nOPV2 Readiness Verification and Dose Release Process

Interim guidance for the Initial Use Phase

Readiness Verification

Overview

Roll out of novel oral polio type 2 vaccine (nOPV2) will require verification that a country has met all readiness requirements for use of nOPV2 under the Emergency Use Listing (EUL). All countries considering the use of nOPV2 will be required to be verified as ready prior to approval of dose release from the nOPV2 stockpile. Doses will not be released without a verification that the country has completed all requirements. The readiness verification process set out here will be reviewed and updated after initial uses of nOPV2 based upon lessons learned.

nOPV2 Readiness verification will not include an assessment of campaign strategy, scope, target population or timing proposals.

Readiness verification is conducted by a Readiness Verification Team (RVT), which is established by the Global Polio Eradication Initiative (GPEI) to oversee this process. Representatives include nOPV2 focal points from the regional offices of WHO and UNICEF, the nOPV2 Working Group (which will Chair the RVT), Outbreak Preparedness and Response Task Team (OPRTT), Surveillance Task Team (STT), United States Centers for Disease Control and Prevention (CDC) Safety Team, and Global Communications Group nOPV2 Project Team, supported by a dedicated secretariat.

Two Steps of Readiness Verification

There are two steps to readiness verification: (1) Ongoing progress monitoring and (2) Readiness verification.

(1) Ongoing progress monitoring

Under this step, the following will take place:

- Country provides periodic updates on progress in nOPV2 readiness planning. Countries are encouraged to update on progress regularly so that it does not impede potential future release of vaccine should there be notification of an outbreak.
- Regional and global colleagues review and flag any concerns they may have proactively—I.e. while nOPV2 preparations are ongoing.
- Any requirement that is 'met' can be signed off immediately as soon as completed.

(2) Readiness verification

- Once it has been confirmed that all requirements have been met, a country receives its nOPV2 readiness verification and is eligible for the dose release process.
- The readiness verification step can take place before an nOPV2 response is planned, or in conjunction with planning a specific nOPV2 response. If done in advance of a specific response, especially during the initial use phase, some elements (for example, Environmental Surveillance presence in outbreak response area), may need to be verified again prior to sign-off.

Membership of the RVT

The RVT will include the following membership, each of whom will review readiness elements within their own area of expertise.

- Relevant nOPV2 regional focal points from WHO and UNICEF
- nOPV2 Working Group – Will chair the RVT and ensure linkages across various workstreams
- Outbreak Preparedness and Response Task Team (OPRTT)
- Surveillance Task Team (STT)
- CDC Safety Team
- Global Communications Group nOPV2 Project Team
- Dedicated secretariat

Step 1: Ongoing Progress Monitoring

A. Country submits interim checklist submission

- Within two weeks of starting the planning process, the country's nOPV2 readiness checklist should be submitted to the regional nOPV2 focal point to assess progress.
- Regular updates should be provided at least every two weeks to the regional nOPV2 focal point, through re-submission of the checklist.
- Supporting documents—even in draft form—can be shared for input; any documents that are already completed/ready to be signed off on should be shared as soon as ready.

B. nOPV2 RVT formally reviews progress on at minimum a monthly basis

- nOPV2 RVT reviews the country submission and progress made in preparing for nOPV2.
- The RVT raises any issues of concern with the regional and national nOPV2 focal point for adjustment and corrective actions as necessary. If a country has not appointed an nOPV2 focal point, comments will be provided to the WHO or UNICEF polio and immunization lead in the country.
- The RVT identifies any additional needs for technical guidance/support that may not be in place and works to make them available

Proposed process and timeframe for the monthly progress monitoring review are as follows (total time: 1 week):

- **By Day 2:** after receipt of checklist: review should be completed by nOPV2 RVT
- **By Day 4:** Call of nOPV2 RVT to agree on areas of concern/support needs and provide proposed actions for country consideration

- **By Day 5:** Summary of call to be circulated within 1 working day of meeting
- **By Day 7:** Call scheduled with the national nOPV2 focal point to update them on the group's input (not all nOPV2 RVT members need to join call. Call to be led by regional nOPV2 focal point)

Step 2: Readiness Verification

A. Country submits completed readiness checklist and supporting documents

- Once all the actions outlined in the nOPV2 readiness checklist are completed and the supporting documents available, the country is ready to request its readiness verification.

- To verify readiness, the following documents must be submitted
    - Completed nOPV2 readiness checklist
    - Documentation of the following:
        - National decision to proceed with nOPV2 use
        - Approval for the use of the vaccine in the country
        - Approval for the import of the vaccine into the country
    - *Supporting documents***
        - Documents should only be those that we MUST see to verify readiness and that have not already been approved
        - See Annex A for a list of all required documents

B. nOPV2 RVT reviews submission

Proposed review process and timeline for readiness verification

- **Day 0**:
    - Receipt of documents: nOPV2 RVT secretariat will share the documents with the relevant nOPV2 RVT members
- **Day 0-2**:
    - 48h for RVT members to review the documents in their specific area of expertise and ensure readiness compliance. For their area of expertise, RVT members should flag any:
        - **'critical gaps'** (i.e. verification must be withheld until addressed)
        - **'issues to address'** (i.e. areas of concern, but which we feel can be jointly addressed in a timely manner and thus verification can proceed)
    - Submit assessment to secretariat by end of day 2.
- **By Day 3**: Call held of RVT to discuss critical gaps and issues to address
    - The secretariat will present the summary of the assessments received, focusing on areas where readiness has not been met.
    - Subject matter experts will be asked to present their proposed next steps for addressing identified issues/critical gaps; other RVT members provide input.

Assuming there **are no critical gaps**

- **By Day 5**: verification of readiness will be granted.
    - The nOPV2 RVT secretariat will share a note for the record with the country and simultaneously share with the OPRTT

        - Note will include any issues that need to be addressed prior to nOPV2 use and support available to do so.
    - NOTE: This step can be shortened to occur by Day 3/4 if there is an urgent need for RVT approval and/or there are no/limited issues to address

If there are critical gaps,

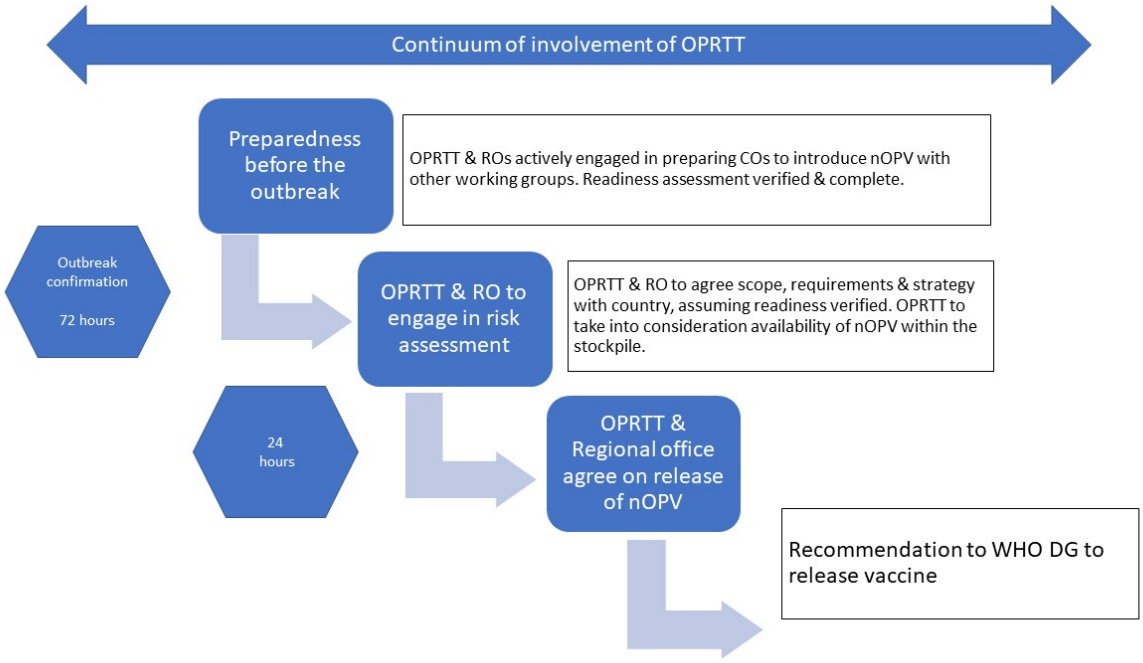
- **By Day 6**:
    - The nOPV2 RVT chair and secretariat will schedule a call with the national nOPV2 focal point and the relevant nOPV2 RVT members
    - Call will aim to:
        - Explain why verification of readiness was not granted.
        - Discuss options for rapidly addressing the critical gaps, and implications on timing of proposed nOPV2 response in doing so.
- **By Day 9:**
    - A plan to address critical gaps developed jointly by region, nOPV2 national focal point and nOPV2 RVT is agreed upon with a timeline for implementation.
    - Alternately, country may decide to switch to planning an mOPV2 response.

Process for the release of nOPV2

Introduction/context

This document outlines the process for the release of nOPV2, which will be introduced as a new outbreak response tool. The document takes into consideration the unique requirements that must be met for the introduction of nOPV2 which will be made available for outbreak response under an Emergency Use Listing (EUL) recommendation. This document is developed with the assumption that a country has already completed all 27 requirements outlined in the readiness assessment checklist (for initial use) and has been assessed as ready to introduce nOPV2 for outbreak response activities, as outlined earlier. This document is aligned with the Global Polio Eradication Initiative (GPEI) document Standard Operating Procedures for Responding to a Poliovirus Event and Outbreak.

The nOPV2 release from a stockpile will require approval of the WHO Director-General at least for the initial use period, which will extend for the first 2-3 months after the EUL. Any request to use nOPV2 in response to isolation of VDPV2, will be reviewed and vetted by the Outbreak Preparedness and Response Task Team (OPRTT) of the Eradication & Outbreak Management Group (EOMG), together with the relevant regional team (WHO/UNICEF) before submitting it to the WHO Director General. As showing in Figure 1., the OPRTT will be actively involved working with countries to support all phases of outbreak response working closely with regional offices of WHO and UNICEF.



OPRTT and ROs will continue to be actively engaged in preparing countries for the eventual use of nOPV and understand the contextual realities at field level. OPRTT and regional colleagues will be well familiar with the quality of preparedness, which will be particularly important throughout the initial use phase and until nOPV2 is licensed and pre-qualified.

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

The country team would initiate the process of developing a detailed risk assessment with the support of the regional (includes Hub, RRT) team and OPRTT. All regional offices (WHO and UNICEF) will nominate a focal point who will be actively engaged in working with the country team to finalize the risk assessment within 72 hours of confirmation of an outbreak, for review and approval. They will remain the point of contact and engagement throughout this process. The OPRTT will have a small team to be engaged in this process. While laboratory and epidemiologic investigative steps correspond in general to standardized processes for following-up any poliovirus detection, the risk assessment aims to characterize the virus transmission and the implications for its further spread. It assesses the critical factors which will influence the type and scale of response, and make recommendations for appropriate actions. For type 2 poliovirus, the risk assessment focuses specifically on addressing three core questions (1) What is the nature of the virus (e.g. WPV, Sabin, or VDPV)? (2) Is there evidence of circulation? and (3) what is the risk of further spread? The RO/Hub/OPRTT will work with the country team to develop the risk assessment, including information on the characteristics of the cases, areas drained by the environmental samples collection sites, population immunity against type-2 poliovirus, surveillance sensitivity / quality, population movement, program capacity to implement SIAs and any other relevant/specific information (the secretariat will share the risk assessment template to the country and regional programs, as guidance). The risk assessment should outline options and vaccine requests as part of the proposed outbreak response activity. As outlined above this process assumes that country has taken the decision to use nOPV2 and is fully ready and prepared to introduce the vaccine for outbreak response activities. The completed readiness assessment endorsed by the GPEI Readiness Verification Team (VRT) will accompany the submission of the risk assessment by the country team.

Step 2: within 72 hours of outbreak confirmation

The OPRTT leadership and regional team will:

1. Review risk assessment (combined HQ/RO/CO risk assessment) which should include country context, genetic data, analysis of risk
2. Decide if the situation warrants the use of nOPV2
3. Review country vaccine request and assess the quantity of vaccine (nOPV2), if required
4. Ensure that the proposed vaccination response satisfies the initial use framework criteria of 12 weeks since last mOPV2 and 6 weeks since last bOPV campaign in the same area)
5. Advise the WHO Director-General on nOPV2 vaccine release from the global or national stockpile for supplementary immunization activities (SIAs).

The OPRTT and regional team will advise the country team on:

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

Within 48 hours of the submission of the risk assessment[1], the OPRTT leadership team and regional focal points will review the vaccine request and response plan prepared by the requesting country. Through the Director of the WHO Polio Department, the OPRTT will advise the WHO Director General on the request and their recommendation. A secretariat will process all necessary communication throughout this process as outlined below.

The OPRTT leadership team and regional focal points for each of the concerned WHO and UNICEF regional offices will be jointly responsible for deciding (1) if the situation warrants the use of vaccine and, if vaccine use is approved, (2) the vaccination campaign's geographic scope. The decision on the scope of campaigns and the release of vaccines from the stockpile requires a **majority** decision. If the members are not able to reach a decision, the matter will be immediately referred to the GPEI EOMG by the secretariat.

The DG will decide within 24 hours of receiving the request whether to release the vaccine from the global stockpile. The WHO DG authorizes nOPV2 vaccine release for first and subsequent SIAs. This can be done in a single request or multiple phases, if needed. As per the outbreak SOPs, the country team would then submit a nOPV2 Vaccine Request Form signed by the appropriate Government Ministry of Health official to the secretariat with copy to the relevant WHO and UNICEF regional offices within 2 days following the DG approval.

The secretariat coordinates the communication of the DG's decision to the EOMG, nOPV2 working group (throughout the initial use and EUL period), OPRTT, UNICEF supply division and other relevant parties (e.g., incident managers, outbreak coordinators etc.). The secretariat will maintain the records of the risk assessments, DG approvals, VRFs, and number of doses released by UNICEF supply division for each transaction.

Secretariat

The existing mOPV2 Advisory Group secretariat will support the OPRTT to coordinate the decision-making process for the release of nOPV2. WHO Headquarters hosts it with a nominated lead in the WHO Polio Eradication Programme.

Tracking of vaccines

Given the VSTT's accountability to plan and manage the Global OPV2 Stockpile and OPRTT's role in advising WHO DG on nOPV2 release to the countries, both groups will work closely to ensure that vaccine distribution plans align with the global supply, as well as identifying and addressing risks associated to nOPV2 supply for response to cVDPV2 outbreaks. The OPRTT will engage with the WHO Global Stockpile focal point and UNICEF supply division to develop and report weekly to the EOMG on the vaccine distribution plans. The WHO Global Stockpile focal point and UNICEF supply division will support OPRTT in tracking the decisions of the OPRTT/RO, the WHO DG and the distribution of the vaccines to each country. The UNICEF country program will be expected to report back to the secretariat on nOPV2 stocks in the country two weeks after the end of each SIA, when a subsequent SIA is not planned. Use of nOPV2 in country will be guided by the document *nOPV2 Management, Monitoring, Removal and Disposal (in 50 dose vials with VVM type 2) Interim Technical Guidance for Initial Use Period.*

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

Annex A

Required Documents for Readiness Verification

Category	Requirement	Guidance notes	Supports checklist req. #
Approvals	Confirmation of national decision to use nOPV2	Confirmation by NITAG (or other national immunization, polio coordination body, or Ministry of Health if no NITAG) Option 1: Meeting minutes which should include: - Signature by chair - List of members - Date Option 2: Formal letter	B1
	Approval from NRA for the import and use of nOPV2	Formal letter/written authorization which should include: all official forms required for the import of the vaccine into the country. Where there is no NRA in country, this can come from the Ministry of Health	B2
Cold Chain and Vaccine Management	nOPV2 vaccine management and logistics plan	Vaccine Management Plan which includes - Outline of how containment requirements will be met, including plans for - reverse logistics requirement - vial disposal - Confirmation that impact of 50 dose vial presentation has been factored into tools and capacity estimates	C1
	Cold Chain Equipment Inventory and Gap Analysis for estimated campaign scope	Short summary of cold chain capacity which should include - date of last inventory - assumptions of gap analysis, along with confirmation it looked at freezer, cold box and vaccine carrier capacities and that they are sufficient for nOPV2 campaign needs	C2
Surveillance	Country's updated surveillance guidelines and supporting documents	Country's updated surveillance guidelines and supporting documents which include details on: - How active case searches will be carried out in all priority sites in each geographic area where nOPV2 was used, one month following nOPV2 use in that area - How vaccination coverage data from age-matched, randomly selected community members around AFP VDPV2 cases will be collected - * How systematic contact sampling of all AFP cases for 6 months after an nOPV2 outbreak response will be done	D1/D2/D5

Surveillance (con't)		- * Written confirmation that the lab has been informed that ES samples will be collected twice per month for 6 months after nOPV2 use (can be provided as an email, note verbale, letter, meeting minutes etc). Further details can be found in the *Polio Field and Laboratory Surveillance requirements in the context of nOPV2 use*	
	Case Investigation Form (CIF) for last 3 AFP cases in country	CIF should clearly note - Routine and SIA OPV doses - Date of last IPV/OPV dose received	D3
	*Surveillance desk review and plan	- Desk review completed - Surveillance strengthening plan - PID checklist completed	D4
	*Country's Situation report (SitRep) or equivalent report showing the country data (past 12 months)	SitRep or equivalent report which includes; - NPAFP rate $\geq$2 at national and 80% of all districts with < 15 year old population more than 100,000 over past 12 months - Stool adequacy $\geq$80% at national level and in at least 80% of districts expected to report AFP cases over past 12 months	D6/D7
	* Country Environmental Surveillance (ES) dashboard	ES Dashboard includes: - Geocodes - Location/char of ES site - Collection frequency - ES indicators for at least 1 functional ES site where nOPV2 will be used (EV detection $\geq$ 50%)	E1/E2
Safety	Safety monitoring plan	Country should adapt the global guide into their own country specific guide. At a minimum the country specific guide should include: - case definitions - country specific surveillance processes (flow)-- this should include an adaptation of Figure 2 from the global guide - data flow - country specific forms - roles and responsibilities table The submission should also include a budget for this work with an indication that there are sufficient resources available to cover the costs.	F1
	Safety training plan for nOPV2 roll out	List of planned trainings includes details on - Dates of trainings - Facilitator for each session - Designation of participants	F2

Safety (con't)	TORs for causality committee	Meeting minutes from a recent meeting confirming committee exists and confirming its membership (if committee is new or not yet established, the training needs for its establishment should be included in the training plan)	F3
	VRE plan	VRE must show evidence of collaboration across safety, comms and surveillance teams in country in its development	F4
Advocacy, Communications and Social Mobilization	Integrated communications plan (including advocacy, C4D, and crisis comms)	Description of types and details of the stakeholders that are identified to support OBR. Description of at-risk population and analysis of missed children, refusals and reasons from previous campaigns. Front Line Worker (FLW) training plan which clarifies plans for both training of trainers and cascade training reach all vaccinators Crisis Communication Committee SOP for crisis response SOP for misinformation management system.	G1/G2/G3

Regional/global lab coordinators will be asked to confirm the readiness of the laboratory serving this country, no supporting documents will be required as part of the readiness verification process.

Outbreak operations and national coordination status should be indicated on the readiness checklist, no additional supporting documents are required

***** denotes documents/considerations that are only required during the initial use phase