tOPV MANAGEMENT, MONITORING, REMOVAL AND DISPOSAL (without a vaccine vial monitor)

Addendum to *mOPV2 management, monitoring, removal and disposal - Technical Guidance, version 2*

January 2021

Acronyms and abbreviations

#	Number
30 DTR	30-day temperature recorder
bOPV	Bivalent oral polio vaccine
CCO	Cold-chain officer
cVDPV1	Circulating vaccine-derived poliovirus type 1
cVDPV2	Circulating vaccine-derived poliovirus type 2
cVDPV3	Circulating vaccine-derived poliovirus type 3
DVAM	District vaccine accountability monitor
EPI	Expanded Programme on Immunization
GPEI	Global Polio Eradication Initiative
ltr	litre
LWG	Logistics Working Group
mOPV2	Monovalent oral polio vaccine
NAC	National Authority for Containment of poliovirus
NLWG	National Logistics Working Group
NPCC	National Polio Certification Committee
OPV	Oral polio vaccine
PQS	Performance, quality and safety (WHO)
RTMD	Remote temperature monitoring device
SIA	Supplementary immunization activity
tOPV	Trivalent oral polio vaccine
TRD	Temperature recording device
UNICEF	United Nations Children's Fund
VAM	Vaccine accountability monitor
VVM	Vaccine vial monitor
WHO	World Health Organization
WPV1	Wild poliovirus type 1

Introduction

In 2021, over four years after the global switch to bivalent oral polio vaccine (bOPV), the world is facing increasing circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreaks in parts of Africa, South-East Asia and the Middle East. Several factors drive these outbreaks, including declining immunity levels to the type 2 virus among young children born after the switch, insufficient routine immunization coverage with inactivated polio vaccine, regional migration patterns and low-quality outbreak response immunization campaigns. Monovalent Sabin OPV2 (mOPV2) has been the vaccine available to respond to these outbreaks. In some countries, the length and large scale of mOPV2 responses have displaced planned bOPV supplementary immunization activities (SIAs); in other countries, concurrent ongoing wild poliovirus type 1 (WPV1) circulation or concurrent cVDPV1, 2 or 3 circulations 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 oral polio vaccine (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 use before, during and after a campaign, such as:

- availability only from a global stockpile controlled by WHO;
- a special request mechanism to access the vaccine;
- precise storage and transaction records at all supply chain levels;
- the containment of stocks between SIA rounds; and
- the proper disposal of tOPV2 in accordance with national or Global Polio Eradication Initiative (GPEI) guidance after all immunization response rounds are completed; this disposal should take place according to the GPEI's recommendations and in compliance with local regulations.

Countries using tOPV should follow the same key actions as for mOPV2 distribution and management, as outlined in mOPV2 management, monitoring, removal and disposal – Technical Guidance, version 2.

The tOPV is manufactured to the same specifications as when the use of tOPV was stopped globally in 2016. However, the evaluation of vaccine vial monitor (VVM) compatibility for WHO prequalification has changed; 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 for two years at -20°C but is more sensitive to heat above 8°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.

This addendum for implementing countries describes the strict temperature management procedures to follow in addition to the usage protocols mentioned above.

Purpose

The purpose of this document is to provide guidance on strict tOPV temperature management procedures, which differ from those used in mOPV2 response to poliovirus type 2 events and outbreaks. For cold-chain logistics and vaccine management guidance, readers should refer to mopv2 management, monitoring, removal and disposal – Technical Guidance, version 2 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, tOPV will only be used as an outbreak response tool in select countries that agree to its use, and not in routine immunization. tOPV should not replace bOPV use in routine Expanded Programme on Immunization (EPI) schedules at this time.

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

- mOPV2 Technical Guidance (including annexes), available here
- tOPV request form, available here
- tOPV forms can be found in the annexes to this document:
  Form A - tOPV Utilization and Disposal Report, tOPV Supervision Checklist, Vaccine Accountability Monitoring Reporting Form (tOPV), District Vaccine Accountability Monitoring Form, tOPV Vial Disposal Report, Overview of key tOPV management activities, tOPV Tally Sheet – the tOPV Request Form will be available on the GPEI website.

The 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 appropriately boost immunity for the polio outbreaks, tOPV will be supplied without a VVM attached to the vial. To simplify the management of tOPV, the main characteristics of tOPV, bOPV and mOPV2 are presented in the following table.

[1] World Health Organization. Meeting of the Strategic Advisory Group of Experts on Immunization, 31 March–1 April 2020: conclusions and recommendations. Weekly epidemiological record. 2020;95(22):241-56. Available from: https://apps.who.int/iris/bitstream/handle/10665/332218/WER9522-eng-fre.pdf?ua=1&ua=1 (accessed 7 January 2021).

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
Multi-dose vial policy 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 the 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 outbreak response	Not required, can be used for routine immunization	The Outbreak Preparedness and Response Task Team decides	The Outbreak Preparedness and Response Task Team decides
Verification of vial collection	Not applicable	Yes, by supervisors	Yes, by supervisors
Validation of collection	Not applicable	The Outbreak Preparedness and Response Task Team will decide after concluding the outbreak response	The Outbreak Preparedness and Response Task Team will decide after concluding the outbreak response

Comparative stability of tOPV

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

(Refs: Bio Farma, Vaccine Vial Monitor performance specification (WHO/PQS/E006/IN05.3) and U. Kartoglu, *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, as well as 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.

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

What to do when 30-day temperature recorders (30 DTRs), freezers and frozen ice packs are not available at the health facility where the vaccinators receive their daily vaccines for the SIA and the 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 protects the vaccine and frozen ice packs and a 30 DTR are not available for the outreach, the total time of distribution and use (including outreach and reverse logistics) be a maximum of 10 days before the unopened vials are returned to a freezer.

Note: This number of 10 days is arbitrarily based on the heat sensitivity of tOPV at temperatures above 8°C; 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 that will be used during the SIA.

Activities required before the campaign

All oral polio vaccines (OPV) are heat sensitive and require careful temperature management throughout the entire supply chain and during SIAs. During routine immunizations and SIAs, this temperature management is supported by the use of a VVM on each vial and electronic temperature recording devices, which are monitored at least twice daily. 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 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 prequalified long-range cold boxes and vaccine carriers is recommended to obtain the maximum cold life to enable the transport and allow vaccinators to reach as far as possible as stipulated in the microplans without potential damage to the vaccines.

Important considerations for vaccine carrier planning[2,3] and when electronic temperature loggers are not available at the team level

Cold life with frozen water packs is measured from the moment the container lid is closed until the temperature of the warmest point in the vaccine storage compartment reaches +10°C (**cool life** = +20°C), at a constant ambient temperature of +43°C according to WHO/performance, quality and safety (PQS) standards.
The goal during an SIA 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 an average net vaccine storage volume of 1.9 ltr, and use four ice packs (0.4 ltr each). To increase cold life, two additional ice packs requiring approximately 1 ltr of space (which 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 an average net vaccine storage volume of 0.85 ltr, and use two ice packs (0.4 ltr each). To increase cold life, one additional ice pack requiring approximately 0.5 ltr of space (which can fit in together with limited vaccines) should extend the cold life to approximately 15 hours.
Vaccine carriers should be tested 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 liquid), the inner temperature of the vaccine carrier is approximately 5°C; at this temperature it is reasonably acceptable to continue using them to protect the cold life and vaccines.
When frozen ice packs become unfrozen to a state similar to water packs (all liquid), their temperature is approximately 5°C or above 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 (see WHO Vaccine Management Handbook, Module VMH-E7-02.1).

(See also the case study in Annex 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 the required procurement of electronic temperature loggers (one 30-day temperature recorder [30 DTR] for each refrigerator, cold box and vaccine carrier). See the text box on "important considerations for vaccine carrier planning" when 30 DTR is not available and the case study in Annex 9.

- Electronic 30 DTRs (or user programmable devices)[4]

  Temperature monitoring devices are the most important mechanism to protect the vials and their contents. Remote temperature monitoring devices (RTMDs) are the preferred method to validate the

[2] See Performance Quality Safety (PQS) devices catalogue. Geneva: World Health Organization; April 2020. Available from: https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx (accessed 8 January 2021).
[3] Vaccine vial monitor (VVM) assignments for different WHO-prequalified vaccines and their proper handling. Information Bulletin. Geneva: World Health Organization and United Nations Children's Fund (UNICEF); July 2014. Available from: https://www.who.int/immunization/programmes_systems/service_delivery/EN_Information_Bulletin_VVM_assignments.pdf (accessed 8 January 2021).
[4] Annex 8 provides a summary of a random sample taken from the PQS devices catalogue with its important attributes for tOPV SIAs for electronic temperature loggers.

tOPV vials without VVM in large storage facilities. If RTMD is not available, a 30 DTR or other continuous temperature data logger with data printout capability will suffice. 30 DTRs will automatically trigger a low-temperature alarm when placed in a freezer or with frozen ice packs; these alarms should be ignored but the temperature should still be checked to ensure that it is well below 0°C – the low-temperature alarm is triggered at -0.5°C for one hour as per WHO/performance, quality and safety (PQS) standards. The objective of 30 DTRs with tOPV is to monitor high-temperature alarms only. A new low-cost programmable data logger[5] is now available for $18. If a user programmable device is used for tOPV, only the high-temperature alarm should be set at ≥8°C for 10 hours.[6] Introducing new temperature monitoring equipment will require extensive additional training[7] with new standard operating procedures 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 for a 30 DTR. Training for both vaccinators, supervisors and vaccine accountability monitors (VAMs), district vaccine accountability monitors (DVAMs) and cold-chain officers (CCOs) will be required. These devices also require a computer to download the temperature data if the national level wishes to study the temperature profiles obtained during the SIA for future rounds, and some devices require an additional cradle attached to the computer for the downloads, which should also be included in the training. 30 DTRs are limited in the number of days of data they 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 include:

- 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 outbreak response, and adequate time is required to ensure the rental and installation of additional freezer space and frozen ice packs if required (see the text boxes above and Annex 9 for alternative considerations).
- Freezers to prepare and supply frozen ice packs to 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 require fresh frozen ice packs every day for their vaccine carriers and cold boxes or may require additional frozen ice packs 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

[5] See PQS devices catalogue, section 006.

[6] WHO specification for continuous electronic temperature monitoring devices.

[7] In a recent case study, the cost of training for Fridge-Tag 2 amounted to 10% of purchase cost (see Programmatic and financial benefits of establishing an effective temperature monitoring system in the vaccines supply chain: Case study in Cameroon, Final report. TechNet-21; January 2019. Available from: https://www.technet-21.org/en/?option=com_resources&task=downloadTrlFiles&id=6557, accessed 14 January 2021).

workers' or village homes but great care must be taken to ensure that they are not defrosted by the time they are used (see the text boxes above and Annex 9 for alternative considerations).

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

It may be appropriate for countries that have already procured long-term passive devices for their EPI to locate long-term passive storage devices. If long-term passive devices are not available, long-range cold boxes filled with frozen ice packs (see the PQS devices catalogue, section 004) can be obtained from 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 (but these ice packs are larger than normal and may not fit into the vaccine carriers to be used so testing is needed before use).

If the campaign strategy requires the vaccinators to remain at the point of vaccination for longer than the vaccine carrier's PQS rated cold life (50% thereof to compensate for opening), it is essential that the ice packs in the vaccine carrier be replaced with fresh frozen ones to extend the cold life of the vaccine carrier and to protect the vaccines (see the 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 cold life extension for the vaccinators;[10]
- indelible marker pens (provided by WHO);
- sealable bags;
- cargo bags;
- additional droppers for COVID-19 protection (the guidelines specify a new dropper for every new vial); and
- any personal protective equipment required for COVID-19 protection.

As soon as the cold-chain equipment preparation has been finalized, a **logistics plan** must be prepared that includes the following:[11]

- the 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 arrangements;
- the training of storekeepers, transport officers, CCOs, supervisors, DVAMs, VAMs and vaccinators in:

[8] Annex 8 provides a summary of a random sample taken from the PQS devices catalogue with its important attributes for tOPV SIAs for cold boxes.
[9] Annex 8 provides a summary of a random sample taken from the PQS devices catalogue with its important attributes for tOPV SIAs for vaccine carriers.
[10] Annex 8 provides a summary of a random sample taken from the PQS devices catalogue with its important attributes for tOPV SIAs for ice packs.
[11] See Expanded Programme on Immunization and Global Polio Eradication Initiative. mOPV2 management, monitoring, removal and disposal - Technical Guidance, version 2. Geneva: World Health Organization; 2020. Available from: http://polioeradication.org/wp-content/uploads/2020/05/mOPV2-Technical-Guidance-20200525.pdf (accessed 8 January 2021).

- storing vaccine in freezers, using frozen ice packs in passive containers and replenishing ice packs for vaccinators, and extending the cold life of vaccine carriers;
- activating and reading electronic temperature recording devices, including keeping temperature reading records and following procedures in case of a high-temperature excursion (alarm);
- for CCOs: downloading, analysing and interpreting data from the temperature recording devices;

- campaign cold-chain logistics/vaccine management activity, including cold-chain equipment maintenance, 30 DTR procurement, and a rental and installation budget.

Activities required during the campaign

Specific features of tOPV are different from bOPV.

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

Usable vials (unopened) need cold-chain protection until they are delivered back to the district (issuing) store for redistribution at the beginning of the next day.

After the round, all vials (including unopened ones) will be disposed of at the regional or national level; therefore, from the district store to the higher levels, reverse cold-chain logistics will not be required for disposal.

VERY HEAT SENSITIVE – WITHOUT 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. 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 the text box on "cold life" for information on the replacement of ice packs when unfrozen. See also the text boxes above on 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, with vaccinators using the same 30 DTR every day), and temperature readings must be taken twice per day by the store personnel and vaccinators and verified by the team supervisor or VAMs. The temperature reading records on the device must be inspected carefully for unacceptable temperature excursions, and the daily, weekly and 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: the 30 DTR 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 Reporting Form and the affected vials removed from the usable vials. To enable the verification of temperature records, the vial batch numbers and the accompanying temperature logger device serial numbers are recorded on the Tally Sheet and on the Vaccine Accountability Monitoring Reporting Form.
- The VAM must certify on the Vaccine Accountability Monitoring Reporting Form that the electronic temperature records of all the vials were monitored throughout the campaign for compliance with the requirements.

[12] See 30-day electronic refrigerator temperature logger performance specification (WHO/PQS/E006/TR06.3).

Activities required after the campaign

Specific features of tOPV are different from bOPV.

- Reports on all the tOPV vials together with temperature data verification information should be sent to the next higher level.
- All unusable vials must be retrieved and disposed of at the regional or national level according to *mOPV2 management, monitoring, removal and disposal - Technical Guidance, version 2* and to the local regulations for health waste disposal.
- If required, the national level will conduct a final analysis of the downloaded temperature data (only where needed) for all the vials to determine the quality of the SIA cold chain for future rounds.

REMINDER: For cold-chain logistics and vaccine management guidance, readers should refer to mOPV2 management, monitoring, removal and disposal - Technical Guidance, version 2 and WHO/UNICEF effective vaccine management guidelines.

ANNEX 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 administrative level (i.e. national, regional, province, district, subdistrict) you are reporting from and enter the address:

☐ National ☐ Regional ☐ Province ☐ District ☐ Subdistrict

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 in 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 the lower level	# of vials unaccounted for	Physical inventory balance of vials in stock for disposal	# of vials returned to the 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, the supervisor must remove all the relevant vials from the immunization activities and mark them for disposal.

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

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

Vaccine:

- tOPV is a vaccine used only to respond to an outbreak of poliovirus type 2 and is used in areas with either ongoing or high risk of co-circulation of cVDPV2 with cVDPV1, cVDPV3 or WPV1.

- As poliovirus type 2 is an eradicated pathogen, 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; 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 in charge should complete 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 of completing each SIA round.

*- The immunization officer responsible at the district/regional level should retrieve **all tOPV vials (opened and unopened)** within 5 days of completing 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 Outbreak Preparedness and Response Task Team recommendations, physically counted and their continuous temperature record status checked.

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

ANNEX 2

tOPV Supervision Checklist for district supervisors and vaccine accountability monitors

tOPV Supervision Checklist for district supervisors and vaccine accountability monitors						
S/No.	**Indicator**	**Team no.**	**Team no.**	**Team no.**	**Team no.**	**Team no.**
		Yes/No	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**
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	Is the number of ice packs inside the vaccine carriers adequate? *(check that there are a minimum number of ice packs as per PQS specifications)*					
3	Is tOPV vaccine stored only in the vaccine carriers? *(only tOPV, ice packs and temperature recorders are kept in the vaccine carrier)*					
4	Is 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 an 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 workplan)*					
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 droppers are required for COVID-19 response)*					
8	Does the vaccination team have adequate and correct forms for documenting the vaccination activity? *(check if the teams have the right vaccinator tally sheets with provision for documenting the number of vaccine vials received)*					
9	Are the forms being completely and accurately completed for each transaction? *(check if the number of vials received has been documented and that each child vaccinated is recorded immediately)*					
10	Is the number of sealable bags adequate for unused, used and partly used vaccine vials to reduce wastage? *(check if all vials are kept in sealable bags: unused and in-use vials in the vaccine carriers and used vials separately 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					

ANNEX 3
Vaccine Accountability Monitoring Reporting Form (tOPV)

Vaccine Accountability Monitoring Reporting Form (tOPV)

Instructions:

1. **This form should be completed 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 of completing each SIA round using the section for VAM. If any mOPV2 vial is found, immediately inform the district EPI manager.**
4. **The district VAM supervisor should sample at least 30% of the subdistrict levels to verify the absence of tOPV vials and report results using the portion for the district VAM supervisor.**
5. **All (opened and unopened) vials of tOPV must be returned to a district vaccine store; no tOPV vial may remain at any other level of the health infrastructure in the district.**

Name and title of the reporting officer:
_____

SIA round #: _____ Starting date: _____ Ending date: _____

Name of subdistrict 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 completed by the VAM				*This section to be completed by the district VAM supervisor*		
# of tOPV vials received at the district level	**# of vials distributed to the subdistrict level**	**# of vials (opened or unopened) returned to the district level**	**# of vials missing**	**# of subdistrict 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: _____**

High-temperature excursions found:

Total duration of the high-temperature excursion(s):
If >10 hours, the supervisor must remove all the relevant vials from the immunization activities and mark them for destruction.

Date of excursion	Duration of excursion	Batch # of all the vials affected	Serial # of the temperature recording device showing alarm	Location where the excursions occurred[14]

[14] Can be team number and date, or health facility or store name.

ANNEX 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 by health facilities**					
S/No.	Name of health facility	# of vials received by health facility	Batch #	Name of health facility cold-chain officer (CCO)	Signature of health facility CCO	# of unopened vials returned by health facilities	# of opened vials returned by health facilities	Total # of vials returned by health facilities	# of unaccounted vials	Batch #	Signature of health facility CCO
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I=G+H**	**J=C-I**	**K**	**L**
	Total										

Name of store manager: …… Signature: …… Date: ……

ANNEX 5
tOPV Vial Disposal Report

tOPV Vial Disposal Report	
Date:	**Round # (GPEI #):**
Region:	**District:**
Disposal site:	

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

Vials received for destruction		
No.	**Health structures**	**Quantities (# of vials)**
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
Total		

Total # of vials disposed:	

Attendees			
No.	**Name**	**Position**	**Signature**
1			
2			
3			
4			
5			

Additional comments:

ANNEX 6
Overview of key tOPV management activities, roles and responsibilities

Before the campaign

S/No.	Task	Level	Responsible	Timelines
1	Use the standard tOPV vaccine request form to prepare a request for the vaccine (estimate the vaccine requirements using a wastage factor of 1.15 for 20 dose vials)	National	National EPI manager/National Logistics Working Group (NLWG)	Within 3 days of notification as part of the risk analysis
2	Conduct an inventory and gap analysis for cold-chain equipment and plans to bridge gaps, especially: • Freezer storage space • Ice pack freezing capacity • 30 DTR or user programmable devices • Vaccine carriers • Ice packs • Transport of cold boxes with ice packs • Indelible marker pens	National/ Subnational	NLWG/Lower level Logistics Working Groups (LWGs)	After submission of the vaccine request and before each round
3	Prepare a logistics plan for the campaign, which should include trainings, distribution plans, the identification of alternative storage and freezing sites, transport plans for forward and reverse logistics, waste management and disposal	National	National CCO/NLWG	Within 3 days of notification
4	Prepare a logistics and vaccine management budget in line with the logistics and vaccine management plan	National	National CCO/NLWG	Within 7 days of notification
5	Procure the electronic temperature loggers, vaccine carriers and cold boxes required (if locally available (from the gap analysis)	National	National CCO/NLWG	Within 7 days of notification

6	On reception, inspect, count and verify vaccine quantities received with shipping documentation	All	National and subnational CCOs/DVAMs/VAMs	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	Complete and transmit the tOPV Vaccine Arrival Report to the UNICEF country office	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	National and subnational CCOs	Within 24 hours of transactions
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 SIA use”	All	National and subnational 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 and a cold chain for unopened vials during vaccination, for the disposal of vials	National and subnational	National and subnational 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	National and subnational CCOs	Day 7
13	Purchase sealable bags for all vaccination teams for the 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 microplans or the last implemented workplan	Lowest distribution	SIA focal persons/LWGs	One week before the campaign

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

During the campaign

S/No.	Task	Level	Responsible	Timelines
1	Distribute daily requirements of vaccines and other logistics inputs based on daily implementation workplans	From district to subdistrict (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	Ensure vaccinators receive unopened tOPV vaccine vials together with a continuous temperature monitoring device, and record the number of vials received and the serial number of the devices on the tally sheet	Team	Vaccinators	Daily
3	Sign the vial monitoring form after receiving the vials and temperature monitoring device; make sure the number of vials and serial number of the devices are correct as documented and received	Team	Vaccinators	Daily
4	Place vials and the temperature monitoring device in sealable plastic bags before putting them in the vaccine carrier	Team	Vaccinators	Daily
5	Place used, empty and damaged vials in separate plastic bags	Team	Vaccinators	Daily
6	Ensure the 30 DTR is in activated mode upon receipt	Team	Vaccinators	Daily during field activity
7	Conduct spot checks on subdistrict-level distribution points and vaccination teams	Subdistrict distribution point/Team	Senior supervisors/ DVAMs/VAMs	Daily
8	Monitor vaccine availability at each level during the campaign and respond to stock-outs as soon as possible	All	CCOs/EPI-SIA focal persons at all levels	Daily

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

After the campaign

S/No.	Task	Level	Responsible	Timelines
1	Retrieve, count and report all tOPV vials to the next higher level together with the temperature data reports	All	National, subnational, district level CCOs and subdistrict EPI focal point	1 to 7 days after the campaign
2	Remove all vials from the cold chain and prepare for inactivation and disposal at the regional or national level	All	National, subnational, district level CCOs and subdistrict EPI focal point	1 to 7 days after the campaign

3	At the end of all SIA rounds, ensure subnational stores at the provincial and district levels use Form A to report all stock balances, opened, empty and unaccounted vials, sending it with a summary temperature monitoring report to the national EPI manager	National and subnational	National and subnational level CCOs	1 week after the campaign
4	Ensure the national EPI manager sends the completed and signed reports (Form A) to the UNICEF country office	National	EPI manager	Within a maximum of 2 weeks after the campaign
5	Take all the 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 subnational	National and subnational level CCOs	1 to 2 weeks after the campaign
6	Report the disposal of the vials using the disposal report template; the report must be signed by the disposal committee and shared with the UNICEF regional office and headquarters	National and subnational	EPI manager	Immediately after disposal
7	Reconvene the National Polio Certification Committee (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, and what to do in case tOPV is found	National	NAC/EPI manager	2 days after convening the NPCC or NAC (Day 0 of the containment activity)
9	Conduct the validation exercise to confirm the absence of tOPV or mOPV2 in the system	NPCC	NAC/NPCC/EPI manager	Within 1 month
10	Obtain a validation report from the NAC or the nominated independent national	National	EPI manager	1 week after the conclusion of the

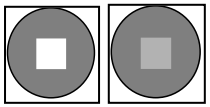
	body on the absence of tOPV stocks based on the reports from the monitors			validation activity
11	Share the destruction and verification reports with the NPCC for inclusion in the annual report	National	EPI manager	1 week after the destruction
12	Check for tOPV (and mOPV2) vials during all visits to all sites, especially in cold-chain stores (check inside fridges/freezers as well as cold boxes and vaccines carriers) to validate tOPV (and mOPV2) retrieval	All	All supervisors (government and partners)	Ongoing

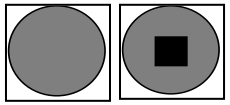
ANNEX 7

tOPV Tally Sheet (minimum information required) (note: VVM not yet available on the vial)

Status of VVM

VVM OK = CAN BE USED **VVM NOT OK = DO NOT 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 (TRDs) received (serial #s)				**Temperature recording devices returned at the end of the day (serial #s)**		
Beginning of the day	Replenishment 1	Replenishment 2	**Total TRDs received**	TRDs without alarm	TRDs with alarm	**Total TRDs returned**

ANNEX 8

Summary of a random sample of long-range passive devices taken from the PQS devices catalogue, section 004

Picture	PQS ref. 004#	Vaccine storage capacity (ltr)	Weight fully loaded (kg)	Cold life (hrs)	Number and 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 and size (ltr) of ice packs
Cold boxes (note: the maximum weight for 1 male health worker is 25 kg, less for a female worker)					
	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 devices 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 devices catalogue, section 006

Picture	PQS ref. 006#	Programme	Readable screen	Maximum 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 of data
	040	Pre-programmed	Yes	30 days	66 months	USB	PDF – 60 days of 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	16 000 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	Bluetooth app on smart device	Various with some analysis

ANNEX 9
Case study for determining and managing passive cold-chain devices

1. **A polio emergency outbreak response requires the following:**
    a. tOPV without a VVM;
    b. a SIA microplan indicating 500 teams will perform house-to-house vaccinations starting from five health facilities and spending 7 hours in the field vaccinating until they report back to the five health facilities on the same day; and
    c. a SIA microplan indicating 500 teams will perform house-to-house vaccinations starting from five health facilities at 10:00, travelling for 6 hours, sleeping overnight in remote villages and spending 4 hours in the field vaccinating the next day, then travelling back to the five health facilities on the same day and arriving at the five health facilities after 18:00.
2. **What is known:**
    a. The average ambient temperature is 30°C; tOPV is very sensitive to heat above 8°C (more sensitive 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, 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. The EPI has adequate short-range vaccine carriers and adequate long-range cold boxes available for SIA use.
    f. The EPI has no electronic temperature monitors for vaccinators during house-to-house SIAs.
3. **Calculations and considerations:**
    a. Cold life is defined as the time it takes until the inside of the passive device (with frozen ice packs) reaches 10°C in an ambient temperature of 43°C (see the PQS devices catalogue).
    b. The average cold life of a short-range vaccine carrier is 10 hours (50% of the PQS rating).
    c. The number of 20-dose vials per team is five per day. The total volume per team is 0.055 litres.
    d. The number of standard ice packs per vaccine carrier is 2 x 0.4 litres.
        i. 500 teams linked to the health facilities will require 1000 ice packs (200 at each health facility) for each day and will need to deliver all the vials within the remaining 3 hours of cold life back to the district store to freeze the unopened vials. Any unopened vials in a vaccine carrier received at the district store with totally unfrozen ice packs (resembling a water pack with all the ice melted that when shaken does not produce the clinking sound of ice) should be marked for disposal.
        ii. 500 teams in remote villages will require 1500 ice packs (300 at each health facility) for each departure day. As they cannot transport cold boxes on motorcycles, each team must have a vaccine carrier and an additional ice pack (two will not fit unless a long-range vaccine carrier is used), which can be frozen in the village before the vaccination session to extend the cold life of the vaccine carrier for the next day. This requires an additional 500 ice packs and freezer space in the remote villages. The 4 hours of vaccination and 6 hours of travelling plus delivery to the district store will exceed the cold life of the vaccine carrier and therefore the additional frozen ice pack (50% more ice packs) serves to deliver the vaccine to the district store in good condition. Any unopened vials in a vaccine carrier received at the district store with totally unfrozen ice packs (resembling a water pack) should be marked for disposal.
    e. The net vaccine volume per vaccine carrier is 0.9 litres with five vials taking 0.055 litres of space. One additional ice pack comprises 0.530 litres. Because the vaccine carrier used may differ, its capacity must be tested well before the SIA with comparable 20-dose vials and ice packs. If an additional ice pack cannot be placed in the vaccine carrier to extend its cold life, an alternative option is to use a larger volume long-range vaccine carrier with an average cold life of 19 hours (50% of the PQS rated cold life). This avoids the need to transport extra ice packs to the villages and is adequate to return the vials to the district store before the end of the vaccine carrier's cold life. Removing unusable

vials for the return to the health facilities to provide space for a frozen ice pack may not extend the cold life adequately because the internal temperature may have risen too much.

f. The net vaccine volume per cold box is 20 litres, and 1000 teams will need 100 000 doses per day (5000 vials). That total volume is 55 litres, which can fit into three cold boxes, or approximately 33 300 doses per health facility, but each facility only requires 10 000 doses per day. Therefore 10 cold boxes will be required (each filled at less than half capacity or with 10 000 vaccine doses). This number, however, is based on an average and some health facilities may need more or fewer doses per day as described in the SIA microplan.

g. The total ice pack capacity per cold box is 44 (its own capacity) plus 50 ice packs in net storage volume, for a total of 94 ice packs per cold box. Another 2500 frozen ice packs for distribution to the health facilities will be required for the vaccine carriers (1000 teams, two per vaccine carrier plus one additional ice pack for each of the 500 remote teams) per day. These 1000 ice packs for the five health facilities and 1500 for the other five health facilities will require 11 plus 16 cold boxes for a total of 27, each filled with 94 frozen ice packs for the vaccine carriers. The 27 cold boxes thus hold 2538 ice packs. Each fully loaded cold boxes weighs approximately 45 kg.

h. The average cold life of cold boxes is 67 hours (2.8 days) (50% of the PQS rating) when filled with vaccine. This should be adequate to cover all the transport routes between the different level stores and health facilities to protect the vaccines as well as provide storage space at the health facilities for one or two days depending on the time it takes to reach the health facility.

i. The largest ice pack freezer in the PQS devices 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 these ice pack freezers. This number of freezers is generally not available at the district level such that arrangements will have to be made to use the nearest freezer rooms to supply the required (or additional) number of frozen ice packs per day. A best practice recommendation is to ensure that double the number of ice packs required are available to guarantee that enough time is available to freeze one set while the other is in use (PQS devices catalogue).

4. Conclusions:

a. Without a VVM and electronic temperature monitor, the vaccine must be protected from losing potency by maintaining it below 10°C (with current PQS specification ratings for passive devices).

b. Using long-range vaccine carriers will increase the space available for an additional ice pack and will reduce the risk of high-temperature excursions on long duration outreach activities 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[15] and should be replaced with frozen ice packs immediately.

c. The length of time in the field of every team and the number of teams will depend on the cold life of the vaccine carrier and the number of frozen ice packs available (the number of ice pack freezers and the corresponding freezing capacity).

d. Attempting to save on ice packs will compromise the potency of the vaccine by shortening the cold life.

[15] How to use passive containers and coolant-packs for vaccine transport and outreach operations. WHO Vaccine Management Handbook: Module VMH-E7-02.1 (WHO/IVB/15.03). Geneva: World Health Organization; July 2015. Available from: https://apps.who.int/iris/bitstream/handle/10665/183584/WHO_IVB_15.03_eng.pdf?sequence=1 (accessed 11 January 2021).