Introduction of Inactivated Polio Vaccine (IPV) in Routine Immunizations

A handbook for regional consultants, policy makers, and programme managers on policy and operational aspects related to introduction of IPV as it relates to the Polio Eradication and Endgame Strategic Plan

Version date: May 15, 2014

NOTE: This is a working draft that will be revised based on ongoing feedback and availability of new IPV related information.

For the most up-to-date information please visit: http://tinyurl.com/ipv-intro

Ce document est aussi disponible en Francais. Consultez http://tinyurl.com/ipv-intro pour info
# TABLE OF CONTENTS

**1.** Introduction of IPV introduction planning & preparation ........................................... 3

**2.** Preparing an IPV introduction plan .............................................................................. 4

**3.** Technical aspects of IPV ................................................................................................. 7

- **3.1.** IPV formulations.............................................................................................................. 7
- **3.2.** Schedule for IPV ............................................................................................................. 8
  - **3.2.1.** SAGE Recommended Schedule .................................................................................. 8
  - **3.2.2.** Rationale for administering IPV at 14 weeks of age or later .................................... 10
- **3.3.** Administration of IPV .................................................................................................. 11
- **3.4.** Safety of IPV & multiple injections ................................................................................. 11
- **3.5.** Contraindications to IPV ............................................................................................... 12
- **3.6.** Use in premature infants ............................................................................................... 12
- **3.7.** Use in immunodeficient populations ............................................................................. 12

**4.** Vaccine Management, Cold Chain, and Logistics ............................................................ 13

- **4.1.** Estimation of Vaccine Requirements .......................................................................... 14
- **4.2.** The Cold Chain .............................................................................................................. 16
  - **4.2.1.** Estimating required net volume for vaccine storage ..................................................... 17
  - **4.2.2.** Common cold chain equipment .................................................................................. 18
  - **4.2.3.** Temperature monitoring ............................................................................................ 18
  - **4.2.4.** Vaccine storage ........................................................................................................ 19
- **4.3.** Safe Administration of IPV and waste management .................................................. 20
  - **4.3.1.** Preparing IPV ............................................................................................................ 20
  - **4.3.2.** Steps to Administer IPV ............................................................................................ 21
  - **4.3.3.** Multi-Dose Vial Policy ............................................................................................... 22
  - **4.3.4.** Vaccine wastage ....................................................................................................... 22
  - **4.3.5.** Waste management ................................................................................................ 23
5. Monitoring, Evaluation, and Supervision of IPV introduction .............................................. 24
   5.1. Monitoring.......................................................................................................................... 24
   5.1.1. Information Systems ...................................................................................................... 24
   5.1.2. Recording IPV doses & vials ....................................................................................... 25
   5.1.3. Calculating IPV coverage ............................................................................................ 26
   5.2. Supervision ...................................................................................................................... 27
   5.3. Evaluation ........................................................................................................................ 27

6. Communication & Advocacy .................................................................................................. 28

7. Reporting of adverse events following immunization (AEFI) ............................................... 28

Annex 1: IPV introduction status by tiers for priority, WHO 2013 ............................................. 1
# Abbreviations & Glossary of Terms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AFP</strong></td>
<td>Acute Flaccid Paralysis</td>
</tr>
<tr>
<td><strong>bOPV</strong></td>
<td>Bivalent Oral Polio Vaccine</td>
</tr>
<tr>
<td><strong>cVDPV</strong></td>
<td>Circulating Vaccine-Derived Poliovirus</td>
</tr>
<tr>
<td><strong>cVDPV1</strong></td>
<td></td>
</tr>
<tr>
<td><strong>cVDPV3</strong></td>
<td></td>
</tr>
<tr>
<td><strong>EPI</strong></td>
<td>Expanded Programme on Immunization</td>
</tr>
<tr>
<td><strong>GPEI</strong></td>
<td>Global Polio Eradication Initiative</td>
</tr>
<tr>
<td><strong>IPV</strong></td>
<td>Inactivated Polio Vaccine</td>
</tr>
<tr>
<td><strong>NVIP</strong></td>
<td>New Vaccine Introduction Plan</td>
</tr>
<tr>
<td><strong>OPV</strong></td>
<td>Oral polio vaccine</td>
</tr>
<tr>
<td><strong>PIE</strong></td>
<td>Post-Introduction Evaluation</td>
</tr>
<tr>
<td><strong>PV1</strong></td>
<td>Poliovirus type 1</td>
</tr>
<tr>
<td><strong>RI</strong></td>
<td>Routine Immunization</td>
</tr>
<tr>
<td><strong>SAGE</strong></td>
<td>Strategic Advisory Group of Experts on Immunization</td>
</tr>
<tr>
<td><strong>tOPV</strong></td>
<td>Trivalent oral polio vaccine</td>
</tr>
<tr>
<td><strong>VPD</strong></td>
<td>Vaccine-preventable disease</td>
</tr>
<tr>
<td><strong>VVM</strong></td>
<td>Vaccine Vial Monitor</td>
</tr>
<tr>
<td><strong>WHA</strong></td>
<td>World Health Assembly</td>
</tr>
<tr>
<td><strong>WHO</strong></td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>

Version: February 14, 2014
INTRODUCTION

Why this document?

In May 2012, the World Health Assembly declared the completion of poliovirus eradication to be a programmatic emergency for global public health and called for a comprehensive polio endgame strategy. In response, the Global Polio Eradication Initiative developed The Polio Eradication and Endgame Strategic Plan\(^1\) which provides a detailed approach and concrete timeline for complete eradication of polio. This plan deals with the eradication and containment of polio caused not just by wild viruses but also cases associated with oral polio vaccine (OPV). To address risks associated with OPV use, the Plan calls for a phased withdrawal of OPV globally beginning with removal of the type 2 component of OPV through a switch globally from trivalent OPV (tOPV) to bivalent OPV (bOPV, containing only types 1 and 3) in 2016. To ensure that a substantial proportion of the population is protected against type 2 polio after OPV type 2 withdrawal, 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, prior to the tOPV-bOPV switch.

SAGE recommends that all polio endemic and high-risk countries develop a plan for IPV introduction by mid-2014 and that the remaining OPV only using countries develop a plan by end-2014.

Each country should develop country-specific plans on how IPV can be introduced in a manner that strengthens the existing national immunization programme and is part of an integrated strategy to introducing other new vaccines (e.g., rotavirus, pneumococcal).

What is included in this document?

This document provides information and guidance to assist consultants and national managers to consider the operational preparations that should be included in an IPV introduction plan, once a decision to introduce has been made.

Who is the target audience?

Regional consultants, policy makers, and programme managers are the primary target audience. This manual can also be adapted to a field guide for training health workers based on local needs and situation.

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\(^1\) The complete Endgame Plan and other resources related to GPEI can be found at http://www.polioeradication.org/resourcelibrary/strategyandwork.aspx
The key messages of this document differentiating IPV from other vaccines in EPI include:

- While many of the operational aspects of introducing IPV will be similar to those for other injectables (e.g., pneumococcal), some unique aspects of IPV must be considered and are the focus of this manual and the supporting annexes. These include: the rationale, the number of doses, the schedule and the presentation of IPV, and the GAVI application process (if applicable).

- SAGE has recommended that all countries introduce at least one dose of IPV into the routine immunization schedule before the end of 2015 according to Polio Endgame Strategy

- All polio endemic and other high risk should develop an introduction plan for IPV by mid-2014 and all other OPV-only using countries by end-2014

- IPV is recommended for use in routine immunization programmes, at or after 14 weeks of age at the time of the DTP3/penta3/OPV3 contact

- IPV is given in addition to the existing doses of OPV and does not replace any OPV dose.

- GAVI eligible and GAVI-graduating countries are eligible to receive IPV support from the GAVI Alliance based on a one dose schedule and supplies

- Currently, IPV is prequalified by WHO as a liquid, stand-alone vaccine in 1-dose and 10-dose preparations, with 5-dose presentation possibly being available in 2014 in limited quantities

- Stand-alone IPV is preserved with 2 phenoxy-ethanol, and thus open multidose vials of this vaccine must be discarded at the end of the immunization session or within 6 hours after opening, whichever comes first

- The estimated wastage rates for stand-alone IPV should be estimated based on wastage rates for other non-preserved multi-dose injectables for which the Multi dose vial policy requires that the vaccine be discarded at the end of the immunization session of after 6 hours whichever comes first (eg. measles vaccine), and can reach up to 30% for the 5-dose vial and 50% for the 10-dose vial

- The estimated impact of one dose of IPV on cold chain systems is limited (packed volume per dose in cm³ is 2.46 for 10 dose vial)

- Because current vaccine forecasts are based on estimates of wastage and demand, monitoring IPV use and wastage rates will be important for accurately forecasting vaccine needs particularly during the first six months after introduction
1. Overview of IPV introduction planning & preparation

To maximize the impact of IPV it is important to prepare a comprehensive and realistic introduction plan and conduct preparatory activities for a successful integration of IPV into the national immunization programme.

The introduction process for IPV entails 4 inter-related phases which are outlined in Figure 1:

- **Phase 1 – Prepare an introduction plan:** Identify the strategies and activities needed for the introduction of IPV into the national immunization programme
- **Phase 2 – Conduct preparatory activities:** Undertake strategies and activities outlined in the plan according to a defined timeline
- **Phase 3 – Introduce IPV:** Plan and conduct activities around the launch of IPV
- **Phase 4 – Conduct post-introduction monitoring and evaluation:** Evaluate and address programmatic issues caused by the introduction of IPV

This document is intended as a guide for providing consultants with an overview of phases 1 & 2. The document highlights areas that need consideration during planning of the introduction of IPV and provides a framework for the discussion that needs to take place in a country when a national immunization programme is introducing IPV.

Figure 1: Overview of key activities related to introduction of IPV in the routine immunization programme
Introduction of Inactivated Polio Vaccine (IPV) in Routine Immunizations

Key documents and materials that support or directly relate to the sections covered in this guide include:

- The GAVI Application Form for Country Proposals (for IPV), if applicable: [http://www.gavialliance.org/support/apply/]
- Handbook on the background and technical rationale for introducing at least one dose of IPV in the routine immunization schedule: [http://tinyurl.com/ipv-intro]
- Slide decks covering the technical and operational aspects of introducing at least one dose of IPV [http://tinyurl.com/ipv-intro]

Note: While the document covers general aspects of planning and preparing for introducing one dose of IPV, some aspects outlined in this manual may not be applicable for all countries. The manual should be adapted to meet the needs of the country.

2. Preparing an IPV introduction plan

SAGE recommended all OPV-only using countries prepare a plan for the introduction of IPV—countries at higher risk (Annex 1) should develop a plan by mid 2014 and all others by end-2014.

WHO has developed a New Vaccine Introduction Plan (NVIP) template that is intended to be a guide for national immunization staff to prepare a plan for the introduction of a new vaccine in to their national immunization programme. This template is comprehensive as it considers issues relevant for all new vaccines.

GAVI support for IPV

All 73 GAVI eligible and GAVI-graduating countries are eligible to receive IPV based on a one-dose schedule and supplies (auto-disable syringes and safety boxes). An introduction plan is required to apply for GAVI support. For complete information on how to apply for GAVI support, please visit http://www.gavialliance.org/support/apply/

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3 http://www.gavialliance.org/support/apply/
Please note that not all sections of the WHO NVIP template are necessary for GAVI review of IPV applications or relevant for non-GAVI countries as they plan to introduce IPV according to the Endgame Plan.

Countries applying for GAVI support should only complete the sections of the WHO NVIP template indicated in the application instructions and answer questions as they related to the country’s plans for IPV introduction. Countries are encouraged to use detail from existing new vaccine introduction plans if the information is still current and directly relevant to the plan for IPV.

Consultants should carefully review the NVIP template and the GAVI Application Form. The key elements of the GAVI Application Form and the NVIP relevant to IPV introduction are summarized in Table 1. The remaining sections of the document cover operational aspects relevant to the introduction of IPV that are important to consider when developing the country introduction plan.
### Introduction of Inactivated Polio Vaccine (IPV) in Routine Immunizations

#### Table 1. Checklist of the components of the IPV introduction plan for the GAVI Application

<table>
<thead>
<tr>
<th>Section</th>
<th>Key components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Summary (2 pages)</td>
<td>✅ Summary of the introduction plan activities</td>
</tr>
<tr>
<td></td>
<td>✅ Outline benefits to the population of introducing IPV, costs to the programme, and plan to sustain costs</td>
</tr>
<tr>
<td></td>
<td>✅ Economic assessments, financial needs and sustainability</td>
</tr>
<tr>
<td></td>
<td>✅ Capacity to introduce IPV</td>
</tr>
<tr>
<td></td>
<td>✅ List of preparatory activities</td>
</tr>
<tr>
<td></td>
<td>✅ Key risks and mitigating strategies</td>
</tr>
<tr>
<td></td>
<td>✅ Key milestones and activities</td>
</tr>
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<td></td>
<td>✅ Overall cold chain situation</td>
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<tr>
<td></td>
<td>✅ Impact on health system and monitoring</td>
</tr>
<tr>
<td>Justification for introduction of IPV and national decision-making process</td>
<td>✅ Technical and operational feasibility</td>
</tr>
<tr>
<td></td>
<td>✅ Describe involvement of all key decision-makers</td>
</tr>
<tr>
<td>Overview of IPV</td>
<td>✅ Vaccine preference and introduction date</td>
</tr>
<tr>
<td></td>
<td>✅ Licensing information and procurement obstacles</td>
</tr>
<tr>
<td></td>
<td>✅ Estimated target population for vaccination through 2018</td>
</tr>
<tr>
<td>Introduction and Implementation Consideration</td>
<td>✅ Policy development issues (i.e., schedule, doses, phased vs. national)</td>
</tr>
<tr>
<td></td>
<td>✅ National coordination mechanism to ensure successful intro</td>
</tr>
<tr>
<td></td>
<td>✅ Affordability and sustainability</td>
</tr>
<tr>
<td></td>
<td>✅ Overview of cold chain capacity</td>
</tr>
<tr>
<td></td>
<td>✅ Provision for waste management and injection safety</td>
</tr>
<tr>
<td></td>
<td>✅ Planned healthcare worker training and supervision</td>
</tr>
<tr>
<td></td>
<td>✅ Risks and challenges</td>
</tr>
<tr>
<td>Situational Analysis</td>
<td>✅ General country context, health system overview and priorities</td>
</tr>
<tr>
<td></td>
<td>✅ Barriers to immunization</td>
</tr>
<tr>
<td></td>
<td>✅ Summarize findings from programme reviews</td>
</tr>
<tr>
<td></td>
<td>✅ EVM assessment findings and improvement plan</td>
</tr>
<tr>
<td></td>
<td>✅ Brief description of vaccine stock management</td>
</tr>
<tr>
<td></td>
<td>✅ Brief description of healthcare worker knowledge: training &amp; supervision</td>
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<tr>
<td></td>
<td>✅ Immunization coverage for past two years</td>
</tr>
<tr>
<td>Monitoring and Evaluation</td>
<td>✅ Plans for updating monitoring tools</td>
</tr>
<tr>
<td></td>
<td>✅ Adverse events following immunization (AEFI) monitoring and reporting policy</td>
</tr>
<tr>
<td>Advocacy, Communications, and Social Mobilization (ASCM)</td>
<td>✅ Plans and strategy</td>
</tr>
</tbody>
</table>
3. Technical aspects of IPV

3.1. IPV formulations

IPV is available in two formulations:

- **Stand-alone vaccine (Table 2):** is the *only currently prequalified product* by WHO. It is available in fully liquid 1-dose and 10-dose presentations. WHO expects a 5-dose presentation to be available in the second half of 2014.
- **Combination product** with diphtheria, tetanus, acellular pertussis, hepatitis B, or Hib antigens in tetravalent, pentavalent, or hexavalent formulations. The combination products currently available use acellular pertussis, which is significantly more expensive than the whole cell pertussis. *A combination product with whole-cell pertussis is not currently available.*

**Table 2. IPV product presentations projected to be available (final list after UNICEF tender anticipated to be completed in early 2014)**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Presentations available</th>
<th>Vaccine Vial Monitor</th>
</tr>
</thead>
</table>
| Bithoven Biological         | ✓ 1-dose vials (prequalified)  
  ✓ 5-dose vials (not prequalified) | ✓ Present |
| GlaxoSmithKline             | ✓ 1-dose vials          | ✓ Present            |
| Sanofi                      | ✓ 5-dose vials (not prequalified)  
  ✓ 10-dose vials (prequalified) | ✓ Present |
| Statens Serum Institute     | ✓ 1-dose vials (not available in the short term) | ✓ Present |

Some important aspects to note about **stand-alone IPV** include:

✓ Stand-alone IPV is preserved with 2 phenoxy-ethanol. This means that *open multidose vials of this vaccine must be discarded at the end of the immunization session or within 6 hours after opening*, whichever comes first (see Section 4.3.3).

**Note:** Currently, only the stand-alone IPV is prequalified by WHO.
Introduction of Inactivated Polio Vaccine (IPV) in Routine Immunizations

☑ Stand-alone IPV is sensitive to heat and freezing and must be handled appropriately, stored at 2°C - 8°C (see Section 4.2.2).
☑ IPV is freeze sensitive and should not be frozen. The shake-test will not detect damage by freezing.
☑ IPV has a shelf life of 24-36 months when stored in a refrigerator at 2°C - 8°C and protected from light.

3.2. Schedule for IPV

Schedules in countries currently using IPV

IPV-containing vaccines are recommended and currently used in routine immunization programs of over 60 countries worldwide either as:

☑ IPV-only schedules
☑ Sequential schemes with OPV
☑ IPV-only schedules supplemented by SIAs with OPV

Most of these countries are using either the stand-alone IPV or in combination with other antigens in the routine infant immunization series. In countries recommending IPV-only schedules, the recommendations typically call for 4 or 5 doses according to different schedules:

- 2 + 1 + 1 (ie., 2 doses in primary infant series, 1 booster dose at 6 mos - 2 years, and additional booster during preschool age)
- 3 + 1 + 0 (ie., 3 doses in primary infant series, 1 booster dose at 6 mos - 2 years, no booster during preschool)
- 3 + 0 + 1 (ie., 3 doses in primary infant series, no dose at 6 mos - 2 years, and 1 booster during preschool age)
- 3 + 1 + 1 (ie., 3 doses in primary infant series, 1 booster dose at 6 mos - 2 years, and additional booster during preschool age)

Schedule in countries currently using OPV

It is important to note that for countries currently using OPV only, SAGE has recommended at least one dose of IPV alongside OPV (i.e., IPV does not replace OPV) according the schedule described in the next section. For the 73 GAVI eligible and GAVI-graduating countries, the GAVI Alliance will provide IPV support based on a one-dose schedule.

3.2.1. SAGE Recommended Schedule

SAGE provided the following schedule recommendations for IPV introduction globally in the context of the polio endgame, including:

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Countries introducing **1 dose of IPV** into the routine immunization schedule should administer the dose **at or after 14 weeks of age**, in addition to the 3-4 doses of OPV in the primary vaccination series (see Section 3.2.2).

- All children who are behind on their IPV schedule should receive one dose of IPV at the first immunization contact after 14 weeks of age.

**Countries have flexibility to consider alternative schedules** (e.g. earlier IPV administration) based on local conditions or needs (e.g. documented risk of vaccine-associated paralytic poliomyelitis or VAPP prior to 4 months of age, or high rates of drop-outs between DTP1 and DTP3).

---

**Give IPV In Addition To OPV!**

**Note:** Until polio is eradicated globally, OPV is still the main preventive measure against polio. Thus, IPV is recommended in addition to OPV and does not replace OPV.

---

Figure 3. Potential schedules of incorporating single dose of IPV with DTP/Penta and OPV vaccination schedule, SAGE recommendation, November 2013

<table>
<thead>
<tr>
<th>DTP/Penta dosing schedule</th>
<th>Timing of single dose of IPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>6,10,14 weeks</td>
<td>• Single dose of IPV <strong>at 14 weeks of age</strong> with DTP3-OPV3.</td>
</tr>
<tr>
<td>2,3,4 months</td>
<td>• Single dose of IPV with DTP3-OPV3 <strong>at 4 months</strong></td>
</tr>
<tr>
<td>2,4,6 months</td>
<td>• Single dose of IPV with DTP3 and OPV3 <strong>at 6 months</strong>, though DTP2-OPV2 can also be considered</td>
</tr>
</tbody>
</table>

A catch-up strategy is **not recommended for IPV**. Children born before the vaccine introduction date will have been vaccinated with tOPV, and thus immunized against all three types of polio, particularly type 2. It is also important to note that IPV should be administered at the first immunization contact after 14 weeks of age, but **waiting until 9 months of age is not recommended**. Waiting until 9 months to administer IPV would mean leaving a large pool of susceptible hosts (all children aged 0-8 months) to be infected by or to transmit type 2 vaccine derived polioviruses.
3.2.2. Rationale for administering IPV at 14 weeks of age or later

Administer one dose of IPV 14 weeks of age or later

Note: Due to the interference from maternally derived antibody, the immune response to IPV is lower when given at younger ages (<2-3 months of life). Thus, when countries are introducing one dose of IPV in the context of the Endgame, SAGE recommends that the dose be administered at or after 14 weeks of age.

A detailed review of available evidence in June 2013 showed that the optimal timing for administering 1 dose of IPV in a routine immunization schedule is at age 14 weeks or older which is typically at the DTP3/OPV3 contact in the EPI schedule.

The scientific rationale for administering IPV with DTP3 is because IPV performance is negatively affected by higher levels of maternally-derived antibody at the younger ages when DTP1 and DTP2 are typically administered, even after taking into account the potentially lower level of vaccine coverage due to drop-out rates between DTP1 and DTP3. In short, administering IPV with DTP3 when maternal antibody levels were lower more than made up for the deficit resulting from the lower coverage related to drop-outs.

In countries with a 6, 10, and 14 week immunization schedule, this would mean that IPV would be administered at 14 weeks of age (Figure 4). For countries with a 2, 3, and 4 month or 2, 4, and 6 month schedule, the IPV dose could be administered at 4 months of age or 6 months of age, respectively. The dose of IPV will be administered in addition to the 3 or 4 doses of OPV in the primary series—that is IPV will be given at the same visit as OPV3 or OPV4.

Figure 4. Example of a 6, 10, 14 week EPI schedule with one dose of IPV

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Birth</th>
<th>6 weeks</th>
<th>10 weeks</th>
<th>14 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTP-HepB-Hib</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Pneumococcal</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Rotavirus*</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>OPV</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>Stand-alone IPV</strong></td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

*Note that rotavirus vaccine may be 2 or 3 doses
**3.3. Administration of IPV**

IPV is administered by intramuscular (IM) injection, preferably, or subcutaneously (SQ), in a dose of 0.5 ml into the outer part of the thigh. IPV should not be mixed with other vaccines in the same vial or syringe. When given at the same visit, IPV and other injectable vaccines should be given at different injection sites at least 2.5 cm apart. For example, if IPV, pentavalent vaccine, and pneumococcal vaccine are to be given during the same visit, IPV may be given with Pneumococcal vaccine in the same thigh at least 2.5 cm apart; the pentavalent vaccine may be given in the other thigh.

**3.4. Safety of IPV & multiple injections**

IPV is safe and very well-tolerated. Severe adverse reactions are extremely rare. 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. Other, mild side effects such as transient fever have also been reported but fever >40°C has only been reported in <0.1% of infants.

Recently, more low and middle income countries have begun using multiple vaccine injections with the addition of pneumococcal vaccine and recently, inactivated poliovirus vaccine (IPV). For example, South Africa and Brazil have been using 3 injections in their Expanded Program on Immunization (EPI). In Brazil, communication strategies targeting healthcare workers, professional societies, opinion leaders, and parents included materials and messages that focused on the safety of multiple injections, including vaccination visits that involved stand-alone IPV. National surveillance for Adverse Events Following Immunization (AEFI) demonstrated that multiple injections were well-tolerated and not associated with adverse events (and this included not being associated with fever, convulsions or hypotonic-hypo-responsive episodes).

Globally, most middle and high-income countries have been using multiple injections for over a decade without any untoward effects to infants or to the country immunization program. For example, in the United States, infants often receive 3 or more injections during each of the primary series vaccination visits.

Giving a child several vaccinations during the same visit offers 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.

A fact sheet reviewing more information on multiple injections can be found at: [http://tinyurl.com/ipv-intro](http://tinyurl.com/ipv-intro)
3.5. Contraindications to IPV
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, or a history of an allergic reaction following a previous injection of IPV.

3.6. Use in premature infants
IPV can be administered to prematurely born infants (i.e., <37 weeks gestation) at the recommended chronologic age concurrent with other routine vaccinations.

3.7. Use in immunodeficient populations
IPV can be safely administered to children with immunodeficiencies (e.g., HIV, congenital or acquired immunodeficiency, sickle cell disease). In fact, because of the elevated risk of vaccine-associated paralytic polio after the use of OPV in patients with immunodeficiencies, IPV is universally recommended in these children.
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 of reintroduced 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, & 3 antigens  
- Antigen dose 40-8-32 for each vaccine type |
| Method Route of administration | - Intramuscular or subcutaneous injection |
| Immunization Schedule | - WHO recommends 1 dose of IPV with DTP3 and OPV3 which is typically recommended at 14 weeks or at 4 months, based on country EPI schedules and SAGE recommendations. |
| 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  
- DISCARD opened vial at the end of the vaccination session or after 6 hours whichever comes first—do not return open vial to refrigerator. |
| heat & freeze        | sensitivity |
| Presentation & vial  | - WHO prequalified in stand-alone 1 and 10 dose vials (5-dose vials anticipated in the second half of 2014) |
| size                 | Package volume per dose | - 1-dose presentation: 1, 10, & 50 vial cartons with volume per dose (cm³) of 101.4, 26.8, and 12.9 respectively  
- 5-dose presentations (volume information pending)  
- 10-dose presentation: 10 vials cartons with volume per dose (cm³) of 2.46 |
| VVM                  | - VVM7 |
| Co-administration    | - 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. |
| with other vaccines  | |

4. Vaccine Management, Cold Chain, and Logistics

Vaccine management encompasses activities related to handling of vaccines at the country level from the moment they arrive till the moment they are used. It includes:

- Ensuring sufficient storage volume
- Arrival and acceptance procedures
- Effective stock management
- Appropriate temperature monitoring
- Maintaining standards of building, equipment and vehicles
- Vaccine delivery systems, including vaccine handling, transporting people and vaccines
Effective use of policies such as the multi-dose vial policy (MDVP) and the use of vaccine vial monitors (VVM)

Effective vaccine management requires adequately trained staff at all levels from national and sub-national program managers, district health management teams, cold chain technicians, logisticians, drivers, and health facility team. These individuals deal with all aspects of vaccine management, cold chain system and logistics.

This section deals with vaccine management, cold chain, and logistics considerations that are specific to IPV. For general information on these topics, please consult the additional resources, noted below.5

4.1. Estimation of Vaccine Requirements
Immunization services depend on an adequate supply and quality of vaccine and injection equipment. Efficient management of the vaccine stock is important for ensuring balance between having too much vaccine for too long in one part of the cold chain thereby risking vaccine expiry and having too little vaccine whereby not all the children in the target population can be vaccinated. To be sure that the appropriate amount of vaccine is available, vaccine stocks must be checked continuously, and records kept of all movements of stock in and out of storage areas.

Effective planning, management, and storage of supplies is important for reducing program costs, preventing stockouts and high wastage rates, and ensuring vaccine safety.

The following sections will help managers determine vaccine and injection equipment needs.

4.1.1. Maintain a buffer or reserve stock
Each level of the supply chain should maintain a 25% buffer or reserve stock, which is a quantity of vaccine that can be used if new supplies are delayed or if there is a sudden increase in demand. Facilities should always maintain a buffer stock, which is typically calculated at 25% of the amount expected to be used during a given supply period. Note that reserve stock is not the same as a wastage allowance. Both are needed in forecasting vaccine needs.

A catch-up strategy, where children born before the vaccine introduction date are immunized, is not recommended for IPV. Thus, the vaccine needs during the first year will not differ from future years.

4.1.2. Estimating vaccine wastage

Vaccine wastage is the proportion of vaccine that is supplied but never administered, calculated as shown below:

**Calculating Vaccine Wastage**

**Formula:**

\[
\text{wastage rate} = \frac{\text{doses supplied} - \text{doses administered}}{\text{doses supplied}} \times 100
\]

**Example:**

Doses supplied: 200
Doses administered: 150

\[
\frac{200-150}{200} \times 100 = 25\% \text{ wastage}
\]

**Wastage factor:** \(\frac{100}{(100-25\%)} = 1.33\)

<table>
<thead>
<tr>
<th>Wastage rate</th>
<th>5%</th>
<th>10%</th>
<th>15%</th>
<th>20%</th>
<th>25%</th>
<th>30%</th>
<th>35%</th>
<th>40%</th>
<th>45%</th>
<th>50%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corresponding wastage factor</td>
<td>1.05</td>
<td>1.11</td>
<td>1.18</td>
<td>1.25</td>
<td>1.33</td>
<td>1.43</td>
<td>1.54</td>
<td>1.67</td>
<td>1.82</td>
<td>2.00</td>
</tr>
</tbody>
</table>

Information on factors associated with wastage and policies to mitigate vaccine wastage are described in Section 5.

4.1.3. Estimating vaccine needs on the basis of target population

The annual number of IPV doses needed is a product of the target population, number of doses, planned or desired immunization coverage, and wastage factor. The basic formula for calculating the order size for IPV is:

\[
\text{Target Population} \times \text{Expected coverage} \times \text{Number of IPV doses in the schedule} \times \text{Wastage Factor}
\]

Following the SAGE recommendations, calculations will be based on administration of one dose of IPV per child. The estimated wastage factor for a 10-dose vial of IPV is estimated to be 2.00 (50% wastage) but could vary by region/country depending on presentation, vaccination strategy (fixed site/outreach), population density, and number of children at each session. Because limited data are available on stand-alone IPV use in developing country settings, the predicted wastage should
be based on routine use of measles vaccine, which has the greatest similarity of presentation and formulation to the IPV presentation to be used.

An example of vaccine order size calculation that is adjusted based on the amount of stock on hand and the buffer stock needed is shown below:

**An Example of Calculating Order Size for IPV**

<table>
<thead>
<tr>
<th>Number of doses required</th>
<th>Wastage rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population = 1000</td>
<td>Wastage rate in this district is 25%.</td>
</tr>
<tr>
<td>Expected coverage = 70%</td>
<td>Wastage factor or multiplier: 100/(100–50) = 2.00</td>
</tr>
<tr>
<td>Number of doses per child required = 1</td>
<td>700 doses x 2.00 = 1400 doses</td>
</tr>
<tr>
<td>1000 x 0.70 x 1 = 700 doses</td>
<td></td>
</tr>
</tbody>
</table>

**Number of doses required per supply period**

Supply period in district is every 3 months (0.25 of a year).

1400 x 0.25 = 350 doses

**Vaccine in stock**

The amount of IPV that is needed in the district for this three-month supply period is 350 doses. If the district already has 100 doses in stock, the amount of vaccine to be ordered is 250 doses, not 350 doses. It is a common and costly mistake to order vaccine without adjusting for the amount in stock.

**Reserve stock required**

A percentage should be added for reserve stock. If 25% reserve stock is used, then an additional 88 doses are needed (25% of 350).

**Amount to order:** 250 + 87 = 337 doses

### 4.2. The Cold Chain

IPV is sensitive to heat and freezing and must be kept and transported at the correct temperature range at all points along the way from manufacture to administration. Cold chain is the system used for maintaining vaccine integrity from the time it is manufactured until it is administered. This section deals with aspects of cold chain needs specific to IPV including:

- Estimating cold space needs
- Temperature monitoring
- Equipment selection and maintenance
- Vaccine handling
For further information, reader is referred to additional resources on this topic.6

4.2.1. **Estimating required net volume for vaccine storage**

Step 1: Determine the net volume of vaccine needed for a fully immunized child. This net volume for new vaccines is typically determined by two factors:

- Volume per fully immunized child (FIC): based on number of number of doses for immunization, packed volume per dose (cm³), and wastage factor.
- Desired/projected number of children being immunized during the year (i.e., target population x planned vaccine coverage)

For each of the presentations of IPV, the required volume of IPV (last column) for a target population of 100,000 can be calculated as:

<table>
<thead>
<tr>
<th>No. of doses of IPV per vial</th>
<th>No. of doses per child</th>
<th>Packed volume per dose in cm³</th>
<th>Wastage Factor</th>
<th>Volume per fully immunized child (FIC) in liter (A<em>B</em>C)/1000</th>
<th>No. of children immunized</th>
<th>Required storage volume for IPV in Liters (D*E)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>1</td>
<td>2.46</td>
<td>1.33</td>
<td>0.003272</td>
<td>100,000</td>
<td>327.2</td>
</tr>
</tbody>
</table>

Step 2: Determine required storage capacity: To determine if the necessary cold chain equipment (e.g., cold rooms, refrigerators, cold boxes) can accommodate the necessary volume of IPV requires multiplying the storage volume by a factor of 1.2 to 2.0 that takes into account the space between vaccine boxes due to the need for air circulation.

<table>
<thead>
<tr>
<th>No. of doses of IPV per vial</th>
<th>Required storage volume for IPV in Liters</th>
<th>Equipment volume factor</th>
<th>Annual volume of IPV in Liters (A*B)</th>
<th>Monthly volume of IPV in Liters (C/12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>327.2</td>
<td>2</td>
<td>654.4</td>
<td>54.4</td>
</tr>
</tbody>
</table>

---

Step 3: Determine if cold storage space can handle IPV storage capacity: Subtract current vaccine storage volume from the total refrigerator capacity. If this difference exceeds the monthly volume of IPV, then the health facility storage capacity should be sufficient. If not, the officer in charge should select & request the appropriate model of refrigerator.

4.2.2. Common cold chain equipment

Once the capacity needs for cold chain have been identified for IPV, persons responsible for procuring storage equipment can select or request the appropriate equipment including:

- Cold rooms
- Freezers and refrigerators
- Cold boxes and vaccine carriers
- Icepacks

An important aspect of this task also includes appropriate management of the equipment, which requires:

- Keeping an equipment inventory
- Planning and budgeting for maintenance and repair
- Planning and budgeting for replacements
- Preparation for emergencies

4.2.3. Temperature monitoring

The capacity of IPV to produce neutralizing antibodies is destroyed by freezing and heat. Proper storage of vaccines at every stage of the cold chain is essential for avoiding loss of IPV potency. Once vaccine potency is lost, it cannot be regained. Damaged vaccines must be destroyed, which can leave a country without adequate stocks.

- IPV is quite stable (at least 2 years) at refrigerator temperatures between 2° - 8° Celsius.
- IPV is sensitive to freezing and heat and should be stored and transported between 2° - 8°C at all levels of the cold chain from primary vaccine store to the health post.

**Do NOT Freeze IPV! If Frozen, Discard.**
The "Shake Test" does not work for determining if IPV was frozen.

**IPV is FREEZE SENSITIVE:** Liquid vaccines, including IPV, must not be frozen or placed on a frozen icepack. If frozen, liquid vaccines lose their potency and provide no protection against the disease. Previously 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 ineffective in determining whether IPV has been frozen. If there is doubt or suspicion that vaccine was frozen, the vial must be discarded.

**IPV is HEAT SENSITIVE:** IPV loses potency when exposed to high temperatures. Heat impact on vaccines is cumulative. The Vaccine Vial Monitor (VVM) on IPV indicates whether the vaccine has been exposed to a combination of excessive temperature over time and whether it is likely to have been damaged (Figure 5). It clearly indicates to health workers whether a vaccine can be used.

**Figure 5. How to read a Vaccine Vial Monitor (VVM)**

---

### 4.2.4. Vaccine storage

Proper handling of vaccines requires correct packing and storing of vaccines. In general, the following storage and handling principles should be noted with regard to IPV:

---
Each vial shows an expiry date. Never use vaccines beyond the expiry date, even if the VVM is still good. Apply the earliest-expiry-first-out (EEFO) principle. The suggested maximum length of storage of IPV at health-facility level is 1 month, keeping in mind that the VVM status and expiry dates must be monitored and checked each time prior to opening a vial.

### 4.3. Safe Administration of IPV and waste management

This section provides further detail on safe vaccine administration with specific recommendations for multi-dose stand-alone IPV presentation and waste management.

#### 4.3.1. Preparing IPV

1. Check the child’s immunization status, age, and contraindications (section 3.4 to 3.7 and Table 3 for example).
2. Take IPV out of the fridge and check expiry date for validity.
3. Check the VVM for potential damage by heat (see Figure 5).
4. Inspect if the vaccine is frozen. If evidence of exposure to freezing temperatures or suspicion for freezing exists, discard the vaccine. Notice that the “shake test” will not be able to detect damage by freezing in IPV.
4.3.2. Steps to Administer IPV

**Step 1:** Inform caregiver of the vaccines given, possible side effects and what to do.

**Step 2:** Draw up 0.5 ml with a new auto-disable syringe (AD). IPV should not be mixed with other vaccines in the same vial or syringe.

**Step 3:** Administer an intramuscular injection (preferably) in the anterolateral right or left thigh of the infant. IPV may also be given subcutaneously in the anterolateral fat of the infant’s thigh.

NOTE: Simultaneous administration of IPV with other vaccines should be given at different injection sites – separated by at least 2.5 cm. For example if Pentavalent vaccine is given in the left thigh, then IPV should be given in the right thigh.] If IPV, Pentavalent vaccine, and Pneumococcal vaccine are to be given during the same visit, IPV may be given with Pneumococcal vaccine in the same thigh at least 2.5 cm apart; the Pentavalent vaccine may be given in the other thigh.

**Step 4:** All used injection equipment should be placed in a safety box **(without recapping)**, immediately after use. Dispose of filled safety boxes according to national guidelines.

**Step 5:** Record dose on tally sheet, immunization card, and immunization register. **NOTE:** IPV data should be recorded separately from OPV and other vaccines (i.e., not lumped under “polio vaccine”)

**Step 6:** Remind caregiver to return for the next health visit.
4.3.3. Multi-Dose Vial Policy

Discard Multidose IPV vials after 6 hours or at session end, whichever comes first!

**Note:** An opened multi-dose vial of IPV contains several doses of IPV from which one or more doses have been taken. WHO prequalified stand-alone IPV is unpreserved or preserved with 2 phenoxy-ethanol. This means that open multidose vials of this vaccine must be discarded at the end of the immunization session or within 6 hours after opening, whichever comes first.

The WHO prequalified presentations of stand-alone IPV are unpreserved or preserved with 2 phenoxy-ethanol, which does not pass WHO requirements to effectively preserve the vaccine for 28 days. Therefore, for all current prequalified IPV presentations, opened vials must be discarded at the end of the immunization session or 6 hours after opening, whichever comes first. The current presentations are considered suitable for supply through the UN. Each country planning introduction of any of these IPV presentations will need to ensure its programmatic readiness to do so and ensure a plan for monitoring and supervision of its correct use.

To mitigate against potential programmatic risk, countries should ensure that they:

- Understand the benefits and potential contamination risks of the multi-dose unpreserved presentation of IPV and understand the need for special training to enhance immunization worker practices.
- Conduct post introduction evaluations to determine levels of health care worker knowledge and compliance with the correct handling of IPV; and implement corrective training if needed.

Prior to vaccine introduction countries should:

- Ensure training materials are in place in immunization centers prior to the launch of IPV.
- Place stickers on refrigerators at all levels indicating that opened vials of the vaccine must be discarded at the end of the immunization session or six hours after opening, whichever comes first (see Annex 1). The stickers should be in place prior to the launch of the vaccine.

4.3.4. Vaccine wastage

Appropriate management at all levels of immunization services can reduce vaccine wastage and improve cost efficiency. Monitoring of vaccine wastage and supply will be particularly important during the introduction period to accurately predict demand. Weekly monitoring of adequate stock...
levels is necessary, recognizing that social mobilization may increase vaccine demand substantially in some areas and result in stock-outs of IPV.

Factors associated with wastage can be categorized as unavoidable and avoidable.

**Unavoidable wastage factor:**

- As discussed in previous section, WHO prequalified stand-alone IPV is unpreserved or preserved with 2 phenoxy-ethanol. This means that open multidose vials of this vaccine must be **discarded** at the end of the immunization session or within 6 hours after opening, whichever comes first.

**Avoidable wastage factors:**

- Poor stock management can result in over-supply and vaccine reaching expiry before use (recall the EEFO principle)
- Exposure to unacceptably high or low temperatures due to cold chain failure
- Administration of excess vaccine dosage beyond the recommended 0.5 mL for each IPV injection
- Lost, broken, or stolen vials

---

**Recording number of doses & vials used is important!**

**Note:** Monthly reporting of IPV doses administered and vial utilization should be completed by each health facility to the district level. At the district level, these reports should be compiled and submitted to the sub-national level, and subsequently compiled/submitted to the national level (refer to section).

---

**4.3.5. 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. Vaccinators should place all used needles and syringes in a safety box immediately after administering the vaccine, without recapping them, tape the nearly (i.e. not more than 3/4) full box securely shut and store the box in a safe place until it can be properly disposed according to national guidelines.
5. Monitoring, Evaluation, and Supervision of IPV introduction

Introduction of a new vaccine may pose some new challenges in service delivery. EPI monitoring, evaluation, and supervision are basic processes that facilitate the collection and analysis of the data required to verify whether activities planned under the program are being implemented effectively, or to what extent the objectives and targets defined have been achieved.

Monitoring and evaluation will require that information systems be updated to facilitate collection of core indicators related to IPV introduction as described in following sections. These sections provide a broad overview of monitoring systems, methods, and tools for the collection, analysis, and dissemination of information on coverage, drop-outs, and quality of services.

These monitoring and evaluation activities are not unique to IPV and are described in detail at: http://www.who.int/immunization/monitoring_surveillance/resources/IIP_Module7.pdf

5.1. Monitoring

Monitoring the introduction of IPV may be done through:

- Weekly coordination meetings by the EPI focal persons and Coordinating Task Force members to verify that all introduction activities are occurring on time in a quality manner
- Regular monitoring of core indicators of the implementation of the IPV immunization plan to identify achievements and gaps that need to be addressed. These core indicators will include:
  - IPV doses administered in relation to the target population under 1 (see section 5.1.3)
  - Vaccine stock & wastage

The basic tools and methods used for monitoring are described below.

5.1.1. Information Systems

Adding IPV will require updating the forms, vaccination cards, or electronic databases used for recording and reporting vaccine administration, forms for ordering vaccines, and vaccine stock ledgers, and any other forms that list the national immunization program vaccines. These include:

- Patient registers
- Vaccination cards
- Tally sheets
- Stock ledgers
- Electronic databases

In addition to the forms, the various information systems that use these data will also need to be updated to reflect the addition of IPV. This includes systems that aggregate immunization coverage data from subnational levels upwards, including reporting at the national level to UNICEF/WHO.
Early communication with the national health information system is needed to ensure adequate lead-time to change the system.

The introduction of IPV and other new vaccines can be an opportunity to review how information is gathered and used for the immunization program and to improve the quality of routinely reported data as well as using that data to improve program performance at all levels.

**Note:** Evaluation of IPV introduction will be based on monitoring vaccine coverage and other indicators of successful introduction activities (e.g., vaccine stockouts, wastage) and not on disease burden. **Thus, it is important to note that record keeping of IPV use must not be aggregated with OPV use.**

The main recording tools that are used for immunization-related activities should be adapted to include IPV vaccine.

**Main Recording Tools**

- **Immunization or child health card:** The IPV dose should be recorded on the child’s immunization card, which is kept with the child to report their vaccination status, and other information such as monitoring of growth. The updated card will clearly indicate the clinic where the IPV dose was received and date of administration should be entered. If a child already has an older card without space for recording IPV administration, the information should be transferred to a new updated card.
- **Tally sheet:** Tally sheets are important for monitoring vaccine demand by supervisors.
  - Using the new tally sheets, record the monthly tally and the count for children immunized with IPV, alongside all other vaccines.
  - Also record the number of open vials and unopened vials with reason (VVM change, expiry, freezing, breakage, other)
- **Register:** New books with a column for IPV will be provided for recording the date when IPV is administered, alongside all other vaccines at the same contact.
- **Stock record:** Accurate vaccine forecasting and ordering depends on knowing the quantity of vaccines in stock at all times
- **Integrated monthly report:** Stock record forms will vary for the health facility versus the district and subnational levels.

**5.1.2. Recording IPV doses & vials**

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 and each vaccine should be recorded and monitored separately.**

Because of the MDVP, wastage is also important to monitor particularly during the first six months after introduction of IPV.
The number of IPV doses administered and vials used should be tracked at the health facility using a simple form (see example), ideally one that is integrated through the existing reporting forms for other vaccines.

<table>
<thead>
<tr>
<th>Health Facility ________________</th>
<th>Month ________________</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Doses Administered</strong></td>
<td></td>
</tr>
<tr>
<td>IPV</td>
<td></td>
</tr>
<tr>
<td>Penta3</td>
<td></td>
</tr>
<tr>
<td><strong>Vials</strong></td>
<td></td>
</tr>
<tr>
<td>IPV vials available at start of month</td>
<td></td>
</tr>
<tr>
<td>IPV vials received this month</td>
<td></td>
</tr>
<tr>
<td>IPV vials opened</td>
<td></td>
</tr>
<tr>
<td>IPV vials available at end of month</td>
<td></td>
</tr>
</tbody>
</table>

### 5.1.3. Calculating IPV coverage

While serosurveys are likely to be considered in a few select settings, these are not a logistically feasible or cost-effective approach for monitoring IPV coverage. Thus, the primary approach for monitoring IPV coverage at the national and subnational level will use routinely collected administrative data.

**Compiling Coverage Data**

1. List each geographic area or community being served by the health facility and the target population of infants under one year of age.
2. Write the number of doses of vaccine administered to the target age group during the preceding 12 month period.
3. Calculate the coverage for the current year by,

\[
IPV\ coverage = \frac{\text{Doses administered in preceding 12 months}}{\text{Target population} < 1\ year\ of\ age\ (or\ live\ births)} \times 100
\]

A coverage monitoring chart which shows doses administered is a simple, effective tool for monitoring progress and graphically showing doses given compared to the number of infants eligible to receive them. The chart can track the progress being made towards immunization of infants under one year of age each month and throughout the year.
5.2. Supervision
Supportive supervision is intended to reinforce the messages provided during the training to health workers. The supervisory visit should include a review of the monitoring data, injection practices, social mobilization, logistics, stock management, and vaccine handling practices at the healthcare center.

Note: Conducting supportive supervision within 2 months post-introduction has been found to be particularly valuable after the recent introduction of a new vaccine into the immunization program.

Further information can be found at: http://www.who.int/immunization/documents/MLM_module4.pdf

5.3. Evaluation
Introduction of a new vaccine requires evaluation to address challenges and gaps, as well as to share successes. Evaluations can be categorized based on their general 2 functions:

- **Corrective action**: these are ongoing evaluations that should occur at the district and sub-national levels and are documented in written reports on a monthly basis that are submitted up to the higher levels of the program. The reports should list the challenges and successes in the forms of observations or indicators and the corrective action. Potential information in the report might include:
  - Proportion of target children vaccinated
  - Timeline of activities: training, arrival of vaccine, first use of vaccine
  - Training: quality, gaps
  - Adequacy of recording/submission of information
  - Reports of AEFI
  - Vaccine management/cold chain adequacy
  - Social mobilization

- **Assessing overall implementation**: these programmatic evaluations are typically coordinated at the national level and conducted within 6-12 months of introduction for maximum benefit to the program. A manual for this evaluation can be found at: http://whqlibdoc.who.int/hq/2010/WHO_IVB_10.03_eng.pdf
6. Communication & Advocacy

A national communication and advocacy strategy geared towards different audiences, partners, stakeholders, communities, and parents, is a critical component of a successful new vaccine introduction program. The benefits of a well-defined and executed communication and advocacy strategy might include:

- To create awareness and demand for IPV
- To foster trust
- To avoid rumors and misinformation
- To improve immunization coverage
- To enhance reporting and detection of potential AEFI
- To build strong community support for the immunization program
- To bring positive attitude change on immunization

In Annex 1-3, frequently asked questions (FAQs) are provided, as well as general and technical issues relevant to IPV. Additional communications materials can be accessed at: [http://tinyurl.com/ipv-intro](http://tinyurl.com/ipv-intro)

7. Reporting of adverse events following immunization (AEFI)

Adverse events following immunization (AEFI) are defined as any untoward medical occurrences which follow immunization - it may not necessarily have a causal relationship with the usage of the vaccine. An adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. Additional information can be found at: [http://www.vaccine-safety-training.org/detection-and-reporting.html](http://www.vaccine-safety-training.org/detection-and-reporting.html)
The following should be reported to the relevant manager by mobile phone immediately upon detection by a health worker:

1. Serious AEFI (i.e., untoward medical occurrence that at any dose results in death, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is life-threatening);
2. Signals and events associated with a newly introduced vaccine;
3. AEFIs that may have been caused by an immunization error;
4. Significant events of explained cause occurring with 30 days after a vaccination;
5. Events causing significant parental or community concern;
6. Swelling, redness, soreness at the injection site IF it lasts for more than 3 days or swelling extends beyond nearest joint.

Although serious AEFI caused by IPV are extremely rare, coincidental occurrence of a serious AEFI and sensational media coverage may seriously undermine immunization activities.

**Note:** Program managers must plan in advance a special communication strategy regarding AEFI, so that the program is prepared to respond if there is a problem.

Risk communication is important to build trust with the public. This includes information on possible side effects in the information, education and communications (IEC) materials and when communicating with parents and the community. Awareness among health workers and the public of possible adverse events will also facilitate early recognition and treatment of side effects, which may reduce their consequences. A poor response to a real or imagined adverse event can rapidly lead to a loss of trust that can take years to rebuild. Since the exact nature of the crisis will not be known until it arises, it is not possible to plan for a detailed response ahead of time. However, countries can have in place the basic elements of a crisis plan, which may include:
an AEFI committee at different levels that can meet immediately to discuss an action plan; identified, well-respected spokespersons at all levels;

- clear channels of communication with various media;
- engaging with credible opinion and traditional leaders to address misconceptions and rumors;
- training of health workers in how to communicate with the public about AEFIs and safety concerns;
- and having an AEFI action plan with specific roles for immunization program partners.

For the most up-to-date information please visit: http://tinyurl.com/ipv-intro

Ce document est aussi disponible en Francais. Consultez http://tinyurl.com/ipv-intro pour info
Annex 1: IPV introduction status by tiers for priority, WHO 2013

Tier 1
WPV endemic countries OR countries that have reported a cVDPV2 since 2000

Tier 2
Countries who have reported a cVDPV1/cVDPV3 since 2000 or which are large-/medium-sized countries with DTP3 coverage <80% in 2009, 2010, 2011 as per WUNIC

Tier 3
Large-/medium-sized countries adjacent to Tier 1 countries that reported WPV since 2003 or countries that have experienced a WPV Importation since 2011

Tier 4
All other OPV only using countries

Annex Table 1. Countries* eligible for GAVI support for IPV introduction† by WHO polio risk tiers

<table>
<thead>
<tr>
<th>Tier 1 (n = 13)</th>
<th>Tier 2 (n = 14)</th>
<th>Tier 3 (n = 12)</th>
<th>Tier 4 (n = 33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
<td>Azerbaijan</td>
<td>Angola</td>
<td>Armenia</td>
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<td>Cambodia</td>
<td>Bangladesh</td>
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<td>Benin</td>
<td>Bolivia</td>
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<td>Guinea</td>
<td>Burkina Faso</td>
<td>Comoros</td>
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<td>Ethiopia</td>
<td>Haiti</td>
<td>Burundi</td>
<td>Cuba</td>
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<td>India</td>
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<td>Congo</td>
<td>Cuba</td>
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<td>Kenya</td>
<td>Lao PDR</td>
<td>Cote d’Ivoire</td>
<td>DR Korea</td>
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<td></td>
<td>Timor Leste</td>
<td></td>
<td>Kiribati</td>
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* Italics indicate GAVI-graduating country (n = 17).
† Ukraine (GAVI-graduating) not included in the list as they have already introduced IPV.

Abbreviations: DR = democratic republic; PDR = people’s democratic republic.
Annex Table 2. All OPV-only using countries by Tier

<table>
<thead>
<tr>
<th>Tier 1 (n = 14)</th>
<th>Tier 2 (n = 19)</th>
<th>Tier 3 (n = 14)</th>
<th>Tier 4 (n = 77)</th>
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