

# nOPV2 Readiness Verification and Dose Release Process



## Using nOPV2 under an Emergency Use Listing

*Updated version: October 2021*

### Readiness Verification

#### Overview

Roll out and use of novel oral polio type 2 vaccine (nOPV2) will require verification that a country has met all readiness requirements for use of nOPV2 under the Emergency Use Listing (EUL). Doses will not be released from the global stockpile without verification that the country has met all requirements.

To be verified for nOPV2 use, countries will need to meet a set of 17 requirements across the following areas: Coordination, Approvals (Regulatory and National decision making), Vaccine Management/Cold Chain, Surveillance, Safety, ACSM (Advocacy, Communications and Social Mobilization), and Laboratories. For the detailed list of nOPV2 readiness requirements, please consult Annex A or consult [Preparing for nOPV2 use: an overview on requirements for countries](#).

nOPV2 Readiness verification will not include an assessment of campaign strategy, scope, target population, operational issues or timing proposals; these will be looked at as part of nOPV2 dose release.

#### Readiness Verification Process

There are two steps to readiness verification: (1) Ongoing progress monitoring, which is done by WHO and UNICEF regional offices and (2) Readiness verification, which is conducted by the global GPEI Readiness Verification Team (RVT), with support from the regional offices.

##### **(1) Ongoing progress monitoring- Led by regional offices**

- Upon expressing interest in preparing for nOPV2 use, a country coordinates with their regional nOPV2 focal point to provide regular updates on progress
- The regional nOPV2 focal point and regional subject matter experts provide input/guidance to countries on draft documents
  - Once country has completed all the requirements in one area (i.e. Safety, Surveillance etc) the region reviews the submission for completeness, and then forwards the documents onwards for verification at global level
  - Any critical gaps identified will be addressed jointly with the country prior to submitting documentation onwards to global level.
- The region may request the global RVT to review and provide input on draft documents at any point in time.

## (2) Readiness verification- Led by Global level

- Global level subject matter experts review submissions
- When all components of a given readiness requirement have been met, that requirement is considered verified
- Once it has been confirmed that all requirements have been met, a country receives its nOPV2 readiness verification and is eligible for the dose release process.
- The readiness verification step can take place before an nOPV2 response is planned, or in conjunction with planning a specific nOPV2 response

### Global RVT Review timelines

- **Working Day 0:**
  - Receipt of documents from region: nOPV2 RVT secretariat acknowledges submission and shares with the relevant nOPV2 RVT members for review
- **Priority countries (those flagged by regions as priority—i.e. with active outbreaks):**
  - **Working Day 0-2:**
    - 2 working days for RVT members to review the documents in their specific area of expertise and ensure readiness compliance. For their area of expertise, RVT members should flag any:
      - **'critical gaps'** (i.e. verification must be withheld until addressed)
      - **'issues to address'** (i.e. areas of concern, but which we feel can be jointly addressed in a timely manner and thus verification can proceed)
    - Submit assessment to secretariat by end of working day 2.
  - **Working Day 3:**
    - Secretariat consolidates inputs, requests clarification from RVT members if needed, and sends feedback to regional team for onward distribution
- **All other countries:**
  - **Working Day 0-4:**
    - 4 working days for RVT members to review the documents in their specific area of expertise and ensure readiness compliance. For their area of expertise, RVT members should flag any:
      - **'critical gaps'** (i.e. verification must be withheld until addressed)
      - **'issues to address'** (i.e. areas of concern, but which we feel can be jointly addressed in a timely manner and thus verification can proceed)
    - Submit assessment to secretariat by end of working day 4.
  - **Working Day 5:**
    - Secretariat consolidates inputs, requests clarification from RVT members if needed, and sends feedback to regional team for onward distribution
- **At conclusion of the review period**
  - The nOPV2 RVT secretariat will share an updated readiness report with the country and simultaneously share with the Outbreak Response and Preparedness Group (ORPG)
  - The readiness report will include any issues that need to be addressed prior to nOPV2 use and support available to do so.
  - Should critical gaps be identified, either global or regional level teams may request a call with the country to align on next steps; if the country has concerns upon receipt of the readiness checklist, they can request a call as well.

## Submission guidance

- **PREPARE.**
  - Technical guidance documents are available to support countries in pulling together the necessary documentation to achieve verification. Please see Annex A for additional details.
  - Countries are encouraged to reach out directly to regional nOPV2 and technical focal points for support and guidance. Contact [nOPV2@who.int](mailto:nOPV2@who.int) with any questions
- **CHECK.**
  - Before submission for verification please CHECK the document to see if it matches all criteria and make sure that it has been REVIEWED by the relevant in-country partners. Rushing to submit incomplete documents is consistently leading to delays in verification.
- **SUBMISSION FORMAT.**
  - **PLEASE NAME YOUR DOCUMENT USING THE FOLLOWING CONVENTION**
    - **Start with the reference code for the requirement** (i.e F2)
    - **Next add your country name** (i.e F2\_Somalia)
    - **Provide a description of document** (i.e F2\_Somalia\_operational plan)
    - **Add the date, for version control** (i.e F2\_Somalia\_operational plan\_14feb22)
  - **TRY TO CONSOLIDATE.** One combined document should be submitted per indicator, where possible.
    - **Where there are multiple components to a requirement that can not be submitted jointly**, please name them as per the requirements table (Annex A)—i.e. vaccine management tools would be *C1b\_Tajikistan\_updated vaccine management tools\_1mar22* and vaccine management plans would be *C1c\_Tajikistan\_vaccine management plans\_9mar22*
  - **FILE TYPE.** Documents should be submitted in a format that allows for comments to be added in the document (i.e. word, excel, if needed PDF)
- **SENDING.**
  - Countries should submit documents to their regional nOPV2 team; regional teams in turn submit to global RVT after regional review is complete
- **QUESTIONS.**
  - Questions can be directed to [nOPV2@who.int](mailto:nOPV2@who.int)

## Membership of the Global RVT

Readiness verification is conducted by a Readiness Verification Team (RVT), which is established by the Global Polio Eradication Initiative (GPEI) to oversee this process. The RVT will include the following membership, each of whom will review readiness elements within their own area of expertise.

- nOPV Working Group – Will chair the RVT and ensure linkages across various workstreams
- Outbreak Response and Preparedness Group (ORPG)
- Surveillance Task Team (STT)
- Safety subject matter experts
- Global Communications Group representatives
- Dedicated secretariat

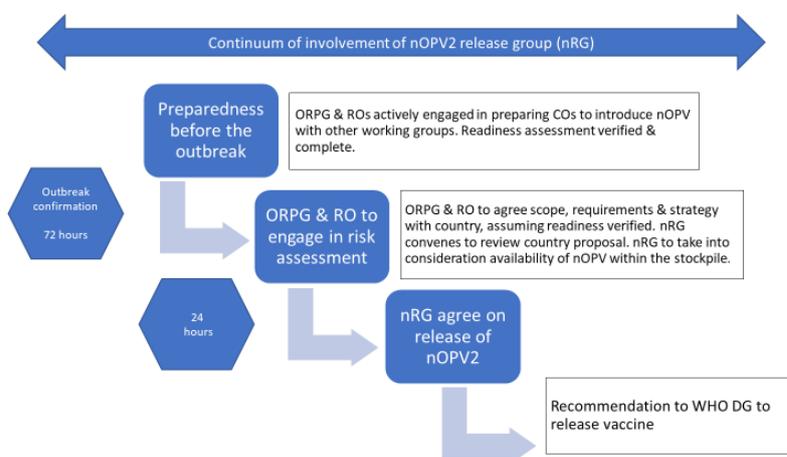
## Process for the release of nOPV2

### Introduction/context

This document outlines the process for the release of nOPV2 and takes into consideration the unique requirements that must be met for the use of nOPV2 under an Emergency Use Listing (EUL) recommendation. This document is developed with the assumption that a country has already completed all 17 requirements for readiness verification (see Annex A). This document is aligned with the Global Polio Eradication Initiative (GPEI) document Standard Operating Procedures for Responding to a Poliovirus Event and Outbreak.

The nOPV2 release from the global stockpile requires the approval of the WHO Director-General. Any request to use nOPV2 in response to isolation of VDPV2, will be reviewed and vetted by the nOPV2 Release Group (nRG). The nRG is a group of experts that looks at the countries' proposals and advise the WHO DG on vaccine release. The group mainly consists of members from the GPEI Outbreak Response and Preparedness Response Group (ORPG) as well as members from respective WHO and UNICEF regional offices. A laboratory expert may also be involved in the decision discussions, to provide additional analysis of risk to inform the final decision. As showing in Fig. 1, the nRG will be actively involved working with countries to support all phases of outbreak response working closely with regional offices of WHO and UNICEF.

Fig. 1. Continuum of involvement of nOPV2 release group (nRG)



Source: WHO, 2021

ORPG and ROs will continue to be actively engaged in preparing countries for the eventual use of nOPV2 and given the contextual realities at field level. ORPG and relevant regional focal point will be well familiar with the quality of preparedness of any given country, which will remain particularly important until nOPV2 is licensed and pre-qualified.

## Step 1: upon confirmation of an outbreak of cVDPV2 (Day 0)

The country team initiates development of a detailed risk assessment with the support of the regional (includes Hub, RRT, IMST) team and ORPG. All regional offices (WHO and UNICEF) will nominate a focal point who will be actively engaged in working with the country team to finalize the risk assessment within 72 hours of confirmation of an outbreak, for review and approval; they will remain the point of contact and engagement throughout this process. The ORPG will have a small team engaged in this process.

While laboratory and epidemiologic investigative steps correspond in general to standardized processes for following-up any poliovirus detection, the risk assessment aims to characterize the virus transmission and the implications for its further spread. It assesses the critical factors which will influence the type and scale of response, and make recommendations for appropriate actions. For type 2 poliovirus, the risk assessment focuses specifically on outlining the virological risk and contextual risk of further transmission and potential for international spread. The risk assessment would address three core questions (1) What is the nature of the virus (e.g. WPV, Sabin, or VDPV)? (2) Is there evidence of circulation? and (3) what is the risk of further spread? The RO/Hub/IMST/RRT ORPG will work with the country team to develop the risk assessment, including information on the characteristics of the cases, areas drained by the environmental samples collection sites, population immunity against type-2 poliovirus, surveillance sensitivity / quality, population movement, program capacity to implement SIAs and any other relevant/specific information (the secretariat will share the risk assessment template to the country and regional programs, as guidance). The risk assessment should outline options and vaccine requests as part of the proposed outbreak response activity.

As outlined above this process assumes that country has taken the decision to use nOPV2 and has already been verified for nOPV2 use. The completed readiness report from the global Readiness Verification Team (RVT) will accompany the submission of the risk assessment by the country team.

Following the decision to release nOPV2, the country team will be asked to submit an outbreak response plan that outlines how the country will implement quality campaigns.

## Step 2: within 72 hours of outbreak confirmation

The nOPV2 Release Group (nRG) will:

1. Review risk assessment (combined HQ/RO/CO risk assessment) which should include country context, genetic data, analysis of risk
2. Decide if the situation warrants the use of nOPV2
3. Review country vaccine request and assess the quantity of vaccine (nOPV2), if required
4. Ensure that the proposed vaccination response is 4 weeks after any other polio campaign in the same area
5. Advise the WHO Director-General on nOPV2 vaccine release from the global or national stockpile for supplementary immunization activities (SIAs).

The nRG will advise the country team on:

- scope of the nOPV2 SIAs in terms of geographical scale, target age group and number of children to be targeted including using available program GIS data, such as GRID3; and
- nOPV2 vaccination outside of SIAs in special situations during active outbreaks, e.g. access opportunities in longstanding inaccessible areas, outreach to special populations (like trapped populations etc.), transit vaccination etc.

Within 48 hours of the submission of the risk assessment<sup>1</sup>, the nRG will review the vaccine request and response plan prepared by the requesting country. Through the Director, Polio Eradication WHO the nRG will advise the WHO Director General on the request and their recommendation. The nOPV2 secretariat will process all necessary communication throughout this process as outlined below.

The nRG is responsible for deciding (1) if the situation warrants the use of vaccine and, if vaccine use is approved, (2) the vaccination campaign's geographic scope. The decision on the scope of campaigns and the release of vaccines from the stockpile requires a **majority** decision. If the members are not able to reach a decision, the matter will be immediately referred to the GPEI Strategy Committee (SC) through the Executive Management Unit (EMU) by the secretariat for final decision.

The DG will decide within 24 hours of receiving the request whether to release the vaccine from the global stockpile. The WHO DG authorizes nOPV2 vaccine release for first and subsequent SIAs. This can be done in a single request or multiple phases, if needed.

## Secretariat

The nOPV2 secretariat provides coordination and support to the nRG. WHO headquarters hosts it with a nominated lead in the WHO Polio Eradication Programme.

## Tracking of vaccines

Given GPEI's accountability to plan and manage the Global OPV2 Stockpile and advising WHO DG on nOPV2 release to the countries, the Vaccine Supply Group (VSG) will work closely with ORPG to ensure that vaccine distribution plans align with the global supply, as well as identifying and addressing risks associated to nOPV2 supply for response to cVDPV2 outbreaks.

The ORPG will engage with the WHO Global Stockpile focal point and UNICEF supply division to develop and report weekly on the vaccine distribution plans. The WHO Global Stockpile focal point and UNICEF supply division will support ORPG in tracking the decisions of the ORPG/RO, the WHO DG and the distribution of the vaccines to each country.

The UNICEF country office will be expected to report back to the secretariat on nOPV2 stocks in the country two weeks after the end of each SIA, when a subsequent SIA is not planned. Use of nOPV2 in country will be guided by the document [nOPV2 Management, Monitoring, Removal and Disposal \(in 50 dose vials with VVM type 2\): Technical Guidance](#).

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<sup>1</sup> The Risk Assessment template can be found online at <http://polioeradication.org/wp-content/uploads/2020/12/0-Risk-assess-template-nOPV2-AE-20201208.pptx> (accessed on 8 December 2020).

## Annex A: Requirements for nOPV2 readiness verification

For more information please see: [Preparing for nOPV2 use: an overview on requirements for countries](#)

Category	Ref #	Requirement	What needs to be submitted	Available guidance + template
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.	Verified by region. Contact your regional office for further details.	n/a
Approvals	B1	Official documentation (letter, meeting minutes) confirming national decision by the relevant national immunization body to use nOPV2 for outbreak response.	Confirmation by NITAG (or other national immunization, polio coordination body, or Ministry of Health [MoH]) as follows: <ul style="list-style-type: none"> <li>• <i>Option 1:</i> Meeting minutes which should include: <ul style="list-style-type: none"> <li>○ Signature by chair</li> <li>○ List of members</li> <li>○ Date</li> </ul> </li> <li>• <i>Option 2:</i> Formal letter from the NITAG or MoH confirming decision to proceed with use of nOPV2.</li> </ul>	n/a
	B2	Documentation from the NRA confirming approval for the import and use of nOPV2.	A formal letter/written authorization from the National Regulatory Authority (NRA) authorizing the import of the vaccine into the country and its use. Where there is no NRA in country, this can come from the MoH	n/a
Cold Chain / Vaccine Management	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 developed for nOPV2 use that addresses/includes the following components: <ul style="list-style-type: none"> <li>• The active cold chain inventory (less than one year old)</li> <li>• The passive cold chain inventory (less than one year old)</li> <li>• 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, measles)</li> <li>• Plan to address any gaps in capacity, if identified</li> <li>• 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 Excel/paper tools)</li> <li>• Plans for training/capacity building of cold chain logistics staff and campaign staff on nOPV2 vial management</li> <li>• Description of processes to ensure vial tracking and accountability, along with post-campaign disposal.</li> </ul>	<a href="#">Cold Chain and Vaccine Management Requirements in the Context of nOPV2 Use</a>  <a href="#">Novel Oral Polio Vaccine (nOPV2) Management, Monitoring, Removal and Disposal (in 50-dose vials with VVM type 2): Technical Guidance</a>

Category	Ref #	Requirement	What needs to be submitted	Available guidance + template
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 exam 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.	Country's updated surveillance guidelines to reflect nOPV2-specific requirements (document itself updated, or addition of an annex) and supporting documents which include details on the following post-campaign activities: <ul style="list-style-type: none"> <li>How active case searches will be carried out in all priority sites in each geographic area where nOPV2 was used, within 6 weeks following nOPV2 use in that area.</li> <li>How 60-day follow-up will be done for all AFP cases with nOPV2 detection in stool.</li> <li>How vaccination coverage data from age-matched, randomly selected community members around AFP VDPV2 cases will be collected.</li> </ul>	<a href="#">Polio Field and Laboratory Surveillance requirements in the Context of nOPV2 Use</a>
	D2	Provide evidence that the CIF has been adapted (if needed) and records polio routine and SIA doses by submitting 3 filled in CIFs.	At least three completed CIFs should be submitted with the following clearly noted: <ul style="list-style-type: none"> <li>Routine and SIA OPV doses</li> <li>Date of last IPV/OPV dose received</li> </ul>	<a href="#">Polio Field and Laboratory Surveillance requirements in the Context of nOPV2 Use</a>
	D3	A primary immunodeficiency disorder (PID) diagnostic capacity checklist has been completed.	A completed PID checklist is submitted. NOTE: there is no requirement for PID capacity in the country for nOPV2 use; but where it exists, data will be collected.	<a href="#">Polio Field and Laboratory Surveillance requirements in the Context of nOPV2 Use</a>
Safety	F1	Confirmation of nOPV2 safety surveillance monitoring activities including: (a) an active AESI safety monitoring protocol for nOPV2; and (b) a national AEFI surveillance manual or abridged guide and key forms.	<ul style="list-style-type: none"> <li>AESI active search protocol</li> <li>AEFI surveillance manual or abridged guide (if submitting abridged guide also submit the AEFI reporting form and AEFI investigation form).</li> </ul>	<a href="#">Vaccine Safety Requirements in the Context of nOPV2 Use</a>  <a href="#">Guide for Surveillance of Adverse Events of Special Interest (AESI) during Novel Oral Polio Vaccine Type 2 (nOPV2) Use</a>
	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.	<ul style="list-style-type: none"> <li>Operational plan for implementing nOPV2 safety surveillance activities.</li> <li>Key components of the VRE response plan.</li> <li>Data sharing process and timelines (for sharing of data globally and with other countries).</li> </ul>	<a href="#">Vaccine Safety Requirements in the Context of nOPV2 Use</a>
	F3	Key nOPV2-related safety trainings have been completed or are planned.	Completed training status template, which covers trainings already conducted and outlines those planned. NOTE: Causality Assessment Committee trainings are in F4.	<a href="#">Vaccine Safety Requirements in the Context of nOPV2 Use</a>
	F4	Causality Assessment Committee is oriented on nOPV2 and equipped to conduct AEFI/AESI causality assessments as demonstrated through (a) terms of reference (TORs) along	Formal documents that recognize the work of the causality assessment committee should be submitted including: <ul style="list-style-type: none"> <li>TORs for Causality Assessment Committee.</li> </ul>	<a href="#">Vaccine Safety Requirements in the Context of nOPV2 Use</a>

Category	Ref #	Requirement	What needs to be submitted	Available guidance + template
		with list of members (noting their specialty), (b) training plans and (c) if applicable, previous meeting minutes.	<ul style="list-style-type: none"> <li>List of expert committee members and specialty (if specialties not included in the official list, please add a separate document to specify specialties of members).</li> <li>Training reports: details on dates, facilitators and agenda for Causality committee both on general refresher and nOPV2 specifics.</li> <li>If the committee is already functional, the minutes of the last expert committee meeting should be included. If the committee is newly established, certificates demonstrating all members have completed the trainings should be provided prior to the start of the campaign.</li> </ul>	
ACSM	G1	Finalized advocacy strategy for key in-country stakeholders (e.g., medical practitioners, religious and community leaders).	Advocacy strategy	<a href="#">Programme Advocacy package for cVDPV Outbreak Response and nOPV2 Introduction</a>
	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.	C4D Plan, including the components noted.	<a href="#">Communication for Development Guidance for cVDPV2 Outbreak Response including the use of Novel OPV2 (nOPV2)</a>  <a href="#">Template for Designing a Behavioral Strategy</a>  <a href="#">nOPV2 Use under EUL Communication Focus</a>
	G3	A crisis communications plan that addresses possible vaccine-related events and possible public controversy.	<p>Crisis communications plan should also include:</p> <ul style="list-style-type: none"> <li>Detailed digital and misinformation management plan and implementation structure description.</li> <li>Tailored social listening approaches, content to respond to misinformation on-line and offline</li> <li>Plan on how crisis communications training was/will be conducted</li> </ul>	<a href="#">nOPV2 Crisis Communications Toolkit</a>  <a href="#">Vaccine Misinformation Management Field Guide</a>
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	Verified by region; please contact your regional office for further details.	<a href="#">Polio Field and Laboratory Surveillance requirements in the Context of nOPV2 Use</a>
	H2	Relevant laboratories are prepared to ship samples to CDC or NIBSC for complete genome sequencing	Verified by region; please contact your regional office for further details.	<a href="#">Polio Field and Laboratory Surveillance requirements in the Context of nOPV2 Use</a>