

Monitoring the Switch from tOPV to bOPV

Guidelines for Developing National Monitoring Plans

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Acronyms

AFP	Acute Flaccid Paralysis
bOPV	Bivalent Oral Polio Vaccine
DPT3	Third dose of diphtheria-pertussis-tetanus vaccine
DSO	District Surveillance Officer
EPI	Expanded Programme on Immunization
IPV	Inactivated Polio Vaccine
NGO	Non-governmental Organization
NIP	National Immunization Program. Sometimes used interchangeably with EPI
OPV3	Third dose of Oral Polio Vaccine
tOPV	Trivalent Oral Polio Vaccine
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Introduction

The World Health Assembly has endorsed the SAGE recommendation for a synchronized switch from tOPV to bOPV in all 156 OPV using countries and regions during a two week period in April 2016 (April 17-May 1, 2016, if endorsed by SAGE in October 2015). A key component of a successful switch involves effective monitoring of health facilities after the national switch date in all countries to ensure that tOPV is no longer available for administration. Ensuring that tOPV is no longer being administered or in the cold chain is a country responsibility. This document **outlines for countries GPEI's recommended monitoring strategy** for withdrawal of all tOPV from cold chain storage points. The document provides step by step guidance on planning, preparing, collecting and reporting data, and corrective actions for monitoring the switch (Box 1).

The key objectives of the monitoring strategy are to:

- 1) Conduct site visits at **all cold chain stores** from the national to the district levels (where the largest quantities of tOPV will generally be stored at the time of the switch), as well as **selected service delivery points** (health facilities), in order to verify removal of these stocks from the cold chain;
- 2) Take corrective action to remove tOPV stocks from the cold chain if found and mark these stocks for disposal;
- 3) Assess performance of the switch; and
- 4) Assess the status of bOPV and IPV distribution at monitored facilities.

Monitoring the withdrawal of tOPV from cold chain stores and service points is a separate process from the certification of containment or destruction of poliovirus at laboratories and vaccine production facilities.

The destruction and containment of poliovirus at laboratories and vaccine production facilities described in the *Global Action Plan to Minimize Poliovirus Facility-associated Risk after Type-specific Eradication of Wild Polioviruses and Sequential Cessation of Routine OPV Use* (known as GAP-III) is a separate process from the withdrawal of tOPV. As a result, the requirements for the certification of the containment or destruction of poliovirus at laboratories and vaccine production facilities do not apply to the monitoring of tOPV withdrawal. However, switch monitoring activities may occur simultaneously with efforts to certify containment or destruction of poliovirus at laboratories and vaccine production facilities and may involve the same key staff.

BOX 1: MONITORING OVERVIEW

Objectives of Switch Monitoring

- Ensure and validate withdrawal of tOPV (primary)
- Assess introduction of bOPV (secondary)
- Assess distribution of IPV (secondary)

Independent Monitoring Period: completed within 2 weeks of the national switch date in April 2016

Planning and preparing for the monitoring:

- a. Convene a committee (e.g., National Switch Validation Committee) that is independent from switch implementation activities to provide monitoring oversight and validate switch
- b. Develop TORs for the Switch Monitors
- c. Develop data collection tools and reporting mechanism for the independent monitoring
- d. Hire and train the Switch Monitors

Monitoring site selection:

- a. Independently monitor ALL facilities down to the district level
- b. Independently monitor a SAMPLE of the service points (health care facilities) using a risk-based, purposive strategy described in Section 3.

Corrective action: All monitoring efforts should be linked with corrective action (in other words, removal of tOPV from the cold chain).

Reporting: Monitors should report data to the National Switch Validation Committee. The National Switch Validation Committee should report the validation results to the World Health Organization within two weeks of the national switch date.

Additional monitoring: Supportive supervision visits can supplement independent monitoring of health facilities to provide additional verification of the adequate withdrawal of tOPV from the cold chain. These additional monitoring activities for tOPV withdrawal should be completed as soon as possible, while tOPV disposal should occur within 3 months of the switch; these activities can be conducted through regular activities of national immunization programs. ***NOTE: The data collected through supportive supervision visits are not part of the validation process that should occur within 2 weeks of the national switch date.***

What are the general principles of this document?

What is included in this document?

This document provides a framework for countries to consider when developing and implementing their plans for monitoring the switch. This document focuses on the minimal recommendations for monitoring the withdrawal of tOPV, the introduction of bOPV, and the distribution of IPV (health facilities should have both bOPV and IPV stocks on the National Switch Day) during the two weeks following the switch. Countries can go beyond these recommendations by adding more activities and indicators that are specific to their National Immunization Program goals.

This document can also be adapted to a field guide for training based on local needs.

Who is the target audience?

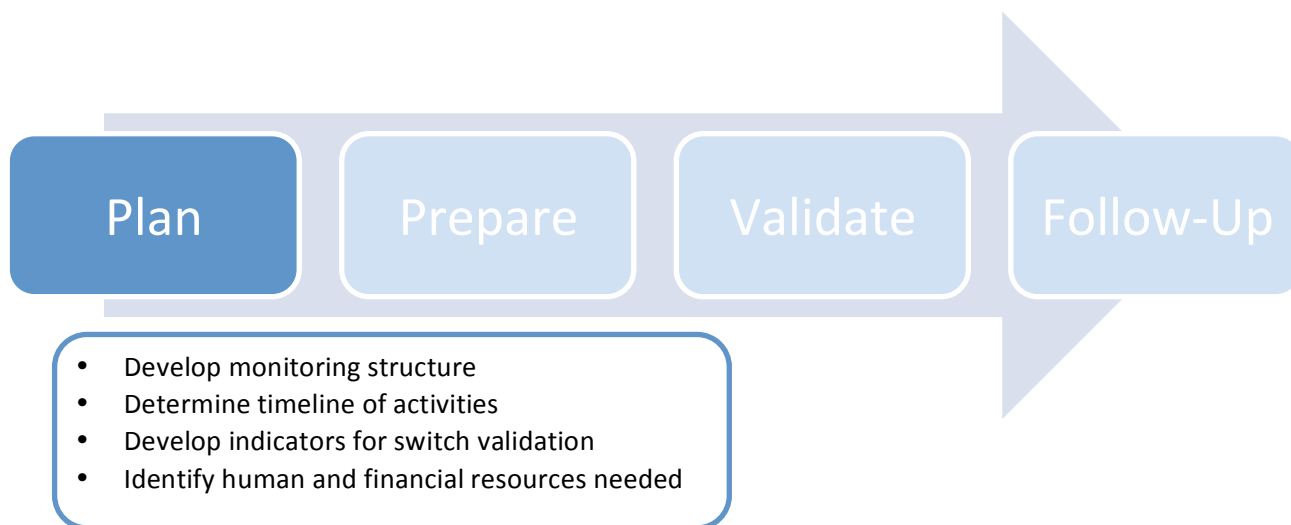
Members of the National Switch Validation Committee, country policy makers, program managers, logisticians, and consultants who are involved in the planning, preparation, and implementation of the switch are the primary target audience. This document explains how to establish a system that will provide timely and useful data for validating the switch.

Recap – Monitoring on a page

The table below summarizes the key activities of the monitoring activities.

Independent Monitoring Period	Plan	By September 2015 <ul style="list-style-type: none"> – Develop monitoring structure – Determine timeline of activities – Develop indicators for switch validation – Identify human and financial resources needed
	Prepare	October 2015 – February 2016 <ul style="list-style-type: none"> – Develop questionnaires and data collection tools – Develop training materials – Create roster of facilities to monitor – Recruit supervisors and monitors – Train supervisors and monitors – Develop micro-plans – Develop contingency plans
	National Switch Day	A day chosen during the last 2 weeks of April 2016 <i>(Date to be finalized by SAGE in October 2015)</i>
	Validate	April 2016 - During the two weeks after the National Switch Day <ul style="list-style-type: none"> – Monitors visit cold chain stores and service delivery points – Data reported and aggregated – Develop validation report
Follow-up Monitoring Period	Follow-Up	2-3 months ongoing after the switch <ul style="list-style-type: none"> – Additional monitoring of tOPV withdrawal as needed – Correcting identified problems – Monitoring tOPV disposal as desired

1. Plan



1.1. Develop a Monitoring Structure

Identify the staff that will be included in monitoring activities at each level of the health system. Review the descriptions of each of the key players for the monitoring structure below and determine which National Immunization Program staff will be used, if other health workers will be needed, and if partner organizations should also be included in the monitoring activities.

National Switch Validation Committee: A body independent from switch implementation activities that is authorized by the government to validate the switch and certify that tOPV has been withdrawn from the cold chain. A country's National Certification Committee could be used for this purpose if it is active, or members of the National Switch Validation Committee could be drawn from the National Certification Committee or other authorities not part of the Switch Management Committee.

Monitoring Coordinators or Supervisors: Staff independent from switch implementation activities that are responsible for managing monitors and collecting and responding to data. Coordinators and supervisors:

- Identify cold chain stores to be visited
- Select service delivery points to be visited
- Develop and provide training material
- Facilitate logistics for the training and transportation of independent monitors.
- Facilitate reproduction and distribution of questionnaires and guidelines for monitors.
- Develop a micro-plan for independent monitors and their supervisors. The plan will be accompanied by a map and will assign each monitor to areas to be monitored each day

WHO or UNICEF Country Offices may provide coordinators to manage switch monitoring. In larger countries, separate switch monitoring supervisors may be needed for individual states, provinces, or districts. However,

such state and local switch monitoring supervisors should ultimately report to a national switch coordinator who will work with the National Switch Validation Committee.

Independent Monitors: Persons who will assess the cold chain storage sites and service points with a questionnaire. These persons should not be directly involved with the organizations implementing the switch itself because their independence from those organizations is important for allowing them to provide honest assessments.

Switch Management Committee (not part of monitoring structure):

- Plans, manages, and oversees all activities relating to the switch, including identification of the sites to be monitored at the regional and national levels
- Receives updates on monitoring activities and findings
- Takes appropriate programmatic action in case large amounts of tOPV are found at cold chain stores or service points and/or IPV and bOPV is not available.

Working groups used during SIAs could potentially serve as regional or national Switch Management Committees.

Box 2: What does “independent” mean?

For monitoring the switch, “independent” refers to the use of coordinators/supervisors and monitors who are not directly involved with executing the switch and are therefore more likely to provide unbiased assessments of the switch’s implementation. These individuals may come from the health sector and may be employed by the government or come from local NGOs or universities. However, if these individuals were directly involved with switch execution or planning activities in a given region or district, they should not participate in monitoring activities in these areas, but can participate in other regions or districts where they have not been directly involved with executing the switch. Independent coordinators and monitors may be from other countries, but it is not necessary to have international monitors for switch validation.

Overall, individuals who can provide unbiased, credible assessments of how well the switch has been performed are well suited to be being involved with switch monitoring.

1.2. Timeline of Activities

Determine the major activities to schedule for switch monitoring. The exact activities and their timing may vary by country.

April 2016 Calendar

Sun	Mon	Tue	Wed	Thu	Fri	Sat
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18 National Switch Day	19	Stop use of tOPV and remove tOPV from the cold chain. Begin use of bOPV and disposal of tOPV			23
24	25	26	27	28	29	30
1	2 National Validation Day	3	4	5	6	7
8	9	10	Complete disposal of tOPV as soon as possible, but no later than 3 months after National Switch Day			

Pre-Switch Activities:

- Identify monitors - 1-2 months before switch
- Notify monitors of switch activities - 1 month before switch
- Train monitors - 2-4 weeks before switch
- Develop monitoring plans for which cold chain stores or service points will be visited by each monitor - 1-2 weeks before switch
- Distribute data collection tools to monitors - 1 week before switch

2 week Switch Validation Activities:

- Monitors collect information on switch performance during the 2 weeks after the National Switch Day
- Monitors withdraw tOPV if found at any site
- Monitors and their supervisors report information to the National Switch Validation Committee within 3 days of the assessment and no later than 2 weeks after the National Switch Day
- Data aggregated by National Switch Validation Committee and reported to the Switch Management Committee. - Continuous process, but should ideally be completed within 2 weeks of the National Switch Day

Post-Switch Activities:

- After validation, provide supportive supervision for 2-3 months to increase confidence that tOPV has been fully withdrawn from all service points
- Dispose of all tOPV- As soon as possible, but no later than 3 months after the National Switch Day

1.3. Switch Validation Indicators

National Immunization Program and health sector staff, including the Switch Management Committee, will need to determine the core indicators to validate that the switch has occurred at each level of the cold chain. The

following indicators should be considered the minimum needed for Switch validation, with the indicators related to tOPV being the most important:

- The number and percent of cold chain stores and service points where tOPV is present
- Among cold chain stores and service points with tOPV, the number and percent of sites at which at least one tOPV vial was found inside the cold chain
- Among cold chain stores and service points with tOPV, the number and percent of sites at which at least one vial of tOPV was found outside the cold chain
- The number and percent of cold chain stores and service points with bOPV
- The number and percent of cold chain stores and service points with IPV

See **Annex C** for an example of a data collection form that can be used to collect the information needed for these minimum indicators from cold chain stores and service points.

Additional indicators can be included if the National Immunization Program program is interested in collecting other types of information. Data collection forms and the monitoring structure can be adapted to the needs of the country National Immunization Program program and their current management structure.

1.4. Identify Human and Financial Resources

Based on the planned activities, identify the human resources that will be needed with any other resources such as transportation, supplies, data reporting tools, etc. The budget tool that was provided to the National Switch Management Committee can be used for estimations.

2. Prepare



2.1. Develop data collection tools

Monitors will need to use questionnaires (for an example, see **Note:** *The forms included in this guide include the core indicators that are needed to validate the switch. Additional indicators can be included if switch monitors are tasked with collecting information on other immunization activities.*

Annex C: Example Forms

Survey Form for Independent Monitors – tOPV Storage Site) in order to capture all of the information needed to validate the switch. Depending on the rigor of the validation process, the forms can vary in length and depth. The forms should include enough questions to capture the information needed for the minimum indicators for validating the switch.

The forms can also include instructions for what monitors should do if they find tOPV at a cold chain store or service point. For some countries, SMS or other electronic mechanisms can be used to collect the information needed for switch validation.

Collection tools can be a simple paper based form that compiles the required information to compute the minimum indicators required (for an example see Annex C: tOPV Withdrawal Tally Sheet). For a complete report on the switch, the collection tool can also be an Excel file that captures the all data issued from the questionnaire.

Table 1. Data fields collected by tools

Simple collection tool	Complete collection tool
<ul style="list-style-type: none"> • Facility type/name: • Date of the visit • Number of vials of tOPV found • tOPV kept in or outside of the cold chain: <ul style="list-style-type: none"> ○ In the cold chain ○ Outside of the cold chain • bOPV present at the facility: <ul style="list-style-type: none"> ○ Yes ○ No • IPV present at the facility: <ul style="list-style-type: none"> ○ Yes ○ No 	<ul style="list-style-type: none"> • Facility type/name: <ul style="list-style-type: none"> ○ National (name) ○ Regional (name) ○ District (name) ○ Service Point (name) • Date of the visit • Date of the switch on site • tOPV present at the facility: <ul style="list-style-type: none"> ○ Yes ○ No • Number of vials of tOPV found • tOPV kept in or outside of the cold chain: <ul style="list-style-type: none"> ○ In the cold chain ○ Outside of the cold chain • Plans for tOPV: <ul style="list-style-type: none"> ○ Destroy it on-site ○ Keep it out of the cold chain ○ Transport it to a tOPV disposal site ○ Wait for someone to pick up the tOPV • Reasons for not disposing or transferring the tOPV <ul style="list-style-type: none"> ○ Unaware of need to dispose of or transfer tOPV ○ Did not receive clear guidelines ○ Need additional assistance ○ Did not have time yet to do it. • Destination for tOPV withdrawn • bOPV present at the facility:

Simple collection tool	Complete collection tool
	<ul style="list-style-type: none"> ○ Yes ○ No • Staff started to administer the bOPV or distribute it for administration <ul style="list-style-type: none"> ○ Yes ○ No, but plan to start administering or distributing the vaccine soon ○ No, and have no plans to start administering or distributing the vaccine • IPV present at the facility: <ul style="list-style-type: none"> ○ Yes ○ No • Staff started to administer the IPV or distribute it for administration <ul style="list-style-type: none"> ○ Yes ○ No, but plan to start administering or distributing the vaccine soon ○ No, and have no plans to start administering or distributing the vaccine

2.2. Develop training materials

The training material should cover the following topics:

- Information about the switch
- Purpose of the monitoring activity, its objectives and the role of independent monitors
- Timeline of the independent monitoring
- Description of the behaviour and profile of an independent monitor and his/her interaction with health workers
- Description of the tasks of the independent monitor
- Review of tools (forms) used: exercise and examples
- Addressing concerns, previous mistakes and handling misleading information
- Developing independent monitoring micro-plan and how to follow it
- Plans for tOPV disposal activities.

2.3. Identify Facilities for Monitoring

The goal here is to identify which facilities in the cold chain need to be visited for the efficient validation of tOPV withdrawal and bOPV introduction. The recommended risk-based purposive (in other words, non-random) sampling monitoring strategy is intended to rapidly identify the cold chain stores and service points possibly holding the largest stocks of tOPV after the switch and facilitate immediate corrective action.

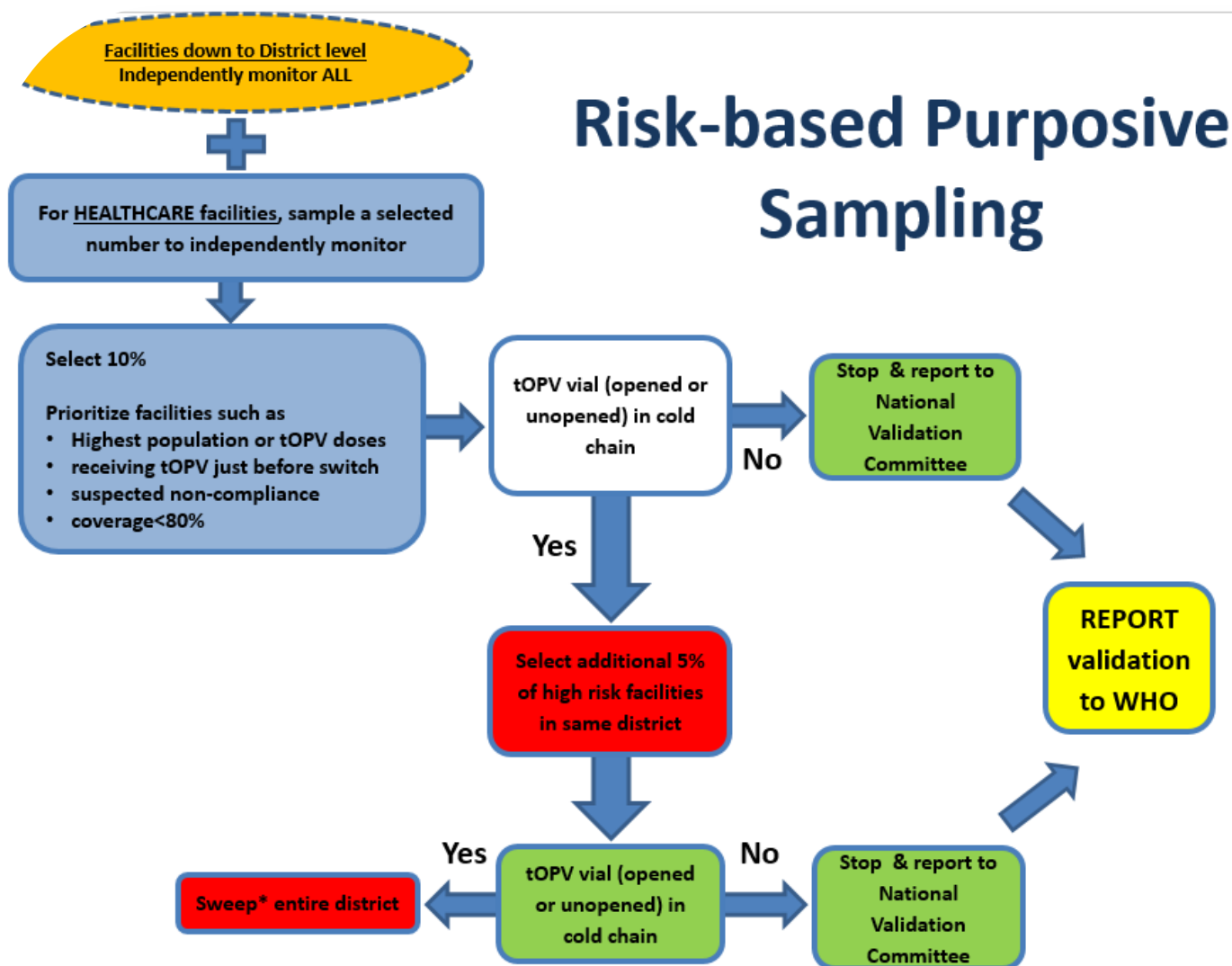
Steps:

1. Generate a line-list of cold chain stores that stock tOPV from the national to the district level (in other words, all national, regional, and district cold chain stores) along with their last known tOPV stock levels (if possible). Monitors should **visit all of these stores**.
2. Generate a line-list of the service points that can store tOPV in a working refrigerator or freezer for more than 1 night. The monitors, based on standardized criteria set by the national level, should **visit a sample of these service points**. Select 10% of the service points with the highest population. Prioritize facilities that have:
 - tOPV received just before the switch
 - A history of non-compliance with immunization program policies
 - DPT3 coverage <80%
 - Management issues
 - Other high risk characteristics (see Annex B)

This strategy will provide complete information on all cold chain stores from the national to the district level and will provide information on many service points. These data will provide reasonable assurance of a successful national switch within two weeks of the national switch date.

Results from the sampled service points will not be generalizable to all service points. Therefore, countries are encouraged to ensure tOPV withdrawal from all service points through supportive supervision during the 2-3 months that follow the completion of independent monitoring.

Figure 1 below further illustrates how the purposive sampling should be conducted at the service point (health facility) level.



** Sweep denotes intensified monitoring of all other health facilities with involvement of staff from the regional level or higher*

2.4. Develop Micro-Plans

Using the list of stores that need to be monitored (all stores from the national to the district level) as well as the list of service points that need to be visited based on the purposive sampling strategy; micro-plans should be developed for each independent monitor (or monitoring team, if district or region is large). These micro-plans should include the following:

- Schedule of stores to be visited over the monitoring period after the National Switch Day
- Mechanisms and procedures for reporting to supervisors
- Protocol for mop-up with stores if they cannot be visited on schedule
- Policies for what to do if tOPV is found
- Contact information for all stores to be visited
- Contact details of coordinators and supervisors (to be added when recruited).

Next, determine the modes of communication and data flow for each of the key participants. Consider the following:

- Is there a mechanism already in place for information sharing?
- How frequently will information be shared between switch monitoring participants? What information? Is the mechanism used to share information up the monitoring system (for example, from monitors to supervisors or coordinators) as well as down the monitoring system (for example, from the National Switch Validation Committee to the coordinators)?
- How will information be shared with the individuals implementing the switch?
- How quickly can information be passed from one participant to the next?

2.5. Develop Contingency Plans

Consider developing contingency plans for switch monitoring. For example:

- What will be done if not all of the cold chain stores and the selected service points are visited during the monitoring period following the National Switch Day?
- What will be done if the number of service points that need visits increases because many of the initial service point visits indicate that there have been problems with tOPV withdrawal?

Many problems can be dealt with during the mop-up monitoring period, but some problems may need to be dealt with during the independent monitoring phase.

2.6. Recruit supervisors & monitors

It is recommended that one supervisor be recruited per region. The independent monitors should not be directly involved with implementing the switch itself so that they can provide unbiased assessments of the implementation of the switch. In-country partner organizations, such as non-governmental organizations, universities, or professional groups, may be able to assist with providing people or other resources.

Main responsibilities for the supervisors:

- Provide the independent monitors with lists of sites to be assessed
- Provide training to independent monitors
- Ensure that the independent monitors are able to travel to their assigned sites and move from one to another as required.
- Visit independent monitors in the field to check on the quality of work.
- Observe performances of independent monitors and provide adequate feedback with corrective measures as needed.
- Be available for independent monitors to contact by phone at all times during monitoring period.
- Arrange periodic debriefings with independent monitors, including at the end of the independent monitors' period of work
- Collect the forms from independent monitors, review quality and reliability of data collection process, and correct if required
- Compile data and analyse the data
- Send summaries of findings to individuals coordinating the implementation of the switch in the area of the supervisors' responsibility.

- Investigate to identify reasons for leftover tOPV and/or no introduction of bOPV and/or IPV.
- Advise switch implementation staff on corrective actions in case tOPV is found at cold chain stores or service points and/or IPV and bOPV is not available.
- Provide the monitoring coordinator with any information needed to write the report for validation.
- Facilitate the payment of the Independent monitors

Main responsibilities for the Independent Switch Monitors:

- Carry out the field monitoring activity
- Complete the monitoring forms provided.
- Submit the completed forms daily to the supervisors
- Report to supervisor details about left over of tOPV and/or no introduction of bOPV and/or IPV.
- Record any additional observation that may be helpful in identifying problems with the immunization program
- Remove any tOPV found on visits to cold chain stores and service points unless the amount of tOPV found is so large as to make this impractical. Hand over tOPV removed to supervisor or deliver to disposal site as specified in the micro-plan.

Suggested criteria for selecting independent monitors

- **Education:**
 - Completed at least a high school or secondary school level (BEPC)
 - Have a good mastery of the official language of the country
 - Be able to speak the local language and be able to operate in the local culture.
- **Behaviour:**
 - Behave in line with the customs of the community visited
 - Observe basic politeness rules: greetings, giving reasons for the visit
 - Have the ability to work in a team and under pressure
 - Know how to reformulate questions to make them more understandable without losing the substance
- **Experience:**
 - Some familiarity with logistics or the health care system
 - More experience will likely be needed for inspecting larger cold chain store facilities such as national or regional cold chain stores
- **Cultural aspects:**
 - Be familiar with the country's cultures and the languages and able to interview cold chain and health facility staff
 - Same ethnic and religious group as members of communities who may not cooperate with members of different ethnic or religious groups

2.7. Train supervisors & monitors

The training should be conducted immediately prior to the switch in order to complete the entire monitoring activity within the shortest time possible.

Trainers

- The national independent monitoring coordinator with the assistance of WHO/UNICEF staff should do an initial training of trainers.

- Following the national training of trainers, local training should be conducted by trained persons including consultants where needed.

Organization of training

- A maximum of 30 trainees at one time is desirable. The method should focus on practical operational issues with exercises and role-play to ensure the participation and involvement of the participants.
- Supervisors must attend the training and have additional sessions to train them on quality supervision and to highlight their roles and responsibilities during the activity.

The monitors should be trained on:

- Roles and responsibilities
- Using micro-plans
- Verifying the absence of tOPV at selected facilities
- Removal of tOPV if any residual tOPV is found in facilities
- Completing recording forms to avoid data quality problems
- Communicating and reporting outcome of facility visits to supervisor
- If appropriate, confirming that there is a plan for tOPV disposal at each facility, if disposal has not been completed

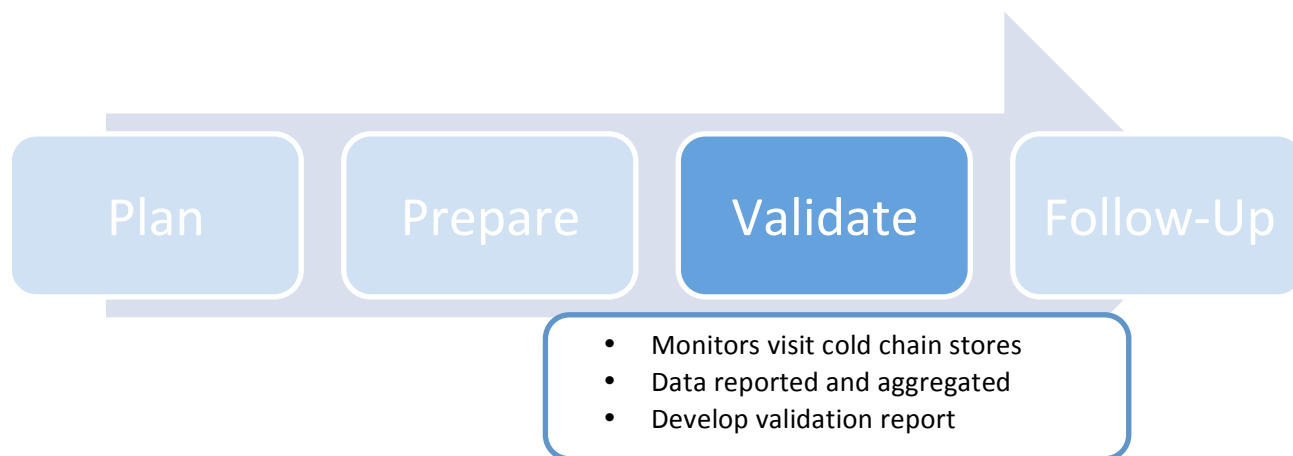
2.8. Pre-position supervisors & monitors

Supervisors and monitors must travel to their respective locations according to the plan and be ready to start the independent monitoring in their designated sites on the National Switch Day.

Supplies required for independent monitors and supervisors:

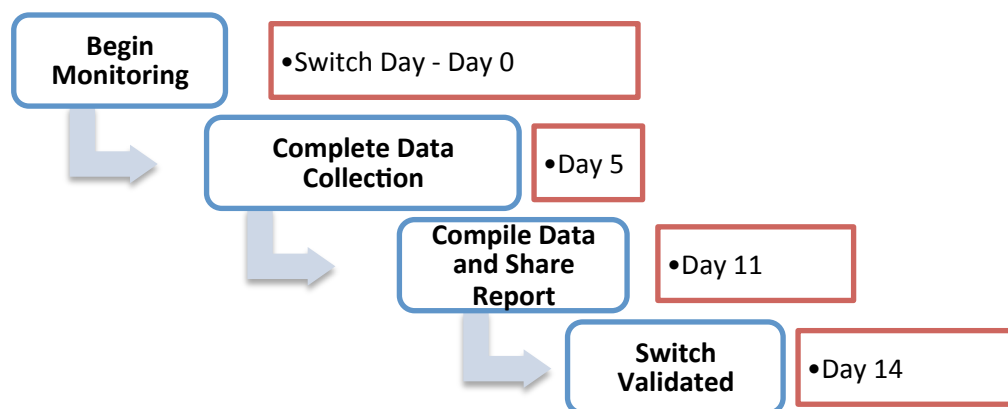
- ID cards and reference letter;
- Phone credit;
- Questionnaires;
- Guidelines;
- Plastic bag and stickers in case tOPV is found;
- Notepad;
- Pens.

3. Validate



The validation process should include all tasks from the start of monitoring activity until the validation report is developed, approved by the National Switch Validation Committee, sent to the ministry of health, and reported to the WHO country office. The figure below shows a timeline with milestones, which can vary from country to country with the goal of the validation process being completed within two weeks of the National Switch Day.

Figure 2: Example timeline to validate the switch



3.1. Monitors visit cold chain stores and service delivery points

Beginning on the day after the National Switch Day, all independent monitors should systematically monitor vaccine cold chain stores and service points as described:

National to District level stores: Independent monitors will visit 100% of the vaccine cold chain stores from the national to the district level. If tOPV is found, the monitor will be expected to remove the vial(s) from the cold chain and facilitate delivery to disposal site as described in the collection plan developed by the Switch Logistics Working Group prior to the switch, document his/her findings, and report to the supervisor. If the amount of

tOPV found is large (would require another vehicle to transport), the monitor may not be able to remove all of the tOPV and a follow-up visit may be needed to confirm that tOPV has been correctly withdrawn.

Service points: Independent monitors will monitor a sample of the facilities as described above. Finding tOPV in the cold chain should prompt corrective action (removal of tOPV) and may trigger visits to additional sites for verification of tOPV withdrawal.

In case one or more tOPV vials (opened or unopened) are found in the cold chain of the service points:

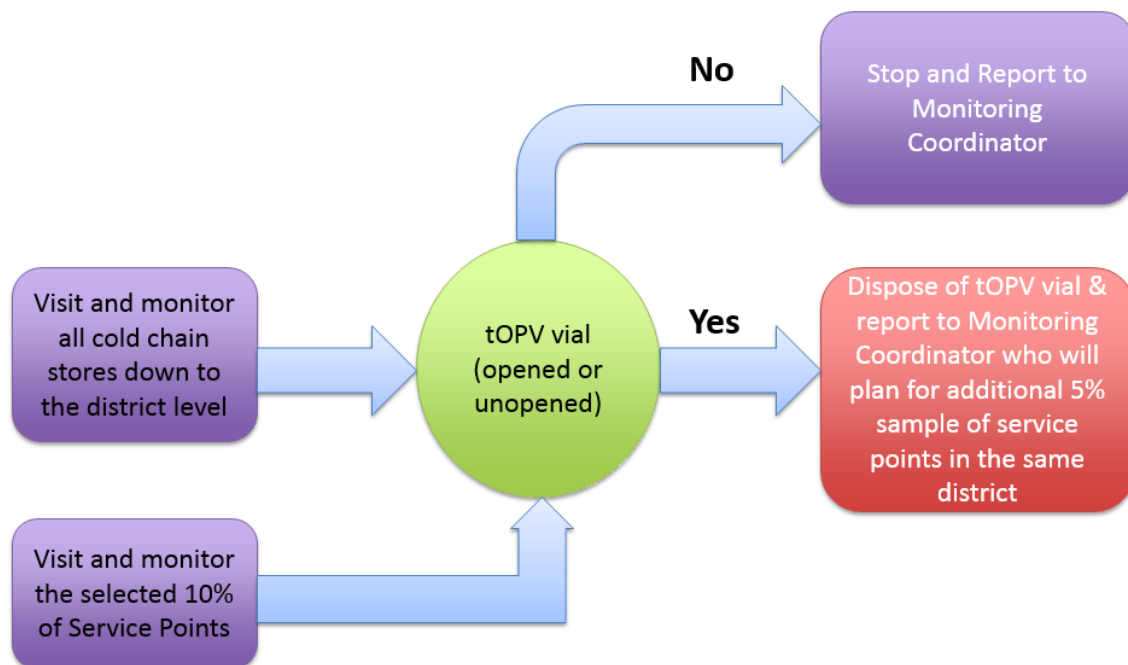
- The monitor will remove the vials from the cold chain and transport them to the nearest district or region disposal site according to the disposal plan. The monitor may wait to transport the tOPV to the disposal site until after he or she has completed his or her other monitoring activities.
- The supervisor will select an additional 5% of health facilities for monitors to visit.

If one or more tOPV vials containing vaccine (opened or unopened) are found in the additional 5% of visited facilities, a sweep of all service points should be conducted for the whole district. Sweeping would mean an intensified monitoring exercise with involvement of more district, regional and national staff, etc.

This strategy should continue until supervisors and coordinators feel all tOPV has been withdrawn from the cold chain, even if this extends beyond the country validation date. If the visits to the service points will extend beyond the two weeks following the National Switch Day, then they should fall under the usual National Immunization Program's supervision.

The graphic below further illustrates how the purposive sampling would be conducted at the service point (health facility) level.

Figure 3: Site Visits and Corrective Action by Independent Monitors



Decision to Sweep a District or Region

- **Sweeping district:** If tOPV is found after the second round of monitoring (i.e., additional 5% of sites), the Monitoring Coordinator with the support of district immunization staff is responsible for overseeing a SWEEP of entire district
- **Sweeping region:** If 2 or more districts require sweeps, then involve regional and national staff to conduct a broader assessment of the entire region

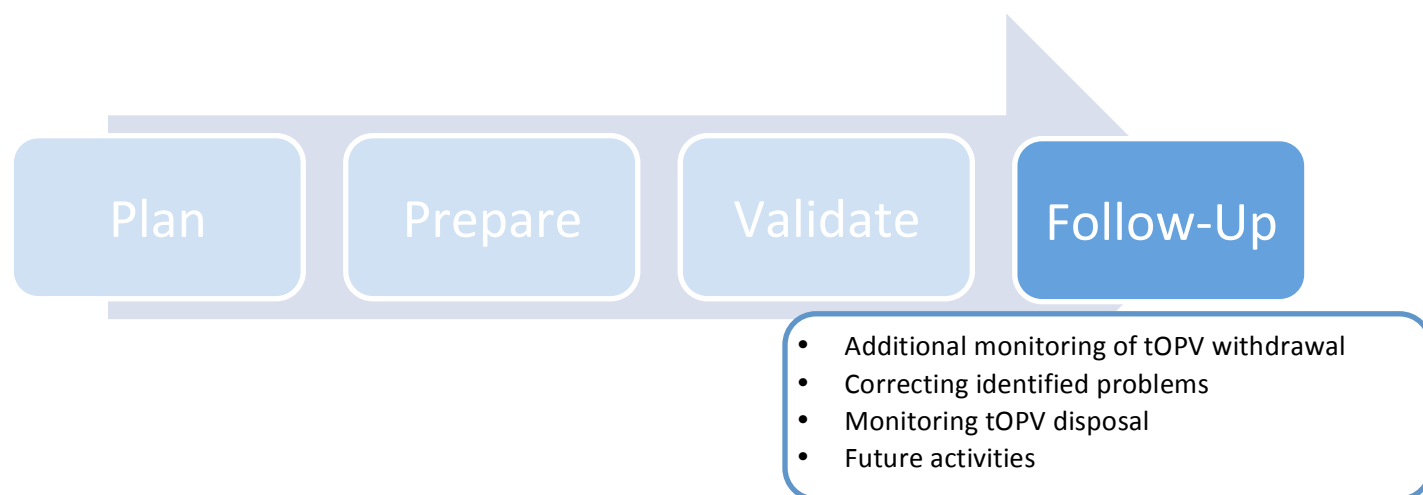
3.2. Data Reported and Aggregated

- **Independent monitors**
 - Hand over all questionnaires to their supervisors on a daily basis or discuss findings of questionnaires over the phone.
- **Coordinators/Supervisors**
 - Collect questionnaires and review the quality of information
 - Compile questionnaires into collection tool
 - Follow-up with monitors who have not turned in questionnaires for their assigned facilities, according to their micro-plans
 - Send data to coordinator
 - Collect all summary sheets and monitoring forms
 - Aggregate results for National Switch Validation Committee to review
 - Determine if any programmatic action is needed to remove tOPV if it is found in numerous cold chain stores, and, if so, what action is needed
- **National Switch Validation Committee**
 - Will declare monitoring completed once it is satisfied that all national to district level cold chain stores have withdrawn tOPV and that no further assessments or sweeps of service points are needed under the guidelines described above.
 - Will make the ultimate decision about whether or not the country can validate that there is no longer tOPV being administered or present in the cold chain after the National Switch Day.
 - May request the Switch Management Committee to gather additional information if they feel they do not have enough data to validate the switch.
 - Will report findings of the switch to national government, who should then send the report to the WHO.

3.3. Develop validation report

After the National Switch Validation Committee has concluded whether or not the country can validate that there is no longer tOPV being administered or present in the cold chain after the National Switch Day, the committee should report its findings to the national government. The national government should in turn report on the status of the switch, including a validation of the switch, to the country and regional office of the World Health Organization.

4. Follow-Up



Although the vast majority of the switch monitoring activities should take place during the 2 weeks immediately following the National Switch Day, countries are encouraged to conduct mop-up activities through supportive supervision in order to ensure that tOPV has been sufficiently removed from the cold chain and that the risk of tOPV administration after the switch is low. The mop-up activities will also address problems with bOPV and IPV introduction identified during the initial two weeks of monitoring. National Immunization Program staff can carry out this mop-up activity during routine supervision. The mop-up should occur as soon as possible after the switch and last no later than 2-3 months after the National Switch Day.

Countries may also consider developing a plan for monitoring tOPV disposal, which would be carried out over a longer period than the 2 weeks of independent monitoring focused on tOPV withdrawal. Disposal of tOPV may not be completed within the first two weeks following the National Switch Day, but disposal of tOPV and monitoring of that disposal should be completed also within 2-3 months after the National Switch Day (see the waste management section of the logistics guideline).

4.1. tOPV Withdrawal

While independent monitoring data collected during the first two weeks after the switch date are needed for validation, mop-up activities through supportive supervision will further increase confidence in successful withdrawal of tOPV. As the information on tOPV withdrawal collected from sampled service points will not be generalizable to all service points, visits by National Immunization Program supervisors or district surveillance officers to these sites is an important component of a successful switch.

National to District level cold chain stores: If the amount of tOPV found at a specific cold chain store was too large to pick-up during the monitoring period, a follow-up visit may be needed to confirm that tOPV has been correctly withdrawn. This follow-up visit may happen following the two weeks of independent monitoring but should be prioritized and conducted as soon as possible.

Service points: Identification of tOPV remaining in the cold chain at sampled service points should prompt monitoring visits to 5% additional service points, a sweep of service points in a district, or both. Some or all of these additional visits or sweep activities may need to occur following the two weeks of independent monitoring but needs to happen as soon as possible.

As the information on tOPV withdrawal collected from sampled service points will not be generalizable to all service points, visits by National Immunization Program supervisors or district surveillance officers to service points, particularly ones not visited by independent monitors, is an important component of a successful switch. These supportive supervision visits should occur as soon as possible after the switch and no later than 2-3 months after the switch date.

4.2. Problems Identified during Monitoring

Problems with bOPV and IPV distribution identified through switch monitoring should have been reported to National Immunization Programs' staff, but may not have triggered further assessments by switch monitors or immediately triggered sweeps of additional service points. All activity to follow-up on problems with bOPV and IPV distribution and to assess the effectiveness of that follow-up will be handled through a National Immunization Program's existing methods of tracking vaccine distribution and coverage.

Annexes

Annex A: Monitoring tOPV Disposal

See the Waste Management section in the Logistics Guide for additional information on disposal and definitions of types of disposal sites.

In addition to monitoring tOPV withdrawal, bOPV introduction, and IPV distribution, countries may also want to develop efficient mechanisms for assessing if tOPV is being promptly disposed of. Depending on a country's resources and preferences, some disposal activities may happen during the two weeks following the switch, simultaneously with the independent monitoring of the switch, while others may occur more than two weeks after the switch. Disposal of tOPV should occur as soon as possible, but no longer than 3 months after the National Switch Day. Planners should refer to the waste management section of the Logistics Guideline to develop a disposal monitoring plan.

As explained in the Logistics Guideline, prior to the switch it will be important:

- To conduct an inventory of all disposal equipment, recording if equipment is working and the volume of material (vials, if possible) that the equipment can dispose of in 1 day.
- To develop a tOPV collection plan in sufficient detail that the movement of tOPV from collection to disposal sites can be predicted and monitored. Individual plans may need to be developed at the national, regional, and district levels of the health system and within each district.

The Logistics Guideline also describes options for collection and handing of tOPV, including:

- Supervisors pick up tOPV from cold chain stores and take to disposal site
- Staff from cold chain stores drop-off tOPV at a disposal site
- tOPV can be amassed from multiple health structures at district level and then can be moved to a regional or national disposal site and disposed of

A collection/disposal plan should show the schedule for the planned movement and disposal of tOPV, which is useful for planning supervisory visits. For example, all cold chain stores using a particular disposal site could move their tOPV to that site on the same day or could move their tOPV to the disposal site on different days.

Due to the two week time limit on the operations of the independent monitors, they can help identify that tOPV has been removed from a cold chain store or service point and confirm that plans are in place for disposal. However, it is unlikely that the monitors will be able to confirm that tOPV has been disposed, where it has been disposed of, and when. However, information collected in the independent monitoring questionnaires, along with information collected during supportive supervision visits, can be used to help track whether or not the cold chain stores and service points have returned their tOPV and where it has been sent for disposal.

Monitoring tOPV disposal

1. Monitoring of tOPV disposal should focus on disposal of tOPV from national, regional, and district cold chain stores because the volumes of tOPV stored at those facilities is potentially much greater than the volume of tOPV stored at service points.
2. Cold chain store and service points should fill a short form or sticker listing the number of vials of tOPV that are being sent for disposal along with the tOPV vials (see for example Form for Transfer of tOPV

from Health Structures to Disposal Site). Preferably, the same information will be printed on the sticker that goes on the bags when withdrawing the tOPV from the cold chain.

3. Disposal sites can use a form to check off when tOPV from a given cold chain store or a service point has been received and disposed of (see for an example tOPV Disposal Form – Disposal Sites).
 - i. Alternative solutions, such as electronic data management systems, could also be used to record vials of disposed tOPV
4. Supervisors should visit tOPV disposal sites to make sure that tOPV has been collected and promptly disposed of. The records kept by the disposal site staff may be very helpful to the supervisors.
 - a. If the supervisor visits a disposal site and finds that it either has not received tOPV from all expected stores or has not finished disposing of the tOPV it has received, he or she should schedule a repeat trip. Multiple repeat trips may be needed before all expected tOPV has been collected and disposed of.
5. Supervisors record the amount of tOPV that a cold chain store or a service point sends for disposal and the site of disposal using a questionnaire during visits to cold chain stores and service points (see for an example tOPV Disposal Form – Supervisors)
6. Supervisors should ideally cross-check the amount of tOPV reported as having been sent for disposal by cold chain stores with the amount of tOPV that disposal sites record as having been received and destroyed to ensure that all vials were destroyed
7. Information collected on questionnaires by supervisors should be compiled and sent to the Switch Management Committee.

Annex B: Categorizing Risk of tOPV Use

Suggested criteria for identifying High Risk districts/sub districts:

- **AFP surveillance:**
 - Recent or on-going wild poliovirus circulation, either suspected or confirmed from AFP surveillance or environmental surveillance.
 - Clusters of AFP cases.
 - Recent polio compatible cases
 - Silent or underreporting areas
 - Locality where the supervision is weak
- **Immunization:**
 - Low routine immunization coverage with DTP3 or OPV3
 - Under-performance in previous campaigns
 - Discrepancies in numbers of children vaccinated between administrative data and coverage surveys
 - History of stock-outs
 - Poor communications with or reporting to National Immunization Program or EPI
- **Demographic and geographic characteristic:**
 - Densely populated areas
 - Slums, displaced populations, refugee camps, crowded and highly populated urban area with dense high-rise buildings, mobile communities including nomads and seasonal workers, conservative communities, areas with administrative instability, management problems or insecurity, etc.
 - Border and hard to reach districts/areas

Risk of tOPV Stored and Used During the Switch

Level of Supply Chain		Hypothetical scenario of tOPV storage and use	Likelihood of occurrence
District and higher store levels		Storage of large stocks of tOPV in the cold chain at district level and subsequent distribution to service points after the switch either intentionally (for example, in response to stockout of bOPV) or unintentionally (for example, because of confusion with bOPV)	Low-Medium
Service points	Short term	Service points continue to use tOPV during the first month following the switch.	Low
	Long term	Service points store tOPV after the switch and use it months after the switch, either accidentally or intentionally during a bOPV stockout.	Low-Medium
Use of scavenged tOPV		If cold chain stores or service points withdraw tOPV from the cold chain but do not promptly dispose of it, that tOPV may be scavenged and used for immunization or non-immunization purposes.	Low

Note: The forms included in this guide include the core indicators that are needed to validate the switch. Additional indicators can be included if switch monitors are tasked with collecting information on other immunization activities.

Annex C: Example Forms

Survey Form for Independent Monitors – tOPV Storage Site

Facility type: ☐ National ☐ Regional ☐ District ☐ Service Point
Region: **District:** **Facility:**
Date of the visit: **Date of the switch on site:**
Monitor name: **Monitor phone number:**
Supervisor name: **Supervisor phone number:**

ID	Question	Options
1.	Is tOPV present at the facility?	<input type="checkbox"/> Yes <i>Go to question #2</i> <input type="checkbox"/> No <i>Go to question #6</i>
2.	How many vials of tOPV?	
3.	Is the tOPV kept in or outside of the cold chain?	<input type="checkbox"/> In the cold chain <input type="checkbox"/> Outside of the cold chain
4.	What are the facility staff planning to do with the tOPV?	<input type="checkbox"/> Destroy it on-site <input type="checkbox"/> Keep it out of the cold chain <input type="checkbox"/> Transport it to a tOPV disposal site <input type="checkbox"/> Wait for someone to pick up the tOPV
5.	Why has the facility not already disposed of tOPV or transferred it to a disposal site?	<input type="checkbox"/> Unaware of need to dispose of or transfer tOPV <input type="checkbox"/> Did not receive clear guidelines <input type="checkbox"/> Need additional assistance <input type="checkbox"/> Did not have time yet to do it.
6.	Where has the tOPV been sent or destroyed?	
7.	Is bOPV present at the facility?	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Go to question #9</i>
8.	Have the facility staff started to administer the bOPV or distribute it for administration?	<input type="checkbox"/> Yes <input type="checkbox"/> No, but plan to start administering or distributing the vaccine soon <input type="checkbox"/> No, and have no plans to start administering or distributing the vaccine
9.	Is IPV present at the facility?	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Stop</i>
10.	Have the facility staff started to administer the IPV to children or distribute it for administration?	<input type="checkbox"/> Yes <input type="checkbox"/> No, but plan to start administering or distributing the vaccine soon <input type="checkbox"/> No, and have no plans to start administering or distributing the vaccine

Any comments? (for example, if you found any tOPV, where did you find it?) May use other side of paper

tOPV Withdrawal Tally Sheet

To be completed by independent monitor

Region:

District:

Supervisor name:

Supervisor phone number:

	Health Facility Name	Date of Visit	# of tOPV vials found	In/out of the cold chain?	bOPV present?	IPV present?	Follow-up needed?	Comments if follow-up is necessary
1				<input type="checkbox"/> In <input type="checkbox"/> Out	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2				<input type="checkbox"/> In <input type="checkbox"/> Out	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3				<input type="checkbox"/> In <input type="checkbox"/> Out	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4				<input type="checkbox"/> In <input type="checkbox"/> Out	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5				<input type="checkbox"/> In <input type="checkbox"/> Out	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6				<input type="checkbox"/> In <input type="checkbox"/> Out	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7				<input type="checkbox"/> In <input type="checkbox"/> Out	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
8				<input type="checkbox"/> In <input type="checkbox"/> Out	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
9				<input type="checkbox"/> In <input type="checkbox"/> Out	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
10				<input type="checkbox"/> In <input type="checkbox"/> Out	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Total number of health facilities monitored:	Number of health facilities that need follow-up:
Number of health facilities with tOPV not withdrawn from cold chain:	Number of health facilities with no bOPV :
Number of health facilities with no IPV:	
Additional comments:	

Form for Transfer of tOPV from Health Structures to Disposal Site

Date:

Cold Chain Store or Service Point sending tOPV:

Disposal Site Receiving Vaccine:

Vials of tOPV being sent:

tOPV Disposal Form – Disposal Sites

(Disposal site fills out)

Disposal Site Name:

Disposal Site Supervisor's name:

Disposal Site Supervisor phone number:

Region:

District:

To be completed when cold chain store (facility) delivers or sends tOPV to disposal site							To be completed as disposal site destroys tOPV from each facility	
	Facility name- returning tOPV	Facility Type*	Region	District	Date tOPV received by disposal site	# of tOPV vials from facility	Date tOPV vials destroyed	# of tOPV vials destroyed
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
Total								

*Write one of the following types of facilities: National store, Regional store, District store, Service Point (SP)

Form may be modified as needed to suit needs of country.

tOPV Disposal Form – Supervisors

(Monitor fills out)

Disposal Site Name:

Supervisor name:

Supervisor phone number:

Region:

District:

	Disposal Site Name	Level of Disposal Site*	Region	District	Date of Visit	tOPV Disposal Completed?	# of tOPV vials disposed of to date	Date of Visit	tOPV Disposal Completed?	# of tOPV vials disposed of to date	Date of Visit	tOPV Disposal Completed?	# of tOPV vials disposed of to date
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													
16													
17													
18													
19													
	Total												

*Write one of the following types of facilities: National store, Regional store, District store, Service Point (SP).

Form may be modified as needed to suit needs of country.