# The switch from tOPV to bOPV

## Implementation guidelines

*A handbook for national decision makers, programme managers, logisticians, and consultants*

Version date: April 25, 2015

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

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## List of abbreviations

| | |
|---|---|
| **bOPV** | Bivalent Oral Polio Vaccine |
| **EPI** | Expanded Programme on Immunization |
| **GPEI** | Global Polio Eradication Initiative |
| **ICC** | Interagency Coordinating Committee |
| **IPV** | Inactivated Polio Vaccine |
| **MOH** | Ministry of Health |
| **NSVC** | National Switch Validation Committee |
| **OPV** | Oral polio vaccine |
| **RI** | Routine immunization |
| **SAGE** | Strategic Advisory Group of Experts on Immunization |
| **SM** | Independent switch monitor |
| **SST** | Switch support team |
| **tOPV** | Trivalent oral polio vaccine |
| **WHA** | World Health Assembly |
| **WHO** | World Health Organization |

# NOTE:

**This document does not discuss the technical rationale or questions related to the global decision on the timing of the switch.**

**It assumes that the switch will occur in April 2016.**

PAHO Note:

As of July 10, 2015, this version contains some adaptions for the Region of the Americas.

All differences are marked in yellow for easy identification.

The original document can be found here: http://www.who.int/entity/immunization/diseases/poliomyelitis/endgame_objective2/oral_polio_vaccine/switch_guidelines-april2015.pdf?ua=1.

### 1.1.1 Why this document?

In May 2012, the World Health Assembly declared the completion of poliovirus eradication to be a "programmatic emergency for global public health" and called on the Director General of WHO to develop a comprehensive polio endgame strategy. The Global Polio Eradication Initiative's *Polio Eradication and Endgame Strategic Plan 2013-2018*, approved by the Executive Board of WHO in January 2013, requires the removal of all oral polio vaccines (OPVs).

The removal of OPVs must be done in a phased manner, from both routine programs and campaigns, to minimize the risk of new polio cases. The first phase of OPV removal is a switch from the current trivalent oral polio vaccine (tOPV), containing antigens for poliovirus types 1, 2, and 3, to bivalent OPV (bOPV), containing only types 1 and 3. The use of tOPV led to the eradication of wild poliovirus type 2, with the last detected case occurring in 1999.

**The global switch from tOPV to bOPV is expected to occur in April 2016.** Prior to the switch, manufacturers will cease production of tOPV. The supply of tOPV will be finite leading up to the switch, and no tOPV will be available after the switch.

The switch also must be a **globally coordinated process**. Any use of tOPV after April 2016 could jeopardize polio eradication by generating circulating vaccine-derived polioviruses from the type 2 component of the vaccine.

To prepare for the switch in April 2016, it is imperative that all OPV-using countries begin switch planning during Q1-Q2 2015 and **finalize a budgeted national switch plan by September, 2015**. Timely planning and implementation of a switch plan will increase the probability of a successful removal and disposal of tOPV, minimize tOPV wastage, and ensure a world free of circulating vaccine-derived polioviruses type 2.

### 1.1.2 What is included in this document?

This document provides guidelines and a framework for countries to consider when developing and implementing their national switch plans. Country needs will vary and **national switch plans should be adapted to meet local implementation needs**.

### 1.1.3 Who is the target audience?

These guidelines were created for policy makers, program managers, logisticians, and consultants. The guidelines may be adapted to become a field guide for training based on local needs.

### 1.1.4 Where can I get more information on the switch?

The following documents are available to help countries plan, prepare for, and implement the switch.

- ☑ SAGE position & WHO position paper [http://www.who.int/wer/2014/wer8901/en/index.html ]
- ☑ A briefing note on the switch, frequently asked questions and Powerpoint decks:

http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/oral_polio_vaccine/en/

**Date of switch:** April 2016

**Initiate planning:** Quarter 2, 2015

**Finalize national switch plans:** by September, 2015

**Primary objectives of the switch**

- Successfully recall tOPV and introduce bOPV in April 2016
- Minimize tOPV wastage after switch
- Ensure all children are vaccinated (avoid tOPV stockouts before and bOPV stockouts after the switch)
- Validate that the country is free of tOPV

## 1.2 Switch calendar

| | |
|---|---|
| **Plan** | **By June 2015** |
| | - Establish management structure<br>- Establish National Switch Validation Committee (NSVC)<br>- Conduct situation analysis<br>- Draft national switch plan (budgeted and finalized by 1 Sept 2015) |
| **Prepare** | **May to September 2015** |
| | - Complete detailed tOPV inventory; adjust tOPV delivery*<br>- Secure funding and finalize national switch plan<br>- Develop monitoring plan |
| | **October to November 2015** |
| | - Complete second tOPV inventory; adjust tOPV orders and/or delivery<br>- Confirm bOPV order<br>- Develop waste management protocol<br>- Hire switch support staff |
| | **December 2015 to January 2016** |
| | - Receive last tOPV delivery to country; **<br>- Redistribute remaining tOPV stock within country as required<br>- Prepare training materials and implement communications strategy<br>- Begin bOPV deliveries to country *** |
| | **February to March 2016** |
| | - Deliver last 1-2 months of tOPV to periphery; redistribute as needed<br>- Identify switch monitors |
| **Implement** | **Two to four weeks prior to the switch** |
| | - Train switch monitors<br>- Train health workers<br>- Distribute bOPV to periphery and service points |
| **National Switch Day** | **A day chosen during the first two weeks of April 2016** |
| | - Stop use of tOPV and remove tOPV from cold chain<br>- Begin use of bOPV |
| **Validate** | **During the two weeks after the switch** |
| | - Complete disposal of tOPV<br>- Validate tOPV disposal at selected sites (switch monitors)<br>- Collect and review data and validate switch (NSVC) |

* tOPV orders and delivery may vary based on country ordering cycle

** Unless tOPV stock out

*** Could extend to March 2016 due to logistics

## 1.3 Overview of key country activities

Countries are responsible for:

1. **Setting a National Switch Date**: Decision-makers must establish a **switch date** during a 2 week window in April 2016. This is the date when tOPV is removed from all facilities, sent for proper disposal, and replaced with bOPV.
2. **Establishing management structures**: By mid-2015, countries are encouraged to establish switch coordination committees (e.g., ICC) at national and subnational levels. These committees are responsible for developing the switch plan and providing implementation oversight.
3. **Developing a switch plan**: All OPV-using countries should **complete planning for the switch by end Q2 2015** and **finalize a national switch plan by September 2015 using the recommended template**, leaving ~10 months to prepare and implement activities.
4. **Preparing for the switch:** Countries are expected to implement their national switch plans, complete training; distribute bOPV to periphery; withdraw and dispose of tOPV according to the timelines outlined in their plan. Countries are encouraged to **hire staff (i.e. switch support teams)** assigned specifically to prepare and implement the switch plan.
5. **Implementing the switch:** All countries should stop using tOPV and destroy remaining stocks of tOPV after their designated switch day in April 2016 to avoid re-emergence of circulating vaccine-derived polioviruses type 2. Ongoing use of tOPV after April 2016 may threaten or postpone the global eradication of polio.
6. **Validating absence of tOPV:** During the two weeks following the Switch Date, countries must validate that facilities are free of tOPV using appropriate methods of disposal as recommended in this document.
7. **Completing national validation:** Countries are encouraged to delegate authority to an independent body (e.g. National Switch Validation Committee) to review disposal data and validate the country free of tOPV within two weeks of the National Switch Date. Personnel involved in validation should be independent of the Ministry of Health and the Switch Implementation Team.

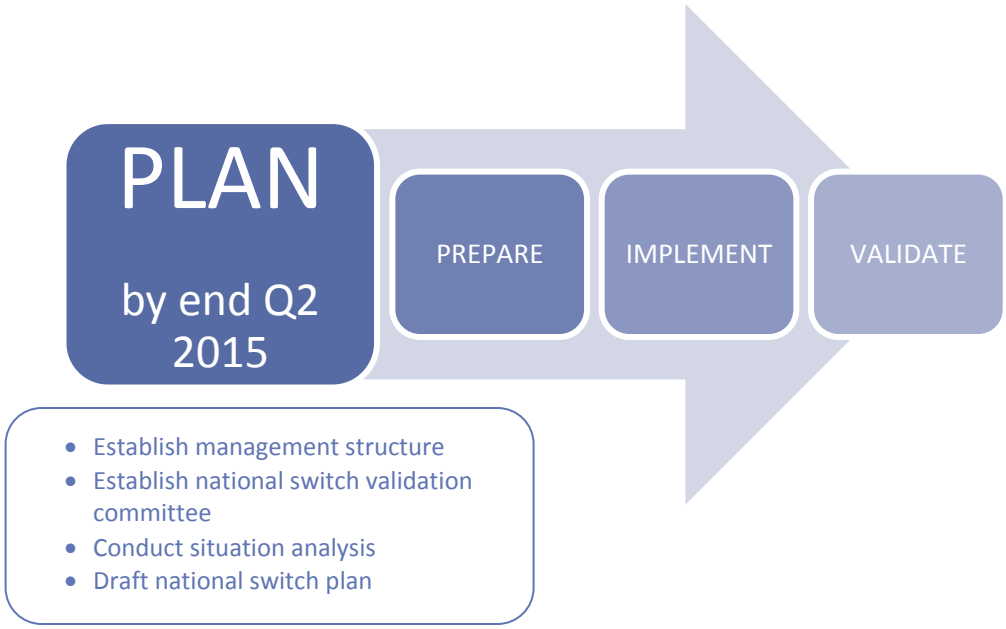
**Minimizing tOPV wastage** is a priority at global, regional, and country levels. Ultimately, countries are responsible for minimizing the quantity of tOPV stocks remaining in the country after the switch. Residual stocks of tOPV increase the risk that they will be used after the switch and increase costs to countries associated with destruction of vaccine. While reducing tOPV stocks to zero (0) will be difficult without risking stock-outs prior to the switch, countries can minimize the risk of residual stocks of tOPV after April 2016 by conducting nationwide inventories of tOPV stocks at least two times prior to the switch and incorporating this information into vaccine procurement plans.

**Figure 1: Overview of key activities related to a successful switch**

| Phase 1<br>**PLAN**<br>(by end Q2 2015) | Phase 2<br>**PREPARE**<br>(Q2 2015-Q1 2016) | Phase 3<br>**IMPLEMENT**<br>(2 weeks before Switch Day) | **NATIONAL SWITCH DAY** | Phase 4<br>**VALIDATE**<br>(during 2 weeks post switch) | **NATIONAL VALIDATION DAY** |
|---|---|---|---|---|---|
| -Switch commitment made<br><br>-Coordination committees at all levels have been established.<br><br>-Certification Committee assembled<br><br>-Situational analysis completed<br><br>- Preliminary national switch plan has been developed.<br><br>National switch plan with budget **finalized (by September 2015)** | -Funding secured<br><br>-Staff hired<br><br>-tOPV inventories calculated<br><br>-tOPV orders are confirmed<br><br>- bOPV orders subitted<br><br>-cold chain and logistics needs assessed<br><br>-Communication prepared<br><br>-Training prepared<br><br>-Waste management capacity assessed<br><br>-Monitoring plans finalized<br><br>-Information systems updated | - Switch Monitors trained<br><br>- HCWs trained<br><br>- bOPV delivered to all service points | -bOPV-only use begins<br><br>-tOPV recalled<br><br>-tOPV disposal begins | - Validation data collected on tOPV disposal and reported to NSVC | - Switch validated and reported to RCC |

**Note:** The above outline may be adapted to meet local needs.

# 2 Phase one: PLAN




## 2.1 Establish a management structure

Countries are encouraged to establish national and regional switch management committees (see sample terms of reference in Annex 1) to plan, manage, and oversee all activities related to the switch. This management body could be the Interagency Coordination Committee (ICC) or a similar body.

Finance, procurement, regulatory, legal authorities outside MOH should be included in the switch management committee, particularly in self-procuring countries where disposal of state-procured vaccine may become a problem. The structure, roles and responsibilities will vary depending on the country situation.

Initial actions by the national switch management committee include:

- **Select a National Switch Day:**
  - A National Switch Day should occur during two week period in April 2016 identified by WHO as the switch window. It is the day that tOPV will stop being used in the country and will be replaced with bOPV.
- **Form subcommittees**
  - Subcommittees on vaccine supply, communications, logistics, process monitoring and reporting should be formed at the national and sub-national levels. Subcommittees should include all relevant stakeholders in discussions (e.g., manager of national cold stores or central medical stores, national regulatory authority, procurement unit, ministry overseeing private sector vaccine procurement, etc.).
- **Identify points of contact:**
  - Focal points should be identified for all national and regional committees and their contact information (names, telephone numbers, email addresses) circulated to members.

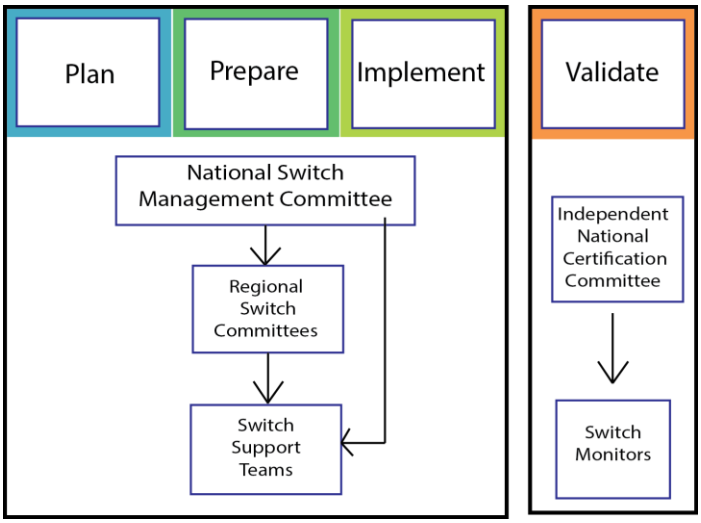
- A central telephone number and email address should be made available to answer questions from public or professionals.

- **Establish operations center:**
  - Countries should consider establishing an operations center to coordinate national, regional activities with up-to-date status of activities related to the switch.

## 2.2 Establish National or Sub-Regional Certification Committees

Validating that a country is tOPV free is crucial. The National or Sub-Regional Certification Committee for the Polio Endgame is authorized by the government to collect and validate data on tOPV recall and disposal (see section 3.4.4). After verifying tOPV recall and disposal, this committee will submit country documentation to the Regional Certification Committee.

Switch supervisors must be independent from those responsible for managing or implementing the switch (see Sections 2.1 and 3.3.2). The National or Sub-Regional Certification Committee should include experts in public health, epidemiology, logistics, and clinical medicine.




## 2.3 Conduct situation analysis

While management structures are established, key structures, systems, and policies should be identified and understood. The questions below can be used to assess appropriate structures, systems and policies:

**Supply and distribution of OPV:**

- How is vaccine procurement organized: through procurement agency, directly by MOH, or a mix?
- What is the tOPV stock status at national, departmental, and district levels one year prior to the switch?
- How often is tOPV supplied to the country, departments and districts?

**Vaccine licensing:**

- Does the country accept bOPV for routine use based on WHO prequalification or is national licensure required? Is an expedited procedure acceptable or is full national licensure required?
- If licensure is required, has the process for NRA licensing of bOPV for routine use begun? What is the standard timeline for licensure?
- Is the country willing to provide an emergency waiver for initial importation if licensure is not initiated or completed before the switch?

**Private sector provision of OPV:**

- Is tOPV offered in the private sector and in which facilities (NGOs, hospitals, private clinics, and/or pharmacies)?
- What percentage of tOPV is currently delivered in the private sector? Is it possible that private sector providers will exit from offering OPV products due to financial risk? If so, what increased demand may occur in the public sector?
- How and from where does the private sector source and procure their tOPV (from local agents/suppliers, directly from suppliers)?
- Does the National Regulatory authority or other relevant agency have regulatory oversight over medical supplies imported into the country and delivered through the private sector?
- How can countries engage the private sector in participating in the switch and through which associations/agencies (e.g., NRA, National Medical Council, ministry of commerce, etc.)?

**Vaccine communications:**

- What are the barriers and enablers to the switch among key stakeholders, e.g. health workers, medical specialists and scientists, specific interest groups, public and media?

**Waste management:**

- How is vaccine waste disposal organized in both public and private sector, if applicable, and how can disposal of tOPV be aligned with these guidelines while also considering WHO guidance?

**Existing expertise:**

- Do any of the national staff have experience with previous vaccine switches or vaccine recalls? Are there any lessons to be learned from those experiences?

**Funding:**

- What additional funding will be required for managing implementation of the switch, including procurement of bOPV for routine, logistics for implementation/distribution, disposal of vaccines, etc.?
- What resources within a national vaccination program are available to help with the switch?
- Are any resources external to the vaccination program available to help with the switch?

**External environment:**

- What other demands will be placed on vaccination program resources before and during the switch?
- Are any predictable events, such as elections, going to occur that could complicate the switch?

All points requiring action should be included in the national switch plan.

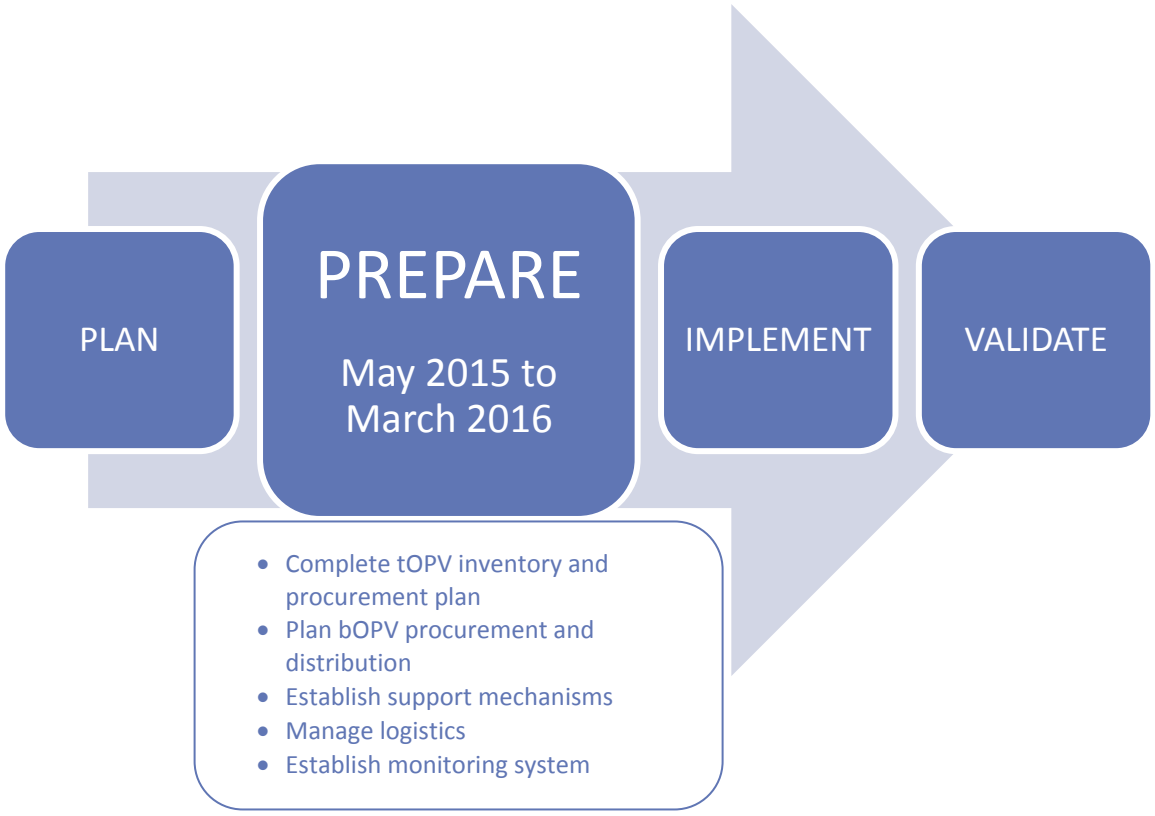
## 2.4 Draft a national switch plan

All countries should begin drafting a national switch plan, including a budget by end of Q2-2015 to meet country needs (see Table 1). A plan should be finalized and approved by the ICC **by September 2015**.

**Table 1. Checklist of the components of a sample national switch plan**

| Section | Key components |
|---|---|
| **Executive Summary (2 pages)** | ☑ Summary of the switch plan activities<br>☑ Date selected for the National Switch Day<br>☑ Overview of national coordination mechanism<br>☑ Capacity to implement the switch (e.g., financial needs and resources)<br>☑ List of preparatory activities, including plans for tOPV inventory<br>☑ tOPV disposal and validation strategy<br>☑ Key risks and mitigating strategies: supply, logistics, validation<br>☑ Key milestones and activities |
| **Management and operational oversight of switch – national coordination mechanisms** | ☑ Organizational chart with roles and responsibilities<br>• National Coordination Committee<br>• Departmental and municipal switch committees<br>• Switch support teams<br>☑ Information flow – who informs whom and with what frequency<br>☑ Budget for switch activities<br>☑ Work plan and timeline |
| **Validation Committee** | ☑ Roles and responsibilities<br>☑ Validation and reporting process |
| **Situation Analysis** | ☑ Supply and distribution process for OPV (public and private sector)<br>☑ Licensing and regulatory approvals needed for bOPV<br>☑ Capacity of existing medical waste management system<br>☑ Stock of tOPV and bOPV to date |
| **Preparation** | ☑ Switch support<br>○ Available budget<br>○ Composition of switch support team<br>○ Communications materials and dissemination<br>☑ Supply assessment<br>○ National inventory of tOPV<br>○ Plan for tOPV procurement<br>○ Plan for bOPV procurement, storage, and distribution<br>☑ Logistics<br>○ Plan for healthcare worker training and supervision<br>○ Plan for updating information systems (paper and software)<br>○ Plan for delivering bOPV to service points<br>○ Plan for tOPV recall and disposal<br>☑ Monitoring<br>○ Process monitoring: assessing switch activities/milestones<br>○ Outcome monitoring: collecting bOPV disposal data and validating tOPV removal and disposal |

# 3 Phase two: PREPARE




## 3.1 Complete tOPV inventory and procurement plan

**Three principles should guide tOPV procurement in the final year prior to the switch:**

1. Unlike other product transitions, where countries are allowed to exhaust the existing stocks of the old product before using the new product, **this will not be the case for a global cessation of tOPV and synchronized switch to bOPV**.
2. All tOPV that remains in countries after the switch date will need to be **removed and destroyed,** which will incur additional costs for disposal.
3. **Accurate forecasting and procurement planning, close inventory management, and regular monitoring of stock levels** will be critical for countries to minimize wastage of vaccine after the switch.

### 3.1.1 Assess and manage tOPV inventories

Inventory control is critical to avoid stockouts of tOPV prior to the switch and minimize excess tOPV stock after the switch.

WHO recommends that countries conduct at least two inventories with at least one down to the district level (or lower):

- First inventory: ~ 1 year prior to the switch (as soon as possible in 2015)
- Second inventory: ~6 months prior to the switch (October-November 2015)

The inventory should be exhaustive and include stock located in:

- Central medical/cold chain stores, including regional warehouses/depots in both government-owned and autonomous agencies
- Provincial warehouses
- District/municipal warehouses
- Any hospital at district, provincial, and tertiary level where immunization services are provided
- Private sector, including pharmacy stores, warehouses, or other location that provides OPV to customers
- Supply balances from recent SIA activities
- Pipeline deliveries (recently received but not yet registered, or supply already on order and pending delivery)

### 3.1.2 Decide timeline for tOPV forecasting, ordering, and shipment

**General guidance for tOPV procurement for all countries:**

- **Review current** procurement plans, orders, and requests for tOPV and their delivery schedules.
- **Ensure that quantities forecasted are sufficient** to meet tOPV routine immunization requirements until April 2016.
- Plan to deplete most **buffer stock by April 2016 at all levels,** leaving sufficient supply (e.g., 1-2 weeks) to respond to localized stockouts.

**Ordering cycles:** Countries have different ordering cycles, lead times and processes for vaccine procurement[1]. Procurement may be done by countries directly with manufacturers or through an intermediary/local supply agent; or through UNICEF, PAHO, or other UN agency. Countries should coordinate directly with their relevant procurement agency for specific guidance around ordering vaccine supply in the context of the switch. Below is guidance on tOPV procurement (also elaborated in Figure 1 below).

- **Countries are encouraged to maintain existing ordering processes and cycles as much as possible. However, a risk assessment** should be completed **based on the situation analysis described in Section 2.3** to determine if any adjustments are required to minimize risk of overstock and associated financial loss.
- If possible, split annual orders into at least 2 deliveries during the year before the Switch. These deliveries can be smaller in the last few months prior to the switch. Then the FINAL delivery can be adjusted to meet stock needs for the switch while avoiding excess tOPV stock after April 2016
- **Verify if it is possible to make adjustments after the final order is placed.**
    - Countries procuring through PAHO and/or UNICEF may have several opportunities to adjust their requirements **prior to an order being placed with a supplier.**
    - **Procurement processes for self-procuring countries may not allow for such adjustments, depending on contractual arrangements.**

[1] "**Ordering", "placing an order" or "issuing a purchase order"** as described in this guide is defined as a legally-binding contract with a supplier. In these cases, such binding contractual arrangements with suppliers often entail payments made to a supplier to produce the vaccine and may incur financial losses if changed or cancelled.

- **Countries that conduct an annual procurement and receive a single delivery of their annual supply requirements** are advised to split their procurement into a minimum of two orders (and a minimum of two deliveries) to allow for adjustments in requirements prior to placing the last order.
- Feasibility will **depend on procurement mechanism, procurement lead times, payment processes, and in-country procurement laws.** Additional funding may need to be allocated to cover any additional costs associated with additional shipment costs and import fees.

## 3.2 Plan bOPV procurement and distribution

### 3.2.1 Countries procuring bOPV through the PAHO Revolving Fund

In most cases, countries will receive 3-6 months of supply for the first order of bOPV. Countries receiving only 3 months' supply will need to receive several more shipments of bOPV to fill the supply chain. This will need to be treated as a new vaccine introduction with additional deliveries to fill the supply chain.

**During the two-week period prior to National Switch Day, both bOPV and tOPV will be together in the vaccine cold chain at the periphery.** Presence of both vaccines will be longer (~2 months) at major storage points at the central level. To minimize the time that both tOPV and bOPV will be in the cold chain at the periphery, some countries may consider exchanging bOPV for tOPV a few days prior to the switch. For example, staff responsible for maintaining vaccine stock at the periphery would go to the district level to return residual tOPV and collect bOPV.

- Countries should have sufficient financing to procure bOPV by March 2016 latest while maintaining tOPV requirements through Q1/April 2016.

To minimize the time that both tOPV and bOPV have to be in the cold chain together, the following steps are suggested:

- ☑ Procure bOPV 6 months prior to the switch (Oct-Nov 2015)*: order at least 3-6 month supply of bOPV (e.g., first 3 month supply + 1 month of buffer)
- ☑ Plan for bOPV to be delivered 1-3 months prior to the switch
- ☑ Distribute bOPV to the periphery two weeks prior to the Switch
- ☑ Remove all tOPV from the cold chain on the switch day

**NOTE:** Self-procuring countries have completely different timelines than UNICEF and their procurement laws may not be conducive to flexible procurement.

### 3.2.2 Self-procuring countries

Self-procuring countries may need to conduct additional activities when developing their procurement plans, tenders and contracts with suppliers:

- Determine tOPV supply needs through April 2016.
- Determine lead times required for changing product type.
- Determine payment schedules (100% upon signature with supplier or partial payment upon delivery).

- Investigate procurement laws and determine the feasibility of submitting amendments to contracts to convert tOPV to bOPV in line with the switch.
- Notify the department responsible for procuring vaccines as soon as possible so orders can be adjusted.
- For new tenders and contracts with suppliers, build in flexibility with suppliers to adjust and change product type (e.g. convert any excess tOPV orders into bOPV).

## 3.3 Establish support mechanisms

### 3.3.1 Secure funds

The national switch management committee is responsible for securing funds to implement national switch plan activities. These activities include hiring additional staff, managing logistics, assessing tOPV inventories and determining tOPV and bOPV supply needs, and covering costs associated with additional shipments to countries, waste management, and training.

### 3.3.2 Establish a switch support team

National authorities will need to delegate staff at national and regional levels to conduct preparatory and implementation activities related to the switch. These staff will comprise the switch support team (SST). The primary function of the SST is to support the MOH and switch management committee in:

1. Making reliable inventories of tOPV at departmental, district and service provider level
2. Strengthening vaccine management
3. Assisting with the switch in all relevant domains: logistics, social mobilization, training, etc.

The number of members on the SST can evolve during the process, with more members at a central level in the initial phases and increasing number of persons at peripheral levels closer to the switch.

Staff at the central level will require strong communication skills. Staff at regional and peripheral levels should be literate and credible candidates such as teachers and students.

### 3.3.3 Develop and implement a communications strategy

A strategic communications and advocacy plan should be a key component of the national switch plan. This plan should describe key stakeholders and elaborate on how the country will share information with them.

- **Stakeholder consultations:** As soon as possible, the communications sub-committee should organize meetings and consultations to inform health staff, partners, NGO, private sector and other groups potentially involved or affected by the switch. Consultations with key decision-makers and scientific community should be organized early to obtain buy-in before the switch.
- **Materials**: In parallel, the sub-committee can adapt or create contextually appropriate messages and materials to support meetings and consultations on the switch. Existing tools including global and regional materials can be leveraged (see Annex 3 for an example), such as FAQs, fact sheets, training materials, videos, posters, and labels.

- **Health worker training:** staff responsible for developing communications materials and strategy should closely link with those developing the training materials for health workers to ensure that switch dates, procedures, and messages about the rationale for the switch are coordinated.

**A guide to support national planning of communication activities will be published in August 2015 and will be available at:**
http://www.paho.org/hq/index.php?option=com_content&view=article&id=11015&Itemid=1707&lang=en.

## 3.4 Manage logistics

### 3.4.1 Develop training materials

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, leveraging existing materials where possible.

- Rationale for the switch and relevance to polio eradication
- Date to start using bOPV and stop using tOPV (National Switch Day)
- Suggestions for how to make best use of storage capacity in the weeks prior to the switch when both tOPV and bOPV will be in the cold chain together
- 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
    - Remove from cold chain
    - Mark with sticker
    - Send to nearest disposal site according to procedure

An information packet for health workers could be used to reinforce training. Basic materials to consider including in the information pack are listed below (and see Annex 3):

- Powerpoint overview with key messages
- FAQs
- Job aid to support tOPV removal and interactions

Global templates that may be adapted for training will be made available at:
http://www.paho.org/hq/index.php?option=com_content&view=article&id=11015&Itemid=1707&lang=en.

### 3.4.2 Assess cold chain capacity

Cold chain capacity to store both bOPV and tOPV during these 2 weeks prior to the switch will be short-term in nature, and for this reason renewal of equipment will likely be unnecessary, specifically since many countries will likely have increased capacity for IPV introduction.

Countries that have done regular SIAs have a storage capacity sufficient to cover a National Immunization Day (NID) equaling five birth cohorts. These countries should have sufficient capacity to store one-quarter of a cohort (3 months of bOPV) for the switch.

In some situations, such as when countries may need to do a pre-switch tOPV campaign, cold chain capacity may be insufficient. **The following steps may offer relief:**

- Increase the frequency of deliveries and reduce the size of each shipment.
- Repair equipment with minor defaults.
- Reallocate equipment to ensure that each service point has adequate **temporary** storage capacity.

### 3.4.3 Update information systems

Switching from tOPV to bOPV may require updating the forms, vaccination cards, or electronic databases used for recording and reporting OPV administration, forms for ordering vaccines, and vaccine stock ledgers, and any other forms that list the national immunization program vaccines. The following materials may need to be updated prior to the switch:

- Patient registers
- Vaccination cards
- Tally sheets
- Stock ledgers
- Electronic databases
- Vaccine management systems

### 3.4.4 Develop disposal strategy

A tOPV disposal strategy should be informed by current waste management capacity and expected disposal volume. Countries are advised to **assess their waste management systems** and estimate disposal volume before developing a disposal strategy.

**The following formula can be used to estimate disposal volume**:

$$\text{Approximate disposal volume (in liters) per week} = \frac{total\_population}{100,000} x2$$

**Figure 2. Sample country disposal volume**

$\frac{10,000,000}{100,000} x2 = 200$ liters to dispose for one week tOPV supply

In the example above, a country with a total population of 10 million would need to dispose of approximately ~200 liters of vaccine after the switch, assuming 1 week worth of excess tOPV. A country of 170 million would need to dispose of approximately 3,400 liters of vaccine following the switch.

**Select disposal sites**: At its earliest opportunity, countries 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 subnational or national (primary) level. If not feasible at subnational or national levels, 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

**Determine appropriate disposal strategy:** The disposal strategy for tOPV should incorporate one or more of the following acceptable ways to dispose of unused and opened tOPV vials. WHO considers some options for disposal better than others depending on national and regional capacity (Annex 5). In general, the options can be categorized as:

1. Encapsulation and disposal in a landfill (sanitary landfill preferred)
2. Direct disposal in an engineered landfill
3. Incineration
4. Chemical inactivation

Note that the first three options do not require opening unopened vials of tOPV.

## 3.5 Monitoring of the switch

### 3.5.1 Monitor planning and implementation process

Process monitoring should be done at all levels.

The national committees are responsible for **selecting, monitoring, and reporting on indicators (see box on right) and milestones (see below)** based on the country situation. All sub-national monitoring efforts should feed back to the national switch management committee. This committee then can **report to the WHO and UNICEF country offices** on a few agreed upon indicators relevant to global planning such as *developed plan, completed tOPV inventory, and vaccine delivery (TBD)*.

**Process Monitoring**

- ✓ Purpose: Monitoring switch planning and implementation
- ✓ Responsibility: Switch Management Committees or ICC
- ✓ Potential indicators (see Section 1.4):
  - National plan completed
  - Budget determined
  - OPV procurement plan completed
  - tOPV inventories completed
  - Disposal plan completed
  - Vaccine delivered
  - Training completed
- ✓ Reporting:
  - Monthly to ICC, until Feb 2016
  - Weekly from March 2016

**Suggested key milestones to track in process monitoring:**

- ✓ tOPV procurement plan drafted; first tOPV inventory completed (Mar-Apr 2015)*
- ✓ Switch budget submitted to national authorities (June 2015)*
- ✓ bOPV is licensed/registered or country accepts pre-qualified product (July 2015)*
- ✓ Budgeted national switch plan is endorsed (1 Sept 2015)
- ✓ Country budget approved (Oct 2015)
- ✓ Switch Support Team established (Oct 2015)
- ✓ Second tOPV inventory completed (Oct-Nov 2015)
- ✓ bOPV ordered (Oct-Nov 2015)
- ✓ Funds arrive at sub-national level (Feb 2016)
- ✓ bOPV delivered at national level (Jan-Mar 2016)
- ✓ Switch monitors trained (March 2016)
- ✓ All health workers have been trained
- ✓ bOPV use starts at all vaccination points on National Switch Day (April 2015)
- ✓ Validation data reviewed (April 2016)

***NOTE: these activities must begin in parallel with drafting and finalization of the national switch plan**

### 3.5.2 Monitor outcomes

The National or Sub-Regional Certification Committee certifies the validation of tOPV removal and disposal.

Validation involves evaluating data collected by staff hired by the MOH (i.e., Switch Monitors) who are independent from the switch process.

**Validation will occur during the 2 weeks after the National Switch Day.**

**Outcome Monitoring**

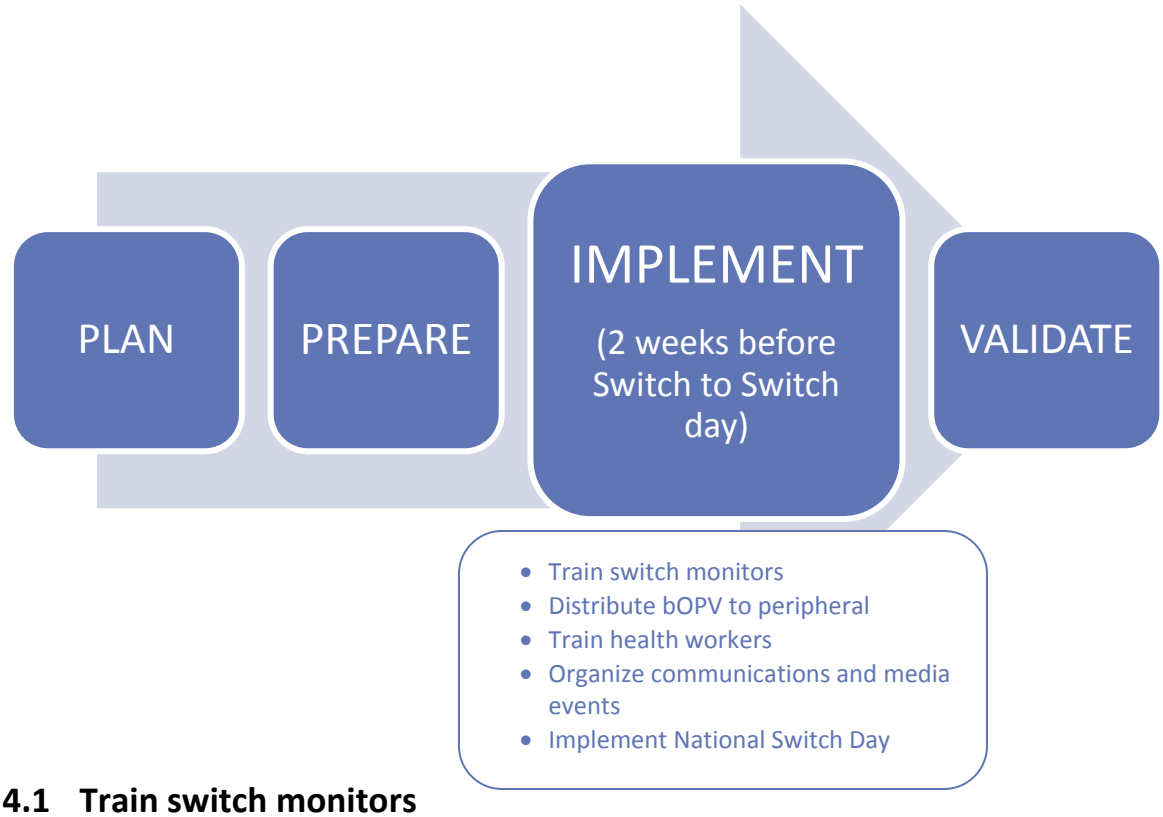
- ✓ Purpose: validate tOPV recall and disposal
- ✓ Responsibility: National or Sub-Regional Certification Committee
- ✓ Potential indicators:
  - Absence of tOPV in certain proportion of storage and service facilities validated by switch monitors (criteria depends on the risk status of country as determined by GPEI)
- ✓ Reporting:
  - National or Sub-Regional Certification Committee within 2 weeks of the Switch
  - Regional Certification Committee by end of April 2016

- **Identify switch monitors:** Switch monitors are responsible for visiting storage facilities to confirm recall and disposal of tOPV.
- **With enough time prior to the switch**, switch monitors should be identified. Switch monitors should be independent from the MOH and must have credibility. A national or partner health official can recommend switch monitors and verify that person has performed well in a previous activity in a similar capacity. Once all switch monitors are identified, a roster of **Independent Switch Monitors (SM)** should be created in line with the independent monitors of SIA.
- **Develop a micro-plan for the SMs:**
  - **Site selection**: The type and number of facilities visited by SMs will depend on the country prioritization (to be developed). *GPEI is currently developing a framework for site selection, which will be shared with countries.* The guiding principle will be to visit at a minimum facilities with large quantities of tOPV (such as central, regional, and district stores). It is also

important to visit destruction sites and health centers that are selected at random, as well as those that are considered high-risk to implement all of the recommendations.

  - **Develop recording forms (see example in Annex 4):** Recording forms should include staff name and signature, SM name and signature, date, facility type, number of tOPV vials found and disposed, and certification signature.
  - **Site visits:** Supervisory visits can be used as the instrument for doing these visits.
  - **Reporting plan:** SMs should report daily to the Ministry of Health.
- **Plan for data analysis at national level:** at the national level, all reports from SMs should be compiled into a single dataset and analyzed by the National or Sub-Regional Certification Committee for final validation
- **Develop contingency plan:** for sites that have not withdrawn or destroyed tOPV; if such sites are identified, the extent of the problem may be broader and would need to be addressed by country authorities.

# 4 Phase three: IMPLEMENT




## 4.1 Train switch monitors

Two weeks prior to the switch, initiate training of the previously-selected independent switch monitors. The monitors should be trained on:

- Roles and responsibilities
- Selecting the regional, district, and service facilities based on the country risk
- Verifying the absence of tOPV at selected facilities
- Disposal of tOPV if any residual tOPV is found in facilities
- Communicating and reporting outcome of facility visits to reporting authorities

## 4.2 Distribute bOPV to all peripheral levels

Two weeks prior to the switch, begin distributing bOPV to all service facilities. During this period, both bOPV and tOPV will be in the cold chain across the country.

## 4.3 Train health workers

Use approaches similar to other vaccine introductions and SIAs (e.g., cascade training) to train health workers on relevant aspects of the switch.

To prepare for the training:

- ☑ Develop materials in advance (see Section 3.3.1)
- ☑ Reserve a full day for training
- ☑ Notify participants in advance
- ☑ Book a venue
- ☑ Set a training agenda
- ☑ Invite at least one health worker per facility
- ☑ Set a maximum limit per training session
- ☑ Ensure objectives are understood

## 4.4 Organize communications and media events

On the National Switch Day, countries may want to broadly disseminate key reminders related to the tOPV removal and disposal from all service facilities. Organizing media and press activities as a strategy to remind and motivate vaccinators could also be considered.

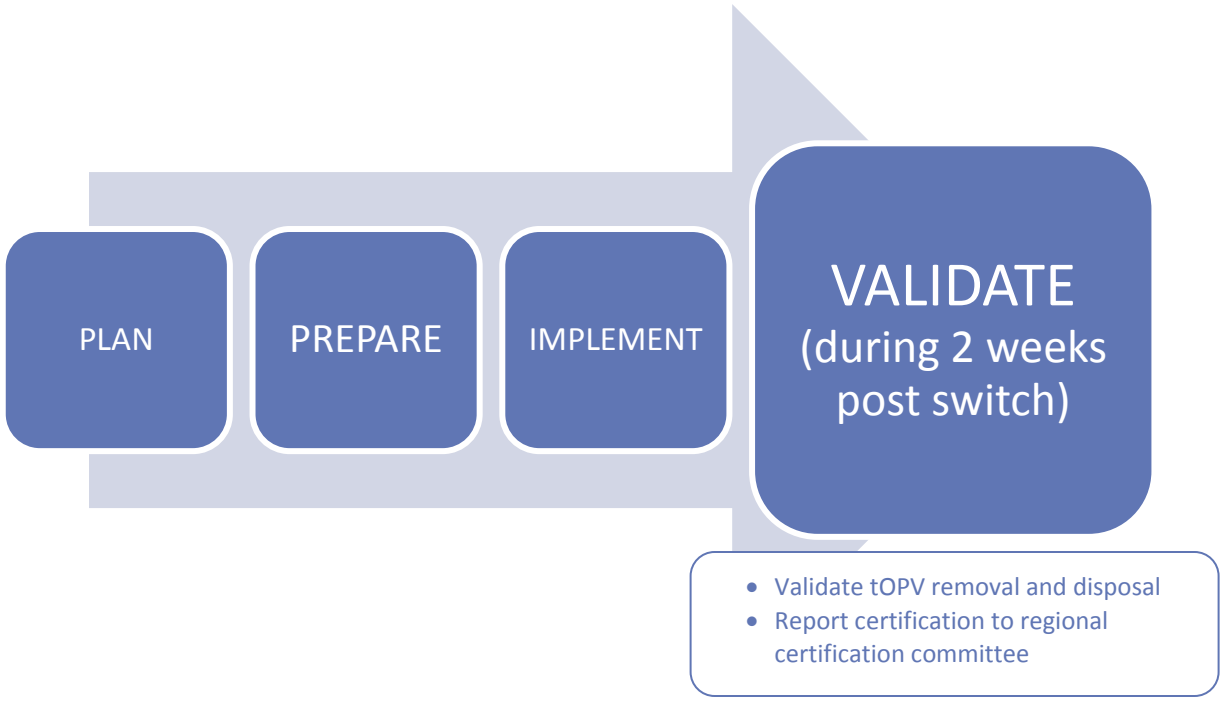
## 4.5 Implement National Switch Day


On switch day all tOPV should be taken out of the cold chain so that it no longer claims storage capacity.

Although tOPV will lose its potency quickly outside the cold chain, precautions should be taken to ensure that nobody could inadvertently get a dose of tOPV that has been outside the cold chain.

Place a sticker (see example figure) on the tOPV primary packaging and transport vaccine out of the cold chain to the agreed site for disposal (see Section 3.4.4).

# 5 Phase four: VALIDATE



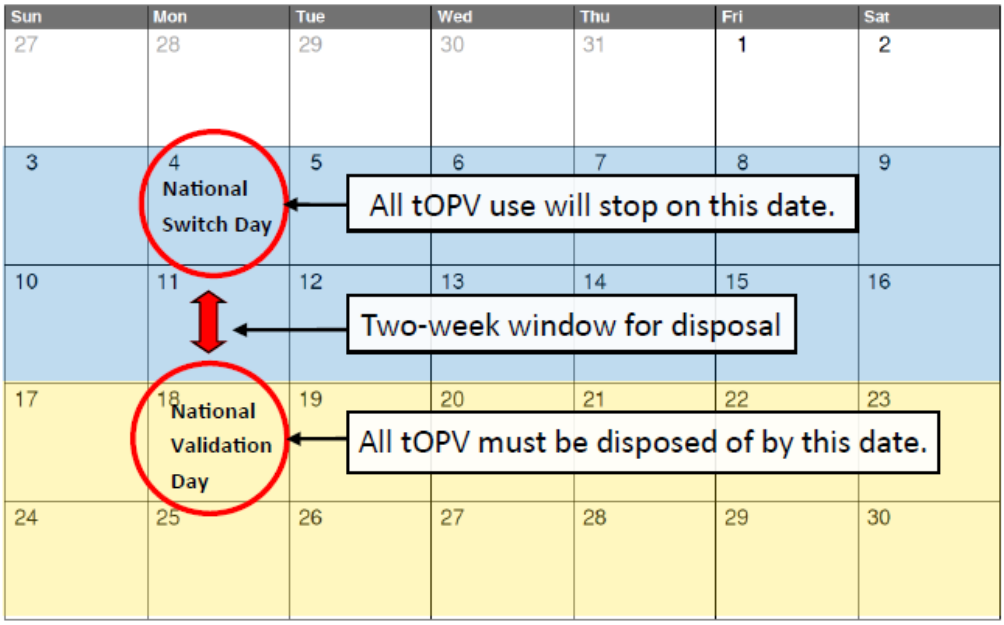

## 5.1 Validate tOPV removal and disposal

Trained switch monitors are responsible for validating the appropriate disposal of tOPV at randomly selected sites according to validation micro-plans (see Section 3.5.2). Validation should occur during the two weeks following the National Switch Date.

- ☑ Select and visit sites to validate tOPV free
- ☑ Record tOPV information
- ☑ Properly dispose of residual tOPV
- ☑ Report validation results to Coordination Committee and the Ministry of Health by the **National Validation Day, exactly two weeks after the National Switch Day (see figure below)**

Example of a National OPV Switch Month

April 2016




## 5.2 Report certification to regional certification committee

During the two weeks after the National Validation Day, the National or Sub-Regional Certification Committee is responsible for collating and analyzing the validation data collected by the SMs. Following data analysis, the Committee must either:

☑ Validate the country tOPV free and report status to the Regional Certification Committee through the PAHO representation in the country.

OR

☑ Recommend activating contingency plans for addressing remaining stocks of tOPV

# Annex 1: Sample Terms of Reference for Switch Management Committees and Support Teams

**Sample Terms of Reference (TORs) for the National Switch Management Team or ICC**

| | Members | Responsibility | Meeting Frequency |
|---|---|---|---|
| **Inter Agency Coordination Committee (ICC)** | - Presided by high-level staff from the Ministry of health, the ICC should be composed of high-level staff from relevant ministries (communication, sanitation, etc.), partners, and major NGOs.<br>- At least one SST member (see below) should be invited to the ICC to ensure adequate information flow between the planning and implementation levels. | - Elaborate the national switch plan with clear functions, responsibilities and deadlines<br>- Establish an operations room for coordination, information and communication<br>- Assure complete implementation of the National Switch Plan<br>- Report to higher-level authorities<br>- Communicate with partners and the press<br>- Monitor progress using a dashboard with key indicators (e.g., vaccine ordered and supplied, funds arrived, etc.)<br>- Take corrective action when needed | With increasing frequency from monthly in the early phase to daily during the switch. |

**Sample TOR for Switch Support Team**

| 6-12 months prior to switch | 2 months prior to switch | During the switch | After the switch |
|---|---|---|---|
| **National and Departmental level** | **Municipal level** | **Municipal level** | **Municipal, departmental and national level** |
| **National level:**<br>- Co-organize with the ICC a full day meeting with regional health staff and administrative authorities to explain the switch.<br>- Help compile stock inventories.<br>- Based on the inventory, estimate remaining tOPV requirements (plus a margin of two weeks)<br>- Calculate bOPV requirements for the rest of the year following the switch.<br>- Share the requirements with the EPI Focal Point and the PAHO Revolving fund.<br>- Participate in ICC meetings.<br>- Ensure adequate information flow between national and regional levels.<br><br>Departmental level (visits to all municipalities in the department):<br>- Organize a half-day meeting with local health staff and administrative authorities to explain the switch.<br>- Inventory existing tOPV stock | Organize an informational meeting with all the proges<br>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.<br><br>Visit all districts as well as an agreed proportion of immunization service points to:<br>1. Ensure the district and service points are aware of the switch and have the necessary communication materials.<br>2. Ensure the district received the necessary stationary for bOPV.<br>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.<br>4. Refine the OPV inventory and share inventory data with the EPI focal point and UNICEF.<br>5. Ensure districts storage capacity is sufficient when both products are present and adequate steps are taken when it is not.<br>6. Discuss stock management procedures with the EPI focal point and stock manager using a simple checklist. | - Same activities as before, but focused on risk areas.<br>- Ensure availability of enough vaccine carriers on the day of the switch.<br>- Confirm disposal sites are ready.<br>- Ensure availability of updated stationary and forms.<br>- Inform higher-level officials of anything that could derail the switch. | - Visit an agreed proportion of service points to confirm the absence of tOPV.<br>- Assist at district level to ensure all tOPV (routine and SIA) is sent back to regional level within 6 days.<br>- Make a simple report on the switch at district level and share the report with superiors.<br>- Move to the regional level and support all activities related to the tOPV removal. |

# Annex 2: Briefing note on the switch

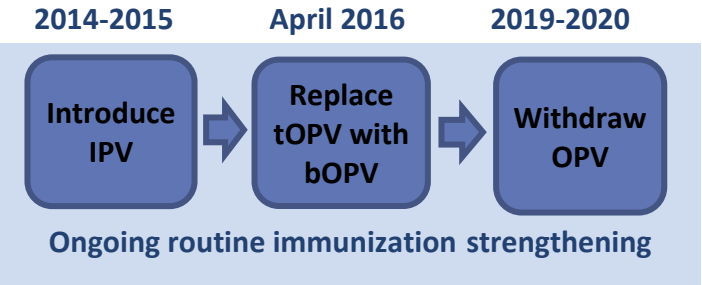
## Preparing for the withdrawal of all oral polio vaccines (OPVs): Replacing trivalent OPV (tOPV) with bivalent OPV (bOPV)

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 Global Polio Eradication Initiative's *Polio Eradication and Endgame Strategic Plan 2013-2018*, approved by the Executive Board of WHO in January 2013, requires the phased removal of all oral polio vaccines (OPVs). This will eliminate the risks of vaccine-associated paralytic polio (VAPP) and circulating vaccine-derived poliovirus (cVDPV).

**If not already underway, planning for OPV cessation must start now, while efforts are being intensified to interrupt transmission of the remaining strains of wild poliovirus.** Preparation for the removal of OPVs includes introducing at least one dose of inactivated polio vaccine (IPV) into routine immunization programmes in all countries by the end of 2015.

**The *Endgame Plan* requires the removal of all OPVs in the long term, beginning with a switch from trivalent OPV (tOPV) to bivalent OPV (bOPV), removing the type 2 component (OPV2) from immunization programmes.** After all wild polioviruses have been fully eradicated, then all OPVs will be withdrawn.

**The current target date for the switch to bOPV is April 2016,** during the 'low' season for poliovirus transmission in many countries with endemic polio or recent polio cases.




## The rationale for OPV withdrawal

Currently, 145 countries use tOPV to vaccinate children against polio in their routine immunization programmes. tOPV contains all three poliovirus serotypes (1, 2 and 3), and the use of this vaccine has led to the eradication of wild poliovirus type 2 (WPV2), with the last case occurring in 1999. The last detected case of WPV3 was in 2012. Furthermore, four of the six WHO regions have been certified as polio-free.

**Even as the remaining strains of wild poliovirus are being eradicated, the switch from tOPV to bOPV will be a major step to combat cVDPV and VAPP.** Over 90% of cVDPV cases, and approximately 40% of VAPP cases, are due to the type 2 component of tOPV. The type 2 component of tOPV also interferes with the immune response to poliovirus types 1 and 3.

Given the risk the type 2 component of tOPV poses to a world free of WPV2, tOPV will be replaced in routine programmes and supplementary immunization activities (SIAs) by bOPV. bOPV contains type 1 and 3 serotypes only, to help stop transmission of WPV1 and 3, and to reduce the risk of VAPP and cVDPVs.

The introduction of IPV will help to reduce risks associated with the withdrawal of OPV type 2, facilitate interruption of transmission with the use of monovalent OPV type 2 in the case of outbreaks, and hasten eradication by boosting immunity to poliovirus types 1 and 3.

## Preparing for the switch

The primary risk associated with the cessation of use of type 2 OPV is the re-introduction of disease-causing type 2 poliovirus into a population with increasing susceptibility to type 2 poliovirus. **The switch from tOPV to bOPV must therefore be globally synchronized to minimize the risk of new cVDPV type 2 emergence.**

**As soon as possible, countries are advised to develop operational plans for implementing the switch,** involving all relevant national entities (for example, the Inter-agency Coordination Committee).

Early preparation of national plans will help establish clear timelines for:

- **Vaccine supply planning, including close ongoing management and monitoring of tOPV inventories and requirements up to April 2016**
- Calculating projections of bOPV needs
- Procuring bOPV (for self-procuring countries)
- Planning and budgeting the collection, transport, storage, and proper disposal of tOPV once withdrawn from the cold chain
- Training health workers on the rationale and process of the switch
- Communicating with local experts and other stakeholders

## Registration of bOPV for routine use

Currently, bOPV is only licensed for use in supplementary immunization activities. Based on clinical data, the labelling of bOPV is expected to be revised by mid-2015 to enable use of this vaccine in routine immunization. While formal licensing and national registration procedures are underway, countries will be encouraged to accept the use of this vaccine on the basis of WHO prequalification.

## Planning for a final procurement of tOPV

**Countries should plan their forecasts and procurement in a way that aims to minimize any residual tOPV stocks on hand by April 2016, while avoiding stock-outs prior to the switch.** Minimal tOPV stocks will reduce the costs and logistics of disposal of all remaining unused tOPV after the switch.

### KEY DATES

**March 2015**
National authorities begin operational planning.

**May 2015**
The World Health Assembly considers a resolution on the switch.

**September 2015**
National plans are finalized.

**October 2015**
SAGE will assess the epidemiology of persistent type 2 cVDPVs as part of a readiness review.

**April 2016**
Expected date for switch from tOPV to bOPV.

**April and May 2016**
Validation of the removal of all tOPV.

**From May 2016**
**tOPV will no longer be used globally, neither in routine immunization, nor in SIAs.**

**For countries procuring through UNICEF or PAHO Revolving Fund, close coordination and sharing of stock levels with UNICEF and PAHO country offices is critical to minimizing excess stocks of tOPV remaining in April 2016.** For self-procuring countries, forecasts should be shared and jointly reviewed with vaccine suppliers to help facilitate the timely procurement of appropriate amounts of tOPV and bOPV for the transition. WHO and UNICEF will be available to facilitate this process as required.

Technical assistance and guidance on aspects such as operational planning, stock management, and communications will be shared in due course.

# Annex 3: Sample key messages for 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 {***insert National Switch Date***}. This means that beginning on that date, **no more tOPV** will be used **anywhere** and for any progamme, neither private nor public, in the country.

- **Distribution of bOPV** will begin **2-4 weeks** prior to the switch. You will be informed when you will be supplied.

- On switch day you will:
    - **Stop using tOPV** and start using bOPV instead;
    - **Take all tOPV out of the cold chain**;
    - **Mark all tOPV** with the stickers supplied with for that purpose.
- **All tOPV** will be **removed from the cold chain** and safely **disposed** of in approved disposal sites. You will be given separate guidance on how to dispose of tOPV.
- **<u>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.</u>**
- 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 immediately.

## Annex 4: Sample validation forms for tOPV – disposal facility

| **tOPV Recall Form** | | ID (code or name of department, municipality and facility) |
|---|---|---|
| Type: Hospital □ Health Center □ Vaccination Post □ Other □ _____<br>Name: | | |
| Name of Responsible Staff | Title | Signature and Date |
| **Inspection of Facility** | | |
| Existing tOPV viales (unopened or opened) | Yes □ No □ | |
| Number of vials removed | | |
| Sent to final destruction site | Sí □ No □ | |
| Name of final destruction site | | |
| **Received at Destrucction Site by:** | | |
| | Name / Title | Signature and Date |
| Observations: | | |

Two copies: one for the health center and one for the destruction site

| **Monitor's tOPV recall Form** | | ID (code or name of department, municipality and facility) |
|---|---|---|
| Type: Hospital □ Health Center □ Vaccination Post □ Other □ _____<br>Name: | | |
| Name of Responsible Staff at the Health Center: | Title | Signature and Date |
| **Inspection of Facility** | | |
| Is there a tOPV recall form? | Yes □ No □ | |
| Are there existing tOPV viales in the center (unopened or opened) | Yes □ No □ | |
| Was tOPV sent to the final destrucction site? | Yes □ No □ | |
| Name of final destruction site | | |
| **Monitor certification** | | |
| Name | Title | Signature and Date |
| Observations: | | |

Two copies: one for the health center and one for the supervisor

# Annex 5: WHO recommendations for the disposal of tOPV

There are several ways to dispose of unused and opened tOPV vials. WHO considers some options for disposal better than others depending on national and regional capacity. Note that within each of the four categories below, the best options are listed first:

1. **Incineration:** Incineration can be an option in countries with access to high or medium-temperature incinerators.
    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.
2. **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.
3. **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.
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.

**NOTE:** the first three options do not require opening unopened vials of tOPV

# Annex 6: Template and chronogram for developing a national switch plan

This generic template is to guide countries in developing a practical national plan for the tOPV-bOPV Switch. It is intended to provide suggestions for key areas to be considered, and as such, may be missing some items relevant to a particular country, or equally may contain some items that are not relevant.

## Executive summary of the National Switch plan

- Summary of the switch activities
- Date selected for the National Switch Day
- Overview of national coordination mechanism to ensure a successful switch
- Overview of monitoring and supervision mechanism
- Overview of validation mechanism
- Current procurement process (PAHO Revolving Fund or self-procuring)
- Budget and funding sources

## 1. Management, coordination and validation mechanisms

### 1.1. National management/coordination mechanism to ensure a successful switch

- Describe the national and sub-national level management structure and process to oversee and implement the switch, including any national and sub-national switch committees and/or subcommittees.
- Provide an organizational chart with roles and responsibilities for:
    - National and sub-national Switch Committees
    - Switch Support Teams
- Outline reporting and information flows and frequency
- Provide a workplan and timeline
    - Select the National Switch Day
    - Include the timeline/date for the withdrawal of tOPV and delivery of bOPV at each distribution level
- Explain how the switch activities are synergized with other planned public health and immunization activities, including new vaccine introductions.

### 1.2. Validation mechanism

- A description of the validation of tOPV withdrawal from routine immunization system including from the stores at the national and sub-national levels; All tOPVs are recalled including unopened intact vials, expired vials, partially used and empty vials; validate that no tOPV is left out or stored in a cold chain for use at any level; validate through review reports from programme/administrative reports, switch monitors reports, independent survey reports, etc.
- Describe the validation structure and process.
- Develop an organizational chart with roles and responsibilities and reporting structures of the:

- National or Sub Regional Certification Committee for Polio Endgame should report to the Regional Certification Commission for Polio Endgame.
- Switch Monitors (can be at different levels and composed of individual experts from partners, members of the pediatric association and other medical professional bodies, members of the national task force for laboratory containment for polioviruses, members of the national Expert Review Committee for Polio Eradication, former EPI managers, former EPI cold chain managers, former EPI cold chain engineers, faculty from public health schools/universities, representatives of private clinics, hospitals, laboratories, pharmacies, former SIA monitors and SIA monitor supervisors, etc.). Switch monitors may report back to the National or Sub Regional Certification Committee for Polio Endgame.
- Develop a workplan and timeline for monitoring and validation activities.

## 2. Budget

Summarize the budget and financing of the national switch. A template is provided in Annex 7.

## 3. Supply Analysis and Procurement Plan

### 3.1. tOPV supply analysis

- Indicate current tOPV supply mechanism (e.g., through PAHO Revolving Fund).
- Provide current tOPV stocks by national, sub-national, and lowest distribution levels.
- Indicate whether an initial tOPV inventory has been completed or timeline for completion. Include private sector in supply analysis.
- Provide overview of current tOPV ordering and delivery schedules.

### 3.2. bOPV licensure and procurement

- State whether national vaccine licensure will be needed for bOPV for use in routine immunization, in addition to WHO prequalification, and if so, describe the procedure and its duration. State whether the country plans to accept the Expedited Procedure for national registration of WHO-prequalified vaccines.
- Provide the actual licensure status of the bOPV that will be used.
- Indicate whether specific requirements apply with reference to local customs regulations, requirements for pre-delivery inspection, special documentation requirements that may potentially cause delays in receiving the vaccine. If such delays are anticipated, explain what steps are planned to handle these.
- Indicate the quantity of bOPV that will be required and whether procurement will take place through PAHO Revolving Fund or directly with suppliers.

## 4. Implementation preparation

### 4.1. Learning from past vaccine switches

Indicate whether country has done a vaccine switch before and, if so, include any lessons learned.

### 4.2. Logistics

- Overview of cold chain capacity at district (3rd administrative level), provincial/regional (2nd administrative level) and central levels (national level).
    - Describe adequacy of storage and distribution capacity for tOPV and bOPV at each level of the cold chain, taking into account other planned vaccine introductions. Take into account the period during which both tOPV and bOPV will be stored simultaneously at national and some sub-national levels.
    - Where capacity is deficient, provide a plan to address.
    - Identify private sector facilities for vaccine storage.
- Provide a description of the transport system available for withdrawal of tOPV from public and private sectors.
- Describe transport system for delivery of bOPV to the periphery. Please address whether the frequency of deliveries needs to be increased or type of vehicle and vaccine carrier must be changed, and if so, whether there are sufficient funds, e.g. for vehicles, drivers, fuel, and per diem for distribution of the new vaccine at all levels.
- tOPV disposal:
    - Describe existing biological waste management processes and facilities at all levels.
    - Develop a plan for disposal of tOPV after withdrawal (follow the national guidelines for unused vaccine vials and empty vial disposal)

### 4.3. Updating information systems

Review current recording of polio vaccination/vaccination card/health card and indicate whether cards will need to be updated. If cards currently refer to OPV, updating may not be required.

### 4.4. Communication materials and dissemination, partner and stakeholder engagement

- Develop a communications plan.
- Describe plans to sensitize political and opinion leaders at national, regional, and district levels on the switch, benefits to the population, and contribution to the Polio Endgame Strategy.
- Describe plans for addressing potential issues, including an outlined process for determining what constitutes an issue, who can respond to inquiries, particularly from the media, training spokespeople and identifying a point person to handle communication issues.
- Identify monitoring mechanism for communication activities.

### 4.5. Health worker training and supervision

- Describe how human resources will be trained for smooth implementation of tOPV withdrawal and bOPV introduction across all sectors of the immunization program (e.g. for vaccine storage and management, in-country distribution, supervision, delivery both for public and private sectors, NGOs involved in routine immunization, etc.)
- Consider whether or not health workers have previous, recent experience with vaccine recalls. If so, use that experience in developing switch-related materials.

- Describe how health workers will be oriented about the switch and use of bOPV instead of tOPV, especially ensuring no use of tOPV after the switch date as well as the process for disposal of tOPV.
- Outline any plans for increased supervision activities before, during and after the switch day.

### 4.6. Monitoring

Explain how all aspects of the switch will be monitored:

- Preparedness
- Implementation of switch
- Withdrawal and disposal of tOPV
- Reporting mechanisms
- Identify whether any additional staff will be recruited for these monitoring activities.

### 4.7. Risk identification and mitigation

- Identify risks and challenges to the switch, e.g. financial and programmatic (including those issues identified in previous vaccine switches) and outline the plans to address them.
- Mention whether a switch control room will be established at national and sub-national level for close supportive supervision and crisis management.

**Table: Sample timeline used to visualize and track a number of tasks, milestones, deadlines, persons or agencies responsible.**

| Activity | Apr 15 | May 15 | Jun 15 | Jul 15 | Aug 15 | Sep 16 | Oct 15 | Nov 15 | Dec 15 | Jan 16 | Feb 16 | Mar 16 | 1 Apr | 8 Apr | 15 Apr | 22 Apr | 29 Apr | May 16 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Develop a procurement plan | | | | | | | | | | | | | | | | | | |
| First tOPV stock inventory | | | | | | | | | | | | | | | | | | |
| Country budget proposal submitted | | | | | | | | | | | | | | | | | | |
| Conduct ICC to oversee all activities relating to The Switch | | | | | | | | | | | | | | | | | | |
| Establish an operations room for coordination, information and communication | | | | | | | | | | | | | | | | | | |
| Development of appropriate training materials for The Switch | | | | | | | | | | | | | | | | | | |
| Order to cover use tOPV needs from Sept. 15 till Feb. 16 | | | | | | | | | | | | | | | | | | |
| National switch plan is developed and endorsed | | | | | | | | | | | | | | | | | | |
| bOPV is licensed and registered with NRA | | | | | | | | | | | | | | | | | | |
| Conduct workshops on The Switch | | | | | | | | | | | | | | | | | | |
| Positive Switch decision by SAGE | | | | | | | | | | | | | | | | | | |
| Country budget proposal accepted | | | | | | | | | | | | | | | | | | |
| ICC meeting with regional (health) authorities to explain The Switch | | | | | | | | | | | | | | | | | | |
| Establish a Switch Support Team (SST) | | | | | | | | | | | | | | | | | | |
| Forms and software affected by The Switch are listed | | | | | | | | | | | | | | | | | | |
| Train SST | | | | | | | | | | | | | | | | | | |
| Develop training material for health staff | | | | | | | | | | | | | | | | | | |
| Meeting with health staff and authorities to explain The Switch. | | | | | | | | | | | | | | | | | | |
| Ensure districts storage capacity is sufficient | | | | | | | | | | | | | | | | | | |
| Second tOPV stock inventories | | | | | | | | | | | | | | | | | | |
| Develop a recall plan for tOPV (including private sector if applicable) | | | | | | | | | | | | | | | | | | |
| Place bOPV order for the first 3 months after The Switch. | | | | | | | | | | | | | | | | | | |
| Place tOPV order for the period until the switch | | | | | | | | | | | | | | | | | | |
| Printing of new stationary, adapted to the use of bOPV | | | | | | | | | | | | | | | | | | |
| Design of simple "tOPV, do not use" sticker | | | | | | | | | | | | | | | | | | |
| Develop monitoring plan | | | | | | | | | | | | | | | | | | |
| Funds arrive at regional level | | | | | | | | | | | | | | | | | | |
| Develop distribution plan for bOPV | | | | | | | | | | | | | | | | | | |
| Select and train Switch Monitors | | | | | | | | | | | | | | | | | | |
| All vaccine delivered at national level | | | | | | | | | | | | | | | | | | |
| Inform regions and districts of the nearest disposal sites | | | | | | | | | | | | | | | | | | |
| Distribution of bOPV and tOPV to the regions | | | | | | | | | | | | | | | | | | |
| Training medical staff | | | | | | | | | | | | | | | | | | |
| Districts received OPV and stationary | | | | | | | | | | | | | | | | | | |
| Confirm disposal sites are ready. | | | | | | | | | | | | | | | | | | |
| **The Switch** | | | | | | | | | | | | | | | | | | |
| Return all tOPV to the nearest agreed disposal site | | | | | | | | | | | | | | | | | | |
| Final inventory for tOPV | | | | | | | | | | | | | | | | | | |
| Mark all tOPV with stickers and remove from cold chain | | | | | | | | | | | | | | | | | | |
| Return all tOPV to the district | | | | | | | | | | | | | | | | | | |
| Switch monitors assist and check recall of routine tOPV | | | | | | | | | | | | | | | | | | |
| Compile reports from Switch Monitors | | | | | | | | | | | | | | | | | | |
| Produce the statement confirming the absence of tOPV | | | | | | | | | | | | | | | | | | |

**Table: Key milestones as listed in the timeline**

| Activity | Apr 15 | May 15 | Jun 15 | Jul 15 | Aug 15 | Sep 16 | Oct 15 | Nov 15 | Dec 15 | Jan 16 | Feb 16 | Mar 16 | 1 A | 8 A | 15 A | 22 A | 29 A | May 16 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Develop a procurement plan | | | | | | | | | | | | | | | | | | |
| Country budget proposal submitted | | | | | | | | | | | | | | | | | | |
| National switch plan is developed and endorsed | | | | | | | | | | | | | | | | | | |
| bOPV is licensed and registered with NRA | | | | | | | | | | | | | | | | | | |
| Positive Switch decision by SAGE | | | | | | | | | | | | | | | | | | |
| Country budget proposal accepted | | | | | | | | | | | | | | | | | | |
| Establish a Switch Support Team (SST) | | | | | | | | | | | | | | | | | | |
| Second tOPV stock inventories | | | | | | | | | | | | | | | | | | |
| Printing of new stationary, adapted to the use of bOPV | | | | | | | | | | | | | | | | | | |
| Funds arrive at regional level | | | | | | | | | | | | | | | | | | |
| All vaccine delivered at national level | | | | | | | | | | | | | | | | | | |
| Districts received OPV and stationary | | | | | | | | | | | | | | | | | | |

# Annex 7: Budget template for the national plan

**Table: Sample budget for non-vaccine costs associated with the switch.**

| | Total Budget | Amount by funding source | | | |
|---|---|---|---|---|---|
| | | WHO | UNICEF | Govt. | Other |
| Document production | | | | | |
| Human resources | | | | | |
| Immunisation session supplies | | | | | |
| Logistics | | | | | |
| Planning and preparations | | | | | |
| Communications and stakeholder engagement | | | | | |
| Training and meetings | | | | | |
| Transport for implementation and supervision | | | | | |
| Waste management | | | | | |
| Additional items (specify) | | | | | |
| Miscellaneous | | | | | |
| Contingency | | | | | |
| **Grand total** | | | | | |