

## Preface for National Planners: How to use this document

### What is the purpose and intended audience of this document?

This document is intended to help national planners convey simple, straightforward guidelines for EPI logisticians to apply when preparing and carrying out all Switch-related logistical activities. It is organized by level of the cold chain, in order for each individual to quickly identify the responsibilities most relevant to him or her. This includes:

- National cold chain logisticians
- Regional cold chain logisticians
- District cold chain logisticians
- Health facility staff

### What is my role in shaping this document?

Before sharing this document with EPI logisticians throughout the cold chain, customize it for your country context, and to reflect the specific Switch-related decisions you will have to make to execute the Switch. These decisions may include the following factors, as illustrated in Table 1.

**Table 1. Key decisions and actions for the National Planner prior to customizing this document**

Key Decision	Factors To Consider
Exact timing for Switch Day and/or Switch Schedule	<ul style="list-style-type: none"> <li>• Take into account routine delivery schedule from district to health facility level to ensure that collection of tOPV and distribution of bOPV on Switch Day can be made in sync with existing processes where possible</li> </ul>
Choice of Switch Mechanism at lower levels <ul style="list-style-type: none"> <li>• “Push” Exchange: District delivers bOPV to facilities and picks up tOPV</li> <li>• “Pull” Exchange: Facilities collect bOPV from district and surrender tOPV</li> <li>• Preposition: Deliver bOPV to Health facilities just before Switch day</li> </ul>	<ul style="list-style-type: none"> <li>• Risk/ benefit analysis of each option (see page 14 of this guide)</li> <li>• Funding available for reliable transportation to enable Districts to deliver to Health Facilities within tight timeline / Funding mechanism to ensure Health Facility staff come to exchange tOPV for bOPV within tight timeline</li> <li>• Stringency of country regulations around disposal at different levels</li> <li>• Global guidelines for the criteria upon which Switch Validation will be assessed</li> </ul>
Disposal mechanism	<ul style="list-style-type: none"> <li>• Existing national regulations around disposal and capacities in country</li> </ul>
Contingency Planning	<ul style="list-style-type: none"> <li>• Funding available for unplanned, emergency dispatch of antigens</li> </ul>
Cold Chain Coping Mechanisms	<ul style="list-style-type: none"> <li>• Existing cold chain space vs. requirements for the Switch               <ul style="list-style-type: none"> <li>◦ National planners may use the WHO EPI Logistics Forecasting Tool<sup>1</sup> to identify required cold chain capacity</li> </ul> </li> <li>• Particular levels that will be constrained by the need to store bOPV and tOPV simultaneously for a short period of time prior to the Switch</li> <li>• Funding available for special delivery mechanisms such as increased frequency of delivery</li> </ul>

<sup>1</sup>[http://www.who.int/immunization/programmes\\_systems/procurement/v3p/platform/module3/product\\_information/direct\\_links/en/index2.html](http://www.who.int/immunization/programmes_systems/procurement/v3p/platform/module3/product_information/direct_links/en/index2.html)

Given that several of these decisions will have financial implications, national planners are recommended to:

- Advocate early for sufficient funds from national and partner sources to finance relevant Switch activities. Advocacy efforts should use as a basis the comprehensive, costed national Switch plan
- Design processes which are realistic in light of expected funding
- Ensure the secured funds efficiently flow down to the level at which they are required:
  - E.g. in the case of a “push exchange” scenario, transportation funds are required at district level; in the case of a “pull exchange” scenario, transportation funds must be provided to health facility level

### **How should I best adapt this document for use in my country?**

You should adapt this document to retain only the information that is relevant to your country-specific situation and the Switch mechanisms you choose. In order to do this:

- Replace [text in orange brackets] throughout the guide with the appropriate information for your country. This includes, for instance, the exact date of the Switch.
- Identify which distribution/disposal scenario [in purple text] applies to your country
  - Retain the relevant paragraphs which apply to your country situation
  - Delete the scenarios that do not apply to your country situation
  - For instance, if your country has chosen a push exchange for the Switch to take place at health-facility level, remove the guidance indicated as “pull” in the purple sections.
- Omit this preface (pages i and ii) and share only the adapted guidance with all EPI logisticians.
  - E.g. central store logisticians could receive only page 3-5 and 6 - 9
  - E.g. district-level logisticians could receive only pages 3-5 and 13-16

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# Managing the Switch

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A Logistics guide for Cold Chain staff

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## Introduction: A Logistics guide for Cold Chain staff

### 1. What is “the Switch”?

Eradicating polio requires a globally coordinated effort to shift from the use of Oral Polio Vaccine (OPV) to Inactivated Polio Vaccine (IPV) through a phased approach.

- As a first step, all countries must introduce in 2015 at least one dose of IPV into routine immunization systems as a complement to the OPV schedule.
- As a second step, the World Health Assembly (WHA) mandates that all countries switch from using trivalent OPV (tOPV) to bivalent OPV (bOPV) for routine immunization and campaign immunization activities. This will drastically reduce occurrences of the two forms of vaccine-derived polioviruses associated with the type two component of tOPV: Vaccine Associated Paralytic Poliomyelitis (VAPP) and Circulating Vaccine-Derived Poliovirus (cVDPV).
- Finally, after the projected global certification of polio eradication in 2018, there will be a need for the global cessation of OPV usage, leaving IPV as the sole polio vaccine used in routine immunization.

This document centers on the second step of polio eradication: **the replacement of tOPV with bOPV** (“the Switch”), which will occur in April 2016 across the world. Shortly before this date, all manufacturers will stop producing or distributing tOPV. As of the date of the Switch, no child should be vaccinated with tOPV.

The Switch must be a **globally coordinated process**; ongoing tOPV use after April 2016 would jeopardize polio eradication due to possible outbreaks of cVDPVs.

The recap of the Switch activities is presented on page 4.

### 2. What are the logistical implications?

tOPV and bOPV require the same number of doses for full immunization, and have the same administration process and schedule. Thus, the impact of the Switch on vaccine delivery will be limited.

However, the Switch differs from a traditional vaccine replacement process, because tOPV usage must stop on the same day throughout the country, and all unused tOPV must be destroyed soon thereafter. In short, the Switch involves both the recall and destruction of tOPV and the new vaccine introduction of bOPV.

Thus, the Switch presents **unique challenges for supply chain and logistics systems** both in country and globally. These include, for instance:

- The need for countries to carefully forecast tOPV stock to minimize wastage yet avoid stock outs prior to the Switch
- The short-term complexity in the cold chain logistics system as both bOPV and tOPV will be stored in the system leading up to Switch Day
- The need to design contingency distribution plans in case of stock outs or polio outbreak before the Switch
- The need to properly dispose of the tOPV at all levels of the cold chain.

### 3. Recap - Switch on a page

The table below summarizes the key activities of the Switch. Logistics-related activities for which guidance is provided in this document **are bolded**.

<b>Plan</b>	<b>By June 2015</b>
	<ul style="list-style-type: none"> <li>- Establish management structure</li> <li>- Establish National Switch Validation Committee (NSVC)</li> <li>- Conduct situation analysis</li> <li>- <b>Draft national switch plan</b> (budgeted and finalized by 1 Sept 2015)</li> </ul>
<b>Prepare</b>	<b>May to September 2015</b>
	<ul style="list-style-type: none"> <li>- <b>Complete detailed tOPV inventory; adjust tOPV delivery*</b></li> <li>- Secure funding and finalize national switch plan</li> <li>- Develop monitoring plan</li> </ul>
	<b>October to November 2015</b>
	<ul style="list-style-type: none"> <li>- <b>Complete second tOPV inventory; adjust tOPV orders and/or delivery</b></li> <li>- <b>Order bOPV</b></li> <li>- <b>Develop waste management protocol</b></li> <li>- Hire switch support staff</li> </ul>
	<b>December 2015 to January 2016</b>
<ul style="list-style-type: none"> <li>- <b>Receive last tOPV delivery to country; **</b></li> <li>- <b>Redistribute remaining tOPV stock within country as required</b></li> <li>- Prepare training materials and implement communications strategy</li> <li>- <b>Begin bOPV deliveries to country ***</b></li> </ul>	
	<b>February to March 2016</b>
	<ul style="list-style-type: none"> <li>- <b>Deliver last 1-2 months of tOPV to periphery; redistribute as needed</b></li> <li>- Identify switch monitors</li> </ul>
<b>Implement</b>	<p><b>Two to four weeks prior to the switch</b></p> <ul style="list-style-type: none"> <li>- Train switch monitors</li> <li>- Train health workers</li> <li>- <b>Distribute bOPV to periphery and service points</b></li> </ul>
<b>National Switch Day</b>	<p><b>A day chosen during the first two weeks of April 2016</b></p> <ul style="list-style-type: none"> <li>- Stop use of tOPV and remove tOPV from cold chain</li> <li>- <b>Begin use of bOPV</b></li> </ul>
<b>Validate</b>	<p><b>During the two weeks after the switch</b></p> <ul style="list-style-type: none"> <li>- <b>Complete disposal of tOPV</b></li> <li>- Validate tOPV disposal at selected sites (switch monitors)</li> <li>- Collect and review data and validate switch (NSVC)</li> </ul>

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

\*\* Unless tOPV stock out

\*\*\* Could extend to March 2016 due to logistics

#### 4. What is this document? What are its general principles?

This document provides guidelines for EPI logisticians to apply when preparing and carrying out all Switch-related logistical activities.

- It is organized by level of the vaccine supply chain, in order for each individual to quickly identify the information most relevant to him/her.
- It can serve as a stand-alone, comprehensive, user friendly checklist for each level.

The guidelines here presented were developed at global level, in order to facilitate a coordinated Switch across countries. The main principles underpinning this guidance are:

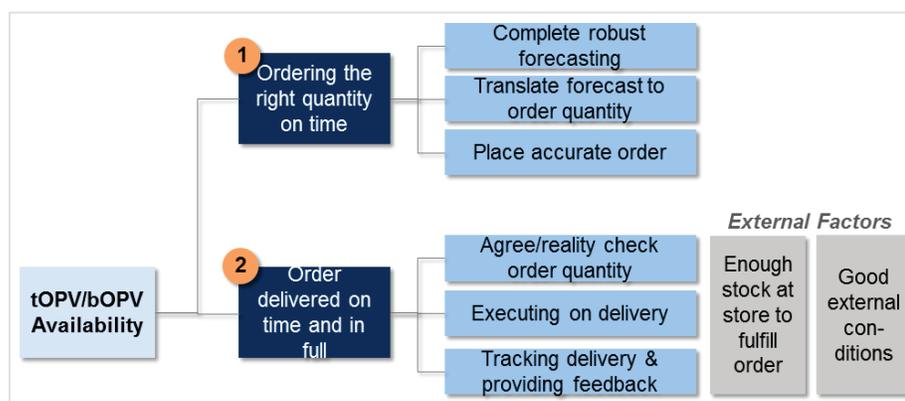
- Stock management practices for the Switch should, as much as possible, build on existing routine supply and cold chain processes in country
- There is a “right balance” which must be found between two imperatives of the Switch: minimizing wastage and avoiding stock outs of tOPV before the Switch.

In addition, these guidelines aim to reinforce **general best-in-class stock management principles**. This includes ensuring that **appropriate quantities of tOPV/bOPV are ordered** and subsequently **delivered on-time and in-full** to the service delivery site.

- One way to improve the accuracy of ordering is to improve forecasting, which requires knowing accurate stock levels. This guide recommends conducting physical counts of OPV stock to verify stock records
- Executing a stock order requires communicating order quantities to packers, ensuring the availability of transport in advance (if needed) and tracking whether orders were received in good quality. This guide recommends planning well in advance for the pick-up/delivery and Switch of tOPV/bOPV stock.

These principles will ensure the tOPV/bOPV Switch runs smoothly.

**Figure 1.** Levers to ensure tOPV/bOPV stock availability



## Central Vaccine Store

### Overview

Central Vaccine Store staff are responsible for:

1. Conducting and coordinating two tOPV inventories
2. Reviewing and adjusting procurement plans/delivery schedules from suppliers/UNICEF/other agency to avoid overstocking tOPV
3. Communicating the switch schedule and plan to lower levels
4. Distributing last shipment of tOPV and first shipment of bOPV to lower levels, and organize in-country redistribution as required
5. Putting in place a contingency plan and maintaining a buffer stock for emergency deliveries
6. Disposing of excess tOPV after the Switch

### 1. Conduct inventories at Central Vaccine Store and coordinate inventories in all lower levels

To inform the amount of stock to distribute in order to minimize tOPV wastage, two national inventories of tOPV should be conducted in the year leading up to the tOPV/bOPV Switch. The first inventory will be used to adjust shipments of tOPV over the next year in order to eliminate the upfront risk of over-stocking, while the second tOPV inventory should be conducted prior to the final tOPV shipment in order to more precisely inform the final order, enable in-country redistribution, and minimize overall wastage. While many countries already have stock management tools in place (such as SMT, LMIS and DVDMT's), due to the level of precision required for forecasting for the Switch, physical counts will be necessary.

- **Conduct Two Inventories at the Central Vaccine Store in line with the following principles:**
  - **Timing.**
    - **First Inventory:** Conduct approximately 12 months before the Switch (~May 2015 or just prior to the next earliest planned shipment) in order to revise the quantity and timing of subsequent shipments to the country and avoid overstocking
    - **Second Inventory:** Conduct approximately 6 months before the Switch (~October/November 2015 or prior to the final shipment of tOPV) in order to fine tune the final shipment quantity and redistribute supply in-country if necessary
  - **Methodology.** Conduct a direct physical count of all available tOPV stock in the Central Vaccines Store, including data on the following:
    - Supply balances from recent SIA activities
    - Orders recently received or pending, which are not yet recorded in stock records
    - Expiration date of tOPV
    - Packaging
    - VVM status of tOPV
  - After the physical count is performed, update data in the national stock management systems with the revised, accurate figures.
- **Coordinate stock inventories at all levels of the supply chain**
  - Include the following types of facilities and stores in the inventory exercise
    - Regional-level stores (both government-owned and autonomous)
    - Provincial stores
    - Districts stores
    - District/Provincial/Tertiary hospitals

- Private-sector pharmacies, warehouses or other locations providing tOPV. A separate coordinating mechanism may be needed for private-sector facilities to report to staff at the Central Vaccine Store.
- Communicate expectations to regional and/or district-level staff to make their responsibilities for the inventories clear. A national-level directive from the Ministry of Health (i.e., letter or official circular) may be necessary to direct the process and timeline for stock inventories. The instructions should clearly outline the following:
  - All levels should conduct their physical count within a one-week time frame to minimize the risk of double-counting stock designated for delivery down the supply chain
  - District and regional-level staff should report (via phone call or SMS message) total tOPV levels up the supply chain, with the national-level staff receiving all data from regional-level stores.
- Aggregate all the data at the Central Vaccine Store level for analysis (see below). The inventory tool<sup>2</sup> developed by UNICEF may be used to summarize the stock information collected.

## 2. Review and adjust procurement plans based on tOPV inventories

- Collect and analyze inventory data **prior** to placing orders, in order to minimize both the risk of tOPV stockouts prior to the Switch, and the risk of excess stocks of tOPV that will need to be disposed of after the Switch. Use the following formula to calculate the total quantity of tOPV on-hand:

$$\text{Total tOPV} = \text{Quantity in-stock} - \text{expired tOPV stock} - \text{tOPV stock with VVM stage 3 or 4}$$

- Calculate tOPV requirements so that all tOPV be consumed by [Switch day] with the exception of a **two weeks-worth of** extra supply as contingency stock to be able to respond to the risk of localised stockouts
  - One week of contingency stock should sit at the Central Vaccine Store level, while one week should sit at either the Regional or District level (depending on cold chain capacity) as a way to respond nimbly to localized stockouts.

## 3. Communicate the Switch schedule and plan to lower levels

In 156 countries, the Switch will occur in April 2016; national planners for each country have chosen the exact day at which it will take place. **In your country “Switch Day” will occur on [XYZ DATE].** This day is when tOPV is removed from all service points and storage facilities, tOPV is discarded, and bOPV is introduced. This also begins the tOPV disposal process.

The Central Vaccine Store staff should use the in-country distributions that will take place over the next year as an opportunity to remind regional store staff of the upcoming Switch. In particular, when distributing the bOPV stock for the first time and tOPV for the last, the central level staff should remind the regional staff of the need to ensure lower level distribution in time to ensure a complete Switch to bOPV on Switch Day.

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<sup>2</sup> Web address at which the tool developed by Gael Maufrais du Chatellier is hosted to be added here

#### 4. Distribute last shipment of tOPV and first shipment of bOPV to lower levels, and organize in-country redistribution as required

- **Calculate quantity and distribute last shipments of tOPV.**
  - In order to ensure that enough tOPV is available for administration until the Switch, use the following method to calculate the amount of tOPV you must distribute to each region for the final delivery:
    - Calculate amount to distribute to each Regional Vaccine Store =  $((\text{Annual target population of the region} \times \text{number of doses needed per person} \times \text{Wastage factor}) \times (\text{number of days of stock to be delivered}/365)) - (\text{Stock remaining as reflected in the second inventory for this region})$ 
      - Some regions' may have inaccurate target populations estimates. For these regions, one may consider:  $\text{stock at the beginning of a period} + \text{in} - \text{current} = \text{tOPV used over a given period}$
    - If a one-week contingency stock will be held at the regional level or district level, include this amount in the allocation and delivery for each region
    - If there are Polio Supplementary Immunization Activities planned, include the quantity required in the allocations delivered to each region.
  - This formula holds for the final delivery, which may be a few months ahead of the Switch. For example, if delivering on a quarterly schedule, use this for the January 2016 delivery to the regional level.
    - Where the first inventory showed an overstock of tOPV of more than three months, adjust delivery for the second to last-delivery using the results from the first inventory using the same methodology.
- **Distribute adequate quantity of bOPV to Regional Vaccine Store.**
  - Central Vaccine Store staff must develop a distribution plan and share it with lower levels. The bOPV should be distributed early enough to arrive at the district level two weeks before the Switch, meaning that if you are on a quarterly schedule, the bOPV should be distributed with the January 2016 wave of distribution.
  - In order to ensure that enough bOPV is available for administration immediately on the day of the Switch, distribute to the next level the following amount of bOPV for routine immunization:  $(\text{Annual target population of the region} \times \text{number of doses per person} \times \text{Wastage factor}) \times (\text{number of days of stock to be delivered}/365) = \text{amount to distribute to each Regional Vaccine Store}$ .
- **Ensure that bOPV is stored separately from tOPV.** In order to avoid any risk of being mixed with tOPV deliveries and administered to patients prior to the Switch, keep stocks of bOPV separate from tOPV while awaiting distribution.
  - E.g. store on different shelves in the walk-in cold room or on opposite sides of the fridge.
  - It is recommended to print special tOPV labels to place on the secondary package of tOPV stock, clearly stating this tOPV should not be used after the day of the Switch.
  - It is recommended for the Regional Vaccine Store to provide the "tOPV collection form" to the District Vaccine Stores at the same time as the last tOPV shipment. This form should be completed by Regional and District Vaccine stores on [Switch day] to register all unused tOPV to be disposed.
- **Implement cold chain coping mechanism if necessary.** We do not expect major issues with cold chain capacity for two reasons: bOPV and tOPV are both small in volume, and many countries are used to storing additional stock of OPV for SIAs. Yet, as bOPV will have to be stored in the cold chain along with tOPV during the last distribution cycle leading up to the day of the Switch, you may be instructed by national planners to implement a coping mechanism to ensure that bOPV and tOPV are properly distributed within the cold chain. You may draw on the WHO EPI Logistics

Forecasting tool to identify the capacity needs at each level, before defining the appropriate coping mechanisms<sup>3</sup>. Coping mechanisms will draw on prior experience with New Vaccine Introduction storage planning, and may include:

- Storage of bOPV at higher capacity levels, combined with expedited delivery of bOPV to lower levels closer to the Switch.
- If a storage constraint exists at higher levels, special delivery directly to the next level with adequate capacity (e.g. from custom clearance directly to regions).

## 5. Coordinate contingency plan and maintain a buffer stock for emergency deliveries

Supply disruptions may arise from inaccurate forecasting or higher than expected demand or wastage. To be prepared for such events:

1. Store the equivalent of one week of national supply of tOPV at the Central Vaccine Store, ready for distribution for any new/unscheduled delivery
2. Dedicate a focal point to field emergency requests for additional supply of tOPV who has the authority to allocate and distribute tOPV accordingly, either through:
  - a. Increasing quantity of next scheduled delivery
  - b. Dispatching an out-of-schedule delivery
3. Communicate to regional and district vaccine stores who to contact and under what circumstances, which may include:
  - a. Inaccurate inventory count at Regional or District store
  - b. Higher use than planned, due to unusually large demand (e.g. polio outbreak leading to new campaign needs) or unexpectedly large wastage (e.g. temperature excursion)

## 6. Dispose of excess tOPV after the Switch [awaiting input from TWG]

- **Prepare for tOPV disposal.** The disposal of unused tOPV immediately after the Switch calls for a unique focus on disposal practices and capacities. In order to adequately prepare for the post-Switch disposal, national planners and Central Vaccine Store staff are encouraged to as of Q2 2015:
  - Assess the disposal capacity at each level
  - Develop a collection plan
  - Develop tools to monitor tOPV disposal immediately after the Switch
- **Dispose of tOPV.** On Switch Day, remove any remaining tOPV from the cold chain in the central store and dispose of it through the defined disposal guidelines
- **Communicate disposal guidelines to subnational levels.**

<sup>3</sup>[http://www.who.int/immunization/programmes\\_systems/procurement/v3p/platform/module3/product\\_information/direct\\_links/en/index2.html](http://www.who.int/immunization/programmes_systems/procurement/v3p/platform/module3/product_information/direct_links/en/index2.html)

## Regional Vaccine Store

### Overview

Regional-level staff are responsible for:

1. Conducting and coordinating two tOPV inventories
2. Communicating the inventory process to staff at lower levels of the supply chain
3. Collating and reporting up the inventory data received from district vaccine stores
4. Distributing adequate amounts of tOPV and bOPV to District Levels on time for the Switch; and organizing redistribution across districts as required
5. Understanding and putting in place the supply contingency plan communicated from Central Vaccine Store
6. Collecting and disposing of excess tOPV according to guidelines.

### 1. Conduct Inventories at Regional Vaccine Store and Coordinate Inventory at District Level

To inform the amount of stock to order and distribute in order to minimize OPV wastage, two national inventories of tOPV should be conducted in the year leading up to the tOPV/bOPV Switch. The first inventory will be used to adjust shipments of tOPV over the next year in order to eliminate the upfront risk of over-stocking, while the second tOPV inventory should be conducted prior to the final tOPV shipment in order to more precisely inform the final order, enable in-country redistribution, and minimize overall wastage.

- **Conduct Two Inventories at the Regional Vaccine Store in line with the following principles:**
  - **Timing.**
    - First Inventory: Conduct approximately 12 months before the Switch (~May 2015 or just prior to the next earliest planned shipment) in order to revise the quantity and timing of subsequent shipments to the country and avoid overstocking
    - Second Inventory: Conduct approximately 6 months before the Switch (~October/November 2015 or prior to the final shipment of tOPV) in order to fine tune the final shipment quantity and redistribute supply in-country if necessary
  - **Methodology.** Conduct a direct physical count of all available tOPV stock in the Regional Vaccines Store, including data on the following:
    - Supply balances from recent SIA activities
    - Orders recently received or pending, which are not yet recorded in stock records
    - Expiration date of tOPV
    - Packaging
    - VVM status of tOPV
- **Coordinate stock inventories at District Level.**
  - Communicate to district-level staff their responsibilities in the inventory, including the following:
    - All levels should conduct their physical count within a one-week time frame to minimize the risk of double-counting stock designated for delivery down the supply chain
    - District staff should report (via phone call or SMS message) to you the total tOPV levels as outlined above
  - Compile inventory data received from all district vaccine stores in the region, and collate together into a single database. Report information up via phone call or SMS to the Central Vaccine Store, which is responsible for collating all data nationwide.

## 2. Distribute last shipment of tOPV and first shipment of bOPV to district level, and organize redistribution within region as required

- **Calculate quantity and distribute final orders of tOPV.**
  - In order to ensure that enough tOPV is available for administration until the Switch, use the following method to calculate the amount of tOPV you must distribute to the next level during the last shipment:
    - Calculate amount of tOPV to distribute to each District Vaccine Store =  $(\text{Annual target population of the district} \times \text{number of doses needed per person} \times \text{Wastage factor}) \times (\text{number of days of stock to be delivered}/365) - (\text{Stock remaining as reflected in the second inventory for this district})$
    - If a one-week contingency stock will be stored at the District Level, include this allocation in the quantity delivered to each District Vaccine Store
  - If delivering on a quarterly schedule, use this formula for your January 2016 delivery to District Vaccine Store.
- **Distribute adequate quantity of bOPV to District Vaccine Store.**
  - Regional Vaccine Store staff must develop a distribution plan and share it with districts. In order to ensure that enough bOPV is available for administration immediately on the day of the Switch, distribute to the next level an amount required for routine immunization two weeks before the Switch the following amount:
    - Amount of bOPV to distribute to each District Vaccine Store =  $(\text{Annual target population} * \text{number of doses per person} * \text{Wastage factor}) \times (\text{number of days of stock to be delivered}/365)$
    - If delivering on quarterly schedule, use this formula for your January 2016 delivery to District Vaccine Store.
    - It is recommended for the Regional Vaccine Store to provide the “tOPV collection form” to the District Vaccine Stores at the same time as the last tOPV shipment. This form should be completed by Regional and District Vaccine stores on [Switch day] to register all unused tOPV to be disposed.
- **Ensure that bOPV is stored separately from tOPV.** In order to avoid any risk of being mixed with tOPV deliveries and administered to patients prior to the Switch, keep stocks of bOPV separate from tOPV while awaiting distribution.
  - E.g. store on different shelves or opposite sides of the fridge
  - Use special tOPV stickers on tOPV secondary packaging, if available
- **Implement cold chain coping mechanism if necessary.** As bOPV will have to be stored in the cold chain along with tOPV during the last distribution cycle leading up to the day of the Switch, implement the special delivery instructions communicated to you by the Central Vaccine Store .

## 3. Execute Contingency Plan

To ensure that you have sufficient tOPV to last until the day of the Switch:

1. When you receive your final tOPV delivery, conduct a physical count and compare to the total amount you will be required to distribute to each district store;
2. If there is a shortfall in the amount you received or a gap due to higher than expected demand or wastage (e.g. a temperature excursion) that you identify during routine checks for minimum stock quantity, quantify the additional amount you require.

In either scenario, call the identified focal point at Central Vaccine Store and request the additional amount and date by when you require it (if there is insufficient time for you to receive the supply before delivering supply to the next level through the routine delivery schedule, Central Vaccine Store may choose to deliver directly to the appropriate level, e.g. straight to district stores affected).

#### 4. Dispose of excess tOPV after the Switch

- **Prepare for tOPV disposal.** The disposal of unused tOPV immediately after the Switch calls for a unique focus on disposal practices and capacities. In order to adequately prepare for the post-Switch disposal, national planners and Regional Vaccine Store staff are encouraged to as of Q2 2015:
  - **Assess the disposal capacity at each level**
  - **Develop a collection plan**
  - **Communicate guidelines to district levels. Dispose of tOPV.** On Switch Day, remove any remaining tOPV from the cold chain in the regional store and [dispose of through the defined disposal guidelines]
- **Dispose of tOPV in regional store.** On Switch Day, remove any remaining tOPV from the cold chain in the regional store and [dispose of through the defined disposal guidelines]
  - **Conduct disposal/destruction of tOPV where necessary.**
  - **Coordinate disposal at lower levels if applicable.**

## District Vaccine Store

### Overview

The role of District-level staff in the Switch will be to:

1. Conduct two inventories of tOPV and report results up to the Regional Vaccine Store (or Central Vaccine Store where applicable)
2. Receive and properly store tOPV and bOPV in preparation for the Switch
3. Establish contingency plan and maintain a buffer stock for emergency deliveries to health facilities
4. Conduct the Switch (three scenarios)
5. Dispose of excess tOPV after the Switch

### 1. Conduct inventories at District Vaccine Store

To inform the amount of stock to order and distribute in order to minimize tOPV wastage, two national inventories of tOPV should be conducted in the year leading up to the tOPV/bOPV Switch. The first inventory will be used to adjust shipments of tOPV over the next year in order to eliminate the upfront risk of over-stocking, while the second tOPV inventory should be conducted prior to the final tOPV shipment in order to more precisely inform the final order, enable in-country redistribution, and minimize overall wastage.

**Conduct two Inventories at the District Vaccine Store in line with the following principles:**

- **Timing.**
  - First Inventory: Conduct approximately 12 months before the Switch (~May 2015 or just prior to the next earliest planned shipment) in order to revise the quantity and timing of subsequent shipments to the country and avoid overstocking
  - Second Inventory: Conduct approximately 6 months before the Switch (~October/November 2015 or prior to the final shipment of tOPV) in order to fine tune the final shipment quantity and redistribute supply in-country if necessary
- **Methodology.** Conduct a direct physical count of all available tOPV stock in the District Vaccines Store, including data on the following:
  - Supply balances from recent SIA activities
  - Orders recently received or pending, which are not yet recorded in stock records
  - Expiration date of tOPV
  - Packaging
  - VVM status of tOPV
- **Reporting.** Report information up via phone call to the Regional Vaccine Store, which is responsible for reporting to the Central Vaccine Store.

### 2. Receive and properly store tOPV and bOPV in preparation for the Switch

- **Ensure that bOPV is stored separately from tOPV.** In order to avoid any risk of being mixed with tOPV and administered to patients prior to the Switch, keep bOPV separate from tOPV while awaiting distribution.
- **Implement cold chain coping mechanism if necessary.** As bOPV will have to be stored in the cold chain along with tOPV during the last distribution cycle leading up to the day of the Switch, implement [the special delivery instructions] communicated to you by Regional or Central levels.

### 3. Establish contingency plan and maintain a buffer stock for emergency deliveries

To ensure that you have sufficient tOPV to last until the day of the Switch, you will be given a buffer stock that is equivalent of one week of supply of tOPV, in addition to the amount you will require for distribution to Health Facilities for routine administration.

- **How to handle the amount required for routine immunization:**

- When you receive your final tOPV delivery, conduct a physical count and compare to the total amount you will be required to distribute to each district store
- If there is a shortfall in the amount you received or due to higher than expected demand or wastage (e.g. a temperature excursion) quantify the additional amount you require
- Call the identified focal point at the Regional Vaccine Store and request the additional amount and date by when you require it.
- **Contingency Buffer Stock:**
  - Keep this amount stored and ready for any unexpected need that may arise in the Health Facilities you supply
  - Communicate to all the Health Facilities in your district how to contact you with any unexpected additional need for tOPV
  - Be prepared to swiftly distribute or dispense any additional amount required to Health Facilities up until the Switch Day. The funding to enable this will be included in the budget and disbursed to you by national planners.

#### 4. Implement tOPV to bOPV Switch

On the day of the Switch, all health facilities must stop tOPV usage. This requires careful planning with public and private health facilities. National planners will communicate guidelines on how the Switch will be implemented in your country. An “exchange” process (either “push” or “pull”) between tOPV and bOPV is preferable, in order to avoid presence of tOPV in Health Facilities after the Switch day. However, national planners may recommend a “prepositioning” mechanism under certain circumstances, e.g. for remote facilities with difficult access (security, outbreaks).

##### Scenario 1: Organized “Push” - Exchange (with no Health Facility disposal)

- **Before the Switch:** Design a micro-plan/delivery schedule to visit every Health Facility in your district on the day of the Switch/*within the week* of when the Switch begins and secure the required transportation budget where applicable.
- **On the day of the Switch/*when the one week period of the Switch begins:***  
Visit each Health Facility to:
  - Collect any remaining tOPV in their cold chain storage and dispose of according to guidelines and collection / disposal plan.
  - Once Health facility staff have surrendered their tOPV, deliver their allocated bOPV supply
  - Record the quantity of tOPV you have collected in special “tOPV collection register” form.
- **Risk/Benefit:**
  - Risk: Will require significant additional funding and logistical capacity
  - Benefit: Approach with greatest assurance that:
    - All health facilities receive their bOPV uniformly on time, as most last mile delivery systems are an ad hoc mix of pick up and delivery and largely dependent on availability of constrained funds for transportation in either direction
    - tOPV is removed from Health Facilities

##### Scenario 2: Organized “Pull” - Exchange ( with no Health facility disposal)

- **Before the Switch:**
  - Communicate by phone, SMS or in person to every Health Facility the following:
    - [1 month prior] The date of the Switch, on which they must travel to the District Vaccine Store to drop off their remaining tOPV in order to pick up their allocation of bOPV; and other key elements of the collection and disposal plan you define.

- [2 days prior] A reminder that they MUST bring their remaining tOPV supply in order to receive their bOPV supply
    - Ensure that funds to reimburse transportation costs for Health Facility staff to travel to the District Vaccine Store are available at District Vaccine Store
  - **On pick up day:**
    - Collect tOPV left in the district store and the tOPV submitted to you by facilities aside for disposal, ensuring that it is removed from the cold chain and according to disposal guidelines
    - Record each Health Facility who successfully exchanges their tOPV for bOPV, and record the quantity of tOPV you have collected in special “tOPV collection register” form
    - Record any Health Facility that forgets to bring their tOPV
      - [IF Health Facility-based disposal is NOT allowed]: Do not issue bOPV and instruct them to come back the following day/or note that you will need to visit them directly to distribute bOPV and pick up tOPV need to be visited directly
      - [IF Health Facility-based disposal is allowed]: Instruct them on how to destroy their remaining tOPV before issuing their bOPV;
  - **After the pick-up day**
    - [Next day] Contact the following:
      - tOPV forgetters - call them to remind them to bring tOPV and pick up bOPV on the following day
      - Non-attenders - call them to remind them to bring tOPV and pick up bOPV on the following day
    - [Within three days after Switch day]: Directly visit the remaining Health Facilities to collect remaining tOPV
  - **Risk/Benefit:**
    - Risks:
      - Incomplete and untimely exchange of bOPV for remaining tOPV stock, as this system is highly dependent on district staff having funds available to reimburse facility staff for travel to District Vaccine Store on a single designated day, health facility staff reliably traveling to District Vaccine Store on designated day despite promise of reimbursement at the district level, and remembering to bring their remaining stock of tOPV.
      - In addition, possibility of missed immunization sessions given health care worker time to travel and exchange.
      - May require additional funds for “mop up” activities on the part of the District Vaccine Store
    - Benefit: Less resource intensive for district-level staff than a full “push” delivery of bOPV

### Scenario 3: Positioning bOPV stock at Health Facilities (Least Stringent: Health Facility Disposal allowed, validation criteria is tOPV usage)

- **Before Switch Day:**
  - Create a microplan listing each Health Facility that receives vaccine supply from you
  - Communicate with every Health Facility regarding Switch date, and follow up with regular reminders
  - Preposition bOPV stock through routine deliveries prior to the Switch, reminding Health Facilities to store bOPV and tOPV in separate places within cold storage to reduce confusion at the time of delivery. It is recommended to also provide health facilities with stickers “tOPV for disposal on [Switch date]”, which should be placed on a closed bag containing all tOPV on the day of the Switch.
  - Remind Health Facilities to store bOPV and tOPV in separate places within cold storage to reduce confusion

- **On Switch Day:** Communicate (in person, via phone, or by SMS) to each Health Facility to stop using tOPV stock and destroy any excess; begin using bOPV instead, remove from the cold chain, and dispose of according to guidelines
  - It is recommended for Health Facilities to put all tOPV stock in a closed bag, identified with appropriate sticker “tOPV for disposal on [Switch date]”
- **Risk/Benefit:**
  - Risk: Incomplete and untimely exchange of bOPV for remaining tOPV stock, as there may be confusion or reluctance to Switch tOPV for bOPV; less ability to monitor actual Switch and oversee wastage disposal
  - Benefit: Less resource intensive than a full “push” or “organized pull” system, and can be performed through routine systems

## 5. Dispose of excess tOPV after the Switch

- **Dispose of tOPV in district store according to the collection plan.** Remove any tOPV submitted to the District Vaccine Store by Health Facilities and any remaining tOPV from the cold chain in the district store and dispose of through the defined disposal guidelines
- **Communicate guidelines and coordinate disposal at lower levels where necessary.**

## Health Facility Level

### Overview

Health Facility Staff are responsible for:

1. Communicating any unplanned tOPV needs through the contingency mechanism
2. Executing the Switch (three scenarios)
3. Disposing of tOPV, only in the special case where Health facility-level disposal is authorized by national planners.

### 1. Communicate any unplanned tOPV needs through contingency mechanism

In order to minimize excess tOPV that must be disposed of after the Switch, tOPV stock leading up to the Switch will be minimal. Therefore, any unexpected wastage or demand will leave a Health Facility at greater than normal risk of stock out. However, tOPV administration must continue as normal until the day of the Switch. Therefore:

- When you receive your final tOPV delivery, conduct a physical count and compare to the total amount you will be required to administer until the day of the Switch (District Vaccine Store to communicate exact date)
- If there is a shortfall in the amount of tOPV you received or due to higher than expected wastage (e.g. a temperature excursion) or demand, quantify the additional tOPV amount you require
- Call or SMS the identified focal point at District Vaccine Store and request the additional amount and date by when you require it.

### 2. Execute the Switch

On the day of the Switch, all health facilities must stop tOPV usage. This requires careful planning for both public and private health facilities. National planners will communicate guidelines on how the Switch will be implemented in your country. An “exchange” process (either “push” or “pull”) between tOPV and bOPV is preferred, in order to avoid presence of tOPV in Health Facilities after the Switch. However, national planners may recommend a “prepositioning” mechanism under certain circumstances, e.g. for facilities with difficult access.

#### Scenario 1: Organized “Push” - Exchange (with no Health Facility disposal),

- On the scheduled day communicated to you by the District Vaccine Store, collect and submit all tOPV remaining in the facility’s fridge to the District representative when they arrive at the Health Facility. You must be absolutely sure not even one vial of tOPV remains in the facility.
- Begin administering and recording bOPV on the day of the Switch and going forward

#### Scenario 2: Organized “Pull” - Exchange (with no Health Facility disposal)

- On the scheduled day communicated to you by the District Vaccine Store, travel to the District Vaccine Store with your remaining tOPV in order to pick up your allocation of bOPV. You may receive special “tOPV for disposal on [Switch day]” stickers
- Surrender your tOPV in order to receive your bOPV
- Begin administering and recording bOPV on the day of the Switch and forward

#### Scenario 3: Prepositioning bOPV stock at Health Facilities

- Although less stringent, this scenario may be considered most appropriate by National planners for health facilities with difficult access, e.g. due to security issues, outbreaks.

- When you receive your bOPV stock, in order to avoid any risk of being mixed with tOPV and administered to patients prior to the Switch, keep bOPV separate from tOPV while awaiting distribution.
  - E.g. store on different shelves or on opposite sides of the fridge
- On the scheduled day communicated to you by the District Vaccine Store, remove tOPV from the cold chain and destroy/set aside according to guidelines (TBD)
  - It is recommended to put all tOPV stock in a closed bag, identified with appropriate sticker “tOPV for disposal”
- Begin administering and recording bOPV on the day of the Switch and forward

### **3. Dispose of excess tOPV after the Switch**

Dependent on guidelines still under development