

Technical Guidance

**mOPV2 vaccine management,
monitoring,
removal and validation**

October 2016

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Abbreviations

Please refer to abbreviations in the following the document http://polioeradication.org/wp-content/uploads/2016/09/Responding-to-a-poliovirus-event-and-outbreak-SOPs-Part-1_EN.pdf

Introduction

The last detected case of wild type 2 poliovirus (WPV2) was in northern India in 1999. In September 2015, the Global Commission for the Certification of Poliomyelitis Eradication (GCC) declared that worldwide eradication of wild type 2 poliovirus (WPV2) had been achieved. However, continued use of live attenuated Sabin type 2 poliovirus contained in the trivalent oral polio vaccine (tOPV) posed an ongoing risk of circulating vaccine-derived poliovirus 2 (cVDPV2) and vaccine-associated paralytic poliomyelitis (VAPP).

Consequently, in a globally coordinated move in April/May 2016, all 155 countries and territories using tOPV switched to the bivalent oral polio vaccine (bOPV) for routine immunization and supplementary immunization activities (SIAs). Surveillance was improved to detect any occurrence of type 2 poliovirus (wild, vaccine-derived or Sabin) in any human or environmental sample. At present, any case or isolate of vaccine-derived type 2 poliovirus (VDPV2) is considered a potential global public health threat that requires a rapid, coordinated response involving the Global Polio Eradication Initiative (GPEI) and national and subnational public health agencies.

This response may include rapid mass vaccination with monovalent type 2 oral polio vaccine (mOPV2). However, use of this vaccine also reintroduces live attenuated type 2 poliovirus into populations and the environment, and therefore poses a risk of emergence of a new VDPV2.

Thus, where the use of mOPV2 is essential to stop a type 2 poliovirus outbreak, and in order to mitigate the risk of emergence of VDPV2, the strictest vaccine management protocols must be enforced. The geographical extent of the vaccination campaign will be confined to defined outbreak zones.

The criteria for mOPV2 use following a detection of type 2 poliovirus are described in the GPEI's Standard Operating Procedures (SOP) for responding to a poliovirus event and outbreak¹, in particular part two. Before the EOMG Advisory Group on mOPV2 provision (the Advisory Group) recommends the use of mOPV2, the following criteria must be met: positive laboratory result from an accredited Global Polio Laboratory Network (GPLN) laboratory; a risk assessment of further poliovirus transmission, and the proposed immunization response plan. Ultimately, the decision to release mOPV2 from global or national stocks is under the authority of the WHO Director-General.

The purpose of this guidance note is to outline the best practice for
(1) mOPV2 management in the field, during and between SIA rounds, and
(2) validating removal of residual mOPV2 stocks from all subnational levels for safe storage centrally.

Inactivation and safe disposal of mOPV2 once recommended by the Outbreak Response Assessment (OBRA) team will take place at all levels of the country health infrastructure.

¹http://polioeradication.org/wp-content/uploads/2016/09/Responding-to-a-poliovirus-event-and-outbreak-SOPs-Part-2-Protocol-for-PV-Type-2_EN.pdf
and http://polioeradication.org/wp-content/uploads/2016/09/Responding-to-a-poliovirus-event-and-outbreak-SOPs-Part-1_EN.pdf

1. Characteristics of the mOPV2 vaccine

mOPV2 has the **same operational characteristics as bOPV²**:

- WHO-prequalified
- Licensed by the national regulatory authority (NRA) in the producing country.
- Administered orally – 1 dose = 2 drops
- Presented in 20-dose vials with a vaccine vial monitor (VVM) on the label.
- Requires storage volume of 0.48 cm³ per dose, including secondary packaging containing 100 vials of 20 doses each.
- Keep at –20 °Celsius or between 2 and 8 °Celsius, if freezer is not available.
- Heat sensitive – always check the VVM has not reached the discard point before using the vaccine



Figure 1 :
mOPV2 vial

2. Protocol for release of mOPV2 and its use in countries

The mOPV2 vaccine used in response to an event or outbreak is released *from the global stockpile of mOPV2* under a **strict protocol** and supplied to countries by the UNICEF Supply Division only upon release authorization from the WHO Director-General through the Advisory Group on mOPV2 provision.

Self-producing countries *with a national stock of mOPV2* must also obtain authorization from the WHO Director-General before they can use this vaccine in the target population.

Countries that require mOPV2 vaccine in response to a confirmed event or an outbreak must receive approval by the Advisory Group following a review of their response plan and vaccine requirements.

An event is described as detection of poliovirus with no evidence of transmission; an outbreak has occurred when there is evidence of transmission. An event could be reclassified as an outbreak once there is evidence of transmission. This is further described in the document *SOP: Responding to a poliovirus event and outbreak, Part 1: General SOPs*³.

The Advisory Group will take into account the quality of any previous campaigns, vaccine stock balance in the country and the country immunization plan, which includes a risk analysis, to endorse further delivery of mOPV2. Approval of the WHO Director-General is required only once for the response, but approval of the Advisory Group is required for each subsequent delivery of mOPV2.

Countries that have residual mOPV2 supplies after an outbreak or an event response will require authorization from the Advisory Group if they undertake any new, additional or expanded activities, or if they target any populations or regions outside the scope of their original response plan.

Vaccine request form for mOPV2 vaccine is available on GPEI website at <http://polioeradication.org/tools-and-library/field-resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/>

²Insert leaflet available at: https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&ID=234#Attachments

³ <http://polioeradication.org/tools-and-library/field-resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/>

3. Handling of mOPV2 in response to a type 2 poliovirus event or outbreak

Stringent monitoring of the storage, distribution, usage and destruction of mOPV2 is critical for ensuring that the vaccine is not mixed up with or mistaken for another vaccine (or vaccines) and that no vials are left within the country once the SIA rounds are completed and the Outbreak Response Assessment team (OBRA) recommends mOPV2 destruction. Key considerations in managing the deployment of mOPV2 and monitoring its usage are outlined below.

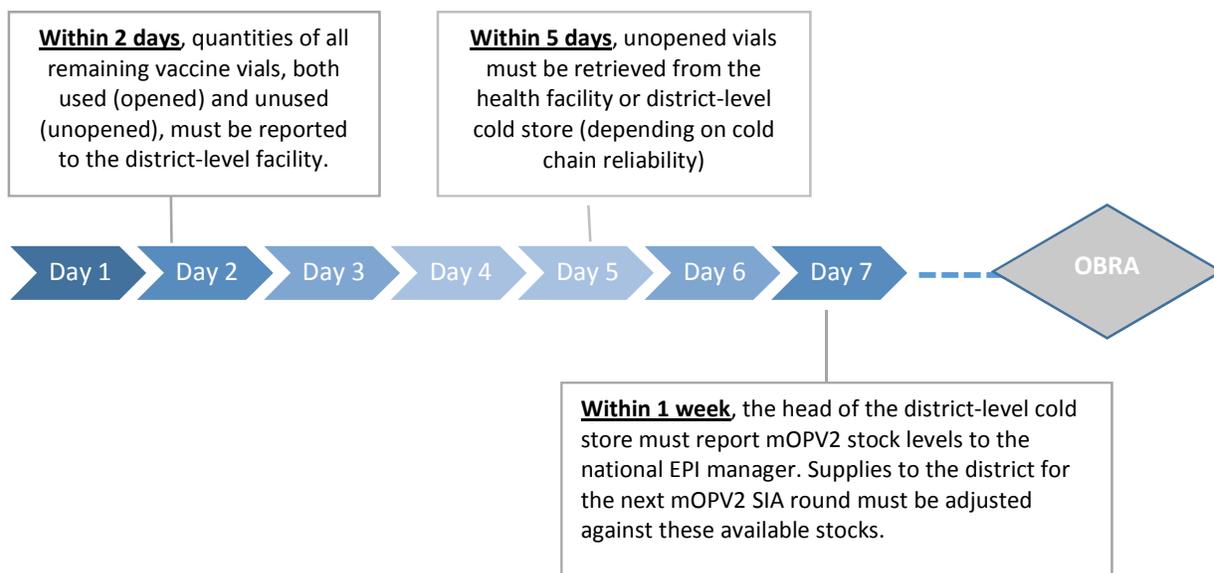
Managing deployment of mOPV2 in a country

- When a VDPV2 event or outbreak is notified, there are **no mOPV2 stocks** in countries.
- In most cases, **immunization response with mOPV2 must start within 2 weeks** following laboratory confirmation of type 2 poliovirus.
- Complete the **vaccine arrival report** (VAR) and provide to the UNICEF country office within 24 hours of the arrival of the vaccine consignment (within 72 hours for other vaccines).
- **Label the vaccine clearly** to be easily identifiable.
- **Store and transport separately** from other vaccines in the cold chain.
- Deploy **mOPV2 only** to the outbreak-affected areas per the immunization plan and the terms and conditions in the mOPV2 request form.
- **Supply mOPV2 to outbreak zones in separate, clearly identified cold chain containers prepared with frozen icepacks.**
- **At the end of each SIA round, return all open (fully or partially used) and unopened vials to the health facility.**
 - Promptly *inactivate and safely destroy* all **open vials (fully or partially used)** at the health facility. If this cannot be done at the health facility, send open vials to the district level. See Annex 1 guidance notes for the inactivation and safe destruction of mOPV2.
 - *Safely store* all **unopened vials** at the health facility if the *cold chain* is reliable, or return for storage to the district-level facility where the cold chain is reliable.
- **At the end of the last SIA round, return all unopened vials of mOPV2 to the central-level facility,** and ensure they are safely stored, labelled and identified, until the MOH, in line with the advice from the OBRA team, instructs further use or destruction. If destruction is recommended, inactivate and safely dispose of all unopened vaccine vials in order to return to zero stock throughout the cold chain.
- **Provide full documentation of the number of mOPV2 vials used,** including the final stock balance, to the EPI/immunization programme for monitoring purposes.
- **Ensure final validation of mOPV2 removal from the country is endorsed by the body entrusted with that responsibility.**

4. Important deadlines for the collection and reporting of mOPV2

Listed below are timelines for the collection and reporting of mOPV2 stocks and stock balances following completion of an SIA round.

Figure 2: Timelines for the collection and reporting of mOPV2 stocks and stock balances following completion of an SIA round



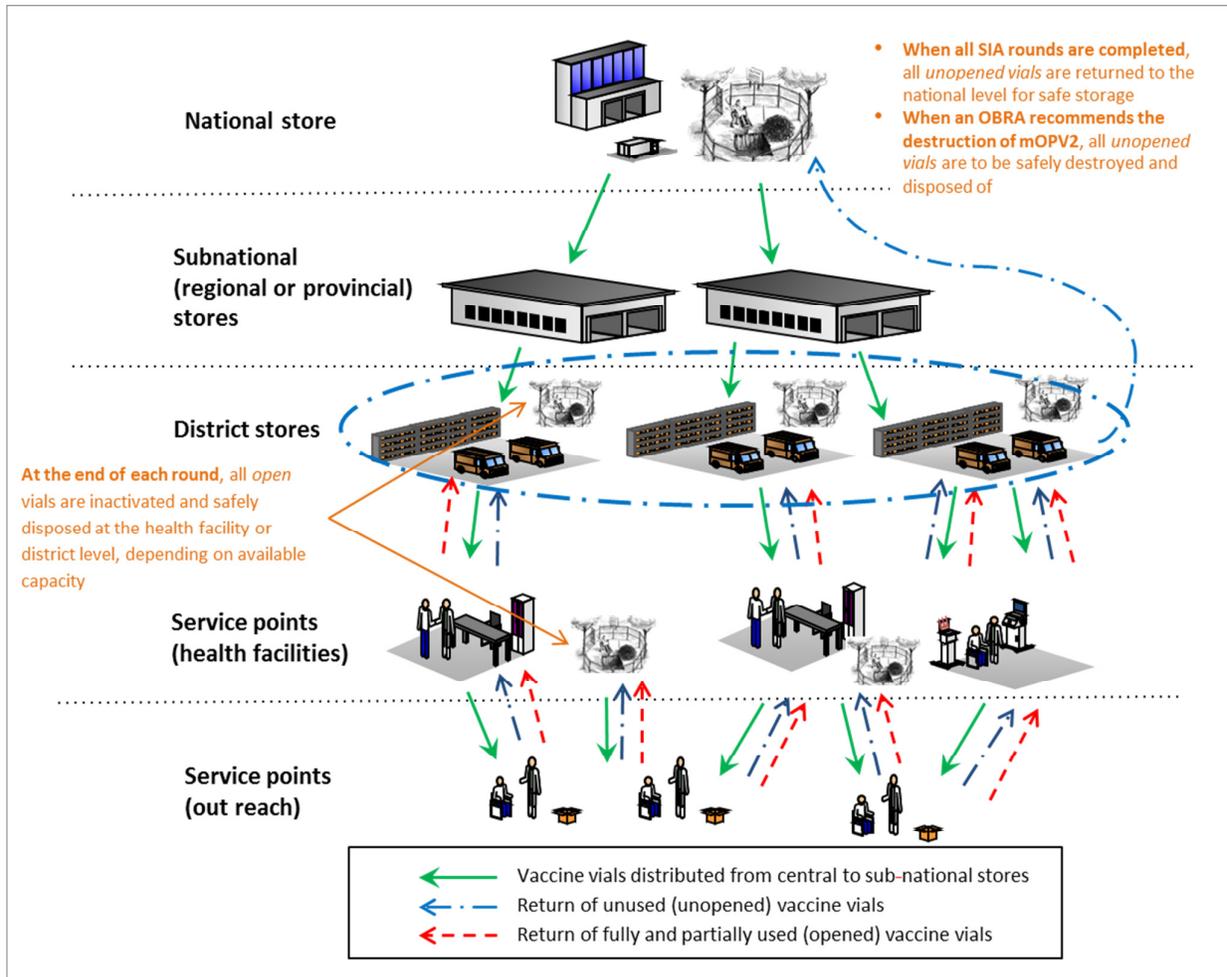
- Following completion of all SIA rounds, countries must report their remaining mOPV2 stocks to the WHO and UNICEF **within a maximum of 2 weeks.**
- **Once an OBRA team recommends the destruction of mOPV2,** all unopened vials of mOPV2 will be inactivated and safely disposed in order to return to zero stock of mOPV2 throughout the cold chain.

5. Monitoring of mOPV2 distribution

Most countries have an established vaccine distribution and stock monitoring system involving batch cards and vaccine stock recording books. However, because of the traceability of mOPV2 vials and their specific handling, destruction and disposal requirements, it is important to establish a recording/reporting system similar to that used for the switch from tOPV to bOPV. This can facilitate and ensure accurate accountability of the mOPV2 vials.

Figure 3 depicts the cold chain infrastructure with the flow of unopened and opened (partially or fully used) vials from the national level down to subnational vaccine stores. It also illustrates the flow of returned vials back to the supply chain between SIA rounds and at the end of the outbreak response.

Figure 3: Supply and cold chain infrastructure for the monitoring of mOPV2 distribution



A **tracking system** must be put in place to:

1. manage deployment of mOPV2 to the outbreak-affected area;
2. ensure that all vials of mOPV2 from the central store are properly distributed through the supply chain to the immunization points;
3. monitor utilization patterns and stock balances at each level;
4. ensure that all opened (fully or partially used) vials are returned from immunization sites to health facilities or the district level;
5. ensure that all opened vials are inactivated and safely destroyed in compliance with national regulations for medical waste management
6. monitor mOPV2 stock at regional and national level pending recommendation from the OBRA team on further strategic use and destruction
7. validate the removal of all mOPV2 vials from the cold chain following completion of all SIA rounds and recommendation from an OBRA to destroy remaining unopened mOPV2 vials

6. Handling of mOPV2 from national stores to vaccination sites

Every country has a set of procedures to be followed when importing and distributing a vaccine. The following factors are critical for proper handling of mOPV2 across the supply chain, from its arrival to its administration:

- **clear labelling and marking of vaccine containers at each level of the cold chain;**
- **separate storage/packaging of mOPV2 from other vaccines (); and**
- **clear reporting and tracking, at each level, of all doses and vials used, with unopened and partially used vials returned to district stores after each SIA round and all unopened vials returned to the central store after completing all SIA rounds.**

National vaccine store

- The customs authority of the receiving country must have the authorization to clear the vaccine for import and use in the outbreak-affected areas within the country. The immunization programme should ensure there is adequate provision for any custom fees required for clearance of the vaccine.
- The NRA or designated authority must check the consignment for compliance with vaccine specifications.
- The national EPI manager or designated authority must complete the vaccine arrival report (VAR) and submit it to the UNICEF country office within 24 hours.
- The national cold chain officer (or designated staff) is responsible for ensuring the transfer of the vaccine to the central (or regional, if applicable) storage facility.
- Prior to the arrival of the vaccine consignment in the receiving country, the national cold chain officer responsible should ensure there is enough storage space⁴.
- The boxes of mOPV2 must be separated and clearly marked using labels, coloured scotch tape or markers to avoid any confusion and ensure they are not mistaken for other vaccines in the cold/freezer room.
- Labelling must be repeated at every step within the cold chain system when there is a change in packaging, from the insulated containers used for transport to the secondary packaging (boxes of 100 vials), and so on.
- Upon arrival of each vaccine consignment, specific details such as the quantity, batch number, and so on, are recorded as required in the vaccine stock book. For mOPV2, some of these data should also be recorded in a separate form. In **Annex 2**, a sample intermediate reporting form (named **Form A**) is provided for reporting to EPI manager and national polio partners, UNICEF and WHO after completion of each SIA round. The form can be used at each level: central, regional/district and the health facility.
- The national cold chain manager or staff responsible should have the distribution plan that was provided along with the vaccine request form; prior to dispatch of mOPV2, they must inform the provincial/district cold chain responsible of the space requirements and the expected arrival date.
- When all SIA rounds have been completed, all opened and unopened vials of mOPV2 must be retrieved. Once the OBRA team recommends the destruction of mOPV2, the unopened vials will be inactivated and safely destroyed at the national level as per the national regulations for medical waste disposal. See **Annex 1** for guidance on mOPV2 destruction procedures. The national cold chain responsible should report on vaccine utilization and remaining stock of unopened mOPV2 vials to the national EPI manager, who in turn should report to the WHO and UNICEF country offices within a maximum of 2 weeks following the last SIA round.

⁴ The vaccine is packed in insulated containers, each containing 1600 vials of 20 doses (32 000 doses in total). The size of each insulated container is 51 cm x 39 cm x 62 cm. If the insulated containers are stored in the cold room, the space requirement must be calculated with a volume of 3.85 cm³ per dose (instead of 0.48 cm³).

Subnational vaccine stores (regional and district)

- At the subnational level, the vaccines should be unpacked from insulated containers and the vaccine carton⁵ placed preferably in a cold/freezer room (if available) or in a dedicated refrigerator. The vaccine boxes must be clearly labelled, for example: '*mOPV2 FOR POLIO OUTBREAK ONLY*'. If separate dedicated cold chain equipment is available, a similar notice should be placed on the refrigerator door, and additional steps may be taken to make the mOPV2 stocks easily identifiable and thus minimize the risk of confusion. In all cases, the vaccine and the box that contains the vaccine vials must be clearly and visibly marked as '*mOPV2 FOR POLIO OUTBREAK ONLY*'.
- The quantity of mOPV2 and all other required information about the vaccine should be recorded in the vaccine stock book at regional and district levels, including the date when the vaccines were dispatched and received, the quantities dispatched and received, and the location or source that the vaccines were dispatched from. Form A, provided in Annex 2, can be used to report to the upper level on vaccine stocks and utilization.
- The district/regional stores should retrieve all mOPV2 vials within 5 days of completion of each SIA round, and report to the national level within 7 days.
- At the end of all SIA rounds, the subnational stores – at the provincial and district levels – should report to the central level within 7 days.

Health facility (vaccination site)

- Because the vaccine is taken out of the manufacturer's packaging, there is a greater risk of inadvertently administering mOPV2. The person responsible for administering the vaccine must prepare the containers or plastic bags to keep all mOPV2 vials together in the refrigerator with a label on the box or a plastic bag clearly bearing the marking '*mOPV2 FOR POLIO OUTBREAK ONLY*'.
- The person preparing the vaccine carrier should record for each vaccinator the number of vials provided, the SIA round and the date. The vaccinators must return all unopened vials as well as fully or partially used vials to the health facility at the end of each day.
- The number of all opened vials (partially or fully used) and the remaining stock balance (unopened vials) should be reported to the district level within 2 days following completion of each SIA round. The proposed Form A in **Annex 2**, which is commonly used for each level of the cold chain infrastructure, could be used to report to the district on the number of vials used and in stock.
- After each SIA round, the remaining opened vials (partially or fully used) of mOPV2 must be taken out of the cold chain, inactivated and securely destroyed at the health-facility level in accordance with the guidelines issued for vaccine destruction and disposal in Annex 1. If the health facilities do not have the capacity to inactivate and safely destroy partially and fully used mOPV2 vials, the vials should be sent to the district level.

The reverse cold chain

The balance of unused vials with mOPV2 may be used for mop up activities in poorly covered areas, or for another SIA. It is therefore critical to maintain the highest quality.

Storage and transport of mOPV2 through the reverse cold chain should meet the same standards applied to the distribution of tOPV or bOPV.

Because mOPV2 is not damaged by repeated freezing and thawing, storage in a freezer will extend its life time.

⁵ To estimate the storage space at this level, a volume of 0.48 cm³ per dose will be used. For example, 10 000 vials will represent a volume of 96 000 cm³ or 100 litres (10 000 vials x 20 doses each x 0.48 cm³ per dose = 96 000 cm³ or 96 litres).

Upon return of the vaccine at central level, the store manager needs to check the vials:

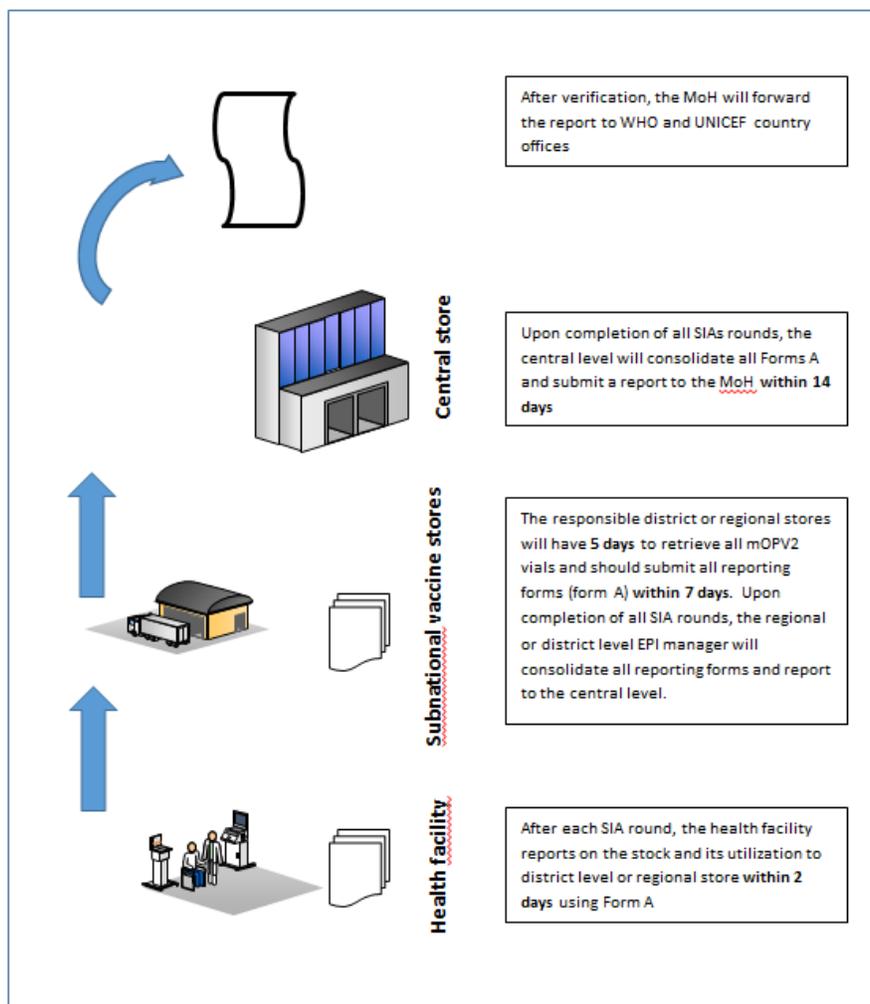
- VVM status;
- Are the labels still readable;
- Any sign of damage that may have compromised the quality of the vaccine inside.

Any vial not meeting the standards should be disposed of after correction of the stock records.

Vaccine utilization record (VUR)⁶: Vaccine utilization in the SIA rounds should be recorded rigorously. SIA reports from all levels of service delivery and the supply chain should include the number of vaccine doses used as well as the number of children immunized. This will enable the national programme to compile the vaccine utilization record (VUR) as per the standard operating procedures for vaccine stock management, in accordance with the usual reporting protocols for all vaccines used in any polio SIA and also using standard reporting tools.

The flow of reporting and the timelines are illustrated in figure 4.

Figure 4: mOPV2 vaccine utilisation and stock reporting timelines



⁶ English Version http://polioeradication.org/wp-content/uploads/2016/09/Cold-chain-logistics-and-vaccine-management-during-SIA_Nov2015_EN.pdf ; French Version: http://polioeradication.org/wp-content/uploads/2016/09/Cold-chain-logistics-and-vaccine-management-during-SIA_Nov2015_FR.pdf ; e-learning course: <https://agora.unicef.org/course/view.php?id=1776>

7. Monitoring and validation of mOPV2 removal

To minimize the risk of mOPV2 remaining in the cold chain, the absence of mOPV2 must be validated. This does not include validation of mOPV2 inactivation or destruction, nor does it include validation of the presence of mOPV2 or type 2 poliovirus in laboratories or manufacturing facilities.

Many elements of the validation process, such as training, microplanning, selection of staff, and so on, are similar to the monitoring process undertaken during the switch from tOPV to bOPV⁷, or the independent monitoring process undertaken during SIA rounds. This chapter therefore does not provide an exhaustive overview of the validation process, but instead focuses on those operational elements that are specific to mOPV2 removal after a response campaign.

7.1. The main steps

The key steps of the validation strategy are to:

- 1) nominate the National Certification Committee, or any other independent national body, to validate the absence of mOPV2 stocks following the response campaigns;
- 2) develop a national plan with details on where and when to monitor, what to do in case mOPV2 is found, and so on;
- 3) select and train independent monitors;
- 4) conduct site visits at **all cold chain stores, including private stores**, from the national to the regional and district levels, and **selected service delivery points** (health facilities) below the district area;
- 5) take corrective action to remove any mOPV2 stocks found in the cold chain and mark these stocks for destruction; and
- 6) obtain validation, from the National Certification Committee or the nominated independent national body, of the absence of mOPV2 stocks based on the reports from the monitors.

Because of the urgent need for the timely removal, inactivation and destruction of mOPV2, the outbreak OBRA⁸ will in most cases not follow the same timeframe.

The first OBRA has the responsibility to formulate clear recommendations as to what should happen with the balance of mOPV2 after the last planned round. Each successive OBRA refreshes the recommendations on basis of an assessment of the current situation. This may include the recommendation, not to wait until close of outbreak for the destruction of the mOPV2 balance . .

The figure above outlines the various deadlines for vaccine removal, inactivation, destruction and disposal.

⁷ http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/oral_polio_vaccine/monitoring/en/

⁸ The first OBRA takes place 3 months after the first case of VDPV2.

7.2. Identification of facilities for monitoring

Although it is expected that larger quantities of mOPV2 will be present at national, regional and district-level stores after a response campaign, the risk of inadvertently using mOPV2 is higher at the health-centre level. This is why a specified percentage of service points need to be checked.

The sampling method used is a combination of random and risk-based purposive sampling, similar to the sampling method that was used during the switch from tOPV to bOPV.

The total number of service points to be visited should be at least 25% of the service points randomly selected in each district, plus districts with one or more specific risk factors, as mentioned below.

The steps of the sampling process are as follows (see Annex 3 for a summary of the whole process):

1. Preparation

- a. Generate a line-list of national, regional and district cold chain stores. In the outbreak area, monitors should **visit all of these stores**.
- b. Generate a line-list of the service points used for distribution of mOPV2 to the vaccination teams during the campaign. These may be private clinics, regular health centres with an active cold chain or temporary distribution points supplied with the vaccine in a cold box.
- c. Have the following data available: independent monitoring data of previous SIA rounds, routine immunization data, stock management reports from previous SIA rounds, VDPV2 history, and so on.
- d. Depending of the role of the private sector, these facilities should be informed and visited.

2. Sampling

- a. **Within the outbreak area**, select all district and regional vaccine stores.
- b. **At the regional level**, determine which districts are at risk of having mOPV2 stocks remaining, using one or more of the risk factors listed below. In these districts, all service points should be visited:
 - i. $\geq 15\%$ of children missed during the previous SIA round;
 - ii. DPT3 (diphtheria-tetanus-pertussis) vaccine coverage $< 85\%$;
 - iii. absent or incomplete stock reports during previous immunization rounds;
 - iv. a history of non-compliance with immunization programme policies;
 - v. management issues (low scores on the latest vaccine management assessment);
 - vi. variable and unpredictable access due to security issues; and
 - vii. other high-risk characteristics.
- c. For all other districts, select all service points with any of the risk characteristics listed above, and randomly select additional service points to reach a total of 25% of facilities to be visited.

The final number of facilities sampled should comprise all regional and district vaccine stores, all service points in high-risk districts, all service points at risk in lower-risk districts, and 25% of randomly selected service points in remaining districts.

7.3. Supervision

There should be roughly one supervisor for five urban monitors and one for three rural monitors. Their tasks consist of:

- Support the selection and training of the monitors;
- Facilitate the work of the monitors for transport, availability of tools (paper, pens, etc.)
- Selection of facilities to be visited;
- Summarize monitor's reports and transmit them to higher levels;
- Ensure the need for sweep operations are correctly communicated with the authorities in the areas concerned.

7.4. Determining the number of monitors and supervisors

The only task of the monitors should be to verify the absence of mOPV2 in the places they visit. Although there can be exceptions, a reasonable workload of a monitor is eight visits per day in an urban setting and five in a rural setting.

The number of monitors should be calculated as follows:

$$\text{Total monitors} = \text{urban monitors} + \text{rural monitors}$$
$$\text{Urban monitors} = \frac{\left(\frac{\%_{\text{urban pop}} \times N}{n_d} \right)}{n_{\text{sp urban}}}$$
$$\text{Rural monitors} = \frac{\left(\frac{\%_{\text{rural pop}} \times N}{n_d} \right)}{n_{\text{sp rural}}}$$

N = number of sites to be visited

%_{urban or rural pop} = Proportion of urban or rural population

n_d = number of monitoring days

n_{sp urban or rural} = number of service points per day in a urban or rural area

Reminder: Supervisors should plan for

- one supervisor per five monitors in urban settings
- one supervisor per three monitors in rural settings.

7.5. Implementation

As illustrated in figure 5, the field work or data collection phase of the validation process should follow certain procedures to minimize the risk of missing mOPV2 vials.

The selected monitors must commence their work immediately after the day the service points send the remaining unopened vials to the designated medical waste disposal sites.

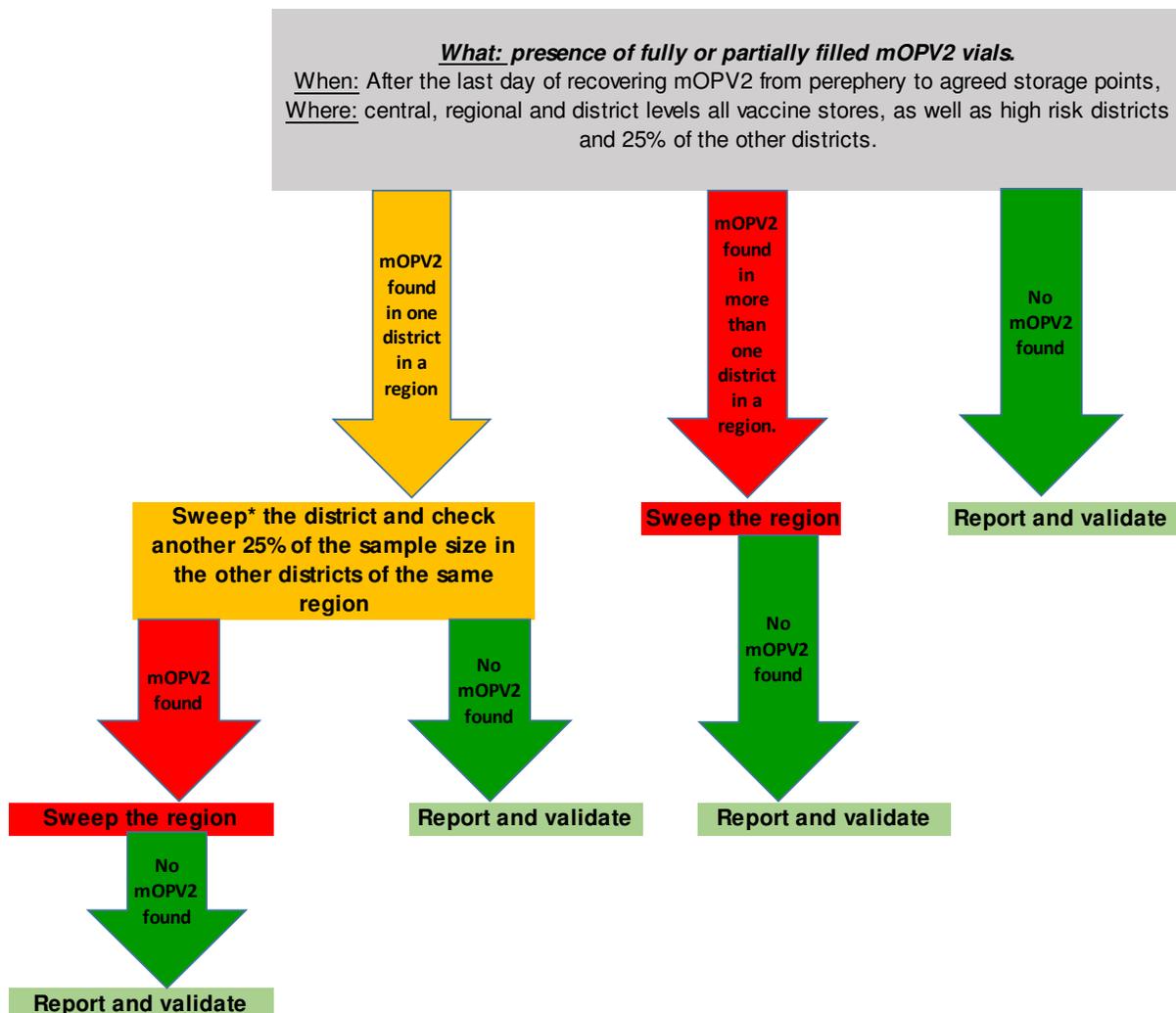
At the end of the first phase, there are three possibilities:

1. No monitors report having found partially used or unused vials. The report is sent to the appropriate authorities at the central level.
2. One of the monitors reports having found mOPV2 in partially used or unused vials in one district. This has the following consequences:
 - a. the entire district should be swept⁹, meaning that all service points must be visited; and
 - b. other districts should check an additional 10% of service points.

If additional mOPV2 vials are detected anywhere in the region, the entire region must be swept.

3. Feedback from monitors indicates the presence of leftover mOPV2 vials in several districts. In this case, the whole region should be swept, including district stores as well as service points.

Figure 5: Decision making flowchart for mOPV2 vaccine monitors



* Intensified monitoring of all other health facilities in the district with involvement of staff from the regional level or higher.

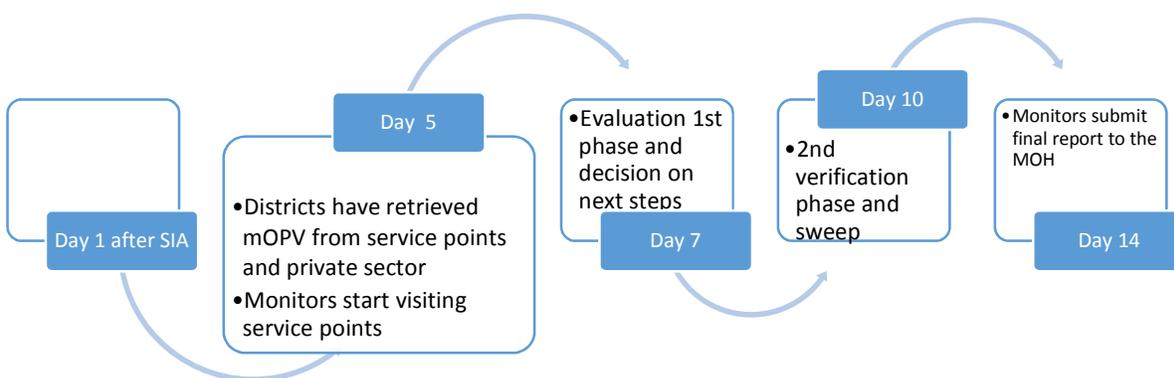
⁹ A sweep operation, targeting all facilities in an area, should be done under the guidance of the monitors, but with the support of the regular health staff.

7.6. The timeline

The timeline in figure 6 indicates the various phases of field work during the validation process, rather than the exact cut-off points, which the Ministry of Health (MOH) will share in due course.

The timeline starts after submission of form A, 15 days after the last SIA round.

Figure 6: Proposed timeline for field work phases during the mOPV2 removal validation process



7.7. The validation forms

Forms for monitoring mOPV2 removal are provided in Annex 4.

1. **Form 1** is used to collect data at the lowest level of the cold chain: the service points (health centres and outreach sites with temporary storage). It must be completed by the validation monitor on-site.
2. **Form 2** is intended for subregional, regional and central-level stores. Each store will aggregate data from the lower level or structure.

Annex 1: Safe destruction and disposal of mOPV2

mOPV2 destruction and disposal guidelines are adapted from the guidelines used for tOPV disposal in conjunction with the global switch from tOPV to bOPV.

Destruction of mOPV2

In the event that mOPV2 is deployed in a country, these guidelines are to be followed for the destruction and subsequent disposal of used and partially used mOPV2 vials between SIA rounds, and for the destruction and subsequent disposal of used, partially used and unopened mOPV2 vials after the final SIA round.

Several options for the inactivation and destruction of residual mOPV2 stocks are described below. Countries should adapt these guidelines according to their medical waste disposal and containment regulations.

Basic principles

- The VDPV2 event or outbreak response plan should include a detailed mOPV2 collection and destruction plan for the country, both between SIA rounds and after the final SIA round.
- Destruction of mOPV2 should be in accordance with national regulations. If the national regulations do not provide clear guidance, refer to the approaches for mOPV2 destruction discussed below.
- mOPV2 should be inactivated prior to destruction. The following are the recommended methods for inactivation, destruction and subsequent disposal of mOPV2:
 - Inactivation by autoclaving, boiling, chemical inactivation, encapsulation or incineration
 - Destruction and disposal by transporting to the waste facility or burying.

Steps for destruction

The inactivation and destruction of mOPV2 can be summarized as follows:

- Step 1: Evaluate the total volume of mOPV2 vials to be destroyed.
- Step 2: Determine the composition of the mOPV2 vials to be destroyed.
- Step 3: Choose an appropriate method to inactivate mOPV2.
- Step 4: Destroy and dispose of the inactivated mOPV2 vials.

Step 1: Assess the total volume of mOPV2 vials to be destroyed

Estimating volume of mOPV2 vials to be destroyed (estimates should be validate estimates by physical stock count):

- ✓ If the number of mOPV2 vials is known:

$$mOPV2 \text{ volume for destruction (in litres)} = (mOPV2 \text{ vials} * 10) / 1000$$

- ✓ If only target population known:

$$mOPV2 \text{ volume for destruction (in litres)} = (target \text{ population} * wastage \text{ factor} * number \text{ of rounds} * 0.5) / 1000$$

Assumptions: mOPV2 will be supplied in 20-dose vials and the cold-chain storage space is 0.48 cm³ per dose when the vials are in box of 100 vials

Step 2: Determine the composition of the mOPV2 vials to be destroyed

- At present, WHO-prequalified mOPV2 supplied by UNICEF will be in glass vials.
- Ideally, a temperature of >1100 °C is needed for safe destruction of glass vials containing mOPV2 (for example, using rotary-kiln incinerators and industrial furnaces).

Step 3: Choose an appropriate method to inactivate mOPV2

mOPV2 can be inactivated by autoclaving, boiling, chemical inactivation, encapsulation or incineration of the mOPV2 waste. Each method of inactivation is described below, with its pros and cons. The country and context will determine which method is used at each level.

Methods for inactivation of mOPV2, and their associated pros and cons:

- **Autoclaving:** Autoclaving uses high-temperature steam. It is the most environmentally friendly method. Unopened glass vials full of liquid should be loosened before autoclaving to avoid rupture, unless the autoclave has an integrated shredder. However, glass vials that contain little liquid do not need to be opened. After autoclaving, vials will be sterile but must still be destroyed in accordance with national or local waste management guidelines for municipal waste.
- **Boiling:** Boiling involves immersing vials in boiling water for approximately 30 minutes, which destroys pathogenic microorganisms. Glass vials can be safely boiled, and do not need to be opened prior to boiling. After boiling, the inactivated vials should be destroyed in accordance with national or local waste management guidelines.
- **Chemical inactivation:** Chemical inactivation of mOPV2 involves opening and immersing mOPV2 vials in 0.5% chlorine solution for at least 30 minutes. The solution should be nine parts clear water to one part household bleach. Immersing 20 vials in 4 litres of solution will safely inactivate mOPV2. After this treatment, vials and leftover chlorine solution must both be destroyed in accordance with national or local waste management guidelines.
- **Incineration (inactivation and destruction):** Incineration should be carried out at a temperature of ≥ 1100 °C for safe destruction of glass vials containing mOPV2 (for example, using rotary-kiln incinerators and industrial furnaces).
 - It is important to note that the temperatures reached in the primary waste chamber of the incinerator can vary. For instance, low-temperature burning (<800 °C) using single-chamber cement or brick-covered incinerators is not recommended because this is environmentally hazardous.
 - Additionally, medium-temperature burning (800–1100 °C) using dual-chamber incinerators may cause glass vials to explode or partially melt, and is also not recommended.
 - Co-incineration in industrial furnaces (such as cement kilns) will both inactivate and destroy mOPV2 vials and can be done in partnership with an industrial facility.
 - The resulting ash and any other post-incineration residue must be treated as toxic waste and destroyed in accordance with national or local waste management guidelines.
- **Encapsulation (sequestration and destruction):** Encapsulation destroys mOPV2 without immediate inactivation (and without opening the vials) but makes it inaccessible and unusable. This method involves filling containers three-quarters full with mOPV2 vials, adding an immobilizing material (such as sand, cement or clay) and sealing and burying the containers. The encapsulated waste must be destroyed in accordance with national or local waste management guidelines.

Step 4: Destroy the inactivated mOPV2 vials

After mOPV2 has been inactivated, the waste (following one of the above methods, except for encapsulation) must be destroyed using either of the following two recommended approaches:

- transport the waste materials to a waste facility (for example, a sanitary landfill, municipal dump, industrial waste site or another facility meeting national and local waste guidelines); or
- bury the waste materials onsite in a secured and fenced-off burial site.

The following special precautions should be applied:

- **Environmental considerations** related to waste management
- **Universal standards precautions** for health care workers
http://www.who.int/csr/resources/publications/EPR_AM2_E7.pdf
http://www.who.int/injection_safety/toolbox/en/AM_HCW_Safety_EN.pdf

To be noted:

- Glass vials may shatter and harm the operator, or they may melt and cause damage to the incinerators.
- Sealed vials may explode under pressure (during incineration and autoclaving) and endanger the operator.
- Opened mOPV2 vials can be safely inactivated by any method.

Annex 2: Intermediate reporting form (Form A)

Form A: End of round mOPV2 vial distribution and utilization report

Name and title of reporting programme manager: _____ Signature: _____

SIA Round #: _____; starting date: ____/____/____; ending date: ____/____/____

Please tick the type of administrative level (i.e. national, regional; district or health facility) you are reporting from and enter the address

Name of National ; Regional ; District ; facility : _____

Address _____

–

Reporting date: ____/____/____

mOPV2 vials received and distributed at the end of each round

# of vials in stock at the beginning of the round*	# of vials received to conduct the SIA round	# of vials distributed for the SIA round	# of opened vials received from lower level at the end of the SIA round	# of unopened vials received from lower level at the end of the SIA round	# of unopened vials returned to higher level at the end of the SIA round	Physical inventory balance of usable, unopened vials in stock at the end of the SIA round**

Destruction/disposal of open vials at the end of the SIA round

# of partially or fully used vials safely destroyed at the site of the facility	Date vials were destroyed	If partially or fully used vials were not destroyed at the site, name and type of facility where vials were sent	# of vials sent for final destruction	Date vials were sent for final destruction

Instructions to report on utilization of mOPV2 vials at the end of each SIA round

Vaccine:

- *mOPV2 is a vaccine used exclusively to respond to an outbreak of type 2 vaccine-derived poliovirus (VDPV2). This vaccine should not be available in the country before SIA.
- Type 2 poliovirus is an eradicated pathogen and so it is critical to have very precise counts of mOPV2 vaccine vials at each level of the health infrastructure.
- Once all SIA rounds are completed, all unopened vials must be returned to the national vaccine store and no mOPV2 vial should remain at any level of the health infrastructure.

Stock reporting:

- Form A should be used to report on mOPV2 stock levels from all administrative areas conducting mOPV2 SIAs.
- Vaccine quantities should be recorded as vials rather than doses.
- The vaccine cold chain responsible should fill the form to be reviewed by the immunization programme manager.
- **The immunization officer responsible at the facility level should report to the district level within 2 days** following completion of each SIA round.
- **The immunization officer responsible at the district/regional level should retrieve all mOPV2 vials (opened and unopened) within 5 days** following the completion of each SIA round and report to the upper level within 7 days.
- **All unopened vials at the end of each round should be physically counted and their VVM status checked.

Destruction and disposal:

- At the end of each round, all opened vials of mOPV2 (partially or fully used) should be inactivated by boiling, chemical inactivation (by soaking in bleach) or autoclaving (if there is a dedicated autoclave for hospital waste).
- Methods for destruction and final disposal include incineration, encapsulation, crushing and burying in compliance with national regulations for hospital waste disposal.
- If there is no capacity at the health facility to inactivate opened vials and safely destroy them, the vials can be packed in sealed plastic bags and sent to the upper level where such facilities are available.

Annex 3: Summary of the mOPV2 removal validation process

Objectives of mOPV2 validation¹⁰

Ensure and confirm withdrawal of mOPV2 from the cold chain

Sites visited during validation

- *From national stores down to the district level:*
 - ✓ *Independent monitors should verify that mOPV2 has been removed from the cold chain in all vaccine cold chain stores from the national to the district level within 2 weeks after the last mOPV2 SIA round.*
- *Service delivery points:*
 - ✓ *Owing to the large number of service points, combining risk-based purposive sampling with random sampling is recommended for independent monitoring.*

mOPV2 destruction and disposal

The focus of mOPV2 removal validation is not to monitor the destruction and disposal of mOPV2. Disposal of mOPV2 is likely to take longer than its withdrawal from the cold chain, so it should ideally be completed within 1 month of the last SIA round.

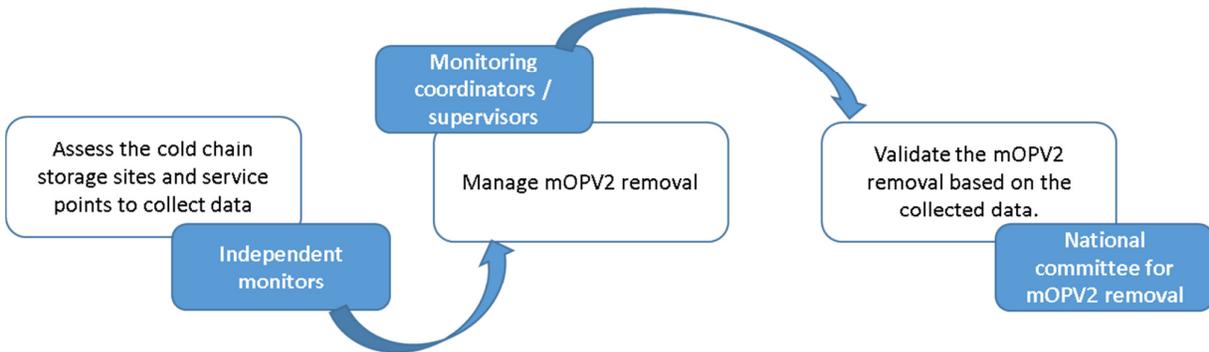
If mOPV2 is found at a primary, subnational or lowest distribution level store:

- mOPV2 should be removed from the cold chain immediately.
- Partially used vials of mOPV2 should be destroyed as soon as possible in the health center; unopened vials should be sent to the district or national as per instructions from the MOH.
- The monitor should ensure that mOPV2 has been removed from the cold chain and report findings to their supervisor.
- As all stores at the primary, subnational and lowest distribution level are being visited anyway, finding mOPV2 at one of them should not affect monitoring of others.
- It is of utmost importance to ensure that stores at the primary, subnational and lowest distribution level do not have mOPV2 in the cold chain after the mOPV2 campaign has ended.
- Sweep operations, where all facilities in an area are visited, should be done in each district where mOPV2 was found. It should be done in the whole region if mOPV2 is found in more than one district.

¹⁰Parallel to but distinct from the certification of type 2 poliovirus containment at laboratories and vaccine production facilities.

Reporting findings of mOPV2 withdrawal validation

Roles and responsibilities related to monitoring, supervision and validation:

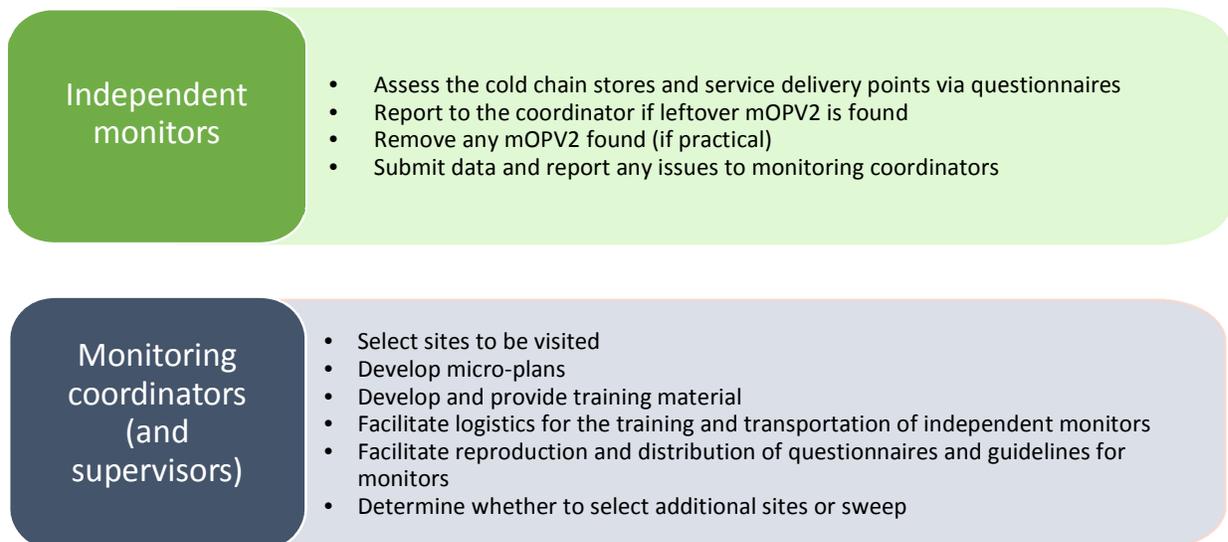


**The National committee for mOPV2 removal should be a body independent from implementation activities. If a national certification committee (NCC) exists, it can be used for the purpose.*

Monitoring the private sector

- Private sector facilities with mOPV2 can be potentially identified with help from: manufacturers, wholesalers, professional groups, regulators and the national immunization programme.
- mOPV2 manufacturers and wholesalers should be included in monitoring, but private health-care providers can usually be omitted from this process owing to their small stocks.

Roles of independent monitors and monitoring coordinators/supervisors



Annex 4: Validations forms

Form 1: Sample Monitoring Data Collection Tool for mOPV2 removal

To be filled out at the lowest level service point from where teams were supplied with vaccine.
 Use one form for all service points that obtain the vaccine from the same store, usually at the district level.
 Make visits after the planned date for service points to send unopened vials to a higher-level store and to destroy used and partially used vials.

District store for service points below _____
 Region/State/Province _____
 Name and title of person in charge _____
 Does vaccination take place in the facility during SIA (Yes=1, No=0) _____

Name of Monitor: _____
 Date of Monitoring _____
 Number of service points with mOPV2

Name of supervisor _____
 Date of supervision _____
 Signature of monitor _____
 Date report rendered to supervisor _____
 Signature of supervisor _____

If yes, use the first line for vaccine in that facility

	Name of service point	Date of visit	Date the service point should have destroyed or sent away remaining mOPV2	# partially used or unopened vials of mOPV2 found in the centre		Are all mOPV2 vials labelled as per instructions (Yes = 1 No = 0)	# partially used vials destroyed at time of monitoring	# unopened vials sent for destruction	Number of vials at start of this last round: balance + received	Destruction method (Multiple codes okay)**	Corrective actions*** (Multiple codes okay)	Date of revisit if required	Signature of person in charge of health centre
				If vials found, go to next question; If not, go to question i									
				# Partially used	# unopened								
	A	B	C	D	E	F	G	H	I	J	K	L	M
1													
2													
3													
4													
Total	# sites =			# vials =	# vials =	# yes =	# vials =	# vials =	# vials =	# 1 = # 2 =	# 1 =	# dates =	

# 3 =	# 4 =	# 2 =
# 5 =	# 6 =	# 3 =
# 7 =		# 4 =

*Codes for destruction method: (1): Autoclave (2): Boiling (3): Incineration (4): Encapsulation (5): Burial (6): Burning (7): Other

**Codes for corrective action: (1): mOPV2 removed (2): Onsite re-training (3): Officials at higher administrative level notified (4): Other (please specify)

*** Partially used does not apply to completely used vials, with a few drops left.

Form 2: Aggregate Monitoring Data Collection Tool for mOPV2 removal

To be filled out at vaccine storage facilities at subregional, regional and central levels. Use one form per level.

vaccinee store level (encircle)	District / subregional / Regional / National	Name of Monitor: _____	Date report rendered to supervisor _____	Signature monitor _____
	Name of District / subregional / Regional / National	Date of Monitoring _____		Signature supervisor _____
	Name and title of person in charge _____	Name of supervisor _____	Date of supervision _____	Number of districts _____

Number of districts with mOPV2	If one district with mOPV2, sweep that district. If more than one district with mOPV2, sweep the region
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Totals from form 1

	District	Number of service points	# partially used*** or unopened mOPV2 vials found in the centre		Are all mOPV2 vials outside of the cold chain	Are all mOPV2 vials labeled as per instructions	# partially used vials destroyed at time of monitoring	# unopened vials sent for destruction	Number of vials at start of this last round: balance + received	destruction method (Multiple codes okay)**	Corrective actions*** (Multiple codes okay)	Number of revisits	Signature person in charge of health centre
			# Partially used	# unopened	<i>number of Yes</i>	<i>number of Yes</i>	number of vials	number of vials	<i># of vials</i>	" of vials per type of	" per type		
	A	B	C	D	E	F	G	H	I	J	K	L	M
1													
2													
3													
4													
5													
6													
7													
Total # sites			# yes =	# yes =	# yes =	# vials =	# vials =	# vials =	# 1 =	# 2 =	# 1 =	# dates =	
									# 3 =	# 4 =	# 2 =		
									# 5 =	# 6 =	# 3 =		
									# 7 =		# 4 =		

*Codes for destruction method: (1): Autoclave (2): Boiling (3): Incineration (4): Encapsulation (5): Burial (6): Burning (7): Other
 **Codes for corrective action: (1): mOPV2 removed (2): Onsite re-training (3): Officials at higher administrative level notified (4): Other (please specify)
 *** Partially used does not apply to completely used vials, with a few drops left.