Practical Guide

Inactivated Poliovirus Vaccine (IPV) Introduction

Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

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Comprehensive Family Immunization Unit
Department of Family, Gender and Life Course
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Foreword

In May 2012, the World Health Assembly declared the completion of polio eradication as a "programmatic emergency for global public health" (*1*). On 25 January 2013, the Executive Board of the World Health Organization (WHO) approved the targets, goals, and timelines of the Polio Eradication and Endgame Strategic Plan 2013-2018, which seeks to simultaneously eradicate wild poliovirus and eliminate vaccine-derived poliovirus (Sabin, vaccine-derived) (*2*).

The objectives of this Strategic Plan are to detect and interrupt poliovirus transmission; to strengthen immunization programs and withdraw the trivalent oral poliovirus vaccine, commencing with the withdrawal of the type 2 component by switching from the trivalent (serotypes 1, 2 and 3) to the bivalent (serotypes 1 and 3) vaccine; to contain poliovirus and certify the interruption of transmission; and to plan how to utilize the legacy of the fight against poliomyelitis.

For the globally synchronized switch from the trivalent to the bivalent oral poliovirus vaccine—scheduled for 2016—WHO recommends that all countries currently using only the oral poliovirus vaccine introduce at least one dose of the inactivated vaccine into their routine vaccination programs to ensure that new cohorts of newborns have some protection against the type 2 poliovirus, either wild or vaccine-derived.

In order to meet this objective, each country should develop a plan for the introduction of the inactivated polio vaccine before the end of 2014.

This practical guide presents the information and describes the strategies that health teams in the countries of the Americas should be aware of in order to draw up their plans for the introduction of the inactivated polio vaccine into their routine vaccination programs.

Acronyms

AFP	Acute flaccid paralysis
bOPV	Bivalent oral poliovirus vaccine; containing serotypes 1 and 3
cVDPV	Circulating vaccine-derived poliovirus
DPT	Diphtheria-pertussis-tetanus vaccine
ESAVI	Event supposedly attributable to vaccination or immunization
IPV	Inactivated poliovirus vaccine
mOPV	Monovalent oral poliovirus vaccine
OPV	Oral poliovirus vaccine
PAHO	Pan American Health Organization
SAGE	Strategic Advisory Group of Experts on Immunization of the World Health Organization
TAG	Technical Advisory Group on Vaccine-preventable Diseases of the Pan American Health Organization
tOPV	Trivalent oral poliovirus vaccine
VAPP	Vaccine-associated paralytic poliomyelitis
WHO	World Health Organization

I. Background

In September 1985 at the XXXI Meeting of the Directing Council of Pan American Health Organization (PAHO), Member States unanimously adopted the resolution establishing the goal to eradicate polio (*3*).

In the Region of the Americas, the polio vaccination strategy was adopted and national vaccination days were added to routine programs. At the same time, countries continued to strengthen their routine immunization programs (*4*). The high vaccination coverage reached with the trivalent oral poliovirus vaccine (tOPV) managed to interrupt transmission of the wild poliovirus in the Region.

Following polio control in the Region of the Americas, the Forty-first World Health Assembly adopted in 1988 the resolution on global polio eradication that marked the creation of the Global Polio Eradication Initiative spearheaded by the World Health Organization (WHO) (*5*).

The last case of this disease caused by wild poliovirus in the Region was detected in 1991 in Peru. In 1994, the Global Commission for the Certification of the Eradication of Polio reviewed the tests available in each country or territory and concluded that indigenous circulation of the wild virus had been interrupted in the continent, making the Americas the first region in the world to achieve this target.

The last case of this disease caused by wild poliovirus in the Region was detected in 1991 in Peru.

In the following years, three more regions received the certification of eradication: the Region of the Western Pacific in 2000; the Region of Europe in June 2002; and the Region of Southeastern Asia (including India) in March 2014. Today, only three endemic countries remain: Afghanistan, Nigeria, and Pakistan. However, following several years with no circulation of the wild virus some non-endemic countries have reported imported polio cases that have generated secondary cases (*6*).

In May 2012 the World Health Assembly declared the completion of poliovirus eradication to be a "programmatic emergency for global public health" and called on the Director-General of WHO to develop a comprehensive polio endgame strategy. The Polio Eradication and Endgame Strategic Plan 2013-2018 was developed to avail of this new opportunity to put an end to poliomyelitis. Its goal is to eradicate the wild virus and eliminate circulating vaccine-derived poliovirus (cVDPV).

That same year, WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recommended suspending use of the type 2 component of tOPV in all national vaccination programs. This recommendation is based on the fact that type 2 poliovirus was eliminated in 1999 and the continued use of tOPV in areas where coverage is inadequate contributes to the emergence of cVDPV cases (*2*). Before switching from tOPV to the bivalent oral poliovirus vaccine (bOPV), SAGE recommends that all countries introduce at least one dose of the inactivated polio vaccine (IPV) into their infant vaccination schedules, as a risk mitigation measure as this would provide immunity in the event of a possible type 2 virus re-emergence or reintroduction (*7*).

In January 2013, the WHO Executive Board approved the goals, targets, and timelines of the Polio Eradication and Endgame Strategic Plan 2013-2018. This plan has four objectives:

1. To detect and interrupt poliovirus transmission
2. To strengthen immunization systems and withdraw OPV
3. To contain poliovirus and certify interruption of transmission
4. To plan how to utilize the legacy of the fight against polio.

In this context, at its meeting in July 2014, the PAHO Technical Advisory Group on Vaccine-preventable Diseases (TAG) issued recommendations for the Region of the Americas regarding the introduction of IPV. On this occasion, TAG reiterated the recommendations presented during it special meeting held in April 2014:

- TAG supports renewed polio eradication efforts and the endgame eradication goals. Such efforts are directed, among other objectives, toward the permanent withdrawal of OPV (Sabin vaccine) from routine vaccination programs.
- During the IPV introduction phase, countries should take sequential schedules into account; ideally countries should consider using two IPV doses, followed by two OPV doses. However, if a country is considering the possibility of a single IPV dose, this should be administered with the first Diphtheria-Pertussis-Tetanus (DPT) dose, followed by three OPV doses.
- At this stage countries should not consider switching to an IPV only schedule unless they fulfill the criteria previously recommended by both TAG and WHO (low risk of transmission and importation, high homogenous coverage and good sanitation).

II. Epidemiology

Poliomyelitis is a communicable disease caused by the poliomyelitis virus, an enterovirus belonging to the Picornaviridae virus family, which is subdivided into three serotypes, called 1, 2, and 3.

Poliomyelitis is a communicable disease caused by the poliomyelitis virus, an enterovirus belonging to the *Picornaviridae* virus family, which is subdivided into three serotypes, called 1, 2, and 3.

The predominant transmission mode of this disease in developing countries is the fecal/oral route, since the virus replicates in the intestines and is basically excreted in feces. If sanitation conditions 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. The incubation period is usually 7 to 10 days, though it can be 4 to 40 days.

Infection can be inapparent (without symptoms) in approximately 72% of cases; in about 24% it causes mild disease with transitory fever, discomfort, somnolence, headache, nausea, vomiting, constipation, and sore throat, in various combinations; it manifests as aseptic meningitis in about 4% of cases; and on rare occasions (< 1%) it presents as paralytic poliomyelitis (*8*).

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.

Vaccines containing live attenuated viruses are very effective against the wild virus, but in a few cases they can cause AFP by means of two mechanisms:

1. Re-acquiring neurovirulence

   Live attenuated viruses in OPV can, through prolonged replication in immunocompromised persons or in a community with low vaccination coverage, reacquire the neurovirulence and transmissibility characteristic of the wild poliovirus. These vaccine-derived viruses can cause cases or outbreaks of paralytic poliomyelitis. The genetic divergence of type 1 and 3 polioviruses should be over 1%, while for type 2 virus it should be over 0.6% (9).

   Vaccine-derived polioviruses are subdivided into three categories:

   a. cVDPV: when there is evidence of person-to-person transmission in the community. First recognized in 2000 during an outbreak on the island of Hispaniola (Haiti and the Dominican Republic), recent experience indicates that low vaccination coverage is a major risk factor for cVDPV outbreaks. These viruses have the capacity to become endemic, as observed in Hispaniola, Nigeria, and Egypt, and can be imported and spread in a community with low vaccination coverage even in developed countries, as occurred in an Amish community in the United States of America (9).
   b. Immunodeficiency-associated vaccine-derived viruses: excretion of the virus is prolonged in people with immune system disorders; excretion has been reported to persist in some cases for 10 years or more.
   c. Ambiguous vaccine-derived viruses: clinical isolates from people with no known immunodeficiency or sewage isolates of unknown source.

2. Mutation toward neurovirulence

   This mechanism causes vaccine-associated paralytic poliomyelitis (VAPP). This is a rare event—associated with OPV administration—caused by viral mutation and the regaining of neurovirulence. In the Region of the Americas, the estimated risk of VAPP in vaccine recipients or in close contacts is 1 in 7.68 million doses administered (95% confidence interval, from 1 in 6.73 to 1 in 8.95 million doses administered) (10). There are an estimated 250 to 500 cases of VAPP per year worldwide; of which, nearly 40% are due to the type 2 component of tOPV (7).

III. Polio vaccines: OPV and IPV

To date, two types of polio vaccines have been used throughout the world and are available on the international market: tOPV and IPV.

To date, two types of polio vaccines have been used throughout the world and are available on the international market: tOPV and IPV.

tOPV use has made it possible to eradicate polio in the Americas and other regions thanks to its immunological characteristics. When OPV is administered, the virus in the vaccine is ingested orally, replicates in the intestines, and can generate three types of 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 wild virus in feces, which means that children vaccinated with tOPV coming into contact with this virus are less likely than unvaccinated children to excrete it in their feces (*11*).

Furthermore, those vaccinated with tOPV excrete the vaccine virus in feces, spreading it into the environment, which can then immunize others who have not been vaccinated.

tOPV has produced undeniable benefits in paralytic polio eradication. Before the World Health Assembly launched the Global Polio Eradication Initiative in 1988, the wild virus caused more than 350 000 cases of paralysis per year across more than 125 countries. In 2013, only 416 cases were recorded across eight countries (*6*). Nonetheless, though very infrequently, tOPV can cause some undesirable events such as cases of VAPP and the appearance of cVDPV.

In turn, IPV stimulates a good humoral response. As we know, polioviruses are also transmitted through oral secretions, and IPV is as effective as tOPV in blocking this type of transmission. However, on its own it does not induce the same level of intestinal immunity as OPV, which means that it does not prevent the wild virus from being excreted in feces and spreading in the environment (Table 1).

TABLE 1. Comparison of the advantages and disadvantages of the trivalent oral poliovirus vaccine (tOPV) and the inactivated poliovirus vaccine (IPV)

Vaccine	Advantages	Disadvantages
tOPV	■ Humoral immunity ■ Better intestinal immunity ■ Easy to administer via drops ■ Inexpensive	■ Rare cases of VAPP: in the Americas, 1 case per 7.68 million doses administered[a] (*10*) ■ Rarely, vaccine viruses can reacquire neurovirulence and transmissibility characteristic of wild viruses and induce cVDPV
IPV	■ Humoral immunity ■ As effective as tOPV in inducing immunity in oral cavity, thus stops oral transmission of virus	■ Insufficient to prevent replication of wild poliovirus in intestines of those vaccinated, if they become infected, which means that it can still be transmitted through feces ■ Injection: trained professionals required ■ More expensive than tOPV

Source: Reference *11*.

Note: VAPP: vaccine-associated paralytic poliomyelitis; cVDPV: circulating vaccine-derived poliovirus.

[a] 95% confidence interval: 1 in 6.73 to 1 in 8.95 million doses administered.

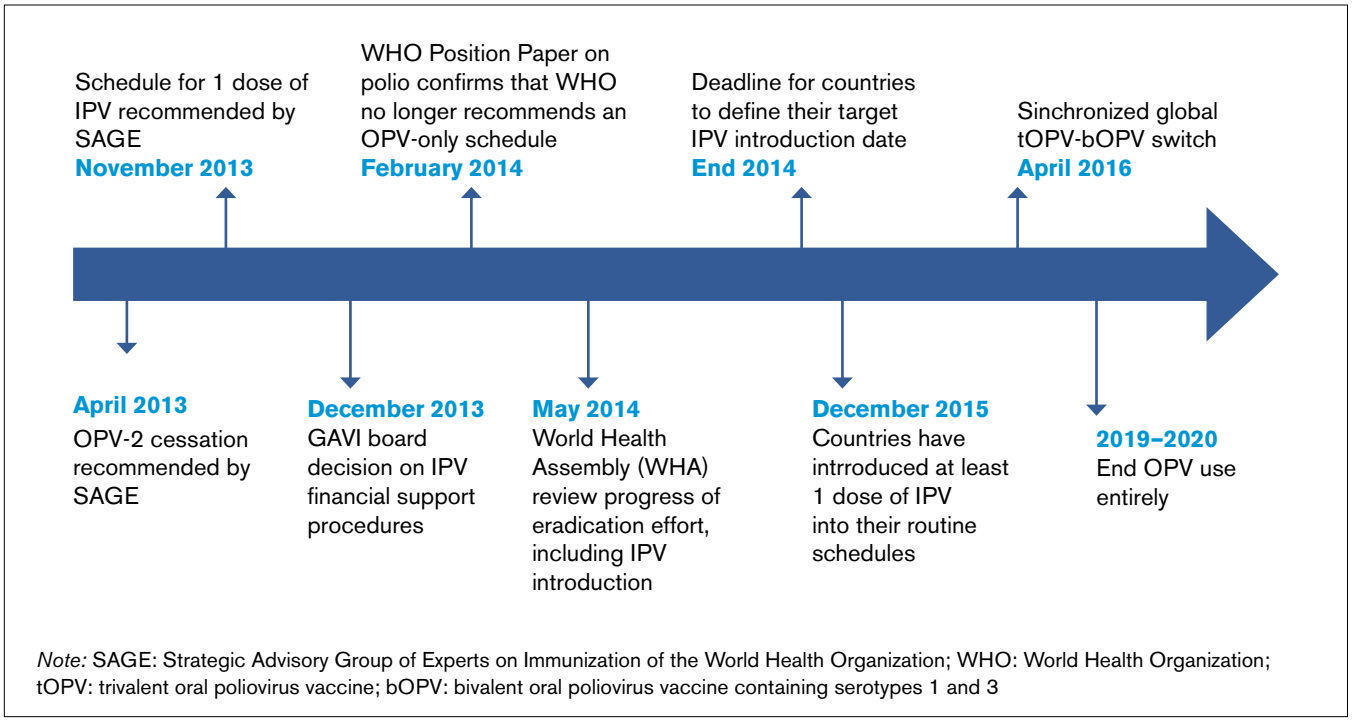
IV. Switching from tOPV to bOPV and IPV introduction

Although type 2 wild poliovirus appears to have been eradicated globally in 1999, vaccine-associated type 2 viruses continue to cause the majority of cVDPV outbreaks and VAPP cases. As a result, in this final global polio eradication phase, the type 2 component of tOPV presents greater risks than benefits, thus hindering global eradication efforts. For this reason, tOPV will be replaced by bOPV, which will continue to target types 1 and 3 viruses. Once these two types are eradicated, bOPV will also be withdrawn from the market. Thus, SAGE has called for the withdrawal of tOPV from the world market in 2016, and once global eradication is achieved—envisioned for 2018—, bOPV use will also cease. As a risk mitigation measure, prior to switching from tOPV to bOPV, SAGE recommends that all countries currently using only tOPV in their vaccination programs introduce at least one IPV dose into their routine vaccination schedules before the end of 2015 (Figure 1).

In this final global polio eradication phase, the type 2 component of tOPV presents greater risks than benefits, thus hindering global eradication efforts.

Introducing at least one IPV dose in routine vaccination programs is justified by the gap that would be left following tOPV withdrawal in population immunity against the virus type 2. After tOPV withdrawal, countries that have not introduced IPV would be at greater risk of polio outbreaks—or even lead to the re-emergence of global transmission—in the case of reintroduction of this virus type or the emergence of cVDPV type 2. Vaccinating the population with IPV would reduce the risk of

FIGURE 1. Timeline for inactivated poliovirus vaccine (IPV) introduction



Note: SAGE: Strategic Advisory Group of Experts on Immunization of the World Health Organization; WHO: World Health Organization; tOPV: trivalent oral poliovirus vaccine; bOPV: bivalent oral poliovirus vaccine containing serotypes 1 and 3

sustained transmission. If type 2 poliovirus is reintroduced post-eradication, it would be rapidly controlled with the monovalent oral poliovirus vaccine (mOPV) type 2 as the population would have already received at least one IPV dose and therefore would already have some degree of immunity (*12*) (Table 2).

TABLE 2. Benefits of withdrawing the trivalent oral poliovirus vaccine (tOPV) and the introduction of the inactivated poliovirus vaccine (IPV)

- **To reduces risks.** Once tOPV is withdrawn from the global market, there will be an increase in the population susceptible to the type 2 poliovirus. IPV use will help maintain immunity and prevent the reappearance of the disease in the event of the reintroduction or emergence of this type of virus.
- **To interrupt transmission in the case of outbreaks.** IPV introduction could facilitate the control of future outbreaks, because if type 2 mOPV was required to control an outbreak, it would be easier to reach the levels of immunity necessary to stop transmission in a population previously vaccinated with IPV.
- **To hasten eradication.** bOPV generates better immunity against types 1 and 3 than tOPV.

The endgame plan requires countries that use the tOPV alone to introduce at least one IPV dose before the end of 2015.

The introduction of IPV is a key element of this strategic plan aimed at preparing all countries to reduce the risks associated with the withdrawal of OPV. The endgame plan requires countries that use the tOPV alone to introduce at least one IPV dose before the end of 2015. The principal role of IPV will be to maintain immunity against type 2 virus while tOPV is being withdrawn from the world market.

V. Strategy to follow for switch

Although previously most polio eradication efforts centered on campaigns, WHO now recommends that at this stage in polio eradication that IPV be introduced as an integral part of routine vaccination programs.

For IPV introduction, the use of catch-up strategies—where children born before the vaccine introduction date are vaccinated—are not recommended because these children would have already started the OPV vaccination schedule and would therefore be protected against type 2 poliovirus.

VI. Vaccination schedules

At its meeting in July 2014, concerning IPV introduction, TAG confirmed that countries should apply sequential schedules. Countries should consider two IPV doses followed by two or three OPV doses as the first option. However, if a country decides to introduce only one IPV dose, this should be administered at the start of the vaccination program, and followed by three or four OPV doses (Table 3). It is recommended to administer the first IPV dose to children together with the first DPT dose, always at the start of the vaccination program.

TABLE 3. Vaccination schedules recommended for the introduction of the inactivated polio vaccine (IPV) in combination with the oral poliovirus vaccine (OPV)

Schedule	Basic			Booster	
	1st	2nd	3rd	1st	2nd
First option	IPV	IPV	OPV	OPV	OPV
Alternative option	IPV	OPV	OPV	OPV	OPV

This schedule, in addition to preparing countries for the switch from tOPV to bOPV, has the added advantage of helping to reduce the incidence of VAPP, since around 50% of cases recorded in our Region are related to the first OPV dose (*10*).

It is recommended to administer the first IPV dose to children together with the first DPT dose, always at the start of the vaccination program.

VII. Components of the IPV introduction plan

To incorporate a new vaccine into the immunization program, a plan should be drawn up within the framework of the country's annual action plan for the Expanded Program on Immunization. This plan should encompass all elements necessary for its implementation at national, departmental/state/provincial and local/municipal levels (*13*). The program director should manage the process according to this plan and the established timeline.

In addition to providing both the national and international background to the introduction of the IPV and the rationale for it, goals and targets also need to be established. The Committee of Immunization Practices and policy decision-makers should be convened to analyze epidemiological and financial aspects and to determine the schedule that the country will adopt for IPV introduction, based on TAG recommendations.

Once this technical decision has been made, a strategy is established to simultaneously implement the addition of the new vaccine to the national vaccination program throughout the country.

a. Planning and programming

The introduction plan should be prepared at the national level with sufficient notice so that once the technical decision is reached, vaccine supply and procurement requirements can be estimated. The plan should encompass all components, including an assessment of the program at all levels in order to determine what is required for the introduction.

A feasible timeline should be established for all activities, taking into account the simultaneous introduction throughout the country.

b. Standardization

Among the elements to be standardized are: technical and operational guidelines for healthcare staff, amendment to the vaccination schedule through a decree or

resolution from the Ministry of Health, changes to vaccination records and transport of vaccines and supplies, definition of new indicators, and supervision guidelines.

c. Coordination

To facilitate the coordination of the IPV introduction process, a technical and administrative committee should be set up and meet systematically to monitor the work done, the advances made, and problems that may arise. The first level of coordination—important for the introduction—should consist entirely of the immunization program network, followed by coordination with other programs to avoid overlapping activities, involving the same people or coinciding critical dates.

Coordination efforts should include the following as well as other actors:

- epidemiology departments: to participate in surveillance of the disease and events supposedly attributable to vaccination or immunization (ESAVI)
- medical scientific societies: to support the transition
- committees integrating different agencies: for support with technical and financial aspects
- intermediate and local health authorities
- national regulatory authorities and drug surveillance teams
- media offices: for the participation of political authorities in messages
- statistic offices.

The agenda of these coordination activities should be available with sufficient notice to avoid clashing with the agenda of the various actors, and—conversely— to facilitate their involvement in support activities for IPV introduction. Time should be dedicated during meetings with each actor in order to coordinate.

The agenda of these coordination activities should be available with sufficient notice to avoid clashing with the agenda of the various actors, and—conversely— to facilitate their involvement in support activities for IPV introduction. Time should be dedicated during meetings with each actor in order to coordinate.

The head of the Expanded Program on Immunization is responsible for making a list of actors and partners who should be involved, and for establishing the necessary communication channels.

d. IPV vaccination

For the successful introduction of IPV, the characteristics of this vaccine and the technical aspects relating to its administration should be taken into account (Table 4).

TABLE 4. Characteristics of the inactivated poliovirus vaccine (IPV) and technical aspects related to its administration

Characteristic	Description
Composition	Each dose contains: Active ingredients (produced in VERO cells) Poliovirus type 1 strain Mahoney (inactivated) 40 DU[a] Poliovirus type 2 strain MEF-1 (inactivated) 8 DU Poliovirus type 3 strain Saukett (inactivated) 32 DU Other components: 2-phenoxyethanol Formaldehyde Medium 199 Hanks Diluent solution IPV may contain traces of streptomycin, neomycin, or polymyxin B.
Route of administration	Intramuscular or subcutaneous depending on the brand, though intramuscular route is preferred
Volume per dose	0.5 mL
Presentation and dosage form	■ WHO prequalified IPV in 1, 5 and 10-dose presentations, liquid. ■ IPV combined with acellular DPT[b] and hepatitis B and *Haemophilus influenzae* type b antigens, in tetravalent, pentavalent or hexavalent presentations.
Storage conditions	Store between 2 °C and 8 °C. **DO NOT FREEZE** (IPV is inactivated if frozen)[c]
Shelf life	From 24 to 36 months if stored between 2 °C and 8 °C and protected from light.
Open vial policy	IPV vials may be used up to 28 days after opening, provided that the criteria for the multi-dose vial policy mentioned on page 16 are fully met.
Minimum age of administration of the first dose	6 weeks Observation: It is recommended that the first dose be administered at 2 months together with other vaccines included in immunization program.
Minimum interval between doses	4 weeks
Co-administration with other vaccines	IPV can be administered at the same time as the other vaccines in the program. However, different syringes and different sites (minimum distance of 2.5 cm between injection sites) should be used.
Immunological response	The immunological response is similar in industrialized and developing countries: ■ 1 dose: 19%-46% against type 1 poliovirus; 32%-63% against type 2; and 28%-54% against type 3. ■ 2 doses: 40%-93% against the three types and more than 90% when the vaccination is started after 8 weeks of age.

[a] DU: appropriate D-antigen unit.
[b] At present, the combined products use the acellular pertussis vaccine. A combined product with whole cell pertussis is not available. WHO recommends countries that use whole cell DPT vaccines not to change to the acellular vaccine (*14*).
[c] The Shake Test does not detect damage from freezing as this is not an adsorbed vaccine (i.e. it does not contain an aluminum adjuvant). If there are any doubts or suspicions that a vaccine has been frozen, discard the vial.

This vaccine is available in several presentations, depending on the manufacturer, though not all are prequalified by WHO (Table 5).

TABLE 5. Inactivated polio vaccine (IPV) presentations

Manufacturer	Presentations available on global market
Bilthoven Biological	■ 1-dose vial (prequalified) ■ 5-dose vial (prequalified)
GlaxoSmithKline	■ 1-dose vial (prequalified) ■ 12-dose vial (prequalified)
Sanofi	■ 5-dose vial (in process of prequalification) ■ 10-dose vial (prequalified)
Statens Serum Institute	■ 1-dose vial (unavailable short-term)

Contraindications to IPV

IPV should not be administered to people with a documented or known allergy to streptomycin, neomycin or polymyxin b, or with a history of an allergic reaction after a previous IPV injection.

Precautions and special groups

Use in population with coagulation deficiencies: subcutaneous administration of IPV is recommended for those with a history of hemorrhagic diseases or on anticoagulation therapy.

Use in premature infants: IPV can be administered to premature infants (born at less than 37 weeks gestation) at the recommended chronologic age concurrent with other routine vaccinations.

Use in immunodeficient populations: IPV can be safely administered to people with immunodeficiencies (e.g., HIV/AIDS, congenital or acquired immunodeficiency, sickle cell disease). In fact IPV is universally recommended in these cases due to the risk of contracting VAPP with use of tOPV.

e. Implementation of the vaccination plan

Once the vaccine is distributed to all health centers, vaccination will proceed according to the schedule selected by the country. Logistic requirements (transportation and human resources for the distribution of materials, etc.) as well as materials (vaccines, syringes, safety boxes, new records forms, cotton balls, vaccination cards, etc.) should be ensured.

f. Procurement of vaccines, cold chain, and logistics

Calculating number of vaccines needed

The annual number of IPV doses needed is the product of the target population, number of doses (depending on vaccination schedule) and wastage factor.

The basic formula to calculate the number of IPV (N) doses to be purchased is:

N = Target population x Number of IPV doses in the schedule x Wastage factor

The annual number of IPV doses needed is the product of the target population, number of doses (depending on vaccination schedule) and wastage factor.

Estimating vaccine wastage

Vaccine wastage is the proportion of vaccine that is supplied but never administered due to a number of reasons:

a. Unopened vials
- expired
- exposure to heat or cold: cold chain or freezing
- breakages

b. Opened vials
- inappropriate use of policy established for open multiple-dose vials
- inefficient use of doses contained in multiple-dose vials.

Each country should calculate its wastage rate based on its history with other vaccines, especially those packaged in multiple-dose vials.

The formula to calculate the wastage rate is:

$$\text{Wastage rate} = \frac{\text{doses supplied} - \text{doses administered}}{\text{doses supplied}} \times 100$$

Maintaining a buffer reserve

A reserve stock of 25% to 50% of the vaccine requirement should be maintained at the central stock supply. This is the estimated quantity of vaccines that would be needed if a new supply is delayed or if there is a sudden increase in demand. At departmental, municipal and the health facility levels, a reserve stock of about 25% the quantity expected to be used during a given supply period should always be kept. A reserve stock is not the same as the allowance for wastage. Both figures are necessary when estimating vaccines requirements.

Estimating required net volume for vaccine storage

To calculate the net volume for vaccine storage, the target population, number of doses in the vaccination schedule, wastage factor, expected reserve, and storage volume per dose according to presentation should be considered. Table 6 presents storage volume per dose by presentation and number of vials per pack.

IPV should not be administered to people with a documented or known allergy to streptomycin, neomycin or polymyxin b, or with a history of an allergic reaction after a previous IPV injection.

Table 6. Prequalified IPV storage volume per dose, by manufacturer, presentation, and vials per box/tray

Manufacturer	Presentation	Vials per box/tray	Storage volume per dose (cm^3)
Bilthoven Biologicals B.V.	1 dose	360	15.7
	5 dose	280	4.0
GlaxoSmithKline	1 dose	1	…[a]
		10	…[a]
		100	…[a]
	2 dose	1	…[a]
		10	…[a]
		100	…[a]
Sanofi Pasteur	10 dose	10	2.46
Statens Serum Institut	1 dose	1	101.4
		10	26.8
		50	12.9

Source: Reference *15*.
[a] information not available.

Cold chain equipment

Once the cold chain storage capacity required for IPV has been identified, the manager of the immunization program should decide if any adjustments are warranted; either changes to frequency of vaccine deliveries or procuring additional refrigeration equipment. Those responsible for procuring refrigeration equipment can select the most appropriate, depending on the capacity and infrastructure of the storage spaces. When selecting the equipment, WHO's PQS (Performance, Quality, and Safety) catalog of prequalified products is recommended as a reference for the following products:

- cold rooms
- refrigerators
- cold boxes and insulated vaccines carriers
- ice packs.

Temperature monitoring

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. Once a vaccine loses its potency, this cannot be regained. Damaged vaccines should be discarded according to current national guidelines on good practices in injection safety.

Do NOT freeze IPV
Discard if frozen
The Shake Test does not work to determine if IPV was frozen.

Vaccine storage

Proper management of vaccines requires that they be properly packed and stored. In general, the same principles that apply to other vaccines also apply (Table 7).

TABLE 7. Appropriate vaccine storage conditions

- In top-opening refrigerators (ice-lined): store IPV and other freeze-sensitive vaccines on top.
- In front-opening refrigerators: store IPV and other freeze-sensitive vaccines on the lower shelves.
- IPV could be damaged if placed in direct contact with frozen ice packs that were inadequately conditioned. Water Ice packs should be conditioned according to the procedure recommended by PAHO.

Conditioning water ice packs

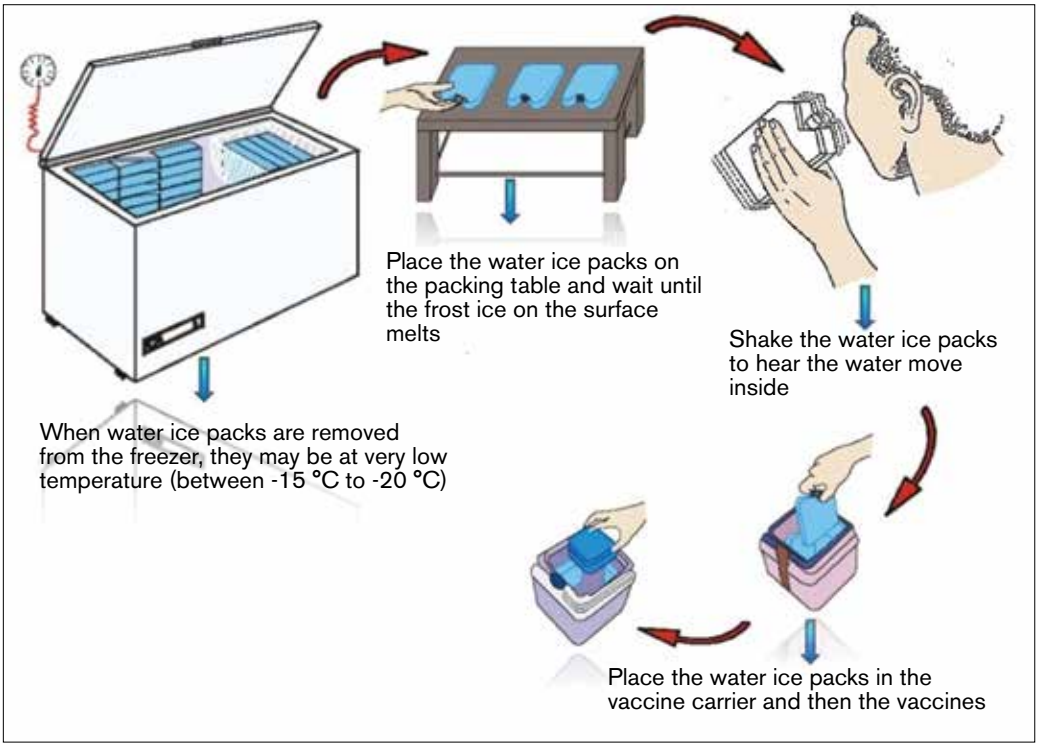
In order to ensure correct storage of vaccines, the following procedure should be followed (Figure 2):

- Ensure a clean and air-conditioned environment.
- Ensure that containers (insulated carriers) are clean before use and at end of the day.
- A packing table is needed.
- Remove water ice packs from freezer and place on table to defrost. Packs are ready to use when there are physical signs of thawing; no ice and drops of water on surface, and liquid is observed inside.
- Dry the packs and line the walls of the insulated container with them. Place the vaccines inside and ensure that the container is properly closed (Figure 3).

The procedure of allowing ice packs to reach room temperature means that the initial freezing temperature is lost, so the temperature in the insulated carrier does not drop below 0 °C.

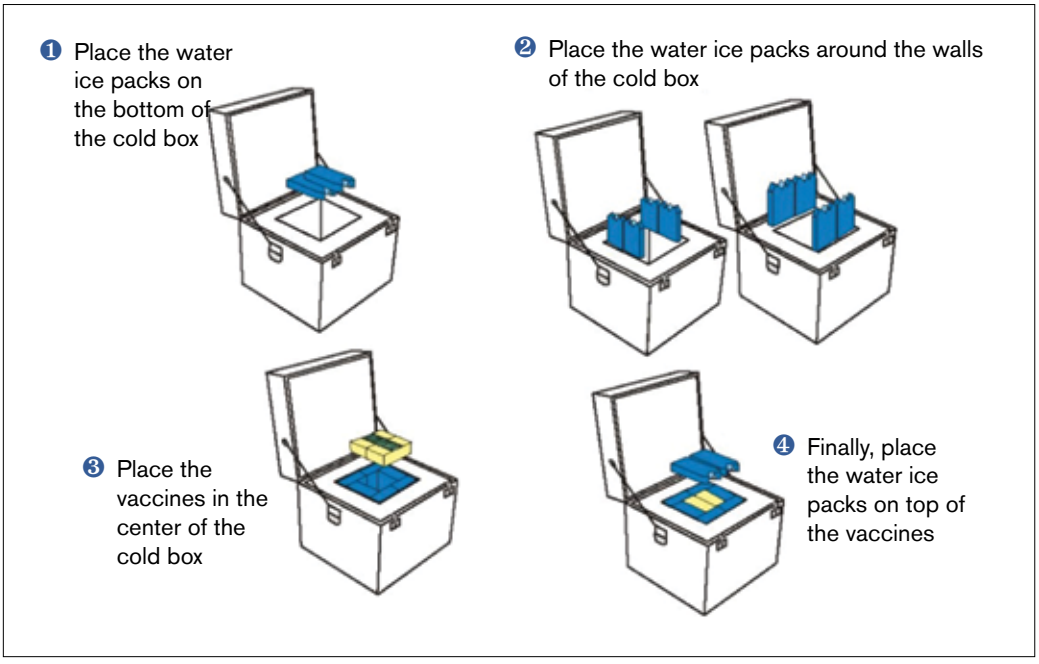
Properly conditioned water ice packs constitute the best method to maintain the temperature of the insulated carriers and cold boxes.

FIGURE 2. Conditioning of water ice packs



There should be sufficient ice packs to ensure that the vaccines are totally surrounded during transportation.

FIGURE 3. Placement of water ice packs in coolers for the transport of vaccines



The inventory control system should ensure that units with the nearest expiry date are used first in a system known as FEFO (*first-expired, first-out*). A maximum of 1 month is recommended for storage of IPV in a health facility, and the expiry date should be checked whenever a vial is opened.

Each vial shows an expiry date.
Never use vaccines after the expiry date.

g. Safe IPV vaccination

This section provides additional information on safe vaccine administration, open vial policy, waste management and ESAVI monitoring.

Safe injection

The steps to follow for safe IPV administration are shown in Table 8.

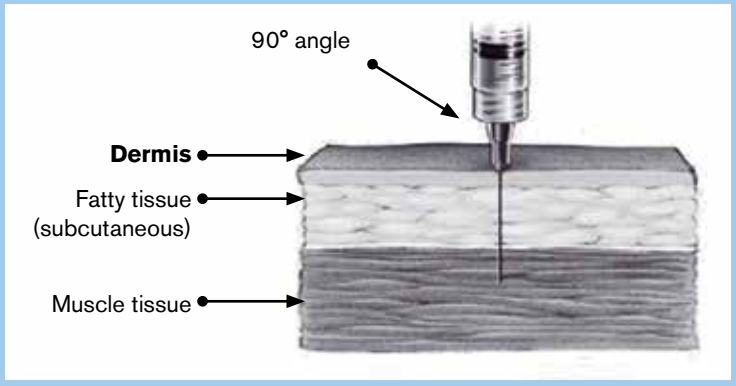
TABLE 8. Steps to follow to administer IPV

Step 1: Check the expiry date and wash hands.

Step 2: Draw up 0.5 ml of the vaccine with a single-use disposable syringe. IPV should not be mixed with other vaccines in the same vial or syringe.

Step 3: Administer the vaccine as an intramuscular injection (preferably) in the anterolateral right or left thigh of the infant. Some IPV presentations can be administered subcutaneously, but the preferred route is intramuscular.

NOTE: Simultaneous administration of IPV with other vaccines should be given at different injection sites. For example, if the pentavalent vaccine is injected in the left thigh, then IPV should be injected in the right thigh. When the vaccination schedule includes IPV, pentavalent and pneumococcal vaccines, the IPV and pneumococcal vaccine can be injected in the same thigh at least 2.5 cm apart; the pentavalent vaccine may be given in the other thigh.



Step 4: Immediately dispose of the used syringe, without recapping, in a safety box.

Step 5: Record the dose administered according to national regulations and note it in the immunization card.

NOTE: The IPV dose should be recorded separately from the OPV dose, in other words, do not group both under "polio vaccine", in order to keep a record of the children who received one or two IPV doses, according to the new vaccination schedule defined by the country.

IPV presented in 5 dose-vials, produced by Bilthoven Biologicals, has been prequalified and approved for use up to 28 days after opening, provided that:

- *the expiration date of the vaccine has not passed, and*
- *the vaccine vial has been, and will continue to be, stored at WHO recommended temperatures.*

Open vial policy

IPV presented in 5 dose-vials, produced by Bilthoven Biologicals, has been prequalified and approved for use up to 28 days after opening, provided that the following WHO defined criteria are fully met (*16*).

1. **The vaccine is currently prequalified by WHO.** In order for a vaccine to be prequalified, WHO independently evaluates data on vaccine quality, safety and efficacy. This evaluation includes examining the effectiveness of preservatives, as well as the stability of the vaccine under different temperature conditions. In addition, the prequalification program assesses such things as the quality of vials, stoppers, caps and labels.
2. **The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO.** For injectable vaccines, this means that the vaccine contains appropriate type and amount of preservative.
3. **The expiration date of the vaccine has not passed.** This condition is part of immunization best practice and is included here to emphasize the importance of not using a vaccine vial after the product has expired. The expiration date may be reached over the course of the 28 days so, in line with good practice, the expiration dates of all opened vials should be checked prior to every use.
4. **The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer-recommended temperatures.** All vaccines should be stored according to WHO or manufacturer recommended temperatures, normally between +2°C to +8°C, and should be protected from freezing and sunlight. If a vaccine vial is labelled as freeze-sensitive and is suspected of having been frozen, or a temperature alarm indicates exposure to sub-zero temperatures, the vaccine should be discarded.

Waste management

Vaccinators should place all needles (without recapping them) and syringes used in a safety box immediately after administering the vaccine. Close the container securely when full (i.e. up to ¾ its capacity) and store in a safe place until it can be transported, according to national guidelines, to its final destination.

ESAVI monitoring

IPV is safe and well tolerated. Serious adverse reactions are extremely uncommon. Redness at injection site has been reported in 0.5%-1.5% of vaccinated infants, swelling in 3%-11% and pain in 14%-29%. Other effects have also been reported, such as transitory fever, but only in 0.1% of vaccinated infants did fever go over 40 °C.

ESAVI monitoring has demonstrated that multiple injections are well tolerated and not associated with a higher incidence of adverse events.

As with the other vaccines, any ESAVI should be reported subject to current national regulations.

Crisis plan

Any process involving the introduction of a new vaccine should have a crisis plan. Although serious ESAVI caused by IPV are extremely rare, the temporary association between vaccine administration and a serious ESAVI or the circulation of rumors or misinformation could seriously undermine immunization activities which justifies having a crisis plan in place.

h. Training

All healthcare staff should receive adequate training on all the aspects related to the IPV introduction.

Some key subjects to be addressed in the training are:

- vaccination programs
- benefits of sequential schedules
- vaccination records
- vaccine storage
- open vial policy.

Steps should be taken to ensure that vaccination centers have duly trained staff prior to IPV introduction.

i. Social mobilization and communication

A national communication and advocacy strategy aimed at different audiences, partners, stakeholders, communities, and parents is a critical component for the success of the introduction of a new vaccine. The communication and advocacy strategies should aim at achieving the following objectives:

- raise awareness of all parties on the importance of IPV use in the first dose or first two doses, depending on the schedule
- promote confidence in the vaccination schedule, its safety and effectiveness
- avoid rumors and misinformation
- improve vaccination coverage
- enhance detection and reporting of possible ESAVI.

A national communication and advocacy strategy aimed at different audiences, partners, stakeholders, communities, and parents is a critical component for the success of the introduction of a new vaccine.

The three recommended communication strategies are:

- Advocacy: raise awareness and commitment among decision-makers at all levels, so that they support and facilitate the introduction and implementation of the IPV in the country
- Social mobilization: involve partners and civil society in awareness and resource mobilization activities
- Information on the change to the vaccination schedule: raise awareness, promote behavior changes, and call for the action of communities, parents, and caregivers.

The methodology for each one of these strategies should be adapted to the national, regional, and local conditions.

Steps should be taken to ensure the population receives the necessary information on the nature and benefits of introducing IPV. Communication strategies should be analyzed and agreed upon. Materials and dissemination methods (TV ads, posters, notes for spokespersons, informative spots for radio or broadcasting) should be determined at the different levels of the health system.

Communication strategies targeting healthcare workers, professional associations, opinion leaders and parents should contain materials and messages that clearly explain why IPV is being introduced and why OPV is being kept in sequential schedules.

Among the topics that could and should be included are:

- the global polio eradication process, now in its final stage
- the epidemiological polio situation in the Region and the world, and the need for readiness for the final eradication phase
- the role played by OPV in polio eradication in the Americas
- OPV as a critical component in the strategic plan until polio transmission is contained everywhere
- the introduction of IPV as part of the final strategy for global polio eradication
- the use of both vaccines as a means of improving protection against polio
- IPV introduction as the first step in withdrawing OPV once the disease has been eradicated, and initiating the switch from tOPV to bOPV
- the need to continue using OPV as long as polio cases exist in the world to ensure it is not transmitted in the community
- why children who have already received OPV will not be administered IPV
- the importance of administering all vaccines in the routine program, according to age, in a single visit.

Annex 1 outlines other important issues, and frequently asked questions are answered.

j. Adapting the information system

The introduction of IPV will require updating of forms, vaccination cards, and the electronic databases used for recording and reporting vaccines administration, vaccine ordering forms, vaccine stock and reserve stock ledgers, and any other form used in the national immunization program, as well as those for ESAVI reporting.

From the outset, it is important to coordinate actions with those responsible for the national health information system to allow them enough time to implement the necessary changes to the system.

Adequate records of the IPV doses administered are essential to evaluate the success of the introduction of this vaccine.

It is important to ensure that the records of IPV doses administered are kept separate from the records of tOPV doses.

k. Epidemiological surveillance

Although polio eradication in the Americas has been certified, polio transmission still exists in other regions of the world. Thus, it is imperative to continue to investigate each case of AFP in children under 15 years, as well as any suspected cases of polio in people of any age, in order to promptly detect any imported cases and to immediately implement the necessary control measures.

It is fundamental to detect, report, investigate—including taking samples and home visits—and to classify the cases after 60 days of paralysis onset.

It is fundamental to detect, report, investigate—including taking samples and home visits—and to classify the cases after 60 days of paralysis onset.

- All cases of AFP in children under 15 years should be investigated regardless of the cause– except cases of severe trauma– as well as cases in people of any age with suspected polio diagnosis.
- Each AFP case reported should be investigated within 48 hours of the report, and a stool specimen taken for laboratory diagnosis within 14 days of disease onset.

Each country should have a suspected AFP notification system where health centers report weekly, to the next highest level, the absence or presence of AFP cases, even if this involves reporting "zero cases."

The detection of probable cases should be carried out at health services through active searches.

AFP monitoring quality indicators

The following four indicators should be evaluated and reported on a regular basis:

1. percentage of reporting units that submit reports every week: at least 80%
2. notification rate: at least one case of AFP per 100 000 children under 15 years
3. percentage of cases where an adequate sample was taken: at least 80%
4. percentage of cases with timely investigations: at least 80%

For further information on AFP monitoring: www.paho.org/immunization/poliofieldguide

l. Monitoring and evaluation

As in every process involving the introduction of a new vaccine, the following points should be kept in mind and systematically monitored:

- Implementation of the introduction plan should be monitored by a technical-administrative commission
- Preparation of forms and adaptation of IT system: in the case of computerized systems, reprogramming times and adequate testing of the changes to the system should be considered
- Vaccination coverage indicators
- Wastage: given the possibility of using multidose vials for vaccination, it is important to determine wastage, in order to adjust vaccine procurement and distribution plans
- ESAVI: according to the current ESAVI monitoring protocol in each country.

Evaluation meetings should be scheduled to monitor the progress of vaccine introduction at all levels.

m. Calculating the costs of the plan

The IPV introduction plan should clearly indicate the unit cost of each activity, the total cost, and the sources of financing. Fixed costs of activities that form part of the regular program should be defined, and whether further investment will be required.

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Annexes

Annex 1. Frequently asked questions

Why should countries introduce IPV?

Introducing IPV is a key element of the Polio Eradication and Endgame Strategic Plan 2013-2018 and global readiness to reduce risks associated with OPV withdrawal. The strategic plan urges countries that use only OPV to introduce at least one IPV dose by the end of 2015. The primary role of IPV will be to maintain immunity against type 2 poliovirus while removing OPV, which contains that virus, from the world market. The purpose of introducing IPV is twofold:

- **To reduce risks. Once OPV**—which contains the attenuated type 2 poliovirus—is withdrawn from the world market there will be an unprecedented accumulation of people susceptible to this type of virus. IPV use will help maintain immunity and prevent the emergence of type 2 virus in the event of its reintroduction or re-emergence. Thus, a region immunized with IPV would have a lower risk of disease from either wild or vaccine-derived type 2 poliovirus.

- **To interrupt transmission in the case of outbreaks.** Should the use of type 2 mOPV be required to control an outbreak, it will be easier to reach the immunity levels necessary to stop transmission in a population previously vaccinated with IPV. Thus, introducing IPV would facilitate future outbreak control.

The position paper on polio vaccines is available online at: http://www.who.int/wer/2014/wer8909.pdf

Why do countries need to switch from tOPV to bOPV?

There are three types of wild polioviruses—known as type 1, 2 and 3—each of which is targeted by a different component of the tOPV: Sabin virus 1, 2 and 3, respectively.

Live attenuated vaccines are very effective against the wild virus, but in very rare cases they can cause serious problems:

- VAPP: For every cohort of 1 million newborn babies, 2 to 4 cases of VAPP are recorded in the group of countries using only OPV. This translates into 250-500 cases of VAPP per year in the world. Of these, about 40% are caused by the type 2 component of the tOPV. In the Region of the Americas, the estimated risk of VAPP in vaccine recipients or in close contacts is 1 per 7.68 million doses administered (95% confidence interval, 1 in 6.73 to 1 in 8.95 million doses administered).

- cVDPV outbreaks: These rare outbreaks occur when the vaccine virus is transmitted from one person to another—basically in areas of low vaccination coverage— due to mutations that occur over time causing the virus to

reacquire the transmissibility and neurovirulence characteristic of the wild virus. Almost all recent cVDPV outbreaks have been caused by OPV type 2.

Although the type 2 wild poliovirus seemed to have been eradicated globally in 1999, vaccine-related type 2 viruses continue to cause the majority of cVDPV outbreaks and many VAPP cases. As a result, tOPV now generates more risks than benefits and undermines global polio eradication efforts. Thus, tOPV will be replaced with bOPV, which will continue to protect against types 1 and 3. Once these two types of virus are eradicated, bOPV will also be withdrawn from the market and replaced with IPV.

When do countries need to introduce IPV and switch to bOPV?

To withdraw OPV, first it is necessary to switch from tOPV (containing type 2) to bOPV (containing only type 1 and 3 poliovirus) in routine vaccination programs. According to SAGE, this is necessary in order to be able to withdraw tOPV from the world market by 2016. This sets the stage for ending bOPV use in 2019-2020, after global eradication. As a risk mitigation measure, SAGE recommends that before the switch from tOPV to bOPV all countries that currently use only OPV in their routine vaccination programs introduce at least one IPV dose into their polio vaccination programs by the end of 2015.

Why should countries introduce IPV before the tOPV-bOPV switch?

The withdrawal of tOPV would leave a gap in population immunity against type 2 poliovirus. As a result, immediately after global withdrawal of tOPV, countries that have not introduced IPV would be at a greater risk of outbreaks in the case of reintroduction or emergence of this virus. In either of these cases, type 2 cVDPV could result in substantial polio outbreaks or even reestablishment of global transmission. Vaccinating the population with IPV as part of routine immunization programs would reduce the risk that reintroduction would lead to sustained transmission. If reintroduction of type 2 poliovirus occurs post-eradication, it could be rapidly controlled with mOPV type 2 in a population that had received IPV and, hence, already has some immunity.

What are the risks for countries if they do not introduce IPV?

There are two main risks associated with tOPV (containing type 2 poliovirus) withdrawal:

- immediate time-limited (one to two years) risk of cVDPV type 2 emergence
- medium- and long-term risks of poliovirus reintroduction from a vaccine manufacturing site, research center, or diagnostic laboratory.

All countries face a time-limited risk of an outbreak caused by cVDPV type 2 during tOPV withdrawal if they have not previously introduced an IPV dose.

What happens if an outbreak of type 2 polio occurs after market withdrawal of tOPV and bOPV?

A global reserve of mOPV (1, 2 and 3 separately) is being prepared to be used in the event of a polio outbreak after the complete withdrawal of all OPV types. This reserve will allow a type-specific response and will ensure rapid outbreak control and interruption of transmission in a population already protected with IPV.

What is the difference between IPV and OPV?

IPV and OPV induce different immunological responses and each has advantages and disadvantages, as illustrated in the following table.

Comparative table of the advantages and disadvantages of the trivalent oral poliovirus vaccine (tOPV) and the inactivated polio vaccine (IPV)

Vaccine	Advantages	Disadvantages
tOPV	■ Humoral immunity ■ Better intestinal immunity ■ Easy to administer via drops ■ Inexpensive	■ Rare cases of VAPP: in the Americas, 1 case in every 7.68 million doses administered.[a] ■ Rarely, vaccine viruses can reacquire neurovirulence and transmissibility characteristic of wild viruses and induce cVDPV
IPV	■ Humoral immunity ■ As effective as tOPV in inducing immunity in oral cavity, thus stops oral transmission of virus	■ Insufficient to prevent replication of wild poliovirus in intestines of those vaccinated, if they become infected, which means that it can still be transmitted through feces ■ Injection: requires trained professionals ■ More expensive than tOPV

Surce: Reference *10*.
[a] With a 95% confidence interval: 1 in 6.73 to 1 in 8.95 million doses administered.
Note: VAPP: vaccine-associated paralytic poliomyelitis; cVDPV: circulating vaccine-derived poliovirus.

In order to successfully complete the polio eradication process and to optimize the benefits of each one, they should be used together.

How safe is IPV?

IPV is a very safe vaccine. The most common side effects are local and self-limiting, while serious events are very uncommon.

As it is administered at the same time as other vaccines, the appearance of adverse effects is possible, probably coincidental. The national system should be notified of any adverse event associated with its administration.

What types of protection do polio vaccines offer?

When OPV is administered, the vaccine virus enters the mouth, is replicated in the intestines, and can generate three types of immunological response:

- 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 spreading in this way
- intestinal or mucosal immunity: prevents excretion of the wild virus in feces, which means that children vaccinated with tOPV coming into contact with this virus are less likely than unvaccinated children to excrete it in their feces.

The predominant mode of transmission of this disease in developing countries is via the fecal-oral route, as the virus replicates in the intestines and is basically excreted in the feces. If sanitation conditions and personal hygiene are inadequate, others can become infected through dirty hands or food and contaminated water. Therefore, intestinal immunity is important to prevent transmission.

As its name indicates, IPV is an inactivated vaccine (contains dead viruses) that promotes a good humoral response (antibodies in blood) in children after only 1 or 2 doses. IPV also prevents children transmitting the virus through their oral fluids—one of the viral transmission modes—as effectively as OPV. However, IPV alone does not induce as much intestinal immunity as OPV; consequently, although those vaccinated with IPV are individually protected against the disease, they can excrete the virus and possibly transmit it.

IPV and bOPV together combine the advantages of both vaccines: protection with antibodies against the two serotypes contained in bOPV (types 1 and 3) and strong oral and intestinal immunity. This combination provides the best protection for both children and their communities.

Annex 2. Calculating national vaccine requirements

As IPV vials may be used up to 28 days after opening, provided that the criteria for the multi-dose vial policy mentioned on page 16 are fully met, the following example estimates a wastage factor, for 5-dose vials, of 1.18, corresponding to a 15% wastage rate.

This rate may vary by region or country, depending on the presentation, vaccination strategy (at a permanent health facility or an outreach program), the density of the population and the number of infants vaccinated per session. Due to the limited availability of data on the use of vaccines in 5-dose vials in the Region of the Americas, this example uses the wastage rate suggested by WHO, but each country should adjust according to their experience with other multi-dose vaccines.

In planning IPV procurement needs, each country should contemplate a 6-month stock reserve (or as established nationally) as shown in the following table.

Vaccine	Population < 1 year *a*	Dose per child[1] *b*	Total number of doses per year *c = a x b*	Wastage rate (%) *d*	Wastage factor *e = 100/100 – d*	Number of doses needed per year[2] *f = c x e*	Stock reserve *g = 50 % x f*	Annual procurement *h = f + g*
IPV	50 000	2	100 000	15	1.18	118 000	59 000	177 000
IPV	50 000	1	50 000	15	1.18	59 000	29 500	88 500

[1] Variable depending on vaccination schedule adopted.
[2] Including wastage.

Example of calculating vaccine requirement at the local level

The following is an example of how to calculate the number of vaccines to order at a decentralized level, taking into account the quantity available in storage and the stock reserve required, in accordance with the following parameters:

Number of doses required per child (for a target population of 1 000 children)

1 000 x 2 = 2 000 doses (for schedules with 2 doses per child)

1 000 x 1 = 1 000 doses (for schedules with 1 dose per child)

Wastage rate: 15% (wastage factor: 1.18)

2 000 doses x 1.18 = 2 360 doses (for schedules with 2 doses per child)

1 000 doses x 1.18 = 1 180 doses (for schedules with 1 dose per child)

Number of doses in district/municipality (25% annual total) per supply period (3 months)

2 360 x 0.25 = 590 doses

1 180 x 0.25 = 295 doses

Vaccines in stock

The number of IPV doses needed in a district/municipality for a 3-month supply period in a country with a 2-dose IPV vaccination schedule is 590 doses. However, if the district already has 240 doses in stock, the number of IPV doses to order is only 350, adding up to the total 590 doses calculated. It is a common and costly error to order vaccines without adjusting for the amount in stock. A similar analysis should be conducted in countries that implement a single IPV dose vaccination schedule.

Reserve stock required

A 25% reserve should be added to district/municipal stocks, which would be an additional 150 doses for 2-dose vaccination schedules (25% of 590). Although 25% of 590 is actually 147.5, this value must be rounded to 150, because the number of doses needs to be a multiple of 5, following the presentation being used in this example.

Final number of vaccines to order according to this example

Two dose schedule = 350 + 150 = 500 doses

Single dose schedule = 55 + 75 = 130 doses

Population < 1 year *a*	Dose per child[1] *b*	Total number of doses per year *c = a x b*	Wastage rate (%) *d*	Wastage factor *e*	Number of doses required per year[2] *f = c x e*	Number of doses required for 3-month supply period *g = 25 % x f*	Quantity to request considering doses in stock *h = g – 240*	Doses required for reserve stock *i = 25 % x g*	Final quantity to order for a 3-month period *j = h + i*
1 000	2	2 000	15	1.18	2 360	590	350	150[3]	500
1 000	1	1 000	15	1.18	1 180	295	55	75[3]	130

[1] Varies depending on vaccination program.
[2] Including wastage rate.
[3] These values must be rounded to 150 and 75, because the number of doses needs to be a multiple of 5, following the presentation being used in this example.

Example for calculating wastage rate and wastage factor

Starting data: doses supplied: 200; doses administered: 170

$$\textbf{Wastage rate} = \frac{\text{doses supplied} - \text{doses administered}}{\text{doses supplied}} \times 100$$

$$\frac{200 - 170}{200} \times 100 = \textbf{15\%}$$

$$\textbf{Wastage factor} = \frac{100}{100 - \text{wastage rate}}$$

$$\frac{100}{100 - 15} = \textbf{1.18}$$

Wastage rate (%)	5	10	15	20	25	30	35	40	45	50
Corresponding wastage factor	1.05	1.11	1.18	1.25	1.33	1.43	1.54	1.67	1.82	2.00

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