

OPV Cessation

Protocol for a global coordinated switch from trivalent OPV to bivalent OPV

(Draft version 9 October 2014)

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Glossary

cVDPV	Circulating Vaccine Derived Polio Virus
EPI	Expanded Programme on Immunization
ICC	Inter Agency Coordination Committee
IPV	Inactivated Polio Vaccine
GPEI	Global Polio Eradication Initiative
GVD	Global Validation Day
mOPV1 or 3	Monovalent Oral Poliomyelitis Vaccine type 1 or 3
NCC	National Certification Committee
NSD	National Switch Day
NVD	National Validation Day
OPV	Oral Polio Vaccine, can be trivalent (tOPV) or bivalent (bOPV1&3)
RCC	Regional Certification Committee
RSC	Regional Switch Committees
SIA	Supplementary Immunization Activities
SM	Switch monitor
SST	Switch Support Team
VAPP	Vaccine Associated Paralytic Polio
WPV	Wild Polio Virus

Foreword

The purpose of this protocol is to explain the event titled The Switch and to help countries prepare for its implementation. The Switch refers to a globally coordinated event, likely in the first half of 2016, when all countries cease using trivalent oral polio vaccine (tOPV) and replace it with bivalent OPV (bOPV) types 1 and 3.

The objective of The Switch is to stop the emergence of circulating strains of vaccine-derived polio type 2 (cVDPV2) and Vaccine Associated Paralytic Poliomyelitis (VAPP) caused by the type 2 attenuated strain of trivalent OPV. The eventual withdrawal of type 2 is an important milestone in the endgame strategy for polio eradication that was endorsed by Member States during the Sixty fifth World Health Assembly in 2012 (see Annex).

This publication is designed to provide information, resources and tools to guide all levels of technical and non-technical staff working within the Expanded Programme of Immunization (EPI) or other relevant units within the Ministry of Health (e.g., sanitation, communication, environment) as well as relevant partner agencies and NGOs, on the implementation of The Switch. Countries are encouraged and supported to create their own country-specific work plans to anticipate logistical, communication and management challenges that may arise to ensure a smooth transition.

Additional resources and communication materials are included in the annex to help countries implement The Switch: key messages, sample stock management forms, tOPV identification stickers. More materials will be forthcoming over the coming months.

What is not in the protocol?

The topics covered in this document are restricted to the operational aspects of The Switch. Only a minimum of introductory remarks on the global context and the epidemiology of polio are included because they are considered necessary for a better understanding and correct implementation of The Switch. Please refer to the bibliography for further reading.

Issues indirectly related to The Switch, but not addressed in this document include the following:

- **Global issues of vaccine supply.** A team of experts from the United Nations Children's Fund (UNICEF), WHO, the Bill & Melinda Gates Foundation and U.S. Centers for Disease Control and Prevention is working closely with prequalified OPV manufacturers and local producers to secure adequate supplies of appropriate vaccines.
- **Containment of type 2 strains.** [Clear recommendations for containment of type 2 polioviruses \(WPV2, cVDPV2 and OPV2/Sabin2\) will be made available prior to The Switch.](#)
- **Surveillance.** Various initiatives are focused on strengthening surveillance, including environmental sampling.
- **Issues related to vaccine stockpile.** A stockpile of type 2 polio vaccine (mOPV2) is being created to address unexpected outbreaks.
- **Post-switch outbreak response.** The Global Polio Eradication Initiative has developed a separate protocol for addressing post-switch outbreak response. Please refer to the bibliography for further reading.

1 What is The Switch?

Since its launch at the Forty first World Health Assembly in 1988, the Global Polio Eradication Initiative (GPEI) has reduced the global incidence of polio by more than 99 per cent and the number of countries with endemic polio from 125 to 3. While this progress is immense, a great deal of work is still required for full eradication of the disease.

1.1 A polio endgame milestone

On 26 May 2012 the Sixty fifth World Health Assembly declared ending polio a “programmatic emergency for global public health” (WHA65/13.10). The Assembly requested that the Director General, “undertake the development, scientific vetting, and rapid finalization of a comprehensive polio eradication and endgame strategy, and inform Member States of the potential timing of **a switch from trivalent to bivalent oral poliovirus vaccine for all routine immunization programmes...**”¹

In response, the GPEI developed the Polio Eradication and Endgame Strategic Plan 2013–2018 in consultation with national health authorities, global health initiatives, scientific experts, donors and other stakeholders. The four objectives of the Endgame Strategic Plan are:

1. **Poliovirus detection and interruption.** This objective seeks to stop all wild poliovirus transmissions by the end of 2014 and any new outbreaks due to cVDPV within 120 days of confirmation of the index case.
2. **Immunization system strengthening and OPV withdrawal.** This objective targets the eventual withdrawal of all OPV beginning with the type 2 component of tOPV. More specifically, this objective involves strengthening immunization systems, introducing at least one dose of affordable inactivated polio vaccine (IPV) into the routine immunization schedule globally, and then replacing tOPV with bOPV in all OPV-using countries. The two-week window for replacing tOPV with bOPV is now referred to as the Global Switch Window.
3. **Containment and certification.** This objective focuses on disease containment and certification that transmission has been interrupted.
4. **Legacy planning.** The objective seeks to maintain a polio-free world and ensure that investments made to eradicate polio contribute to future health goals after the completion of polio eradication.

The Switch is the term used to refer to the global replacement of tOPV with bOPV in all routine immunizations and Supplementary Immunization Activities (SIAs) around the world. It represents a tremendous and coordinated global effort, as it must be completed in a two-week window. The first possible date for the Switch will be in early 2016.

1.2 Rationale

There are several reasons why The Switch is a necessary step in the polio endgame.

Wild polio virus type 2 is no longer in circulation. The last case of wild polio virus type 2 was seen in 1999, making the type 2 component of the polio vaccine unnecessary.

Bivalent OPV does not cause type 2 cVDPV or type 2 VAPP. The type 2 component of tOPV has been the leading cause of circulating Vaccine Derived Polio Viruses (cVDPVs) and remains a risk, especially in the context of sharply declining and near-interruption of transmission of wild polio virus (Table I).

¹ See Full text in Annex

Table I: Proportion of total polio cases caused by cVDPV, 2000 - 2013²

	2000-2004	2005-2009	2010-2013
Cases of polio due to WPVs	5159	8546	2641
Cases of polio due to cVDPVs	31	424	264
Total cases of polio	5190	8970	2905
Proportion due to cVDPVs	0,6%	4,7%	9,1%

Figure 1: cVDPV type 2 cases, 2011–13

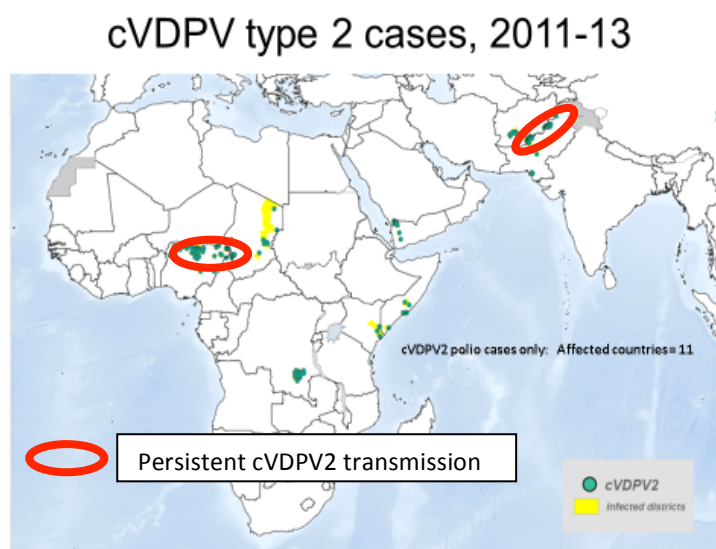
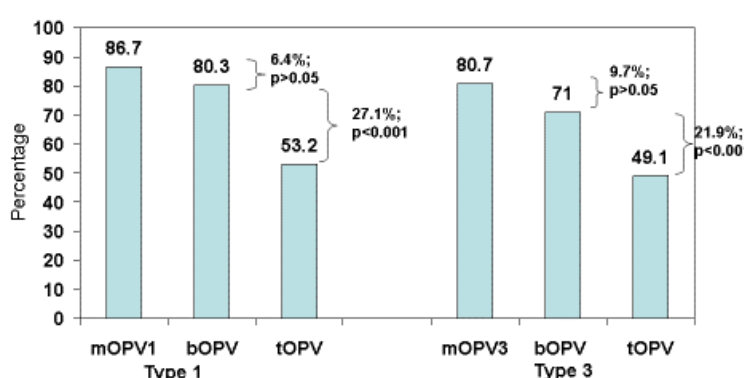


Figure 2: Seroconversion and bOPV

Seroconversion After 2nd Dose, by Study Arm, bOPV Trial, India, 2008-09



Of the 719 cases of cVDPVs reported between 2000 and 2013, type 2 cVDPVs accounted for 87% (628 cases) of the total, affecting 11 countries, including persistent transmission in Pakistan and Nigeria (Figure 1). cVDPVs associated with types 1 and 3 accounted for 11 percent (79 cases) and 2 percent (12 cases) of reported cVDPVs respectively. Of the type 1 cases, 46 were reported during a single outbreak in Indonesia in 2005.³

Another major advantage of The Switch from tOPV to bOPV is the elimination of type 2 Vaccine Associated Paralytic Polio (VAPP).

The bivalent OPV vaccine is also safe. More than 4.5 billion doses of bOPV have been given since its initial use in December 2009.

Bivalent OPV is highly effective against types 1 and 3. Bivalent OPV is more effective than trivalent OPV against polio virus 1 and 3 and only slightly less effective than monovalent OPV types 1 and 3. The advantages of bOPV were illustrated in a 2008 study conducted in India (Figure 2) which showed that a second dose of bOPV results in a seroconversion of 80.3% against type 1 polio virus, a bit lower than the 86.7% of mOPV1,⁴ but much higher than the 53.2% for tOPV. Levels of seroconversion against type 3 show similar differences. The better performance of bOPV has played a key role in the disappearance of WPV type 3, the last case of which was reported in Nigeria in November 2012.

² Numbers compiled from various WHO Global Updates

³ Updated information published on the website every week at <http://www.polioeradication.org/Dataandmonitoring/Poliothisweek.aspx>.

⁴ Sutter RW¹, John TJ, Jain H, Agarkhedkar S, Ramanan PV, Verma H, Deshpande J, Singh AP, Sreevatsava M, Malankar P, Burton A, Chatterjee A, Jafari H, Aylward RB. Immunogenicity of bivalent types 1 and 3 oral poliovirus vaccine: a randomised, double-blind, controlled trial. *Lancet*. 2010. 13;376(9753):1682-8. doi: 10.1016/S0140-6736(10)61230-5.

1.3 Risk mitigation

The epidemiology of polio requires a high level of synchronization when withdrawing the vaccine from circulation. Any country or area continuing to use tOPV after all others have switched to bOPV puts communities with sub-optimal population immunity against type 2 at risk of a cVDPV2 outbreak. This risk increases over time as population immunity against type 2 declines. To counter the emergence of cVDPV2 and the risk of the occurrence of VAPP, WHO recommends in its position paper of January 2014 (Weekly Epidemiological Record, 28 February 2014) a combination of the use of inactivated polio vaccine (IPV), improved routine immunization, and the cessation of tOPV use.

All cVDPV outbreaks have low population immunity in common. To protect communities with low population immunity, The Switch is a globally synchronized event completed within a limited time period.

Countries with low population immunity against type 2 polio virus will need to undertake risk mitigation activities consisting of additional SIA with tOPV within 6 months prior the switch. These criteria will be based on an epidemiological assessment of risk levels and recommended by the SAGE working group in November 2014.

2 Timing of The Switch

The Global Switch Window has not yet been announced. The best time for countries to make The Switch is the low season of polio virus circulation in the countries with the most recent, persistent transmission, and at least six months after the last case of cVDPV2 has been identified.

2.1 Earliest opportunity for The Switch to occur

In Pakistan and Nigeria (the last two countries with recent and persistent transmission), the final case of cVDPV2 is expected to occur in late 2014 or early 2015. Six months later, if no new cases of the same strain are detected, then transmission can be considered interrupted. At this time, the World Health Assembly will decide whether to endorse the Switch plan, in principle. In September 2015, GPEI will conduct a risk assessment to determine whether The Switch would be appropriate and feasible. Because the Switch needs to occur during the low season of polio virus circulation (January through May) and requires at least six months for preparation, the **earliest opportunity for The Switch to occur is in early 2016**.

If transmission is not successfully interrupted or if there is insufficient time to prepare, then the GPEI may decide to postpone The Switch to early 2017.

When The Switch is confirmed a “go,” GPEI will announce two dates: 1) the Switch Window: the two-week period from which countries can select a National Switch Day and 2) a Global Validation Day: the deadline for all countries to dispose of their tOPV stocks and declare themselves free of tOPV and the final date will be determined in September by the SAGE group of experts, based on a global risk assessment conducted by GPEI.

Global Switch Window: The two-week period from which all countries can select a National Switch Day.

National Switch Day: The first day that all health facilities in a country start using bOPV and begin recalling tOPV for disposal.

National Validation Day: The day a national government formally announces the absence of tOPV stocks in all public and private sector facilities.

Global Validation Day: The day WHO announces the absence of tOPV stocks globally and validates that all countries have ceased using tOPV

2.2 The Switch timeline from a country perspective

While many planning and preparatory activities need to take place before The Switch, the actual “switch period” in a country is only four weeks (**Error! Reference source not found.**).

The last supply of tOPV should be sent to service points about four weeks prior to National Switch Day based on the most recent inventories collected. The supply to service points should include a 1-week buffer to ensure no child remains unimmunized.

Two weeks prior to National

Switch Day: Service points are gradually stocked with a 3-month supply of bOPV. However, tOPV is used for vaccination. This is the only period that tOPV (for vaccination in that period) and bOPV (for vaccination after National Switch Day) will both be in the 2 to 8°C cold chain.

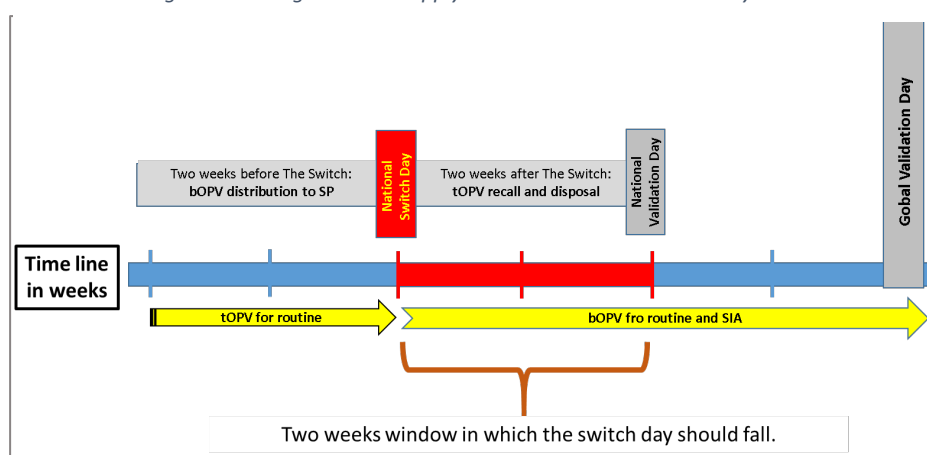
National Switch Day: Service providers stop using tOPV and start vaccinating with bOPV (in both routine and campaigns). Service providers **immediately** remove tOPV from the cold chain and mark vials with the appropriate stickers.

Two weeks following National Switch Day: All tOPV is shipped to prepared disposal sites and safely disposed. Based on the assessments completed by independent monitors, national authorities declare the country free of tOPV stocks (National Validation Day).

Distributing bOPV to service points two weeks prior to the National Switch Day will help ensure a smooth transition. However, it is imperative to avoid the simultaneous use of tOPV and bOPV during this period.

Though the total time required to implement The Switch at the country level is four weeks, the flexible switch window means it can take up to six weeks to complete The Switch at the global level.

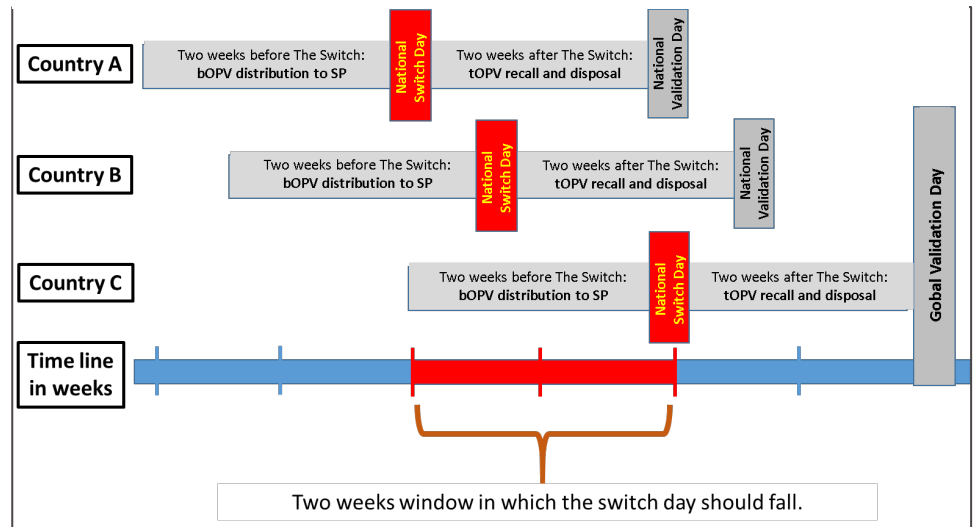
Figure 3: Timing and OPV supply around The Switch at country level



The scenario below (**Error! Reference source not found.**) shows the implication of different country choices on the global duration of The Switch process.

- Country A wants to switch the first day of the Global Switch Window. To do so, country A begins distributing bOPV to service points two weeks prior to National Switch Day.

Figure 4 : Switch timeline for three countries



- Country B starts somewhere within the two week switch window.
- Country C switches the last day of the window and completes recall and disposal two weeks after country A.
- All three countries make their declaration at the National Validation Day, after recall and disposal, but before the Global Validation Day, the deadline of the whole process.

3 Global level preparation

The Switch is a highly sensitive event, requiring near perfect synchronization and implementation. It may attract a good amount of attention from the media. To successfully prepare for The Switch, a number of activities have been coordinated at the global level.

- Completion of a comprehensive research agenda to provide a solid scientific basis for The Switch
- Involvement of vaccine manufacturers and concerned NRAs to make sure bOPV is licensed/registered and available at the right time
- Consultation with vaccine manufacturers about strategies and vaccine presentations to reduce wastage
- Development and dissemination of communication materials
- Development of specific information for countries not procuring their tOPV through UNICEF
- Implementation of a major advocacy initiative to establish global consensus about the event itself as well as the timing
- Endorsement of the initiative by WHO member states through a World Health Assembly resolution

In addition, monitoring systems are being put in place at global, regional and country levels to:

- Monitor progress in countries using a set of pre-established indicators (e.g. timely arrival of vaccine and funds, etc.). (See Annex for sample monitoring tool: Indicators for global monitoring)
- Define thresholds that trigger corrective action
- Develop guidance in case of sporadic continued use of tOPV
- Develop a mechanism for reporting and exchanging information both within countries and between WHO offices at national and global levels.
- Develop contingency plans
- Respond to media enquiries

4 National level preparation

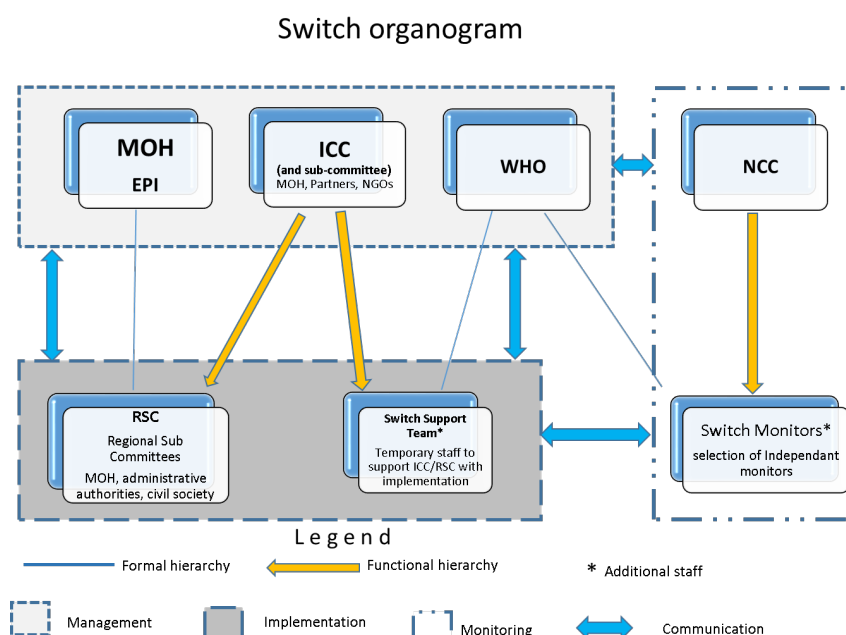
Preparation for The Switch at the national level can and should begin about a year prior to the switch. This section elaborates a number of important decisions and preparatory activities that countries can undertake well before a go/no go decision from GPEI.

The Organizational Chart in Figure 5 provides a big-picture overview of the four critical areas of work, the bodies in charge of each area, and how they relate to one another.

1. **Management:** overall coordination occurs at the national level where The Switch is endorsed and where the conditions are created for the implementation
2. **Communication:** Given the tremendous importance and the cross cutting character of communication, it is presented as a series of lines that link critical areas to one another.
3. **Implementation:** Under the leadership of the Inter Agency Coordination Committee (ICC), regional sub-committees (RSCs) and switch support teams work “on the ground” to ensure that all logistics, communications, deliveries, recall, and disposal procedures go according to plan.
4. **Monitoring:** Independent monitoring is led by the National Certification Committee and involves verification that tOPV is completely and safely disposed at all levels.

Two entities (ICC and RSCs) are composed of existing members who are requested to take on new roles related to The Switch. Two other bodies (Switch Support Teams and Switch Monitors) are made up of new staff, recruited by WHO Country Offices for the purpose of The Switch.

Figure 5: Organizational chart for The Switch at country level



4.1 National Switch Plan

Although all countries will be implementing The Switch during the same time window, every country has unique circumstances that will require customized work plans and timelines. A National Switch Plan details the various aspects of The Switch as it will be implemented within a country. The plan should summarize many of the activities described in this protocol and should be adapted to national circumstances and constraints.

Because countries will have only about six months to prepare for the Switch after the global decision is made and because some elements require a longer period of preparation, WHO recommends countries begin developing the National Switch Plan about a year ahead of The Switch. This is particularly important to ensure timely ordering of the appropriate quantities of vaccine, address any required legal and/or regulatory changes, prepare communication materials, etc.

The following outline may be used as a guide to create a customized National Switch Plan.

General context

- Short background on polio eradication in the country
- Key partners
- Organizational Chart of the MOH and EPI
- Description of EPI: vaccination schedule, etc.
- Private sector provision of tOPV (if applicable)
- Date selected for National Switch Day

Management bodies

- Organizational chart
- Description of roles and responsibilities
 - ICC
 - Regional switch committees
 - Switch support team
- Information flow: who informs who and at what frequency
- Managerial work plan and timeline
- Contingency plan

Communication

- Organizational chart
- Communications work plan and timeline
 - Key messages relating specifically to the country
 - Materials
 - Media strategy
 - Crisis management plan

Logistics

- Organizational chart
- Logistics work plan and timeline
 - Vaccine ordering procedures and timeline
 - Regulatory approvals required for bOPV
 - Cold chain requirements for both tOPV and bOPV
 - Training required at various levels
 - List of stationary and forms affected by The Switch
 - Estimated inventories of tOPV at time of The Switch
 - Distribution plan for bOPV (including private sector if applicable)
 - Recall plan for tOPV (including private sector if applicable)
 - Sites selected for disposal
 - Disposal procedures
- Contingency plans for all elements of the logistics plan

Monitoring

- Organizational Chart
- Monitoring work plan and timeline
 - Training of SM
 - Information flow
 - Data collection and analysis
- Validation system

Please refer to the annex for a sample work plan that links detailed activities to a calendar-based timeline.

4.2 Management

The Switch is an important and complex event that requires good management and dedicated staff. This section describes the people and entities that should be put in charge of implementation.

4.2.1 Inter Agency Coordination Committee

A year in advance of The Switch, the MOH should invite the Inter Agency Coordination Committee (ICC) or a similar body to oversee all activities relating to The Switch (including, in high-risk countries, the SIA that will be conducted in advance of The Switch).

The ICC must be given the authority to advise the Minister of Health to declare the country free of tOPV or to do so itself.

The ICC should be composed of high-level staff from the MOH (EPI and others), other ministries (communication, transport, sanitation, etc.), central medical stores/national cold stores, key relevant donors, partners and major NGOs. Primary responsibilities of the ICC are listed in Table II.

For day-to-day implementation, monitoring and oversight at national level, the ICC may form an ICC sub-committee consisting of focal points from the MOH and the agencies. The ICC sub-committee's role is to put ICC decisions into practice and form a bridge between the ICC and the other structures involved in The Switch.

In the very early phases of preparation for The Switch, it is the ICC sub-committee's responsibility to elaborate the National Switch Plan, ensure that vaccine orders are placed and communication materials developed.

Members		Responsibility	Meeting Frequency
Inter Agency Coordination Committee (ICC)	<ul style="list-style-type: none">- Presided by high-level staff from the Ministry of health, the ICC should be composed of high-level staff from MOH and other ministries (communication, sanitation, etc.), partners, and major NGOs.- At least one SST member (see below) should be invited to the ICC to ensure adequate information flow between the planning and implementation levels.	<ul style="list-style-type: none">- Elaborate the national switch plan with clear functions, responsibilities and deadlines- Establish an operations room for coordination, information and communication- Take final responsibility for implementation- Report to higher authorities- Communicate with partners and the press- Monitor progress (dashboard with key indicators: vaccine ordered and supplied, funds arrived, etc., see Annex)- Take corrective action when needed	With increasing frequency from monthly in the early phase to daily during The Switch.

Table II: Membership and responsibilities of the ICC

4.2.2 Regional Switch Committees (RSCs)

At regional and district level The Switch should be implemented by the same Regional Committees that coordinate the local implementation of SIAs. For this purpose they could be renamed Regional (and District) Switch Committees (RSC). Membership and responsibilities for the RSCs are elaborated in Table III.

Table III: Membership and responsibilities of the Regional Switch Committees

Members		Responsibility	Meeting Frequency
Regional Switch Committees (RSC)	<ul style="list-style-type: none">- Presided by staff selected by the ICC, Regional Committees should consist of technical staff directly involved in implementation.- At minimum RSC's should include local authorities, core EPI staff (e.g., EPI focal point, logistician) and the person in charge of communication.- Depending on the local conditions, people with contacts with nomadic groups or special populations may be indispensable.	<ul style="list-style-type: none">- Elaborate work plans for all levels- Provide support to ensure timely arrival of funds, vaccine, etc.- Provide support to ensure involvement of anybody directly or indirectly relevant for The Switch (traditional healers, private clinics,⁵ religious groups, women associations, community leaders, etc.)- Organize training on The Switch- Address tasks that may contribute to a smoother Switch- Prepare a weekly report to the ICC- Collaborate closely with Switch Support Teams (see below)	With increasing frequency: monthly in the early phase, weekly from about 4 weeks prior to the Switch, daily during The Switch period

Countries that do not already have regional committees should establish them and select staff directly involved in field implementation: EPI focal point, logistician, administrator, social mobilization, civil society, traditional leaders, and anybody whose presence is indispensable for a successful switch.

4.2.3 Switch Support Team (SST)

Once the global decision is made to go ahead with the Switch, WHO Country Offices (and partners) will be asked to establish a Switch Support Team (SST) to help national authorities cope with the expected increase in workload. SSTs should be made up of local consultants with strong written and oral communications skills and who are able to interact with central authorities as well as community members.

As described in table Table IV, SST members will initially assist the MOH at national level, and then direct their energies toward regional and district levels during the preparation and implementation phases of The Switch. The terms of reference for SST members is elaborated below (see Table IV); however, their primary activities can be summarized as follows:

1. Maintain reliable inventories of tOPV at regional, district and service point levels using a questionnaire on vaccine stock management (see the Questionnaire vaccine management in the annex).

⁵ In case a large portion of the private sector is involved in vaccination, it may be worthwhile to set up a special sub-committee to develop adapted plans for the private sector, particularly dealing with logistics and communication.

2. Support good vaccine management by submitting completed questionnaires in a timely manner to the central level.
3. Assist with the actual switch in all relevant domains: logistics, social mobilization, training, etc.

Table IV: Timeline of key activities for Switch Support Teams (SST)

6 months before The Switch National and Regional level	2 months before The Switch District level	During the campaign District level	After The Switch District, regional and national level
<p>National level:</p> <ul style="list-style-type: none"> - Co-organize with the ICC a full day meeting with regional health staff and administrative authorities to explain The Switch. - Help compile stock inventories. - Participate in ICC meetings. - Ensure adequate information flow between national and regional levels. <p>Regional level (visits to all districts in a region):</p> <ul style="list-style-type: none"> - Organize a half-day meeting with local health staff and administrative authorities to explain The Switch. - Make a tentative inventory of tOPV stocks. - Make an estimate of monthly consumption. - On that basis, estimate remaining tOPV requirements (plus a margin of two weeks), and bOPV requirements for the first three months after The Switch. - Share the data with the EPI focal point and UNICEF. - Discuss stock management procedures with the EPI focal point and stock manager using a simple checklist.⁶ 	<p>Co-organize with the ICC sub-committee and the RSC an information meeting with all service providers. Service providers should be asked to bring their vaccine stock records.</p> <p>Visit all districts as well as an agreed proportion of immunization service points to:</p> <ol style="list-style-type: none"> 1. Ensure the district and service points are aware of The Switch and have the necessary communication materials. 2. Ensure the district received the necessary stationary for bOPV. 3. Confirm that all service providers including private clinics or whoever else might give polio vaccine have been informed about and are prepared for The Switch. 4. Refine the OPV inventory and share inventory data with the EPI focal point and UNICEF. 5. Ensure districts storage capacity is sufficient when both products are present and adequate steps are taken when it is not. 6. Discuss stock management procedures with the EPI focal point and stock manager using a simple checklist. 	<ul style="list-style-type: none"> - Same activities as before, but focused on risk areas. - Ensure availability of enough vaccine carriers on the day of The Switch. - Confirm disposal sites are ready. - Ensure availability of updated stationary and forms. - Inform higher-level officials of anything that could derail The Switch. 	<ul style="list-style-type: none"> - Visit an agreed proportion of service points to confirm the absence of tOPV. - Assist at district level to ensure all tOPV (routine and SIA) is sent back to regional level within 6 days. - Make a simple report on The Switch at district level and share the report with superiors. - Move to the regional level and support all activities related to the recall.

The number of members on the SST can evolve during the process. Fewer members will be required in the early stages when the work is predominantly at the central and regional levels. More members will be required in the period two months prior to The Switch when district level activities become predominant.

⁶ See Questionnaire vaccine management in the Annex

4.2.4 Suggested timeline for establishing management bodies

Table V below summarises the main bodies involved in The Switch, when they should be in place and what they should consider their main tasks (for a complete detailed time table see the annex).

Table V: Teams involved in Switch preparation and implementation

Timing	Which teams	Main tasks
12 months prior to The Switch	<ul style="list-style-type: none"> • Assign responsibility for general oversight to the ICC or comparable body • Select ICC sub-committee 	<ul style="list-style-type: none"> • Elaborate a National Switch Plan • Develop an initial vaccine management plan • Place vaccine orders • Develop a communication plan
6 months prior to The Switch	<ul style="list-style-type: none"> • Assign responsibility for implementation to existing regional EPI/SIA committees or comparable bodies. Rename these groups, Regional Switch Committees (RSC). • Select Switch Support Teams to assist with all aspects of implementation 	<ul style="list-style-type: none"> • Maintain up-to-date vaccine inventories • Develop new forms and stationary • Train health and logistics staff • Implement communications plan • Address other tasks necessary for the preparation of The Switch
1 month prior to National Switch Day	<ul style="list-style-type: none"> • Select Switch Monitors 	<ul style="list-style-type: none"> • Monitor the completeness of tOPV replacement

4.3 Communications

WHO headquarters is developing a comprehensive communication plan in Q3 2014 to help ensure that all necessary materials and messaging to support The Switch are available by the time of the expected global decision in September 2015. The communications plan will be used to guide global and country communication efforts, support consistent messaging and assist immunization partners and stakeholders in understanding and implementing The Switch.

At the country level, communications efforts will focus on the following stakeholder groups:

- National officials, technical advisors, EPI staff, and implementation partners
- Health workers and other healthcare delivery staff
- Paediatricians, community leaders, traditional leaders, and informed members of the public, including caregivers

4.3.1 Proposed materials and resources

To help countries manage the accelerated timelines, WHO HQ will be creating generic materials and making them available to countries for local adaptation, as needed:

- Briefing notes
- PowerPoint slides to facilitate awareness and communication among decision makers
- Frequently Asked Questions (FAQs)
- A template to assist in the development of national communication plans, including guidance on media relations, crisis management, and broader stakeholder engagement
- A health worker information pack including a PowerPoint overview with key messages, FAQs, guidelines on collection and disposal of tOPV and data recording, and a job aid to support recall
- Updated web content

These materials can be found on the WHO web site focused on IPV introduction, OPV withdrawal and routine immunization strengthening:

http://www.who.int/immunization/diseases/poliomyelitis/inactivated_polio_vaccine/en/

4.3.2 Proposed key messages

It is important that stakeholders and participants understand exactly why The Switch is a necessary and important step in the polio elimination endgame. Anticipating potential areas of confusion and misunderstanding well in advance will help facilitate management of The Switch and reduce potential problems. See the Annex for draft messaging that may be adapted to the local context.

4.3.3 Timeline for communications support

Following is a draft timeline of subsequent steps for communications:

- Q3 2014: Development of detailed communication plan
- Q4 2014 to Q2 2015: Development and finalization of all core materials and messaging, in consultation with regions and key countries
- September 2015 (following announcement): Dissemination of full communication pack to regions and countries
- From October 2015: follow up and any communications technical support for countries to assist in adaptation of messaging and materials, as well as to capture and document any relevant learning

4.4 Logistics

The logistical implications of The Switch are significant. Below is a description of some of the major logistical issues that must be addressed prior to and during The Switch.

4.4.1 Ordering vaccine for 2015 and 2016

In anticipation of a possible Switch date in early 2016, all countries that procure vaccines on a yearly basis are encouraged to break-up their 2015 order for tOPV into multiple parts:

1. An initial order of tOPV covering the period until the global decision is taken in September 2015.
2. A second three-month supply (plus two week buffer) of tOPV covering the last 3 months before The Switch
3. A final three-month supply of bOPV for the first three months after The Switch

Reducing the orders to cover periods shorter than 3 months would be counterproductive, as it would multiply the number of orders and increase transportation costs.

After The Switch is announced, individual countries should regularly calculate tOPV inventories (at both public and private sector facilities). Up-to-date inventories are critical to a successful Switch, as they allow countries to:

- Adjust the size of the last tOPV order and limit leftover vaccine that will have to be disposed
- Remain flexible in case the decision is made to postpone The Switch
- Share plans with vaccine suppliers to reduce the risk of shortages
- Anticipate required and available storage capacity before and after The Switch

SAMPLE PLAN: The following sample plan is based on a hypothetical country that orders vaccine on a yearly basis. It applies to both self-procuring countries and countries that purchase vaccines through UNICEF. Should UNICEF set up special procedures, those procedures will take priority over the ones described here.

In preparation for a possible Switch, the country breaks up its yearly order of OPV for routine immunization into three parts:

12 months before The Switch (Q1 2015)

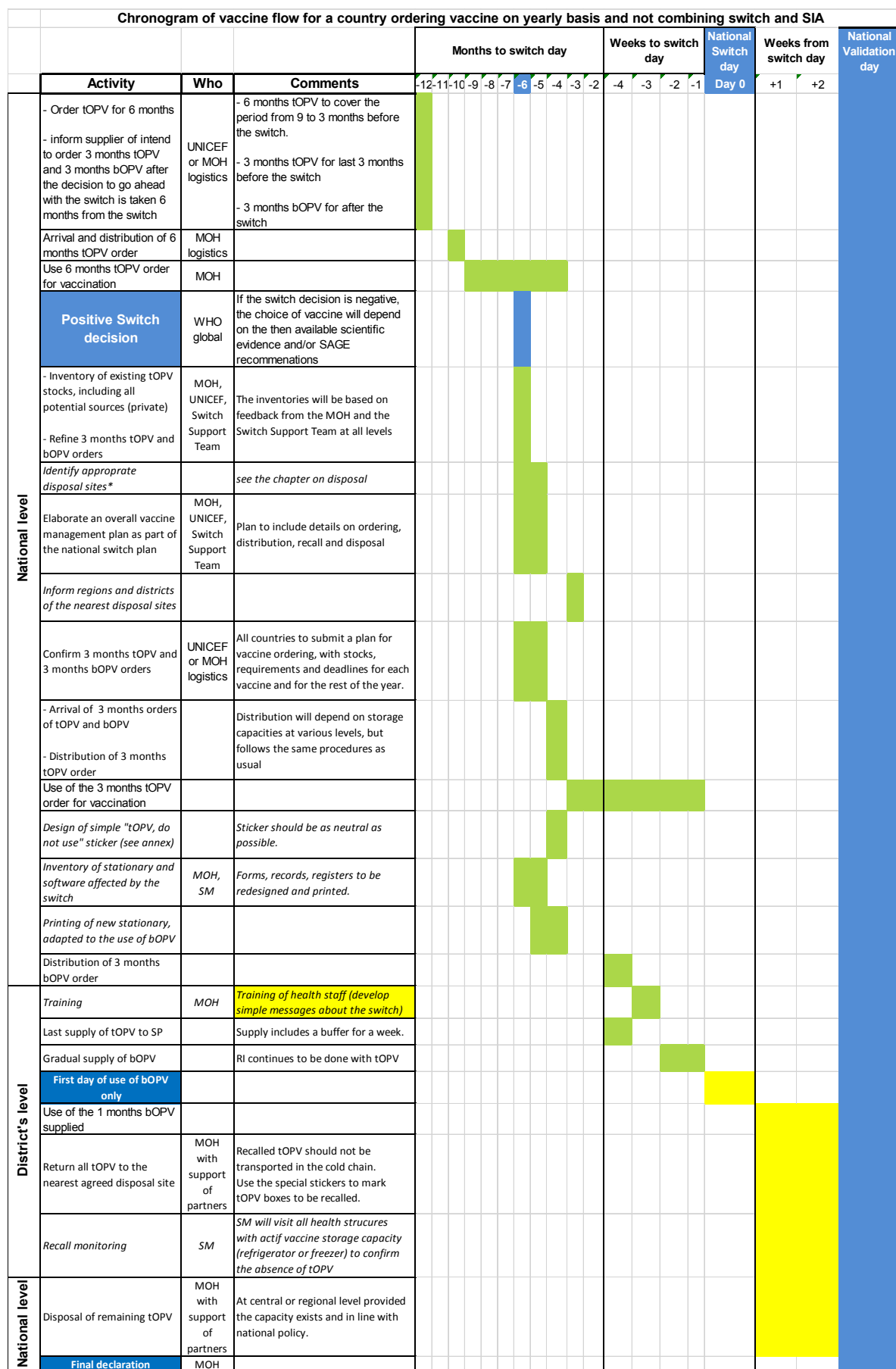
- Country places an order of tOPV for 6 months of use to cover the period from nine to three months before The Switch.
- Country informs UNICEF or its supplier of the intent to place (1) a three-month (plus two week buffer) order of tOPV to cover the three months before The Switch and (2) a three-month order of bOPV to cover the first three months after The Switch.

6 months before The Switch (Q3 2015)

- If the announcement is made to go ahead with The Switch, the country confirms the three-month orders of tOPV and bOPV with UNICEF or its supplier. Based on recent inventories collected by MOH and SST at regional and district levels as well as from private sector providers, the country may also refine its 3-month orders of tOPV and bOPV. Doing the inventory much earlier risks a lack of precision.
- If the decision is made to postpone The Switch, the country will follow the advice by WHO/SAGE.

Vaccine to be used for routine immunization should arrive in the country at least four weeks before it is needed to allow for enough time for distribution to regional and districts levels. See Figure 6 for a sample timeline that shows the flow of vaccine from the day it is ordered to the day it is used or disposed.

Figure 6: Work plan showing the flow of vaccine from time of order to final use or disposal



4.4.2 Securing regulatory approvals

Each country must examine the regulatory implications of introducing bOPV into routine immunization. The current recommendation for bOPV use has thus far been limited to mass campaigns or outbreak response while tOPV remains the vaccine of choice for routine immunization. Before The Switch, bOPV must be licensed/registered in all countries intending to use it for routine immunization. The label change to extend the indication of bOPV from SIA to a use in all routine vaccination programmes has regulatory implications. This requires a variation to the license file that must be approved by National Regulatory Authorities of the countries where the vaccine is produced and where the vaccine will be used. In several countries, at least one dose of IPV will be introduced prior to The Switch from tOPV to bOPV. This IPV use will also have regulatory implications. An accelerated procedure to jointly review registration of both products is currently being organized to meet the timeline for The Switch.

In undertaking regulatory issues, note that bOPV has the same characteristics as tOPV in terms of volume, heat sensitivity, VVM, and wastage, provided the same vial size is used.

4.4.3 Anticipating issues in self-procuring countries

Countries that are self-procuring may have specific procurement laws and timelines that could reduce their ability to accommodate changes in supply requirements. In addition, budget planning for 2015–2016 procurement may have already begun in some countries. Suggested activities that may be conducted and planned within national procurement procedures are listed below.

- Map out the procurement laws and budget planning timelines for 2015–2016 procurement, tender processes (annual tender vs. more frequent tenders), delivery schedules (annual deliveries vs. staggered deliveries), and feasibility of changes in supply after contracts are established with suppliers.
- Develop a procurement plan for 2015–2016 taking into account possible volume and product requirements for tOPV and bOPV.
- Discuss procurement issues relating to The Switch with relevant MOH/MOF officials and staff as early as possible and before launching any tenders with the relevant national agency that regulates vaccine procurement. Advocate for any potential modifications in tender timelines, how contracts are established with suppliers, and/or frequency of deliveries made during this period to minimize risks.
- Engage in appropriate planning and negotiations with suppliers on potential changes in product requirements once The Switch is confirmed (for countries with annual tenders only.)

Self-procuring countries that expect to face challenges are encouraged to reach out to UNICEF and WHO colleagues to facilitate access to the appropriate supply and/or receive technical support.

4.4.4 Coordinating with private sector providers of OPV

Most of this document addresses The Switch from the point of view of vaccination as a public service, which is close to the reality in most, if not all, tier one countries.

However, if tOPV is given through the private sector, a number of issues need to be addressed:

- Special legislation may be needed to ensure that private sector providers 1) fully cooperate with The Switch, 2) report all tOPV stock and inventory to the MOH, 3) are willing to exchange tOPV stocks for bOPV at no additional cost to the provider.

- Based on national legislation, arrangements must be made for expenses suffered by the private sector due to the withdrawal of tOPV. The simplest and least sensitive option may be to replace their tOPV with bOPV.
- Communication messages must be adapted to the private sector to ensure their buy-in and full cooperation.
- Stock inventories must include the private sector.
- The operational plan from collection to disposal of tOPV should include the private sector.

4.4.5 Calculating cold chain capacity

For a two-week period prior to National Switch Days, both bOPV and tOPV will be together in the vaccine cold chain (possibly longer at major storage points). Up-to-date vaccine inventories may be used to develop an overall plan for ordering, storing and distributing vaccine at each level in the cold chain so as not to overwhelm existing capacity.

Cold chain capacity issues during The Switch will be short-term in nature, and for this reason renewal of equipment will likely be unnecessary. The following steps may offer sufficient relief:

- Increase the frequency of deliveries and reduce the size of each shipment.
- Make best use of existing vaccine cold chain capacity by removing diluents that do not require refrigeration, expired products, and products not related to vaccination.
- Minimizing excessive cold water storage and limit suboptimal use refrigerators and freezers.
- Repair equipment with minor defaults.
- Reallocate equipment to ensure that each service point has adequate storage capacity.

4.4.6 Training health staff (including private providers, if necessary)

WHO is developing generic training and communication materials for health staff for adaptation in countries. These materials will include a thorough explanation of the necessity for The Switch and the integral role that health workers will play in its success (see Annex for a sample memo that can be adapted to individual country contexts: “Key messages to be issued to health staff”).

Because health staff will likely be confronted with many questions regarding The Switch, they should also be prepared to offer answers to basic questions. Training activities should address both the rationale and the practical implications of The Switch:

- A general overview of the background and rationale for The Switch
 - Status of GPEI
 - Disappearance of wild type 2
 - Risk of cVDPV2
 - Rationale for switching to bOPV
 - Why SIAs with tOPV are necessary prior to the switch (if applicable)
- Practical implications of The Switch on their work:
 - When to start using bOPV and stop using tOPV (National Switch Day)
 - How to make best use of storage capacity in the weeks prior to The Switch when both tOPV and bOPV require cold chain space
 - Strategies to ensure bOPV is not used prior to The Switch and tOPV is not used after The Switch
 - Procedure for handling tOPV after the National Switch Day (i.e., remove from cold chain, mark with sticker, send to nearest disposal site)

4.4.7 Updating forms and stationary

Replacing tOPV with bOPV requires changes to many forms and stationary, including, but not limited to the following:

- The basic vaccination card
- Other health cards
- Stock records
- Tally sheets

All relevant forms and records (including computer databases and software programs) should be identified, modified and re-printed at a national level early enough to ensure availability at all levels prior to The Switch. Particular attention should be paid to the consistency of the interrelationships between various forms (see the forms in the annex as examples).

4.4.8 Recalling and disposing tOPV

Although OPV is the most heat sensitive vaccine and OPV viruses are rapidly killed when taken out of the cold chain, remaining stocks will need to be managed carefully to ensure that type 2 vaccine viruses do not survive. For this reason, national recall and disposal procedures may differ from those of other vaccines that have expired or been damaged.

It is unnecessary to reclassify tOPV (e.g., in terms of medical waste or bio hazardous materials) after The Switch.

4.4.8.1 Recalling tOPV vaccine on National Switch Day

Recall procedures should begin on National Switch Day and include the following three steps:

1. Immediately remove all opened and unopened tOPV vials from the cold chain.
2. Place tOPV vials in a bag or container and label it as waste.
3. Send it to the appropriate disposal facility as instructed by the district or provincial switch committee.

Recalled tOPV should not be kept in the cold chain for two reasons: 1) it will be destroyed and should not use up cold chain storage space, and 2) the longer it is out of the cold chain, the more rapidly it will lose its potency.

4.4.8.2 Estimating disposal volume

WHO developed a simple calculator for estimating total disposal volume based on the assumptions outlined in Table VI:

Total population (in millions) x 10 = approximate disposal volume (in liters) per week

Table VI: Estimated volume of tOPV per million inhabitants

Average OPV doses per million inhabitants	Volume per dose of tOPV in cc (20 dose vial including	Total volume of tOPV per million inhabitants in liters	Assuming vials are half-filled on average, volume is doubled	Total volume of tOPV per million inhabitants per week in liters
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	packaging)			
170 000	1.5	255	2	10

If tOPV deliveries are carefully monitored in the months prior National Switch Day, most countries will have a minimum of a few days and a maximum of two weeks of remaining tOPV in stock at each service point.

A country with a total population of 10 million would therefore need to dispose of approximately 100 to 200 liters of vaccine after The Switch. This amount is expected to be within country management capacity.

4.4.8.3 *Selecting disposal sites*

At its earliest opportunity, the MOH should select appropriate sites for the disposal of remaining tOPV.

WHO recommends that safe collection and disposal points be established in convenient locations at the provincial or national level, however, in certain circumstances if this is not feasible, local disposal is acceptable provided monitoring and certification activities are carried out in these areas.

Selection criteria for disposal sites should include:

- Presence of the right staff, equipment and facilities to safely dispose of the tOPV (see preferred methods of disposal below)
- Availability and accessibility of the site during the two weeks after National Switch Day
- Accessibility of the site for monitoring purposes
- Current readiness of the site, or ability and ease of preparing the site
- Reliability of the site, including cleanliness and quality of general management

4.4.8.4 *Preferred methods of disposal*

There are several ways to dispose of unused tOPV vials.^{7,8} WHO considers some options for disposal better than others depending on national and regional capacity. The best options are listed first for each method:

1. **Encapsulation and disposal in a landfill (sanitary landfill preferred):** Encapsulation involves immobilizing the vials in a solid block within a container (e.g., plastic or steel drum) that has not previously contained hazardous materials. Containers can be filled to ¾ of their capacity with vaccine vials and the remaining space capacity can be filled with cement or sand. Once the drums or containers are full and sealed they should be placed at the bottom of a landfill and covered with other waste or soil. Sanitary landfills are recommended over municipal landfills.
2. **Direct disposal in an engineered landfill:** In some areas, it may be necessary to dispose waste directly into a land disposal site without prior treatment or preparation. Engineered landfills are preferred over open and uncontrolled dumps.
 - a. If disposal in an open and uncontrolled dump is the only available option for disposal, then waste should be encapsulated before it is disposed in the dump.
 - b. If encapsulation is not possible in an open and uncontrolled dump, then incineration or chemical inactivation is recommended.
3. **Incineration:** Incineration can be an option in countries with access to high or medium-temperature incinerators.

⁷ Guidelines for Safe disposal of Unwanted Pharmaceuticals in and after Emergencies, WHO 1999

⁸ Safe management of wastages from health-care activities, WHO 2013

- a. High temperature incineration: If available, incineration in a high-temperature, dual-chamber incinerator that meets emission standards is an excellent disposal option. Industries such as cement kilns or foundries usually have furnaces that operate at temperatures well in excess of 850 degrees and that disperse exhaust gases via tall chimneys and can be a good alternative for high temperature incineration.
 - b. Medium temperature incineration: Most countries lack access to high-temperature incinerators and can use medium temperature incinerators as an alternative. Medium temperature incinerators operate at a minimum temperature of 850 degrees and are a good alternative to direct disposal in open, uncontrolled dump.
 - c. Burning in open containers or open pits: Burning waste in open containers or pits is not recommended as a method of disposal for tOPV, even in small quantities. Instead, vials should be sent to a higher level for proper disposal.
4. **Chemical inactivation:** Chemical inactivation involves the immersion of open vials into 10 times their volume of 1% hypochlorite (e.g., bleach) solution for at least 10 minutes. The liquid solution can be then disposed of normally. This option is not recommended as it poses some logistical challenges, such as the need to open all vials to inactivate them.

4.5 Monitoring and validation

All countries going through The Switch must develop an independent monitoring plan as part of the national switch plan and in coordination with the local WHO and/or UNICEF office.

In addition, countries must establish a validation system to confirm the absence of any tOPV stock and make their findings credible to the global community.

4.5.1 Monitoring and the role of Switch Monitors (SM)

In low-risk countries, monitoring may be conducted by national staff according to guidelines set out in the monitoring section of the National Switch Plan.

High-risk (tier one and two) countries are required to use independent Switch Monitors. In these countries, WHO Country Offices will be responsible for selecting and training Switch Monitors at the national and regional levels three weeks prior to The Switch. Selection procedures could be similar to those used to select Independent Monitors during SIA. At a minimum, switch monitors must be literate, independent from the MOH, and trustworthy. Because the National Certification Committee already has a reputation for independence, competence and respectability, it may be the appropriate body to take functional responsibility for supervising switch monitors.

The main task of the Switch Monitor is to visit all districts and service points with active cold storage (i.e., refrigerators and cold rooms) after The Switch and confirm the absence of tOPV.

Primary responsibilities of Switch Monitors:

- Work under supervision of NCC, but in collaboration with the MOH at regional and district levels for a period of 14 days after National Switch Day.
- Visit an agreed number of service points to confirm the absence of tOPV. Or, if tOPV is found, follow the national protocol for collection and disposal: collect and pack the vaccine, put a tOPV sticker on the packaging, have the service provider sign a report, and bring the tOPV back to the district.
- Debrief at district level where the assessment was made.
- Communicate the outcome of each visit and the absence or presence of tOPV to the ICC in a timely manner.
- Give the ICC the information necessary to determine whether an affirmative validation statement can be made.
- Oversee and certify the disposal of remaining tOPV. A monitoring and supervision form has been produced and can be found in the Annex.

4.5.2 Validation

All countries should establish a credible system for validating the successful completion of The Switch. A well-functioning system should be able to:

- Report the most recent tOPV stock inventories at each tOPV storing facility, including private facilities.
- Confirm the availability updated forms and stationary at all service points.
- List all national, regional and district stores and service points with an active cold chain that have been visited by a Switch Monitor (in tier one and two countries) or monitoring staff (in other countries) to confirm the absence of tOPV or (if found) dispose of it according to national guidelines.
- Compile all daily reports sent from Switch Monitors to the National Certification Committee into a single document with data analysis.

- Produce a statement from appropriate national authorities and partners confirming the absence of tOPV anywhere in the country.

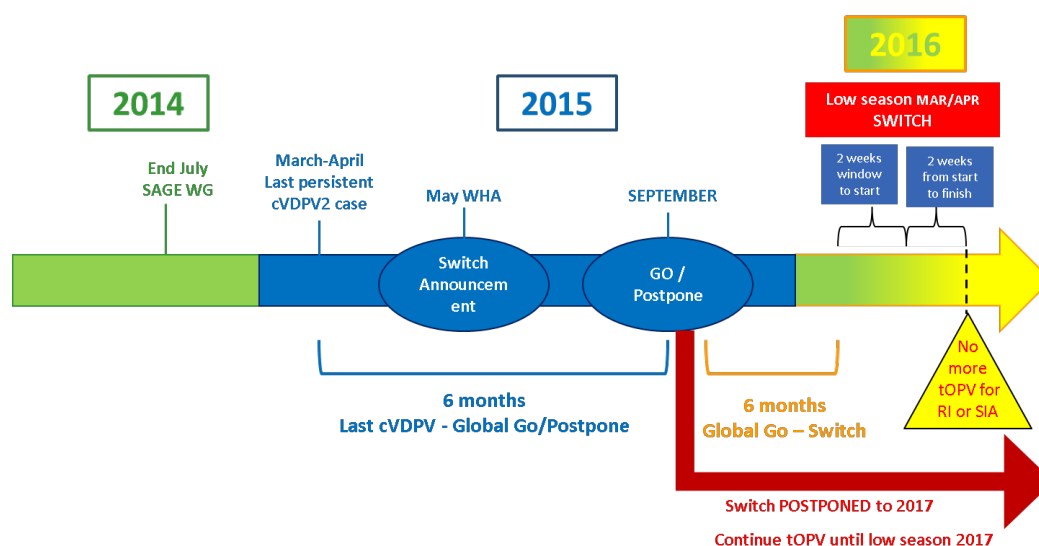
Validation guidelines and sample forms are provided in the Annex.

Note: the validation system described here only concerns the presence of tOPV vaccine anywhere in the country. It is not associated with the presence or absence of live polio virus in laboratories or vaccine manufacturing facilities. The latter is the subject of certification, which includes validation of the absence of tOPV stocks, but also addresses a much wider spectrum of activities.

5 Ten points to remember about The Switch

1. The Switch is the **replacement of trivalent Oral Polio Vaccine (tOPV with types 1, 2 and 3) by bivalent OPV (types 1&3) in routine immunization and Supplementary Immunization Activities (SIA)**. It will take place during the period coinciding with the low transmission season of polio in high-risk countries, at least 6 months after the last case of the outbreaks of persistent circulating Vaccine Derived Polio Virus type 2 (cVDPV2). The first opportunity is early 2016.
2. The **objective of The Switch** is to stop the **emergence of cVDPV2 and Vaccine Associated Paralytic Poliomyelitis (VAPP)**, caused by the type 2 attenuated strain of trivalent OPV. The eventual withdrawal of type 2 is part of the global end game strategy of polio eradication that was endorsed by the member states in resolution **WHA 65.5 in 2012**.
3. Countries will have a window of **2 weeks** in which to choose a day to do The Switch. This Switch day is the first day **tOPV is banned** and **bOPV** will be used in **routine as well as SIA**.
4. After The Switch **manufacturers will no longer supply tOPV**. There will be **an emergency stock of type 2 OPV**.
5. Before The Switch, bOPV must be **licensed/registered** in all countries intending to use it for routine immunization.
6. Timely **budgeting and ordering of vaccines** is key for a successful switch.
7. **Clear and timely information** should be disseminated to all stakeholders, the public in particular, to ensure a good understanding of the rationale of The Switch.
8. The general oversight of The Switch should lie with the **Inter Agency Coordination Committee (ICC)**, or a similar existing body. The ICC will be assisted by a **Switch Support Team** to monitor inventories of tOPV and operationalize the recall of tOPV after The Switch.
9. In higher-risk countries, **Independent Switch Monitors** will make an evaluation after the National Switch Day and the recall period to confirm the absence of all tOPV stocks.
10. Recalled tOPV **should not be stored or transported in the cold chain** as it will be destroyed.

Figure 7: Switch timeline with key events



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Agenda item 13.10 26 May 2012

Poliomyelitis: intensification of the global eradication initiative

The Sixty-fifth World Health Assembly,

Having considered the report on poliomyelitis: intensification of the global eradication initiative;¹

Recalling resolution WHA61.1 on poliomyelitis: mechanism for management of potential risks to eradication, which requested the Director-General, inter alia, to develop a new strategy to reinvigorate the fight to eradicate poliovirus and to develop appropriate strategies for managing the long-term risks of reintroduction of poliovirus and re-emergence of poliomyelitis, including the eventual cessation of use of oral poliovirus vaccine in routine immunization programmes;

Recognizing the need to make rapidly available the necessary financial resources to eradicate the remaining circulating polioviruses and to minimize the risks of reintroduction of poliovirus and reemergence of poliomyelitis after interruption of wild poliovirus transmission;

Noting the finding of the Independent Monitoring Board of the Global Polio Eradication Initiative in its report of October 2011 that “polio simply will not be eradicated unless it receives a higher priority – in many of the polio-affected countries, and across the world”² and its recommendation in its April 2011 report that the World Health Assembly “considers a resolution to declare the persistence of polio a global health emergency”;

Noting the report of the meeting in November 2011 of the Strategic Advisory Group of Experts on immunization at which it stated “unequivocally that the risk of failure to finish global polio eradication constitutes a programmatic emergency of global proportions for public health and is not acceptable under any circumstances”;

Recognizing the need for Member States to engage all levels of political and civil society so as to ensure that all children are vaccinated in order to eradicate poliomyelitis;

Having noted the current high cost and limited supplies of inactivated polio vaccine that are hampering the introduction and scaling-up of inactivated polio vaccine, resulting in major programmatic and financial implications to developing countries;

Noting that the technical feasibility of poliovirus eradication has been proved through the full application of new strategic approaches;

Noting that continuing poliovirus transmission anywhere will continue to pose a risk to poliomyelitis-free areas until such time as all poliovirus transmission is interrupted globally,

1. DECLARES the completion of poliovirus eradication a programmatic emergency for global public health, requiring the full implementation of current and new eradication strategies, the institution of strong national oversight and accountability mechanisms for all areas affected by poliovirus, and the application of appropriate vaccination recommendations for all travellers to and from areas affected with poliovirus;¹
2. URGES Member States with poliovirus transmission to declare such transmission to be a “national public health emergency” making poliovirus eradication a national priority programme, requiring the development and full implementation of emergency action plans, to be updated every six months, until such time as poliovirus transmission has been interrupted;
3. URGES all Member States:

(1) to eliminate the unimmunized areas and to maintain very high population immunity against polioviruses through routine immunization programmes and, where necessary, supplementary immunization activities;

(2) to maintain vigilance for poliovirus importations, and the emergence of circulating vaccine-derived polioviruses, by achieving and sustaining certification-standard surveillance and regular risk assessment for polioviruses;

(3) to make available urgently the financial resources required for the full and continued implementation, to the end of 2013, of the necessary strategic approaches to interrupt wild poliovirus transmission globally, and to initiate planning for the financing to the end of 2018 of the polio endgame strategy;

(4) to engage in multilateral and bilateral cooperation, including exchanging epidemiological information, laboratory monitoring data, and carrying out supplementary immunization activities simultaneously as appropriate;

4. REQUESTS the Director-General:

(1) to plan for the renewed implementation through 2013 of the approaches to eradicating wild polioviruses outlined in the Global Polio Eradication Initiative Strategic Plan 2010–2012 and any new tactics that are deemed necessary to complete eradication, including the enhancement of the existing global polio eradication initiative within the Organization;

(2) to strengthen accountability and monitoring mechanisms to ensure optimal implementation of eradication strategies at all levels;

(3) to undertake the development, scientific vetting, and rapid finalization of a comprehensive polio eradication and endgame strategy, and inform Member States of the potential timing of a switch from trivalent to bivalent oral poliovirus vaccine for all routine immunization programmes; and include budget scenarios to the end of 2018 that include risk management;

(4) to coordinate with all relevant partners, including vaccine manufacturers, to promote the research, production and supply of vaccines, in particular inactivated polio vaccines, in order to enhance their affordability, effectiveness and accessibility;

(5) to continue mobilizing and deploying the necessary financial and human resources for the strategic approaches required through 2013 for wild poliovirus eradication, and for the eventual implementation of a polio endgame strategy to the end of 2018;

(6) to report to the Sixty-sixth World Health Assembly and the subsequent two Health Assemblies, through the Executive Board, on progress in implementing this resolution.

Tenth plenary meeting, 26 May 2012 A65/VR/10

Tier definition

1. Tier 1: WPV endemic countries OR countries that have reported a cVDPV2 since 2000
2. Tier 2: Countries who have reported a cVDPV1/cVDPV3 since 2000 or which are large-/medium-sized countries with DTP3 coverage <80% in 2009, 2010, 2011 as per WUNIC
3. Tier 3: Large-/medium-sized countries adjacent to Tier 1 countries that reported WPV since 2003 or countries that have experienced a WPV Importation since 2011
4. Tier 4: All other OPV only using countries

Tier 1 (n = 14)	Tier 2 (n = 19)	Tier 3 (n = 15)	Tier 4 (n = 76)	
Afghanistan	Azerbaijan	Angola	Albania	Macedonia
Chad	Cambodia	Bangladesh	Algeria	Maldives
China	Central African Republic	Benin	Antigua and Barbuda	Mauritius
Cameroon	Dominican Republic	Burkina Faso	Argentina	Moldova
DR Congo	Equatorial Guinea	Burundi	Armenia	Mongolia
Ethiopia	Gabon	Congo	Barbados	Morocco
India	Guinea	Cote d'Ivoire	Belize	Namibia
Kenya	Haiti	Egypt	Bhutan	Nauru
Madagascar	Indonesia	Eritrea	Botswana	Nicaragua
Niger	Iraq	Iran	Cape Verde	Panama
Nigeria	Lao PDR	Nepal	Bolivia	Peru
Pakistan	Mali	Sudan	Comoros	Paraguay
Somalia	Mauritania	Tajikistan	Chile	Rwanda
Yemen	Mozambique	Turkmenistan	Colombia	Sao Tome & Principe
	Myanmar	Uganda	Cook Islands	Senegal
	Papua New Guinea		Cuba	Sierra Leone
	Philippines		DR Korea	Sri Lanka
	South Sudan		Djibouti	Solomon Islands
	Timor Leste		Dominica	Swaziland
			Ecuador	St Kitts and Nevis
			El Salvador	Saint Lucia
			Fiji	Saint Vincent and the
			Georgia	Grenadines
			Ghana	Samoa
			Grenada	Serbia
			Guatemala	Seychelles
			Guinea Bissau	Solomon Island
			Guyana	Tanzania
			Honduras	Thailand
			Jamaica	The Gambia
			Kiribati	Togo
			Kyrgyzstan	Tonga
			Lesotho	Trinidad e Tobago
			Liberia	Tunisia
			Libya	Uzbekistan
			Malawi	Vanuatu
				Venezuela
				Vietnam
				Zambia
				Zimbabwe

Key messages to be issued to health staff

The success of The Switch will largely depend on the understanding health staff at various levels has concerning the event and the crucial role they play in it.

It is therefore of the uttermost importance that the MOH issues a memo or brief guideline to all health professionals (including the private sector) in which the following key messages appear:

- Within the context of the Global Polio Eradication Initiative, the World Health Assembly has issued a resolution stipulating that **all tOPV** (containing types 1, 2 and 3) used for routine immunization or SIA should be **replaced by bOPV** (types 1 and 3).
- This event is called The Switch.
It is a global event, which in our country will take place **{date to be filled out}**.
This means that beginning that date **no more tOPV** will be used **anywhere** and for any programme, private nor public, in the country.
- **Distribution of bOPV** will start **2 weeks** before The Switch. You will be informed on time when your structure will be supplied.
- On **switch** day you:
 - will **stop using tOPV** and only use bOPV instead;
 - will take **all tOPV out of the cold chain**;
 - will **mark all tOPV** with the stickers you were supplied with for that purpose.
- **All tOPV** will be **recalled** and safely **disposed** of in approved disposal sites. You will be informed to which disposal site your leftover tOPV should be brought.
- It is **strictly prohibited to immunize children with tOPV** on or after switch day in **any circumstance**, whether it is to finish remaining stocks or because you were not supplied with bOPV.
- Independent **Switch Monitors** will visit all health structures with potential stocks of tOPV for routine or SIA to verify the **absence** of tOPV stocks. If 2 weeks after The Switch you still have tOPV and/or you were not visited by a Switch Monitor, you must inform your superior for rapid rectification.
- On **{date}** the national governments will make an **official statement** confirming that in compliance with the WHA resolution **{name of the country}** is **free of stocks of tOPV**. Your kind **cooperation** in the correct implementation of The Switch is therefore of critical importance and highly **appreciated**.

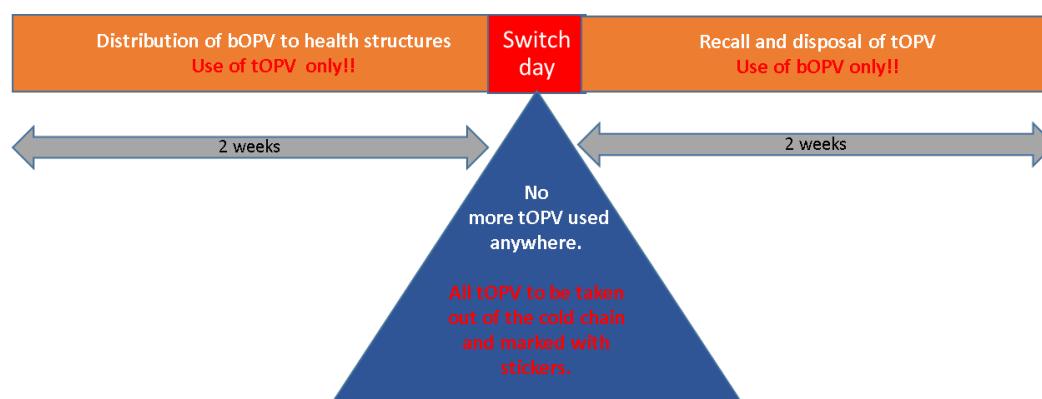


Figure 8: Critical dates at SP level

Indicators for global monitoring

Monitoring tools should be simple, action oriented and indicator-based; they need not capture each detail of the monitoring process.

The table below is an example of monitoring tool at global level that should be adapted for each level or topic (e.g., logistics, communications).

When (time to or from switch)	Indicator	Critical threshold	Action
-6 months	Adhere to switch	>70% of countries adhered	<70% postpone The Switch
-5 months	National Switch Committee selected	Any country without a ICC	HQ and/or RO to contact country
-5 months	Switch Support Teams selected	Any country that did not select SST	HQ and/or RO to contact country
-4 months	National Switch plan was written	Any country without Switch plan	HQ and/or RO to contact country
-4 months	Budgets have been submitted	>50%	If <50% emergency meeting with partners
-3 months	Vaccine orders are placed		UNICEF ensures orders are placed
-2 months till -3 weeks	Arrival of vaccine in national store	No	Launch contingency plan
- 3 weeks	Funds arrive in the regions	>60%	If <60% ensure prefinancing at regional level
- 2 weeks	All countries selected SM		
- 1 week before The Switch	Funds arrive in the districts		
+2 days	All countries report recall has started		
+5 days	Half the reporting sites have completed recall to at least regional level		
+21 days	All countries declare to be free of tOPV		

General switch work plan and timeline

To be adapted locally

Categories	Code activity type	Activities	Required documents	Months from the switch												Weeks from Switch												National Switch Day	1	2	National Validation Day
				-12	-11	-10	-9	-8	-7	-6	-5	-4	-12	-11	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1							
Management and monitoring	m	ICC assigned general Switch oversight	TOR of ICC																												
	m	First meeting of ICC	Template for minutes																												
	m	Elaboration of a national switch plan																													
	m	Selection of ICC sub-committee																													
	m	MOH issues a statement for health staff explaining the switch plus the timeline. The statement should include the private sector.	MOH memo																												
	m	Adapt the protocol to the country's specifics	Protocol adapted																												
	f	Budget proposal submitted																													
	f	Budget proposal accepted																													
	m	Select Switch Support Team (SST) at national and regional levels	TOR of SST																												
	m	Train SST	Training module																												
Communication	f	Funds arrive at national level. In 2 phases																													
	m	Sub committees report	Template																												
	m	Official statement: there is no more tOPV in the country																													
	c	Finalise communication plan	Plan																												
Logistics	c	Development of appropriate communication materials for health staff and hte community.	Communication materials																												
	c	Start of communication activities for switch																													
	I	Development of appropriate training materials for switch implementation	Training materials																												
	Iv	Inventories of existing tOPV stocks at regional level, including private clinics.	Inventory template																												
	I	Assign a working group to make inventory of changes needed in forms, records, registers as well as software due to the switch from tOPV to bOPV																													
	I	Redesign and print changed stationary																													
	Iv	Assesment of tOPV requirements until the switch																													
	Iv	bOPV for RI ordered																													
	Iv	tOPV orders																													
	Iv	Vaccine arrives at national level																													
	If	Stationary, funds, and vaccine (tOPV and bOPV) arrive at regional level.	Vaccine in/out form for regional level																												
	If	Distribution of funds, stationary and vaccine (tOPV and bOPV) to the districts																													
	WHO	Select Switch Monitors																													
	c	Intensification of communication strategies																													
	I	Training medical staff and SM	Switch monitors training guide.																												
	I	The switch.																													
	Im	Switch monitors assist and check recall of routine tOPV																													
	Im	All tOPV returned to district level. tOPV out of the cold chain. tOPV boxes marked with stickers																													
	Im	District supervisors and switch monitors check each health structure that does RI for remaining tOPV.																													
	Im	No HC with remaining tOPV either for SIA or for RI																													
	Im	Final inventory and transport tOPV from district to regional level.																													
	Im	Final inventory and transport tOPV from regional to national level.																													
	Im	Depending on national policy, disposal of remaining tOPV under supervision of independant national/international authorities/consultant.																													
		National Validation Day																													
Legend		Activity type																													
Activities		in bold are critical milestones																													
m		Management and monitoring																													
f		Funds																													
c		Communication																													
I																															
If																															
Im																															
Iv																															

Sample tOPV sticker

Example of a sticker of 10x15 cm to mark the recalled tOPV.



Examples of stock management forms

[illegible][illegible]

Questionnaire vaccine management

Q no.	EVM QUESTION	Result
E0	Complete these facility-specific questions before continuing.	
0.1	Answers to these questions switch indicators below on and off.	
E0:01a	What type of cold chain equipment is used in the store? [Select one or more options]:	
A	Vaccine is stored in cold room(s) and/or freezer room(s) [Y, N]	
B	Vaccine is stored in refrigerators or long-term cold boxes [Y, N]	
C	Vaccine is stored in freezers [Y, N]	
D	Coolant-packs, including ice-packs and/or cool-packs and/or PCM-packs are prepared in the store [Y, N]	
E	Vaccines are kept in standard passive containers only (cold boxes and/or vaccine carriers). There is no active refrigeration. [Y, N]	
Notes:		
E0:02a	Where are vaccines and diluents, syringes and safety boxes stored? [Select one option only]:	
A	Only vaccines are stored. The facility is not responsible for syringes and safety boxes [Y, N]	
E0:03a	What type of equipment is used to deliver and/or collect vaccine at this store? [Select one or both options]:	
A	Cold boxes, vaccine carriers and/or other passive containers [Y,N]	
B	Refrigerated vehicles [Y,N]	
Notes:		
E0:05a	Specify all transport types used for vaccine delivery or collection at this level. [Select at least one option]:	
A	On foot [Y, N]	
B	Bicycles and/or motorcycles [Y, N]	
C	Cars, vans, trucks, refrigerated trucks and other road vehicles [Y, N]	
D	Aircraft [Y, N]	
E	Railway [Y, N]	
F	Boat [Y, N]	
G	Other [Y, N. Enter description in notes box]	
Notes:		
E6	Stock management systems and procedures are effective.	
6.1	Standardized recording and reporting of all stock transactions is carried out. Preferably this is computerized at primary level and in all other large stores.	
E6:01a	Is a computerized stock control system in use? [Y, N]. If not, go to question E6:03a	
E6:02a	CONDITION: If computerized stock control is used. Computerized stock control checklist:	
A	Is the software fit for purpose [Y, N]	
C	Is there up-to-date anti-virus software on the computer [Y, N]	
D	Has the storekeeper received training in its use [Y, N]	
E	Is the computer suitable for its purpose and in working order? [Y, N].	
H	Are stock records printed out and filed as a permanent record at least once a month? [Y, N].	
Notes:		
E6:03a	Are all vaccine arrivals and vaccine dispatches recorded and stock balances updated within one working day of the transaction? [Y, N].	
Notes:		
E6:04a	Do the stock records record the following information for all vaccines:	
A	Type of vaccine [Y, N]	
B	Vaccine presentation (vial size) [Y, N]	
C	Quantity received in doses [Y, N]	
D	Vaccine manufacturer [Y, N]	
E	Manufacturing batch or lot number [Y, N]	
F	Expiry date of each vaccine batch [Y, N]	
G	VVM status where applicable [Y, N, n/a]	
Notes:		
E6:05a	Do the stock records record the following information for all diluents that are packed separately from the vaccine to which they belong:	
A	Type of diluent [Y, N]	
Notes:		
E6:09a	Do stock records and/or stock in hand demonstrate that vaccine is issued according to the 'earliest-expiry-first-out' (EEFO) principle? [Y, N].	
Notes:		

E6:12a	Do the vaccine quantities recorded on the sampled issue vouchers consistently match the relevant entries in the stock records? [Y, N].	<input type="checkbox"/>	<input type="checkbox"/>
E6:15b	CONDITION: If vaccine is stored at the facility. Checklist for management of damaged or expired stock:	<input type="checkbox"/>	
C	If the stock control system records wastage in unopened and/or opened vials, do the records and other on-site evidence show that the system is being used? [Y, N]		<input type="checkbox"/>
D	Do staff know that expired and damaged vaccine should be clearly labelled and stored out of the cold chain until final disposal? [Y, N]		<input type="checkbox"/>
Notes:			
E6:17a	Are disposal facilities and procedures in accordance with WHO and/or national norms? [Y, N].	<input type="checkbox"/>	<input type="checkbox"/>
Notes:			
6.2 Stocks of vaccines and consumables are maintained between the safety stock level and the maximum stock level.			
E6:20b	CONDITION: If vaccine is stored at the facility. Assess stock level policy:	<input type="checkbox"/>	
A	Is a maximum stock level set for each vaccine and commodity? [Y, N]		<input type="checkbox"/>
B	Is a reorder level set for each vaccine and commodity? [Y, N]		<input type="checkbox"/>
C	Is a safety (minimum) stock level set for each vaccine and commodity? [Y, N]		<input type="checkbox"/>
D	Can responsible staff explain the concepts of maximum stock, safety stock and reorder level? [Y, N]		<input type="checkbox"/>
E	If a maximum stock level is set for DTP containing vaccine, did the stock of this vaccine remain below the maximum level throughout the review period? [Y, N]		<input type="checkbox"/>
Notes:			
E6:21a	CONDITION: If vaccine is stored at the facility. Assess adequacy of annual supply of DTP containing vaccine:	<input type="checkbox"/>	
A	What is the forecasted demand (doses) for DTP containing vaccine for the review period?		<input type="checkbox"/>
B	What is the total quantity (doses) of DTP containing vaccine received during the review period?		<input type="checkbox"/>
Notes:			
6.3 Periodic physical inventories are conducted.			
E6:22a	CONDITION: If vaccine is stored at the facility. Physical inventory frequency checklist:	<input type="checkbox"/>	
A	Enter the planned vaccine supply period, in months		<input type="checkbox"/>
B	Enter number of recorded physical counts of vaccine stocks carried out during the 12 month review period		<input type="checkbox"/>
Notes:			
E6:23b	CONDITION: If vaccine is stored at the facility. Choose a sample freeze-dried vaccine and diluent.	<input type="checkbox"/>	
A	Enter choice of vaccine:		<input type="checkbox"/>
B	Carry out a physical count of the sample vaccine. Enter number of doses counted:		<input type="checkbox"/>
C	Carry out a physical count of the sample diluent. Enter number of doses counted:		<input type="checkbox"/>
D	Check stock records for sample vaccine. Enter number of doses recorded as currently in stock:		<input type="checkbox"/>
E	Check stock records for sample diluent. Enter number of doses recorded as currently in stock:		<input type="checkbox"/>
F	How many doses are at the VVM discard point or beyond?		<input type="checkbox"/>
G	Scoring: Score 4 if stock count and records match exactly AND vaccine and diluent quantities are within 1% of one another AND no VVMs are at the discard point (see results). Use your judgement to adjust the score between 0 and 4.		<input type="checkbox"/>
6.4 Good warehousing practices are followed.			
E6:25a	CONDITION: If vaccine is stored at the facility. Checklist for vaccine storage arrangements:	<input type="checkbox"/>	
A	Is the vaccine stock secure? [Y, N]		<input type="checkbox"/>
B	Are contents labels fixed to all cold chain equipment indicating vaccine type, lot no. and expiry date [Y, N, n/a].		<input type="checkbox"/>
C	Are vaccines correctly stored? [Y, N].		<input type="checkbox"/>
E	Is the vaccine store clean, dry and pest-free? [Y, N]		<input type="checkbox"/>

Phased removal of OPVs – to secure a lasting polio-free world

Rationale for OPV cessation

Why OPV cessation?

Oral polio vaccine (OPV) is extremely safe and effective at protecting children against lifelong polio paralysis. Over the past ten years, more than 10 billion doses of OPV have been given to nearly three billion children worldwide. More than 10 million cases of polio have been prevented, and the disease has been reduced by more than 99%. It is the appropriate vaccine through which to achieve global polio eradication.

OPV contains attenuated (weakened) polioviruses. On extremely rare occasions, use of OPV can result in cases of vaccine-associated paralytic polio (VAPP) and circulating vaccine-derived polioviruses (cVDPVs). For this reason, the global eradication of polio requires the cessation of all OPV in routine immunization, as soon as possible after the eradication of wild poliovirus (WPV) transmission.

Phased approach to OPV cessation – the trivalent OPV to bivalent OPV switch

OPV is available in different formulations:

- Trivalent OPV – containing type 1, 2 and 3 serotypes
- Bivalent OPV – containing type 1 and 3 serotypes
- Monovalent OPV – containing one serotype (i.e. type 1, 2 or 3)

The different formulations are used to eradicate polio during supplementary immunization activities (SIAs), based on the then predominantly circulating serotype. Trivalent OPV is the only formulation used in routine immunization programmes. Bivalent OPV is the most widely-used formulation during SIAs to more rapidly interrupt the remaining strains of WPV1 and 3 transmission – the only remaining WPV strains in circulation. WPV2 has been eradicated since 1999.

With WPV2 transmission already having been successfully interrupted, the only cases of paralytic polio now caused by the type 2 serotype component in trivalent OPV. Over 90% of cVDPV cases are due to the type 2 component, which is also responsible for up to 38% of VAPP cases, hence a switch from trivalent OPV to bivalent OPV will be associated with significant public health benefits.

A switch will be implemented from trivalent OPV to bivalent OPV in routine immunization programmes and SIA, even before the remaining strains of WPV1 and WPV3 transmission are eradicated.

Following WPV1 and WPV3 eradication, use of all OPV in routine immunizations will subsequently be stopped.

In addition to these significant humanitarian benefits, OPV type 2 cessation would provide the GPEI with a 'push' for global OPV cessation of all OPVs. Feasibility of OPV cessation would be underscored in practice, and would ensure a 'trial run' for all OPV cessation. Key lessons would be learnt to ensure that this process can be implemented in the safest and most efficient manner.

Defining The Switch

- The OPV switch refers to the replacement of all trivalent OPV (tOPV) with bivalent OPV (bOPV) in all the countries in the world that are currently using oral polio vaccines within the same timeframe.
- To counter the risk of cVDPV type 2, WHO recommends a combination of the use of Inactivated Polio Vaccine (IPV), improved routine immunization coverage, and the replacement of trivalent OPV with bivalent OPV.

Objectives and benefits of The Switch

- Wild poliovirus type 2 was eradicated globally in 1999, so there is no longer a need for the type 2 component of OPV. Further, the type 2 component of OPV is responsible for the majority of cVDPV, so its removal will reduce the already small risk of vaccine associated polio.
- WHO recommends the replacement of trivalent OPV with bivalent OPV, which does not contain the type 2 component, to counter the risk of cVDPVs. Bivalent OPV will continue to target the remaining types (types 1 and 3). IPV will protect against poliovirus type 2 once the type 2 component of OPV is withdrawn. IPV will also provide additional immunity against types 1 and 3.
- The Switch from trivalent OPV to bivalent OPV, combined with the use of IPV, will significantly reduce the risk of VAPP and cVDPV, as well as increase population immunity to types 1 and 3. This will move us even closer to the eradication of polio worldwide.
- bOPV is more effective against poliovirus types 1 and 3 than tOPV.

The Switch is an important milestone

- The Switch from tOPV to bOPV is an important milestone in polio eradication. The eradication of wild poliovirus type 2 in 1999 has made it possible for the removal of the type 2 component of tOPV. This transition will reduce the already small risk of polio caused by vaccines. This is the first step towards the gradual removal of all oral polio vaccines, and reflects impressive efforts internationally to control outbreaks and strengthen routine immunization.

Emphasizing the need to introduce IPV by the end of 2015

- All countries should introduce at least one dose of IPV into their routine immunization schedules by the end of 2015 to be prepared for The Switch.
- IPV provides the only protection against poliovirus type 2 after The Switch, and provides additional protection against types 1 and 3.
- At least one dose of IPV at or around 14 weeks of age must be continued both during and after The Switch.

IPV will eventually be the only vaccine for polio in routine immunization

- The next step towards polio eradication will be the gradual removal of all OPV, including types 1 and 3. Once OPV is phased out, IPV will be the only vaccine for polio in routine immunization.

tOPV will no longer be used in routine immunization or SIAs

- After The Switch, neither routine immunization nor Supplementary Immunization Activities (SIAs) will be conducted with tOPV.
- Manufacturers will no longer supply tOPV after The Switch.

- Health workers must dispose of all tOPV at the time of The Switch. It should not be stored or transported in the cold chain.

Preparing countries and announcement of decisions related to The Switch at each stage

- In April of 2015, if no persistent type 2 cVDPVs have been detected for at least 6 months, the World Health Assembly will announce a decision for a switch from trivalent OPV to bivalent OPV to occur in April of 2016 during the low transmission season of polio. The Switch could be postponed if there is an outbreak of persistent type 2 cVDPV during the process. If The Switch is postponed, it will be postponed until April 2017.
- It is expected that SAGE will announce at the World Health Assembly in May 2015 that the global requirements for the OPV switch have been met. WHO recommends the replacement of trivalent OPV with bivalent OPV to counter the risk of cVDPV type 2. The Switch is expected to occur in April of 2016 under the condition of continued absence of persistent cVDPVs.

Describing the importance of a timely and simultaneous switch

- It is extremely important that all countries switch from tOPV to bOPV at the same time. If countries do not switch during the same timeframe, they put their nation and other countries at risk.
- A country that delays The Switch may have continued circulation of cVDPVs, which could spread to neighbouring countries. A simultaneous switch offers simultaneous global protection.
- Timely budgeting and ordering of vaccine prevents any delays in procuring bivalent OPV. It is imperative that countries avoid any delays that may interfere with a simultaneous global switch and put other countries at risk.

tOPV campaigns prior to The Switch

- If there are remaining pockets of under-immunized children, following the advice from SAGE, countries should consider tOPV campaigns to boost type 2 immunity before The Switch.