POLIO GLOBAL ERADICATION INITIATIVE

Novel Oral Polio Vaccine (nOPV2) Management, Monitoring, Removal and Disposal (in 50-dose vials with VVM type 2)

Technical Guidance

Acronyms

bOPV	Bivalent oral polio vaccine (contains Sabin types 1 and 3)
CAG	Containment Advisory Group
CCO	Cold chain officer
cVDPV	Circulating vaccine-derived poliovirus
cVDPV2	Circulating vaccine-derived poliovirus type 2
DG	Director-General (WHO)
DVAMS	District Vaccine Accountability Monitoring Supervisor
EPI	Expanded Programme on Immunization
EUL	Emergency Use Listing (WHO)
GPEI	Global Polio Eradication Initiative
IPV	Inactivated polio vaccine
LWG	Logistics Working Group
MDVP	Multi-dose vial policy
mOPV2	Monovalent oral polio vaccine (contains Sabin type 2)
NAC	National Authority for Containment
NCC	National Certification Committee for the Eradication of Poliomyelitis
NLWG	National Logistics Working Group
nOPV2	Novel oral polio vaccine type 2
NPCC	National Poliovirus Containment Coordinator
NRA	National Regulatory Authority
OBRA	Outbreak and response assessment
ODK	Open data kit
OPV	Oral polio vaccine
ORPG	Outbreak Response and Preparedness Group
PHEIC	Public Health Emergency of International Concern
RCC	Regional Certification Commission for the Eradication of Poliomyelitis
RI	Routine immunization
SAGE	Strategic Advisory Group of Experts on Immunization
SIA	Supplementary immunization activities
SOPs	Standard operating procedures
tOPV	Trivalent oral polio vaccine (contains Sabin types 1, 2 and 3)
UNICEF	United Nations Children's Fund
VAM	Vaccine accountability monitor
VAR	Vaccine arrival report
VDPV	Vaccine-derived poliovirus
VVM	Vaccine vial monitor
VVM2	Vaccine vial monitor type 2
WHO	World Health Organization
WPV	Wild poliovirus
WPV2	Wild poliovirus type 2

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Introduction

Following the last wild poliovirus type 2 (WPV2) case in northern India in 1999 and the global certification of the WPV2 eradication in September 2015, type 2-containing oral polio vaccines (OPV) were withdrawn from national immunization programmes worldwide in April 2016 to prevent the incidence of vaccine-derived polioviruses (VDPVs) caused by type 2 vaccine virus. Referred to as the "global switch," the withdrawal of the trivalent oral polio vaccine (tOPV) was replaced with the bivalent oral polio vaccine (bOPV).

Today, more than five years after the global switch, the world is facing increasing outbreaks of circulating vaccine-derived poliovirus type 2 (cVDPV2) in parts of Africa, Europe and the Middle East. These outbreaks are driven by several factors that include: declining immunity levels to the type 2 virus among young children born after the switch; insufficient immunization coverage with type 2-containing inactivated polio vaccine (IPV); regional migration patterns; and low-quality outbreak response campaigns with monovalent type 2 Sabin OPV (mOPV2), which has been the selected vaccine for responding to these outbreaks.

In 2021, the Global Polio Eradication Initiative (GPEI) announced a new strategy that addresses cVDPV2 outbreaks as a goal to interrupt all poliovirus everywhere.[1] Included in this strategy is the introduction of a new tool for cVDPV2 outbreak response: the novel oral polio vaccine type 2 (nOPV2).

About nOPV2

- nOPV2 is a genetically modified version of the attenuated Sabin vaccine. It can only be used for outbreak response.
- The vaccine is supplied under a WHO Emergency Use Listing (EUL) and must be approved by each country's regulatory authority prior to use in-country.
- It is supplied in 5ml glass vial with a dropper.
- Each vial contains 50 doses, with 10-vial packs.
- The volume per dose is 0,55cm^3 or 27.5 cm3 per vial.
- The expected wastage factor for a 50-dose vial is 1.33 (wastage rate = 25%). This may be adjusted later based on country experience under the EUL.
- nOPV2 is not affected by freezing and thawing cycles or events.

Important nOPV2 management actions

- The EUL procedures for nOPV2 use require increased monitoring and reporting.
- Under the EUL, there must be a break of four (4) weeks between campaign use of nOPV2 and other OPV campaigns. Use of bOPV in the national immunization schedule does not affect nOPV2 use.
- nOPV2 can be administed jointly with other vaccines during campaigns, including IPV where necessary, as well as non-vaccine interventions (e.g., vitamin A).
- nOPV2 containment refers to controlled and monitored vaccine release, tracking and accounting of all nOPV2 vials with destruction paperwork, enhanced surveillance, including environmental surveillance, and the immediate reporting of knowledge of potential reversion and Phase III clinical data reports to the Containment Advisory Group (CAG).
- Each dose must be fully accounted for throughout its lifecycle in-country: receipt, dispatch, transport, storage, immunization and disposal.
- At the end of the outbreak response, all vials of nOPV2 must be accounted for and removed from all immunization activities and storage areas and equipment, according to recommendation of the Outbreak Response and Preparedness Group (ORPG).

[1] Global Polio Eradication Initiative. Polio Eradication Strategy 2022–2026: Delivering on a promise. Geneva: World Health Organization; 2021 (https://polioeradication.org/gpei-strategy-2022-2026).

Purpose

The purpose of this document is to provide guidance on access, storage, monitoring, withdrawal and disposal procedures for nOPV2.

This guideline follows on the Technical Guidance issued for monovalent Sabin oral polio vaccine type 2 (mOPV2) in May 2021. For cold chain logistics and vaccine management guidance, readers should refer to the Guidance Note on Cold Chain Logistics and Vaccine Management during SIAs and WHO/UNICEF Effective Vaccine Management Guidelines.

Using nOPV2 to respond to type 2 poliovirus events and outbreaks

Safety, immunogenicity and side effects

nOPV2 is a genetically modified version of the existing type 2 OPV that, based on currently available data, provides comparable protection against poliovirus type 2 while being more genetically stable. This makes it less likely to revert into a form that could cause paralysis. The first in-human clinical trial with nOPV2 was conducted in 2017 at the University of Antwerp, Belgium, and data from this Phase I study was published in 2019.[2] Two Phase II trials have also been completed for field activities, and analysis of this data supports the safety and efficacy of the product.[3] While collectively the clinical trials conducted to date provide a solid evidence base around the expected behaviour of the vaccine in humans, Phase III clinical trials are underway, and a thorough evaluation of those data will occur once available.

Data from the clinical studies show nOPV2 to be well-tolerated in adults, young children and infants, with no indication of any increase in general safety risk compared to mOPV2. Moreover, immunogenicity of nOPV2 was found to be non-inferior to mOPV2 in infants, meaning that nOPV2 would be expected to be as effective in preventing paralytic disease as the current vaccine.

nOPV2 use under Emergency Use Listing

The Emergency Use Listing (EUL) of the World Health Organization (WHO) involves careful and rigorous analysis of existing data to enable early, targeted use of products during a Public Health Emergency of International Concern (PHEIC) – which polio has been since 2014. Considering the increasing threat of cVDPV2 outbreaks to vulnerable, under-immunized populations, data generated on nOPV2 have been submitted for review under an EUL to expedite deployment of this vaccine to respond to cVDPV2 outbreaks. In 2019, the Strategic Advisory Group of Experts (SAGE) endorsed accelerated clinical development of nOPV2 and its assessment under this procedure, and in 2020 SAGE endorsed that nOPV2 should become the vaccine of choice to respond to type 2 outbreaks after nOPV2's initial use period, as supply slows.[4] Full clinical development, national licensures and WHO prequalification for nOPV2 are also in progress with an expectation that these can be achieved by end-2023.

Proper introduction and management of nOPV2 is a key element of the GPEI's strategy for successfully stopping cVDPV2 outbreaks. Because the vaccine will be made available under an EUL recommendation for use, implementing nOPV2 in outbreak response will require some additional mandatory preparation,[5] including the authorization of its importation and use by the government of the receiving country as well as the monitoring of activities and tracing of remaining vials during and after vaccination campaigns. It is therefore critical for any country interested in using nOPV2 to begin planning.

[2] Van Damme P, De Coster I, Bandyopadhyay AS, Revets H, Withanage K, et al. The safety and immunogenicity of two novel live attenuated monovalent (serotype 2) oral poliovirus vaccines in healthy adults: a double-blind, single-centre phase 1 study. Lancet 2019;394:148–58 (https://doi.org/10.1016/S0140-6736(19)31279-6).

[3] Sáez-Llorens X, Bandyopadhyay AS, Gast C, De Leon T, DeAntonio R, et al. Safety and immunogenicity of two novel type 2 oral poliovirus vaccine candidates compared with a monovalent type 2 oral poliovirus vaccine in children and infants: two clinical trials. Lancet 2021;397:27–38 (https://doi.org/10.1016/S0140-6736(20)32540-X). De Coster I, Leroux-Roels I, Bandyopadhyay AS, Gast C, Withanage K, et al. Safety and immunogenicity of two novel type 2 oral poliovirus vaccine candidates compared with a monovalent type 2 oral poliovirus vaccine in healthy adults: two clinical trials. Lancet 2021;397:39–50 (https://doi.org/10.1016/S0140-6736(20)32541-1).

[4] See SAGE meeting summary, Oct 2020 (https://apps.who.int/iris/bitstream/handle/10665/337100/WER9548-eng-fre.pdf).

[5] Preparing for nOPV2 use: An overview of requirements for countries (http://polioeradication.org/wp-content/uploads/2021/10/nOPV2-Requirements-Overview-for-Countries.pdf)

nOPV2 and containment requirements

For countries planning on conducting nOPV2 outbreak response campaigns, early discussions and deliberations on evaluating country use should involve the National Authority on Containment (NAC) or another authority (e.g., Ministry of Health [MoH]) and other relevant institutions or committees, National Regulatory Authority [NRA], relevant ministries and advisory groups).

Since nOPV2 is considered poliovirus-infectious material by definition, all nOPV2 vials must be included in the surveys and inventories performed in the containment preparatory phases of GAPIII.[6] This should include reporting to the relevant national authorities in countries (i.e., NAC or MoH), who should inform their National Poliovirus Containment Coordinator (NPCC) or a similar body and the National Certification Committee (NCC) to include these in their annual reports to the Regional Certification Commission (RCC). The information reported should include the number of doses/vials used, the number of remaining opened/unopened vials, verification/validation of collection, disposal of remaining vials, etc.

Until further guidance is issued by the Containment Advisory Group (CAG), **the containment requirements for nOPV2 vial management should be the same as those for mOPV2**.

Comparison of bOPV, mOPV2 and nOPV2

	bOPV	mOPV2	nOPV2
Doses per vial	20	20	50
Vial size	2ml	2ml	5ml
Packed volume per dose	0,55cm³	0,55cm³	0,55cm³
VVM	Yes – Type 2	Yes – Type 2	Yes-Type 2
MDVP during house-to-house campaigns	Yes	Not recommended	Not recommended
Heat sensitivity	similar to mOPV2	similar to bOPV	similar to bOPV and mOPV2
Wastage factor	1,18	1,15	1,33 To be adjusted as needed
Passive cold chain equipment	Standard cold box and vaccine carriers	Standard cold box and vaccine carriers	Standard cold box and vaccine carriers
Temperature monitoring in the field	VVM only	VVM only	VVM only
Containment	Not required	Required	Required
Reverse logistics	Not required	Required for all vials (usable and unusable) after each round	Required for all vials (usable and unusable) after each round
Disposal of empty vials	Local (as per national guidelines)	National or regional (as per national guidelines)	National or regional level (as per national guidelines)
Disposal of unopened vials	Not required, can be used for RI	ORPG decides	ORPG decides
Verification of vial retrieval	Not Applicable	Yes, by supervisors at each level	Yes, by supervisors at each level
Validation of vial collection	Not Applicable	ORPG will decide after concluding the OB	ORPG will decide after concluding the OB

[6] GAPIII: WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use, third edition. Geneva: World Health Organization; 2015 (http://polioeradication.org/wp-content/uploads/2016/12/GAPIII_2014.pdf).

Risks associated with nOPV2 management

- Suboptimal nOPV2 storage temperature management may result in damaged vaccine (wastage in unopened vials).
- The high number of doses per vial may result in higher open vial wastage rate.
- Vaccinators/supervisors might hesitate opening a new vial for a small number of target children to reduce open vial wastage rate (wastage reduction behaviour at the teams level).
- There may be accidental transfer of nOPV2 vaccine to EPI.

Regulatory approval for nOPV2 importation and use

- While nOPV2 has received a WHO EUL recommendation, approval for the importation and use of the product must be obtained from the receiving government's relevant authorities prior to release of doses from the stockpile.
- nOPV2 is accessible only from a global stockpile controlled by the WHO. It is not available for purchasing directly from the manufacturer.
- No minimum shelf life can be guaranteed on arrival, and countries may have to accept products with reduced shelf life. Potency can be maintained throughout the approved shelf life, provided that the vaccine is maintained under the appropriate conditions up until the end of the month indicated on the label as valid shelf life.
- Under the EUL, nOPV2 needs strict stock management practices and accurate storage/transaction records at all supply chain levels, similar to mOPV2, which includes:
    - segregation and retrieval between the supplementary immunization activity (SIA) rounds;
    - disposal of all vials must take place at the national or regional level according to local requirement; and
    - total withdrawal from all health structures at the end of the outbreak response.
- Management or disposal of remaining usable nOPV2 follows ORPG recommendations.
- See **Annex 1** for reports to support nOPV2 use under an EUL.

Activities to be held before the campaign

Protocol for release of nOPV2

The nOPV2 used in response to a high-risk event or outbreak is released from the global stockpile under a strict protocol. To access nOPV2, countries will need to meet the requirements of the EUL recommendation for use. For more information on the specific requirements for vaccine management, please see *Vaccine Management Requirements in the Context of nOPV2 Use.*[7] nOPV2 will be released from the stockpile based on completion of the readiness and risk assessments, and epidemiological data.

The latest version of the nOPV2 Vaccine Request Form is available on the GPEI website.[8]

Upon approval by the WHO Director-General, the nOPV2 vaccine stock with the shortest shelf life will be distributed from the global stockpile. nOPV2 self-producing countries must also seek readiness assessment and WHO DG authorization before using nOPV for outbreak response.

Due to the COVID-19 pandemic and continuing difficulty in finding flights, up to three weeks should be allowed for the physical delivery of vaccines following the receipt of the Vaccine Request Form and the appropriate authorizations. After the arrival of the vaccine, in-country transport procedures should be expedited to distribute all necessary doses at least two days before the initial round.

[7] Global Polio Eradication Initiative. Vaccine Management Requirements in the Context of nOPV2 Use. October 2021. http://polioeradication.org/wp-content/uploads/2021/10/nOPV2-Vaccine-Management-Guidance.pdf
[8] The nOPV2 vaccine request form (VRF) can be found under "Vaccines and Logistics" on the GPEI website (https://polioeradication.org/tools-and-library/resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines).

Estimating nOPV2 campaign needs

A multi-step vaccination strategy has been endorsed by the GPEI for cVDPV2 outbreaks and events. The GPEI vaccination strategy with nOPV2 will consist of at least two SIA rounds (R1 and R2) and a mop-up based on campaign performance and vaccine supply. Where quality of a campaign is inadequate in a large geographic area, breakthrough isolates are identified, or the outbreak continues to spread to unvaccinated areas, additional SIAs should be considered and planned.

Target populations can be based on the administrative population, the number of children vaccinated during previous SIAs, and/or quality microplanning if time allows. A quality microplan is the best source as it contains current information on populations sizes and includes missed children from previous SIAs. The nOPV2 request form allows for a wastage factor of 1.33 (wastage rate of 25%) in estimating the nOPV2 supply requirement. The formula for estimating nOPV2 campaign vaccine consumption is thus:

nOPV2 doses to be used = Target population x 1.33

If population estimates are unreliable, up to a 10% additional buffer stock can be requested for the first round.

During the microplanning stage, target populations per vaccinator per day should be aligned with 50 doses per vial to minimize the open vial wastage. However, vaccinators should be instructed to never miss an opportunity to vaccinate a child and open a new vial whenever required.

nOPV2 cannot be used simultaneously with Sabin OPV2. If a country has a stock balance of **Sabin OPV2** (tOPV or mOPV2) from the previous outbreak response rounds, the number of usable doses from that balance should not be deducted from the estimated nOPV2 need. All mOPV2 vials remaining from previous outbreak response rounds should be retrieved and contained in dedicated freezers at central/regional stores before the nOPV2 campaign. Vials of mOPV2 and nOPV2 should never be mixed.

See **Annex 2** for a summary of key tasks and responsible persons, as well as associated timelines.

nOPV2 reception, storage, distribution, and transport

nOPV2 requires strict temperature management practices at all supply chain levels. Upon arrival, it is advisable to move the vaccines immediately to freezers or walk-in freezer rooms (WIFR) in MoH facilities, where they can be routinely monitored during the completion of vaccine arrival procedures. If this is not possible and the vaccines should remain in the airport cold stores until all arrival and customs procedures are concluded, access should be given to MoH staff to monitor the vaccines regularly. Outbreak response managers should ensure that all institutions/persons responsible for checking and accepting vaccines on arrival are aware that this vaccine is not registered in the country and must be accepted as per the WHO EUL or NRA/MoH provided waiver.

Physical inspection and verification of the nOPV2 shipment will be made by the consignee named in the request form and/or its designated authorized representative, using the vaccine arrival report (VAR) accompanying the shipment. If the consignee reasonably determines that all or part of the vaccine consignment does not conform to the requirements set out in the VAR, the consignee MUST immediately notify WHO and UNICEF of the non-conformity. Requesting countries will receive vaccine with the nearest expiry date, which might be considerably shorter than other products shipped for routine (essential) immunization. This should not be a point of non-conformity.

Each VAR should be duly filled, signed and sent to the UNICEF country office within 24 hours of vaccine arrival. MoH and partner staff must ensure all arrival procedures are carried out, especially inspection and physical count for verification of quantities received, and confirm that accurate records are maintained.

Preparation for nOPV2 distribution and management

- All Sabin OPV2 (mOPV2, tOPV) vials remaining from previous outbreak response rounds should be retrieved and contained in dedicated freezers at central/regional stores before the nOPV2 campaign starts. Vials of mOPV2 and nOPV2 should never be mixed.
- Freezer storage space is required at the lowest possible level, closest to the vaccinator. (See text box below for guidance in the proper use of frozen ice packs where freezer space is not available)
- Freezer storage space is also required for the daily replenishment of ice packs for the vaccinator and for campaign use only. If a country is already using long-term passive storage devices, it may be appropriate to locate long term passive storage devices or long-range cold boxes filled with frozen icepacks (refer to the PQS Catalogue Section 004) at the nearest district store. The unique ice packs of these long-term passive storage devices can also be used as additional (not in place of) cooling device in a vaccine carrier to lower the temperature around the vaccine vials and extend its cold life. (See text box below for guidance in the proper use of frozen ice packs.)
- Develop a budgeted logistics plan for the campaign including distribution, transport and reverse logistics activities, based on available microplans.
- Update the cold chain equipment inventory including cold boxes and vaccine carriers, freezer storage space, ice pack freezing capacity, ice packs and temperature monitoring devices. Freeze-free passive cold chain equipment are not required but can be used at immunization points.
- Clearly mark all storage and distribution items: **"nOPV2 ONLY – for SIA use."**
- Identify alternative freezer storage sites (for vaccines and ice packs) detailing requirements and period of possible engagement in cases of emergency. Share emergency contact details and conduct constant follow-up.
- Train all campaign staff (vaccinators, team leaders, supervisors, cold chain managers, etc.) on nOPV2 management, recording and reporting requirements.
- Prepare simple written job aids and make printed copies available to all campaign participants.
- Inform staff that all vials they receive for each round should be returned to the nearest district-level facilities either for disposal at the higher level or for storage in freezers for further rounds. Storage of vials for further rounds must be done in a freezer or a walk-in freezer room (WIFR).
- Estimate, budget and procure all packing and transportation material requirements for retrieval before the campaign.
- Prepare a vaccine vial disposal plan (part of the National Logistics Plan) detailing the method and site of inactivation, transport to disposal sites, validating quantities received for disposal, method of disposal, disposal committee members and timelines (similar to mOPV2).

Proper use of frozen ice packs

When frozen ice packs become unfrozen to a state similar to conditioned ice packs (half solid and half water), the vaccine carrier's inner temperature is approximately 5°C and it is reasonably okay 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 5°C and should be replaced immediately to protect the cold life of the passive device and vaccines. Totally defrosted ice packs (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).

Pre-campaign temperature management and storage considerations

REMEMBER: The type 2 vaccine vial monitor (VVM2) on the vials will reach its discard point after approximately 46 days at 15°C and after 10 days at 25°C (days at the given temperatures are counted from the time that the vials arrive in the country). It is therefore recommended that only cold-life PQS rating is used to calculate the time available for distribution and outreach with the cold boxes and vaccine carriers to be used.

- Solidly frozen ice packs are required to maintain the rated cold life of a passive storage device (cold box and vaccine carrier). Conditioned ice packs or chilled water packs should be avoided as they produce a markedly shorter cold life (≤10°C) or cool life (≤20°C) of the vaccine carrier. Freeze-free vaccine carriers also require frozen ice packs. At the lowest level of distribution (i.e., outreach to vaccination point), the reverse logistics must be executed as part of the total cold life of the vaccine carrier. If an extension of this cold life limitation is required, and a country uses long-term passive devices, then a long-term passive storage device (see PQS Catalogue section 004) can provide a cold life of 35 days; however it is heavy when fully loaded (25,6Kg) and will require two health workers to handle and off course a motor vehicle to transport.
- Where freezer space is not available at the health facility or district level, it is important to rent freezers and ice packs to place at the district (or sub-district) store from where frozen ice packs can be supplied to the health facility on a daily or two-days basis, depending on the cold life of the cold box used. Freezing of ice packs (not vaccines) can also be done in domestic freezers such as at the houses of health workers or other village inhabitants.
- Note that Solar Direct Drive (SDD) and smaller freezers take very much longer to freeze water packs and may not be suitable for campaign use.
- Reverse logistics of usable unopened nOPV2 vials should follow the same procedures as the normal distribution SOPs.
- For multiple day outreaches, separate long-range vaccine carriers or cold boxes should be used as storage containers for additional icepacks.
- Cold boxes to be used between primary store and all lower stores; Type of and size will depend on the travel time required and the number of doses. The fully packed weight of the cold box will also determine how many health workers are required to lift it and move it (one male person max 25Kg). 1 million doses of nOPV2 requires 550 litres of storage space.

Storage and stock management

- Ensure that an adequate logistics management system is in place to manage the nOPV2 stocks. Maintain records of all transactions using standard national recording templates (e-stock management tools, ledgers, issue/receipt vouchers, stock and bin cards, etc.) duly signed by appropriate authorities.
- Separate nOPV2 boxes from other vaccines and clearly mark all boxes using labels, coloured scotch tape or marker pens. Repeat this procedure at every step when there is a change in packaging – region, district, or health centre - within the cold chain system.
- Ensure dedicated equipment (freezers/refrigerators) are provided for storage of nOPV2 at each level clearly labelled “nOPV2 ONLY – for SIAs use.” Where dedicated equipment is not possible, ensure that the vaccines are stored in clearly marked and closed containers and separated from other vaccines.
- Where neighbouring districts/health facilities that are not implementing the response activities are used for temporary storage, all balance of nOPV2 stocks must be removed immediately after completion of the activity.

- In this context, a usable vial means an unopened vial, which according to the attached vaccine vial monitor (VVM), has not reached the discard point (see the tally sheet for VVM reading) and has not exceeded its expiry date.
- Clearly mark all cold chain equipment (freezers, refrigerators, cold boxes, vaccine carriers) containing nOPV2 at every level to prevent unapproved usage.

A **toolkit for vaccine management** has been developed and includes:

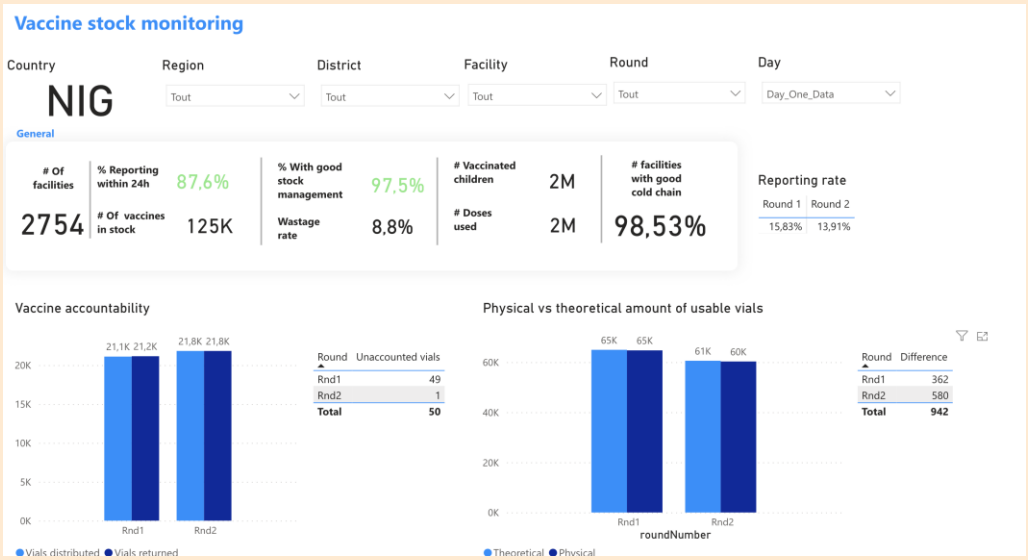
1. A generic tally sheet with the suggested part for vaccine management
2. The daily summary sheet
3. The daily summary sheets for health facilities and districts
4. The vaccine vials monitoring forms for health facilities and districts
5. The form A
6. The transfer slips for usable and usable vials
7. The disposal report
8. The supervision form to check vaccine management best practices in health facilities
9. The summary sheet for the supervision forms
10. The data collection tool for spot check of absence of type 2 vaccines
11. The reporting form for NCC to endorse the absence of type 2 vaccine
12. The evaluation form to rate performances of vaccine accountability monitors
13. The summary sheet for the evaluation of vaccine accountability monitors
14. The form for physical inventories

Electronic tools are also available upon request. These include:

- **Open data kit (ODK) questionnaire** for Vaccine Stock Control tool to monitor consumption of type 2 vaccine. This is to be completed at the point of service where vaccination teams receive their vaccine at the start of the day and return at the end of the day. A form should be used each day.
- **ODK questionnaire Form A for type 2 vaccine:** This form must be used only once at the end of each round, in all health structures and at all levels.
- **Real-time online dashboards** to display performances on vaccine management, stock balances and unaccounted vials.

Training modules on ODK questionnaires and online dashboard are also available upon request from your UNICEF regional office or by contacting nOPV2@who.int.

Note that the use of the electronic system cannot replace the paper-based system.



Activities to be held during the campaign

At the beginning of each campaign day, vaccinators must be provided with vaccines placed in small (12cmX15cm) re-sealable or locally available clear plastic bags with an additional stock of empty bags. These bags are then placed in a vaccine carrier with the appropriate number of frozen ice packs. At the end of the campaign day, vaccinators must return all vials (unopened, fully or partially used), placed in the re-sealable plastic bags, to the same health facility or sub-district/district distribution point where they received the vaccine vials in the morning.

Health facilities/sub-district vaccine distribution points must then keep the remaining unopened usable vials in the cold chain (preferably frozen), to be used for the next day. All unusable vials must be kept in thick plastic cargo bags and returned to the district/regional level at the end of the campaign for disposal in accordance with national guidelines.

To ensure proper nOPV2 management in the country, it is necessary to set up a parallel monitoring system covering both forward and reverse nOPV2 logistics, in addition to the existing vaccine management system. This parallel system should be used by vaccine accountability monitors (VAM) to monitor daily utilization patterns, stock balances and unaccounted vials as well as temperature recording data.

COVID-19 considerations

Please refer to the GPEI Interim Guidelines For Frontline Workers On Safe Implementation Of House-To-House Vaccination Campaigns (25 March 2021) in the Context Of COVID-19. The COVID-19 pandemic has impacted immunization activities, particularly through the distribution and availability of personal protective equipment (**PPE**) for logistics staff and every vaccinator, as well as the number of **droppers** required for vaccination (i.e., new dropper for each new vial; dropper should be discarded if it has touched the child, including lips). It is recommended that 2-5% additional droppers should be requested for each shipment. PPE requires additional waste collection bags for destruction after the session. **Training** must also comply with the prescribed requirements.

Multi-dose vial policy (MDVP) during nOPV2 campaigns

The 2014 revision of the multi-dose vial policy (MDVP) defines several conditions under which multi-dose vaccine vials can be kept open for extended periods of time during outreach activities and campaigns.9 It is worth mentioning that the MDVP was revised well before the tOPV/bOPV switch and the introduction of nOPV2 under containment requirements and EUL procedures.

It is not recommended to implement MDVP in nOPV2 campaigns. First, it is difficult to ensure that the nOPV2 vials continue to be kept at the recommended temperatures after opening because of the possibility of substandard vaccine carriers and the inability of VVMs to reflect short, high-temperature exposures. Secondly, it is nearly impossible to keep open vials free of contamination in field conditions. Thirdly, because nOPV2 use requires 100% accuracy in vaccine accountability records, MDVP implementation would reduce the precision of accountability reporting since it would not be possible to accurately count the leftover doses in opened vials at the end of the day. Although preventing vaccine wastage is important, maintaining full accountability for a vaccine under containment, such as nOPV2, is imperative for the GPEI.

[9] WHO policy statement: multi-dose vial policy (MDVP): handling of multi-dose vaccine vials after opening, Revision 2014. World Health Organization. https://apps.who.int/iris/handle/10665/135972

Roles and responsibilities

Cold chain officers (CCOs)

At lowest-level storage points (district/sub-district/health facility stores)

- Ensure the vaccine vial monitoring form (or stock book) is signed by the team supervisor as the team is receiving the vaccine vials.
- Receive and count all open vials (fully or partially used) and unopened vials at the end of the campaign day. Compare the batch number on returned vials with those of vials issued in the morning and ensure a match.
- Clearly mark the vaccine vial monitoring form accordingly at the end of each implementation day and ensure that the form is counter-signed by team supervisors.

Team supervisors

- Issue unopened vaccine vials of accepted quality (not expired, VVM not reached to-discard point, labels intact) placed in clear plastic bags to the vaccinators on a daily basis.
- Distribute additional plastic bags to the vaccinators to be used during implementation and for returning of all vials at the end of the day.
- Count and check all opened vials (fully or partially used) and unopened vials at the end of the day; receive, update and sign the tally sheet and ensure it is signed by the vaccinators.
- Return all the vials to the health facility or sub-district distribution point where they received them from and submit the signed vial monitoring form.

Vaccinators

- Receive unopened vials (not expired, VVM not reached to-discard point, labels intact) from the supervisor; document the number of vials received on the tally sheet and sign. In case additional vials are resupplied during the day, ensure that these are added on the tally sheet.
- Place unopened vaccine vials in sealable plastic bags to protect their labels from moisture and keep them in the vaccine carrier with frozen ice packs to maintain the cold chain.
- Once a vial has been opened, place in a separate sealable plastic bag designated for opened vials (fully or partially used) and keep the plastic bag safely inside the vaccine carrier.
- Return all opened and unopened vials kept in separate bags to the supervisor or health facility at the end of each day; record the number of vials returned in the tally sheet.

Vaccine accountability monitors (VAMs)

Vaccine accountability monitors (VAM) are the newest members of the vaccination teams during nOPV2 campaigns (similar to mOPV2). One vaccine accountability monitor is recommended for every two to five vaccination teams working in the same sub-district. Teachers, higher education students or graduates residing in the same district are good potential VAM candidates. The VAMs are trained on the accountability process for nOPV2 and the use of the vaccine vial monitoring form during training for nOPV2 campaigns at the district level. Below are the activities expected from VAMs during nOPV2 campaigns:

- Liaise with the store manager (or local campaign manager) to understand the daily vaccine distribution plan.
- Record details of all vials given to each team (number of vials, batch number of each vial, team number, and the name and phone number of the team supervisor) in the vaccine accountability monitoring forms at the beginning of each day. Both VAM and store manager should keep a separate copy of the vaccine accountability form.
- Visit two to five of the assigned vaccination teams during the day and fill the monitoring checklist (as provided in **Annex 2**).
- Receive all used and unused vials from team supervisors at the end of the day, with store manager.
- Check and compare all returned vials with the recorded details, together with the store manager and team supervisors. If details match, the team supervisor signs off for the day and the VAM reconciles the data with the store manager.
- Return the vial count summary to the district and present during the evening review meeting.

- Reconcile, with the store manager, the children immunized with the number of doses/vials used before transmitting data to the district. If there are missing vials, the vaccinator and the team supervisor must prepare an incident report explaining the reasons.
- Check at the sub-district level for the absence of nOPV2 (and mOPV2/tOPV if used earlier) vials at the end of the round and report it to the district level (using reporting format in Annex 1). Finding any mOPV2/tOPV vials should also be reported immediately to the district supervisor for immediate action, which may include a complete sweep of the district.

District vaccine accountability monitoring supervisors (DVAMSs)

In order to enhance nOPV2 vaccine accountability, the programme shall engage district vaccine accountability monitoring supervisors (DVAMSs). DVAMSs will collaborate with CCOs and other team members to collectively coordinate nOPV2 management activities. DVAMSs will be trained on the accountability process which includes monitoring and supervision of the VAMs within the district, liaising with the district team, and monitoring and reporting daily on vaccine balance and temperature records during implementation and the end of implementation activities. Their role will include the following:

- Cross-check the quantity of nOPV2 vials received by the district through a physical inventory
- Participate in the distribution of vaccines to the sub-district distribution points, ensuring that the district vaccine accountability forms are completely and correctly filled with VVM status verified.
- Visit select sub-district level distribution points on a daily basis to ensure compliance with standard operating procedures (SOPs) for nOPV2 management
- Visit some vaccination teams on a daily basis to ensure compliance with SOPs for nOPV2 management
- Check the VVM status and identify vaccine vials which have been exposed to high temperature excursions or the VVM reached discard point, supervise the removal of such vials from vaccination activities and ensure that they are all accounted for.
- Ensure that all nOPV2 vials are returned and accounted for at the end of the campaign using the nOPV2 district vaccine accountability forms (see Annex 2).
- Check all cold chain equipment at the district and selected sub-district levels to verify absence of any OPV type 2-containing vaccine (nOPV2/mOPV2/tOPV) vials in the system.
- Prepare and share a report with the district and provincial teams on the absence of type 2 vaccines in the district (see **Annex 1**).

Activities to be held after the campaign

nOPV2 retrieval and disposal

- After each campaign round, the district stores should retrieve all nOPV2 vials within two (2) days of completion of the rounds. All nOPV2 vials should be counted and quantities reported to the national level within seven (7) days using the standard Form A (see **Annex 1**). The National Logistics Working Group (NLWG) should collate all Form As from the lower levels and summarize them into the national-level Form A. The National EPI Manager then transmits the national Form A to UNICEF country office for onward transmission to UNICEF regional office and headquarters 14 days after the campaign round.
- Remaining opened nOPV2 vials (partially or fully used), as well as expired and damaged vials with VVMs that have reached to-discard point (unusable stage), must be taken out of the cold chain and destroyed together with other medical waste at regional/national level according to national guidelines. This process should be reported using the Vial Disposal Report (see Annex 1).
- Remaining unopened and usable nOPV2 vials should be kept in a designated regional-level store (or higher) with negative (-25°C to -15°C) temperature storage facility until the next response round, outbreak response assessment (OBRA) or ORPG mission. Temperature management MUST be maintained at all times during storage of the nOPV2 stock. On the recommendation of ORPG, all remaining unopened vials should be transported to central level to be safely destroyed as per national regulations for medical waste disposal.

Data verification, monitoring and correction

At each level, a tracking system must be put in place by national and state/provincial Logistics Working Groups, district CCOs or EPI focal points, and sub-district heads of SIAs teams to:

- Manage timely deployment of nOPV2 to the outbreak-affected area only.
- Ensure that all vials of nOPV2 from the central store are properly distributed through the supply chain to the immunization points.
- Obtain a better understanding of the wastage rates and reasons thereof and use it to determine needs for the next round/shipment
- Ensure that all opened (fully, partially used or broken) vials are returned from immunization teams to the district level.
- Ensure that all unopened vials with VVM which have reached the to-discard point are returned from immunization teams to the district level.
- Ensure that all opened vials are retrieved and safely disposed at the national/regional level at the end of the rounds in compliance with national guidelines and national regulations for medical waste management
- Monitor nOPV2 stock at regional and national level pending recommendation from the ORPG team on further strategic use or destruction
- Produce a final report within two (2) weeks after each SIA round using the Form A that details the status of the nOPV2 stock at each level with doses received, used, wasted, lost and returned in good condition. This report will be the basis of the OBRA validation.
- Ensure 100% accountability in 100% of storage and distribution points and at the team level. All personnel handling nOPV2 must account for the total number of vials they received at the end of the day or campaign. MoH and national polio partners must ensure implementation of the accountability framework at each level.

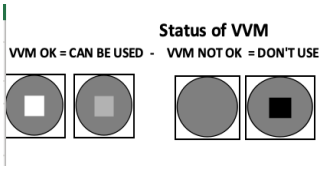
Recording, reporting and monitoring

With the aim to support the national authorities in the vaccine management for nOPV2 campaigns and to get a better oversight of vaccine usage, wastage, losses and balances, countries should use the simple forms and reports provided in **Annex 1**. These forms can be translated by implementing countries but should not be modified.

Tally sheet

Some parts of the tally sheet are country-specific; however, all countries should ensure that the vaccine management section reflects the following:

- The number of vials received is recorded in the morning before the team begins vaccination.
- The number of vials received during the day (2nd reception) must also be noted on the tally sheet on the “replenishment” columns.
- The number of vials at the end of the day cannot exceed the total received in the morning, plus replenished vials.
- The form must be signed by the vaccinators and the team supervisor.
- The form should avoid deletions or overwriting.



Vials received				Vials returned at the end of the day		
Beginning of the day	Replenishment 1	Replenishment 2	**Total vials received**	Usable Vials (1)	Unusable Vials (2)	**Total vials returned**

(1) Usable Vials : vials that have not been opened, whose VVM has not passed the discard point, whose label is legible and whose expiry date has not passed.
(2) Unusable Vials : empty vials, all opened vials (opened vials must not be reuse the next day), vials with an unreadable label and/or a VVM that has passed the discard point

Vaccine accountability report

Vaccine accountability for nOPV2 is very important. For the purposes of nOPV2 management, accountability is defined as the responsibility of each member of the team handling nOPV2 to account for all vials of the vaccine received or kept in their custody and to properly document and return all vials to the next upper level at the end of the campaign. Each VAM is expected to provide a report after the round using the format provided in **Annex 1**.

Form A (nOPV2 distribution and utilization report)

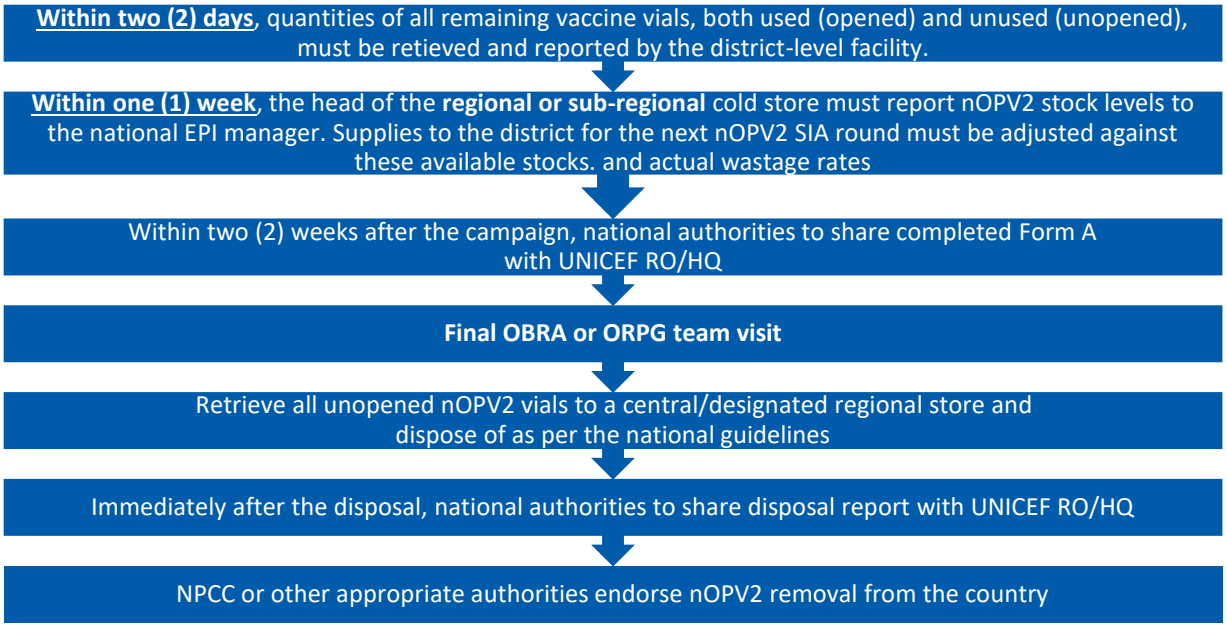
This form is provided for reporting nOPV2 stock levels to the EPI manager, national polio partners and UNICEF after completion of each SIA round. The form can be used at each level: central, regional/district and the sub-district. A copy of this form is provided in **Annex 1**.

- At the end of all SIA rounds, the sub-national stores – at the regional and district levels – and central store should report to the national EPI manager within seven (7) days.
- The national EPI manager should report to UNICEF country office within a maximum of two (2) weeks following each SIA round using a signed copy of the consolidated Form A.

nOPV2 vial disposal report

To ensure proper accountability and disposal of all nOPV2 vials, a vaccine vial disposal report (empty and opened vials and unopened vials with VVM beyond the discard point, expiry date reached or damaged label) should be prepared and submitted by the VAM to the district or regional store after the disposal exercise is carried out at district/regional level. The vaccine vial disposal report should contain the number of vials received for disposal and the actual quantity of vials disposed.

Figure 1: Timelines for collection and reporting of nOPV2 stocks and stock balances following completion of an SIA round



Managing broken vials of nOPV2 (or any type 2-containing OPV) post-switch

In the course of handling nOPV2 or any type 2- containing OPV (mOPV2, tOPV), there could be breakages. Care should be taken to ensure that the environment is not contaminated with the contents of the vial. All cold chain equipment where vial breakage is noticed should be disinfected immediately with 0.5% chlorine solution (one-part household bleach and nine parts clean water). If there is a spill on the ground of a cold/freezer room, it should be soaked with the same solution to ensure all risk of contamination is eliminated. Vehicles used to transport empty, partially used vials or vehicles in which leakage of nOPV2 vaccine is suspected should also be disinfected using 0.5% chlorine solution.

Monitoring and validation of type 2 OPV withdrawal

To minimize the risk of type 2-containing OPV remaining in the country after concluding the outbreak, the absence of nOPV2 (and mOPV2 or tOPV) must be validated, if required by the ORPG. This does not include validation of type 2-containing OPV inactivation or destruction, nor does it include the presence of type 2 poliovirus in laboratories or manufacturing facilities. Many elements of the validation process, such as training, microplanning, staff selection, and so on, are similar to the monitoring process undertaken during the switch from tOPV to bOPV.

Key steps of the validation strategy

1) Nominate the National Certification Committee (NCC), or any other independent national body, to validate the absence of nOPV2 stocks following the response campaigns.
2) Develop a national plan with details on where and when to monitor, what to do in case type 2-containing OPV vaccines are found,
3) Select and train independent monitors.
4) Conduct site visits at all cold chain stores, including private stores, from the national to the regional and district levels, and selected service delivery points (health facilities) below the district area.
5) Take corrective action to remove any type 2-containing OPV stocks found in the cold chain and mark these stocks for destruction.
6) Obtain validation from the NCC or the nominated independent national body of the absence of nOPV2 stocks based on the reports from the monitors.

ANNEXES

Annex 1: nOPV2 utilization and disposal reports

Form A
End of round nOPV2 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: _____ Actual Wastage Rate: _____ (to be used for next shipment)

nOPV2 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 usable vials (1) received from lower level	# of unusable vials (2) received from lower level	# of vials, unaccounted for	Physical inventory balance of usable vials (1) in stock	# of usable vials (1) returned to higher level
A	B	C	D	E	F	G	H

(1) Usable vials: vials that have not been opened, whose VVM has not passed the discard point, whose label is legible and whose expiry date has not passed.
(2) Unusable vials: empty vials, all opened vials (opened vials must not be reused the next day), vials with an unreadable label and/or a VVM that has reached the discard point, and vials that have passed expiry date.

Title and name of the reporting officer : _____

Signature : _____

Reporting date : _____

Instructions to report on utilization of nOPV2 vials at the end of each SIA round
Vaccine: *nOPV2 has been introduced to be used under WHO's EUL procedures. It is critical to have very precise counts of nOPV2 vaccine vials at each level of the health infrastructure.* • *Once all SIA rounds are completed, all unopened vials must be returned to the national vaccine store, and no nOPV2 vial should remain at any level of the health infrastructure.* • *Stock reporting: Form A should be used to report on nOPV2 stock levels from all administrative areas conducting nOPV2 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 one (1) day following completion of each SIA round.* • *The immunization officer responsible at the district level should retrieve all nOPV2 vials (opened and unopened) within two (2) days following the completion of each SIA round and report to an upper level.* • *The immunization officer responsible at the regional level should report the stock levels following the completion of each SIA round within seven (7) days.* • *All unopened vials at the end of each round should be physically counted and their VVM status checked.*

nOPV2 VIAL DISPOSAL REPORT

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

Disposal method	
Inactivation/destruction	**Disposal**
☐ Boiling ☐ Chemical inactivation ☐ Incineration ☐ Encapsulation ☐ Autoclave sterilization ☐ Other (please explain):	☐ Burying ☐ Transfer to a 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:

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 usable (*) vials returned by health facilities	No. of unusable (**) vials returned by health facilities	Total no. of vials returned by health facilities	No. of unaccounted vials	Batch no.	Signature of team supervisor
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I=G+H**	**J=C-I**	**K**	**L**
	Total										

(*) Usable vials: vials that have not been opened, whose VVM has not passed the discard point, whose label is legible and whose expiry date has not passed.

(**) Unusable vials: empty vials, all opened vials (opened vials must not be reused the next day), vials with an unreadable label and/or a VVM that has passed the discard point, and vials with expiry date passed.

Signature of store manager…… Name……

Date……

nOPV2 Monitoring Checklist for Vaccine Accountability Monitors and District VAM Supervisors						
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 ice packs inside the vaccine carriers? *(Check that there are minimum ice packs as per PQS specification)*					
3	Is nOPV2 vaccine stored only in the vaccine carriers? *(Only nOPV2 and icepacks are kept in the vaccine carrier)*					
4	Are vaccinators keeping the vial in the vaccine carrier between each vaccination. (*Observe the vaccinator as they handle the vial between each administration of the vaccine)*.					
5	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 workplan)*					
6	Does the vaccination team have a dropper for each nOPV2 vaccine vial? *(Check if the number of droppers and number of vials are the same)*					
7	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)*					
8	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)*					
9	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)*					
10	Did the vaccinator check and record the VVM status on the vials at the start and end of each immunization session and record any VVMs at or beyond the discard point? *(Check that VVMs at or beyond discard point are recorded against the batch numbers of the affected vials – and remove them from the usable vials)*					
	Total Yes					
	Total No					

VACCINE ACCOUNTABILITY MONITORING REPORTING FORM (nOPV2)

Instruction guide:

1 This form should be filled by the vaccine accountability monitor (VAM) after each nOPV2 round.

2 Vaccine quantities should be recorded as vials only in this report, not doses.

3 The VAM should report to the higher level within two (2) days following completion of each SIA round using the portion for VAM. If any nOPV2 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 nOPV2 vials and report using the portion for district VAM supervisor.

5 Make sure all (usable and unusable) vials of nOPV2 are returned back to a district vaccine store and that no nOPV2 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 portion to be filled by VAM				*This portion to be filled by district VAM supervisor*		
# of nOPV2 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 nOPV2 vials	# of sites visited where any nOPV2 vials were found	# of vials of nOPV2 found

Remarks:

Signature:_____ **Reporting date:**_____

Annex 2: Overview of key nOPV2 management activities, roles and responsibilities

Table 2a. Pre-campaign activities

S/N	Task	Level	Responsible	Timelines
1	• Inform managers on the need for authorities to provide waiver based on WHO EUL status for accepting the vaccine. • Apply for regulatory approval of EUL product. • Apply for approval to import genetically modified vaccines, if the country requires this for PHEICs.	National	UNICEF / WHO / NITAG	Within three (3) days of notification
2	• Use the standard nOPV2 vaccine request form to prepare request for the vaccine (estimate vaccine requirements using wastage factor of 1.33 for 50-dose vials for the first shipment and adjust thereafter for each round/shipment)	National	National EPI manager / National Logistics Working Group (NLWG)	Within three (3) days of notification as part of the risk analysis
3	• Conduct inventory and gap analysis for cold chain equipment and plans to bridge gaps especially: ○ Freezer storage space ○ Ice pack freezing capacity ○ Vaccine carriers ○ Ice packs ○ Transport cold boxes with ice packs ○ Indelible finger marker pens	National / sub-national	NLWG / lower-level Logistics Working Groups (LWGs)	After submission of vaccine request and before each round
4	• 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	National CCOs / NLWG	Within three (3) days of notification
5	• Prepare logistics and VM budget in line with the logistics and VM plan.	National	National CCOs / NLWG	Within seven (7) days of notification
6	• Procure cold chain equipment required (from gap analysis), to be delivered in time for SIA.	National	National CCOs / NLWG	Within three (3) days of notification

7	• On reception, inspect, count and verify vaccine quantities received with shipping documentation	All levels	National & sub-national CCOs / DVAMS / VAM / vaccinators	Within 24 hours
8	• Keep nOPV2 in the freezer at all times, preferably at the national vaccine store during customs clearance procedures	National	National CCOs / national EPI manager	Ongoing
9	• Fill and transmit the nOPV2 VAR to UNICEF country office	National	National CCO	Within 24 hours of receipt of vaccines
10	• Record transactions in national standard registers (e-stock tools, ledgers, stock cards, etc.), first register nOPV2 as new product	All levels	National & sub-national CCOs	Within 24 hours of transaction
11	• Identify and mark all cold chain equipment to be used for storing or transporting nOPV2 using labels, scotch tape or marker pens with "nOPV2 ONLY – for SIAs use"	All levels	National & sub-national CCOs	Three (3) days before receipt of deliveries
12	• Train all campaign staff on the basics of nOPV2 management and handling including the need for reverse logistics, including cold chain for unopened vials, for disposal of opened/destroyed vials or storage of unopened and usable vials	National and sub-national levels	National & sub-national SIA focal persons / LWGs	Day 7 to day 10
13	• Develop a distribution plan for the nOPV2 (where indicated plan with available stock balances)	All levels	National & sub-national CCOs	Day 7
14	• Purchase resealable plastic or ziplock bags for all vaccination teams for storage of vaccines and empty/opened/damaged vials	National	National CCOs / NLWGs	Within seven (7) days
15	• Prepare daily workplan and vaccine distribution to teams based on microplans or the last implemented workplan	Lowest distributio n level	SIA focal persons / LWGs	One week before campaign
16	• Distribute other logistics inputs, such as data tools, pen markers, sealable bags, cargo bags, etc.	National	National CCO	Five (5) days before the campaign

Table 2b. Intra-campaign activities

S/N	Task	Level	Responsible	Timelines
1	• Distribute daily requirements of vaccines and other logistics inputs based on daily implementation workplans	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 nOPV2 vaccine vials and record number of vials received on the tally sheet	Team level	Vaccinators	Daily
3	• Sign the vial monitoring form after receiving the vials. Make sure the number of vials and batch numbers are correct as documented and received.	Team level	Vaccinators	Daily
4	• Place vials 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	• Conduct spot checks on sub-district level distribution points and vaccination teams	Sub-district distribution point / team level	Senior supervisors / DVAMS / VAMs	Daily
7	• Monitor vaccine availability daily at each level during the campaign and respond to stock-out as soon as possible	All levels	CCOs / EPI-SIA focal persons at all levels	Daily
8	• At the end of the day, return all opened vials (fully or partially used) and unopened vials to supervisors and update the supervisor's vial monitoring form.	Team level	Vaccinators	Daily
9	• Ensure the vial monitoring form is signed by the team supervisor	Team level	Team supervisor	Daily

10	• Submit all the vials to the store where you received them, and sign the vial monitoring form	Team level	Team supervisor EPI-FP / VAM / DVAMS	Daily
11	• Reconcile returned vials with collected vials at the distribution point level and, if any VVMs are at or beyond discard point, remove the unopened vials from stock and place them with the damaged stock for destruction	Sub-district distribution point	EPI focal point / VAM	Daily
12	• Report vaccine status to upper level	All levels	EPI focal point	Daily
13	• 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

Table 2c. Post-campaign activities

S/N	Task	Level	Responsible	Timelines
1	• Retrieve, count and report all nOPV2 vials to the next higher level.	All levels	National, sub-national, district-level CCOs and sub-district EPI focal point	1 – 7 days after campaign
2	• Maintain all usable nOPV2 in walk-in freezer room (WIFR) or freezers at -25°C to -15°C at all times, until further guidance from ORPG is received	Designated higher store level for storage of nOPV2	Store manager at designated store	During storage
3	• Remove all opened and partially used vials as well as heat-damaged vials from the cold chain and prepare along with empty vials for disposal	All levels	National, sub-national, district-level CCOs and sub-district EPI focal point	1 – 7 days after campaign
4	• At the end of all SIA rounds, sub-national stores at the regional and district levels should use the Form A to report all stock balances, opened/empty, unusable, and	National and sub National	National and sub-national-level CCOs	1 week after the campaign

	unaccounted vials to the National EPI manager			
5	• The national EPI manager should send the completed and signed reports (Form A) to UNICEF country office within a maximum of **two (2) weeks** after each SIA round.	National	EPI manager	2 weeks after the campaign
6	• Take all expired, damaged and unusable nOPV2 vials out of the cold chain, securely destroy them at the appropriate level as per country regulations	National and sub-national	National and sub-national level CCOs	1 – 2 weeks after the campaign
7	• On the recommendation of ORPG, collect all remaining unopened vials and safely destroy them at the national level as per national regulations for medical waste disposal or suggested guidance	National	National CCOs / EPI manager	2 weeks after the recommendation from OBRA or ORPG
8	• Report all disposal of the vials using the disposal report template immediately after the disposal. The report must be shared with the UNICEF RO and HQ.	National and sub-national	EPI manager	Immediately after disposal
9	• Develop a national plan with details on where and when to monitor, what to do in case nOPV2 is found.	National	NAC / EPI manager	Two (2) days after convening the NPCC or NAC (day 0 of containment activity)
14	• Check for nOPV2 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 nOPV2 retrieval	All levels	All supervisors (government and partners)	Each visit