Ministry of Health

Inactivated Polio Vaccine Introduction in Routine Immunization in Kenya

A Guide for Health Workers
October 2015
PREFACE

This training guide has been developed primarily for health workers involved in immunization services delivery in Kenya to prepare them for the introduction of the Inactivated Polio Vaccine (IPV) that will be introduced into the national infant immunization schedule from October 2015. The training guide was adapted from the WHO guidelines for the IPV introduction and also incorporates product information from the current manufacturer of the IPV (Imovax®Polio) Sanofi Pasteur. As such, all references made to IPV in this manual refer to IMOVAX POLIO, a clear suspension formulation presented in a 10 dose vial.

Although this training guide is being released with the introductory process for the IPV, it will continue to be a useful reference point long afterwards for new health workers being inducted into immunization services delivery. This guide was developed by the technical committees formed to spearhead the introduction of the IPV led by the Training Committee, an effort of all of the technical staff of the Unit of Vaccines & Immunization Services and dedicated officers from various partner agencies. Over a period of three months, a remarkable amount of individual time, energy and patience has been committed to the process.

It is the hope of the Ministry of Health, and especially the Unit of Vaccines & Immunization Services that the guide will improve immunization service delivery for all infants in Kenya.

Dr. Ephantus Maree

Head, Unit of Vaccines & Immunization Services
The Ministry of Health through the Unit of Vaccines and Immunization Services (UVIS) is grateful to all partners and individuals whose valuable contributions and technical support made it possible to develop this guide for health workers.

We wish to thank the Head, UVIS and his team for the exemplary leadership during the process. We wish to acknowledge the collaboration and support of partners in the preparation of this guide and in the introduction activities. Special thanks goes to, WHO, UNICEF, USAID-MCSP, CHAI, LDS, JSI, CORE Group and HENNET for their financial and technical support.

Though not possible to list all who participated in the preparation of this guide individually, the Ministry of Health sincerely appreciates all contributions made and the commitment to the process.

Dr. Patrick Amoth

Head, Division of Family Health
The eradication of polio is a top global health priority. Since the World Health Assembly (WHA) endorsed the goal to eradicate polio in 1988, the number of polio cases has drastically declined from an estimated 350,000 cases per year in 1988 to only 416 cases in 2013 and 342 cases in 2014 (as of 24 December 2014). This success has been largely related to wide-scale use of oral polio vaccine (OPV).

The Ministry of Health, through the UVIS and the support of GAVI and Partners will be introducing a new Polio vaccine into routine infant immunization schedule from October 2015, targeting 1.5 million children under 1 year of age. This is in line with the Global Polio Eradication Initiative Endgame Strategic Plan and is hoped to facilitate the eradication of Paralytic Polio Disease.

The Inactivated Polio Vaccine will be administered together with the third dose of Oral Polio Vaccine at 14 weeks of age.

Poliomyelitis is a debilitating paralytic disease that is transmitted through the fecal-oral route and affects mainly non immune children. IPV administered at 14 weeks in addition to the four doses of Oral Polio Vaccine will further boost mucosal immunity and accelerate polio eradication. Given that the use of both vaccines simultaneously induces better immune responses than either vaccine alone it is practical that we advocate for scaling up of access to and utilization of both vaccines.

This training guide is intended to equip health workers at all levels with sufficient information to ensure smooth integration of IPV into the routine infant immunization schedule.

It is my sincere hope that the Inactivated Polio Vaccine will be introduced successfully and sustained smoothly for the benefit of all Kenyan children.

Dr. Jackson Kioko

Director, Directorate of Preventive & Promotive Health Services
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<td><strong>bOPV</strong></td>
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Poliomyelitis or polio otherwise known as infantile paralysis is an acute communicable disease caused by any 1 of 3 poliovirus serotypes (types 1, 2 or 3). Polioviruses are human enteroviruses of the Picornaviridae family and possess a single-stranded, RNA genome and a protein capsid. There are 3 serotypes of polioviruses with slightly different capsid proteins (type 1, 2 and 3). Polioviruses share most of their biochemical and biophysical properties with other enteroviruses. Polioviruses are resistant to inactivation by many common detergents and disinfectants, including soaps, but the viruses are rapidly inactivated by exposure to ultraviolet light. The viral infectivity is stable for months at +4°C and for days at +30°C.

**EPIDEMIOLOGY**

In the pre-vaccine era when poliovirus was the leading cause of permanent disability in children, virtually all children became infected by polioviruses, with, on average, 1 in 200 susceptible individuals developing paralytic poliomyelitis. However the trends have changed since the 1980’s.

In 1988, when the annual global burden of paralytic poliomyelitis was estimated to be >350 000 cases, with wild poliovirus (WPV) transmission reported in >125 countries, the WHA resolved to eradicate poliomyelitis by the year 2000 and the Global Polio Eradication Initiative (GPEI) was established. Worldwide, sustained use of polio vaccines since 1988 has led to a sharp drop in the global incidence of poliomyelitis by >99% and the number of countries with endemic polio from 125 to just 3 as at 2014 and only 2 as of September 2015. In 2012 and 2013, respectively, 223 and 403 poliomyelitis cases were reported. Globally, the last case of poliomyelitis caused by naturally circulating WPV type 2 (WPV2) occurred in India in 1999. No case due to WPV type 3 (WPV3) has been detected since 10 November 2012.
Despite the overall success of the global polio eradication initiative (GPEI), as at 2015, Pakistan and Afghanistan remain endemic for transmission of WPV type1 (WPV1). Nigeria which was an endemic country has not reported any wild polio virus since 24 July 2014. India has been polio free since 2013. The Horn of Africa which reported an explosive outbreak in 2013 has been polio free since August 2014.

The Horn of Africa, Cameroon, and parts of the Middle East (Egypt, Israel, and Syria,) also reported WPV1 circulation associated with imported WPV1 in 2013, resulting in clinical cases following a period of elimination. Israel, which switched to an all inactivated poliovirus vaccine (IPV) routine immunization schedule in 2004, reported detection of WPV1 in sewage samples as from February 2013 but no clinical cases of paralytic poliomyelitis have been reported in Israel, the West Bank or Gaza (as of 31 December 2013).

**MODE OF TRANSMISSION**

Polioviruses are spread by fecal-oral and oral-to-oral transmission. Where sanitation is poor, fecal-to-oral transmission predominates, whereas oral-to-oral transmission may be more common where standards of sanitation are high. In most settings, mixed patterns of transmission are likely to occur.

**CLINICAL PRESENTATION**

Most people infected with poliovirus have no symptoms, with viral replication occurring in, and limited to, the alimentary tract or pharynx. Approximately 25% of those infected develop minor symptoms, usually fever, headache and sore throat. The incubation period is usually 7–10 days (range 4–35 days). Paralytic poliomyelitis occurs in <1% of infected children aged <5 years. It occurs when poliovirus enters the central nervous system and replicates in anterior horn cells (motor neurons) of the spinal cord. The ratio of paralytic cases to infections varies with serotype and age of infected individual. It is estimated at approximately 0.5, 0.05 and 0.08 per 100 infections
respectively for serotype 1, 2 and 3. Depending on the degree and extent to which motor neurons are affected, temporary or permanent paralysis of the affected muscles may occur. In rare cases, viral destruction of bulbar cells results in respiratory paralysis and death.

The typical clinical manifestation of paralytic poliomyelitis is acute flaccid paralysis (AFP) affecting the limbs, principally the legs, usually asymmetrically. Sensation remains intact. Persistent paralysis and resulting deformities are common sequelae. The case-fatality rates among paralytic cases range from 5% to 10% in children and from 15% to 30% in adolescents and adults, predominantly associated with bulbar involvement. Post-polio syndrome, with symptoms appearing 15–30 years after recovery from the original paralytic attack, occurs in 25%–50% of cases; symptoms include acute or increased muscular weakness, pain in the muscles and fatigue.

**DIAGNOSIS**

The diagnosis of paralytic poliomyelitis is supported by:

1. Clinical course,
2. Virological testing,
3. Imaging studies and neurophysiological diagnoses, and
4. Residual neurologic deficit 60 days after onset of Symptoms.

The WHO case definition of Acute Flaccid Paralysis (AFP) is as in the text box below:

*Any child under 15 years of age with acute (sudden) onset of weakness or floppiness of one or more limbs or any person of any age with paralytic illness in whom a clinician suspects poliomyelitis.*

However, a virological finding is essential for confirmation of the diagnosis of poliomyelitis. This involves isolation and characterization of poliovirus from the stools of
patients with AFP to determine whether the viruses are wild, vaccine-associated or vaccine-derived.

**Treatment**

No specific anti-viral drugs are available for poliomyelitis and most cases of paralytic polio are irreversible. Treatment consists of supportive, symptomatic care during the acute phase, including respiratory support in cases with respiratory muscle paralysis. Neuromuscular complications are mitigated by physiotherapy and orthopedic treatment.

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**IMMUNITY, PROTECTION AND PREVENTION**

Immunocompetent individuals infected by poliovirus develop immunity through humoral (circulating antibody) and mucosal (secretory immunoglobulin A) immune responses. The presence of neutralizing antibody against polioviruses indicates protective immunity for poliomyelitis. Detectable antibody is an excellent correlate of protection against paralytic disease. However, immunity is serotype-specific with no cross-protection between serotypes. Mucosal immunity decreases the replication and excretion (shedding) of the virus, thus providing a potential barrier to its transmission. Individuals with B-cell related immunodeficiency disorders are at increased risk for paralytic manifestations of poliomyelitis or prolonged excretion of virus.

The best protection and prevention against poliomyelitis is through vaccination with polio vaccines. Other effective control measures against poliomyelitis include; exclusive breastfeeding during the first 6 months of the child’s life, good nutrition, environmental sanitation, and hand-washing with soap and water.

Two types of vaccine are used throughout the world to combat polio.

- Live attenuated (weakened) oral polio vaccine (OPV) called Sabin vaccine.
- The Salk vaccine, or inactivated poliovirus vaccine (IPV)

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**THE POLIO ERADICATION AND ENDFGAME STRATEGIC PLAN**

In 2013, the World Health Assembly endorsed *The Polio Eradication and Endgame Strategic Plan* which addresses the eradication and containment of poliovirus. The plan
calls for a phased withdrawal of OPV globally beginning with removal of the type 2 component of tOPV through a global switch from trivalent OPV (tOPV) to bivalent OPV (bOPV), containing only types 1 and 3 by 2016. The WHO’s Strategic Advisory Group of Experts (SAGE), has recommended that all countries introduce at least one dose of inactivated polio vaccine (IPV) in their routine immunization programs before end of 2015.

As part of the polio endgame strategy, Kenya introduced IPV in outbreak setting where IPV was used during outbreak vaccination response in Dadaab refugee camp and its adjacent districts.

**JUSTIFICATION FOR INTRODUCTION OF IPV**

The primary role of IPV will be to maintain immunity against type 2 polio virus while OPV type 2 is withdrawn globally. Withdrawal of OPV type 2 will be done in April 2016 in a globally coordinated event being referred to as tOPV to bOPV switch.

Inactivated Polio Vaccine (IPV) closes the immunity gaps in OPV-vaccinated children by inducing a higher sero-conversion rate and increased antibody titers to all 3 serotypes (Types 1, 2, and 3).

More specifically, IPV needs to be introduced for the following reasons:

a. **To reduce risks of re-emergence of type2 polio outbreak.** Once OPV type 2 is withdrawn globally, IPV will help fill the immunity gap by priming populations against type 2 polio viruses should it be reintroduced. A region immunized with IPV would have a lower risk of re-emergence or reintroduction of wild or vaccine-derived type 2 polio virus.

b. **To interrupt transmission in the case of outbreaks.** Should monovalent OPV type 2 (mOPV2) be needed to control an outbreak, the immunity levels needed to stop transmission will be easier to reach in an IPV vaccinated population compared to a completely unvaccinated population. Thus introducing IPV now could facilitate future outbreak control.
c. **To hasten eradication.** IPV will boost immunity against poliovirus types 1 and 3 in children who had previously received OPV, which could further hasten the eradication of these two wild polio viruses.

**MECHANISM OF ACTION OF OPV AND IPV**

When a child ingests **OPV**, the vaccine virus enters the child’s mouth and gut and replicates. The child then mounts immune responses in three places:

1. Antibody response in the blood that protects against the virus invading the nervous system and causing paralysis,
2. Immune response in the mouth which prevents shedding of virus in oral secretions and spread from those secretions and
3. Intestinal immunity (also known as gut or mucosal immunity), which prevents shedding of the virus in the stool.

Thus, children vaccinated with OPV who come into contact with wild poliovirus are less likely to excrete poliovirus in their oral fluids or stool than unvaccinated persons. The predominant mode of transmission in the developing world is thought to be fecal-oral. Virus is shed in the feces and, in poor sanitary conditions and with suboptimal hygiene measures, can infect other persons if transmitted by dirty hands or contaminated food and water. Therefore, **strong intestinal immunity** prevents transmission.

**IPV** is a killed vaccine that stimulates a very good humoral response (antibodies in the blood) in children after only 1 or 2 doses. IPV also prevents children from excreting virus in their mouths as effectively as OPV and hence to the extent that Polioviruses are transmitted through oral secretions, IPV is very effective at blocking that type of transmission. However, IPV alone does not induce the same level of intestinal immunity as OPV. Thus, while individuals vaccinated with IPV alone are protected against paralysis, they may excrete the virus and allow it to spread.

When IPV is administered after a few doses of OPV, the IPV not only enhances protection against paralytic disease but also boosts intestinal immunity, even more than an additional dose of OPV would provide. Thus, combining IPV with bOPV provides the advantages of both vaccines: strong intestinal immunity and antibody protection against
the two serotypes in bOPV, types 1 and 3. This combination gives both the child and
the child’s community the best protection.

2. POLIO VACCINE FORMULATION

There are two types of polio vaccine: the Oral Polio Vaccine (OPV) and the Inactivated
Polio Vaccine (IPV). OPV is taken orally as drops and is easily administered while IPV is
given as an injection by a registered clinician. In countries still at risk of polio, OPV
remains the main preventive measure against polio. In countries still using OPV, IPV
does not replace the OPV vaccine, but is used in addition to OPV to strengthen a
child’s immune system and protect them from polio.

Trivalent OPV (tOPV) and IPV protect against all three types of polio viruses while
bivalent OPV (bOPV) targets type 1 and type 3, but not type 2.

Inactivated Polio Vaccine (IPV) is a killed vaccine with the 3 serotypes of polio virus
types 1, 2, &3. It is a WHO prequalified liquid vaccine that comes in 1, 5 and 10 dose
vials. Kenya will be introducing the 10 dose vial. IPV is a vaccine that in most settings
closes the immunity gaps in OPV-vaccinated children by inducing a higher sero-
conversion rate and increased antibody titers to all 3 serotypes (Types 1, 2, and 3).

IPV is available in two formulations:

1. **Stand-alone vaccine**: the currently prequalified product by WHO and it is
available in a liquid 1 dose, 5 dose and 10 dose vials.

2. **Combination product**: in combination with diphtheria, tetanus, acellular pertussis
and either hepatitis B or Hib antigens (pentavalent) or both hepatitis B and Hib
(hexavalent) formulations.
Table 1: Comparison between OPV and IPV

<table>
<thead>
<tr>
<th>ORAL POLIO VACCINE (OPV)</th>
<th>INACTIVATED POLIO VACCINE (IPV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Taken orally as drops</td>
<td>▪ Given through injection</td>
</tr>
<tr>
<td>▪ Easily administered</td>
<td>▪ Requires a trained health worker</td>
</tr>
<tr>
<td>▪ Main preventive measure against polio</td>
<td>▪ In countries still using OPV, it is given in addition to OPV</td>
</tr>
<tr>
<td></td>
<td>▪ Strengthens the immune system and provides further protection from polio</td>
</tr>
</tbody>
</table>

VACCINATION SCHEDULE

Timing is critical for IPV vaccine administration. Due to the interference from maternally, the immune response to IPV is lower when given at younger ages (<2-3 months of life).
UVIS therefore recommends that infants be given one dose of IPV vaccine at 14 weeks with OPV, pentavalent and PCV10.

**Until polio is eradicated globally, OPV remains the main preventive measure against polio. Therefore, IPV is recommended in addition to OPV and does not replace OPV.**

Table 2: Immunization schedule after IPV introduction

<table>
<thead>
<tr>
<th>Contact</th>
<th>Vaccine dose</th>
<th>Age of child</th>
<th>Dosage</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BCG</td>
<td>At birth or at first contact</td>
<td>0.05 ml</td>
<td>Intradermal</td>
</tr>
<tr>
<td></td>
<td>OPV birth dose</td>
<td>At birth or at first contact (within the first two weeks of life)</td>
<td>2 drops</td>
<td>Orally</td>
</tr>
<tr>
<td>2</td>
<td>OPV I</td>
<td>At six weeks of life or at first contact</td>
<td>2 drops</td>
<td>Orally</td>
</tr>
<tr>
<td></td>
<td>DPT-HepB+Hib 1</td>
<td>0.5 ml</td>
<td>Intramuscular into the upper outer aspect of the thigh</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PCV 10-1</td>
<td>0.5 ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ROTA-1</td>
<td>At 6 (six) weeks or at first contact &lt; 1yr</td>
<td>1.5ml(entire tube)</td>
<td>Orally</td>
</tr>
<tr>
<td>3</td>
<td>OPV II</td>
<td>At 10 weeks or 4 weeks after OPV I DPT-HepB-Hib 1 PCV10-1</td>
<td>2 drops</td>
<td>Orally</td>
</tr>
<tr>
<td></td>
<td>DPT-HepB+Hib 2</td>
<td>0.5 ml</td>
<td>Intramuscular into the upper outer aspect of the thigh</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PCV10-2</td>
<td>0.5 ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ROTA-2</td>
<td>At 10 (Ten) weeks or 4 weeks after Rota 1</td>
<td>1.5ml(entire tube)</td>
<td>Orally</td>
</tr>
<tr>
<td>4</td>
<td>OPV III</td>
<td>At 14 weeks or 4 weeks after, OPV II DPT-HepB-Hib 2</td>
<td>2 drops</td>
<td>Orally</td>
</tr>
<tr>
<td></td>
<td>DPT-HepB+Hib 3</td>
<td>0.5 ml</td>
<td>Intramuscular into the upper outer aspect of the left thigh</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PCV 10 - 3</td>
<td>PCV 10 - 2</td>
<td>0.5 ml</td>
<td>Intramuscularly into right anterolateral thigh</td>
</tr>
<tr>
<td></td>
<td>IPV</td>
<td>IPV</td>
<td>0.5 ml</td>
<td>Intramuscularly into right anterolateral thigh at least 2.5 cm (2 fingers apart)</td>
</tr>
</tbody>
</table>
5. Measles 1\textsuperscript{st} dose
   - At 9 months or first contact after 9 months
   - 0.5 ml
   - Subcutaneous into the left upper arm (deltoid muscle)

6. Yellow fever
   - At 9 months or first contact after 9 months – \textit{in four special districts}
   - 0.5 ml
   - Subcutaneous into the right upper arm (deltoid muscle)

7. Measles 2\textsuperscript{nd} dose
   - At 18 months or first contact after 18 months
   - 0.5 ml
   - Subcutaneous into the right upper arm (deltoid muscle)

8. Vitamin A
   - 100,000 IU
   - At 6 months of age
   - One capsule
   - Orally

9. Vitamin A
   - 200,000 IU
   - At 12 months of age
   - One capsule
   - Orally

10. Vitamin A
    - 200,000 IU
    - At 18 months of age
    - One capsule
    - Orally

The schedule for routine vaccination is up to 18 months. However, a child who is less than 5 years and has either not received any vaccine or has not received all vaccinations due, should receive vaccines as appropriate. In addition, children should continue to receive vitamin A every 6 months till 5 years of age and weight should monitored monthly.

\textbf{INACTIVATED POLIO VACCINE (IPV) STORAGE}

IPV is \textbf{freeze sensitive}. Liquid freeze sensitive vaccines, including IPV, must not be frozen or placed on a frozen icepack. If frozen, these vaccines lose their potency and provide no protection against the disease. Frozen vaccines may also cause "aseptic abscesses". Because stand-alone IPV is not an adsorbed vaccine (i.e., no aluminum adjuvant), the "shake test" is not effective in determining whether IPV has been

\textbf{Inactivated Polio Vaccine Introduction Guide 2015}
If there is doubt or suspicion that IPV has been frozen, the vial must be discarded.

**HOW TO AVOID FREEZING DURING TRANSPORT OF IPV**

IPV is transported using fast cold chain equipment (cold boxes or vaccine carriers and conditioned ice packs). Use only conditioned ice packs or chilled water packs to transport IPV. **Close contact with frozen ice packs can cause the vaccine to get frozen.**

**Steps in conditioning ice packs:**
- Lay out frozen ice packs, preferably in single rows but never in more than two rows
• Wait until there is a small amount of liquid water inside the ice packs. This will take up to one hour at +20°C and rather less at higher temperatures.
• Shake one of the ice packs every few minutes.
• The ice is conditioned as soon as it begins to move about slightly inside the ice pack.

Before packing into the vaccine carrier, put the vials in a polythene (nylon) bag to keep the vials dry and prevent the label from peeling off. Place the bag in the top level of the cold box/vaccine carrier.

HOW TO PREVENT HEAT EXPOSURE DURING SESSIONS:
At immunization sites, vaccine carriers large enough to hold at least 4 ice packs and a foam pad are used to keep vaccines at recommended temperatures during the sessions.
3. ADMINISTERING THE INACTIVATED POLIO VACCINE

Due to the interference from maternally derived antibody, the immune response to IPV is lower when given at younger ages (<2-3months of life). Therefore it is recommended that infants be given one dose of IPV vaccine at 14 weeks in addition to OPV. During the same visit the pentavalent vaccine, and pneumococcal vaccine should also be given.

A catch-up strategy, where children who have completed their primary OPV schedule, is not recommended for IPV. A child who has already received OPV 3 at the time of introduction will not be eligible.

IPV will be administered on the right thigh, at least 2.5cm (2 fingers apart) from PCV 10 site and pentavalent vaccine will be given on the left thigh. It is administered by intramuscular (IM) injection in a dose of 0.5ml and should not be mixed with PCV – 10 or any other vaccines in the same vial or syringe.
Figure 4: Vaccines and their administration sites
SAFETY OF IPV & MULTIPLE INJECTIONS

IPV is safe and very well-tolerated. Severe adverse reactions are extremely rare (<0.01%). Mild reactions such as, Redness (0.5%-1.5%), swelling (3% -11%) and soreness (14% - 29%) at the injection site are reported. Other, mild side effects such as transient fever have also been reported.

Giving multiple injections on same sitting is safe and does not lead to increase in adverse events. Giving a child several vaccinations during the same visit offers the following three major advantages:

- First, immunizing children as soon as possible provides protection during the vulnerable early months of their lives. Often, diseases are more severe in babies.
- Second, giving several vaccinations at the same time means parents and caregivers do not need to make as many vaccination visits.
- Third, it means that health care providers are able to more efficiently provide and deliver other health services by reducing the time they need to spend providing vaccinations.
CONTRAINDICATIONS TO IPV

There are very few contraindications to IPV, however IPV should not be administered to infants with

- known or documented allergy to streptomycin, neomycin, or polymyxin B, which are inactive components of the vaccine

- history of an allergic reaction following a previous injection of IPV

USE IN IMMUNODEFICIENT POPULATIONS

IPV can be safely administered to children with immunodeficiency (e.g., HIV, congenital or acquired immunodeficiency, sickle cell disease).

Table 3: Summary of IPV Profile

<table>
<thead>
<tr>
<th>Rationale for IPV use</th>
<th>- Lowers the risk of reemergence of type 2 wild and vaccine-derived poliovirus and facilitates control and interruption in case of reemerging type 2 polioviruses in conjunction with targeted use of monovalent OPV.</th>
</tr>
</thead>
</table>
| Type of vaccine                                                  | - Inactivated (killed) vaccine with types 1,2,8&3 antigens  
- Antigen dose 40-8-32 units for each vaccine type |
| Route of administration  | - Intramuscular |
| Schedule                                                          | - at 14 weeks with Pentavalent 3 and OPV3 and PCV10 3 |
| Target age group                                                 | - Infants under 12 months of age |
| Volume per dose                                                  | - Each dose is 0.5 ml |
| Storage conditions:                                               | - Store at 2°C - 8°C. DO NOT FREEZE |
| Presentation & vial size                                         | - WHO prequalified 10 dose vials |

It is safe to administer more than one vaccine injection at the same visit; the benefit of the protection from the multiple injections outweighs the pain the child may experience.
| Co-administration with other vaccines | - Can be co-administered with other injectable vaccines but with separate syringe in a separate injection site (at least 2.5 cm apart)  
- IPV can be co-administered with OPV in the same session. |

| Contraindication | - Known allergy to streptomycin, neomycin, or polymyxin B,  
- History of an allergic reaction following a previous injection of IPV. |

**USE IN PREMATURE INFANTS**

IPV can be administered to prematurely born infants at the recommended schedule concurrent with other routine vaccinations.

**PREPARATION AND ADMINISTRATION**

Before administering IPV, follow steps below:

1. Check the child’s immunization status, age, and contraindications
2. Take IPV out of the fridge and check expiry date for validity.
3. Check the VVM for potential damage by heat
4. Inspect if the vaccine is frozen

If there is evidence of exposure to freezing temperature for suspicion for freezing exists, **discard the vaccine.**

**Note:** “Shake test” will not be able to detect damage by freezing in...

To administer IPV, carefully follow the steps below:

**Step 1:** Inform caregiver of the vaccines to be given, possible side effects and how to respond.
Step 2: Draw up 0.5 ml with an auto-disable syringe (AD). (IPV should not be mixed with other vaccines in the same vial or syringe).

Step 3: Administer an intramuscular injection in the RIGHT anterolateral thigh of the infant, the infant injections should be given at 90° degrees angle.

Step 4: All used injection equipment should be placed immediately in the safety box at the point of use (without recapping the needle). Dispose the filled safety boxes according to national injection waste management guidelines.

Step 5: Record the dose administered on immunization register, Mother Child Health Booklet (MCHB), and tally sheet on the IPV column/row.

Step 6: Remind or give caregiver next return date.

4. DOCUMENTATION

IPV vaccinations given to infants should be recorded in the same way as other vaccines in the program. However, it should be noted that both IPV and OPV will be administered simultaneously at 14 weeks and each vaccine should be recorded and monitored separately.

Just like any other EPI vaccine, IPV should be recorded on all relevant tools including the following:

- Mother and Child Health Booklet MOH 206
- Immunization Permanent Registers MOH 510
- Tally sheets MOH 702
- Monthly Summary sheet MOH 710
- Vaccines Stock ledgers

Mother and Child health booklet (MCHB):
IPV dose should be recorded in the MCHB, on other vaccines section Page 19 and the booklet is kept by parents/caretakers of the child to report their vaccination status, and other information such as monitoring of growth.

**Tally sheet:**
Record IPV on its own row that comes after the row for OPV3.

**Monthly summary sheet**
At the end of each month, the total doses of IPV administered should be recorded on the monthly summary sheet and reported routinely using the existing mechanisms.

**Child Permanent Register:**
This has been updated and column for IPV provided for recording the date when IPV is administered, alongside all other vaccines at the same contact.

**Vaccine Stock ledgers:**
IPV stock should be recorded on its own ledger just like the existing vaccines.

---

**5. WASTE MANAGEMENT**

Sharps waste can cause serious health and environmental problems. Unsafe disposal can spread some of the very same diseases that we are trying to prevent. Leaving used syringes and needles in the open puts the community at risk. Most frequently, the unfortunate victims of needle-stick injuries from haphazard disposal of needles are children and health workers.

Safety boxes are puncture resistant, impermeable containers for the safe disposal of used syringes and needles and other contaminated sharps. Place all used needles and syringes in a safety box immediately after administering the vaccine, without recapping them. Do not fill the safety box more than ¾. Seal the ¾ filled box securely and store the box in a safe place until it can be properly disposed according to national waste management guidelines.
6. ADVERSE EVENTS FOLLOWING IMMUNIZATION

DEFINITION

An adverse event following immunization is any medical incident that occurs during or after an immunization and is considered to be related to immunization. Serious adverse events following immunization are rare but have potential to cause loss of public confidence in the immunization program if not handled properly.

Table 4: Classification of AEFI

<table>
<thead>
<tr>
<th>Type of AEFI</th>
<th>Event caused or precipitated by:</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine product-related reaction</td>
<td>The vaccine due to one or more of the inherent properties of the vaccine product.</td>
<td>e.g. Fever after vaccination with Measles Vaccine</td>
</tr>
<tr>
<td>Vaccination error-related reaction</td>
<td>Inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable</td>
<td>Transmission of infection by contaminated multi-dose vial</td>
</tr>
<tr>
<td>Vaccination anxiety-related reaction</td>
<td>Anxiety about the vaccination</td>
<td>Fainting spell in a teenager after vaccination</td>
</tr>
<tr>
<td>Coincidental event</td>
<td>Something other than the vaccine product, vaccination error or injection anxiety</td>
<td>A fever occurs at the time of the vaccination (temporal association) but is in fact caused by malaria. Coincidental events reflect the natural occurrence of health problems in the community with</td>
</tr>
</tbody>
</table>
REPORTING OF ADVERSE EVENTS FOLLOWING IMMUNIZATION

Adverse events following immunization occur rarely but need to be reported and fully investigated.

ADVERSE EVENTS FOLLOWING IMMUNIZATION TO BE REPORTED:

- Serious Events (Life-threatening or results in death, hospitalization, persistent or significant disability)
- Allergic reaction- anaphylaxis, urticaria, bronchospasm, swelling of the lips
- Injection site abscesses
- BCG Lymphadenitis (Lumps In The Armpit Following BCG Vaccination)
- Local reaction (pain, swelling or redness persisting > 3 days; or inability to move the limb)
- Fever (≥ 38°C) occurring together with another reportable adverse event
- Clusters of events (> 2 cases of same event in same month) apart from fever
- Any Uncommon Or Unexpected Events that may be of public concern
*Serious AEFI and clusters of events should be reported to the next level immediately (e.g. via telephone) for quick response

*Submission of a report does not mean admission that the health worker or manufacturer or the product caused or contributed to the event.

For guidelines on Management of AEFI please refer to Immunization Manual for Health Workers, page 104
AEFI INVESTIGATION

The goal is to determine the cause of AEFI and take corrective measures where possible; ideally within 24 hours.

Components of AEFI investigation:

• Identify specifications of implicated vaccine
• Examine operational aspects which may have led to vaccination errors
• Search for other potential AEFI cases/clustering
• Compare background risk to reported rate of AEFI
• Confirm (or propose) the diagnosis and determine outcome
• Expert opinion

Communicating about AEFI:

• When a serious AEFI or cluster of AEFI occurs, inform the next level immediately (e.g. by telephone).

• All other AEFI reports should be submitted to the next level within 7 days.
• Reassure the caregiver but do not speculate on the cause of the AEFI; instead explain that investigations are going on.

• Once investigations are complete, give factual information to concerned parties.
  Do not address media, direct them to higher technical authorities.

Rates of Adverse Reactions to IPV

- IPV is safe and very well-tolerated. Serious adverse reactions are extremely rare (<0.01%).
- Redness at the injection site is reported in 0.5% to 1.5%, swelling in 3% to 11%, and soreness in 14% to 29% of infants.
High fever of >40°C has only been reported in <0.1% of infants.

7. COLD CHAIN AND VACCINE MANAGEMENT

VACCINE MANAGEMENT

Each level has to calculate requirements, monitor vaccine usage, stocks and report to avoid vaccine stock-outs and over-stock:

- Maximum Monthly Stock (125%): At any given time, facilities should not have more than their maximum stock level, which is their monthly vaccine requirements plus reserve stock of 25%.
- Minimum Stock (25%): Facilities should not have less than minimum stock level.
- Stock-outs (no vaccine/logistics), below minimum stock levels and over stocks are not acceptable at all levels.
- All levels should monitor vaccine wastage.

Regular monitoring for adequate stock levels is necessary. During the first six months of the introduction period, healthcare workers will need to be more vigilant on the number of IPV doses administered, as well as other vaccines to avoid unanticipated stockouts.

It is important to distinguish between different batches of vaccine because they may have different expiry dates, and the vials with the earliest expiry dates should be used first (FEFO principle) as long as all the vials are in VVM Stage 1. In the event of an adverse event, it is important to know the exact description of the vaccine (e.g. manufacturer, batch number).

MULTI-DOSE VIAL POLICY (MDVP)

WHO MDVP (multi-dose vial policy) applies to both liquid and reconstituted vaccines,
All liquid vaccine vials in our schedule have VVM on the label except PCV 10 with VVM on the cap (has no preservative).

Opened liquid multi-dose vials with VVM on the label can be used up to a maximum of 4 weeks (28 days), provided the vaccine meets the following criteria:

1. The expiry date on the vaccine has not passed.
2. The vaccines are stored under appropriate cold conditions (+2°C to +8°C).
3. The vaccine vial septum has not been submerged in water and label is intact
4. Aseptic technique has been used to withdraw each dose.
5. The VVM has not reached discard point (VVM is still in stage 1 or 2).

**MDVP FOR VACCINES WITH VVM ON THE CAP OR NECK**

BCG, measles and yellow fever vaccines, once reconstituted, the vials of these vaccines MUST BE discarded at the end of each immunization session or at the end of six hours, whichever comes first.

**PCV10 is liquid vaccine without preservative, VVM on the cap of vial and MUST BE DISCARDED after 6 hours or at the end of the immunization session whichever comes first.**

**IPV STORAGE**

IPV is freeze sensitive (unlike OPV). The “shake test” is not effective in determining whether IPV has been frozen. Therefore it is very important that if there is any suspicion that IPV has been frozen, the vial must be discarded.
• Store IPV in a refrigerator, between +2°C and +8°C
• Do not open the door frequently
• Record fridge temperature twice daily including weekends
• Maintain the trays in their rightful position with the correct vaccines as per fridge sticker
• Store similar vaccines in the same area to facilitate easy identification
• Keep at least 2 cm of space between rows for circulation of air
• In top-opening refrigerators, store IPV and other freeze-sensitive vaccines at the top, in fridge baskets DO NOT remove the baskets from the refrigerator
• In front-opening refrigerators store IPV and other freeze-sensitive vaccines in the middle shelf
• Use conditioned icepacks when transporting and storing IPV in cold boxes or vaccine carriers
### Figure 6: Placement of Vaccines in Refrigerator

<table>
<thead>
<tr>
<th>Tray</th>
<th>Vaccine</th>
<th>Tray Color Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PCV</td>
<td>RED</td>
</tr>
<tr>
<td>2</td>
<td>Pentavalent</td>
<td>ORANGE</td>
</tr>
<tr>
<td>3</td>
<td>TT + IPV</td>
<td>YELLOW</td>
</tr>
<tr>
<td>4</td>
<td>Rotavirus</td>
<td>GREEN</td>
</tr>
<tr>
<td>5</td>
<td>BCG + Measles</td>
<td>BLUE</td>
</tr>
<tr>
<td>6</td>
<td>OPV + Yellow fever</td>
<td>PURPLE</td>
</tr>
</tbody>
</table>

### SIBIR V170 GE

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<td>RED</td>
</tr>
</tbody>
</table>

### Figure 7: Placement of vaccines in the chest refrigerator

![Image of vaccine placement in the chest refrigerator]
TEMPERATURE MONITORING

Record temperature on monitoring charts twice daily. IPV should be stored in a refrigerator (+2°C to +8°C). Do not put the vaccine in a freezer. Where applicable, store it in the original secondary package.

**Vaccine Vial Monitor**

A VVM is a label containing a heat sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time. The label has a grey circle with a small white square inside it. It is attached either on the label or cap of a vial or the neck of an ampoule. The colour of the circle remains constant while the inner square changes colour darkening with cumulative heat exposure.

![Vaccine Vial Monitor (VVM)](image)

- ✓ **USE VIAL WHEN THE SQUARE IS WHITE** (stage 1) OR LIGHTER THAN THE CIRCLE (stage 2).
- ✗ **DISCARD VIAL WHEN THE SQUARE IS AS DARK AS THE CIRCLE** (stage 3), OR DARKER THAN THE CIRCLE (stage 4).

Figure 8: Stages of VVM
The gradual and irreversible colour change of VVM makes it possible to assess the cumulative heat exposure and the remaining shelf-life of a vaccine.

**Continuous Temperature Monitoring Devices**

There are several types of continuous temperature monitoring devices that are used during storage or transportation of vaccines. Currently, the recommended temperature monitoring device is the 30-Day temperature recorders. The EPI programme has introduced the Fridge Tag 2.

The Fridge-Tag 2 (FT) is a temperature monitoring device for refrigerators. It records temperature captured during the past 60 days. Events recorded within the past 30 days can be directly viewed from the device while 60-days temperature data can be downloaded from the device with access to a computer. The FT2 displays the following information:

- Current temperature and time
- Maximum and minimum temperature reached in a day
- Heat and freeze alarms in case of excursions

![Figure 9: Fridge Tag 2](image)
A freeze alarm occurs when the temperature drops below 0.5°C for more than 60 minutes. A heat alarm occurs after 10 hours of temperature above 8°C. This information can tell you how a refrigerator is performing.

8. ADVOCACY, COMMUNICATION AND SOCIAL MOBILIZATION

Effective advocacy, communication and social mobilization on the importance of existing and new vaccine introduction are key issues to public health. There is need to gather information on effective messages and IEC materials to address parental concerns and promote the benefits of IPV vaccine.

Three strategies have been employed to ensure successful IPV introduction into the national routine immunization schedule which includes:

- **Advocacy**: to create awareness and commitment among policy and decision makers at all levels to effectively support and facilitate the introduction and implementation of IPV nationwide
- **Social Mobilization**: to involve partners and stakeholders, social mobilizers, etc., in awareness creation and resource mobilization activities
- **Program communication**: to create awareness and change behavior and call for action of the communities, parents, and caretakers through training workshops, interpersonal communication, group communication, media engagement and dissemination of communication materials.
The gather acronym is used for interpersonal communication between the health care provider and the client as demonstrated below.

**Table 5: GATHER approach to interpersonal communication**

- **G**reet the caregiver and infants when they come in for immunization
- **A**sk the caregiver if she has any questions or concerns, because it is very important to listen to the caregiver and her/his concerns. Address all questions/concerns raised.
- **T**ell/inform the caregiver using simple words of all the vaccines the child is going to receive.
- **H**elp the caregiver understand according to what they already know, what they want to know and misconceptions that may exist.
- **E**xplain where possible using IEC materials (lipbooks, visual cards, SMS platforms) for higher retention. Use local examples, language and stories.
- **R**epeated visits - explain to the caregiver the necessity of having all the vaccinations that the child should get at the right time. Request the caregiver to immediately return in case of any AEFI.