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POLIO GLOBAL ERADICATION INITIATIVE

Cold Chain and Vaccine Management Requirements in the Context of nOPV2 Use

EVERY LAST CHILD

Background

Countries facing type 2 polio detection or outbreaks of circulating vaccine-derived poliovirus type 2 (cVDPV2), or countries looking to safeguard against a type 2 polio event, now have the option to use the novel oral polio vaccine type 2 (nOPV2), which is currently available under an Emergency Use Listing (EUL) of the World Health Organization (WHO).[1]

Under the EUL, nOPV2 has been approved for targeted use during a Public Health Emergency of International Concern, which polio has been since 2014. Given the increasing threat of cVDPV2 outbreaks to vulnerable, under-immunized and high-risk populations, the EUL allows for expedited deployment of nOPV2.

To access nOPV2 from the global stockpile, countries must first meet the requirements of the EUL. The new vaccine will only be released under a strict protocol, and countries must submit readiness documentation, risk assessments and epidemiological data to be verified by the WHO.

Under Emergency Use Listing (EUL) procedures and type 2 containment requirements, each vial of nOPV2 must be fully accounted for throughout its lifecycle in-country: from receipt, to dispatch, to transport and storage, to immunization, to retrieval and central store or disposal.

To demonstrate readiness for nOPV2 use, countries must provide detailed plans for cold chain logistics and vaccine management procedures to support tracking and reporting all vaccine, used and unused, both during and after vaccination campaigns.

Furthermore, given the 2015 global certification of wild poliovirus type 2 (WPV2) eradication, nOPV2 is considered potentially infectious material, and containment procedures apply to its use. All nOPV2 vials must be included in the surveys and inventories performed in the containment preparatory phases of GAPIII.[2] nOPV2 containment refers to controlled and monitored vaccine release, tracking and accounting of all nOPV2 vials with destruction paperwork, enhanced surveillance and the immediate reporting of knowledge of potential reversion and Phase III clinical data reports to the Containment Advisory Group (CAG). Country-level reporting should also engage the National Authority on Containment (NAC), the National Poliovirus Containment Coordinator (NPCC) or a similar body, and the National Certification Committee (NCC).

Due to nOPV2 containment, a request mechanism similar to that used for monovalent oral polio vaccine type 2 (Sabin mOPV2) will be applied to requests for nOPV2, and reverse logistics will be required to ensure unused vials and droppers are retrieved for central store and used vials are brought to a disposal point and, where necessary, inactivated or destroyed.

As nOPV2 is not registered in countries using nOPV2, but rather by the WHO, approval for the importation and use of the product must be obtained from the receiving government prior to release of doses from the stockpile. Countries must engage their NAC, Ministry of Health (MoH) and National Regulatory Authority (NRA) or other governing body, as well as other interested ministries, institutions, committees or relevant professional bodies.

[1] Based on a decision by the Strategic Advisory Group of Experts on Immunization (SAGE) that nOPV2 should become the vaccine of choice after the initial use period. See SAGE meeting summary, Oct 2020 (https://apps.who.int/iris/bitstream/handle/10665/337100/WER9548-eng-fre.pdf).

[2] 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).

Objective

This document is intended to assist countries as they prepare to be verified for nOPV2 use under EUL commitments. While several resources have been developed to support nOPV2 use (see **Vaccine management resources** at the end of this document), this guidance outlines the steps required to meet and implement EUL criteria for cold chain logistics and vaccine management. A complete list of all readiness requirements by category is available in **Annex A**.

*The Global Polio Eradication Initiative (GPEI) has prepared this document to highlight what is **required** for all countries using nOPV2 under the EUL. This document should be read in conjunction with Preparing for nOPV2 Use: An overview on requirements for countries.*[3]

Steps toward nOPV2 use in a country

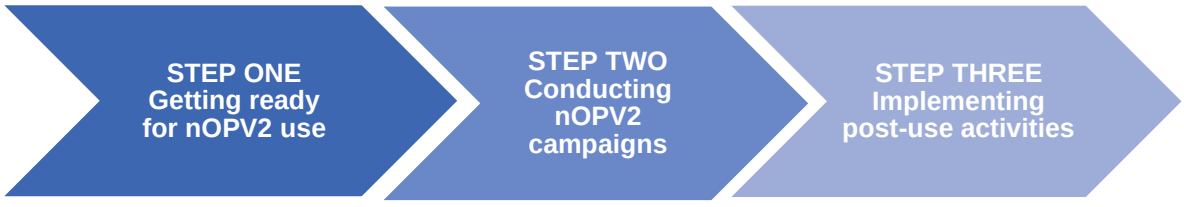
Once a country confirms its interest to use nOPV2 for cVDPV2 outbreak response, the following steps outline activities that need to take place to prepare for nOPV2 use in-country (see **Fig. 1**).

Step 1: Getting ready for nOPV2 use – In order for countries to use nOPV2, they must meet established readiness requirements. For vaccine management, these requirements are focused on updating the national logistics plan to include: (a) a cold chain equipment inventory and gap analysis, (b) updated vaccine management tools for nOPV2, and (c) vaccine management plans that outline how vial tracking and disposal will be handled.

Step 2: Conducting nOPV2 campaigns – Before launching an nOPV2 response, each country must review a checklist of activities to ensure all requirements are met and all systems and processes that were created to support nOPV2 readiness are followed through, implemented and upheld.

Step 3: Implementing post-use activities – Once nOPV2 has been used in a country, all nOPV2 vials must be accounted for, tracked, retrieved and disposed according to rigorous guidelines. Recording, reporting and monitoring of nOPV2 post-use activities is essential both to ensure vaccine accountability and to support validation of nOPV2 withdrawal after the campaign has concluded.

Fig. 1. Steps toward nOPV2 readiness verification, use and implementation



[3] Global Polio Eradication Initiative. Preparing for nOPV2 Use: An overview on requirements for countries. October 2021 (http://polioeradication.org/wp-content/uploads/2021/10/nOPV2-Requirements-Overview-for-Countries.pdf).

Step 1: Getting ready for nOPV2 use

The national logistics plan (NLP) is a central road map for cold chain logistics (CCL) and vaccine management at the country level. As such, the NLP is a critical resource for polio eradication – and beyond. Countries can use the NLP as a template for other vaccination campaigns, whether for inactivated polio vaccine (IPV), measles or COVID-19 vaccines.

The documentation that is required to meet the requirement for CCL and vaccine management is summarized below (see **Table 1**).

Table 1. Summary of vaccine management requirements for nOPV2 use

Req #	Requirement	What needs to be submitted
C1	National logistics plan is updated to include: a. cold chain equipment inventory and gap analysis, b. updated vaccine management tools for nOPV2 (50-dose vial), and c. vaccine management plans, outlining how vial tracking and disposal will be handled.	National logistics plan for nOPV2 use that addresses or includes the following components: 1. The active cold chain inventory (less than one year old) 2. The passive cold chain inventory (less than one year old) 3. The gap analysis in cold chain capacity, given nOPV2 use plans and vaccines for routine immunization and other supplementary immunization campaigns (e.g., COVID-19 or measles) 4. Plan to address any gaps in capacity, if identified 5. Confirmation that vaccine management tools have been updated for nOPV2 use – either through screen shots of the management tools used for supplementary immunization activities (SIAs) or copies of tools (if using spreadsheets or paper tools) 6. Plans for training and capacity building of CCL staff and campaign staff on nOPV2 vial management 7. Description of processes to ensure vial tracking and accountability, along with post-campaign disposal

To prepare an NLP, countries should start by surveying the equipment (active and passive) that will be needed to maintain the cold chain for vaccine vials – from receipt and storage to immunization to retrieval from the field and disposal. Next, countries should outline procedures for distributing, transporting, storing, retrieving and disposing the vaccine, given the particular characteristics of nOPV2. Lastly, the NLP presents country-level tools that will be used to track all vaccine, used and unused, to ensure full vaccine accountability.

C1(a) – Cold chain equipment inventory and gap analysis

nOPV2 requires strict temperature management practices, and temperature management must be maintained at all times during storage of the nOPV2 stock. The NLP for nOPV2 should survey the country's network of cold/freezer rooms, freezers, refrigerators, cold boxes and vaccine carriers that will keep nOPV2 vials at the right temperature (-25°C to -15°C).

Inventories should include:

- ❒ Freezer storage space
- ❒ Ice pack freezing capacity
- ❒ Vaccine carriers
- ❒ Ice packs
- ❒ Transport cold boxes with ice packs
- ❒ Temperature monitoring devices

Once cold storage has been inventoried, countries should assess any gaps in equipment and create plans to bridge those gaps to support cold chain logistics throughout nOPV2 use.

Such gap analyses may yield additional equipment needs, but it may also identify contingency plans that can be leveraged in cases of emergency – for example, in identifying alternative freezer storage sites (for vaccines and ice packs) that can be used to maintain the forward and reverse cold chain if disruption occurs in access to equipment or if equipment malfunctions.

Resources to support countries

Four tools are available to support equipment inventories and gap analyses.

1. Cold chain equipment inventory and gap analysis tool
2. Cold chain equipment sizing tool
3. Expanded Programme on Immunization (EPI) logistics forecasting tool
4. Effective vaccine management assessment (EVMA) and continuous improvement plan

As these resources are updated regularly, countries should contact nOPV2@who.int for the latest link.

Required

1. ***The active cold chain inventory completed and less than one year old.***
2. ***The passive cold chain inventory completed and less than one year old.***
3. ***A gap analysis in cold chain capacity completed, given nOPV2 use plans and vaccines for routine immunization (RI) and other supplementary immunization campaigns (e.g., COVID-19 or measles).***
4. ***Plan in place to address any identified gaps in capacity.***

C1(b) - Updated vaccine management tools for nOPV2

To meet the EUL requirement for cold chain and vaccine management, countries will need to update their existing vaccine management tools to account for the impact of nOPV2 on national vaccine management, as well as campaign planning and implementation.

While nOPV2 shares the containment and reverse logistics requirements of mOPV2, there are characteristics specific to nOPV2 that should be reflected throughout vaccine management and SIA tools and training.

- ***nOPV2 wastage rate = 1.25***
  Following the initial use phase for nOPV2, the wastage rate was revised to 1.25 (from 1.33). This rate may be further revised as countries continue to use nOPV2 under the EUL.
  To estimate nOPV2 campaign need, the formula that should be used is –
  nOPV2 doses to be used = target population x 1.25
  If target population numbers are not reliable, a buffer stock of up to 10 % can be applied for the first round.

- ***50-dose vials***
  Target populations per vaccinator per day (in SIA microplans) 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.

See **Table 2** for a comprehensive comparison of nOPV2 with bOPV and mOPV2.

Required

Confirmation that vaccine management tools have been updated for nOPV2 use—either through screen shots of the management tools used for SIAs or copies of tools (if using spreadsheets or paper tools).

Table 2. Comparison of nOPV2 with bOPV and mOPV2

	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	1,25 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 (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 outbreak	ORPG will decide after concluding the outbreak

* Packed volume is based on OPV products from Bio Farma.

C1(c) - Vaccine management plans

Country use of nOPV2 requires 100% accuracy and precision in vaccine accountability. Strict stock management practices and accurate storage and transaction records at all supply chain levels will be required.

Under EUL procedures, nOPV2 stock management includes:

- segregation and retrieval of nOPV2 vials between the SIA rounds;
- disposal of all vials at the national or regional level according to local requirement; and
- total withdrawal from all health structures at the end of the outbreak response.

To meet the EUL requirements, countries must prepare a vaccine vial disposal plan (as part of the NLP) that provides a description of processes to ensure vial tracking and accountability, along with post-campaign disposal.

The vaccine vial disposal plan should detail distribution and transport to disposal sites, quantities received for disposal (usable and unusable), verification of collection, method of disposal, disposal committee members and timelines.

Similar to mOPV2, management or disposal of remaining usable nOPV2 follows on the recommendations of the Outbreak Response and Preparedness Group (ORPG).

To ensure proper nOPV2 management in-country, it will also be necessary to set up a parallel monitoring system to cover both forward and reverse nOPV2 logistics. This parallel system should be used by the newest members of the vaccination team – vaccine accountability monitors – who will monitor daily utilization patterns, stock balances and unaccounted vials, as well as temperature recording data.

Resources to support countries

Annex B provides sample forms:

- ✓ Form A-End of Round nOPV2 Distribution and Utilization Report
- ✓ Vial Disposal Report
- ✓ Vaccine Accountability Monitoring Form

More retrieval and vaccine disposal tools are available to support countries. As these are updated regularly, countries should contact nOPV2@who.int for the latest link.

Required

Description of processes to ensure vial tracking and accountability, along with post-campaign disposal.

Training and capacity building

As part of fulfilling the EUL requirements for CCL and vaccine management, countries should develop a plan for training all CCL staff and campaign staff on nOPV2 management, recording and reporting requirements. Within the NLP, the training plan helps to build capacity at the field level in nOPV2 vial management.

While training need not be completed ahead of verification for nOPV2 readiness, countries can provide plans for implementing training with cold chain officers, team supervisors, vaccinators, vaccine accountability monitors and district vaccine accountability monitor supervisors. Simple written job aids can be prepared, with plans to make printed copies available to all campaign staff.

Resources to support countries

Training modules and webinars

Prior to an nOPV2 campaign, the GPEI will provide direct support to countries for training staff.

Templates are also available. As these are updated regularly, contact nOPV2@who.int for the latest link.

Required

Plans for training and capacity building of CCL staff and campaign staff on nOPV2 vial management.

Step 2: Conducting nOPV2 campaigns

Conducting nOPV2 vaccine management activities for cVDPV2 outbreak response is similar to vaccine management for other kinds of outbreaks: from requesting release of the vaccine, to estimating vaccine needs, to preparing for vaccine reception, storage, distribution, transport, management, retrieval and disposal.

For nOPV2 campaigns, the following activities are recommended:

- ❒ Confirm sufficient -20C storage capacity for nOPV2 prior to shipment arrival. Prior to a campaign, confirm availability of cold chain space changes based on shipments and use of vaccines (especially with the COVID-19 vaccine).
- ❒ Ensure gaps identified as part of verification have been addressed. This may require procuring or renting equipment or printing stock/vaccine management tools.
- ❒ Ensure budgeted logistics plan is in place and includes distribution, transport and reverse logistics activities, based on available microplans.
- ❒ Complete training for all CCL staff and campaign staff on nOPV2 management, reverse logistics, recording and reporting requirements.
- ❒ Ensure that all institutions or persons responsible for checking and accepting vaccines on arrival are aware that nOPV2 is not registered in the country and must be accepted as per the WHO EUL or NRA/MoH-provided waiver.
- ❒ Ensure the vaccine arrival form is duly filled, signed and sent to the UNICEF country office within 24 hours of vaccine arrival.
- ❒ Inspect, count and verify vaccine quantities with shipping documentation on reception.
- ❒ Confirm no mOPV2 is remaining in the country; or, if doses are awaiting destruction, ensure they are removed from cold chain, counted and stored separately in a central warehouse.

Further details on activities to be held before a campaign are provided in the technical guidance prepared on *Novel Oral Polio Vaccine (nOPV2) Management, Monitoring, Removal and Disposal (in 50-dose vials with VVM type 2): Technical Guidance*.[4] A full pre-campaign checklist across all nOPV2 readiness categories can be found online.[5]

Step 3: Implementing post-use activities

Post-use activities are critical to ensure nOPV2 containment is maintained, vaccine accountability is upheld through the completion of nOPV2 campaign rounds, and campaign reporting itself is shared so as to meet the EUL requirements for monitoring nOPV2 use.

Table 3 summarizes post-campaigns activities for vaccine management. Further details on activities to be held after a campaign are provided in the technical guidance for nOPV2.[4] A full post-campaign checklist across all nOPV2 readiness categories can be found online.[6]

[4] Novel Oral Polio Vaccine (nOPV2) Management, Monitoring, Removal and Disposal (in 50-dose vials with VVM type 2): Technical Guidance. Geneva: World Health Organization; 2021. (http://polioeradication.org/wp-content/uploads/2021/10/nOPV2-Vaccine-Handling.pdf). All documents and guidance on nOPV2 can be found at http://polioeradication.org/nOPV2.

[5] nOPV2 pre-campaign checklist: Activities to complete prior to launch of nOPV2 response. (https://bit.ly/nOPV2-pre-campaign-checklist).

[6] nOPV2 post-campaign checklist: Activities to complete after an nOPV2 response. (https://bit.ly/nOPV2-post-campaign-checklist).

Table 3. Vaccine management and containment post-campaign activities

When to start	Activities
within 2 days of completion of each round	After each campaign round, the district stores should retrieve all nOPV2 vials.
within 7 days of completion of each round	All nOPV2 vials should be counted at district stores and quantities reported to the national level within 7 days using the standard Form A (see Annex B). 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. 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.
Within 14 days of completion of each round	The National Logistics Working Group should collate all Form As from the lower levels and summarize into the national-level Form A. The GPEI coordinator or incident manager (IM) should work closely to ensure this documentation is submitted to the national EPI manager, MoH and UNICEF country office. Form A documentation should be submitted to the UNICEF and WHO regional offices (ROs), Rapid Response Team and ORPG secretariat within 14 days after the campaign.
After conclusion of final round	Opened/damaged vials: Remaining opened nOPV2 vials (partially or fully used), expired, damaged, and with VVM reached to-discard point (unusable stage) must be taken out of the cold chain and destroyed together with other medical waste at the regional/national level according to national guidelines. This process should be reported using the vial disposal report. Unopened/usable vials: If a country has a remaining stock balance after all planned SIAs are conducted, the country team should inform the relevant regional office and ORPG. The country team should have available the stock balance report with expiry dates and the VVM status. The country team should also be able to report on the reason for the remaining stock-balance. On the recommendation of the Outbreak Response Assessment (OBRA) or ORPG and RO, all remaining unopened vials will be inactivated and safely destroyed at the designated national-level store as per national regulations for medical waste disposal.
When the outbreak has concluded	Monitor and validate the withdrawal of nOPV2 by nominating a National Certification Committee (NCC) or other independent national body to validate the absence of nOPV2 stocks following the end conclusion of campaigns. Select and train independent monitors to conduct site visits at all cold chain stores, including from private stores, the national to the provincial or state and district levels, and selected service delivery points (health facilities) below the district area. Take corrective action to remove any type 2-containing OPV stocks found in the cold chain and mark these stocks for destruction. Obtain validation from the NCC or the nominated independent national body of the absence of nOPV2 stocks based on the reports from the monitors.

Annex A: Readiness requirements

For further guidance and details, see: *Preparing for nOPV2 Use: An overview on requirements for countries*

Category	Ref #	Requirement
Coordination	A1	Confirmation that a national coordinating mechanism/body has been created and technical committees have been established to oversee preparations for nOPV2 across the following critical areas: a) cold chain, logistics and vaccine management; b) safety/causality; c) advocacy, communications and social mobilization; d) surveillance; and e) laboratory.
Approvals	B1	Official documentation (letter, meeting minutes) confirming national decision by the relevant national immunization body to use nOPV2 for outbreak response.
	B2	Documentation from the NRA confirming approval for the import and use of nOPV2.
Cold Chain / Vx Mgmt	C1	National logistics plan is updated to include: a) cold chain equipment inventory and gap analysis; b) updated vaccine management tools for nOPV2 (50-dose vial); and c) vaccine management plans, outlining how vial tracking and disposal will be handled.
Surveillance	D1	National surveillance guidelines and supporting documents are updated to include: a) plans for active case search at priority sites; b) plans confirming 60-day follow-up for all AFP cases with nOPV2 detected in stool samples; and c) plan for collecting vaccination coverage data from community members around AFP VDPV2 cases.
	D2	Provide evidence that the CIF has been adapted (if needed) and records polio routine and SIA doses by submitting 3 filled in CIFs.
	D3	A primary immunodeficiency disorder (PID) diagnostic capacity checklist has been completed.
Safety	F1	Confirmation of nOPV2 safety surveillance monitoring activities including: a) active AESI safety monitoring protocol for nOPV2; and b) national AEFI surveillance manual or abridged guide and key forms.
	F2	An operational plan for implementing nOPV2 safety surveillance is developed, which includes plans for implementing AEFI and AESI surveillance, along with plans for managing a vaccine-related event (VRE) and confirmation of data-sharing processes and timelines.
	F3	Key nOPV2-related safety trainings have been completed or are planned.
	F4	Causality assessment committee is oriented on nOPV2 and equipped to conduct AEFI/AESI causality assessments as demonstrated through: a) terms of reference along with list of members (noting their specialty); b) training plans; and c) if applicable, previous meeting minutes.
Advocacy, Communi-cations and Social Mobilization (ACSM)	G1	Finalized advocacy strategy for key in-country stakeholders (e.g., medical practitioners, religious and community leaders).
	G2	C4D action plan that includes: a) nOPV2 communications and messaging adapted to the local context; b) key actors, including frontline workers, have been trained or plans are detailed to provide training; c) all stakeholders have been mapped and plans for sensitization outlined; d) concrete plans for digital platforms have been developed; e) all necessary messaging, tools and products and f) the outline of how the country will meet the communication-specific EUL commitments.
	G3	A crisis communications plan that addresses possible VREs and possible public controversy. Detailed digital and misinformation management plan and implementation structure description. The plan should include tailored social listening approaches, content to respond to misinformation on-line and offline, and plan on how crisis communications training was/will be conducted.
Lab	H1	A plan has been developed to prepare the national lab for nOPV2 use, including updating the isolation algorithms and stocking/ training on the ITD testing kits for both AFP and ES along with modifications to the reporting mechanism.
	H2	Relevant laboratories are prepared to ship samples to CDC or NIBSC for complete genome sequencing.

Category E, which related to environmental surveillance requirements under the initial use phase, is now a recommended but not required activity in the EUL period. No documents/data need to be submitted for verification under category E.

Annex B

Form A: End of round nOPV2 distribution and utilization report

An editable version of this form can be found online: download Form A-End of Round nOPV2 Distribution and Utilization Report

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.*

Vial disposal report

An editable version of this form can be found online: download the Vial Disposal Report

nOPV2 VIAL DISPOSAL REPORT

Date:
Region:
Disposal site:

Round number (GPEI number):
District:

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:

Vaccine accountability monitoring form

An editable version of this form can be found online: download the Vaccine Accountability Monitoring Form

DISTRICT VACCINE ACCOUNTABILITY MONITORING FORM											
Name of District:……				Name of Province:……							
Date:……						Campaign day no:……					
Vaccines received by health facilities						**Vaccines returned from health facilities**					
S/No.	Name of health facility	No. of vials received by health facility	Batch no.	Name of health facility cold chain officer (CCO)	Signature of health facility CCO	No. of 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…….

Vaccine management resources

Resource	Description	For more information
Novel OPV2 Oral Polio Vaccine (nOPV2) Management, Monitoring, Removal and Disposal (in 50-dose vials with VVM type 2): Technical Guidance.	The technical guidance provides detailed vaccine handling guidance for nOPV2: its development to support polio eradication, its regulatory and programmatic requirements under EUL status, its potential management-related risks, its protocols for release from the global stockpile, and its impact on estimating vaccine needs, as well as receiving, storing, transporting, distributing, managing and accounting for all nOPV2 vials. Roles and responsibilities for all vaccine management staff are included, and an overview on key management activities. The technical guidance also includes forms for nOPV2 utilization and disposal.	Link
nOPV2 request form	Request form that should be used by countries for release of nOPV2 from the global stockpile. Review of the form is provided by the WHO Director-General.	Online here, under “Vaccines and Logistics”
Pre-campaign checklist	Details activities that should be completed across all categories of the EUL requirements or areas of work before nOPV2 use.	nOPV2 pre-campaign checklist
Post-campaign checklist	Details activities that should be completed across all categories of the EUL requirements or areas of work before nOPV2 use.	nOPV2 post-campaign checklist
Vaccine management toolkit	Comprehensive materials to support nOPV2 vaccine management. Includes: physical inventories form, a generic tally sheet, daily summary sheets, vaccine vials monitoring forms, transfer slips for usable and usable vials, disposal report, supervision form to check best practices in health facilities, data collection tool to spot check the absence of type 2 vaccine and reporting form for the NCC to endorse the absence of type 2 vaccine.	Contact nOPV2@who.int for the most up-to-date version.
Electronic toolkit	Provides electronic-based, ODK resources for countries that have capacity for digital tools. Includes a questionnaire for Form A, a questionnaire for vaccine stock control and real-time online dashboards on vaccine management, stock balances and unaccounted vials.	Contact nOPV2@who.int for the most up-to-date version.
Guidance Note on Cold Chain Logistics and Vaccine Management during SIAs	Supports national immunization programmes in planning and managing their vaccine supplies in-country. Provides a framework to guide and strengthen country-level cold chain logistics and vaccine management activities.	Link
WHO/UNICEF Effective Vaccine Management Guidelines	Tool to assess and prioritize improvements in the immunization supply chain. EVM2 provides countries with a broader, agile and sustainable solution for improving immunization supply chain systems.	EVM2 extranet site