



Switch from tOPV to bOPV

Guidelines for Developing National Operational Plans

A handbook for national decision makers, programme managers, logisticians, and consultants on operational aspects related to nationwide switch from tOPV to bOPV

Version date: February 20, 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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ABBREVIATIONS & GLOSSARY OF TERMS

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



NOTE to REVIEWERS: This document does not discuss technical rationale or issues related to the global decision on timing of switch. It ASSUMES the Switch will occur APRIL 2016

INTRODUCTION

Why this document?

The World Health Assembly (WHA) mandates that all countries must eventually stop use of OPV beginning with removal of the type 2 component of trivalent OPV (tOPV) through a switch globally to bivalent OPV (bOPV), containing only types 1 and 3, for routine and campaigns. Depending on the epidemiology of poliovirus disease globally, the switch from tOPV to bOPV (the Switch) could occur as early as April 2016. After this date no manufacturers will produce or distribute tOPV. The Switch must be a **globally coordinated process**; ongoing tOPV use in some locations after April 2016 would jeopardize polio eradication due to possible generation of circulating vaccine-derived polioviruses.

To meet this timeline, it is imperative that all OPV-using countries begin Switch planning during Q1, 2015 and **finalize a budgeted National Switch Plan by September 1, 2015**.

Timely planning and implementation of such a plan will lead to successful recall and disposal of tOPV, minimize tOPV wastage, validate a country free of tOPV and ensure a world free of circulating vaccine-derived polioviruses type 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. It is recognized that country needs will vary and **their plans should be adapted to meet those implementation needs**.

Who is the target audience?

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

Date of Switch: April 2016

Initiate Planning: Quarter 1, 2015

Finalize National Switch Plans: by September 1, 2015

Primary Objectives of a Switch Plan

- Successful recall of tOPV & replacement with bOPV in April 2016
- Minimize tOPV wastage after Switch
- Ensure all children are vaccinated (ie, avoidance of tOPV stockouts before Switch and bOPV stockouts after switch)
- Validation that country is free of tOPV

Switch on a page (add months later)

| | |
|----------------------------|---|
| Plan | By June 2015 |
| | <ul style="list-style-type: none"> - Establish management structure - Establish National Switch Validation Committee (NSVC) - Conduct situational analysis - Draft national switch plan (budgeted and finalized by 1 Sept 2015) |
| Prepare | May to September 2015 |
| | <ul style="list-style-type: none"> - Detailed tOPV inventory; adjust tOPV delivery* - Funding secured - Monitoring plan |
| | October to November 2015 |
| | <ul style="list-style-type: none"> - Last tOPV inventory; adjust tOPV orders and/or delivery - Order bOPV - Waste management assessed - Switch support staff hired |
| | December 2015 – January 2016 |
| | <ul style="list-style-type: none"> - Last tOPV delivery to country** - Training materials read - Implement communications strategy - bOPV deliveries to country begin*** |
| Implement | February – March 2016 |
| | <ul style="list-style-type: none"> - Last 1-2 months of tOPV delivered to periphery - Identify Switch Monitors |
| | 2 weeks before the Switch |
| | <ul style="list-style-type: none"> - Train Switch Monitors - Train health workers - Distribute bOPV to periphery and service points |
| National Switch Day | A day chosen during the first 2 weeks of April 2016 |
| | <ul style="list-style-type: none"> - Stop use of tOPV and remove tOPV from cold chain - Begin use of bOPV |
| Validate | During the two weeks after the Switch |
| | <ul style="list-style-type: none"> - Complete disposal of tOPV - Switch monitors to validate at selected sites - Report to NSVC - NSVC reviews data and validates Switch |

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

** Unless tOPV stock out

*** Could extend to March 2016 due to logistics

Key Messages of this document

Manufacturers and UNICEF will stop supplying tOPV for use beyond April 2016. Instead they will supply bOPV for use in routine immunization programs and campaigns

- All countries should stop use of tOPV and destroy remaining stocks of tOPV after 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
- Countries are responsible for:
 1. **National Switch Date**: decision-makers must establish a **Switch Date** during a 2 week window in April 2016 advised by SAGE, when tOPV is removed from all service points and storage facilities, tOPV is discarded, and bOPV is introduced. tOPV disposal process begins.
 2. **Validating absence of tOPV**: during the 2 weeks after the Switch Date, countries must validate that all service points, public and private, and storage facilities are free of tOPV using appropriate methods of disposal as recommended in this document
 3. **National validation**: appropriate national authorities (e.g. National Switch Validation Committee) must review and affirm data to validate country free of tOPV within 2 weeks of Switch Date

All OPV using countries should **begin planning for the Switch in Q1 2015** and **finalize a National Switch Plan by 1 September 2015 using recommended template**, leaving ~10 months to prepare and implement activities:

1. **Management/oversight**: By mid-2015, countries are encouraged to establish Switch Coordination Committees at national and subnational levels responsible for developing the Switch Plan and providing implementation oversight (e.g., interagency coordination committee, ICC)
2. **Preparation**: Countries are encouraged to **hire staff (i.e. Switch Support Teams)** assigned specifically to prepare and implement the Switch Plan
3. **Implementation**: training; bOPV distribution to periphery; tOPV withdrawal and disposal
4. **Validation**: Validation of tOPV absence by a **team (i.e. Switch Monitors) independent of the Ministry of Health (MOH) and Switch Implementation team**. Data to be reviewed and affirmed by an independent body that has delegated authority by the MOH to validate the country free of tOPV (i.e. National Switch Validation Committee)

Minimizing tOPV wastage is a shared responsibility at global, regional, and country levels. Residual stocks of tOPV also increase the risk of leftover tOPV stocks being used after the Switch. 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 various times prior to the Switch and incorporating this information into vaccine procurement plans. Minimizing wastage should never be achieved by not vaccinating eligible children.

Overview of Switch planning, preparation, & implementation

A successful Switch entails 4 inter-related phases that are outlined in Figure 1:

Phase 1 – PLAN:

By end Q2-2015, establish management committees. Draft a National Switch Plan (finalize by 1 September 2015). Identify the strategies and activities needed for a successful nationwide Switch

Phase 2 – PREPARE:

As early as Q2, 2015, undertake strategies and activities outlined in the National Switch Plan

Phase 3 – IMPLEMENT:

2 weeks prior to Switch, begin activities for tOPV recall: train, distribute bOPV, and recall tOPV

Phase 4 – VALIDATE:

During 2 weeks after tOPV recall, review tOPV disposal data and validate country free of tOPV

Figure 1: Overview of key activities related to a successful Switch

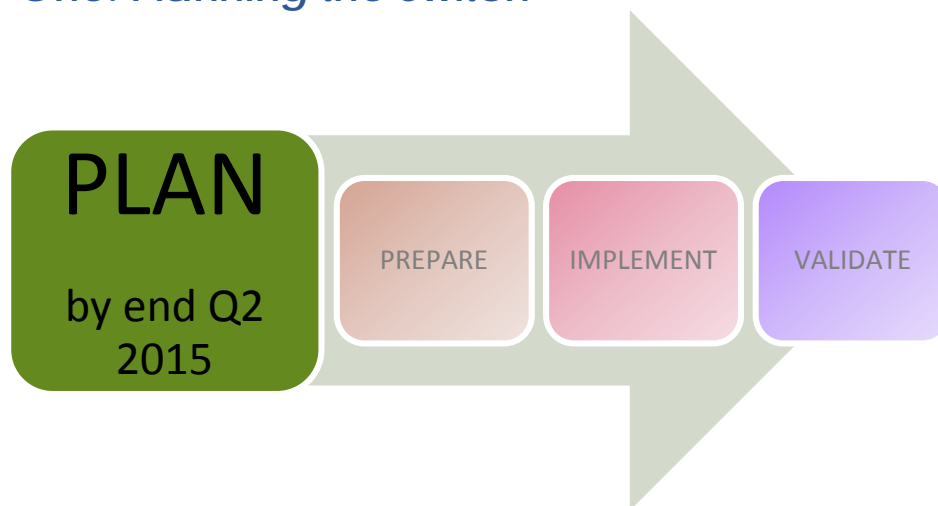
| Phase 1 PLAN (by end Q2 2015) | Phase 2 PREPARE (Q2 2015-Q1 2016) | Phase 3 IMPLEMENT (2 wks before Switch to Switch Day) | NATIONAL SWITCH DAY | Phase 4 VALIDATE (during 2 wks post Switch) | NATIONAL VALIDATION DAY |
|---|--|---|--|--|--|
| <ul style="list-style-type: none"> -Switch commitment -Management committees (e.g., ICC) -Certification Committee -Situational analysis -National Plan with Budget (finalize by 1 September 2015) | <ul style="list-style-type: none"> -Funding secured -Hiring staff -tOPV inventories -bOPV orders -CCL -Communication preparation -Training preparation -Assessment of waste management capacity -Finalize monitoring plans -Update information systems | <ul style="list-style-type: none"> -Train Monitors -Train HCWs -Deliver bOPV to all service points | <ul style="list-style-type: none"> -tOPV recall -tOPV disposal begins -bOPV only use begins | <ul style="list-style-type: none"> -Collect validation data on tOPV disposal -Report to NSVC | <ul style="list-style-type: none"> -Validate switch -Report to RCC |

Key documents and materials relevant to the Switch: [EXAMPLES ONLY – DOCUMENTS NOT FINALIZED]

- ☑ SAGE position & WHO position paper [<http://www.who.int/wer/2014/wer8901/en/index.html>]
- ☑ The Switch Protocol: [<http://tinyurl.com/ipv-intro>]
- ☑ Technical Rationale for the Switch: [[need paper; also refer to Switch Protocol](#)]
- ☑ Slide decks covering the technical and operational aspects of Switch [<http://tinyurl.com/ipv-intro>]
- ☑ Frequently Asked Questions: [<http://tinyurl.com/ipv-intro>]

Note: While this document provides guiding principles for planning and preparing for the Switch, some aspects outlined in this manual may not be applicable for all countries. The intention is for the countries to **adapt their Plan to meet local needs**.

1. Phase One: Planning the Switch



- Establish management structure
- Establish national certification committee
- Conduct situational analysis
- Draft national switch plan (budget and finalize by 1 Sept 2015)

1.1 Establish Management Structure –National & Regional Switch Management Committees

Establish a national and regional management structure (National and Regional Switch Management Committees) that would plan, manage, and oversee all activities relating to the Switch. This management body could be the Interagency Coordination Committee (ICC) or a similar body. Finance, procurement, regulatory, legal authorities outside MOH need to be included in the Switch management Committee, particularly applicable to self-procuring countries where disposal of state-procured vaccine may become a problem. The structure, roles and responsibilities would vary depending on country situation.

These management committees (see Annex 1) would oversee activities that would be implemented by staff hired or delegated by national authorities to prepare and implement the Switch (i.e. **Switch Support Teams**) as described in Section 2.2.2.

The first actions from the National Switch Management Committee would be to:

- **SELECT NATIONAL SWITCH DAY:**
 - Countries select a National Switch Day in the first 2 weeks of April 2016. tOPV use has to stop on this date

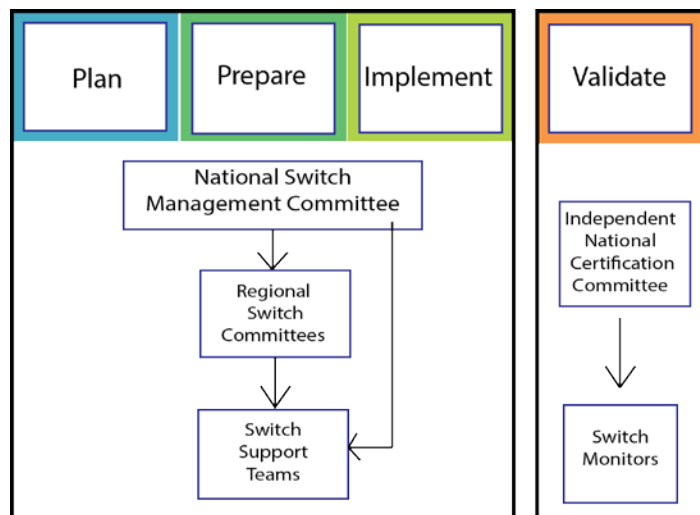
- **FORM SUBCOMMITTEES:** supply, communications, logistics, process monitoring & reporting
 - Ensure similar bodies exist at sub-national level
 - Ensure relevant Supply department is included in discussions
- **DEVELOP NATIONAL SWITCH PLAN:** Develop a National Switch Plan with budget and a timeline of activities (Annex 8), using elements from this document as a template
- **POINTS OF CONTACT:** Establish focal points for all national & regional committee members
 - Prepare roster of their names, telephone numbers and email addresses
 - Establish central telephone numbers and email addresses for questions from public or professionals
- **OPERATIONS CENTER:** Consider establishing an operations center to coordinate national, regional activities with up-to-date status of activities related to the Switch

1.2 Establish National Switch Validation Committee

Validating that a country is tOPV free is crucial. Countries without existing or functional **independent** National Switch Validation Committees (NSVC), (e.g. the national eradication certification committee) should establish them. Existing NSVCs (eg., for polio) should be empowered to undertake the Switch rather than forming new committees. The NSVC could comprise experts in public health, epidemiology, logistics, and clinical medicine **who would be independent of the Switch implementation** (i.e. not part of the Switch Committees).

Note: The NSVC would review data on **validation of tOPV recall and disposal collected by staff (i.e. Switch Monitors)**

independent from those responsible for implementing the switch (see Section 3.6 and Section 4.1)



The NSVC would be authorized by the Government to validate the Switch using indicators for Switch monitoring (see Section 2.4). The NSVC would verify and submit country documentation related to the tOPV recall and disposal nationally to the respective Regional Certification Committee.

Establishing Committees

- ✓ **Switch Management Committees:** plan, manage, and oversee the implementation of the Switch activities.
- ✓ **National Switch Certification Committee:** a body independent from Switch implementation activities that is authorized to validate the Switch.

1.3 Conduct Situational Analysis—Switch-specific things to know before implementation

In conjunction with the Switch preparations & implementation activities, the following information should be evaluated:

- **Supply & distribution of OPV:**
 - How is vaccine procurement organized: UNICEF, directly by MOH, or a mix?
 - What is the tOPV stock status at national, regional, and district levels one year prior to the Switch (see Annex 2)?
 - What is the periodicity of tOPV supply to the country, regions and district?
- **Licensing:**
 - Has the NRA licensed bOPV for routine, or what must be done?
 - Ensure regulatory approval for use of bOPV in routine immunization programs. This may be through in-country licensing of bOPV or through use of WHO supported expedited reviews to fast-track registration of a prequalified vaccine.
- **Private sector:** Is tOPV offered in the **private sectors** or by traditional healers, and how will that affect the Switch? How do they procure tOPV? How can countries ensure that the private sector will participate on the Switch?
- **Communications:** an analysis/overview of barriers and enablers to the switch among key stakeholders, e.g. health workers, key scientists/researchers, specific interest groups, public and media.
- **Waste management:** How is medical waste disposal organized and how can disposal of tOPV be aligned with these guidelines, using WHO guidance?
- **Experience:** 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?
- **Resources:**



- 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?
- 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?

All points requiring action should be included in the National Switch Plan

1.4 Draft a National Switch Plan

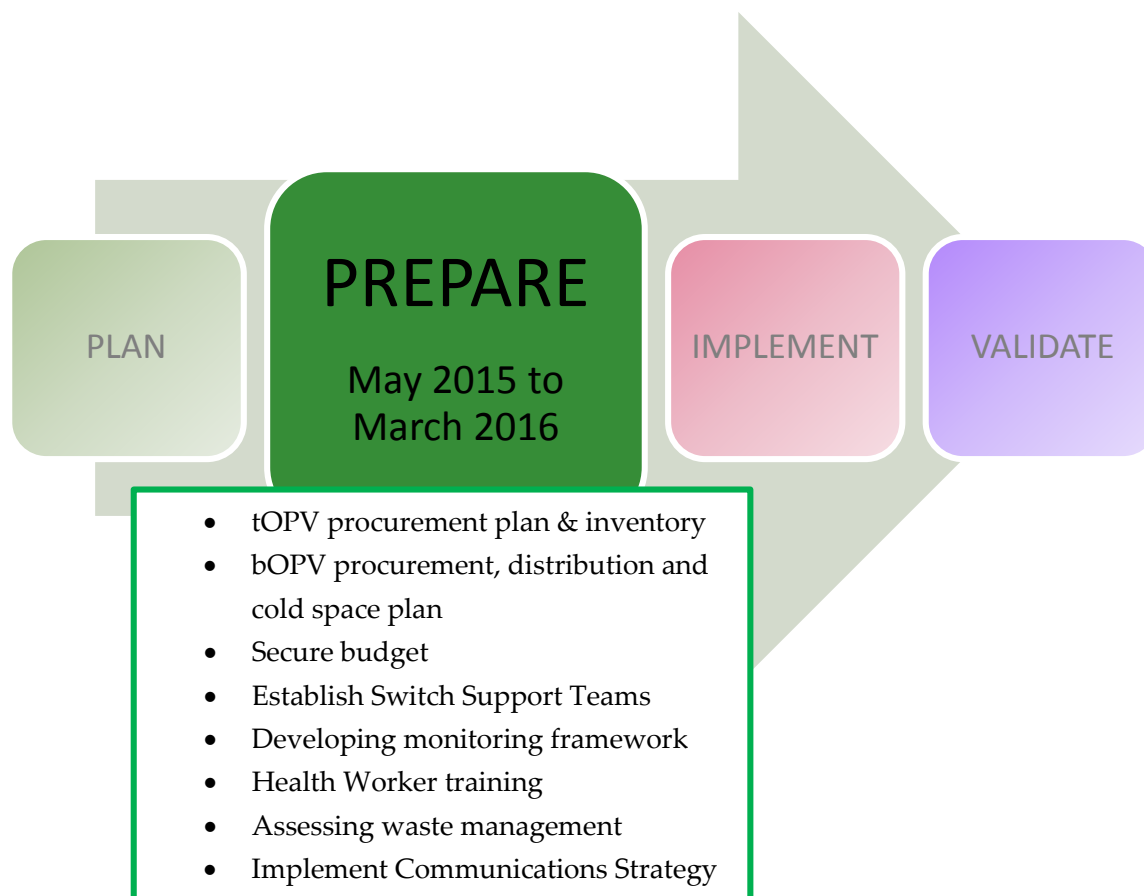
All countries should begin drafting a National Switch Plan, including a budget by end of Q2-2015 **using this document as guidance and template** to meet country needs (Table 1). A plan should be finalized and approved by the ICC **by 1 September 2015**.

Table 1. Checklist of the components of a sample National Switch Plan

| Section | Key components |
|--|--|
| Executive Summary (2 pages) | <ul style="list-style-type: none"> ✓ Summary of the Switch plan activities ✓ Date selected for the National Switch Day ✓ Overview of National coordination mechanism to ensure successful Switch ✓ Capacity to Switch, including financial needs and resources ✓ List of preparatory activities, including plans for tOPV inventory ✓ tOPV disposal & validation strategy ✓ Key risks and mitigating strategies: supply, logistics, validation ✓ Key milestones and activities |
| Section | Key components |
| Management and operational oversight of Switch – national coordination mechanisms | <ul style="list-style-type: none"> ✓ Organizational Chart w/ roles and responsibilities <ul style="list-style-type: none"> • ICC or NSC • Regional Switch Committees • Switch Support Teams ✓ Information flow – who informs whom & with what frequency ✓ Budget ✓ Work plan and timeline |
| Validation Committee | <ul style="list-style-type: none"> ✓ Roles and responsibilities ✓ Validation & reporting process |
| Situational Analysis | <ul style="list-style-type: none"> ✓ Supply & distribution of OPV, including role of private sector ✓ Licensing & regulatory approvals of bOPV ✓ Waste management system including reverse logistics system in place to |

| Section | Key components |
|----------------------------|---|
| | <ul style="list-style-type: none"> collect tOPV ✓ Stock of tOPV and bOPV to date. |
| Preparation | <ul style="list-style-type: none"> ✓ Switch support <ul style="list-style-type: none"> ○ Securing budget ○ Establishing Switch Support Team ○ Communications materials and dissemination ✓ Supply assessment <ul style="list-style-type: none"> ○ tOPV procurement plan & inventory ○ bOPV procurement, distribution, and cold space ✓ Logistics <ul style="list-style-type: none"> ○ Planned healthcare worker training and supervision ○ Updating information systems (paper and software) ○ Waste management – provision for tOPV disposal ✓ Monitoring <ul style="list-style-type: none"> ○ Process monitoring: assessing switch activities milestones ○ Outcome monitoring: validation of tOPV recall & disposal |
| Implementation | <ul style="list-style-type: none"> ✓ Training of Switch Monitors ✓ bOPV delivery or replenishment to service points ✓ Training of health workers |
| National Switch Day | <ul style="list-style-type: none"> ✓ Begin tOPV recall & disposal ✓ Begin bOPV use |
| Validation | <ul style="list-style-type: none"> ✓ Switch monitor site visits ✓ Collect validation data ✓ Review and affirm validation data |

2. Phase Two: Preparation Activities and Actions



To facilitate the Switch in April 2016, preparatory activities should **begin at a national level during Q2 to Q3-2015**. Steps to consider would include:

2.1 Supply Assessment

2.1.1 tOPV procurement plan & inventory

Three principles guide the **tOPV procurement plan in the final year** before the Switch (Annex 2):

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 synchronised switch to bOPV**.
2. All tOPV that remains in countries after the Switch date will need to be **recalled 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.

Below are some recommended practices for countries to incorporate into their tOPV procurement and supply management over the next year.

Develop a tOPV procurement strategy that AVOIDS:

- ☑ Children not being immunized through stockouts BEFORE the Switch
- ☑ Excess tOPV AFTER the Switch (maximum 1-2 weeks stock)

Strategies to minimize excess tOPV stocks or stockouts include:

1. **Maintain existing ordering process BUT it is advised to split orders into minimum 2 deliveries** during year before the Switch
 - a. **Avoid deliveries resulting in stock levels beyond April 2016**
 - b. **Make smaller deliveries** closer to the Switch to adjust for last few months
 - c. The LAST delivery should be adjusted to meet stock needs for the Switch timelines
2. Conduct two tOPV inventories at 12 months and 6 months before the Switch to adjust orders
3. **Conducting the initial inventory as soon as possible in the year** will allow countries to adjust procurement plans, delivery schedules, and quantities to minimize excess stocks

Stock management and inventories:

1. Assess current national (primary) and subnational level stock balances
2. Review and adjust **if required** current procurement plans/orders/requests for vaccines/delivery schedules from suppliers/UNICEF/other agency
3. Conduct 2 inventories, with at least one down to the district level or lower:
 - First inventory: ~ 1 year prior to the Switch (March-April 2015)
 - Second inventory: ~6 months prior to the Switch (October-November 2015)
4. Inventories should include the following:
 - Central medical/cold chain stores, including Regional warehouses/depots. This should include both Government-owned and autonomous agencies.
 - Provincial Warehouses
 - District warehouses
 - Any hospital at district, provincial, and tertiary level where they provide related immunization services (depending on country)
 - Private sector, including pharmacy stores, warehouses, or other location that provides OPV to customers.

Inventories should also take into account the following:

- Supply balances from recent SIA activities



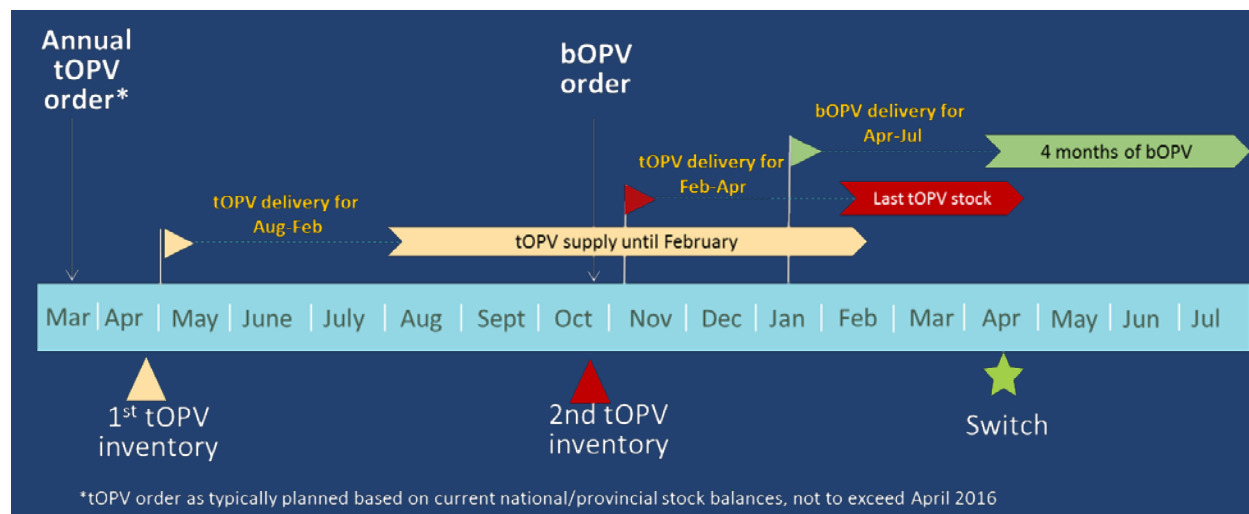
- Pipeline deliveries (recently received but not yet registered, or supply already on order and pending delivery)

Quantities of tOPV for order and consumption:

- Countries should ensure quantities delivered are sufficient to meet routine immunisation consumption requirements at all levels of the health system through April (include ~1-2 weeks of buffer supply).
- Delivery strategies will depend on country context, importation and customs regulations, and logistics.
- **Countries that order 12 months of stock with either 1 or 2 shipments are at highest risk of wastage of tOPV.** These countries are advised to reduce their order requirements and to stagger deliveries in order to make any adjustments during the year.
- **Below is a recommended strategy for countries to consider:**
 - minimum of 2 deliveries of tOPV supply in 2015 to allow for adjustments to be made in the last 1-2 deliveries as required after a national inventory of tOPV supply (See Example Box)
 - Where more than a single delivery not feasible, **countries should review their stock balances and make any adjustments to their requirements and orders to minimize residual stocks.**
 - **Countries with security stock:** quantities ordered and delivery schedules should take into consideration the need to consume any potential security stock by April 2016
 - **Countries scheduled for a pre-switch SIA with tOPV,** should take into consideration existing tOPV stock balances for their SIA orders.

NOTE: Although self-procuring countries may have different lead times compared to UNICEF countries, the principle of breaking down supplies before the switch, allowing for one or more stock inventories, can be the same. Additional recommendations for self-procuring are provided in Annex 2.

1-year tOPV order cycle: example of adjusting tOPV delivery based on tOPV inventory



*tOPV order as typically planned based on current national/provincial stock balances, not to exceed April 2016

- ☑ **NOTE:** this is just an example and should be aligned with COUNTRY ORDERING PROCESS
- ☑ **Annual tOPV order:** in this example, country places tOPV order for the year which should be planned based on the current primary or subnational stock balances, not to exceed April 2016
- ☑ **First tOPV inventory:** ~12 months before the Switch (March or April 2015), conduct a thorough tOPV inventory and adapt deliveries accordingly.
 - Taking tOPV stock **down to the district level** would be preferred.
 - Include private supplies
- ☑ **Adjust delivery:** based on the first inventory adjust delivery from supplier to secure enough tOPV to last until end of February 2016.
- ☑ **Final tOPV inventory:** ~6 months before Switch (Oct/Nov, 2015), conduct a 2nd tOPV inventory
- ☑ **Adjust final delivery:** based on inventory, adjust final tOPV delivery from supplier for Feb to April, sufficient to last through Switch.
 - **Buffer:** Include 2 weeks of buffer (one week central and one week district)
 - **Lead time:** Timing of order should be in line with supplier's advice to arrive latest two months before the Switch
 - **Horizontal re-distribution:** consider redistribution of tOPV from regions with excess stock to regions with insufficient stock
- ☑ **bOPV:** Order bOPV ~6 months before the Switch for ~3-6 months supply to use after the Switch (see Section 3.2.2).

2.1.2. bOPV Procurement and Distribution Plan

bOPV ordering: Countries will receive 3-6 months of supply for the first order of bOPV. However, countries may need to order more depending on their ordering processes. 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 full supply chain.

For a 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 during 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 procure bOPV.

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

- ☑ **Procure*:** order at least 3-6 month supply of bOPV (eg, first 3 month supply + 1 month of buffer) approximately 6 months before the Switch (Oct-Nov 2015)
- ☑ **Delivery:** bOPV will arrive in country with ~1-3 months prior to the Switch
- ☑ **Distribute:** bOPV to the periphery 2 weeks prior to the Switch.
- ☑ Remove all tOPV from the cold chain after the switch day

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

Note the following:

- ✓ 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
- ✓ Cohorts will have no issue storing a quarter of a cohort (3 months of bOPV)
- ✓ Countries should ensure sufficient financing to meet bOPV supply requirements to be delivered in by March 2016 latest, in addition to the tOPV requirements through Q1/April 2016.
- ✓ Countries that have bOPV stock from prior campaigns could consider including this stock for use in the routine program



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 sufficient relief in case needed:**

- Use the **WHO Forecasting tool for cold chain capacity** in “scenario mode” and an overlapping of tOPV and bOPV to spot the potential gaps
- Increase the frequency of deliveries and reduce the size of each shipment.
- Make best use of existing vaccine cold chain capacity by removing expired products, and products not related to vaccination
- Minimize excessive cold water storage and limit suboptimal use of refrigerators and freezers
- Repair equipment with minor defaults
- Reallocate equipment to ensure that each service point has adequate **temporary** storage capacity

2.2 Support

2.2.1 Securing budget

Secure funds to implement the National Switch Plan activities such as hiring, logistics, tOPV supply assessments, waste management assessment, and training.

2.2.2 Establishing a switch support team

National authorities will need to hire or delegate staff at national and regional level to conduct preparatory and implementation activities related to the Switch (i.e. Switch Support Team, SST).

The primary function of the SST is to support the MOH and the Switch Management Committee:

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

Some relevant aspects for SST members to consider include:

- ☑ 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
- ☑ Central level: will require strong communication skills

Other levels: literate and credible candidates such as teachers and students

2.2.3 Develop and implementing a communications strategy



A strategic communications and advocacy plan should be a key component of the National Switch Plan.

Communication Strategies

Advocacy: to create awareness and commitment among decision makers at all levels to effectively support and facilitate the introduction and implementation of the Switch nationwide

Social Mobilization: to involve partners and stakeholders, social mobilizers, etc., in awareness creation and resource mobilization activities

Program communication: to create awareness and change behavior and call for action of the communities, parents, and caretakers through training workshops, interpersonal communication, group communication, media engagement and distribution of

Key strategies for successful deployment of the communications and advocacy strategy for the Switch will include:

- **INFORMATION SHARING:** Organize as soon as possible a meeting to inform partners, NGO, private sector and other groups potentially involved or affected by the Switch.
 - Inform staff in the health system, public as well as private
- **MATERIALS DEVELOPMENT:** Develop contextually appropriate messages and consultations with key decision-makers and scientific community to obtain buy-in before the Switch. Leverage and customize existing tools including global and regional materials.
 - Examples (See: Annexes 3 and 4) include FAQs, fact sheets, training materials, videos, posters, and labels.
 - Healthworker training: staff responsible for developing communications materials and strategy should closely link with those developing the training materials for health workers

2.3 Logistics

2.3.1 Develop training materials

Develop health worker information pack which may include:

- ✓ Powerpoint overview with key messages
- ✓ FAQs
- ✓ Guidelines on collection and disposal of tOPV and data recording
- ✓ Job aid to support recall and interactions

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.

Templates for training will be made available by global partners at: <http://tinyurl.com/ipv-intro>

Emphasize Practical Implications of the Switch

- ☑ 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 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

2.3.2 Updating 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. These include:

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

2.3.3 Waste management – disposal of tOPV

Countries are advised to **assess their waste management systems** in preparation for the Switch because on the National Switch Day any remaining stock of tOPV at any level must be discarded.

2.3.3.1 Estimating disposal volume

A simple calculation for estimating total disposal volume (Annex 7):

$$\text{Approximate disposal volume (in liters)per week} = \frac{\text{Total Population}}{100,000} \times 2$$

Example: $\frac{10,000,000}{100,000} \times 2 = 200 \text{ liters to dispose for a week's tOPV supply}$

Thus, 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 after The Switch.

2.3.3.2 Disposal site selection

- ☑ At its earliest opportunity, 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

2.3.3.3 Disposal strategy

Determine the appropriate disposal strategy for tOPV based on 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 7). 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.

2.4 Monitoring the Switch

Define and implement plans for two types of monitoring:

- ✓ **Process monitoring:** planning & preparation milestones
- ✓ **Outcome monitoring:** validation of tOPV recall and disposal

2.4.1 Process monitoring – planning and preparation milestones

Monitoring the planning and implementation of the Switch process should be done at the national and regional level.

- The National and Regional Switch Management Committees or ICC are responsible for **selecting, monitoring, and reporting of indicators** based on the country situation.
- **Select key milestones** (see Box below).
- Subnational levels should **report to the National Switch Management Committee or ICC**.
- ICC should **report to the WHO and UNICEF country offices** on a few agreed upon indicators relevant to global planning such as *developed Plan, tOPV inventory, and vaccine delivery (TBD)*.

Process Monitoring

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

Countries should define key MILESTONES that must be met:

For example, these could include:

- ✓ Draft tOPV procurement plan; first tOPV inventory (Mar-Apr 2015)*
- ✓ Submit Switch budget to national authorities (June 2015)*
- ✓ bOPV is licensed/registered or country accepts Pre-qualified product (July 2015)*
- ✓ Endorse budgeted National Switch plan (1 Sept 2015)
- ✓ Country budget approved (Oct 2015)
- ✓ Switch Support Team established (Oct 2015)
- ✓ Second tOPV inventory (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)
- ✓ 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**

2.4.2 Outcome monitoring

The National Switch Validation Committee certifies the validation of tOPV recall and disposal.

Validation will be through evaluation of data collected by staff hired by the MOH (i.e. Switch Monitors) independent from the Switch process.

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

Outcome Monitoring

- ✓ Purpose: validating tOPV recall and disposal
- ✓ Responsibility: National Switch Validation Committee (NSVC)
- ✓ Potential indicators: in-person verification by Switch Monitors of absence of tOPV in certain proportion of storage and service facilities – criteria depends on the risk status of country as determined by GPEI (see Annex 5)
- ✓ Reporting:
 - to NSVC within 2 weeks of the Switch
 - to Regional Certification Committee by end of April 2016

SWITCH MONITORS

- ✓ Select **Independent Switch Monitors (SM)** at national level about **1 month prior to the switch**
 - Training of the SM can occur 2 weeks prior to the Switch (See Section 4)
- ✓ **Role:** to visit a representative sample of service points and disposal sites chosen at random within the country to confirm recall and disposal of tOPV.
- ✓ **Qualifications:** independent from the MOH and must have credibility. The credibility and independence can be verified from being recommended by a national or partner health official as having performed well in a previous activity in a similar capacity

- ✓ **One month prior to the Switch,** create a roster of **Independent Switch Monitors (SM)** in line with the independent monitors of SIA.
- ✓ **Develop a micro-plan for the SMs:**
 - **Site selection:** The number of facilities visited by SMs will depend on the country prioritization (Annex 5 -- to be developed). *GPEI is currently developing a framework for site selection which will be shared with countries.*
 - **Develop recording forms (Annex 6):** list: Staff name & signature, SM name, signature, date, facility type, presence of tOPV, 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 NSVC
- ✓ **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 NSVC for certification
- ✓ **Develop contingency plan:** for sites that have not recalled 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.

2.5 Summary of preparation time frame

While the time frame for preparatory activities would vary depending on the country situation and factors such as the tOPV ordering cycle, **Figure 1** illustrates a time frame of activities that would facilitate a successful Switch.

Figure 1 - Preparation time frame

7-11 months before Switch

- Conduct detailed tOPV inventory & adjust delivery
- Order tOPV but not beyond April 2016*
- Secure funding
- Develop monitoring framework

6 months

- Hire switch support staff
- Assess waste management
- Conduct last tOPV inventory and adjust delivery
- Order bOPV

3-4 months

- Last tOPV delivery to country**
- bOPV deliveries begin to country (latest Mar 2016)
- Develop health worker training materials
- Implement communications Strategy

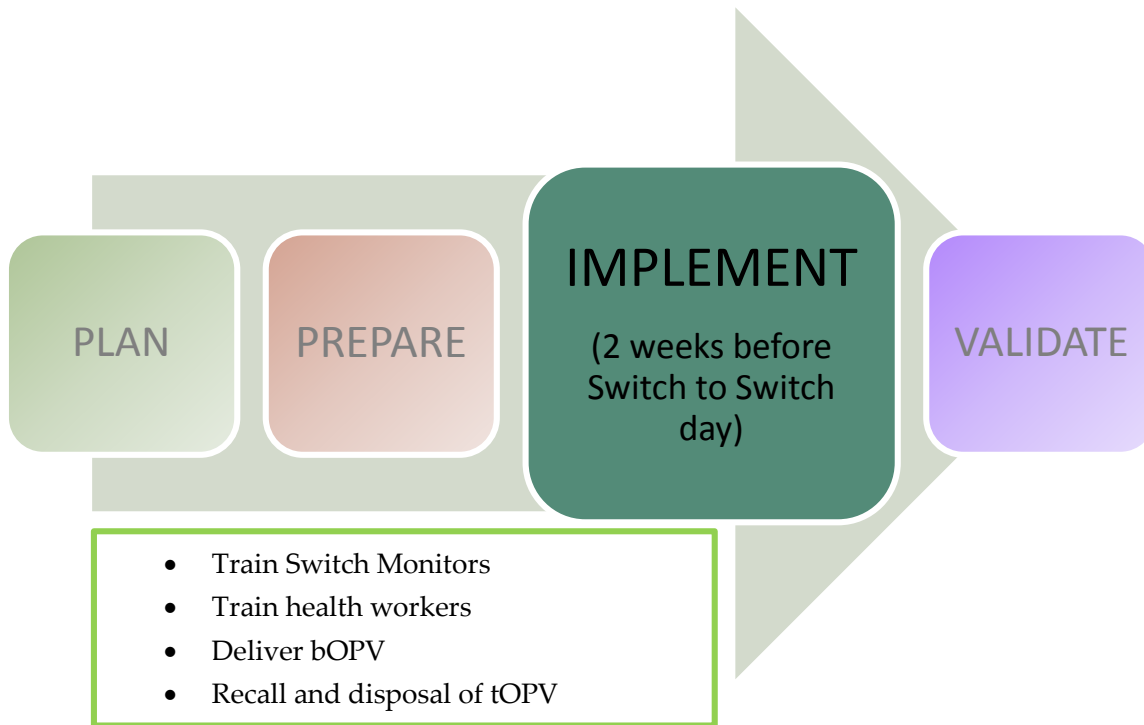
2 months

- Last 1-2 months' tOPV delivered to periphery
- Identify Switch Monitors

*timing depends on country ordering cycle

** unless unanticipated stock out occurs

3. Implementing the Switch



Plan to implement the following **launch activities** two weeks prior to the Switch:

- ✓ Distribute bOPV to all peripheral levels
- ✓ Train Switch monitors
- ✓ Train health workers

3.1 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
- ☑ Verify the absence of tOPV at selected facilities
- ☑ Switch Monitors to dispose tOPV if any residual tOPV is found in facilities
- ☑ Communicate & report outcome of visit to reporting authorities

3.2 *Distribute bOPV to all peripheral levels*

- ☑ Stock bOPV in all service facilities two weeks prior to the Switch. During this period, both bOPV and tOPV will be in the cold chain across the country.
- ☑ To ensure sufficient cold space, service points should be encouraged to remove expired products, and products not related to vaccination.

3.3 *Train health workers*

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

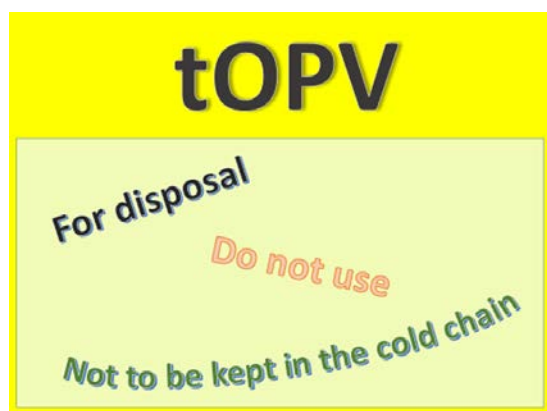
Key steps to consider may include:

- ☑ Materials are developed in advance (see Section 3.3.1)
- ☑ Reserving full day for training
- ☑ Notifying participants in advance
- ☑ Booking venue
- ☑ Setting training agenda
- ☑ Inviting at least 1 health worker per facility
- ☑ Set a maximum limit per training session
- ☑ Ensuring objectives are understood

3.4 *Communications and media events*

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

3.5 *National Switch Day – recall & disposal*

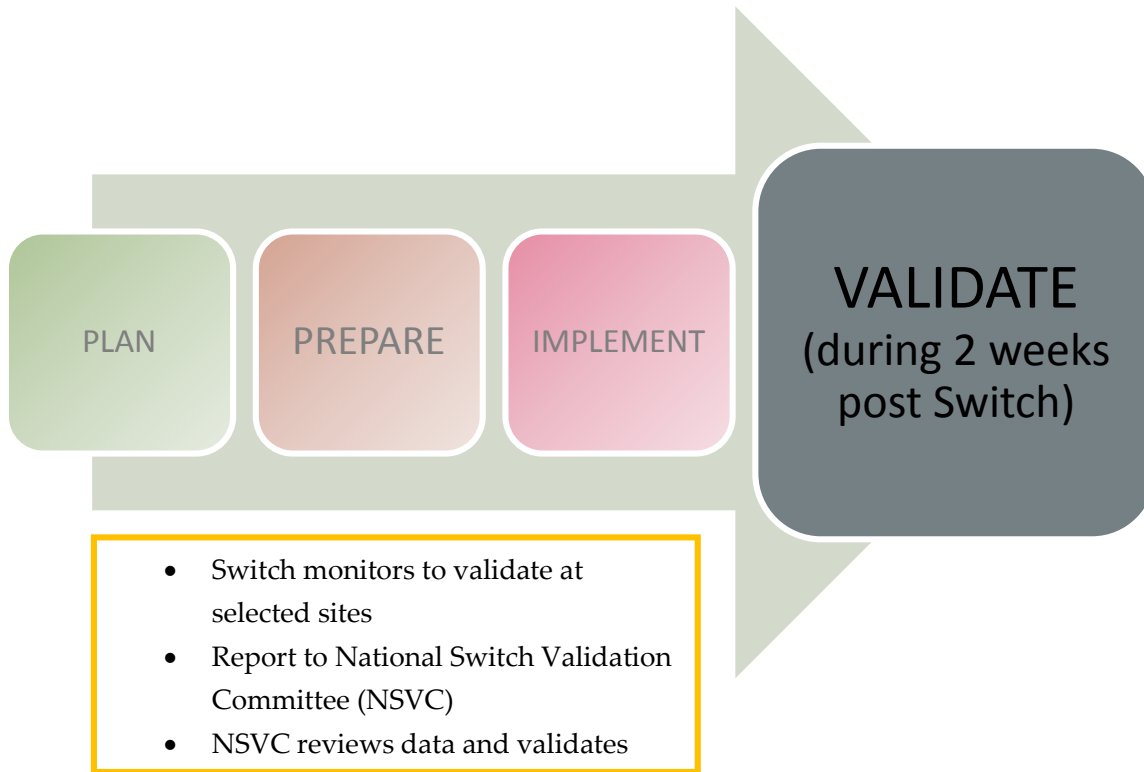


On switch day all tOPV should be taken out of the cold chain. It will therefore not present an extra claim on storage capacity.

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 figure) on the tOPV primary packaging and transport vaccine out of the cold chain to the agreed site for disposal (see Section 3.3.3)

4. Validation



4.1 Validation of tOPV recall & disposal

Trained SMs: Validate the appropriate disposal of tOPV at randomly selected sites according to the Validation micro-plans (see Section 2.6). This should occur during the two weeks following the National Switch Date.

- ☒ Select & visit sites to validate tOPV free
- ☒ Record tOPV information
- ☒ Dispose residual tOPV
- ☒ Report validation results to NSVC by the **National Validation Day, exactly 2 weeks after the National Switch Day (see Figure below)**

Example of a National OPV Switch Month

April 2016

| Sun | Mon | Tue | Wed | Thu | Fri | Sat |
|-----|-------------------------------------|-----|-----|-----|-----|-----|
| 27 | 28 | 29 | 30 | 31 | 1 | 2 |
| 3 | 4 National Switch Day | 5 | 6 | 7 | 8 | 9 |
| 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 National Validation Day | 19 | 20 | 21 | 22 | 23 |
| 24 | 25 | 26 | 27 | 28 | 29 | 30 |

Diagram illustrating the timeline for a National OPV Switch Month (April 2016). The calendar shows days from Sunday 27 to Saturday 30. Key events are marked:

- National Switch Day:** Monday, April 4 (circled in red).
- All tOPV use will stop on this date:** Indicated by an arrow pointing to Monday, April 4.
- Two-week window for disposal:** Indicated by a double-headed red arrow spanning from Monday, April 4 to Monday, April 11.
- National Validation Day:** Monday, April 18 (circled in red).
- All tOPV must be disposed of by this date:** Indicated by an arrow pointing to Monday, April 18.

4.2 Reporting certification to Regional Certification Committee

During the two weeks after the National Validation Day, the NSVC must collate and analyze the validation data collected by the SMs. Following data analysis, the NSVC must:

- ☒ Validate the country tOPV free and report status to the Regional Certification Committee

OR

- ☒ Activate recommend activating contingency plans for addressing existing stocks of tOPV

Annex 1: Example TORs for Switch Management Committees and Switch Support Team

Example Switch related TORs for National Switch Management Team or ICC

| | 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.) - Take corrective action when needed | With increasing frequency from monthly in the early phase to daily during The Switch. |

Example TORs for Switch Support Team

| 6-12 months before The Switch | 2 months before The Switch | During the campaign | After The Switch |
|---|--|---|---|
| National and Regional level | District level | District level | District, regional and national level |
| National level: <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 | 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. Visit all districts as well as an | <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 | <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 |



| | | | |
|---|---|---|--|
| <p>meetings.</p> <ul style="list-style-type: none"> - 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.¹ | <p>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. | <p>Switch.</p> <ul style="list-style-type: none"> - Confirm disposal sites are ready. - Ensure availability of updated stationary and forms. - Inform higher-level officials of anything that could derail The Switch. | <p>6 days.</p> <ul style="list-style-type: none"> - 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. |
|---|---|---|--|

Annex 2: Vaccine supply (in cooperation with UNICEF, PAHO and/or Suppliers)

1. Global Supply

- OPV is supplied through UNICEF, the PAHO Revolving Fund, WHO, or as direct procurement from suppliers or other entities. Global vaccine supply planning for SIA activities is done in coordination with global program partners.
- Approximately 70-75% of the tOPV market for routine is supplied through UNICEF. The remaining is supplied through either the PAHO revolving fund, WHO, and direct procurement by self-procuring countries. This proportion will be the same for bOPV once included in the routine schedule.
- Forecasts for supply **through UNICEF** are based on the global SIA calendar developed by GPEI in coordination with Regions, as well as routine forecasts which are done on an annual basis in end Q3/Q4 through the UNICEF Supply Division Immunization Forecast Exercise.
- Manufacturer forecasts are based on forecasts from UNICEF as well as for requests for supply from self-procuring/producing countries through standard tender processes.
- Forecasts of tOPV and eventual bOPV for routine needs for traditionally self-procuring countries, are not included in UNICEF forecasts to suppliers, unless specifically requested through UNICEF's forecast exercise or through an official communication with UNICEF Supply Division.
- Any traditionally self-procuring countries should advise UNICEF as soon as possible if they intend to, **or are considering**, procuring through UNICEF for any of their requirements in order to secure the supply for the Switch.

2. Minimizing residual stocks through appropriate management of tOPV supply

- 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 synchronised switch to bOPV.**
- All tOPV that remains in countries after the Switch date will need to be **recalled and destroyed**, which will incur additional costs for disposal.
- **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.

Below are some recommended practices that countries may wish to incorporate into their tOPV procurement and supply management over the next year.

Stock management and inventories:

1. Assess current national (primary) and subnational level stock balances
2. Review and adjust **if required** current procurement plans/orders/requests for vaccines/delivery schedules from suppliers/UNICEF/other agency

3. Conduct 2 inventories, with at least one down to the district level or lower. *[WHO will request all countries to conduct 2 inventories – one in March/April; another later in the year around October/November].*

This should include the following:

- Central (Primary) medical stores, including Regional Warehouses/depots. This should include both Government-owned and autonomous agencies.
- Provincial (Secondary) Warehouses
- District warehouses
- Any hospital at district, provincial, and tertiary level where they provide related immunization services (depending on country)
- Private sector, including pharmacy stores, warehouses, or other location that provides oral polio vaccines to customers.

Inventories should also take into account the following:

- Supply balances from recent SIA activities
- Pipeline deliveries (recently received but not yet registered, or supply already on order and pending delivery)

Conducting the initial inventory as soon as possible in the year will provide countries the opportunity to adjust procurement plans, delivery schedules, and quantities to minimize excess stocks.

Quantities of tOPV for order and consumption:

- Countries should ensure quantities delivered are sufficient to meet routine immunisation consumption requirements at all levels of the health system through April (this should include approximately 1-2 weeks of buffer supply).
- Delivery strategies will depend on country context, importation and customs regulations, and logistics.
- **Countries that order 12 months of stock with either 1 or 2 shipments are at highest risk of wastage of tOPV.** These countries are advised to reduce their order requirements and to stagger deliveries in order to make any adjustments during the year.
- **Below is a recommended strategy for countries to consider:**
 - 3-4 deliveries of tOPV supply per year to allow for adjustments to be made after a national inventory of tOPV supply
 - The last 1-2 deliveries could be adjusted to meet the Switch timelines
 - Where more than a single delivery not feasible, **countries should review their stock balances and make any adjustments to their requirements and orders to minimize residual stocks.**
 - Countries traditionally include a 'security stock' of around 3-4 months (some countries include more). By April 2016, the security stock should be consumed.
 - **Countries scheduled for a pre-switch SIA with tOPV**, should take into consideration existing tOPV stock balances for their SIA orders.

4. Planning and ordering bOPV Supply



- Except for countries moving to a full IPV-only schedule, all OPV-using countries should receive an initial supply of 3-6 months of bOPV in their preferred presentation between January and mid-March 2016 (latest).
- Countries may need to be flexible during this transition period in terms of months of supply received, presentation available, number of deliveries, and security stock required.
- As bOPV should not be distributed until the Switch in line with the Switch Protocol (See Section XX), cold chain capacity may need to be adjusted/increased at central level to store the bOPV until it can be distributed down the supply chain.
- Countries should ensure sufficient financing to meet bOPV supply requirements to be delivered in March in addition to the tOPV requirements through Q1/April 2016.
- Due to tight timelines for suppliers to license the bOPV product in many countries and to facilitate timely delivery of bOPV for the switch, **countries should consider accepting the product based on WHO Pre-qualification, or providing a waiver of licensure for importation until the transition period is over.**

5. Countries procuring through UNICEF, WHO or PAHO

- Countries are advised to review forecasts and shipment schedules submitted to any of these agencies, and advise of any changes (ie. UNICEF Supply Division annual forecasts and shipment plans).
- For tOPV orders already submitted, countries should coordinate with the relevant agency in case any adjustments are required (ie. adjustments to Cost Estimates for countries procuring through UNICEF Supply Division).
- All future orders should take into account the Switch when planning their supply and submitting Orders to their respective Agency.
- Countries should coordinate through their Regions and with the respective agency on bOPV requirements.

6. Self-procuring countries

- Countries that traditionally procure their supply directly from Manufacturers may be vulnerable to risks associated with access to bOPV or procuring excess tOPV due to longer timelines for securing supply from manufacturers.
- As the date for the Switch may not be confirmed until September or October 2015, self-procuring countries are advised to ensure sufficient supply of tOPV through the Switch in April 2016.
- Countries should consider the following in their procurement plans, tenders and contracts with suppliers:
 - Sufficient tOPV through April 2016 Switch
 - Build in flexibility with manufacturers and contracts with suppliers to confirm product type in September/October depending on the final date for the Switch.



- Some countries may be in a position to launch a tender in September/October after the confirmation of the Switch date, with 6 month lead time to secure bOPV supply in time for a March delivery. However, early coordination with manufacturers is advisable.
- Countries that have existing contracts in place for tOPV through 2016 should look into procurement laws and feasibility of amendments to contracts to convert tOPV to bOPV if the Switch takes place.
- The Procurement Department responsible for procuring vaccines for the country should be notified as soon as possible of the potential Switch plans, in order to mitigate any risks to accessing bOPV supply or receiving too much supply of tOPV.

Annex 3: OPV Switch – Briefing Note



Preparing for the switch

Commencing in early 2015, countries are advised to develop operational plans for implementing the switch. Development of the plan should involve 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
- Procurement of bOPV (for self-procuring countries)
- Planning and budgeting for collection, transport, storage, and proper disposal of tOPV once withdrawn from the cold chain
- Training of health workers on the rationale and process of the switch
- Communication with local experts and other stakeholders

Registration of bOPV for routine use

Currently, bOPV is only licensed and prequalified by WHO for use in SIAs. 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. Countries for which a formal licensing process is legally required should coordinate this process with manufacturers and WHO in parallel to the 'acceptance for use', in order to avoid jeopardizing the timelines associated with the switch.

Planning for final procurement of tOPV

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

For countries procuring through UNICEF, close coordination and sharing of stock levels with UNICEF country offices will be critical to minimizing excess stocks of tOPV 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 may be available to facilitate this process as required.

For further information

Technical assistance and guidance on aspects such as operational planning, stock management, and communications will be shared in due course. Materials will be available at: <http://tinyurl.com/jpv-intro>.

Key dates

March 2015

Last persistent cVDPV type 2 reported.

National authorities begin operational planning

May 2015

The World Health Assembly endorses the timelines

September 2015

Final decision to proceed with the switch in April 2016 or to postpone for at least a year

October 2015

National plans finalized

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 SIAs.

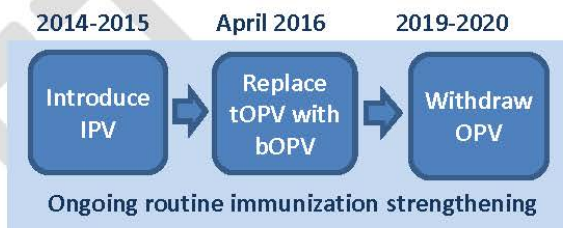


Preparing for the withdrawal of all oral polio vaccines (OPVs): Replacing trivalent OPV (tOPV) with bivalent OPV (bOPV)

As outlined in the Global Polio Eradication Initiative's *Polio Eradication and Endgame Strategic Plan 2013-2018*, the global eradication requires the removal of all oral polio vaccines (OPVs) in the long term. This will eliminate the rare risks of vaccine-associated paralytic polio (VAPP) and circulating vaccine-derived poliovirus (cVDPV).

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 globally.

OPVs will be removed in a phased approach, beginning with removal of type 2 poliovirus strain in a switch from tOPV to bOPV. After all wild polioviruses have been fully eradicated, the use of all OPVs will come to an end.



Why a phased approach to removing OPV?

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 successful eradication of wild poliovirus type 2 (WPV2), with the last case occurring in 1999. In addition, the last detected case of WPV3 was in 2012. Four of the six WHO regions have also 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.

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) with bOPV (containing type 1 and 3 serotypes only), to help stop transmission of WPV1 and 3, and reduce the risk of VAPP and cVDPVs.**

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

Programmatic implications

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. **Therefore, countries must start now to adequately prepare for the switch from tOPV to bOPV. The switch from tOPV to bOPV must be simultaneous within and across countries, to minimize the risk of new VDPV type 2 emergence.**

Annex 4: 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 *{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**



Annex 5: Country Prioritization

To be developed

[illegible]

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Annex 7: tOPV disposal options

ESTIMATING DISPOSAL VOLUME

A simple calculator for estimating total disposal volume based on assumptions outlined in Table I:
Total population (in millions) x 10 = approximate disposal volume (in liters) per week

Table I: Estimated volume of tOPV per million inhabitants

| Average OPV doses per million inhabitants | Volume per dose of tOPV in cc (20 dose vial including packaging) | 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 |
|---|--|--|--|---|
| 170 000 | 1.5 cc | 255 L | 2 | 10 L |

DISPOSAL OPTIONS

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 (Annex 6). Note that within each of the four categories below, the best options are listed first:

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 $\frac{3}{4}$ 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.
 - 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.

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

Annex 8: Chronogram

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Table: An example of a chronogram to visualize and track a number of tasks, milestones, deadlines, persons or agencies responsible.

Table: Key milestones as listed in the chronogram

| Level | Category | Milestone | In charge | Start date | End date | Status | Month / week | Activity | Apr 15 | May 15 | Jun 15 | Jul 15 | Aug 15 | Sep 15 | Oct 15 | Nov 15 | Dec 15 | Jan 16 | Feb 16 | Mar 16 | 1 Apr | 8 Apr | 15 Apr | 22 Apr | 29 Apr | May 16 |
|----------|------------|-----------|-----------|------------|----------|--------|--------------|--|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|-------|-------|--------|--------|--------|--------|
| National | Logistics | Milestone | | | | | Apr 15 | Develop a procurement plan | | | | | | | | | | | | | | | | | | |
| National | Funding | Milestone | | | | | Jun 15 | Country budget proposal submitted | | | | | | | | | | | | | | | | | | |
| National | Management | Milestone | | | | | Jul 15 | National switch plan is developed and endorsed | | | | | | | | | | | | | | | | | | |
| National | Logistics | Milestone | | | | | Jul 15 | bOPV is licensed and registered with NRA | | | | | | | | | | | | | | | | | | |
| global | Management | Milestone | | | | | Sep 15 | Positive Switch decision by SAGE | | | | | | | | | | | | | | | | | | |
| National | Funding | Milestone | | | | | Sep 15 | Country budget proposal accepted | | | | | | | | | | | | | | | | | | |
| National | Management | Milestone | | | | | Oct 15 | Establish a Switch Support Team (SST) | | | | | | | | | | | | | | | | | | |
| Regional | Logistics | Milestone | | | | | Nov 15 | Second tOPV stock inventories | | | | | | | | | | | | | | | | | | |
| National | Management | Milestone | | | | | Dec 15 | Printing of new stationary, adapted to the use of bOPV | | | | | | | | | | | | | | | | | | |
| District | Funding | Milestone | | | | | Feb 16 | Funds arrive at regional level | | | | | | | | | | | | | | | | | | |
| National | Logistics | Milestone | | | | | Mar 16 | All vaccine delivered at national level | | | | | | | | | | | | | | | | | | |
| District | Logistics | Milestone | | | | | 8/04/2016 | Districts received OPV and stationary | | | | | | | | | | | | | | | | | | |