tOPV MANAGEMENT, MONITORING, REMOVAL AND DISPOSAL (without VVM)

An addendum to mOPV2 Technical Guidance

September 2020

INTRODUCTION

In 2020, four years after the global switch to bOPV, the world is facing increasing cVDPV2 outbreaks in parts of Africa, Southeast Asia, and the Middle East. These outbreaks are driven by several factors, including declining immunity levels to the type 2 virus among young children born after the switch, insufficient routine immunization coverage with IPV, regional migration patterns, and low-quality outbreak response immunization campaigns. Monovalent Sabin OPV2 (mOPV2) has been the vaccine available for responding to these outbreaks. In some countries, the length and large scale of mOPV2 responses have displaced planned bOPV SIAs; other countries have had concurrent ongoing WPV1 circulation or concurrent cVDPV1, 2, or 3 circulations that complicate response planning due to alternating bOPV and mOPV2 delivery. Furthermore, the cost of delivery of the cVDPV2 responses is considerable. For these reasons, trivalent OPV (tOPV), which protects against all three types of poliovirus, will be available for cVDPV2 response with only a modest price difference for the vaccine.

tOPV will be subject to the same usage controls that are currently required for mOPV2 before, during, and after a campaign. Such as:

- Available only from a global stockpile controlled by WHO
- A special request mechanism is in place to access the vaccine
- Requires precise storage and transaction records at all supply chain levels
- Containment of stocks is required between the SIA rounds
- Proper disposal of tOPV2 in accordance with national or GPEI guidance is required after all the immunization response rounds are completed. This disposal should take place as per GPEI's recommendations and in compliance with local regulations.

While using tOPV, countries should follow the same key actions on mOPV2 distribution, and management that is available in the Technical Guidance on mOPV2 Vaccine Management, Monitoring, Removal, and Disposal.

The tOPV is manufactured to the same specifications as before the use of tOPV was stopped globally in 2016. However, the evaluation of VVM compatibility for WHO prequalification has changed but this has no relationship to the safety, stability or immunogenicity of tOPV when kept at 2-8°C or at -20°C: the vaccine is stable for six months at 2-8°C and two years at -20°C. The fact that VVM will not be included on the newly-produced tOPV in no way affects the quality and safety of the vaccine itself but is more sensitive to heat above 8°C.

This interim guidance note is for implementing countries describing how to follow strict temperature management procedures in addition to the usage protocols mentioned above.

PURPOSE

The purpose of this document is to provide guidance on strict temperature management procedures of tOPV, which differ from mOPV2 used to respond to poliovirus type 2 events and outbreaks. For cold chain logistics and vaccine management guidance, readers should refer to the Technical Guidance on mOPV2 Vaccine Management, Monitoring, Removal, and Disposal and WHO/UNICEF Effective Vaccine Management Guidelines.

CHARACTERISTICS OF PRESENTLY AVAILABLE tOPV

tOPV can be made available to countries for cVDPV2 outbreak response in subnational areas where there is co-circulation or high risk of co-circulation of cVDPV2 with cVDPV1, cVDPV3 or WPV1 in order to avoid the need to conduct dual mOPV2 and bOPV campaigns.[1]

While this recommendation is made to ensure children are protected from both wild and vaccine-derived polioviruses of all three types trivalent OPV will only be used as an outbreak response tool in select countries which agree to its use, and not in routine immunization. tOPV should not replace bOPV use in routine EPI schedules at this time.

The administrative procedures before, during and after a tOPV campaign are similar to mOPV2 campaigns. Essential documents for the management of tOPV are available as follows;

- mOPV2 Technical Guidance (including Annexes) can be found here
- tOPV request form can be found here
- tOPV Forms can be found in the annexures to this document [Form A Utilization and Disposal reports tOPV, Supervision Checklist tOPV, Vaccine Accountability Monitoring Reporting tOPV, Vaccine Accountability Monitoring tOPV, Vial Disposal Report tOPV, Overview of key management activities tOPV, Tally Sheet tOPV, Safe destruction and disposal of tOPV] – the tOPV vaccine request form will be available on the GPEI website

This current version of tOPV is more heat sensitive at temperatures above 8°C than bOPV and mOPV2 and a VVM matching its temperature stability data is not yet available. Because of the urgency to be able to appropriately boost immunity for the polio outbreaks, tOPV will be supplied without a VVM attached to the vial. In order to simplify the management of tOPV, the main characteristics of tOPV versus bOPV and mOPV2 is presented in the following table.

Comparison between bOPV, mOPV2 and tOPV

	bOPV	mOPV2	tOPV
Doses per vial	20	20	20
Vial size	2ml	2ml	2ml
Packed volume per dose	0,55cm³	0,55cm³	0,55cm³
VVM	Yes – Type 2	Yes – Type 2	No
MDVP during house to house campaigns	Yes	Not recommended	Not recommended
Heat sensitivity	similar to mOPV2	similar to bOPV	more sensitive than bOPV and mOPV2 above 8°C (see text box below)
Wastage factor	1,15	1,15	1,15
Cold Chain Equipment	Standard Cold Box and Vaccine Carriers	Standard Cold Box and Vaccine Carriers	Long Range Cold Box and Vaccine Carriers
Temperature Monitoring in the field	VVM only	VVM only	Digital temperature loggers
Containment	Not required	Required	Required
Reverse logistics	Not required	Required for all vials after each round	Required for all vials after each round
Disposal of empty vials	Local (as per national guidelines)	National or Regional	National or Regional
Disposal of unopened vials after concluding the OB	Not required, can be used for RI	OPRTT decides	OPRTT decides
Verification of vial collection	Not Applicable	Yes, by supervisors	Yes, by supervisors
Validation of collection	Not Applicable	OPRTT will decide after concluding the OB	OPRTT will decide after concluding the OB

Comparative stability of tOPV

	tOPV	**mOPV2(VVM-2)**
At -20 degrees C	**2 years**	**2 years**
At 2-8 degrees C	**6 months**	**6 months**
25 degrees C	**7 days**	**10 days**
37 degrees C	**12 hours**	**2 days**

(Ref: Biofarma, WHO/PQS/E006/IN05.3 and The Book of VVM,2019)

Above 8°C tOPV loses potency faster than mOPV2 (approximately twice as fast) – the effect of heat on the potency is cumulative which means that;
If the tOPV vaccine is exposed to 25°C for 5 hours at the customs store, and 5 hours at the primary store and 5 hours during transport to the District store and another 10 hours at the District store – the vaccine will have only 5-6 days at 25°C left before it must be discarded. Many Countries experience ambient temperatures of 37°C or even above.

This explains why it is very important to keep tOPV in a freezer and a cold box or vaccine carrier with frozen ice packs at all levels to have a reasonable level of certainty that the potency of the vaccine is protected.

What to do when 30 Day Temperature Recorders (30 DTR), freezers and frozen ice packs are not available at the health facility where the vaccinators receive their daily vaccines for the SIA – risk of exceeding 8°C is higher.

It is recommended that when tOPV is removed from a freezer to distribute and use at lower levels where only a refrigerator is used to protect the vaccine and frozen ice packs and 30DTR are not available for the outreach, the total time of distribution and use (including outreach and reverse logistics) is limited to a maximum of 10 days before the unopened vials are returned to a freezer.

Note: This number of ten days is arbitrarily based on the heat sensitivity of tOPV at temperatures above 8°C shown above and the actual temperatures prevailing in the Country can be validated before the SIA by doing a temperature monitoring study at a few of the health facilities using the same cold boxes and vaccine carriers which will be used during the SIA

ACTIVITIES REQUIRED BEFORE THE CAMPAIGN

All OPV vaccines are heat sensitive and require careful temperature management throughout the entire supply chain and during SIAs. During RI and SIAs this temperature management is supported with the use of a VVM on each vial and electronic temperature recording devices, which are monitored at least twice every day. Due to the higher heat sensitivity of tOPV compared to Sabin mOPV2 and the absence of a VVM on the label, temperature management becomes extremely important and is the only method to protect the vaccines and to ensure that a potent vaccine is administered to the child. **Another OPV vial** such as mOPV2 or bOPV with a VVM attached **cannot be used as a proxy** because tOPV is more heat sensitive above 8°C.

The availability of freezer storage space and frozen ice packs during the campaign plays an important role to prevent the vaccines from being exposed to high-temperature excursions, which will reduce the potency of the tOPV. To protect the vaccines and the frozen ice packs during transportation and the campaign, the use of pre-qualified long-range cold boxes and vaccine carriers is recommended to obtain the maximum cold life to enable the transport and vaccinators to reach as far as possible as stipulated in the microplans without potential damage to the vaccines.

Important considerations for planning[2,3] for vaccine carriers to be used and when electronic temperature loggers are not available at team level

Cold life with frozen water-packs is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first reaches +10°C (**cool life** = +20°C), at a constant ambient temperature of +43°C according to WHO/PQS standards.
During an SIA the goal should be to keep the tOPV well below 5°C
Long Range vaccine carriers have an average cold life of 19 hours (below 10°C) and average net vaccine storage volume of 1,9 Ltr and use 4 ice packs (0,4 Ltr each). To increase cold life, 2 additional ice packs requiring approximately 1 Ltr space (can fit in together with limited vaccines) should extend the cold life to approximately 27 hours.
Short range vaccine carriers have an average cold life of 10 hours (below 10°C) and average net vaccine storage volume of 0,85 Ltr and uses 2 ice packs (0,4 Ltr each) To increase cold life, 1 additional ice pack requiring approximately 0,5 Ltr space (can fit in together with limited vaccines) should extend the cold life to approximately 15 hours
Please test your vaccine carriers to be used long before the SIA to verify the space available for additional ice packs.
When frozen ice packs become unfrozen to a state similar to conditioned ice packs (half solid and half water) inner temperature of the vaccine carrier is approximately 5°C and reasonably OK to continue using to protect the cold life and vaccines.
When frozen ice packs become unfrozen to a state similar to water packs (all water) their temperature is approximately at or above above 5°C and should be replaced immediately to protect the cold life of the vaccine carrier and vaccines. Totally defrosted ice packs at 5°C (similar to cool water packs) can reach 20°C within 10 hours at an ambient temperature of 43°C (WHO Vaccine Management Handbook, Module VMH-E7-02.1).

See also the Case Study in Annexure 9

The first step before the campaign is to obtain an **updated cold chain equipment inventory** from which a **gap analysis** (microplans should indicate quantities required) can be performed to determine the availability of cold boxes, vaccine carriers, ice packs, indelible marker pens and required procurement of electronic temperature loggers (one 30DTR for each refrigerator, cold box and each vaccine carrier). See text box above for considerations when 30DTR is not available and also the case study in Annex 9.

- Electronic 30-day temperature recorders (or user programmable)[4]

  Temperature monitoring devices are the most important mechanism to protect the vials and their contents. Remote Temperature Monitoring Devices (RTMD) are the preferred method for validation of the tOPV vials without VVM in large storage facilities. If RTMD is not available, then a 30 Day Temperature Monitoring Device (30DTR) or other continuous temperature data logger with data printout capability will suffice. 30DTR devices will automatically trigger a low temperature alarm when placed in a freezer or with frozen ice packs and such alarms should be ignored but the temperature should still be checked to ensure that the temperature is well below 0°C – the low temperature alarm is triggered at -0,5°C for

[2] PQS Catalogue April 2020
[3] WHO and UNICEF Information Bulleting, July 2014, Vaccine vial monitor (VVM) assignments for different WHO-prequalified vaccines and their proper handling
[4] In the Annexure 8 is a summary of a random sample taken from the PQS Catalogue with their important attributes for tOPV SIAs for electronic temperature loggers

1 hour as per WHO/PQS standards. The objective with 30DTR devices with tOPV is to monitor high temperature alarms only. A new low-cost programmable data logger[5] is now available for $18 each. If a user programmable device is used for tOPV, then only the high temperature alarm should be set at ≥8°C for 10 hours[6] (WHO/PQS specification for continuous electronic temperature monitoring devices). Introducing new temperature monitoring equipment will require extensive additional training[7] with new SOPs and installation effort, time, and cost. Existing equipment should be given preference. Training for a user programmable device is substantially longer and more complex than a 30DTR. Training for both vaccinators, supervisors and VAMs, DVAMs, and CCOs will be required. If the National level wishes to study the temperature profiles obtained during the SIA for future rounds, these devices also require a computer to download the temperature data, and some require an additional cradle attached to the computer for the downloads, which should also be included in the training. 30DTR devices are limited in the number of days of data it can store (30 or 60 days depending on the device) and printouts will have to be made before the limit (number of days) is reached.

Other useful resources for further information and/or reference on these devices

- Fridge-Tag 2 User manual (PDF document)
- How to set up and activate a Fridge-Tag 2 (Video)
- How to read a Fridge-Tag 2 (Video)
- LogTag TRID30-7 User Manual
- How to program a User programmable LogTag TRIX-8

- Freezer storage space at the closest point to the vaccinator teams

  The heat sensitivity and absence of a VVM on the label of tOPV requires freezer storage space at the lowest possible level, closest to the vaccinator. This should be verified during the gap analysis of the cold chain equipment inventory before the OB response, and adequate time is required to ensure the rental and installation of additional freezer space and frozen ice packs if required (see also text boxes above and Annex 9 for alternative considerations).
- Freezers for preparation and supply of frozen ice packs for all teams

  Freezer storage space is also required for the daily replenishment of ice packs for the vaccinators and for campaign use only. The vaccinators will require fresh frozen icepacks every day for their vaccine carriers and cold boxes or may require additional frozen icepacks to extend the cold life of their vaccine carriers when extended outreach is required. Careful calculations of the number of ice packs required for each team must be made to determine the freezer space required for this replenishment. In some instances, commercial freezers may have to be rented to supply the required number of frozen ice packs every day. Where required and appropriate, ice packs can also be frozen in domestic freezers at health workers' or village homes but great care must be taken to ensure that they are not defrosted by the time they are used (see also text boxes above and Annex 9 for alternative considerations).

[5] refer PQS Catalogue Section 006
[6] WHO specification for electronic temperature monitoring devices
[7] In a recent case study (RTMS Cameroon Study Report January 18th, 2019) the cost of training for Fridge-Tag 2 amounted to 10% of purchase cost.

- Long-range cold boxes in good working order, i.e., proper seals and hinges[8]

Where Countries have already procured long term passive devices for their EPI, it may be appropriate to locate long term passive storage devices. If long term passive devices are not available, then long-range cold boxes filled with frozen icepacks (refer PQS Catalogue Section 004) at the nearest District store.

The unique ice packs of these long term passive devices can also be used as additional (not in place of) cooling devices in a vaccine carrier to lower the temperature around the vaccine vials and extend its cold life (note their ice packs are larger than normal and may not fit into the vaccine carriers to be used – test before use).

If the campaign strategy requires the vaccinators to remain at the point of vaccination for longer than the PQS rated cold life (50% thereof to compensate for opening) of the vaccine carrier, then it is essential that the ice packs in the vaccine carrier are replaced with fresh frozen ones to extend the cold life of the vaccine carrier and to protect the vaccines (see also text boxes above and Annex 9 for alternative considerations).

Other items to verify and obtain;

- Long-range vaccine carriers in good working order[9]
- Ice packs for the cold boxes and vaccine carriers as well as additional ice packs for extension of cold life for the vaccinators[10]
- Indelible marker pens (provided by WHO)
- Sealable bags
- Cargo bags
- Additional droppers for Covid-19 protection (Guideline is new dropper for every new vial)
- Any PPE required for Covid-19 protection

As soon as all the cold chain equipment preparation has been finalized the second step is to prepare the **logistics plan** which must include the following[11];

- Distribution plan and alternative storage and freezing sites in case of emergency
- Transport plans for forward and reverse logistics (cold chain)
- Waste management and disposal
- Training of storekeepers, transport officers, cold chain officers (CCO), Supervisors, DVAM, VAM and vaccinators in;
    - Storage in freezers and using frozen ice packs in passive containers and replenishment of ice packs for vaccinators and extending the cold life of vaccine carriers

[8] In the Annexure 8 is a summary of a random sample taken from the PQS Catalogue with their important attributes for tOPV SIAs for cold boxes

[9] In the Annexure 8 is a summary of a random sample taken from the PQS Catalogue with their important attributes for tOPV SIAs for vaccine carriers

[10] In the Annexure 8 is a summary of a random sample taken from the PQS Catalogue with their important attributes for tOPV SIAs for ice packs

[11] See Technical Guidance on mOPV2 Vaccine Management, Monitoring, Removal, and Disposal

- Activating and reading of electronic temperature recording devices to be used including keeping temperature reading records and what to do in the case of a high-temperature excursion (alarm)
- For CCO - Downloading data from the temperature recording devices and how to analyze/interpret it

- The campaign CCL/VM activity including CCE maintenance, procurement of 30DTR, rental and installation budget

ACTIVITIES REQUIRED DURING THE CAMPAIGN

Specific features of tOPV which are different from bOPV

Containment is required and therefore all vials must be accounted for (similar to mOPV2).

Usable vials (unopened) needs cold chain protection until they are delivered back to the District (issuing) store for redistributing at the beginning of next day.

After the round all vials (including unopened ones) will be disposed at Regional or National level and therefore from the District store to the higher levels for disposal reverse cold chain logistics will not be required.

VERY HEAT SENSITIVE – NO VVM - STORE IN A FREEZER

- The absence of a VVM on the label requires strict manual temperature management practices and accurate temperature reading records at all supply chain levels as well as during the SIA in order to verify that the vaccine has not been damaged by high-temperature excursions. Use of another OPV vial such as bOPV with a VVM attached cannot be used as a proxy because tOPV is more heat sensitive at temperatures above 8°C. See also the text box above for replacement of ice packs when unfrozen. See also other text boxes above for temperature sensitivity and planning for outreach when freezers are not available.
- All tOPV vials must be accompanied by a temperature data logger at all times (refrigerators and cold boxes for distribution and vaccinators should use the same 30DTR every day), and the temperature readings must be taken twice per day by the store personnel and the vaccinators and verified by the team supervisor or Vaccine Accountability Monitors (VAM). The temperature reading records on the device must be inspected carefully for unacceptable temperature excursions, and the daily, weekly, monthly stock reports should be clearly certified that the temperature records are acceptable and that no high-temperature excursions exceeding 8°C for ≥10 hours[12] (PQS specification) have occurred. Note: 30DTR only triggers a high temperature alarm for a single event (not cumulative) and therefore the temperature readings must continue to be taken twice daily to avoid temperatures escalating beyond 8°C. If high-temperature excursion alarms did occur (≥8°C for ≥10 hours) such excursions must be recorded on the Vaccine Accountability Monitoring Report form and the affected vials removed from the usable vials. In order to enable verification of temperature records, the vial batch numbers and the accompanying temperature logger device serial numbers are recorded on the Tally sheet and also on the Vaccine Accountability Monitoring Report Form.
- The VAM must certify on the Vaccine Accountability Monitoring Report that the electronic temperature records of all the vials were monitored throughout the campaign for compliance with the requirements.

[12] WHO specification E006/TR06.3

ACTIVITIES REQUIRED AFTER THE CAMPAIGN

Specific features of tOPV which are different from bOPV

- Report all tOPV vials together with temperature data verification reports to the next higher level
- Retrieve and ensure all vials are disposed of at Regional or National level, according to the Technical Guidance on mOPV2 Vaccine Management, Monitoring, Removal, and Disposal and the local Regulations for health waste disposal
- If required, the National level conducts a final analysis of the downloaded temperature data (only where National requires it) for all the vials to determine the quality of the SIA cold chain for future rounds.

REMEMBER: For cold chain logistics and vaccine management guidance, readers should refer to the Technical Guidance on mOPV2 Vaccine Management, Monitoring, Removal, and Disposal and WHO/UNICEF Effective Vaccine Management Guidelines.

ANNEXURE 1

tOPV Utilization and Disposal report

Form A
End of round tOPV Distribution and Utilization Report

GPEI SIA Round #:_____; Round starting date ___/___/___; Round ending date ___/___/___
Please tick the type of administrative level (i.e. National, Regional, Province, District, Sub-District) you are reporting from and enter the address

☐National; ☐ Regional; ☐ Province; ☐ District; ☐ Sub-District:

Name of the reporting store/facility: _____

Number of children targeted: _____ Number of children immunized: _____

Number of doses used: _____ Wastage Rate: _____

tOPV vials received and distributed at this round						
# of vials in stock at the beginning of the round	# of vials received to conduct the SIA round	# of vials distributed from this store	# of Vials received from lower level	# of vials, unaccounted for	Physical inventory balance of vials in stock for disposal	# of Vials returned to higher level
A	B	C	D	E	F	G

Title and name of the reporting officer : _____

Signature : _____

Reporting date : _____

It is hereby confirmed that during the SIA, all useable vials continuous temperature records were verified and NO (or detailed below) cumulative excursions ≥8°C for ≥10 hours were found;
Reporting Officer: _____

Signature:_____ **date:_____**

High temperature excursions found:

Total duration of the high temperature excursion(s). If >10 hours all the relevant vials must be removed from the immunization activities by the supervisor and marked for disposal.

Date of excursion	Duration of excursion	Serial # of temperature recording device	Batch numbers of all the vials	Location where excursions occurred[13]

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

Vaccine:

- tOPV is a vaccine used exclusively to respond to an outbreak of type 2 plus types 1 and/or type 3 poliovirus.

- Type 2 poliovirus is an eradicated pathogen and so it is critical to have very precise counts of tOPV vaccine vials at each level of the health infrastructure.

- Once all SIA rounds are completed, all vials must be returned to the national or regional vaccine store for disposal and no tOPV vial should remain at any level of the health infrastructure.

Stock reporting:

- Form A should be used to report on tOPV stock levels from all administrative areas conducting tOPV SIAs.

- Vaccine quantities should be recorded as vials rather than doses.

- The vaccine cold chain officer 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 tOPV vials (opened and unopened)** within 5 days following the completion of each SIA round and report to the upper level within 7 days.*

- All vials at the end of each round should be disposed of according to the mOPV2 Guidance and local Regulations as per OPRTT recommendations, physically counted and their continuous temperature record status checked.

[13] Can be Team number and date, or health facility name or store name

ANNEXURE 2

tOPV Supervision Checklist for District Supervisors and Vaccine Accountability Monitors

tOPV Supervision Checklist for District Supervisors and Vaccine Accountability Monitors						
S/N°	**Indicator**	**Team No.**	**Team No.**	**Team No.**	**Team No.**	**Team No.**
		Y/N	**Y/N**	**Y/N**	**Y/N**	**Y/N**
1	Does the vaccination team have a vaccine carrier to keep the vaccines in the right condition? *(Each vaccinator must have a vaccine carrier)*					
2	Are there adequate icepacks inside the vaccine carriers? *(Check that there are minimum icepacks as per PQS specification)*					
3	Is tOPV vaccine stored only in the vaccine carriers? *(Only tOPV and icepacks and temperature recorders are kept in the vaccine carrier)*					
4	Is there a continuous temperature data recorder inside the vaccine carrier and is it activated?					
5	Are vaccinators keeping the vial in the vaccine carrier between each vaccination.					
6	Did the vaccination team receive adequate number of vials for the daily target? *(Check and compare the number of vials received with the number of vials planned for the day in the daily work plan)*					
7	Does the vaccination team have a dropper for each tOPV vaccine vial? *(Check if the number of droppers and number of vials are the same) (or more if required for Covid-19 response)*					
8	Does the vaccination team have adequate and correct forms for documenting the vaccination activity? *(Check to see if the teams have the right vaccinator tally sheets with provision for documenting number of vaccine vials received)*					
9	Are the forms being completely and accurately filled for each transaction? *(Check to see if number of vials received have been documented and that each child vaccinated is recorded immediately)*					
10	Are there adequate sealable bags to keep unused and used and partly used vaccine vials to reduce wastage? *(Check to see if all vials are kept in sealable bags - unused and in-use vials in the vaccine carriers and used vials separately kept outside the vaccine carrier)*					
11	Did the vaccinator check and record the temperature inside the vaccine carrier at the start and end of each immunization session?					
	Total Yes					
	Total No					

ANNEXURE 3

VACCINE ACCOUNTABILITY MONITORING REPORTING FORM (tOPV)

VACCINE ACCOUNTABILITY MONITORING REPORTING FORM (tOPV)

Instruction guide:

1. **This form should be filled by the Vaccine Accountability Monitor (VAM) after each tOPV round.**
2. **Vaccine quantities should be recorded as vials only in this report**
3. **The VAM should report to the higher level within 2 days following completion of each SIA round using the section for VAM. If any mOPV2 vial is found inform immediately the district EPI Manager**
4. **District VAM Supervisor should sample at least 30% of the sub district levels to verify absence of tOPV vials and report using the portion for district VAM supervisor.**
5. **Make sure all (opened and unopened) vials of tOPV are returned back to a district vaccine store and that no tOPV vial remains at any other level of the health infrastructure in the district**

Name and title of reporting Officer:_____

SIA Round #:_____ **Starting Date:**_____ **Ending Date:**_____

Name of Sub District Level:_____ **Name of District:**_____ **Name of Province:**_____

No. of Children Immunized:_____ **No. of Vials Used:**_____

Vials received, distributed and returned at the end of the round

This section to be filled by VAM				*This section to be filled by District VAM Supervisor*		
# of tOPV vials received at the district level	**# of vials distributed to the sub district level**	**# of vials opened or unopened returned to the district level**	**# of vials missing**	**# of sub-district level sites visited for verification of the absence of tOPV vials**	**# of sites visited where any tOPV vials were found**	**# of vials of tOPV found**

Remarks:

Signature:_____ **Reporting date:**_____

It is hereby confirmed that during the SIA and after the round all useable vials continuous temperature records were verified and NO (or detailed below) cumulative excursions ≥8°C for ≥10 hours were found;

Signature:_____ **Reporting date:_____**

Temperature excursions found:

Total duration of the high temperature excursion(s). If >10 hours all the relevant vials must be removed from the immunization activities by the supervisor and marked for destruction.

Date of excursion	Duration of excursion	Batch numbers of all the vials affected	Serial no of TRD showing alarm	Location where excursions occurred[14]

[14] Cab be Team number and date, Health facility or store name

ANNEXURE 4

DISTRICT VACCINE ACCOUNTABILITY MONITORING FORM

DISTRICT VACCINE ACCOUNTABILITY MONITORING FORM											
Name of District:…… Name of Province:……											
Date:…… Campaign Day No:……											
Vaccines received by health facilities						**Vaccines returned from health facilities**					
S/No.	Name of Health Facility	No. of Vials Received by Health Facility	Batch No.	Name of Health Facility Cold Chain Officer (CCO)	Signature of Health Facility CCO	No. of Unopened Vials Returned by Health Facilities	No. of Opened Vials Returned by Health Facilities	Total No. of Vials Returned by Health Facilities	No. of Unaccounted Vials	Batch No.	Signature of Health Facility CCO
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I=G+H**	**J=C-I**	**K**	**L**
	Total										

Name and Sign. Of Store Manager…… Name…… Date……

ANNEXURE 5

tOPV VIAL DISPOSAL REPORT

Date: **Round number (GPEI Number):**
Region: **District:**
Disposal site:

Disposal method	
Inactivation/destruction	**Disposal**
☐ Boiling ☐ Chemical inactivation ☐ Incineration ☐ Encapsulation ☐ Other (please explain):	☐ Burying ☐ Transfer to medical waste facility ☐ Others – Furnace, Foundries, etc. (please explain):

Vials received for destruction		
N°	**Health Structures**	**Quantities (Number of Vials)**
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
Total:		

Total number of vials disposed:	

Attendees			
N°	**Name**	**Position**	**Signature**
1			
2			
3			
4			
5			

Additional comments:

ANNEXURE 6

Overview of key tOPV management activities, roles and responsibilities

Before the campaign:

S/N	Task	Level	Responsible	Timelines
1	Use the standard tOPV vaccine request form to prepare request for the vaccine (Estimate vaccine requirements using wastage factor of and 1,15 for 20 dose vials)	National	National EPI Manager/NLWG	Within 3 Days of notification as part of the risk analysis
2	Conduct inventory and gap analysis for cold chain equipment and plans to bridge gaps esp; • Freezer storage space • Icepack freezing capacity • 30DTR or user programmable devices • Vaccine carriers • Icepacks • Transport cold boxes with icepacks • Indelible marker pens	National/Sub National	NLWG/Lower level LWGs	After submission of vaccine request and before each round
3	Prepare a logistics plan for the campaign which should include trainings, distribution plans, identify alternative storage and freezing sites, transport plans for forward and reverse logistics, waste management, and disposal	National	NCCO/NLWG	Within 3 Days of notification
4	Prepare Logistics and VM budget in line with the logistics and VM plan.	National	NCCO/NLWG	Within 7 days of notification
5	Procure electronic temperature loggers, vaccine carriers and cold boxes required (if locally available (from gap analysis)	National	NCCO/NLWG	Within 7 days of notification

6	On reception, inspect, count and verify vaccine quantities received with shipping documentation	All levels	National & Sub National CCOs/DVAMS/VAM	Within 24 hours
7	Keep tOPV in the freezer at all times, preferably at the national vaccine store during customs clearance procedures	National	National CCO/ National EPI Manager	Ongoing
8	Fill and transmit the tOPV Vaccine Arrival Report to UNICEF CO	National	National CCO	Within 24 hours of receipt of vaccines
9	Record transactions in national standard registers (e-stock tools, ledgers, stock cards, etc.)	All levels	National & National CCOs	Within 24 hours of transaction
10	Identify and mark all cold chain equipment to be used for storing or transporting tOPV using labels, scotch tape or marker pens with “tOPV ONLY – for SIAs use”	All levels	National & National CCOs	3-days before receipt of deliveries
11	Train all campaign staff on the basics of tOPV management and handling including the need for reverse logistics, including cold chain for unopened vials during vaccination, for disposal of vials	National and sub national levels	National & Sub National SIA focal persons/LWGs	Day 7 to Day 10
12	Develop a distribution plan for the tOPV (where indicated plan with available stock balances)	All levels	National & Subnational CCOs	Day 7
13	Purchase sealable bags for all vaccination teams for storage of vaccines and empty/opened/damaged vials	National	National CCO/NLWGs	Within 7 days
14	Prepare daily workplan and vaccine distribution to teams based on micro plans or the last implemented workplan	Lowest distribution level	SIA focal persons/LWGs	One week before campaign

15	Distribute other logistics inputs such as data tools, electronic temperature monitors, indelible pen markers, sealable bags, cargo bags, PPE items during Covid-19 and possibly additional droppers	National	National CCO	5 days before the campaign

During the campaign

S/N	Task	Level	Responsible	Timelines
1	Distribute daily requirements of vaccines and other logistics inputs based on daily implementation work plans	From District to Sub district level (or the level teams are supplied with vaccine and consumables)	District CCO/Focal person in Charge of SIA/VAM	Daily (a day before the day's activity)
2	Vaccinators receive unopened tOPV vaccine vials together with a continuous temperature monitoring device and record number of vials and serial number of devices received on the tally sheet	Team level	Vaccinators	Daily
3	Sign the vial monitoring form after receiving the vials and temp monitoring device. Make sure number of vials and serial number of devices are correct as documented and received.	Team level	Vaccinators	Daily
4	Place vials and temp monitoring device in sealable plastic bags before putting in vaccine carrier	Team level	Vaccinators	Daily
5	Place used empty, and damaged vials in separate plastic bags	Team level	Vaccinators	Daily
6	Ensure the 30DTR is in activated mode upon receipt	Team level	Vaccinators	Daily during field activity
7	Conduct spot checks on sub district level distribution points and vaccination teams	Sub district distribution point/Team level	Senior Supervisors /DVAMS/VAMs	Daily
8	Monitor vaccine availability at each level daily during the campaign and respond to stock out as soon as possible	All levels	CCOs /EPI-SIA focal persons at all levels	Daily

9	At end of the day return all opened vials (fully or partially used) and unopened vials together with the temp monitoring device to supervisors and update supervisor's vial monitoring form.	Team level	Vaccinators	Daily
10	Upon return of vials, if the National level requires it, ensure the District CCO downloads the 30DTR file for the day and again records the 30DTR serial number on the vial monitoring form (this is only required if the National CCO requires the temperature data)	Team level	Vaccinator/Team supervisors	Daily
11	Ensure the vial monitoring form is signed by the team supervisor	Team level	Team Supervisor	Daily
12	Submit all the vials together with the temperature excursion records to the store where you received them, and sign the vial monitoring form	Team level	Team Supervisor EPI-FP/VAM/DVAMS	Daily
12	Reconcile returned vials with collected vials at the distribution point level and retain all for disposal	Sub district distribution point	EPI Focal Point/VAM	Daily
13	Report vaccine status to upper level	All levels	EPI Focal Point	Daily
14	Give feedback to lower levels daily on vaccine situation/locations for ease of access	All levels	CCOs /EPI-SIA focal persons at all levels	Daily

After the campaign:

S/N	Task	Level	Responsible	Timelines
1	Retrieve, count and report all tOPV vials to the next higher level together with the temperature data reports	All levels	National, Sub National, District level CCOs and Sub District EPI-FP	1 – 7 days after campaign
2	Remove all vials from the cold chain and prepare for inactivation and disposal at Regional or National level	All levels	National, Sub National, District level CCOs and Sub District EPI-FP	1 – 7 days after campaign

3	At the end of all SIA rounds, subnational stores at the provincial and district levels should use the Form A to report all stock balances, opened/empty, and unaccounted vials together with a summary temperature monitoring report to the National EPI manager	National and Sub National	National and Sub National level CCOs	1 weeks after the campaign
4	The national EPI manager should send the completed and signed reports (Form A) to UNICEF country office within a maximum of **2 weeks** after each SIA round.	National	EPI Manager	2 weeks after the campaign
5	Take all e tOPV vials out of the cold chain, inactivate and securely destroy them at the central or regional level as per national regulations for medical waste disposal or suggested guidance for mOPV2	National and Sub National	National and Sub National level CCOs	1 – 2 weeks after the campaign
6	Report all disposal of the vials using the disposal report template immediately after disposal. The report must be signed by the disposal committee and shared with the UNICEF RO and HQ.	National and Sub National	EPI Manager	Immediately after disposal
7	Reconvene the NPCC or nominate the National Authority for Containment of poliovirus (NAC), or any other independent national body, to validate the absence of tOPV stocks following the response campaigns	National	National EPI Manager/WHO /UNICEF	2 weeks after the last campaign
8	Develop a national plan with details on where and when to monitor, what to do in case tOPV is found.	National	NAC/EPI Manager	2 days after convening the NPCC or NAC (Day 0 of containment activity)
9	Conduct the validation exercise to validate absence of tOPV or mOPV2 in the system	NPCC	NAC/NPCC/EPI Manager	One month
10	Obtain validation report from the NAC or the nominated independent national body, of the absence of tOPV stocks based on the reports from the monitors	National	EPI Manager	One week after conclusion of the validation activity

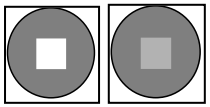
11	Share the destruction and verification reports with the National Certification Committee for inclusion in the annual report	National	EPI Manager	One week after the destruction
12	Check for tOPV (and mOPV2) vials during all visits to all sites especially cold chain stores (Check inside fridges/freezers as well as cold boxes and vaccines carriers) to validate tOPV (and mOPV2) retrieval	All levels	All supervisors (Government and Partners)	Ongoing

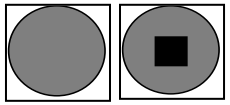
ANNEXURE 7

TALLY SHEET (Minimum information Required) (note: VVM not yet available on vial)

Status of VVM

VVM OK = CAN BE USED **VVM NOT OK = DON'T USE**





Vials received				**Vials returned at the end of the day**		
Beginning of the day	Replenishment 1	Replenishment 2	**Total vials received**	Unopened Vials	Opened Vials	**Total vials returned**

Temperature recording devices (TRD) received (serial numbers)				**Temperature recording devices returned at the end of the day (serial numbers)**		
Beginning of the day	Replenishment 1	Replenishment 2	**Total TRD received**	TRD no alarm	TRD with alarm	**Total TRD returned**

ANNEXURE 8

Summary of a random sample of long-range passive devices taken from the PQS Catalogue Section 004

Picture	PQS Ref 004#	Vaccine storage capacity (ltr)	Weight fully loaded (Kg)	Cold life (hrs)	Number & size (ltr) of ice packs
Vaccine carriers – Long range					
	002	3	7,3	30,3	6X0,3 + 1X0,6
	008	1,35	4,36	40	4X0,4
	020	2,6	4,5	43	4X0,6
	021	1,7	4,0	38	4X0,4
	029	1,5	4,9	41	4X0,3
	040	2,7	6,4	46,4	4X0,6
	050	1,5	8	34	4X0,6

	052	1,6	6,4	30	4X0,4
	053	1,48	3,32	40,5	4X0,4

Picture	PQS Ref 004#	Vaccine storage capacity (ltr)	Weight fully loaded (Kg)	Cold life (hrs)	Number & size (ltr) of ice packs
Cold boxes (note: max weight for 1 male health worker is 25Kg, female is less)					
	005	20	38,9	134,6	24X0,6
	010	18	48,87	140	44X0,4
	013	23	38	130	44X0,4
	018	12	45	156	42X0,4
	045	5,5	22,33	107,5	15X0,6

Cold box – Long term					
	041	5,4	39,4	35 days	8X1,0

Summary of a random sample of ice packs taken from the PQS Catalogue Section 005

Picture	PQS Ref 005#	Size (ltr)	Weight filled (Kg)
	001	0,6	0,655
	002	0,3	0,418
	004	0,3	0,363
	005	0,4	0,432
	006	0,6	0,664

Summary of a random sample of electronic temperature loggers taken from the PQS Catalogue Section 006

Picture	PQS Ref 006#	Program	Readable screen	Max recording time	Activated battery life	Data download method	Data download format
	013	Pre-programmed	Yes	30 days	2-3 years	Special cradle (extra cost)	Various with full analysis – 30 days
	020	Pre-programmed	Yes	30 days	42 months	USB	PDF – 60 days data
	040	Pre-programmed	Yes	30 days	66 months	USB	PDF – 60 days data
	006	User programmable	No	8000 data points at 30 minute intervals = 166 days	3 years	Special cradle (extra cost)	Various with full analysis
	049	User programmable	Yes	16000 data points at 30 minute intervals = 332 days	12 months	USB	PDF
	065	User programmable	Yes	4000 data points at 30 minute intervals = 83 days	12 months	Blue Tooth app on smart device	Various with some analysis

ANNEXURE 9

Case study for determining and managing passive cold chain devices

1. **A polio emergency outbreak response requires the following;**
    a. Vaccine to be used is tOPV without a VVM
    b. SIA microplan indicates 500 teams will do house-to house vaccination starting from 5 health facilities and spend 7 hours in the field vaccinating until they report back to the 5 health facilities on the same day
    c. SIA microplan indicates 500 teams will do house-to house vaccination starting from 5 health facilities at 10h00, travelling for 6 hours, sleep overnight at remote villages and then spend 4 hours in the field vaccinating the next day and then travel back to the 5 health facilities on the same day and arriving at the 5 health facilities after 18h00
2. **What you do know;**
    a. average ambient temp is 30°C. tOPV is very sensitive to heat above 8°C (more than bOPV and mOPV2) and should be stored in a freezer as far as possible.
    b. tOPV requires containment for all vials
    c. Health facilities do not have freezers but can be supplied with frozen ice packs from the nearest District store or higher-level freezer rooms or rented commercial suppliers. Households around the Health facilities and in the villages are prepared to freeze ice packs in their freezers at home.
    d. Transport between the health facilities and the houses/villages will be by motorcycle.
    e. Your EPI has adequate short-range vaccine carriers and adequate long-range cold boxes available for SIA use
    f. Your EPI has no electronic temperature monitors for vaccinators during the house to house SIA
3. **Calculations and considerations;**
    a. Cold life means the time it takes until the inside of the passive device (with frozen ice packs) reaches 10°C in ambient temp of 43°C (PQS Catalogue)
    b. Average Cold life of short-range vaccine carrier is 10 hours (50% of PQS Catalogue rating)
    c. Number of 20 dose vials per team is 5 per day. Total volume per team is 0.055 liter
    d. Number of standard ice packs per vaccine carrier is 2 x 0.4 liter
        i. 500 teams around the HF will require 1000 ice packs (200 at each HF) for each day and need to deliver all vials back within the remaining 3 hours of cold life to the District store for freezing of unopened vials. At the District store any vaccine carrier received with totally unfrozen ice packs (similar to water pack, where all the ice has melted and on shaking ice pack no hitting sound is heard) should mark the unopened vials for disposal.
        ii. 500 teams at remote villages will require 1500 ice packs (300 at each HF) for each day of departure. They cannot transport cold boxes on motorcycles, therefore each team must take their vaccine carrier plus one more ice pack (two will not fit in unless a long range vaccine carrier is used) which can be frozen before the vaccination session in the village to extend the cold life of the vaccine carrier for the next day. This means an additional 500 ice packs together with additional freezer space at remote villages. The 4 hours vaccination and 6 hours travelling plus delivery to the District store will exceed the cold life of the vaccine carrier and therefore an additional frozen ice pack will hopefully be adequate (50% more ice packs) to deliver the vaccine to the District store in good condition. At the District store any vaccine carrier received with totally unfrozen ice packs (similar to water pack) should mark the unopened vials for disposal.
    e. Net vaccine volume per vaccine carrier is 0.9 liter and 5 vials will take 0.055 liter space of the total available space. One additional ice pack will need 0.530 liter. The vaccine carrier can only take 0,9 liter. Because the vaccine carrier to be used may be different, this must be tested well before the SIA with similar 20 dose vials and the ice packs to be used. If an additional ice pack cannot be placed in to extend the cold life of the vaccine carrier, the only alternative option available is to use bigger volume long range vaccine carriers which will give an average cold life of 19 hours (50% of PQS rated

cold life) and avoid the need for transporting extra ice packs to the villages and will be adequate to deliver the returned vials to the District store before the end of the cold life of the vaccine carrier. Removing unusable vials upon return to the HF to provide space for a frozen ice pack may not extend the cold life adequately because the internal temp may have risen too much.

f. Net vaccine volume per cold box is 20 liter. 1000 teams will need 100 000 doses per day (5000 vials). Total volume is 55 liter and can fit into 3 cold boxes or approximately 33 300 doses per health facility, however each health facility only requires 10 000 doses per day – therefore 10 cold boxes will be required (each filled less than half or 10 000 doses with vaccine). Remember that this number is based on average and some health facilities may need more or less per day as described in the SIA microplan.
g. Total ice pack capacity per cold box is 44 (its own) plus 50 ice packs in net storage volume, that equals 94 ice packs per cold box. For distribution to the Health facilities another 2 500 frozen ice packs will be required for the vaccine carriers (1 000 teams, 2 per vaccine carrier plus 1 additional ice packs for each of the 500 remote teams) per day. These 1000 ice packs for 5 health facilities and 1500 for the other 5 health facilities will require 11 + 16 = 27 cold boxes totally filled with frozen ice-packs (all 94 ice packs in each cold box to be used in the vaccine carriers).This means that 27 cold boxes filled with ice packs will require 2538 ice packs. Note that each of these fully loaded cold boxes will weigh approximately 45Kg.
h. The average Cold life of cold boxes is 67 hours (2,8 days) (50% of PQS Catalogue rating) when filled with vaccine. This should be adequate to cover all transport routes between the different level stores and health facilities to protect the vaccines and also provide storage space at the health facilities for one or two days depending on the time it takes to reach the health facility.
i. Number of ice packs per cold box 44 x 0,4 liter. 10 Cold boxes for vaccines will require the freezing of 440 ice packs per day for the vaccine. 27 cold boxes each filled with frozen ice packs for the vaccine carriers will require the freezing of 2538 ice packs.
j. The biggest ice pack freezer in the PQS Catalogue can freeze approximately 96 ice packs per 24 hours. To supply the 10 health facilities with vaccines and frozen ice packs simultaneously, will require 31 (2538+440÷96) of the big ice pack freezers. This number of freezers is generally not available at District level and therefore arrangements will have to be made to utilize the nearest freezer rooms to supply the required (or additional) number of frozen ice packs per day. It is also best practice to have double the required number of ice packs available to ensure that enough time is available to freeze one set while the other is in use (PQS Catalogue)

4. Conclusions:

a. Without a VVM and electronic temp monitor, the only way to protect the vaccine from losing potency for the vaccinator is to keep the vaccine below 10°C (with current PQS specification ratings for passive devices)
b. Using long range vaccine carriers will increase space available for an additional ice pack and also reduce the risk of high temperature excursions on long duration outreach and possible wastage. Totally defrosted ice packs (similar to cool water packs) can reach 20°C within 10 hours at an ambient temperature of 43°C (WHO_IVB_15.03_eng) and should be replaced with frozen ice packs immediately.
c. Length of time in the field for every team and number of teams will depend on the cold life of the vaccine carrier and the number of frozen ice packs available (number of ice pack freezers and corresponding freezing capacity).
d. Attempting to save on ice packs will certainly compromise the potency of the vaccine by shortening the cold life.