigation Form”

Step 2: Vaccinate the mother with TT regardless of previous vaccination status if vaccination has not already done;

Step 3: Mobilize members of the investigation and response team to the island or neighborhood of the NT case. 5 NT Case Investigation Forms, the health worker’s TT Registration Book, five-ten 10-dose vials of TT and sufficient supplies to vaccinate all who are eligible CBA women to receive TT vaccine in the island/Atoll;

Step 4: Ask doctors, pharmacists, homeopaths, NGO workers local leaders etc if additional cases of NT or neonatal deaths (NDs) occurred in 3-28 days old babies in the past 6 months;

Step 5: Investigate any additional cases of NT or ND and vaccinate the mothers of NT cases;

Step 6: Conduct house-to-house visits in the whole Island (of about 1000 population) of the index case home to identify women of child bearing age who are eligible to receive TT. Record the findings on the worksheet on the back of the Neonatal Tetanus Case Investigation Form

Step 7: Vaccinate all eligible CBA women of that area including the mother of the case and register the doses in the Td Registration Book. This additional vaccination response is called Case Response Immunization (CRI); advice unvaccinated women to attend the next scheduled EPI outreach session;

Step 8: Anticipate increased Td vaccine needs for the next scheduled EPI vaccination session.
9.8. Rubella and Congenital Rubella Syndrome (CRS) Surveillance

9.8.1. Case definitions for Rubella and Congenital Rubella Syndrome (CRS)

Rubella:
- **Suspected Rubella case:** Any patient of any age in whom a health worker suspects rubella. Health worker should suspect rubella when a patient presents with fever, maculopapular rash and cervical, suboccipital or post-auricular adenopathy or arthralgia/arthritis.
- Rubella cannot be confirmed clinically. Therefore laboratory confirmation is required.
  - **Laboratory confirmed rubella case:** A laboratory confirmed case is a suspected case with a positive blood test for rubella specific IgM and/or isolation of virus in a clinical sample.
  - **Epidemiologically confirmed rubella case:** A patient with a febrile rash illness that is linked epidemiologically to a laboratory confirmed rubella case

Congenital Rubella Syndrome (CRS):

**Suspected CRS case**

Any infant is less than one year of age in whom a health worker suspects CRS.

- A health worker should suspect CRS where there is a maternal history of suspected or confirmed rubella during pregnancy
- A health worker should suspect CRS when the infant presents with heart disease and/or suspicion of deafness, and/or one or more of the following eye signs: white pupil (cataract); diminished vision; pendicular movement of the eyes (nystagmus); squint; smaller eye ball (microphthalmos); larger eye ball (Glaucoma)

**A clinically confirmed case** is one in which a qualified physician detects two of the complications in section (a) OR one from group (a) and one from group (b).

(a): Cataract and or congenital glaucoma; congenital heart disease; loss hearing; pigmentary retinopathy

(b): Purpura, splenomegaly; microcephaly; mental retardation; meningo-encephalitis; radiolucent bone disease; jaundice with onset within 24 hours after birth
9.8.2. Surveillance of Rubella and CRS

There is evidence that rubella is coming into view so that it is essential to find out the burden of rubella and CRS. Surveillance of CRS requires a comprehensive system to detect suspected CRS cases in infants.

- Identify rubella as a notifiable disease and integrate it with the surveillance of other vaccine preventable diseases.
- Identify rubella outbreaks through serological confirmation of all fever and rash outbreaks. Investigate such outbreaks fully and follow them to find out possible increase in the incidence of CRS in the areas.
- Conduct sentinel surveillance of CRS at neonatology units, eye hospitals and cardiology units, ENT units and Obstetric units.

All suspected CRS cases must be investigated with full clinical and laboratory investigation.

9.8.3. Implementation of CRS surveillance in health facilities

CRS surveillance should focus on,

- Identifying infants 0-11 months of age with CRS
- Reporting annual number of CRS cases
- Reporting annual rate of CRS cases per 1000 live births

HCWs role in Disease Surveillance

1) Identify and report all AFP, Measles, NT and other VPDs.
2) Report AFP case of any children below 15 years of age to DSFP immediately.
3) Report information of live NT case to supervisors or DSFP immediately.
4) Report Neonatal deaths (NDs) occurred in 3-28 days old babies in the past 6 months to supervisors weekly.
5) Report information of Measles cases to supervisors weekly
6) Contact regularly with other health care providers for reporting of AFP, NT, Measles and other VPDs.
7) Create awareness and motivate the community peoples to report AFP, NT, Measles and other VPDs to to CHW or supervisors. Awareness can be developed by organizing community group discussion, giving message during Friday prayer, asking parents in EPI sessions and house to house visit.
8) Assist Medical Officer or Surveillance officer to identify house of suspected case, investigate the case, collect stool samples, and conduct ORI and CRI to protect children against diseases.
10. Reporting System

10.1. Timeliness and completeness of reporting

- Report cannot be compiled and sent within stipulated time if the island’s complete reports are not received timely at atolls and atolls to national EPI unit.
- The programme’s total report cannot be sent within stipulated time if the report are not compiled timely
- Timely analysis of complete report identifies programme errors for correction.

10.2. Different forms and cards used in EPI

1) Child registration and vaccination record
2) Woman registration and vaccination records
3) Child Growth card /Child card
4) Child growth /Woman vaccination card
5) Daily tally sheet
6) Monthly vaccination report (child)
7) Monthly vaccination report (woman)
8) Stock record
9) Refrigerator Temperature chart

All the EPI registration and vaccination records/book should be preserved carefully. The documents should be handover to new staff in case of retirement or transfer.

Drop out:
A child should receive all the antigens as per the EPI recommended schedule before observing \( \frac{1}{2} \) 18 months for being fully vaccinated. The children are considered as drop out when these children miss any dose of the recommended antigens i.e the child received at least one or more doses but did not complete all.

Left out:
The children are considered as left out when these children have not received any doses of the EPI recommended antigens. The child may be registered for vaccination.

10.2.1. Use of Different forms and cards

A. Registration and Vaccination Information Book:

Objectives:

- Total target of the catchment area is known once the name of new born infants’ after birth, date of birth, and name of women are registered.
- Starting date of vaccination for infants (0-18 months) and women (15-49 years) and completion dates are known from the registers.
- Each dose given to every child or pregnant woman in the catchment area should be recorded against their names in the register.
• Helps health workers keep track of the immunization services they offer to each infant and pregnant woman.
• The follow-up can be made for the drop outs to complete the doses.
• Daily target for vaccination is determined on the basis of eligibility of vaccine

**Key Note:** *Health workers should be urged to treat the immunization register with respect and care as it may be the only permanent record of immunization available. The immunization register can also be used as birth register.*

**Information of immunization registers:**
The following information are included in register, as well as any information required by your health facility:
• A registration number
• Registration date (registration after birth or the date of first visit)
• Name of Infant
• Infant’s date of birth
• Infant's Sex
• Name and address of mother/Parent
• Date of eligibility of first dose of Penta and Measles
• Vaccination provided and Vitamin A supplementation dates
• TT vaccination to Child bearing age women and pregnant women.

*Do not create a new entry in the register each time the mother brings the infant for immunization. Ask the mother for the immunization card and look for a corresponding entry in the register. If the immunization card is not available, ask the mother the age of her infant and details of the first immunization to locate the infant’s entry in the register.*

**B. The Immunization Card:**
The immunization card contains the immunization history and status. It is important that immunization cards are completed accurately so that they can be used for tracking defaulters and providing caregivers and pregnant women with information on when to return for services.

**Importance of Immunization Card:**
• It serves as a remainder for parents to return to the clinic for the next dose
• It helps the health workers determine an infant’s immunization and Vitamin A status.
• It is useful when health workers conduct coverage survey.

*Each infant and woman should have a card with immunizations marked correctly.*
C. Tally Sheet:
Tally sheets are forms on which the health workers make a mark every time after administering a dose of vaccine. These are used as a basis for reporting and monitoring. After immunizing an infant/woman, the date of immunization should be recorded also in the register and on the immunization card and the mother should be informed which doses were given.

At the end of each immunization session, total the number of marks recorded during the session. This tells the number of immunization have been given with each vaccine and each dose. This information will be used to monitor performance and prepare a monthly report. The monthly report should be prepared by compiling the daily tally sheets.

D. Monthly Report Form:
The immunization data collected needs to be consolidated in a summary form called Monthly report form. The monthly report form needs to be compiled either manually or electronically from island to atolls and from atolls to national EPI unit.

At each level the data should be analyzed and used to improve the programme. A copy of the report should be sent to next level with date and signature but one copy of the report should be stored for use at facility level.

10.3. Preparing good monthly report
The health worker or the person designated for preparing report should ensure that the reports prepared are:

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

- **Timely**: Check for deadline for report the report from Islands should be submitted to atolls by 7th of next month and from atolls to national EPI Unit by 15th of next month. (Report of January of Islands is to be sent by 7th February to atolls and from atolls to National EPI unit by 15th February)

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

Storing Data and Reports:
At the facility level, tally sheets, registers and reports should be stored for a specific period of 3 years.
11. Communication in EPI

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

Engaging parents in a dialogue on immunization will help clarify doubts, fears and concerns about their benefits,

- To the child who needs protection against dangerous diseases
- To the parents who want a healthy family
- To the community in preventing the possible spread of diseases when not all children are immunized.

11.1. Objectives of Communication

- Publicize one’s new ideas to others
- Exchange of information
- Understand other’s views
- Acceptance of messages to others
- Create motivation
- Change the behavior of client / Change of attitudes

11.2. Effective communication

Effective communication means listening to, understanding, encouraging, and working with individuals and communities to improve their health and the services available to them. Effective communication should be a two-way process and cannot be completed if there is no response or feedback to the sender of information.

11.2.1. Elements of Effective Communication

1. Sender
2. Message
3. Media / Channel
4. Receiver
5. Feedback

11.3. Communication with the community

Keeping community members updated on the progress of the immunization programme is important for increasing and sustaining their involvement and support of services. The strategies for communication with community in table 1.1 will enhance communication and help to build a good relationship and rapport.
Table 1.1: Tips for effective communication with communities

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

**Training health workers to improve communication skills**

To improve immunization services, most managers and health workers need to strengthen their communication skills and technical knowledge. This may require additional training or capacity-building to improve health-worker attitudes towards clients, and to strengthen their ability to communicate messages. To improve this interaction, health worker and client expectations, attitudes and skills may need to change.
## Table 1.2: Tips for effective communication with parents at the fixed or outreach session

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

### Qualities of effective communication:

- Good interpersonal relationship
- Use of short, clear and simple language
- Message should be relevant to clients
- Good listener, which is as important to communication as speaking.
- Respect for people’s opinions, knowledge and ability to change
- Asking questions to check information has been correctly understood
The ideal health worker/caregiver interaction in EPI session:

1) The health worker welcomes, greets and thanks the caregiver in a friendly manner for coming for vaccination and for her patience if she had to wait.
2) The health worker explains to the caregiver in simple terms and the local language the disease(s) against which the vaccination protects.
3) The health worker mentions possible minor side effects (which are normal reactions to vaccines) and explains how to handle them. Health worker also mentions that in extremely rare cases serious post-vaccination reactions may occur that should be reported immediately to the health facility for assistance.
4) If the child has a common mild illness, the health worker explains that vaccination is still safe and effective and important, and administers it.
5) After the vaccination is given, the health worker writes the date of the current vaccination(s) and other details on the immunization card.
6) If the vaccine received is one in a series (e.g. Penta1, 2, 3, OPV 1, 2, 3; or Measles1, MMR IPV1), the health worker explains to the caregiver the need for the child to complete the series to be fully protected against the disease(s). The health worker uses the vaccination chart on the immunization card as an instruction guide.
7) The health worker writes the date for the next vaccination on the immunization card and tells the caregiver about it. If appropriate, the health worker associates the date with a “trigger” such as a holiday or seasonal event that will help the caregiver remember to bring the child back for vaccination. The health worker asks the caretaker to repeat the date, to be certain it has been understood.
8) The health worker explains to the caregiver that if she and/or the child cannot come on the return date, they can obtain the next vaccination at another location or another date but not before to the due date.
9) The health worker reminds the caregiver that she should bring the immunization card (child growth development card) to the location where the child receives the next vaccination and advice to preserve it. This card should be kept like a birth certificate as it is a mandatory for school entry.
10) The health worker congratulates the caregiver if the child is fully vaccinated.
11) The health worker asks the caregiver if she has any questions and politely answers all questions.
12) The health worker should ask to see the mother’s vaccination record in order to determine her tetanus toxoid (TT/Td) status and advise her accordingly.
13) For the vitamin A to being given, the health worker explains to the caregiver that it is important to bring the child back in nine months and eighteen months (and give the dates) for subsequent vitamin-A supplementation to help protect the child from infections.
Method of Communication
1- One way communication
2- Two way communication

A. One way communication:
The sender sends the message to receiver and receiver listens but no feedback. e.g. Radio/Television (these can be 2 way as well, such as in live programs where listener asks questions) news, Lecture. In some cases this is effective and message can be given to many peoples.

B. Two way Communication: In this communication the sender sends the message to receiver and can take feedback and if needed the sender can explain the message. Two ways communication is very effective in disseminating EPI messages to the parents. The health worker asks the parent to repeat the message, to be certain it has been understood.

The communication process is of two types:
a. Inter-personal communication:
   It is direct person to person communication. In this face to face communication 2 to 3 persons can exchange their messages and views.

b. Characteristics of Interpersonal communication:
   i. No change of messages due to direct communication
   ii. Easy and effective exchange of messages and scope of feedback
   iii. Receiver’s concern is known and can be solved
   iv. Easy to motivate receiver/client
   v. Visual aids can be used besides giving message
   vi. Programme related different information can be well-known through Direct conversation.
c. Facilitating interpersonal discussion

- Use simple examples of problems that are important to the parents and families.
  
  ✓ Start with what is already known such as the immunization schedule and focus on completing the schedule and what diseases each vaccine protects child from.
  
  ✓ Use familiar words and avoid technical or scientific language.
  
  ✓ Use illustrations to stimulate discussion.

- Encourage people to ask questions and express concerns.
  
  ✓ Guide the discussion to explore the causes of the problem and possible solutions.
  
  ✓ Remember to listen, which is as important to communication as speaking.
  
  ✓ The participation of children, families and other community members is key to identifying barriers or unforeseen problems that prevent people from acting on the message. They themselves can propose local solutions.

- Show respect for people’s opinions, knowledge and ability to change.

Information at the time of service delivery:

- Communication is a two-way process:
  
  *Listening well, responding to parental concerns, and asking questions to check information has been correctly understood*

- Importance of non-verbal communication:
  
  *Body language, positive approach and respect make a huge difference*

- Speaking confidently, but softly and not condescendingly, to the parents while preparing and giving the vaccine:
  
  *To allay likely anxiety of parent and to make child more comfortable*

- Value and safety of giving one injection to protect against five diseases:
  
  *How to gain parental confidence and address potential concerns*

- Key important information to be communicated to parents at the immunization contact:
  
  *Includes which vaccines the child will receive, the most common side effects and how to treat them, and the date the child should return*

- Importance of asking the parent if he or she has any questions or concerns:
  
  *Making sure the parent knows the danger signs for seeking care*

- Exploring other opportunities for counseling on prevention and treatment of for example pneumonia or diarrhea:
  
  For example at health education sessions offered before the immunization session or as part of community based efforts.
d. Mass Communication:
Communication through different media instead of direct person to person communication is called mass communication. e.g. Radio, Television, leaflet, poster, news paper, folders, brochure, stickers, signboard etc.
Below are some suggestions on how the EPI manager and programme staff can work with the media to communicate information effectively on the immunization programme and activities:

Some suggestions on using the mass media (e.g., television, radio, newspapers)
- Develop an informed media network for accurate reporting on EPI and to be an ally
- Inform the media in advance about EPI programme activities, specifying the date, place and participants of immunization so that these activities may be given wide media coverage
- Sponsor the media to observe immunization activities and events so they can cover stories and broadcast information
- Provide the media with human interest and success stories from the EPI programme like sufferings of children from EPI diseases, cost of treatment and sufferings of parents, benefits of EPI, reduction of infant disease and death and ultimate cost benefit of Vaccination.
- Prepare and issue regular press releases for the media to use in their broadcasts or articles
- Organize regular interviews on EPI diseases, vaccination schedules, benefits with the media, involving different advocates of the programme (e.g. leaders, professional experts, etc.)

11.4. Advocacy and communication for strengthening routine immunization

Advocacy
Advocacy is a process of gathering and communicating information to raise resources and/or gain political and social leadership acceptance and commitment, that will, in turn, assist a society in accepting the programme. The process involves promoting the benefits and value of the EPI service and presenting the rationale for the community’s involvement in Immunization Programme. A process for conducting advocacy could include the following:
- Holding group discussions and/or visits with leaders and the community to discuss: Importance of immunization services, including Place of EPI session and EPI diseases
- Vaccines protect diseases and benefits of vaccination
- Possible side effects, and as far as possible addressing the community’s concerns and requests
- Importance of safe injection practices
- Target groups of advocacy include community groups like islands leaders, religious leaders, private and business sector, NGOs, and community opinion.

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

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

Supportive Supervision in EPI
Supportive supervision is a process of helping staff to improve their own work performance continuously. It is carried out in a respectful and non-authoritarian way with a focus on using supervisory visits as an opportunity to improve knowledge and skills of health staff.

Supportive supervision encourages open, two-way communication, and building team approaches that facilitate problem-solving.

Supportive supervision is joint problem-solving to improve performance, two-way communication and to provide regular and consistent follow-up & training.

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

12.2. Why is supportive supervision?
To improve the quality of performance
- Work with health workers to monitor performance, identify & correct poor practices together
- Take the opportunity to recognize and encourage good performance

12.3. How to do supportive supervision?
- Plan and prepare for the supervisory visit
- Make the visit effective by setting performance expectations
- Use of skills-based checklists
- Provide ongoing assessment, monitoring and feedback over time
Teach and listen effectively

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

12.4. When to do supportive supervision?

Take any opportunity

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

12.5. Where to conduct supportive supervision visits?

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

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

Prepare structure of the visit

- Prioritize locations for EPI session visits based on need
- Choose convenient time for all
- Define objectives and know what topics/issues need follow-up from last visit
- Have materials ready for demonstration/training; prepare them in advance
12.6. What to cover during the visit?
It is important to have a clear understanding of the main objectives of the visit. This could include main tasks to observe, or main topics on which training should be given, etc.
A review of previous supervision reports, checklists, or data analysis, can assist in identifying which topics to cover during supportive supervision visits.

- Always be prepared to use data: vaccination coverage, drop out, left out,
- Review the local data on site during the visit: target for vaccination, achievement, dropout
- Bring summary data, monthly reports, etc. as reference material: EPI daily report, monthly report
- Prepare an agenda for the visit in advance. The agenda should include one or two issues that have already been identified as priorities for the area. e.g Cold chain management, injection safety and non-touch technique, EPI session organization etc.

**Observing immunization session at health-facility:**
Supervisors can obtain a lot of information by simply observing the health-facility environment. For example, they may observe the following:

- Are injection practices correct?
- Is the health facility clean?
- Are there any syringes or open safety boxes lying around that could pose a threat to the community?
- Are there frozen vaccines or expired vaccine vials in the refrigerator/in EPI session?
- Is the health worker interacting well with the community and informing about services?
- Other members of the community?
- Are IEC posters, EPI monitoring charts, etc. displayed on the walls?

**Provide on-site training:**
- Based on locally identified need
- Used to introduce new information
- Quick, practical, effective
- Different Methods:
  - Short interactive lectures on site (about vaccination schedule/side effects/contraindications)
  - Group discussion (discussion with parents on vaccines against diseases, benefits etc)
  - Skills demonstration and practice (by giving injection - correct technique, route etc)
  - Role play (Key EPI messages to parents)
  - Person-to-person mentoring (during vaccination- tell vaccines given against the diseases, side effects, date of next dose, etc)
Follow-up, using supervision register
- Continuity, consistency and reinforcement
- Keep a record of activities to ensure topics are not repeated unless necessary
- Monitors rate and level of improvement

Use of checklists
- Standardize structure and provide continuity for all
- Can include areas of knowledge, practice and skill (what they know and do….)
- Also assessment of performance (how well they are doing it ….)
- Identifies areas for future focus / need

12.7. What are the requirements for Supervision?
A. Supportive Supervisory skills
B. Time
C. Costs for per diem
D. Costs for travel
E. Written feedback and recommendations
F. Standardized supervisory checklists

12.8. Monitoring in EPI
Monitoring is a systematic and continuous process of collecting and examining data linked to implementation of EPI programme activities and measuring progress, identifying areas need specific interventions.

Monitoring tools: an overview
12.8.1. Five Golden Rules of Monitoring

- Establish standard methods of sending/receiving EPI data
- Establish a working routine
- Check all incoming data (daily/monthly EPI report, surveillance report)
- Monitor performance (completeness, accuracy, timeliness of reporting)
- Produce routine reports & feedback (Data compilation at atolls and central level and feedback)

12.8.2. Basic Tools for monitoring

The every health facility should have system of recording immunization data, making record systematically. Following are the basic tools available in Maldives.

1) Immunization registers (children and women):
   The Immunization registers have basic information which includes, identification number, date of registration, name, birth date, sex, address of parents and details of vaccination according to schedule. The immunization register helps health care providers to keep tracking of children and women.

2) Child growth and development card:
   There are several of information’s in the child growth development card including the immunization history and status. This card helps the health care providers to determine the immunization status of children.

3) Daily tally form:
   This form includes total number of daily vaccinated children and women of a EPI session. One copy preserved at the session/health facility for monthly compilation and one copy sent to supervisor.

4) Monthly reporting forms:
   This is aggregated report forms for the month for monitoring the performances and sending to superior level.

5) Vaccine stock ledger:
   Vaccine stock ledger is for maintaining the vaccine records especially for vaccine in and out for that health facility.
6) **Temperature chart for daily monitoring of refrigerators**

Temperature should be checked and marked in the monitoring sheet at least twice daily

**12.8.3 Why is monitoring important?**

Monitoring is an important tool for mid-level managers. It can help improve the quality of the immunization programme by ensuring:

- All Infants and Pregnant women are immunized
- Drop out and left out are calculated
- Vaccines and safe injection equipment are delivered in correct quantities and on time;
- Staff are well trained and adequately supervised;
- Information on disease incidence and adverse events following immunization (AEFI) are collected and analyzed;
- The community has confidence in the vaccines delivered and the immunization service they receive.

**12.9. How to prepare a target, coverage and drop-out rate; and calculate vaccine wastage rate!**

1) **Calculate the annual target population to receive immunization services of infants less than one year of age.**

Use the most accurate existing population figures for infants under one year of age. These can be obtained from official census data or your own community census. If 2 per cent is the estimated percentage of infants less than one year of age in any population.

**For example:** If the total population of a Island is 3600, then the annual target population of infants under one year would be 3600 x 2/100 = 72.
2) Calculate the monthly target population of infants less than one year of age to receive immunization services.

For example: If the annual target under one year is 72, the monthly target is 72/12 = 6. That means each month 6 children should be vaccinated: 6 in January, another 6 in February, another 6 in March etc.

3) Calculate the monthly coverage of Penta3 of infants less than one year of age.

For example: If the Atoll “A” health facility has immunized 5 children for Penta3 for the month of November and target of that health facility is 6 for the same month. So coverage is 5/6X100=83%. Penta3 coverage is 83%.

4) Calculate the cumulative coverage for any antigen for 12 months.

For example: Cumulative means by repeated addition of monthly coverage. For example in atoll “A” number of children immunized for Penta3 for month of January to December are 5, 6, 7, 4, 5, 6, 6, 6, 7, 5 and 6. Therefore, 71 is the total cumulative number for the year and for example 72 is the total target for the year in atoll “A”.

Calculation for cumulative coverage= cumulative number of children for Penta3/Total target for that year X 100. So for atoll “A” cumulative coverage is 69/72X100=96%. Therefore cumulative coverage for Penta3 is 96%.

5) Calculate the total number of drop-outs between Penta1 and Penta3:

(DO in number) = total number of Penta1 - total number of Penta3 from the cumulative.

Calculate the cumulative drop-out rate (DO %) as follows:

\[ \text{DO} \% = \frac{(\text{Penta1 cumulative total} - \text{Penta3 cumulative total})}{\text{Penta1 cumulative total}} \times 100 \]

7) Calculate the wastage rate of Pentavalent vaccine given in a month:

For example: 216 Vials (doses) of Pentavalent were supplied and consumed for the sessions and 210 doses were given to the children. So calculation is: Penta doses consumed for the month - doses administer to children/ Doses consumed for the month X100

\[ \text{Vaccine Wastage} = \frac{216 - 200}{216} \times 100 = 7\% \]

*****For more information, please call 3014495 or email us on immunization495@health.gov.mv*****
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