

**IMPLEMENTATION OF NOVEL  
ORAL POLIO VACCINE TYPE 2  
(nOPV2) FOR CIRCULATING  
VACCINE-DERIVED  
POLIOVIRUS TYPE 2 (cVDPV2)  
OUTBREAK RESPONSE:  
TECHNICAL GUIDANCE FOR COUNTRIES**





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Implementation of novel oral polio vaccine type 2 (nOPV2) for circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreak response: technical guidance for countries

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# Acronyms and abbreviations

**ACSM** Advocacy, communications and social mobilization

**AEFI** Adverse event following immunization

**AESI** Adverse event of special interest

**AFP** Acute flaccid paralysis

**bOPV** Bivalent oral polio vaccine (containing OPV1 and OPV3)

**C4D** Communication for Development

**CCL&VM** Cold chain, logistics and vaccine management

**CDC** U.S. Centers for Disease Control and Prevention

**cVDPV** Circulating vaccine-derived poliovirus

**cVDPV2** Circulating vaccine-derived poliovirus type 2

**EPI** Expanded Programme on Immunization

**ES** Environmental surveillance

**EUL** Emergency Use Listing

**EVM** Effective Vaccine Management

**GPEI** Global Polio Eradication Initiative

**GPSAP** Global Polio Surveillance Action Plan 2018–2020

**IPV** Inactivated polio vaccine

**ITD** Intratypic differentiation

**mOPV1** Monovalent oral polio vaccine type 1

**mOPV2** Monovalent oral polio vaccine type 2

**mOPV3** Monovalent oral polio vaccine type 3

**NIBSC** UK National Institute for Biological Standards and Control

**NITAG** National Immunization Technical Advisory Group

**nOPV2** Novel oral polio vaccine type 2

**NPAFP** Non-polio acute flaccid paralysis

**OPV** Oral polio vaccine

**OPV1** Oral polio vaccine type 1

**OPV2** Oral polio vaccine type 2

**OPV3** Oral polio vaccine type 3

**PDM** Post-deployment monitoring

**PHEIC** Public Health Emergency of International Concern

**SAGE** Strategic Advisory Group of Experts on Immunization

**SIA** Supplementary immunization activity

**SOP** Standard operating procedure

**STT** Surveillance Task Team

**UNICEF** United Nations Children's Fund

**VDPV2** Vaccine-derived poliovirus type 2

**VI** Viral isolation

**VRE** Vaccine-related event

**VVM1** Vaccine vial monitor type 1

**VVM2** Vaccine vial monitor type 2

**WHO** World Health Organization





# Introduction

## Facilitating effective country-level decision-making on nOPV2 use

In 2020, the Global Polio Eradication Initiative (GPEI) launched a new strategy for circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreak response as part of the Polio Eradication & Endgame Strategy. Included in this strategy is the implementation of a new tool for cVDPV2 outbreak response: novel oral polio vaccine type 2 (nOPV2), a modification of the existing oral polio vaccine (OPV) type 2 (OPV2). Clinical trials have shown that nOPV2 provides comparable protection against poliovirus while being more genetically stable, which means it is less likely to revert to a form that can cause paralysis in children who have not been sufficiently immunized.

Following a WHO Emergency Use Listing (EUL) recommendation for use, nOPV2 could be available for countries to use in late 2020. The EUL involves a risk-based assessment of existing data to enable early, targeted use of unlicensed products for a Public Health Emergency of International Concern (PHEIC) such as polio.

Once an EUL recommendation for use is made, countries experiencing cVDPV2 outbreaks will be able to use nOPV2. Because the vaccine will be made available under an EUL recommendation for use, implementing nOPV2 in outbreak response will require some additional mandatory preparation, including the authorization of its importation and use as well as the monitoring of activities during and after vaccination campaigns. It is therefore critical for any country interested in using nOPV2 to begin planning well in advance.

This document aims to support country-level decision-makers in preparing for nOPV2 implementation under an EUL recommendation for use and is specifically intended for those who will be involved in selecting nOPV2 to respond to cVDPV2 outbreaks. This includes but is not limited to Expanded Programme on Immunization (EPI) managers, National Immunization Technical Advisory Groups (NITAGs) or other national immunization bodies that provide technical recommendations for vaccine introduction, appropriate actors in the national health and finance ministries, and relevant regulatory authorities at the country level. The document outlines core elements of the planning process to implement the vaccine and serves as a companion document to the GPEI nOPV2 Vaccine Deployment Readiness Checklist, featured in the Annex.

This resource will be updated so decision-makers have access to the most up-to-date guidance. The next update is currently planned for after the initial EUL recommendation for use is made and the specific EUL requirements that will apply to nOPV2 usage are finalized (Sections 1 and 2 provide more details).

# Section 1: Rationale for nOPV2 implementation

## A new strategy for responding to cVDPV2 outbreaks

Circulating vaccine-derived poliovirus (cVDPV) events and outbreaks can emerge when the weakened strain of the poliovirus contained in the OPV circulates in under-immunized populations for a long period of time. If not enough children are immunized against polio, the weakened vaccine virus can pass between individuals and, over time, genetically revert into a form that can cause paralysis. cVDPV2 is currently the most prevalent form. In recent years, an increase in outbreaks of cVDPV2 across multiple countries has posed a major challenge to eradication efforts.

To better address existing cVDPV2 transmission and help prevent future outbreaks, the GPEI has finalized a new strategy for the control of cVDPV2. The *Strategy for the Response to Type 2 Circulating Vaccine-Derived Poliovirus 2020–2021* is an addendum to the *Polio Endgame Strategy 2019–2023* that was launched in May 2019.

The *Polio Endgame Strategy 2019–2023* positioned the GPEI's current five-year strategic period in relation to the dual emergency facing the polio eradication effort: the programme's urgent need to interrupt both wild poliovirus type 1 and cVDPV transmission. In considering the potential long-term implications for cVDPV outbreaks, the Endgame Strategy signalled the importance of a contingency plan to mitigate the risk of cVDPV through near-term interventions, emergency protocols and policy changes. The *Strategy for the Response to Type 2 Circulating Vaccine-Derived Poliovirus 2020–2021* provides this contingency plan and involves the following core elements:

- Strengthening the speed and quality of responses to cVDPV2 outbreaks
- Optimizing the management of available vaccine stocks
- Implementing nOPV2, an improved version of the existing monovalent oral polio vaccine type 2 (mOPV2), for cVDPV2 outbreak response
- Creating an enabling environment for sustained vaccine uptake and trust in the programme.

These are underpinned by fundamental communications and communication for development (C4D) activities.<sup>1</sup>

The implementation of nOPV2 is therefore a key element of the GPEI's strategy for successfully responding to cVDPV2 outbreaks.

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<sup>1</sup> More background is provided in the GPEI programme strategy documents. Global Polio Eradication Initiative. *Polio Endgame Strategy 2019–2023*. Geneva: World Health Organization; 2020 (<http://polioeradication.org/wp-content/uploads/2019/06/english-polio-endgame-strategy.pdf>, accessed 25 May 2020). Global Polio Eradication Initiative. *Strategy for the Response to Type 2 Circulating Vaccine-Derived Poliovirus, 2020–2021*. Geneva: World Health Organization; 2020 (<http://polioeradication.org/wp-content/uploads/2020/04/Strategy-for-the-response-to-type-2-circulating-Vaccine-Derived-Poliovirus-20200406.pdf>, accessed 25 May 2020).

## nOPV2 AT A GLANCE

A modified version of the existing mOPV2 vaccine

### SAFETY

Data to date indicate that the safety profile is similar to mOPV2, but with decreased risk of reverting to a form that could cause paralysis in areas with low immunization coverage.

### PRESENTATION

It will come in 50-dose vials. The liquid will be similar in colour to mOPV2. The vaccine may also feature a vaccine vial monitor type 1 (VVM1) rather than a vaccine vial monitor type 2 (VVM2).

### ADMINISTRATION

Individuals receive two drops in the mouth.

### USE

It will be used in outbreak response (like mOPV2). Specific guidance for nOPV2 use will be provided through updated GPEI standard operating procedures (SOPs) for outbreak response.

## An innovative tool for outbreak response<sup>2</sup>

nOPV2 is a modified version of the existing OPV2 vaccine (also known as the Sabin OPV type 2 vaccine, or mOPV2) that provides comparable protection against poliovirus type 2. The vaccine is more genetically stable than OPV2, which makes it less likely to revert into a form that could cause paralysis in children who have not been sufficiently immunized. Development on nOPV2 started in 2011, and the first in-human clinical trial with nOPV2 was conducted in 2017 at the University of Antwerp, in Belgium. Data from this phase I study were published in *The Lancet* in 2019.<sup>3</sup> Two phase II trials are now complete, and the analysis of these data shows promising results for

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2 This section presents a summary of the safety and immunogenicity data to date for nOPV2. For more complete details and to consult relevant documents and publications, see the GPEI's nOPV2 landing page at <http://polioeradication.org/nOPV2>. Key documents include the Clinical Development Summary, which outlines the main clinical data findings for the nOPV2 candidate submitted for EUL review. The page also features a section on peer-reviewed publications related to nOPV2, including the 2019 *Lancet* article mentioned in this section.

3 Van Damme P, De Coster I, Bandyopadhyay A, Revets H, Withanage K, De Smedt P 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(10193):148-158. doi:10.1016/S0140-6736(19)31279-6.

both the effectiveness and safety of the vaccine. Data from the clinical studies<sup>4</sup> 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. No serious adverse events have been identified that are considered to be related to vaccination with nOPV2. Moreover, immunogenicity of nOPV2 was found to be non-inferior to mOPV2 in infants, meaning that nOPV2 is expected to be as effective in preventing paralytic disease as the current vaccine. Most importantly, it was established that nOPV2 is significantly more genetically stable and thus less likely to revert to neurovirulence compared to mOPV2. Collectively, the clinical trials provide a solid evidence base around the expected behaviour of the vaccine in humans. Continued monitoring of the vaccine's safety and effectiveness following an EUL recommendation for use will contribute further evidence to characterize nOPV2 safety and effectiveness in a real-world environment.

## Global plans for rollout

Given the urgent public health need to address cVDPV2 and nOPV2's similarity to the existing mOPV2, the GPEI is fast-tracking the development of nOPV2 based on positive clinical trial data to date. Plans are underway to ensure the rapid field availability of the vaccine for outbreak response through WHO's EUL procedure.<sup>5</sup>

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4 Relevant publications include the Lancet article referenced, as well as the following:

- Yeh MT, Bujaki E, Dolan PT, Smith M, Wahid R, Konz J et al. Engineering the live-attenuated polio vaccine to prevent reversion to virulence. *Cell Host & Microbe*. 2020; 27(5):736–751.e8. [doi:10.1016/j.chom.2020.04.003](https://doi.org/10.1016/j.chom.2020.04.003).
- Konopka-Anstadt JL, Campagnoli R, Vincent A, Shaw J, Wei L, Wynn NT et al. Development of a new oral poliovirus vaccine for the eradication end game using codon deoptimization. *npj Vaccines*. 2020; 5:26. [doi:10.1038/s41541-020-0176-7](https://doi.org/10.1038/s41541-020-0176-7).
- Van Damme P, De Coster I, Bandyopadhyay AS, Suykens L, Rudelsheim P, Neels P et al. Poliopolis: pushing boundaries of scientific innovations for disease eradication. *Future Microbiol*. 2019; 14:1321–1330. [doi:10.2217/fmb-2019-0196](https://doi.org/10.2217/fmb-2019-0196).
- Bandyopadhyay AS. Clinical data from novel type-2 oral polio vaccine trials and plan for emergency use listing. SAGE Presentation. Polio Session. Geneva: World Health Organization; 2019 ([https://www.who.int/immunization/sage/meetings/2019/october/Bandyopadhyay\\_polio\\_sage\\_october\\_2019.pdf](https://www.who.int/immunization/sage/meetings/2019/october/Bandyopadhyay_polio_sage_october_2019.pdf), accessed 25 May 2020).
- Bandyopadhyay AS. Summary of nOPV2 clinical data. SAGE presentation. Polio Session. Geneva: World Health Organization; 2020 ([https://www.who.int/immunization/sage/meetings/2020/april/SAGE\\_eYB\\_Mar2020.pdf?ua=1](https://www.who.int/immunization/sage/meetings/2020/april/SAGE_eYB_Mar2020.pdf?ua=1), accessed 25 May 2020).
- Global Polio Eradication Initiative. Clinical summary for novel oral polio vaccine type 2 (nOPV2). May 2020 (<http://polioeradication.org/wp-content/uploads/2020/05/Clinical-development-summary-nOPV2-20200521.pdf>, accessed 25 May 2020).

5 References include the following:

- Roadmap for assessment of nOPV2 manufactured by PT BioFarma under the EUL procedure. Geneva: World Health Organization; 2020 (<https://www.who.int/medicines/news/2020/roadmap-assessment-nOPV2.pdf?ua=1>, accessed 25 May 2020).
- Emergency Use Listing Procedure, Version 9 January 2020. Geneva: World Health Organization; 2020 ([https://extranet.who.int/prequal/sites/default/files/documents/EUL\\_Procedure\\_Jan2020.pdf](https://extranet.who.int/prequal/sites/default/files/documents/EUL_Procedure_Jan2020.pdf), accessed 25 May 2020).

The EUL assessment is currently in progress, with data being reviewed as they are submitted. At the same time, preparations are underway with the vaccine manufacturer, PT BioFarma, to produce 100 million doses of nOPV2 by the third quarter of 2020 to enable the vaccine to be deployed when WHO issues a recommendation for use. The GPEI expects that 200 million doses of nOPV2 will be available in the global stockpile by the end of 2020.

## The initial use period

Because nOPV2 will be used under an EUL, additional criteria must be in place for the initial (i.e. first) uses of the vaccine in a campaign setting. Table 1 lists the essential criteria for the implementation of nOPV2 during the initial use period, which is defined as approximately the first three months when nOPV2 is deployed under an EUL recommendation for use.<sup>6</sup>

These criteria have been endorsed in principle by the WHO Strategic Advisory Group of Experts on Immunization (SAGE).<sup>7</sup>

As mentioned, these criteria pertain to the use of nOPV2 in outbreak response. There are no plans to use nOPV2 in routine immunization, where the use of bivalent oral polio vaccine (bOPV) and/or inactivated polio vaccine (IPV) should continue as planned.

**Table 1. Criteria and additional considerations for nOPV2 use during the initial use period**

Essential criteria for the nOPV2 initial use period	
The detection of vaccine-derived poliovirus type 2 (VDPV2) (as per GPEI standard operating procedures)	The capacity to conduct post-deployment surveillance (acute flaccid paralysis (AFP) surveillance, environmental surveillance (ES), adverse event following immunization (AEFI) surveillance)
The capacity to acquire/distribute vaccine in a timely manner (e.g. suitable country vaccine approval/importation processes)	
The capacity to respond to unanticipated findings	A waiting period of 12 weeks after the last mOPV2 use in the area

<sup>6</sup> References include the following:

- Global Polio Eradication Initiative. Framework for initial use of nOPV2 under EUL. 2020 (<http://polioeradication.org/wp-content/uploads/2020/04/GPEI-framework-for-use-of-nopv2-20200430.pdf>, accessed 25 May 2020).
- World Health Organization. Weekly Epidem Rec. 29 May 2020; 95(22):241–256 ([https://extranet.who.int/prequal/sites/default/files/documents/EUL\\_Procedure\\_Jan2020.pdf](https://extranet.who.int/prequal/sites/default/files/documents/EUL_Procedure_Jan2020.pdf), accessed 30 May 2020).
- <sup>7</sup> World Health Organization. Weekly Epidem Rec. 29 May 2020; 95(22):241–256 (<https://www.who.int/wer/2020/wer9522/en>, accessed 30 May 2020). Another key nOPV2 policy decision involved the SAGE's endorsement of accelerated clinical development of nOPV2 and its assessment under the WHO EUL procedure in October 2019. World Health Organization. Weekly Epidem Rec. 22 November 2019; 94(47):541–560 (<https://www.who.int/wer/2019/wer9447/en>, accessed 25 May 2020). More details and full documentation on these and other nOPV2 policy decisions are available at <http://polioeradication.org/nOPV2>.

**Table 1. Criteria and additional considerations for nOPV2 use during the initial use period (cont.)**

Additional considerations for nOPV2 use in outbreak response	
A waiting period of six weeks after bOPV outbreak response campaigns (to minimize the risk of recombination between nOPV2 and mOPV1/mOPV3)	Access or security issues Vaccine acceptance
Rationale for the 12-week waiting period following mOPV2 use	
<p>Accurately assess nOPV2 performance during outbreak response</p> <p>Correctly attribute any safety signals/AEFIs to the corresponding vaccine</p> <p>Evaluate nOPV2 effectiveness in stopping outbreaks and preventing cases</p> <p>Minimize and assess the risk of recombination<sup>8</sup></p>	

When nOPV2 is first used in outbreak response, it should be used alone, to enable the monitoring of the vaccine’s safety and effectiveness. Sufficient vaccine supply to conduct the full required number of rounds with nOPV2 is required. IPV use can be considered only after the first two rounds with nOPV2 have been completed.

While ultimately dependent on supply availability and the epidemiologic situation at the time the recommendation is issued, the GPEI estimates that between one and three outbreaks could be responded to during this initial three-month period. Countries will work with the relevant regional and GPEI bodies, including the Regional Immunization Technical Advisory Group, to determine if and when countries meet the criteria.

### Beyond the initial use period

Should data further support vaccine safety and effectiveness, nOPV2 use could continue under the EUL after the initial use period until the data are sufficient to support licensure and WHO prequalification of nOPV2. Countries would still need to meet the EUL requirements until the vaccine is fully licensed, which is expected to occur in 2022.

Table 2 provides a high-level overview of the timelines and requirements that can be anticipated for the use of nOPV2 under an EUL recommendation for use. The country-level activities that need to be implemented to meet these requirements are described in Section 2. These activities underscore the need for the decision-making process and the nOPV2 Vaccine Deployment Readiness Checklist, which are also discussed in Section 2.

<sup>8</sup> Recombination with other viruses, which can lead to reversion, cannot be ruled out; however, the modifications made to the vaccine have made reversion much less likely in comparison to mOPV2.

**Table 2. Process overview: nOPV2 rollout under an EUL recommendation for use**

	Initial use period following the initial EUL recommendation for use	Final EUL recommendations following the initial use period	nOPV2 receives WHO prequalification (end of EUL recommendation and listing period)
<b>Timing</b>	The first three months (approximately) following the first use of nOPV2 under an EUL recommendation for use	nOPV2 will continue to be used under the EUL recommendation for approximately 12 - 24 months following the initial use period	To be determined, but not before 2022. Some necessary activities (e.g. studies) were delayed due to COVID-19
<b>Applicable criteria</b>	Essential criteria for initial use  Post-deployment monitoring (PDM) requirements (note that these may evolve over time, based on data and lessons learned)	Post-deployment monitoring (PDM) requirements (note that these may evolve over time, based on data and lessons learned)	Standard conditions of vaccine use; no specific requirements are foreseen
<b>Country-level implementation considerations</b>	Rapidly approving the importation and use of nOPV2 under an EUL recommendation for use  Setting/scaling up surveillance systems, particularly safety surveillance systems, to meet the EUL requirements  Preparing cold-chain and logistics systems to accommodate nOPV2  Establishing communications plans, including crisis communications plans, to support nOPV2 implementation  Training staff and front-line workers on nOPV2 implementation  Additional surveillance and safety monitoring activities to meet the essential criteria for initial use	Rapidly approving the importation and use of nOPV2 under an EUL recommendation for use  Setting/scaling up surveillance systems, particularly safety surveillance systems, to meet the EUL requirements  Preparing cold-chain and logistics systems to accommodate nOPV2  Establishing communications plans, including crisis communications plans, to support nOPV2 implementation  Training staff and front-line workers on nOPV2 implementation	Standard conditions for vaccine use, informed by lessons learned from the implementation of nOPV2 under the EUL recommendation for use

## Section 2: Preparing for nOPV2 use at the country level

This section outlines the country-level decision-making and preparation process for the potential use of nOPV2 for cVDPV2 outbreak response. It describes the activities involved in addressing implementation considerations and preparing for nOPV2 use.

### The country-level decision-making and preparation process

#### Which countries should prepare for nOPV2 use?

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

#### WHY SHOULD COUNTRIES CONSIDER PREPARING FOR nOPV2 USE AS SOON AS POSSIBLE?

Outbreaks often occur with little warning, and planning for nOPV2 use requires lead time.

nOPV2 could become the vaccine of choice for cVDPV2 outbreak response if no concerns are identified during the initial use period.

Countries that prepare for nOPV2 use early on will be ready to implement the vaccine in outbreak response once it becomes widely used.

Other countries in regions where cVDPV2 has been detected that do not meet these criteria but would like to be prepared for a possible VDPV2 detection and subsequent response with nOPV2 may also wish to start preparations now.

#### Initiating the process

The first step in the decision-making process is to convene the relevant national immunization partners to review this document and the other “Key resources” on nOPV2 (included in a list at the end of this document), consider the requirements for nOPV2 implementation, and ultimately decide whether to begin planning for nOPV2 use. The relevant national immunization partners are the ones who are typically involved in the introduction and importation of new vaccines. For many countries, these partners include:



## MORE ON THE RISKS AND BENEFITS OF nOPV2 IMPLEMENTATION

There are numerous benefits associated with nOPV2 implementation, including the increased genetic stability compared to mOPV2 (which likely reduces the risk of additional cVDPV2 outbreaks) and the opportunity to strengthen national surveillance systems by following the EUL requirements.

Yet there are also risks that each country should consider, such as lack of data on effectiveness in outbreak response and potential risks of recombination with other vaccines, as mentioned earlier in this document. The GPEI has already begun working on risk mitigation activities to support nOPV2 use.

Countries are encouraged to discuss the risks and benefits of nOPV2 use with their national immunization partners and with the GPEI to understand the full country-level and programmatic tradeoffs of using nOPV2.

More on the programmatic risks and benefits of nOPV2 is included in the Strategy for the Response to Type 2 Circulating Vaccine-Derived Poliovirus 2020–2021, available at <http://polioeradication.org/nOPV2>

- The NITAG,<sup>9</sup> if one is operational in the country, which will provide technical analysis and recommendations.
- EPI managers and representatives, who will provide programmatic assessments and recommendations.
- Policy-makers from the appropriate bodies, including the health and finance ministries.

Alignment of the relevant national authorities for the importation, use and monitoring of nOPV2 is also essential for implementation.

Engaging with the GPEI is another critical early step that will enable decision-makers to better understand the global and regional planning that is underway for nOPV2 implementation as well as the GPEI resources that will be available to support nOPV2 implementation in countries.<sup>10</sup> While the decision to request nOPV2 for use in outbreak response belongs to the country, the GPEI oversees nOPV2 allocation, taking into consideration available supply,

9 Countries are also encouraged to visit the NITAG Resource Centre (<https://www.nitag-resource.org>), which serves as a central resource for all NITAG-related information. The centre is supported by WHO and features all publications produced by NITAGs, technical reports from partners and scientific publications on immunization.

10 The GPEI has already begun working to identify those countries who are most likely to use the vaccine during the initial use period, based primarily on two factors: risk of experiencing a cVDPV2 outbreak, based on poliovirus epidemiology; and country preparedness to meet the essential criteria for initial use. The GPEI will engage with these countries over the coming months to help enhance preparation for the initial use of nOPV2 and determine where and how best to provide resources and support. More details about country prioritization are forthcoming and will be available on the nOPV2 web page of the GPEI website, <http://polioeradication.org/nopv2>

## COUNTRY-LEVEL DECISION- MAKING AND READINESS PROCESS FOR THE USE OF nOPV2 IN CVDPV2 OUTBREAKS

**1** Review the nOPV2 Vaccine Deployment Readiness Checklist and this document

**2** Convene immunization partners to review all requirements and consider nOPV2 use

**3** Decide if interested in preparing for nOPV2 use. If yes:

**4** Document the decision (e.g. in the minutes of a NITAG meeting)

**5** Complete a draft of the nOPV2 Vaccine Deployment Readiness Checklist

**6** Submit the first draft of the Readiness Checklist to confirm interest in using nOPV2 and indicate where support is needed

**7** On a regular (monthly) basis, share updates of the Readiness Checklist to track progress and identify any needs for additional support

**8** Submit the finalized Readiness Checklist to confirm country readiness ahead of nOPV2 implementation

country readiness, and national and regional poliovirus epidemiology. To help facilitate engagement with the GPEI and overall coordination throughout the readiness process, countries interested in preparing for nOPV2 use are encouraged to designate a national nOPV2 focal point. WHO and United Nations Children's Fund (UNICEF) country offices will be the primary GPEI points of contact and support to national governments throughout the process. Because of their role in coordinating nOPV2 implementation between the global and national levels, countries are also encouraged to engage WHO and UNICEF regional offices, both as indicated in this document and as needed throughout the process.

### Completing the nOPV2 Vaccine Deployment Readiness Checklist and Readiness Report

To support country-level decision-makers in assessing the requirements involved in preparing for nOPV2 use, an nOPV2 Vaccine Deployment Readiness Checklist has been developed (referred to as the Readiness Checklist). This Readiness Checklist, featured in the Annex of this document, is designed to help countries recognize and prepare to meet the requirements for nOPV2 use under an EUL recommendation for use and the additional requirements that will apply to any countries that use nOPV2 during the initial use period.

Because the Readiness Checklist provides not only the list of requirements but also a way to track progress (by recording completed items and status updates), it can also serve as a point-in-time indicator of country readiness status and progress. For this reason, the checklist serves as

the primary component of the nOPV2 Readiness Report, which must be submitted before nOPV2 is released. The report is discussed later in this section.

The flow chart on the previous page provides a snapshot of the country-level decision-making process, from expression of interest in preparing for nOPV2 use to delivery of the Readiness Report at the time of outbreak detection.

## **A closer look at the nOPV2 Vaccine Deployment Readiness Checklist**

Many of the activities that countries will carry out to implement nOPV2 campaigns are the same as those required to implement an mOPV2 campaign. However, some additional activities are required, given the requirements for implementation under an EUL recommendation for use and the differences in nOPV2's presentation (e.g. vial size). The Readiness Checklist was created to outline these requirements and help countries track progress towards the requirements and overall nOPV2 preparedness.

The Readiness Checklist applies to all countries interested in using nOPV2 at any point, and countries can begin completing items on the checklist as soon as they are ready to start preparing for possible nOPV2 use. Each checklist item has a corresponding number (e.g. A1, D3) for easy reference, but items can be completed in any order. The checklist is part of an Excel document that also contains an introductory tab and four tabs with additional considerations pertaining to four categories: safety; surveillance; advocacy, communications and social mobilization (ACSM); and cold chain, logistics and vaccine management (CCL&VM).

### **The Readiness Checklist and its requirements**

The requirements in the checklist cover the following categories: (A) coordination;(B) nOPV2 approvals;(C) cold chain, logistics and vaccine management;(D) AFP surveillance; (E) environmental surveillance; (F) safety monitoring; (G) advocacy, communications and social mobilization;(H) laboratory; and (I) campaign operations.

Table 3 provides a snapshot of the Readiness Checklist, for reference, showing the activities in the first category addressed by the checklist: coordination. The complete Readiness Checklist is featured in the Annex.

**Table 3. Snapshot of the nOPV2 Vaccine Deployment Readiness Checklist**

Category	Reference number	Requirement	Requirements for using nOPV2 under EUL <i>All countries to complete</i>	Additional requirements for initial use period <i>Only required during the initial use period</i>	Date completed	Status of incomplete items (include date of update)
Coordination	A1	A national coordinating mechanism/body has been created and technical committees have been established to oversee preparations for nOPV2 across the following critical areas: 1) cold chain, logistics and vaccine management; 2) safety/causality; 3) advocacy, communications and social mobilization; 4) surveillance; and 5) laboratory	<input type="checkbox"/>			

Activities in the column entitled “Requirements for using nOPV2 under EUL” must be completed by any country planning to use nOPV2 at any point when the vaccine is under an EUL recommendation for use.

Activities in the “Additional requirements for initial use period” column must be completed if the country is implementing nOPV2 during the initial use period under an EUL recommendation for use. As a reminder, the activities in this column must be completed in addition to, not instead of, the activities in the “Requirements for using nOPV2 under EUL” column.

### Additional context on the requirements

For some of the requirements, such as those in the cold chain, logistics and vaccine management (CCL&VM) category (category C), the need for the required activities is immediately understandable. For example, given that nOPV2 is supplied in 50-dose vials and may feature a VVM1 rather than a VVM2,<sup>11</sup> countries will need to update the national register as well as logistics and vaccine management protocols and materials for nOPV2. However, many of the requirements are specifically related to nOPV2’s implementation under an EUL recommendation for use. This subsection aims to provide additional context on these items and to answer initial questions about the rationale for the requirements that may come up as countries read through the checklist and consider all requirements.

<sup>11</sup> Confirmation of the vaccine vial monitor type that will be featured on nOPV2 vials and corresponding guidance from the GPEI on what this will mean in the field are forthcoming.

**nOPV2 approvals (category B):** Approval for use and importation is essential for implementing the vaccine. The February 2020 WHO Executive Board decision urges Member States to implement an expedited process for national approval of the importation and use of vaccines to respond to polio outbreaks, including nOPV2, on the basis of its EUL.<sup>12</sup> While WHO's Vaccine Prequalification team will work closely with the relevant regulatory authorities from potential user countries to ensure they have the relevant information on nOPV2, it is each country's sovereign decision to authorize the emergency use of nOPV2. The activities in category B therefore include securing authorization for use and importation of nOPV2 from the relevant authorities.

**AFP surveillance, environmental surveillance and safety monitoring (categories D, E and F):** All countries that use nOPV2 while it is under an EUL recommendation for use will be required to adhere to a data collection plan. This data collection plan, called the Risk Management Plan and Pharmacovigilance Plan, will describe all required safety and effectiveness monitoring activities – also known as post-deployment monitoring (PDM) requirements – for countries using nOPV2. For countries that use nOPV2 during the initial use period, additional AFP, AEFI and ES activities must be completed to meet the essential criteria for initial use described in Section 1. The required activities in categories D, E and F will enable countries to meet all of these criteria and requirements and to report on safety surveillance, performance monitoring and other relevant data. These data are essential to assessing nOPV2's safety and effectiveness, maintaining the vaccine's EUL status, and eventually completing the submission for licensure and WHO prequalification of nOPV2.

**Advocacy, communications and social mobilization (category G):** ACSM activities will be a critical piece of the nOPV2 preparation and implementation process. Communications messaging, tools and training will be crucial for increasing awareness and acceptance of nOPV2. C4D research on nOPV2 messaging has already been completed in Nigeria, Kenya and the Democratic Republic of the Congo, and the findings have informed GPEI communications materials and guidance.

Communications preparedness will also be essential to help ensure an appropriate and timely response in case of any vaccine-related events. Countries will need to plan for more intensive communication and engagement approaches to mitigate against potential misinformation and the spread of rumours. Additionally, developing an advocacy strategy to engage key local stakeholders (e.g. relevant medical and professional associations, and religious and community leaders) and harness their roles as immunization champions will be crucial. To help countries address these considerations and leverage stakeholders and advocates as they complete the requirements, the GPEI has developed tools, including:

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<sup>12</sup> World Health Organization Executive Board resolution EB146/11. 146th session, 7 February 2020 ([https://apps.who.int/gb/ebwha/pdf\\_files/EB146/B146\(11\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB146/B146(11)-en.pdf), accessed 25 May 2020). More details and full documentation on this and on other policy decisions related to nOPV2 are available at <http://polioeradication.org/nOPV2>.

- **Strategic communications guidance for cVDPV outbreak response including the use of nOPV2**, a guidance document to help countries develop comprehensive communications plans including advocacy, C4D, and crisis communications strategies
- **A vaccine-related event (VRE) response plan template** that defines stakeholder roles/responsibilities in the detection and response to AEFI and adverse events of special interest (AESI), both real and rumoured. Countries can tailor the plan to their context, use it to support communications planning, and ultimately ensure that vaccine safety focal points, EPI program staff, other nOPV2 implementation stakeholders, and communications leads are in alignment about how to respond to any vaccine-related event
- **Additional considerations for ACSM**, which is part of the Readiness Checklist Excel document and provides a helpful list of items to consider across the different aspects of nOPV2 communications planning.

Additional templates and communications products for country use are available on the nOPV2 web page of the GPEI website.

### HIGH-LEVEL TAKEAWAYS FROM C4D RESEARCH ON nOPV2 MESSAGING IN KENYA AND THE DEMOCRATIC REPUBLIC OF THE CONGO

Caregivers will likely accept nOPV2 if it is explained well and their questions are answered. They welcome information from health practitioners and front-line workers and endorsement from traditional and religious leaders, as well as their own social networks.

Front-line workers are open to the vaccine and want confirmation that it has been well tested and is shown to be safe. It will be important to sensitize these workers to the EUL process and its meaning. An information cascade, supported with informational materials and resources, will also be essential.

### Additional considerations for ACSM, surveillance, safety monitoring and CCL&VM

The Readiness Checklist Excel document includes tabs with additional considerations for the following categories: ACSM, surveillance, safety monitoring and CCL&VM. These considerations provide additional context, in the form of specific questions and indicators, that will help countries identify gaps and develop concrete plans for completing the readiness requirements.

Addressing the considerations can also help ensure optimal preparedness for nOPV2 implementation. For example, item D4 (in category D, AFP surveillance) reads: “A Desk Surveillance Review has been completed and a plan has been developed to address identified weaknesses relevant to nOPV2 use (may be performed with support from the GPEI Surveillance Task Team; see “Surveillance” tab)”. The “Surveillance” tab also features additional AFP surveillance indicators for countries to consider monitoring to help ensure readiness. Countries can analyse these considerations and determine whether it is feasible and appropriate to address them based on their specific country context. Example activities/indicators for AFP surveillance include:

- Proportion of high- and medium-priority sites visited monthly: at least 80%
- Proportion of high-priority sites visited weekly: at least 80%.

As a reminder, these considerations are not requirements but help to give additional context to the requirements and provide example targets. Countries are encouraged to analyse and discuss the considerations and implement those that are feasible and appropriate.

### Country workplan

Another important tool to help determine feasible and appropriate activities is the country workplan. Following a review of the requirements and an assessment of the country’s current capacity to meet them, a workplan should be developed to capture the activities that the country will need to carry out to meet the requirements. The items should then be costed out and a plan should be developed to identify and allocate both the financial and human resources that will be needed. Because each country’s context is different, each workplan will be different, which is why countries should develop their own individual plans and discuss any gaps in resources or support with the GPEI early in the readiness process.

### Timing and deadlines: Readiness tracking and reporting

Because the timing of future country-level outbreak events is unknown, there is no calendar-based due date for the checklist. Rather, countries should begin completing items on the checklist as soon as they have decided to start preparing for nOPV2 use and update the checklist as they continue their preparations.

Country nOPV2 focal points are asked to submit the Readiness Checklist to their WHO and UNICEF regional offices at the points indicated in Table 4, as part of an overall readiness tracking and reporting process. The goal of this process is to ensure close communication with GPEI partners about country readiness status and needs throughout the process.

**Table 4. Timing of the readiness tracking and reporting process**

Timing	Activity	Purpose
As soon as the country confirms interest in using nOPV2 and completes a first draft of the Readiness Checklist	<p><b>First checklist submission for initial readiness assessment</b></p> <p><u>Items to submit:</u></p> <ul style="list-style-type: none"> <li>The Readiness Checklist</li> <li>Evidence of the country’s decision to implement nOPV2 (e.g. minutes of a NITAG meeting), if available</li> </ul>	<ul style="list-style-type: none"> <li>To confirm and communicate country interest in preparing for nOPV2 use</li> <li>To indicate areas where support is needed</li> </ul>
Each month following initial submission	<p><b>Monthly checklist updates for readiness progress tracking</b></p> <p><u>Items to share:</u></p> <ul style="list-style-type: none"> <li>Updated Readiness Checklist</li> <li>Other documentation as it becomes available</li> </ul>	<ul style="list-style-type: none"> <li>To ensure the continued communication and assessment of readiness progress</li> <li>To enable countries to leverage GPEI support and resources when available and appropriate</li> </ul>
Once the Readiness Checklist is completed, or after outbreak detection and submission of a request for nOPV2 (whichever comes first)	<p><b>Final Readiness Report</b></p> <p><u>Items to submit:</u></p> <ul style="list-style-type: none"> <li>Updated Readiness Checklist</li> <li>Evidence of the country’s decision to implement nOPV2, if not submitted previously</li> <li>Evidence of country approval of the importation and use of nOPV2</li> </ul>	<ul style="list-style-type: none"> <li>To confirm country readiness ahead of nOPV2 use in cVDPV2 outbreak response</li> </ul>

The GPEI refers to this continued communication and assessment of the readiness process, which begins with the initial submission of the Readiness Checklist, as **readiness tracking and reporting**. This serves as the GPEI’s own checklist and readiness process to ensure country readiness before releasing nOPV2 supply following outbreak detection. The GPEI’s process aligns so closely with the country-level readiness process that all that countries are required to do for the assessment is to follow the readiness process guidelines outlined above and work closely with the GPEI to address any questions or needs.

### Note on the impact of COVID-19

The national and regional epidemiology and response to COVID-19 may affect several aspects of the country-level readiness process. Examples include determining which vaccination activities to prioritize once campaigns can resume



and maintaining the ability to carry out needed surveillance activities. Each country will need to monitor the potential impact of COVID-19 on its ability to meet the specific requirements for nOPV2 use and discuss any implications with GPEI bodies throughout the decision-making process. A few specific considerations related to the impact of COVID-19 are identified in the “Surveillance” tab.

## Outbreak detection and the decision to use nOPV2

When an outbreak is detected, a country that has completed the preparation process may wish to use nOPV2 during the outbreak. nOPV2 will be released through a two-phase process:

- 1. Assessment of country readiness:** As described earlier in this section, assessment is conducted by the GPEI. The primary factors that will be considered in the assessment include country interest in using nOPV2, country-level regulatory approval for the importation and use of nOPV2, and the completion and evaluation of the Readiness Report
- 2. Release of the vaccine and establishment of any additional specifications for outbreak response (e.g. target age):** Factors will include available supply, country-level and regional poliovirus epidemiology, and other potential considerations relevant to the specific context of the outbreak.

The individual country and the GPEI will work together throughout this process. Once the process is complete, the country is prepared to carry out cVDPV2 outbreak responses with nOPV2 under the EUL and will not need to complete the readiness process again.

The procedures and critical activities necessary to plan for and implement a high-quality nOPV2 outbreak response are not part of the Readiness Checklist, but instead are detailed in the GPEI Standard Operating Procedures (SOPs) for Outbreak Response. The SOPs are being updated to provide specific details and guidance that will be important for nOPV2 deployment. Training modules and other materials for front-line workers are also being developed and should be implemented in coordination with the GPEI. The latest resources are available at <http://polioeradication.org/nopv2>

## Next steps

WHO and UNICEF regional and country offices, together with the GPEI, are available to support countries in their assessment of whether nOPV2 is the right vaccine for them at this time and, if so, to help them plan for successful implementation.

The GPEI will coordinate with countries regularly through all relevant national and regional bodies, and will continue to share resources, updates and information as they become available. This document will be updated as soon as an EUL recommendation for use is available, and again when EUL recommendation requirements are finalized.

Global and country-level nOPV2 resources, from FAQs to scientific publications and technical resources for countries, will be updated and made accessible via <http://polioeradication.org/nOPV2>. This will ensure that all relevant nOPV2 resources are available in one place. In addition to the documents featured in the “Key resources” section, the GPEI will share supplementary documents and tools related to nOPV2 implementation as they become available and as countries confirm their interest in preparing for nOPV2 use.

Country-level decision-makers are encouraged to consult the available resources, the nOPV2 Vaccine Deployment Readiness Checklist, and all relevant GPEI offices and teams as they begin – and throughout – the process.

## Key resources

The following resources provide more details on the key topics discussed in this guide. An up-to-date list of relevant nOPV2 materials is maintained on the nOPV2 web page of the GPEI website at <http://polioeradication.org/nopv2>. New documents and tools for nOPV2 implementation continue to be developed and will be posted to the web page as they become available.

- **nOPV2 Frequently Asked Questions (FAQ):** This document addresses questions about nOPV2 and its implementation, and covers a range of topics, from general to regulatory and operational questions. It is available on the GPEI nOPV2 web page at <http://polioeradication.org/nopv2-frequently-asked-questions>
- **Emergency Use Listing Procedure (Version 9, January 2020):** This document defines the steps that WHO follows to establish the eligibility of unlicensed products for assessment under the EUL procedure. It describes the essential information required and the process to be used in conducting the assessment to determine whether an unlicensed product can be listed on a time limited basis, while further data are being gathered and evaluated. The most up-to-date EUL procedure document is available at [https://extranet.who.int/prequal/sites/default/files/documents/EUL\\_Procedure\\_Jan2020.pdf](https://extranet.who.int/prequal/sites/default/files/documents/EUL_Procedure_Jan2020.pdf)
- **nOPV2 Roadmap:** This document outlines the steps, activities, and timelines for WHO's assessment of nOPV2 under the EUL, and the post-recommendation activities. The roadmap is available at [https://www.who.int/docs/default-source/medicines/roadmap-assessment-nopv2.pdf?sfvrsn=368daf0a\\_2](https://www.who.int/docs/default-source/medicines/roadmap-assessment-nopv2.pdf?sfvrsn=368daf0a_2)
- **nOPV2 Clinical Development Summary:** This summary outlines the key clinical data findings for the nOPV2 candidate submitted for EUL review. The document is available online at <http://polioeradication.org/wp-content/uploads/2020/05/Clinical-development-summary-nOPV2-20200521.pdf>
- **Framework for initial use of nOPV2:** Endorsed by the SAGE, this framework provides guidance for the initial use of nOPV2 under the EUL. The framework is available at <http://polioeradication.org/wp-content/uploads/2020/04/GPEI-framework-for-use-of-nopv2-20200430.pdf>
- **Global Polio Surveillance Action Plan (GPSAP) 2018–2020:** The GPSAP outlines surveillance strategies and activities for countries to attain or maintain a surveillance system sensitive enough to detect the circulation of any polioviruses. It is also intended to strengthen coordination between the GPEI's surveillance systems, the Global Polio Laboratory Network, Polio Information Systems, and the management of global, regional and country surveillance teams. Although the surveillance strategies and activities contained in the GPSAP are specifically designed to build capacities within endemic, outbreak and high-risk countries, they are relevant to all countries. The GPSAP also provides information on surveillance strategies for special populations. It is available at <http://polioeradication.org/wp-content/uploads/2016/07/GPEI-global-polio-surveillance-action-plan-2018-2020-EN-1.pdf>

# Annex

## nOPV2 Vaccine Deployment Readiness Checklist

Note: The Readiness Checklist in Excel format is available on the nOPV2 web page at <http://polioeradication.org/nOPV2>

### Introduction to the Readiness Checklist

This checklist and accompanying guidance focus on items unique to nOPV2 as required under the Emergency Use Listing (EUL). Other campaign preparations are outlined in other guidance documents.

Requirements are divided into two lists: “Requirements for using nOPV2 under EUL” (column D) and “Additional requirements for initial use period” (column E); only countries planning to use nOPV2 during the initial use period need to complete column E.

### Objectives of the Readiness Checklist

To summarize the requirements for nOPV2 use under EUL and the additional requirements during the initial use period under EUL.

To provide a tool to identify gaps and monitor progress towards nOPV2 readiness.

To serve as part of the report for assessment of a country’s readiness for nOPV2 for a vaccination response.

### Structure and methodology

The Readiness Checklist and its requirements are featured on the “Checklist” tab. Reference numbers (e.g. A1, D3, etc.) are provided for ease of reference, not for an explicit order or sequence of steps to follow. Countries may choose to perform activities in parallel if possible.

The “CCL&VM”, “Surveillance”, “Safety” and “ACSM” tabs contain additional information and considerations that some countries may find useful during preparations.

### Initial use period

Note: During approximately the first three months after an EUL recommendation is issued, countries using nOPV2 will need to prepare to meet the initial use requirements in column E, in addition to the checklist requirements in column D.

For more details on the Framework for initial use of nOPV2 under EUL, please ask your local WHO or UNICEF office for more information or refer to the Framework document available at <http://polioeradication.org/wp-content/uploads/2020/04/GPEI-framework-for-use-of-nopv2-20200430.pdf>

Upon completion of the initial use period, the additional criteria are lifted and only the requirements in column D of the Readiness Checklist apply.

## **Readiness tracking and reporting**

Countries are asked to submit the Readiness Checklist (“Checklist” tab) to their WHO and UNICEF regional offices as part of an nOPV2 Readiness Report, to ensure close communication with GPEI partners on their readiness status and needs throughout the process.

### **STEP 1: INITIAL READINESS ASSESSMENT**

Once the country confirms interest in using nOPV2, the following should be submitted:

1. The Readiness Checklist (“Checklist” tab) – please indicate the date on which the requirement was most recently reviewed and any notes for incomplete or pending items
2. Evidence of the national decision to implement nOPV2 (e.g. minutes of a NITAG meeting, formal letter, etc.), if available.

### **STEP 2: READINESS STATUS TRACKING**

The checklist should be updated and resubmitted monthly, to communicate progress and needs and to share additional documentation as it becomes available.

Monthly reporting continues until nOPV2 readiness has been achieved.

### **STEP 3: FINAL READINESS REPORT**

Once the Readiness Checklist is completed, or after outbreak detection and submission of a request for nOPV2 (whichever comes first), the following should be submitted to the GPEI to assess readiness for nOPV2 use:

1. The Readiness Checklist (“Checklist” tab) – please indicate the date on which each requirement was completed or most recently reviewed and notes for incomplete or pending items
2. Evidence of the national decision to implement nOPV2 (e.g. minutes of a NITAG meeting, formal letter, etc.)
3. Proof of approval for importation and use of the vaccine.

## nOPV2 Vaccine Deployment Readiness Checklist - National Level

July 2020 version

National nOPV2 focal point (name):

Date of submission:

Contact name:

Contact phone:

Contact email:

Category	Reference number	Requirement	Requirements for using nOPV2 under EUL <i>All countries to complete</i>	Additional requirements for initial use period <i>Only required during the initial use period</i>	Date completed	Status of incomplete items (include date of update)
<b>Coordination</b>	A1	A national coordinating mechanism/body has been created and technical committees have been established to oversee preparations for nOPV2 across the following critical areas: 1) cold chain, logistics and vaccine management; 2) safety/causality; 3) advocacy, communications and social mobilization; 4) surveillance; and 5) laboratory	<input type="checkbox"/>			
<b>nOPV2 Approvals</b>	B1	An official national decision to implement nOPV2 for outbreak response is confirmed and documented by national immunization partners	<input type="checkbox"/>			
	B2	Approval for the importation of nOPV2 has been secured from the relevant national authorities and documented for reference	<input type="checkbox"/>			
	B3	Approval for the use of nOPV2 has been secured from relevant national authorities and documented for reference	<input type="checkbox"/>			
<b>Cold Chain, Logistics and Vaccine Management</b> (see "CCL&VM" tab for further details/ activities to consider)	C1	National register, logistics, vaccine management protocols and other relevant tools have been updated to reflect the unique characteristics of nOPV2 (i.e. 50-dose vial and VVM)	<input type="checkbox"/>			
	C2	A cold-chain inventory assessment has been conducted or updated; freeze capacity and pre-qualified vaccine carrier availability are well documented	<input type="checkbox"/>			
<b>AFP Surveillance</b> (see "Surveillance" tab for further details/ activities to consider)	D1	A plan has been developed to carry out active case searches in all priority sites in each geographic area where nOPV2 was used, one month following nOPV2 use in that area	<input type="checkbox"/>			
	D2	A plan has been developed to collect vaccination coverage data from age-matched, randomly selected community members around AFP VDPV2 cases	<input type="checkbox"/>			
	D3	An AFP Case Investigation Form has been adapted to record routine and SIA OPV doses	<input type="checkbox"/>			
	D4	A Desk Surveillance Review has been completed and a plan has been developed to address identified weaknesses relevant to nOPV2 use (may be performed with support from the GPEI Surveillance Task Team; see "Surveillance" tab)		<input type="checkbox"/>		
	D5	A plan has been developed for systematic contact sampling of all AFP cases for 6 months after an nOPV2 outbreak response		<input type="checkbox"/>		
	D6	The country achieves a NPAFP rate $\geq 2$ at the national level and in at least 80% of all districts with more than 100 000 people aged under 15 years		<input type="checkbox"/>		

Category	Reference number	Requirement	Requirements for using nOPV2 under EUL <i>All countries to complete</i>	Additional requirements for initial use period <i>Only required during the initial use period</i>	Date completed	Status of incomplete items (include date of update)
<b>AFP Surveillance</b> (see "Surveillance" tab for further details/ activities to consider)	D7	The country meets stool adequacy of $\geq 80\%$ at the national level and in at least 80% of all districts reporting AFP cases		<input type="checkbox"/>		
	<b>Environmental Surveillance</b>					
	E1	The country has at least one functional ES site in areas where nOPV2 will be used (i.e. $\geq 90\%$ timely samples collected vs planned and enterovirus detection rate of $\geq 50\%$ in the past 6 months)		<input type="checkbox"/>		
	E2	A plan has been developed to collect ES samples twice per month for 6 months after nOPV2 use		<input type="checkbox"/>		
<b>Safety Monitoring</b> (see "Safety" tab for further details/ activities to consider)	F1	An active AESI safety monitoring protocol has been developed and all national AEFI materials have been updated to reflect nOPV2 variables	<input type="checkbox"/>			
	F2	All AFP and AEFI officers have been trained on nOPV2 variables and on gathering safety monitoring data	<input type="checkbox"/>			
	F3	The causality assessment committee has been trained to conduct AEFI/AESI causality assessment and has been trained on nOPV2 variables	<input type="checkbox"/>			
	F4	The nOPV2 vaccine-related event (VRE) response plan has been adapted to the country context, with stakeholder roles/responsibilities outlined and relevant trainings conducted	<input type="checkbox"/>			
	F5	The plan for the implementation of active safety surveillance in the local context has been finalized and ethical approvals secured if needed in conjunction with the CDC			<input type="checkbox"/>	
<b>Advocacy, Communications and Social Mobilization</b> (see "ACSM" tab for further activities to consider)	G1	Advocacy strategy for key in-country stakeholders (e.g. medical practitioners, religious and community leaders) has been finalized	<input type="checkbox"/>			
	G2	The C4D action plan has been developed. Key components: nOPV2 communications and messaging have been adapted to the local context; key actors including front-line workers have been trained; all stakeholders have been mapped and sensitized; concrete plans for digital platforms have been developed; all necessary messaging, tools and products have been developed	<input type="checkbox"/>			
	G3	A crisis communications plan has been developed and the plan addresses the needs identified in the nOPV2 VRE response plan for AEFI and possible public controversy (including tailored content to respond to misinformation on social media)	<input type="checkbox"/>			
<b>Laboratory</b>	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	<input type="checkbox"/>			
	H2	Relevant laboratories are prepared to ship samples to CDC or NIBSC for complete genome sequencing for post-response monitoring	<input type="checkbox"/>			
<b>Campaign operations</b>	I1	SIA guidelines have been updated to include nOPV2 (including microplanning tools and the SIA preparedness dashboard)	<input type="checkbox"/>			
	I2	An nOPV2 SIA training plan and materials are developed	<input type="checkbox"/>			

### Cold Chain, Logistics and Vaccine Management considerations

The “CCL&VM” tab contains additional area-specific information and reference materials that may be useful during assessment and preparations.

These should be reviewed and considered as you work to complete the requirements for nOPV2 use, which are noted in the “Checklist” tab.

This tab should be viewed in conjunction with other existing cold chain and logistics guidance tools and materials for polio campaign planning, which will provide more detailed guidance.

#### Considerations for baseline assessment: Cold chain and logistics infrastructure and vaccine management practices

1. Is there a functional National Logistics Working Group in the country (with clear terms of reference, conducting routine meetings)?
2. Has the country conducted a cold-chain equipment inventory that includes freezers, cold boxes and vaccine carriers in the past year?
3. Has the country held an Effective Vaccine Management (EVM) assessment and prepared an EVM improvement plan in recent years?
4. Are there vaccination campaign microplans that can be used during an nOPV2 campaign?
5. Are there medical waste management facilities to dispose of nOPV2 campaign waste?
6. Is there an mOPV2 supplementary immunization activity (SIA) Logistics Plan that was prepared in recent years?

#### Additional considerations for nOPV2 readiness

1. Has a cold-chain inventory assessment been conducted or updated, and are freeze capacity and prequalified vaccine carrier availability well documented?\*
2. Have the national register, logistics, vaccine management protocols and other relevant tools been updated to reflect the unique characteristics of nOPV2 (i.e. 50-dose vial and VVM)?\*



3. Have campaign microplanning tools been prepared (if not already present) or adapted for nOPV2 use?
4. Has a gap analysis been conducted to implement an nOPV2 campaign targeting 700 000 children or 1 million doses (or for a best-estimated scope, if available)?
5. Have global nOPV2 CCL&VM guidelines been adapted to the country and COVID-19 context?
6. Have training materials for mid-level managers/supervisors/vaccine accountability monitors/front-line workers been prepared?
7. Have mid-level manager and central supervisor trainings been completed?
8. Is a draft logistics plan ready for an nOPV2 campaign targeting 700 000 children or 1 million doses (or for a best-estimated scope)?
9. Has the waste management plan been prepared? Are long-term agreements or memoranda of understanding signed with medical incineration facilities?
10. Has a CCL&VM plan been drafted?

#### KEY/LEGEND

\*A requirement in the Readiness Checklist for use under EUL

### Surveillance considerations

The “Surveillance” tab contains additional area-specific information and reference materials that may be useful during assessment and preparations.

These should be reviewed and considered as you work to complete the requirements for nOPV2 use, which are noted in the “Checklist” tab.

This tab should be viewed in conjunction with other existing surveillance tools and materials for polio campaign planning, which will provide more detailed guidance.

### Desk surveillance review\*\*

This review is **required** for initial use countries and highly recommended for others.

Once a country has communicated a decision to prepare for and use nOPV2, the GPEI Surveillance Task Team (STT) will support completion of the desk surveillance review within two weeks.

*Note: more information on the desk surveillance review is provided in the PowerPoint*

that is embedded in the Excel Checklist document (on the "Surveillance" tab).

**In addition, the following can be used as guidance to assess the sensitivity of the surveillance system and readiness for nOPV2.**

#### AFP Surveillance (rolling six months)

1. A plan has been established to carry out active case searches in all priority sites in each geographic area where nOPV2 was used, one month after the vaccine was used in that area.\*
2. A plan has been established to collect vaccination coverage data from age-matched, randomly selected community members around AFP VDPV2 cases.\*
3. A plan has been established for systematic contact sampling of all AFP cases for six months after nOPV2 use in an outbreak response.\*\*
4. An AFP Case Investigation Form has been adapted to record routine and SIA OPV doses.\*
5. NPAFP rate:  $\geq 2$  at the national level and in at least 80% of all districts with more than 100 000 people aged under 15 years.\*\*
6. Stool adequacy:  $\geq 80\%$  at the national level and in at least 80% of all districts reporting AFP cases.\*\*
7. Proportion of follow-up exams conducted when the time is due:  $\geq 80\%$ .
8. Proportion of inadequate AFP cases with contact sampling done: 80%.
9. Silent district: 0 (for all districts with more than 100 000 people aged under 15 years) for the last 12 months.
10. Time between the collection of the second stool specimen and arrival at the lab:  $\leq 3$  days when the lab is inside the country;  $\leq 7$  days when the lab is outside the country.
11. Proportion of high- and medium-priority sites visited monthly: at least 80%.
12. Proportion of high-priority sites visited weekly: at least 80%.
13. Proportion of AFP cases reported by private facilities.
14. Proportion of AFP cases reported by community informants.

## Environmental surveillance

1. Performance of all existing ES sites has been reviewed and documented (i.e.  $\geq 90\%$  timely samples collected vs. planned, and EV detection rate  $\geq 50\%$  in the past 6 months)
2. Potential expansion of the ES network in other populated areas has been explored and any suitable sites have been identified
3. The country has at least one functional ES site in areas where nOPV2 will be used (i.e.  $\geq 90\%$  timely samples collected vs planned and enterovirus detection rate of  $\geq 50\%$  in the past six months).\*\*
4. A plan has been developed to collect ES samples twice per month for six months after nOPV2 use.\*\*

## Laboratory

1. A plan has been developed to prepare the national lab for nOPV2 use, including updating the isolation algorithms and stocking/ training on the intratypic differentiation (ITD) testing kits for both AFP and ES along with modifications to the reporting mechanism.\*
2. The National Polio Laboratory is fully accredited by WHO for viral isolation (VI), ITD and ES.
3. The National Polio Laboratory has worked with the Regional Polio Laboratory Coordinators and developed a plan to support nOPV2 implementation in the country. This plan should include: (i) stockpiling of all necessary supplies and reagents for VI and ITD testing (including nOPV2 assay) of AFP and ES samples, (ii) Formal training of the staff on nOPV2 and amended procedures, including Lab DB to capture nOPV2 results, (iii) contracting a Courier to ensure swift shipment of isolates to a sequencing laboratory, (iv) ensuring that a back-up PCR machine is available, and (v) reporting mechanism for all type 2 isolates.
4. The Laboratory plan has been communicated to the national nOPV2 focal point.

### COVID-19 impacts/issues to monitor and communicate

1. Limiting active surveillance.
2. Jeopardizing specimen collection and shipment.

#### KEY/LEGEND

\*A requirement in the Readiness Checklist for use under EUL

\*\*Additional requirements for the initial use period, noted in the Readiness Checklist

### Safety considerations

The “Safety” tab contains additional area-specific information and reference materials that may be useful during assessment and preparations.

They should be reviewed and considered as work progresses to complete the requirements for nOPV2 use, which are noted in the “Checklist” tab.

This tab should be viewed in conjunction with other existing AEFI and vaccine safety guidance tools and materials, which will provide more detailed guidance.

### Initial assessment of infrastructure to detect, investigate and respond to AEFI during nOPV2 use

1. Does the country have national AEFI surveillance guidelines?
2. Has the country conducted an AEFI surveillance assessment since 1 January 2018?
3. Does the country use an AEFI case-based reporting form that includes the minimum 25 key variables, as recommended by WHO?
4. Has the country met WHO’s minimum criteria for AEFI surveillance (>10 AEFI reports per 100 000 surviving infants) in 2018?
  - a. Proportion of reported AEFI determined to be serious AEFI in 2018?
  - b. Proportion of serious AEFI investigated in 2018?
  - c. Proportion of serious AEFI with causality assessment determination in 2018?
  - d. Proportion of districts with non-zero AEFI reporting in 2018?
  - e. Proportion of districts with silent AEFI reporting in 2018?
5. Has the country undergone WHO training in AEFI investigation since 1 January 2018?

- a. At the national level?
  - b. At the subnational level?
6. How many Guillain-Barré Syndrome cases were identified among non-polio AFP cases within the last year? (>0)
  7. Is there an independent national advisory committee for vaccine safety?
    - a. Has the national advisory body for vaccine safety undergone WHO training for causality assessment?
    - b. Does this group have a clear SOP?
    - c. How many times has the committee met within the last year?
    - d. How many causality assessments have been conducted in the last year?
  8. If no national vaccine safety advisory body exists, are there provisions for establishing one to review serious AEFI cases?

#### Implementation steps prior to nOPV2 use

1. National AEFI surveillance guidelines have been established (if not already present).
2. An independent national advisory committee for safety/causality has been established (if not already present).\*
3. An active AESI safety monitoring protocol has been developed and all national AEFI materials have been updated to reflect nOPV2 variables.\*
4. Trainings have been completed for passive AEFI reporting using a reporting form that includes the minimum 25 key variables plus nOPV2-relevant variables.
  - a. At the national level
  - b. At the subnational level
  - c. For front-line healthcare workers.
5. Trainings have been completed for AEFI investigation.
  - a. At the national level
  - b. At the subnational level.
6. The causality assessment committee has been trained to conduct AEFI/AESI causality assessment and has been trained on nOPV2 variables.\*

7. The nOPV2 vaccine-related event (VRE) response plan has been developed and adapted to the country context, with stakeholder roles/responsibilities outlined and relevant trainings conducted.\*
8. The plan for the implementation of active safety surveillance in the local context has been finalized and ethical approvals secured if needed, in conjunction with the CDC.\*\*
9. All AFP and AEFI officers have been trained on nOPV2 variables and on gathering safety monitoring data.\*
10. AESI active surveillance tools have been printed and distributed.
11. AESI active surveillance data systems have been established.

#### Indicators to monitor during and after an nOPV2 outbreak response

1. In districts using nOPV2: Proportion with silent AEFI reporting (<10%).
2. In districts using nOPV2: Proportion with >10 AEFI reports per 100 000 surviving infants (>80%).
3. Number of AEFI reported in the last 30 days (all).
4. Number of serious AEFI reported in the last 30 days.
5. Proportion of serious AEFI investigated = 100%.
6. Time between the identification of serious AEFI, investigation, and the causality assessment (<7 days).

#### KEY/LEGEND

\*A requirement in the Readiness Checklist for use under EUL

\*\*Additional requirements for the initial use period, noted in the Readiness Checklist

### Advocacy, communications and social mobilization considerations

The “ACSM” tab contains additional area-specific information and reference materials that may be useful during assessment and preparations.

They should be reviewed and considered as work progresses to complete the requirements for nOPV2 use, which are noted in the “Checklist” tab.

This tab should be viewed in conjunction with other existing ACSM and front-line worker guidance tools and materials for polio campaign planning, which will provide more detailed guidance.

#### Considerations for establishing communications coordination and partnerships

1. Has the polio emergency operations centre communication (sub-)working group been activated and chaired by the relevant national or subnational health authority?
2. Are GPEI partners among the members of the polio emergency operations centre communication (sub-)working group?
3. Are international nongovernmental organizations and national nongovernmental organizations part of the communication (sub-)working group?
4. Does UNICEF have standby partnership agreements, long-term agreements or memoranda of understanding with:
  - TV and radio production agencies
  - Airtime media buyers
  - Creative design agencies and printshops
  - Digital media engagement specialists
  - National and international nongovernmental organizations for community engagement and social mobilization
  - Telecommunication/mobile companies
  - Religious groups
  - Research and monitoring organizations
  - Capacity-building training professionals.
5. Do national health authorities have special arrangements with national and subnational television and radio stations to broadcast health-specific messages/ public service announcements free of charge or at discounted rates?
6. Do national health authorities have mechanisms to engage other government agencies (e.g. the ministries of education, of information and communication, etc.) in response to polio outbreaks?

7. Are health workers trusted and do they remain the main source of information about child health and well-being (including immunization)?
8. Do national health authorities have partnerships with nongovernmental and civil society organizations at the community level?

### Considerations for finalizing the C4D Action Plan

1. Has the C4D action plan been developed? Key components: nOPV2 communications and messaging adapted to the local context; key actors, including front-line workers, have been trained; stakeholders who have all been mapped and sensitized; the development of concrete plans for digital platforms; and the development of all necessary messaging, tools and products.\*
2. Is the polio C4D strategy and action plan informed by social research (case investigation, and knowledge, attitudes and practices on polio and immunization)?
3. Does the C4D strategy and action plan include special strategies for high-risk and hard-to-reach communities?
4. Does the C4D strategy and action plan include information on anti-vaccination and opposition groups and activities to guard against rumours and misinformation?
5. Does the C4D strategy and action plan include a framework with monitoring and evaluation indicators for ACSM? Examples:
  - Are case social investigation and refusal assessment tools available to and used by partners?
  - Are tools for the rapid assessment of knowledge, attitudes and practices on polio and communication aspects available?
  - Are any digital applications (U-Report, RapidPro, Kobo, ODK, etc.) used for collecting and analysing social mobilization activities?
  - Do GPEI partners or government partners monitor social media for rumours, opinions and perceptions about immunization and vaccines?



### Considerations for updating, designing and producing nOPV2 communications and social mobilization materials

1. What polio print materials have been developed and made ready for production for the following key actors?
  - General public and caregivers (posters, banners, leaflets, fliers, etc.)?
  - Local governments, community and religious leaders, and journalists?
  - Social mobilizers and volunteers?
  - Health workers, including front-line health workers?
2. Has TV and radio broadcast content on polio been developed and pretested (e.g. public service announcements, radio jingles, short videos, documentaries, etc.)?
3. Has a media plan been agreed with TV and radio stations?
4. Has social media content for polio campaigns been prepared for Facebook, WhatsApp, etc.?

### Considerations for the crisis communications plan and risk management plan for AEFI, the vaccine-related event response plan, and possible public controversy regarding nOPV2 use

1. Has a crisis communications plan been developed, and does the plan address the needs identified in the nOPV2 VRE response plan for AEFI and possible public controversy (including tailored content to respond to misinformation on social media)?\*
2. Have key spokespersons and authorized staff been identified and trained within each GPEI partner and health ministry?
3. Have key communication products with key messages for AEFI and vaccine controversy been prepared and made available to key spokespersons?

Considerations for advocacy with medical practitioners, health officials and managers, paediatric society, religious and community leaders, local governments and other opinion-makers conducted in support of an nOPV2 outbreak response campaign

1. Has the advocacy strategy for key in-country stakeholders (e.g. medical practitioners, and religious and community leaders) been finalized?\*
2. Has a team of recognized medical experts (including from the national health promotion department) been formed to conduct advocacy meetings?
3. Have meeting materials been duly produced and distributed at the meetings? Note: These include presentations on country EPI overviews, cVDPV outbreaks, a response strategy including the use of nOPV2 and its advantages, ACSM activities, Q&As, and guidance for healthcare workers and opinion-makers.

**KEY/LEGEND**

\*A requirement in the Readiness Checklist for use under EUL





[HTTP://WWW.POLIOERADICATION.ORG/](http://www.polioeradication.org/)

