A Guide to Introducing Inactivated Polio Vaccine

Based on the Polio Eradication & Endgame Strategic Plan 2013-2018
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# Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AFP</td>
<td>acute flaccid paralysis</td>
</tr>
<tr>
<td>AEFI</td>
<td>adverse events following immunization</td>
</tr>
<tr>
<td>BCC</td>
<td>behaviour change communication</td>
</tr>
<tr>
<td>bOPV</td>
<td>bivalent oral poliomyelitis vaccine; containing types 1 and 3</td>
</tr>
<tr>
<td>CCL</td>
<td>cold chain and logistics</td>
</tr>
<tr>
<td>cVDPV</td>
<td>circulating vaccine-derived poliovirus</td>
</tr>
<tr>
<td>cMYP</td>
<td>comprehensive multi-year plans for immunization</td>
</tr>
<tr>
<td>DTP</td>
<td>Diphtheria tetanus pertussis vaccine</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Programme on Immunization</td>
</tr>
<tr>
<td>EVM</td>
<td>Effective Vaccine Management</td>
</tr>
<tr>
<td>GPEI</td>
<td>Global Polio Eradication Initiative</td>
</tr>
<tr>
<td>ICC</td>
<td>Inter-agency Coordinating Committee</td>
</tr>
<tr>
<td>IM</td>
<td>intramuscular</td>
</tr>
<tr>
<td>IPV</td>
<td>inactivated poliomyelitis vaccine</td>
</tr>
<tr>
<td>MDVP</td>
<td>multi-dose vial policy</td>
</tr>
<tr>
<td>mOPV</td>
<td>monovalent oral poliomyelitis vaccine</td>
</tr>
<tr>
<td>NITAG</td>
<td>National Immunization Technical Advisory Group</td>
</tr>
<tr>
<td>OPV</td>
<td>oral poliomyelitis vaccine</td>
</tr>
<tr>
<td>PCV</td>
<td>pneumococcal conjugate vaccine</td>
</tr>
<tr>
<td>SAGE</td>
<td>Strategic Advisory Group of Experts on Immunization</td>
</tr>
<tr>
<td>SC</td>
<td>subcutaneous</td>
</tr>
<tr>
<td>SIA</td>
<td>supplementary immunization activity</td>
</tr>
<tr>
<td>tOPV</td>
<td>trivalent oral poliomyelitis vaccine</td>
</tr>
<tr>
<td>VAPP</td>
<td>vaccine-associated paralytic poliomyelitis</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children's Fund</td>
</tr>
<tr>
<td>VDPV</td>
<td>vaccine-derived poliovirus</td>
</tr>
<tr>
<td>VVM</td>
<td>vaccine vial monitor</td>
</tr>
<tr>
<td>WHA</td>
<td>World Health Assembly</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WPV</td>
<td>wild poliovirus</td>
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</table>
ABOUT THIS GUIDE

This document is intended for use by national immunization programme managers and immunization partners involved in planning, implementing, and supporting the introduction of the inactivated poliomyelitis vaccine (IPV), either as a full or fractional dose.

General guidance about planning for the introduction of a vaccine into a national routine immunization programme is provided in the document “Principles and considerations for adding a vaccine to a national immunization programme: from decision to implementation and monitoring” published by the World Health Organization (WHO) in 2014 and available online¹.

The specific objectives of this guide are to:

› Provide up-to-date references on the global policy, technical rationale and strategic issues related to the introduction of IPV.
› Inform the policy discussions and planning activities for the introduction of IPV into a national routine immunization programme.

Section 1 of this guide provides background information on polioviruses, polio vaccines, and the rationale for the introduction of IPV. Section 2 outlines the decision-making process and WHO recommendations to consider on schedules and administration of IPV, leading into section 3, which covers planning and operational topics such as cold chain management, monitoring and evaluation, and communications and training. In the Annexes, practical and adaptable tools are provided, including a planning checklist, and sample questions and answers for health workers.

1. INTRODUCTION

1.1 BACKGROUND

In May 2012, the World Health Assembly (WHA) declared the completion of poliovirus eradication to be a "programmatic emergency for global public health" and called on the Director General of the World Health Organization (WHO) to develop a comprehensive polio endgame strategy.

The Polio Eradication and Endgame Strategic Plan 2013-2018\(^1\) was endorsed by Member States at the Sixty-sixth World Health Assembly in May 2013, approving the targets, goals, and timelines to secure a lasting polio-free world.

The four objectives of the Strategic Plan are to:

1. Detect and interrupt poliovirus transmission
2. Strengthen immunization programmes, introduce at least one dose of inactivated poliomyelitis vaccine (IPV), and withdraw oral poliomyelitis vaccine (OPV), starting with the type 2 component
3. Contain poliovirus and certify the interruption of transmission
4. Plan for the legacy of the polio programme

The Plan seeks to simultaneously eradicate wild poliovirus and eliminate vaccine-derived poliovirus.

The withdrawal of OPV commenced in April 2016 with the globally synchronized "switch" from trivalent OPV (tOPV; containing types 1, 2, 3) to bivalent OPV (bOPV; containing only types 1 and 3).

Type 2 wild poliovirus was last detected in 1999, and the continued use of tOPV in areas where routine immunization coverage is inadequate contributes to the emergence of rare circulating vaccine-derived poliovirus (cVDPV) cases.

In preparation for the switch, an updated WHO Position Paper on polio vaccines was published in February 2014\(^2\). WHO recommended that all countries using OPV only should add at least one dose of IPV to the national immunization schedule at or after 14 weeks of age.

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1. The Polio Eradication and Endgame Strategic Plan 2013-2018 can be found at: [http://polioeradication.org/who-we-are/strategy/](http://polioeradication.org/who-we-are/strategy/)
A revised version of the polio Position Paper was published in March 2016, replacing the 2014 version. It reiterates the WHO recommendations and summarizes recent developments in the field. The latest paper also reflects the global OPV switch as planned for April 2016.

The primary purpose of the IPV dose is to ensure that new birth cohorts have some protection against the type 2 poliovirus, either wild or vaccine-derived, hence mitigating the potential consequences of any re-emergence of type 2 poliovirus following the switch. Adding at least one IPV dose will also boost immunity against poliovirus types 1 and 3, and may contribute to hastening their eradication.

IPV can be safely administered with OPV during the same visit and should be given in addition to the 3 or 4 doses of OPV in the primary series.

1.2 POLIO EPIDEMIOLOGY

POLIOMYELITIS IS AN ACUTE COMMUNICABLE DISEASE CAUSED BY ANY ONE OF THREE POLIOVIRUS SEROTYPES (TYPES 1, 2, OR 3).

Polioviruses are human enteroviruses of the Picornaviridae family. 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.

Polioviruses are spread by faecal-to-oral and oral-to-oral transmission. Where sanitation is poor, faecal-to-oral transmission predominates, but in most settings, mixed patterns of transmission are likely to occur. If sanitation and personal hygiene are inadequate, others can be infected through dirty hands or food and contaminated water. Thus, intestinal immunity is important in order to prevent transmission.

No specific anti-viral drugs are available for poliomyelitis. Treatment consists of supportive, symptomatic care during the acute phase.

Infection occurs without symptoms in approximately 72% of cases. In about 24% of cases it causes mild disease with transitory fever, discomfort, somnolence, headache, nausea, vomiting, constipation, and sore throat, in various combinations. In approximately 4% of cases, it presents as aseptic meningitis, and on rare occasions (< 1%) it presents as paralytic poliomyelitis.

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4 Ibid
Paralytic poliomyelitis is manifest as acute flaccid paralysis (AFP), of sudden onset, with maximum progression within a few days (< 4 days). It is usually asymmetrical, with the reduction or absence of tendon reflexes, without alterations of the sensory system.

**Vaccine-associated paralytic polio (VAPP):**

› VAPP is caused by a strain of poliovirus that has genetically changed in the intestine from the original attenuated vaccine strain contained in OPV.
› It is associated with a single dose of OPV administered to a child or can occur in an unvaccinated or non-immune contact who is close to the vaccine recipient excreting the mutated virus.
› There are no outbreaks associated with VAPP. The weakened virus may paralyze the child or his or her contact, but it does not spread to cause other cases of paralysis.
› Globally, the estimated risk of VAPP in vaccine recipients or in close contacts is 1 in 2.4 million doses administered. A recent review found that 26% of recipient VAPP and 31% of contact VAPP cases were associated with type 2 vaccine virus.

**Vaccine-derived polioviruses (VDPDs):**

› On very rare occasions, where immunization coverage is low, a strain of the weakened poliovirus originally contained in OPV may genetically change and revert to a form (a VDPV) that can regain the strength to cause paralysis in humans. If undetected by “environmental surveillance” activities, a VDPV has the capacity for sustained circulation, and is thereby known as a circulating VDPV (cVDPV).
› Low vaccination coverage is a major risk factor for cVDPV emergence. Circulating VDPVs occur when a significant proportion of the population is left susceptible to poliovirus, enabling the sustained transmission of the VDPV and circulation in the environment.
› “Persistent cVDPVs” refer to cVDPVs known to have circulated for more than six months.
› In addition to cVDPVs, there are two other categories of VDVPs:
  - Immune-deficiency associated VDPV (iVDPV): when a VDPV is isolated from persons with proven immunodeficiencies;
  - Ambiguous VDPV (aVDPV): when a VDPV is isolated from persons with or without AFP and with no known immunodeficiency, or from environmental samples, and when there is no evidence of circulation.

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**Polio Eradication as of June 2016**

Before the WHA launched the Global Polio Eradication Initiative (GPEI) in 1988, the wild virus caused more than 350,000 cases of paralysis per year across more than 125 countries.

› Today, polio has been eradicated in the regions of the Americas, Europe, South East Asia, and the Western Pacific.
› The global eradication of wild poliovirus type 2 was declared in September 2015.
› Polio remains endemic in two countries: Afghanistan and Pakistan.

Regular updates available on: www.polioeradication.org

Vaccines that contain live attenuated viruses, such as oral polio vaccine (OPV), are extremely safe and effective for immunizing children against polio. On very rare occasions, however, OPV can lead to vaccine-associated paralytic polio or vaccine-derived poliovirus outbreaks.

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**Wild poliovirus (WPV)**

Infectious virus that invades the nervous system. Can cause paralysis or death.

**Circulating vaccine-derived poliovirus (cVDPV)**

A very rare, circulating infectious virus mutated from the weakened strain of poliovirus in OPV. Under certain conditions, may cause paralysis or death.

**Risk factors**

Low immunization coverage rates, poor sanitation, high population densities.

**To stop transmission**

Increase immunization coverage rates with OPV.

### Strains

- **Type 1:** Caused 100% of 2014 cases
- **Type 2:** Eradicated, last seen in 1999
- **Type 3:** Last seen in 2012

Until April 2016, the **type 2** virus was responsible for up to 90% of all cVDPV cases.

### Total cases in 2014

- **Wild poliovirus (WPV):** 359
- **Circulating vaccine-derived poliovirus (cVDPV):** 56

### Total cases in 2015

- **Wild poliovirus (WPV):** 74
- **Circulating vaccine-derived poliovirus (cVDPV):** 32

Eradicating polio for good requires eliminating both wild and vaccine-derived polioviruses.

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7 Reference: http://polioeradication.org/polio-today/polio-now/this-week/circulating-vaccine-derived-poliovirus/

8 Reference: http://polioeradication.org/polio-today/polio-now/this-week/
To date, two types of polio vaccines have been used throughout the world and are available on the international market: OPV and IPV.

Thanks to its immunological characteristics, the use of OPV has made it possible to eradicate polio in the regions of the Americas, Europe, South East Asia, and Western Pacific. When OPV is administered, the virus in the vaccine is ingested orally, replicates in the intestines, and can generate various immune responses.

- **Humoral immunity**: presence of antibodies in the blood, which protects the organism by preventing the virus from invading the nervous system and causing paralysis.
- **Oral mucosal immunity**: prevents excretion of the virus in oral secretions and its transmission through this route.
- **Intestinal mucosal immunity**: prevents excretion of the poliovirus in faeces, which means that children previously vaccinated with OPV coming into contact with this virus are less likely than unvaccinated children to excrete it in their faeces.

It should be noted that children vaccinated with OPV who have not yet developed intestinal mucosal immunity to poliovirus can excrete the vaccine virus in faeces, spreading it into the environment, which serves to immunize others who have not been vaccinated. Due to its low cost and ease of administration by untrained health workers, OPV has been used by many low and middle income countries where the risk of polio outbreaks has been the greatest.

Unlike OPV, IPV cannot cause VAPP or cVDPVs. IPV stimulates a good humoral response and is as effective as OPV in blocking oral transmission. However, IPV on its own it does not induce the same level of intestinal immunity as OPV, which means that IPV does not prevent wild polio virus from being excreted in faeces and spreading in the environment.

Polio vaccines generate immune responses to the types of poliovirus they contain. A polio vaccine that contains only types 1 and 3 polioviruses generates immune responses to only those types (i.e. immunity to one type of poliovirus does not guarantee immunity to the other two).
**TABLE 2. TYPES OF POLIO VACCINE**

<table>
<thead>
<tr>
<th>CONTAINS</th>
<th>Oral Polio Vaccine (OPV)</th>
<th>Inactivated Polio Vaccine (IPV)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture of live, weakened poliovirus strains.</td>
<td>Mixture of inactivated, killed strains of all three poliovirus types.</td>
</tr>
<tr>
<td></td>
<td><em>Trivalent OPV (tOPV)</em>: All 3 poliovirus types</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Bivalent OPV (bOPV)</em>: Types 1 and 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Monovalent OPV (mOPV)</em>: Any one individual type</td>
<td></td>
</tr>
<tr>
<td>HOW IT WORKS</td>
<td>In response to the weakened virus, the body produces antibodies in the blood and gut.</td>
<td>In response to the inactivated virus, the body produces antibodies in the blood. Protects the individual, but the virus may still replicate in the gut and could spread to infect others.</td>
</tr>
<tr>
<td>ADMINISTRATION AND COST</td>
<td>Easy, oral administration through drops can be given by volunteers. Is used in many countries’ routine immunization programmes and extensively in immunization campaigns. Costs less than US$0.15 per dose.</td>
<td>Vaccine injection is administered primarily through routine immunization programmes by trained health workers. Cost is higher, currently starting at US$1 per dose for low-income countries.</td>
</tr>
<tr>
<td>USE</td>
<td>Extremely effective in protecting children from WPV and cVDPV. Nearly every country has used OPV to stop wild poliovirus transmission because it prevents person-to-person spread of the virus, protecting both the individual and the community.</td>
<td>Extremely effective in protecting children from polio disease due to WPV and cVDPV, but cannot stop spread of virus in a community.</td>
</tr>
<tr>
<td>cVDPV RISK</td>
<td>In extremely rare cases, can cause cVDPV in under-immunized populations. For this reason the global eradication of polio will require the eventual cessation of all OPV.</td>
<td>Cannot cause cVDPV.</td>
</tr>
</tbody>
</table>

**Due to their important but distinct advantages, both OPV and IPV are necessary to eradicate polio.**
Because OPV protects both the individual and the community, it has been an essential tool for countries working to stop wild poliovirus transmission. IPV protects against paralytic polio and cannot cause cVDPVs, and thus is vital to ending polio.
The rationale for IPV introduction

As naturally occurring polio cases decrease, paralysis induced by vaccine-related viruses in OPV will continue to occur, although in extremely small numbers.

The sustained use of OPV is therefore inconsistent with the goal of eradicating all paralytic polio disease. For this reason, all OPV use will eventually be stopped, after types 1 and 3 are certified as eradicated worldwide.

While wild poliovirus type 2 (WPV2) has been eradicated worldwide and is no longer a naturally occurring threat, the type 2 component of OPV has caused the majority of vaccine-related cases since 2000. As a result, in this final phase of global polio eradication, the type 2 component of tOPV presents greater risks than benefits, thus hindering eradication efforts.

Accordingly, WHO called for the withdrawal of tOPV in April 2016 through a globally synchronized switch to bOPV, targeting types 1 and 3 viruses.

To help mitigate the risks of the switch from tOPV to bOPV, WHO recommended that all countries currently using only tOPV in their vaccination programmes introduce at least one dose of IPV into their routine immunization schedules before the end of 2015 (pending available supply). This is to help address the gap in population immunity against the type 2 virus following the switch from tOPV to bOPV.

Vaccination with IPV also reduces the risk of sustained transmission. If type 2 poliovirus is reintroduced post-eradication, it can be more rapidly controlled using monovalent OPV type 2 (or IPV) because the population would have already received at least one IPV dose and will therefore be primed or have some degree of immunity.

Why should countries introduce IPV?

WHO recommends the introduction of at least one dose IPV by the end of 2015 (pending available supply) for all countries that use only OPV. IPV is a key element of the Polio Eradication and Endgame Strategic Plan 2013-2018 and the global readiness to manage risks associated with OPV type 2 withdrawal:

- **To reduce risks**: Once tOPV is withdrawn from the global market in April 2016, there will be an increase in the population susceptible to the type 2 poliovirus. The use of IPV will help to maintain immunity and prevent the reappearance of the disease in the event of the reintroduction or emergence of this type of virus.
- **To help maintain immunity to type 2**: Once the type 2 component of OPV is withdrawn globally, there will be a gradual accumulation of infants susceptible to type 2 poliovirus, and IPV will help to address this gap in immunity.
- **To interrupt transmission in the event of outbreaks**: If the use of mOPV type 2 is required to control a future outbreak, it will be easier to reach the immunity levels needed to stop transmission in a population previously vaccinated with IPV. Introducing IPV can help to facilitate future outbreak control.
### Timeline leading to IPV introduction

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2012</td>
<td>The Strategic Advisory Group of Experts on Immunization (SAGE) recommended the eventual cessation of OPV type 2</td>
</tr>
<tr>
<td>May 2012</td>
<td>The World Health Assembly (WHA) declared the completion of poliovirus eradication to be a &quot;programmatic emergency for global public health&quot;</td>
</tr>
<tr>
<td>January 2013</td>
<td>The WHO Executive Board approved the Endgame Strategic Plan 2013-2018.</td>
</tr>
<tr>
<td>November 2013</td>
<td>SAGE recommended the schedule for at least one dose of IPV</td>
</tr>
<tr>
<td>February 2014</td>
<td>WHO Position Paper on polio is published, confirming that WHO no longer recommends an OPV-only schedule</td>
</tr>
<tr>
<td>May 2015</td>
<td>WHA resolution urges all Member States to prepare for the global withdrawal of the type 2 component of OPV, expected in April 2016</td>
</tr>
<tr>
<td>December 2015</td>
<td>Deadline for countries to have introduced IPV into national immunization schedules (pending available supply)</td>
</tr>
<tr>
<td>March 2016</td>
<td>An updated WHO Position Paper on polio is published</td>
</tr>
<tr>
<td>April 2016</td>
<td>Globally coordinated switch from tOPV to bOPV, from 17 April to 1 May</td>
</tr>
</tbody>
</table>

### 1.5 The switch from tOPV to bOPV

**Why switch from tOPV to bOPV?**

There are three types of wild poliovirus, types 1, 2 and 3, each of which is targeted by a different component of the trivalent oral polio vaccine (tOPV).

OPV consists of a weakened (attenuated) version of the polio virus, administered orally through two drops, and has the advantage of immunizing the intestine, where the virus reproduces. OPV is very effective against the wild virus, but in extremely rare cases can lead to paralysis through VAPP or cVDPV (*see Section 1.2, Polio epidemiology*).

Even though wild poliovirus type 2 has been declared as eradicated worldwide, vaccine-related type 2 viruses are responsible for the majority of cVDPV outbreaks and VAPP cases.

As a result, there were more risks than benefits associated with the use of tOPV. Therefore, it was necessary to replace tOPV with bOPV, which continues to protect against types 1 and 3. Once these two types are eradicated, bOPV will also be withdrawn and replaced completely with IPV.

**Why was it necessary for the switch to be implemented in a globally synchronised manner?**

All programmes using tOPV were required to switch to bOPV in a globally coordinated manner, between 17 April and 1 May 2016, during the "low” season for poliovirus transmission.
If all countries had not switched at the same time, those using bOPV would have some decline in population immunity to type 2, putting them at risk from the countries that continued to use tOPV and could generate and export type 2 cVDPVs.

The highly synchronized nature of the switch during the “low” polio season was important to reduce the risk of the re-emergence of type 2 cVDPVs. A globally coordinated switch was therefore the best way for countries to limit the risk of cVDPV type 2 emergence and spread.

**What happens if an outbreak of type 2 polio occurs after the switch from tOPV to bOPV?**

Following the switch, mOPV type 2 (mOPV2) and IPV will be the two vaccines of choice for responding to any type 2 outbreak or accidental wild poliovirus type 2 (WPV2) release from a laboratory or facility. A global stockpile of mOPV2 and IPV have been procured and will be available for outbreak response.

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### Strengthening Routine Immunization Programmes

**Given that IPV will be administered primarily through routine immunization programmes, it is essential that the system be sufficiently robust.**

High routine immunization coverage establishes adequate population immunity over time to prevent polio outbreaks, and builds a sustainable platform for the delivery of lifesaving vaccines.

Many activities that are carried out to prepare for, implement, and monitor the introduction of IPV, offer opportunities to make improvements in routine immunization programmes. Countries have found that new vaccines tend to perform only as well as the underlying programme, so efforts to make use of the IPV introduction to reinforce and improve the immunization programme should not be neglected.

Routine immunization strengthening and polio eradication efforts can amplify each other’s impact and together more effectively achieve disease prevention targets. Strong routine immunization programmes will also help to sustain the gains already made by polio resources and help ensure that children who are at a greater risk of contracting polio have access to immunization.

While a strong routine immunization system helps maintain population immunity to prevent outbreaks, vaccination campaigns will remain important strategies, for example, in reaching hard-to-access populations and responding to outbreaks. As much as possible, such supplementary campaign activities – and any efforts to add a vaccine to an immunization programme – should allow for adequate planning in a way that complements and augments the routine programme.
How to strengthen immunization programmes and health systems during a new vaccine introduction

Suggestions on how different aspects of an immunization programme and the overall health system can be improved in the process of planning and implementing a vaccine introduction are outlined in Annex 1 of the document *Principles and considerations for adding a vaccine to a national immunization programme* (WHO 2014)⁹. This provides a list of opportunities during the vaccine introduction, organized by the six building blocks of a health system (see diagram below), derived from the *WHO Health System Framework*¹¹, and is based on a body of research conducted in this area.

| **1.** | Invest in a capable and sufficiently resourced national programme management team in each country. |
| **2.** | Invest in tailored vaccination strategies that will identify the under-vaccinated and the unvaccinated and provide them with all needed vaccinations regularly. |
| **3.** | Invest in a coherent planning cycle, from comprehensive multi-year plans to operational annual EPI plans to the quarterly monitoring of implementation of these plans. |
| **4.** | Invest in assuring that sufficient funds reach the operational level of the programme regularly. |
| **5.** | Invest in vaccinators and district managers by regularly and systematically building their capacity, strengthening their performance and providing supportive supervision. |
| **6.** | Invest in modernizing vaccine management and supply chains to make sure that each vaccination session has sufficient amounts of the right and potent vaccines available. |
| **7.** | Invest in an information system that identifies and tracks the vaccination status of everyone targeted. |
| **8.** | Invest in sustainably expanding the routine vaccination schedules to cover the full life course. |
| **9.** | Invest in sharing responsibility on immunization with the community to help reach uniformly high coverage through high demand and quality services. |

**TABLE 4. WHAT TRANSFORMATIVE INVESTMENTS CAN HELP TO ACHIEVE BETTER IMMUNIZATION OUTCOMES?**

The *Global Routine Immunization Strategies and Practices (GRISP)* document⁸ calls on national Governments, global partners and donors to take the following steps to achieving better immunization outcomes:

⁹ Available at: http://www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/nvi_guidelines/en/
The six building blocks of a health system: aims and desirable attributes

**System Building Blocks**

- **Service Delivery**
- **Health Workforce**
- **Information**
- **Medical Products, Vaccines & Technologies**
- **Financing**
- **Leadership/Governance**

**Overall Goals / Outcomes**

- **Access**
  - Improved Health (Level and Equity)
- **Coverage**
  - Responsiveness
- **Quality**
  - Social and Financial Risk Protection
- **Safety**
  - Improved Efficiency
Decision-making at country level

What is the process?

It is important to have a systematic and transparent process for making a decision about introducing any vaccine into the national immunization programme.

Ideally, the national immunization technical advisory group (NITAG\textsuperscript{12}) or an equivalent independent advisory body should be requested to undertake a rigorous review of the evidence and global WHO recommendations, and present their independent guidance to the national government.

A review of background, evidence and WHO recommendations should also include reference to GPEI’s Polio Eradication and Endgame Strategic Plan 2013-2018 – endorsed by Member States at the Sixty-sixth session of the World Health Assembly in May 2013 – as well as the latest WHO Position Paper on polio. Additional guidance is available on the WHO IVB website (www.who.int/immunization/) and includes the document \textit{Principles and considerations for adding a new vaccine}\textsuperscript{13}.

After making a decision, the Inter-agency Coordinating Committee (ICC\textsuperscript{14}) or equivalent should serve to coordinate partner support and funding for the immunization programme activities.

\textsuperscript{12} NITAGs should consist of national experts in a broad range of disciplines – such as senior paediatricians, immunization and vaccine experts, epidemiologists, public health experts, health economists, health system experts and social scientists – who are capable of analyzing the different types of evidence and issues that should be considered in making an informed decision.

\textsuperscript{13} Available at: http://www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/mni_guidelines/en/

\textsuperscript{14} A committee made up of representatives of the Ministry of Health (MOH), WHO, UNICEF and other domestic and external partners to improve coordination among partners for the support of immunization programmes.
WHO RECOMMENDATIONS ON THE IPV VACCINATION SCHEDULE

AS OF FEBRUARY 2014, WHO NO LONGER RECOMMENDS AN OPV-ONLY VACCINATION SCHEDULE. FOR ALL COUNTRIES USING ONLY OPV, AT LEAST ONE DOSE OF IPV SHOULD BE ADDED TO THE NATIONAL IMMUNIZATION SCHEDULE\textsuperscript{15}.

The primary purpose of the IPV dose is to help maintain immunity against type 2 poliovirus during and after the planned global withdrawal of OPV2 and switch from tOPV to bOPV.

\textbf{The primary series consisting of 3 OPV doses plus 1 IPV dose can be initiated from the age of 6 weeks with a minimum interval of 4 weeks between the OPV doses.}

\textbf{If one dose of IPV is used, it should be administered at 14 weeks of age or the nearest immunization visit} (when maternal antibodies have diminished and immunogenicity is significantly higher). IPV can be co-administered with an OPV dose, and should be given in addition to all other scheduled vaccine doses.

For infants starting the routine immunization schedule late (e.g. older than 3 months), the IPV dose should be administered at the first immunization contact.

\begin{table}[h]
\centering
\begin{tabular}{|c|c|}
\hline
\textbf{Schedule} & \textbf{Timing of IPV} \\
\hline
\textbf{6, 10, 14 weeks} & At 14 weeks, with the third dose of pentavalent/OPV: OPV1, OPV2, OPV3+IPV \\
\hline
\textbf{2, 3, 4 months} & At 4 months, with the third dose of pentavalent/OPV: OPV1, OPV2, OPV3+IPV \\
\hline
\textbf{2, 4, 6 months} & At 4 months, with the second dose of pentavalent/OPV: OPV1, OPV2+IPV, OPV3 \\
& or; \\
& at 6 months, with the third dose of pentavalent/OPV: OPV1, OPV2, OPV3+IPV \\
\hline
\end{tabular}
\caption{Examples of when to administer IPV}
\end{table}

For countries that experience any delays or interruptions to IPV supply due to the global shortage in 2016 and 2017, guidance about any potential need to "catch-up" children who missed receiving IPV is under review at the time of writing. Once available supply is confirmed, WHO and UNICEF will facilitate discussions with countries to help assist in planning.

\textsuperscript{15} WHO recommendations on polo vaccines also include other schedule options such as sequential IPV-OPV and IPV-only. For details please see the WHO Position Paper, March 2016. \textit{Weekly Epidemiological Record}, 91. Available at: http://www.who.int/wer/2016/wer9112.pdf
2.3 **SAFETY OF IPV AND ADMINISTRATION**

**IPV IS CONSIDERED VERY SAFE, WHETHER GIVEN ALONE OR IN COMBINATION WITH OTHER VACCINES.**

There is no proven or causal relationship to any adverse events other than minor local erythema (0.5%-1%), induration (3%-11%), and tenderness (14%-29%)\(^{16}\).

A full dose of IPV (non adjuvanted) can be given as an intramuscular (IM; in the thigh) or subcutaneous (SC) injection, although IM administration for IPV has been shown to provide equal immunogenicity and have fewer local reactions than SC. The SC route is a viable alternative for vaccines where this is indicated on the label.

The thigh is the site generally recommended for IM injections. Injection into the deltoid muscle is not recommended for infants due to inadequate muscle mass\(^{17}\).

IPV can be safely administered to children with immunodeficiencies (e.g. congenital or acquired immunodeficiency, or sickle cell disease). In fact, because of the elevated risk of VAPP after the use of OPV in patients with immunodeficiencies, IPV is universally recommended in these children.

IPV should not be administered to infants with known or documented allergy to streptomycin, neomycin, or polymyxin B, or with a history of an allergic reaction following a previous vaccine injection.

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Fractional doses of IPV via the intradermal route

As an alternative to the intramuscular injection of a full IPV dose, countries may consider using fractional doses (one-fifth of the full dose), via the intradermal route.

In the context of an IPV shortage, countries may consider a 2-dose fractional dose schedule, which could ensure that all eligible infants receive IPV. Such a strategy is dose-sparing and results in better immunogenicity than a single full dose of IPV.

A schedule of fractional intradermal doses administered at 6 and 14 weeks ensures early and appropriately-timed protection. The 2 fractional doses should be separated by a minimum interval of 4 weeks. One fractional dose of IPV may be suitable for outbreak response if supplies are limited.

If considering a two-dose fractional dose schedule for IPV, the following programmatic and operational challenges should be carefully assessed:

› The two-dose schedule, which may add time and complexity to existing contacts
› The procurement of appropriate 0.1ml syringes and devices
› The need for added training and supervision of health workers to address the demands of intradermal administration
› The necessary adjustments to registers and home-based records to support tracking and follow up
› The communications strategies and messaging to reassure caregivers and communities about the new practice

Further details on the intradermal administration of IPV and a summary of studies to date comparing seroconversion rates are presented in the WHO Position Paper on polio vaccines published in March 2016\(^\text{18}\). In addition, to support countries in considering and implementing a fractional dose schedule of IPV, a range of background papers and adaptable training materials are available on a dedicated web page\(^\text{19}\).

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2.5 MULTIPLE INJECTIONS IN A SINGLE VISIT

Many countries administer multiple vaccine injections (including more than three injections) to infants in a single visit and achieve high vaccine coverage and acceptability.

Other countries, particularly lower- and middle-income countries, are in the process of introducing additional injectable vaccines into their routine schedule (including pneumococcal conjugate vaccine (PCV) and IPV) which will make receiving three injections during a single visit a common occurrence.

In 2015, a systematic review of evidence on the safety of administering multiple injectable vaccines during a single visit (specifically for IPV, PCV and pentavalent vaccines) showed that when given together these vaccines are safe and generally well tolerated by infants. Data supports co-administration of these vaccines, and no increase in reactogenicity was found when compared with vaccines injected in separate visits.20

Advantages of giving a child two or more vaccinations during the same visit:

- **Protects children at the earliest opportunity**: Immunizing children as soon as possible provides protection during the vulnerable early months of their lives
- **Fewer vaccination visits**: Giving several vaccinations at the same time means parents and caregivers do not need to make as many visits to their health facility
- **More effective use of health resources and workers**: Giving multiple vaccine injections at the same visit means health workers are able to be more efficient in providing and delivering other health services

Studies of health worker and caregiver attitudes indicate that both have concerns about infant pain, potential vaccine side effects, and uncertainty about vaccine effectiveness when multiple vaccines are given. Findings also demonstrate that health workers should make a positive recommendation to the caregiver and not overestimate caregiver concerns about multiple injections.

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When three injections are given, one injection should be administered in one limb, and two injections in the other limb, separated sufficiently to differentiate local reactions. A common acceptable practice is to separate injections in the same limb by 2.5 cm (approximately 1 inch)\textsuperscript{21}.

Countries should not make modifications to recommended immunization schedules with the aim of avoiding multiple injections during the same visit when such changes are not evidence-based.

To support health worker training on multiple injections that include IPV, please refer to the materials available on the Polio Endgame objective 2 website\textsuperscript{22}, specifically training module 8, “Multiple injections and IPV”, and a related adaptable job aid (also available in Annex 4 of this document) for health workers on IPV administration.

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**Studies and experience have demonstrated that caregiver concerns about multiple injections can be addressed with effective communication and immunization practices.**

**HEALTH WORKER TRAINING SHOULD THEREFORE INCLUDE:**

- Vaccine co-administration policy and practices
- Techniques to mitigate pain and distress at the time of vaccination (see below box: “Reducing pain at the time of vaccination”)
- Information about safety and effectiveness of vaccines when co-administered
- Information about the likely overestimation of concerns by parents or caregivers
- Improved communication strategies to provide reassurance of the safety, effectiveness and value of multiple vaccine injections

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\textsuperscript{22} Health worker training materials on multiple injections are available: http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/implementation/en/
Reducing pain at the time of vaccination: WHO position

Better pain management during vaccination is possible and does not decrease the efficacy of the vaccine. There are effective, feasible, non-costly, culturally acceptable, and age-specific evidence-based strategies to mitigate pain at the time of vaccination.

Recommendations for measures that can be taken to reduce pain and anxiety during vaccination, which can be applied in high, middle and low income countries, are summarized below.

› Healthcare personnel carrying out vaccination should be calm, collaborative, and well-informed. They should use neutral words.
› Proper positioning of the vaccine recipient should be ensured, according to age. Infants and young children should be held by their caregiver. Older children should be sitting upright.
› No aspiration (or pulling back of the plunger of a syringe) should be done during intramuscular injections, as this may increase pain.
› When multiple vaccines are scheduled to be injected at the same session, they should be given in order of painfulness, ending with the most painful.


23 In the absence of specified grading of painfulness, healthcare professionals are encouraged to use their practical experience on the painfulness of specific vaccines to determine accordingly the best sequencing of the injections.
3.1 PLANNING FOR A SUCCESSFUL INTRODUCTION

FOR THE MOST PART, THE ADDITION OF IPV TO ROUTINE IMMUNIZATION PROGRAMMES INVOLVES THE SAME PLANNING AND IMPLEMENTATION PROCESS AS FOR OTHER NEW VACCINE INTRODUCTIONS.

General guidance for making decisions about and planning the introduction of a vaccine into a national immunization programme is available in the document *Principles and considerations for adding a vaccine to a national immunization programme*24 and is recommended reading when planning for IPV introduction.

There are, however, some important factors specific to the introduction of IPV that need to be considered.

These include:

› Unprecedented timelines – in which all countries that use only OPV should add at least one dose of IPV before the end of 2015 (pending available supply).

› Impact indicators – the evaluation of IPV will be based on whether it reaches the same level of coverage as for routine DTP-containing vaccines. This is in contrast to indicators used to measure the impact of other vaccines, e.g. reduced mortality or disease rates.

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Once the decision to introduce IPV has been made by the national authorities, the first step will be to develop a plan for IPV introduction. This should be incorporated into the country’s comprehensive multi-year action plan for the immunization programme.

The plan for IPV introduction should take into account the following:

› **IPV-specific planning** – ensuring that the vaccine is licensed, training is scheduled and corresponding materials available, immunization records and registers updated, and logistics plans prepared.

› **Programme management and coordination** – including the formation of a technical and administrative committee, use of accountability frameworks, data management, evidence-based planning, training and supply chain management.

› **Microplanning** – including population mapping, harmonization of routine immunization microplans with those from polio campaigns to enable more complete session planning, vaccine supply management and cold chain logistics.

› **Immunization service delivery** – including monitoring and supervision of immunization sessions, local community coverage and vaccine acceptance, availability of health workers, vaccine delivery and other immunization session logistics.

› **Advocacy and briefings** – including high level advocacy, the engagement of journalists, paediatricians and local community leaders, and house-hold level outreach.

› **A calculation of the costs of the plan** – including the unit cost per activity, the total cost, and the sources of financing. Fixed costs of activities that form part of the regular programme should be defined to see whether further investment will be required.

Annex 1 of this document includes a checklist of core components of an IPV introduction plan. The list can be easily adapted to reflect any country-specific considerations.

**Managing the impact on other immunization programme plans**

Many countries may be planning to introduce other new vaccines around the same time as IPV. There are potential benefits to introducing IPV at the same time as other new vaccines, especially if they share the same target population. Studies in Ghana and Tanzania showed that efficiencies in cost and time can be gained by introducing two vaccines at once.

Countries planning to introduce another new vaccine and IPV may wish to consider a joint introduction. This option should be discussed with regional immunization staff, NITAGs and Ministries of Health as soon as possible, in order to ensure adequate time for planning. Reviews of lessons learned from vaccine introduction experiences to date have identified the importance of early planning as a critical factor for success.

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Vaccine management and procurement considerations

For the successful introduction of IPV, the characteristics of the vaccine and the technical aspects relating to its administration need to be taken into account (Table 6).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of vaccine</strong></td>
<td>Inactivated (killed) vaccine with types 1, 2 and 3 antigens</td>
</tr>
<tr>
<td><strong>Route of administration</strong></td>
<td>Intramuscular is preferred. <em>(For more information, see section 2.3.)</em></td>
</tr>
<tr>
<td><strong>Immunization schedule</strong></td>
<td>WHO recommends at least one dose of IPV with the third dose of DTP and OPV, typically administered at 14 weeks of age (or 4 months, or the nearest immunization visit). <em>(For more information, see section 2.2.)</em></td>
</tr>
<tr>
<td><strong>Target age group</strong></td>
<td>Infants under 12 months of age</td>
</tr>
<tr>
<td><strong>Volume per dose</strong></td>
<td>Each dose is 0.5ml</td>
</tr>
<tr>
<td><strong>Storage conditions</strong></td>
<td><em>Store between 2°C and 8°C. DO NOT FREEZE. Discard if known or suspected to have been frozen. The shake test does not work to determine if IPV was frozen. IPV is also damaged by accumulated exposure to heat and light (level of heat exposure can be determined by the VVM).</em></td>
</tr>
<tr>
<td><strong>Open vial policy</strong></td>
<td>IPV multi-dose vials may be used for up to 28 days after opening, provided that the criteria for the multi-dose vial policy outlined on the next page are fully met.</td>
</tr>
<tr>
<td><strong>Presentation and dosage form</strong></td>
<td>The WHO prequalified vaccine comes in 1, 2, 5 and 10-dose liquid presentations. IPV is also available in combined pentavalent and hexavalent presentations with DTP, hepatitis B and Hib antigens.</td>
</tr>
<tr>
<td><strong>Vaccine vial monitor (VVM)</strong></td>
<td>VVM7 or VVM14, depending on the product</td>
</tr>
<tr>
<td><strong>Co-administration with other vaccines</strong></td>
<td>IPV may be safely co-administered with other vaccines. <em>(For more information, see section 2.4.)</em></td>
</tr>
</tbody>
</table>

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At the time of writing, IPV combined in pentavalent or hexavalent presentations is available in very limited quantities.
Vaccine management

It is essential to handle the vaccines properly from the moment they arrive in country until the moment they are used. Good vaccine management includes:

› Sufficient storage volumes
› Efficient arrival and acceptance procedures
› Effective stock management
› Appropriate temperature monitoring
› Maintaining standards of buildings, storage rooms, 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 (VVMs)

Effective vaccine management requires adequately trained staff at all levels from national and subnational programme 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.

Application of the WHO multi-dose vial policy for IPV

When properly handled and stored, multi-dose vials of IPV (presented in 5 and 10 dose vials; produced by two manufacturers) are approved for use for up to 28 days after opening, based on preservative efficacy data27.

The WHO Policy Statement: Multi-dose Vial Policy (MDVP), Revision 201428, on the use of opened multi-dose vaccine vials specifies the criteria under which opened multi-dose vials can be kept and used for up to 28 days after opening. If the criteria are not met, the multi-dose vials must be discarded at the end of the immunization session, or within six hours of opening, whichever comes first.

The criteria are as follows:
1. The vaccine is currently pre-qualified by WHO
2. The vaccine is approved for use for up to 28 days after opening, as determined by WHO
3. The expiry date of the vaccine has not passed
4. The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer-recommended temperatures. Furthermore, the VVM, if attached, is visible on the vaccine label and is not past its discard point and the vaccine has not been damaged by freezing.

For vials that can be kept for up to 28 days after opening, it is recommended that national programmes orient vaccinators, where possible, to record on the vial the day and month when the vial was opened.

Materials for the training of health workers on vaccine handling practices corresponding to the MDVP and VVM are available for countries and partners to adapt and use as needed29.

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27 For a complete list of WHO prequalified vaccines for polio: http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/
29 Application of the WHO Multi-Dose Vial Policy for IPV: MDVP and IPV job aid, and modules 4A and 4B. Available at: http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/implementation/en/
**Estimating 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 a 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 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 programme costs, preventing stock-outs and high wastage rates, and ensuring vaccine safety.

Vaccine wastage is the proportion of vaccine that is supplied but never administered due to a number of reasons. Each country should calculate its wastage rate based on its experience with other vaccines, especially those packaged in multiple-dose vials.

### Calculating the number of doses of IPV needed

The basic formula for calculating the annual number of IPV doses needed is:

\[
N = \text{Surviving infants} \times \text{target coverage} \times \text{number of doses in the schedule} \times \text{wastage factor}
\]

The formula to calculate the wastage rate is:

\[
\text{Wastage rate} = \frac{(\text{doses supplied} - \text{doses administered})/\text{doses supplied}}{100} \times 100
\]

\[
\text{Wastage factor} = \frac{100}{100 - \text{wastage rate}}
\]

A proper application of the MDVP can decrease wastage while ensuring safety. Taking advantage of using a 28-day discard on opened multi-dose vials, the indicative maximum wastage rate of 20% for 10-dose vials, and 15% for 5-dose vials, can be used in forecasting the estimated vaccine needs.

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. Constraints in the global supply of IPV may mean that initially this level of buffer stock is not possible.
COLD CHAIN CONSIDERATIONS

THE INTRODUCTION OF ANY NEW VACCINE OFFERS A GOOD OPPORTUNITY TO CRITICALLY REVIEW THE COLD CHAIN AND LOGISTICS (CCL) SYSTEM AND TO IMPROVE ITS PERFORMANCE.

Countries may conduct an Effective Vaccine Management (EVM) assessment and develop a CCL improvement plan to guide enhancements. For each vaccine storage site, an assessment is needed to ensure that sufficient capacity is available.

Once the cold chain storage capacity required for IPV has been calculated, the manager of the immunization programme should decide if any adjustments are warranted, for example, changes to the frequency of vaccine deliveries, or additional refrigeration equipment. Those responsible for procuring refrigeration equipment can select the most appropriate, depending on the capacity and infrastructure of the storage spaces. Any decision should be taken in the context of other planned vaccine introductions or campaigns that will be implemented over the coming years.

IPV loses its potency when exposed to temperatures outside the range recommended by the manufacturer. Its capacity to produce neutralizing antibodies is destroyed by both heat and freezing. The heat impact on vaccines is cumulative. Proper storage of vaccines and maintenance of the cold chain during storage and distribution are essential to prevent the loss of potency. Damaged vaccines should be discarded according to current national guidelines on good practices in injection safety.

Proper management and handling of vaccines requires that they be properly packed and stored. In general, the same principles that apply to other vaccines also apply to IPV, for example, inventory control systems should ensure that units with the nearest expiry date are used first in a system known as “first-expired, first-out” (FEFO). The expiry date and VVM status should always be checked whenever a vial is opened.

WASTE MANAGEMENT

In preparing for the introduction of IPV, waste management plans should also be updated, to describe the ultimate destruction of the increased volume of used needles and syringes. Strengthening of the vaccine/healthcare waste management plan can be noted as an action within the vaccine introduction plan.

As a general guide, vaccinators should place all used needles (without recapping them) and syringes directly in a safety box immediately after administering the vaccine. The container should be securely closed when full.

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(i.e. at up to 75% capacity) and stored in a safe place until it can be transported, according to national guidelines, to its final destination for disposal.

No other waste should be put into the safety boxes. Instead, other waste should be disposed of in bins and collected along with the safety boxes, or handled according to national guidelines.

3.4 **MONITORING AND EVALUATION**

**THE INTRODUCTION OF ANY NEW VACCINE CAN POSE SOME CHALLENGES THAT MAY BENEFIT FROM TRACKING CLOSELY.**

Monitoring, evaluation, and supervision are basic processes that facilitate the collection and analysis of data required to verify whether planned activities are being implemented effectively, and to what extent the objectives and targets have been achieved. In the first weeks after introduction, this can take the form of telephone calls and/or visits to health facilities to identify and resolve potential bottlenecks linked to administration.

Monitoring and evaluation information systems need to be updated to facilitate collection of core indicators related to IPV introduction. Monitoring and evaluation activities are not unique to IPV and are described in detail in many other references.\

**MONITORING TOOLS**

The main recording tools used for immunization that should be adapted to include IPV at the service delivery level are:

- Immunization register
- Tally sheet
- Immunization card
- Defaulter tracking system
- Stock record
- Integrated monthly report

**EVALUATION TOOLS**

A range of immunization programme evaluation tools are available and may be used to assess the implementation of IPV. These tools include:

- **EPI reviews**
  
  An EPI review is the chief methodology for assessing the progress of a national immunization programme, identifying challenges and corrective actions, and providing technical recommendations to strengthen the programme. It is undertaken every 3 to 5 years. Tools to be used for the EPI review should be adapted to suit local requirements and to include IPV and any other new vaccine that has been added to the programme.

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Post-introduction evaluations (PIEs):
Now that most countries have extensive experience introducing new vaccines, WHO no longer recommends that a PIE take place 6 to 12 months after the launch. Rather than conduct a stand-alone PIE, it is encouraged that new vaccine introduction questions be combined with the next EPI review or surveillance review.

Following the introduction of a new vaccine, regular supervision and other ongoing monitoring activities should be used to assess the impact on the immunization programme and rapidly identify any problems that require action.

Coverage surveys
National coverage monitoring is important to validate administrative data that is reported throughout the year and allow for comparisons of coverage between vaccines and with the coverage achieved by other countries. Estimates of coverage can be obtained through evaluation surveys using the standard sampling technique for defined geographical areas. Other survey methods may be employed for larger areas.

The WHO Vaccination Coverage Survey Manual\(^{34}\), updated in 2015, focuses on methods to reduce bias and improve the accuracy and precision of survey results.

Reporting on adverse events following immunization
An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. If not rapidly and effectively dealt with, an AEFI can undermine confidence in a vaccine and immunization programme, and ultimately can have dramatic consequences for coverage and disease incidence.

Vaccine-associated adverse events may affect healthy individuals and should be promptly identified to allow additional investigation and appropriate action to take place. As for all vaccines, AEFIs should be reported according to current national regulations.

Guidance from the WHO Global Vaccine Safety Initiative\(^{35}\) includes AEFI investigation, the communications response, a sample AEFI reporting form\(^{36}\) (also shown in Annex 3), and other tools and trainings.

These resources are designed to support the strengthening of national capacity to detect and respond to any event in a clear, factual, and timely manner.

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\(^{34}\) Coverage survey manual: http://www.who.int/immunization/monitoring_surveillance/Vaccination_coverage_cluster_survey_with_annexes.pdf

\(^{35}\) Resources are available through the Global Vaccine Safety Initiative: http://www.who.int/vaccine_safety/initiative/en/

\(^{36}\) AEFI reporting form: http://www.who.int/vaccine_safety/REPORTING_FORM_FOR_ADVERSE EVENTS_FOLLOWING_IMMUNIZATION.pdf
3.5 Communications and Training

Well-planned, adequately funded communications are vital for the successful delivery of immunization services and are particularly needed to achieve vaccination coverage goals and maintain trust in vaccines.

A communications strategy and its activities should all be guided by some degree of formative research, be carefully planned, systematically implemented, and take into account the context of the overall immunization programme or vaccine introduction plan.

The benefits of a well-defined and executed communication and advocacy strategy are many, and include generating demand for IPV and vaccination in general, fostering community support and trust in the immunization programme.

A national communication and advocacy strategy targeted towards implementing partners, professional associations, health workers, communities, civil society, traditional leaders, and caregivers (groups identified through appropriate mapping surveys), should aim to achieve the following objectives:

- Raise awareness and understanding by all parties on the importance of vaccination
- Generate positive intentions and actions towards immunization in general
- Promote trust and confidence in immunization, its safety and effectiveness
- Prevent rumours and misinformation
- Improve and maintain demand for immunization
- Enhance detection, reporting and management of possible AEFI

Core Communication Approaches:

- Advocacy – raising awareness and commitment among decision-makers and key influencers so that they support and facilitate the introduction and implementation of all vaccines
- Community engagement – involving community leaders, civil society, and the relevant professional associations in activities to ensure acceptance, and boost demand and sustainability
- Informational – targeting individuals via information/dialogue on the change to the immunization schedule, promoting health seeking behaviour and calling for the action of caregivers

Key Resources

To support the strategic planning process for communications and issues/crisis management, two adaptable guides are available:

- **IPV Communications Planning Guide**: Includes a range of checklists, tools, templates, and best practices.
- **IPV Issues Management Guide**: Includes guidance on how to write a press release and samples of frequently asked questions.

www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/implementation/en
COMMUNICATION PLANNING FRAMEWORK

To support the addition of IPV to a national immunization programme, a Communications Planning Guide is available. This guide provides a range of checklists, tools, templates and best practices, to inform effective planning and implementation of communication activities associated with IPV and any broader efforts to strengthen routine services. Content and activities can be adapted to local contexts as needed.

Communications planning frameworks typically follow the series of steps shown in the alongside chart “Communications planning framework.” This may be adapted and used for planning communications activities to support the introduction of IPV, any other vaccine, or the overall routine immunization programme.

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37 The IPV communications planning guide is available on this web page, under the heading “Communications planning guide”: http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/implementation/en/
Recommended activities within each step:

**Step 1: Coordination and preparation**
- Establish or reactivate a communication committee
- Establish roles and responsibilities for partners and allies, including key community leaders and civil society

**Step 2: Communications analysis**
- Identify target audiences, and conduct a problem or situation analysis, including formative research that may consist of focus groups, interviews, and mixed methods assessments
- Conduct studies of knowledge, attitudes, behaviours, and communication channels

**Step 3: Strategic planning and design**
- Develop measurable and realistic objectives, and monitoring and evaluation indicators
- Develop a strategy planning matrix, including activities, timelines, and budgets

**Step 4: Creative strategy and material development**
- Develop messages and templates for materials
- Test, revise, and if necessary, retest materials before finalization
- Implement activities, including community consultations and engagement

**Step 5: Monitoring and evaluation**
- Develop a plan for monitoring the implementation of communication interventions
- Plan for evaluation and analysis of implications for subsequent planning

More details on the overall framework and each phase are available in the IPV Communications Planning Guide.

In addition to developing a communications plan to support the introduction of IPV, countries are also encouraged to prepare for any unexpected situations that may arise. Created specifically to support IPV, an Issues Management (or Crisis Communications) Guide can be used as a basis to establish a national issues/crisis management plan. It can be used to help identify an unexpected event, evaluate its potential impact, and have ready in advance an appropriate communications strategy to minimize potential consequences.

Further guidance on advocacy, communications, and social mobilization activities related to vaccine introductions and immunization programmes can be found in a number of other resources.

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38 The issues management guide is available under the heading of same name on this page: [http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/implementation/en/](http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/implementation/en/)


**TRAINING**

One of the core success factors for the introduction of a vaccine is comprehensive, high-quality training about the new vaccine and the disease it prevents. Such training should include all health workers with a role in immunization, their supervisors and all immunization programme staff. The training should also include refreshing of the skills and knowledge of important areas of the immunization programme, especially in areas that may have been previously identified as weak.

If not already available from a recent evaluation, an initial step to plan and design an effective training programme is to conduct an assessment of the knowledge, attitudes and practices (KAP) of health workers involved in immunization. This information will highlight areas where refresher training may be needed and inform the development of a training plan, budget, and the resulting training materials.

**Key communication messages to include in health worker training**

- **IPV is a very safe vaccine**, whether given alone or in combination with other vaccines. It has been used for many years in many countries.
- **Given together with OPV, IPV offers the best protection against polio.**
- **IPV is generally given with the third dose** of a DTP-containing vaccine, such as pentavalent. This enables the child to be protected as soon as possible.
- **It is safe for a child to receive many vaccines at once**, including two polio vaccines. Each vaccine is still equally effective when given together.

Examples of frequently asked questions (FAQs) to support health workers to respond to caregivers and communities are available in Annex 2.

When implementing the trainings, the number of levels through which the training is relayed (e.g. cascade training), should be minimized to maintain the quality of the training content. If cascade training is unavoidable, it should be supported by the use of videos and materials.

The training for IPV should not be conducted too far in advance of the vaccine introduction to ensure proper recollection of learning. For frontline health workers, the training should ideally take place two or three weeks prior to the vaccine launch. It is also important that the training be followed by supportive supervision to ensure that health workers correctly apply their new skills.
Key subjects to address in the training are:

- Updates on polio eradication and the rationale for IPV introduction
- The immunization schedule incorporating the new vaccine, and how to handle infants who are “off-schedule” and come late for vaccination
- IPV presentation, safety and effectiveness, storage, and co-administration policy and practices
- Interpretation of VVMs and implementation of the open vial policy (including writing date/time on opened vials)
- Recording data and reporting on doses administered using the appropriate forms
- Monitoring of coverage, drop outs and vaccine wastage rates
- Benefits of multiple injections and related co-administration practices, including:
  - Safety and effectiveness of vaccines when co-administered
  - The preferred order and placement of injections (see section 2.4. for more information on multiple injection techniques and pain reduction)
  - Information about the likely overestimation of parental concerns, and how to respond and reassure
- Techniques for reducing pain and distress at the time of injection
- Detection, handling and reporting of AEFIs
- Interpersonal skills and improved communication strategies with parents and caregivers about the new vaccine, the schedule, value of multiple injections, and possible side-effects

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**TRAINING MATERIALS ON IPV AND RELATED RESOURCES**

WHO and partners have developed a training package specifically for IPV, including modules on different topics in an adaptable Powerpoint slide format, key messages and frequently asked questions on IPV and polio, and a leave-behind job aid for reference. A number of general immunization training resources are also available and include the Immunization in Practice modules, a series of modules on immunization training for Mid-Level Managers (MLM), and a WHO e-learning course on Vaccine Safety Basics.

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41 The IPV training package includes modules 1-8, a job aid, key messages and frequently asked questions, and review exercises. Available at: [http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/implementation/en/](http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/implementation/en/)
42 The Mid-level Manager training modules can be found at: [http://www.who.int/immunization/documents/training/en/](http://www.who.int/immunization/documents/training/en/)
All materials last accessed August 2016.

Principles and considerations for adding a vaccine to a national immunization programme: From decision to implementation and monitoring. Publication date: April 2014

World Health Assembly resolution: Completion of polio eradication a programmatic emergency for global public health. May 2012. (pdf)

Polio Eradication and Endgame Strategic Plan 2013-2018
http://polioeradication.org/who-we-are/strategy/

World Health Organization. Immunization standards. WHO prequalified vaccines.
http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/

World Health Organization. Department of immunization, vaccines and biologicals. WHO policy on the use of opened multi-dose vaccine vials (2014 Revision)

World Health Organization. Global Polio Eradication Initiative. (web site)
http://www.polioeradication.org/

World Health Organization. Immunization, vaccines and biologicals. IPV introduction, OPV withdrawal and routine immunization strengthening. (website)
http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/en/

WHO papers

http://www.who.int/wer/2016/wer9112.pdf


# Annex 1

## IPV Introduction Plan Checklist

Following is a check list of the core components that should be included in an IPV introduction plan. This may be adapted depending on country-specific considerations.

<table>
<thead>
<tr>
<th>Section</th>
<th>Key Components</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Executive Summary (2 pages)</strong></td>
<td></td>
</tr>
<tr>
<td>- Benefits of introducing IPV</td>
<td></td>
</tr>
<tr>
<td>- Summary of the introduction plan activities</td>
<td></td>
</tr>
<tr>
<td>- Key programmatic considerations, e.g. capacity, cold chain, etc.</td>
<td></td>
</tr>
<tr>
<td>- Economic assessments, financial needs and sustainability</td>
<td></td>
</tr>
<tr>
<td>- Monitoring and evaluation plan and indicators</td>
<td></td>
</tr>
<tr>
<td>- Timeline of activities from preparation to full roll-out</td>
<td></td>
</tr>
<tr>
<td>- Budget summary</td>
<td></td>
</tr>
<tr>
<td><strong>Justification for Introduction of IPV and National Decision-Making Process</strong></td>
<td></td>
</tr>
<tr>
<td>- Overview of the rationale for IPV introduction</td>
<td></td>
</tr>
<tr>
<td>- Technical and operational feasibility</td>
<td></td>
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<tr>
<td>- Approaches to involve all key decision-makers</td>
<td></td>
</tr>
<tr>
<td><strong>Overview of IPV</strong></td>
<td></td>
</tr>
<tr>
<td>- Vaccine presentation preference and introduction date</td>
<td></td>
</tr>
<tr>
<td>- Licensing information and procurement obstacles</td>
<td></td>
</tr>
<tr>
<td><strong>Introduction and Implementation Considerations</strong></td>
<td></td>
</tr>
<tr>
<td>- National coordination mechanism to oversee the introduction</td>
<td></td>
</tr>
<tr>
<td>- Policy considerations (e.g. schedule, doses, phased vs. national)</td>
<td></td>
</tr>
<tr>
<td>- Estimated target population for vaccination</td>
<td></td>
</tr>
<tr>
<td>- Affordability and sustainability plan</td>
<td></td>
</tr>
<tr>
<td>- Operational risks, challenges and mitigating strategies</td>
<td></td>
</tr>
<tr>
<td><strong>Situational Analysis</strong></td>
<td></td>
</tr>
<tr>
<td>- General country context, health system overview and priorities</td>
<td></td>
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<tr>
<td>- Barriers to immunization</td>
<td></td>
</tr>
<tr>
<td>- Summary findings from programme reviews</td>
<td></td>
</tr>
<tr>
<td>- EVM assessment findings and improvement plan</td>
<td></td>
</tr>
<tr>
<td>- Description of vaccine stock management processes</td>
<td></td>
</tr>
<tr>
<td>- Description of health worker knowledge, attitudes, behaviours</td>
<td></td>
</tr>
<tr>
<td>- Immunization coverage for past two years</td>
<td></td>
</tr>
<tr>
<td><strong>Procurement of Vaccines, Cold Chain, and Logistics</strong></td>
<td></td>
</tr>
<tr>
<td>- Calculation of vaccines required</td>
<td></td>
</tr>
<tr>
<td>- Estimation of any added cold chain requirements at all levels</td>
<td></td>
</tr>
<tr>
<td>- Vaccine administration guidance including open vial policy</td>
<td></td>
</tr>
<tr>
<td>- Provision for waste management and injection safety</td>
<td></td>
</tr>
<tr>
<td><strong>Monitoring and Evaluation</strong></td>
<td></td>
</tr>
<tr>
<td>- Plans for updating monitoring tools and information systems</td>
<td></td>
</tr>
<tr>
<td>- Adverse events following immunization (AEFI) reporting processes</td>
<td></td>
</tr>
<tr>
<td>- Plan for monitoring of pre-introduction, introduction and post-introduction follow up activities</td>
<td></td>
</tr>
<tr>
<td><strong>Communications and Training</strong></td>
<td></td>
</tr>
<tr>
<td>- Overall communications plan for IPV introduction</td>
<td></td>
</tr>
<tr>
<td>- Messaging framework, including topics such as multiple injections</td>
<td></td>
</tr>
<tr>
<td>- Plan for any additional resource mobilization or advocacy activities</td>
<td></td>
</tr>
<tr>
<td>- Crisis communications or issues management plan</td>
<td></td>
</tr>
<tr>
<td>- Plan for stakeholder engagement, e.g. media, paediatricians</td>
<td></td>
</tr>
<tr>
<td>- Plan for training health workers and supervision</td>
<td></td>
</tr>
</tbody>
</table>
**Annex 2**

**Frequently Asked Questions about IPV**

The following questions and answers may be a useful starting point for the development of materials to help health workers to answer questions received from caregivers and the community.

<table>
<thead>
<tr>
<th><strong>Question</strong></th>
<th><strong>Answer</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Why does my child need two different vaccines for polio?</td>
<td>Using both vaccines together provides the best form of protection from polio. The additional dose of IPV will help protect your child against polio disease even more – and will give your child the benefits of both vaccines working together.</td>
</tr>
<tr>
<td>What is the benefit of IPV?</td>
<td>IPV provides important additional protection against polio, protecting both your child and children in our community.</td>
</tr>
<tr>
<td>How is IPV different than OPV?</td>
<td>IPV and OPV each provide a different kind of immunity, and are needed together to give you child the best protection against polio.</td>
</tr>
<tr>
<td>Is IPV safe? Does it have any side-effects?</td>
<td>IPV is one of the safest vaccines in humans. After vaccination, there might be a little bit of redness and the skin may feel tender.</td>
</tr>
<tr>
<td>Why is OPV still needed? Is OPV safe?</td>
<td>Until polio is eradicated globally, OPV is still the main preventative measure against polio. IPV is recommended in addition to OPV and does not replace OPV. IPV and OPV are both safe vaccines, and together provide the best protection against polio.</td>
</tr>
<tr>
<td>I only want my child to receive one polio vaccine, IPV or OPV, but not both.</td>
<td>It is important – and best – for your child to receive both IPV and OPV. Together, these two vaccines provide safe and strong protection against polio. If your child only receives one of the vaccines they will not be as well protected.</td>
</tr>
<tr>
<td>Why does my child need three injections on one visit?</td>
<td>Giving a child several vaccinations during the same visit allows your child to be immunized as soon as possible. This provides protection during the vulnerable early months of your child’s life. In addition, giving many vaccines at one time means fewer visits to the health centre.</td>
</tr>
<tr>
<td>Is it safe to give three injections at one visit?</td>
<td>It is safe for your child to receive three (or more) injections at once. Many countries have immunization schedules where children receive multiple vaccine injections at one visit.</td>
</tr>
<tr>
<td>Can multiple injections of vaccines increase the risk of adverse events?</td>
<td>No. Numerous studies have shown that giving multiple vaccinations at the same visit does not result in a higher rate of adverse events. Each of the vaccines is still equally effective when given together.</td>
</tr>
<tr>
<td>Aren’t multiple injections painful for the child?</td>
<td>While receiving multiple injections at once is painful, having to return for additional vaccines forces the child to experience pain on two visits. It is better for the child to experience one, brief moment of discomfort than pain on two separate days.</td>
</tr>
</tbody>
</table>
# ANNEX 3

## AEFI Reporting Form

The form shown below is also available on the ‘Tools and methods’ page of the Global Vaccine Safety Initiative website: http://www.who.int/vaccine_safety/initiative/en/

![AEFI Reporting Form](image)

---

### AEFI Reporting ID number:

**Reporting Form for Adverse Events Following Immunization (AEFI)**

- **Patient Name:**
- **Patient’s full Address:**
- **Telephone:**
- **Sex:** M F
- **Date of birth:** __/__/__
- **Age at onset:** [ ] Years [ ] Months [ ] Days
- **Age Group at onset:** [ ] <1 Year [ ] 1 to 5 Years [ ] >5 Years
- **Date patient notified event to health system:** __/__/__
- **Today’s date:** __/__/__

### Health facility (place or vaccination centre) name & address:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Diluent (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of vaccine</td>
<td>Date of vaccination</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------------</td>
</tr>
</tbody>
</table>

- **Adverse Event:**
  - [ ] Severe local reaction
  - [ ] >3 days
  - [ ] beyond relevant joint
  - [ ] Seizures
  - [ ] Fever
  - [ ] Gastroenteritis
  - [ ] Suspension of syringe
  - [ ] Other

- **Serious:** Yes / No
- **Outcome:** Recovered
- **Date AEFI started:** __/__/__
- **Time:** __:__
- **Describe AEFI (Signs & Symptoms):**
- **Autopsy done:** Yes / No / Unknown

### Medical history:

Past medical history (including history of similar reaction or other allergies), concomitant medication and other relevant information (e.g., other cases). Use additional sheet if needed.

### Investigation needed:

- [ ] Yes
- [ ] No

If yes, date investigation planned: __/__/__

### National level to complete:

- Date report received at National level: __/__/__
- AEFI worldwide unique ID:

### Comments:

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*Compulsory field*
Annex 4

Job Aid on IPV for Health Workers

The following two-page job aid is an adaptable reference that may be shared with health workers during their training on IPV. Standalone English and French versions are available: www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_polio_vaccine/implementation/en/

IPV: Inactivated Polio Vaccine
Giving IPV in 3 easy steps

1. When to give IPV
   - Birth: OPV drops only
   - 6 Weeks: OPV drops only
   - 10 Weeks: OPV drops only
   - 14 Weeks: IPV

14 weeks is the best time to give IPV because it gives the most protection at that time. IPV should be given at the same time as Oral Polio Vaccine (OPV) drops. IPV is safe to give at 14 weeks even for babies born too early or who get sick often. For infants starting the routine immunization schedule after 14 weeks, the IPV dose should be given the first time you see them.

2. How to give IPV
   - Check date and VVM: Check the expiration date and VVM. Discard the vaccine if it is expired, the vial is frozen, or the square in the VVM is dark.
   - 0.5 ml dose: Administer in a 0.5 ml dose.
   - 2.5 cm apart: If giving 3 or more vaccines, make sure injections in the same thigh are given at least 2.5 cm apart.
   - Right angle to thigh: Administer by intramuscular injection (IM). The needle must be at a 90° angle to the child’s thigh.

3. Give with other vaccines
   - Saves time and effort
   - Improves coverage
   - Healthier children

Help the children in your community by giving the right vaccines at the right time. It will save you time, make the health clinic more efficient, and improve coverage. Most importantly it will protect children from serious and sometimes deadly diseases.

3 October 2014
IPV: Inactivated Polio Vaccine
3 things parents and caregivers need to know

1. IPV is very safe
   - Vaccines like IPV protect babies when they need it most.
   - It is safe for your child to get 3 or more injections at one visit.
   - IPV is needed to protect every child and is safe to give at 14 weeks even for babies born too early or who get sick often.

2. You can lessen pain
   - Hold your baby on your lap. Baby’s feet should be between your thighs to help keep baby still. Hold arms still. You can breastfeed while baby is getting vaccinated.
   - Get all recommended shots on time. It is better for your child to experience discomfort during one visit, rather than discomfort during two separate visits.
   - Be gentle around baby’s injection sites. Injection sites may have some redness and feel sore.

3. Baby’s vaccines are important
   - Polio can paralyze your children – but vaccines can protect them from polio.
   - In addition to polio, vaccines can protect your children from other very serious and sometimes deadly diseases.
   - Vaccinations give kids a healthy future, so they can go to school, grow up and have families of their own.

Healthy children