POLIO
GLOBAL ERADICATION INITIATIVE

Preparing for nOPV2 Use:
An overview on requirements for countries

EVERY LAST CHILD

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The Global Polio Eradication Initiative (GPEI) has a new tool to respond to the increasing risk of circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreaks, which can emerge when the weakened strain of the vaccine virus circulates in under-immunized populations and, with time, can genetically revert into a form that causes paralysis.

The **novel oral polio vaccine type 2 (nOPV2)** is a modified version of the existing monovalent oral polio type 2 vaccine (mOPV2, also known as Sabin OPV2). As nOPV2 has been shown in studies to provide comparable protection to mOPV2 against type 2 poliovirus while being less likely to lead to cVDPV2, nOPV2 received a recommendation for use through the Emergency Use Listing procedure (EUL) of the World Health Organization (WHO). The EUL is a regulatory pathway that is available for use in Public Health Emergencies of International Concern, so vaccines and medicines can be made available more quickly to address health emergencies. nOPV2 received its EUL recommendation in November 2020.[1]

Based on their review of data and research available on nOPV2, the Strategic Advisory Group of Experts on Immunization (SAGE) recommended that nOPV2 become the vaccine of choice for responding to type 2 outbreaks and events following an initial use phase.[2] Data from this initial use phase was collected from four countries with over 70 million doses administered from March through August 2021. The Global Advisory Committee on Vaccine Safety (GACVS), tasked with actively reviewing nOPV2 safety data from this period, affirmed there are no serious safety concerns from nOPV2 use. Consequently, in their review of the initial phase, SAGE approved nOPV2 for wider use in October 2021.[3]

Additional information on nOPV2, including FAQs, policy statements and scientific data can be found online at: www.polioeradication.org/nOPV2.

Meeting the nOPV2 readiness requirements

Countries wishing to use nOPV2 under an EUL must meet established criteria to ensure readiness to implement specific activities. Countries at risk of cVDPV2 outbreaks, or countries looking to safeguard against a type 2 polio event, are encouraged to begin their preparations now. (See "Which countries should prepare for nOPV2 use," next page).

Many of the activities to implement nOPV2 campaigns are the same as those required to conduct a standard polio outbreak response; however, some activities, including monitoring for vaccine safety, may be new to country programmes.

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[1] World Health Organization. Recommendation for an Emergency Use Listing (EUL) of Novel Oral Polio Vaccine Type 2 (nOPV2) submitted by PT BioFarma (Persero). Geneva: World Health Organization, 2020 (https://extranet.who.int/pqweb/sites/default/files/documents/nOPV2_EUL_recommendation_0.pdf). For product nOPV2 information, see: https://extranet.who.int/pqweb/vaccines/polio-vaccine-novel-oral-nopv-monovalent-type-2.
[2] See SAGE meeting summary, October 2020 (https://apps.who.int/iris/bitstream/handle/10665/337100/WER9548-eng-fre.pdf).
[3] See SAGE meeting highlights, October 2021 (https://cdn.who.int/media/docs/default-source/immunization/sage/2021/october/sage_oct2021_meetinghighlights.pdf?sfvrsn=3dcae610_11).

nOPV2 is only available through a global stockpile, which is under the oversight of the WHO Director-General. Prior to release of the vaccine, countries must be verified for readiness to use nOPV2. To be verified for nOPV2 use, a country must meet 16 requirements across seven areas:

- Coordination
- Approvals (regulatory and national decision making)
- Cold Chain and Vaccine Management
- Surveillance
- Safety
- Advocacy, Communications and Social Mobilization (ACSM)
- Laboratories

For the detailed list of requirements, **alongside relevant guidance documents and templates**, please consult **Annex A**. For easy reference, each readiness requirement item has a corresponding category and number (e.g., A1, D3).

WHO regional offices have dedicated nOPV2 focal points to liaise with countries. Furthermore, the GPEI has established a global nOPV Working Group to coordinate efforts and address additional queries; they can be contacted at nOPV2@who.int.

Which countries should prepare for nOPV2 use?

Because outbreaks often occur with little warning and because the requirements for using nOPV2 under EUL take time to implement, all countries at risk of a cVDPV2 outbreak are encouraged to start planning for nOPV2 implementation as soon as possible.

Countries considered at high risk for cVDPV2 are:

- Countries with VDPV2 detections in the past 6 months through acute flaccid paralysis (AFP) surveillance or environmental surveillance
- Countries that have had a cVDPV2 detection in the past 6-12 months
- Countries that border countries that meet the above criteria.

Other countries in regions where cVDPV2 has been detected, which do not meet these criteria but would like to be prepared for a possible VDPV2 detection and subsequent response with nOPV2, are encouraged to start preparations to avoid any possible delays.

Receiving verification for nOPV2 use

Countries interested in nOPV2 use will need to follow a prescribed process, supported by their respective regional offices and nOPV2 focal points. This verification process will be required throughout the nOPV2 EUL period, until the vaccine is fully licensed and receives pre-qualification, which is anticipated by end of 2023.

Verification process for nOPV2

1. **Prepare.** Countries begin to prepare for nOPV2 use by reviewing the readiness requirements (see **Annex A**) and working together with GPEI partners at the country and regional levels to complete their readiness planning and corresponding documentation. The nOPV2 requirements can be completed in any order, depending on country preference and programme context.

2. **Submit.** Once requirements have been completed, country documentation is submitted to the nOPV2 focal point at the WHO regional office.

3. **Regional review.** Regional offices review country submissions and flag any concerns.

4. **Global review.** After regional review, for most requirements, the documentation will be forwarded for global review by GPEI subject matter experts, who will evaluate the submission to ensure each EUL requirement has been met.

5. **Feedback.** Upon confirmation from the GPEI that a requirement has been met, an updated readiness report will be shared with the regional team for onwards dissemination to the country programme. If a requirement has not been met, a global subject matter expert will send back an updated readiness report, indicating what needs to be done to meet the requirement and highlighting available support.

6. **Verification.** Once all requirements have been met, the global team will issue a verification report, with a copy to both the regional office and nOPV2 dose release secretariat.

After all 16 requirements have been met, the country is verified for nOPV2 use. This verification is a one-time occurrence: once a country receives verification, they can request nOPV2 as needed in the future without needing to provide readiness documentation again.

Responding to outbreaks with nOPV2

After a country has been verified for nOPV2 use, the country programme can respond to a cVDPV2 outbreak or polio event by requesting nOPV2 from the global stockpile. The release of the vaccine is done on approval of the WHO Director-General. In review of a country's request, any additional specifications for outbreak response may be established (e.g., target age), depending on available supply, country-level and regional epidemiology and other potential considerations relevant to the specific context of the outbreak.[4]

Monitoring the implementation of the nOPV2 requirements outlined in country readiness verification documents is essential to ensuring countries meet the WHO EUL requirements.

To support implementation of nOPV2 activities before, during and after campaigns, pre- and post-campaign checklists that summarize the key activities are available,[5] in addition to the available guidance provided in Annex A.

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[4] The nOPV2 vaccine request form (VRF) can be found on the GPEI website under "Vaccines and Logistics" at https://polioeradication.org/tools-and-library/resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/.
[5] nOPV2 pre-campaign checklist: Activities to complete prior to launch of nOPV2 response. (nOPV2-pre-campaign-checklist); nOPV2 post-campaign checklist: Activities to complete after an nOPV2 response. (nOPV2-post-camoaign-checklist).

Annex A: Requirements for nOPV2 readiness verification

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:
			• *Option 1*: Meeting minutes which should include:
			  ○ Signature by chair
			  ○ List of members
			  ○ Date
			• *Option 2*: Formal letter from the NITAG or MoH confirming decision to proceed with use of nOPV2.
				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: • The active cold chain inventory (less than one year old) • The passive cold chain inventory (less than one year old) • 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) • Plan to address any gaps in capacity, if identified • 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) • Plans for training/capacity building of cold chain logistics staff and campaign staff on nOPV2 vial management • Description of processes to ensure vial tracking and accountability, along with post-campaign disposal.	[Cold Chain and Vaccine Management Requirements in the Context of nOPV2 Use](#) [Novel Oral Polio Vaccine (nOPV2) Management, Monitoring, Removal and Disposal (in 50-dose vials with VVM type 2): Technical Guidance](#)
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	Country's updated surveillance guidelines to reflect nOPV2-specific requirements (document itself updated, or addition of an annex) and	[Polio Field and Laboratory Surveillance requirements](#)

Category	Ref #	Requirement	What needs to be submitted	Available guidance + template
		all AFP cases with nOPV2 detected in stool samples; and (c) plan for collecting vaccination coverage data from community members around AFP VDPV2 cases.	supporting documents which include details on the following post-campaign activities: • 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. • How 60-day follow-up will be done for all AFP cases with nOPV2 detection in stool. • How vaccination coverage data from age-matched, randomly selected community members around AFP VDPV2 cases will be collected.	in the Context of nOPV2 Use
	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: • Routine and SIA OPV doses • Date of last IPV/OPV dose received	Polio Field and Laboratory Surveillance requirements in the Context of nOPV2 Use
	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.	Polio Field and Laboratory Surveillance requirements in the Context of nOPV2 Use
Safety	F1	Confirmation of nOPV2 safety surveillance monitoring activities including: a national AEFI surveillance manual or abridged guide and key forms.	• AEFI surveillance manual or abridged guide including the AEFI reporting form and AEFI investigation form • Recommended but not required: For countries planning to implement active AESI surveillance, please include a copy of the nOPV2 AESI active search guide/protocol	Vaccine Safety Requirements in the Context of nOPV2 Use Guide for Surveillance of Adverse Events of Special Interest (AESI) during Novel Oral Polio Vaccine Type 2 (nOPV2) Use
	F2	An operational plan for implementing nOPV2 safety surveillance, which includes: (1) plans for implementing AEFI ;(2) plans for managing a vaccine-related event (VRE) and confirmation of data sharing processes and timelines.	• Operational plan for implementing nOPV2 safety surveillance activities. • Key components of the VRE response plan. (Table 2 & 3 of the VRE response plan) • Data sharing process and timelines (for sharing of data globally and with other countries). • Recommended but not required: For countries planning to implement active AESI surveillance, please include a copy of the plans for implementing nOPV2 AESI active search	Vaccine Safety Requirements in the Context of nOPV2 Use
	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.	Vaccine Safety Requirements in the Context of nOPV2 Use

Category	Ref #	Requirement	What needs to be submitted	Available guidance + template
	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 with list of members (noting their specialty), (b) training plans and (c) if applicable, previous meeting minutes.	Formal documents that recognize the work of the causality assessment committee should be submitted including: • TORs for Causality Assessment Committee. • 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). • Training reports: details on dates, facilitators and agenda for Causality committee both on general refresher and nOPV2 specifics. • 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.	Vaccine Safety Requirements in the Context of nOPV2 Use
ACSM	G1	Finalized advocacy strategy for key in-country stakeholders (e.g., medical practitioners, religious and community leaders).	Advocacy strategy	Programme Advocacy package for cVDPV Outbreak Response and nOPV2 Introduction
	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.	Communication for Development Guidance for cVDPV2 Outbreak Response including the use of Novel OPV2 (nOPV2) Template for Designing a Behavioral Strategy nOPV2 Use under EUL Communication Focus
	G3	A crisis communications plan that addresses possible vaccine-related events and possible public controversy.	Crisis communications plan should also include: • Detailed digital and misinformation management plan and implementation structure description. • Tailored social listening approaches, content to respond to misinformation on-line and offline • Plan on how crisis communications training was/will be conducted	nOPV2 Crisis Communications Toolkit Vaccine Misinformation Management Field Guide
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.	Polio Field and Laboratory Surveillance requirements in the Context of nOPV2 Use

Category	Ref #	Requirement	What needs to be submitted	Available guidance + template
	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.	Polio Field and Laboratory Surveillance requirements in the Context of nOPV2 Use