

# Polio Field and Laboratory Surveillance Requirements in the Context of nOPV2 Use



## Rationale and Objective

nOPV2 is being made available for outbreak response through WHO’s Emergency Use Listing (EUL) procedure, a rigorous analysis of efficacy and safety data to address public health emergencies of international concern, such as polio. Countries wishing to use nOPV2 under an EUL will be able to introduce the vaccine in accordance with established criteria.

In addition to the regular acute flaccid paralysis (AFP) and environmental surveillance (ES) activities as described in the Global Polio Surveillance Action Plan<sup>1</sup>, GPEI will need to further enhance polio surveillance in countries where nOPV2 will be used in order to:

- rapidly detect and characterize any nOPV2-related virus or VDPV, following the use of nOPV2
- provide support to the Adverse Events Following Immunization (AEFI) system in detecting selected Adverse Events of Special Interest (AESI) that may be related to nOPV2 use
- contribute to the documentation on safety and efficacy of nOPV2 (as required under EUL)

The program must be able to document the safety and efficacy of nOPV2 through a sensitive and robust Acute Flaccid Paralysis (AFP) and AEFI system.

The program needs to ensure and document that a robust and sensitive surveillance system is in place. Throughout this document, an effort will be made to highlight what is necessary for all countries using nOPV2 while it is under EUL, versus additional requirements, which will apply on to “initial use countries”. Initial use countries will have more stringent surveillance criteria, as they will be the first to deploy nOPV2 for large-scale field operations.

This document should be read in conjunction with the *nOPV2 technical guidance for countries*<sup>2</sup>. Activities specifically linked to information management systems will not be detailed in this document, but can be found in the above-mentioned document, or related guidance.

## Steps towards nOPV2 introduction in a country



<sup>1</sup> Global Polio Surveillance Action Plan, 2018-2020. Geneva: World Health Organisation; 2019.

<sup>2</sup> Implementation of novel oral polio vaccine type 2 (nOPV2) for circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreak response: technical guidance for countries Geneva: World Health Organization; 2020.

All documents and guidance on nOPV2 can be found at <http://polioeradication.org/nOPV2>

Once a country has expressed interest in using nOPV2, a series of field and laboratory surveillance related activities will take place. A list of activities will be reviewed in more detail in the next two chapters and in Annex 1.

1. **First Step: Expression of interest** – the country confirms its interest to use nOPV2 for cVDPV2 outbreak response with its WHO Regional Office.
2. **Second Step: Getting ready** – the country develops and implements a plan to meet readiness requirements (see Part 1.1 below). Duration of this step will vary by country; however it is expected that preparations will take 1-3 months.
3. **Third Step: Submission of readiness status** – the country demonstrates that all requirements are met. All documents generated by activities described in the second step ‘getting ready’, are submitted to assess the ‘readiness of the country’ before nOPV2 can be released for use. It is important to note that the readiness checklist can be submitted to the Regional Office (RO) at regular intervals to assess the progress of the country (monthly intervals or otherwise defined by the RO).
4. **Fourth step: ‘Post deployment Monitoring’ (PDM) phase<sup>3</sup>** – starts once nOPV2 has been used for the first time and will last for 12 months after the last nOPV2 supplementary immunization activity (SIA). Some activities may be monitored for six months, while others may require a full 12 months of monitoring. While nOPV2 is under EUL, PDM requirements will be in place for all countries using nOPV2.

## PART I: Field Surveillance

### Field Surveillance Requirements

In anticipation of EUL requirements, a list of “must do” and recommended activities has been developed. The country will be asked to report on the implementation status of these activities.

**Table 1. Field Surveillance Requirements for nOPV2 use for countries under EUL & initial use**

Category	Activity/Element (reference in the nOPV2 checklist <sup>4</sup> )	Requirements for use under EUL- <i>All countries to complete</i>	Additional Requirements for Initial Use period
AFP Surveillance	Complete Desk Surveillance Review; develop surveillance strengthening plan (D4)	NO (but recommended)	YES
	Adapt new Case Investigation Form (CIF) (D3)	YES	YES
	Carry out retrospective case search in all priority sites where nOPV2 was used, one month after first nOPV2 campaign (D1)	YES	YES
	Systematic contact sampling of all AFP cases for 6 months after last nOPV2 use (D5)	NO	YES

<sup>3</sup> The PDM requirements have been proposed by Bio Farma and submitted to the Prequalification (PQ) team in WHO. The EUL recommendation may change during the course of the PQ review.

<sup>4</sup> ‘nOPV2 vaccine deployment checklist’ under <http://polioeradication.org/wp-content/uploads/2020/08/nOPV2-Vaccine-Deployment-Readiness-Checklist-July-2020-FINAL.xlsx>

	Ensure Non-Polio Acute Flaccid Paralysis (NPAFP) rate $\geq 2$ at national level and in at least 80% of all districts with more than 100,000 u15 <b>(D6)</b>	NO (but recommended)	YES
	Ensure stool adequacy $\geq 80\%$ at national level and in at least 80% of all districts reporting AFP cases <b>(D7)</b>	NO (but recommended)	YES
	Collect vaccination coverage data from age-matched, randomly selected community members around AFP VDPV2 cases <b>(D2)</b>	YES	YES
<b>Environmental Surveillance</b>	Ensure one functional ES site in areas where nOPV2 will be used <b>(E1)</b>	NO (but recommended )	YES
	Collect ES samples twice per month for 6 months after nOPV2 use (then monthly for additional 6 months) <b>(E2)</b>	Only for new ad hoc sites	YES (all sites)
<b>AFP surveillance network support to safety monitoring</b>	Support training on data collection tools and modification of information system for nOPV2 AESI <b>(F1-F2)</b>	NO (but recommended )	YES
	Train all AFP officers on nOPV2 variables and collection of safety monitoring data <b>(F2)</b>	YES	YES

## Step 2: Getting ready

### Briefing & Coordination

Before initiating the process, a briefing of the surveillance and laboratory team at the national level should take place, along with the EPI/AEFI team, and the GPEI/outbreak team. The objective is to get everyone aligned on the process, timeline and commitment required. Introducing a new vaccine in an outbreak setting is a challenge that requires coordination among several teams, and at all levels (central to district levels) of the MoH. This briefing can be organized by the nOPV2 national lead, and the regional and global nOPV2 teams are available to support as required.

### Desk review

A **desk review of the polio surveillance** system must be completed for initial use countries, as soon as the country expresses interest in using nOPV2, and preferably within the first two weeks. This assessment will review the strengths and weaknesses of the current surveillance system and highlight the main gaps that may hamper the introduction of nOPV2. Clearly not every gap in the surveillance system will be addressed for nOPV2 introduction but understanding the weaknesses and strengths of the system behind the reported data is essential to reliably assess polio surveillance sensitivity.

**Desk review – essential activity to reliably assess polio surveillance sensitivity**  
*Requirement for Initial use countries.*



*Global-level guidance on desk reviews is available<sup>5</sup>; this activity should be done within 1-2 weeks after the country expresses interest in using nOPV2. Support is available upon request to the RO and Surveillance Task Team (STT).*

## Surveillance readiness plan

Once the desk review has been completed, and as part of the overall readiness plan of the country, a surveillance readiness plan must be developed for initial use countries to address the main gaps identified in the desk review and to plan for nOPV2-specific surveillance activities. This plan should span over a 2-3 month period for implementation. The following key activities should be included:

- review the prioritization of the active surveillance network – with a focus on hard to reach/special populations and community-based surveillance (CBS)
- review and address surveillance shortcomings in underperforming administrative 1 areas (i.e., first subnational level).
- Review and address any additional gaps identified (data management, cold chain, logistics, supervision, etc.)
- Plan for nOPV2-specific surveillance activities
- Complete PID checklist (see Annex 4)

### Readiness Plan

1. **Address the main gaps** identified in the Surveillance Desk Review
  2. **Plan for nOPV2-specific surveillance activities, including completion of PID checklist (Annex 4)**
- (Requirement for initial use countries)**



*The Surveillance plan should be developed and if appropriate, budgeted within a week of the Surveillance Desk Review being finalized*

## Plan for retrospective case search (post nOPV2 use)

In addition to the active surveillance visits conducted weekly or twice a month, a retrospective case search will be done. The objective will be to detect any missed AFP cases, and also to detect any AESI (as per the AEFI protocol). This retrospective case search will review the previous six months of data in = health facility records and focus on all key facilities (priority 1 and 2<sup>6</sup>) in the nOPV2 area of use. This should be done one month after the first nOPV2 campaign.

### nOPV2-related surveillance activities

- Plan for retrospective case search
- Trainings for surveillance & AESI
- Expansion of ES
- Plan for collecting data around VDPV2 cases
- Adapting CIF tool

**Requirement for all countries**



*In their readiness status update, the country should provide evidence that this activity has been planned. The retrospective case search must be documented and any 'missed AFP case' must be investigated and reported through the system*

<sup>5</sup> The desk review template is embedded in the readiness checklist and can be found at [www.polioeradication.org/nopv2](http://www.polioeradication.org/nopv2)

<sup>6</sup> Priority 1 refers to 'very high' and 'high' priority sites with twice weekly or weekly visits; and priority 2 refers to 'medium' priority sites with twice monthly visits.

## Trainings

A series of training will need to take place during the readiness phase.

### Trainings of surveillance officers

Several trainings will need to take place to refresh knowledge of AFP surveillance and to brief surveillance officers on nOPV2 and nOPV2-specific surveillance requirements. Ideally, all districts, nationwide, would receive the training, but at a minimum, training should be held in all districts using nOPV2 and neighbouring districts. Content can be adapted to local needs but must include a module on AFP case investigation and active case search (retrospective and active surveillance visits). In addition, a module on AESI will be necessary to train surveillance officers on identification, reporting, and monitoring of AESI. Some examples of AESI conditions that will need to be actively monitored under enhanced surveillance measures for six months are listed below; the full list can be found in the AESI guidance<sup>7</sup>:

- Anaphylactic reaction
- Aseptic meningitis/encephalitis
- Acute disseminated encephalomyelitis (ADEM)
- Guillain-Barre syndrome
- Transverse myelitis



*Training modules on AFP surveillance and AESI are available upon request to the RO/GPEI's STT/nOPV2 safety team. Webinars/virtual trainings could also be provided by the same groups. In the readiness status update, the country should provide evidence that this activity took place.*

### Training of National Polio Expert Committee

The National Polio Expert Committee (NPEC) will need to be briefed on nOPV2 and related AEFI and AESI. A refresher training must be provided to the NPEC on vaccine-associated paralytic polio (VAPP) diagnostics and other polio differential diagnoses (the percentage of AFP cases with a final diagnosis should be > 80%). Given the key role of the NPEC in classifying AFP cases, it will be requested to support the AEFI Causality Committee. As such, the training should also include a significant component on AESI/AEFI.



*A Training module is available. Webinars/virtual trainings can be provided by RO/STT/nOPV2 safety team. In the readiness status update, the country should provide evidence that this activity took place and monitor the percentage of AFP cases with a final diagnosis.*

### Expansion of environmental surveillance

While most environmental surveillance (ES) sites are considered permanent sites for routine, programmatic poliovirus surveillance, temporary (or ad hoc) sites can be opened in response to an outbreak or due to increased risk of transmission in a certain area. Enhanced environmental surveillance will be conducted in the countries where nOPV2 will be used.

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<sup>7</sup> nOPV2 AESI Surveillance Guide (soon to be posted under the GPEI website)

## Reviewing current ES sites & mapping out potential new sites

The program with the support of the RO/GPEI will review the performance of all current ES sites in country with a focus on the areas of outbreak/nOPV2 use<sup>8</sup>. This is part of the desk review exercise.

If ES does not exist in nOPV2 use areas, the program should assess and explore the feasibility of implementation of environmental site(s), targeting, large population centers of approximately 100,000 population where possible.

## Opening ad hoc sites in nOPV2 areas

Before opening a new site, a discussion must take place between the country program, the laboratory and the RO on feasibility.

- Any new ad hoc site, opened for outbreak response using nOPV2
  - Will collect specimens every two weeks, for the first six months of implementation. After discussion with key decision makers, the frequency may revert to monthly for the remainder of the assessment period (except for initial use countries where sampling frequency should remain twice a month for six months after nOPV2 use)
  - Measures will be implemented for at least 12 months. Ad hoc sites will be assessed at the end of the 12 months for feasibility to continue sample collections for an additional six months
- Existing (routine) ES sites will be monitored as per their current sampling schedule for 12 months (except for initial use countries where they will shift to twice a month sampling frequency for the first six months following the last use of nOPV2)

As it may be difficult to know in advance where nOPV2 will be used in a country, it is recommended to explore and possibly expand the ES network to the main populated areas of the country.



*In the readiness status update, the country should provide evidence on location and performance of the current ES network, feasibility assessment for additional ad hoc sites and decision to open ad hoc sites.*

## Plan for collecting additional data around VDPV2 cases (post nOPV2 use)

The current Standard Operating Procedures (SOPs)<sup>9</sup> on investigation of VDPV2 cases includes collection of stool specimens from healthy children from the community (but not in close contact with the VDPV2 case). The objective of this SOP is to detect evidence of circulation of the VDPV2.

In the context of nOPV2, the investigation around a VDPV2 case will also include another component: the collection of vaccination data on age-matched, randomly selected community members of VDPV2 cases (see Annex 3). The information collected will help to estimate the effectiveness of nOPV2 against paralytic disease caused by VDPV2. For all VDPV2 cases and selected community members, a complete and detailed polio vaccination history will be required.

<sup>8</sup><http://polioeradication.org/wp-content/uploads/2020/06/ES-OBR-nOPV2-revision-20200601.pdf>

<sup>9</sup>Polio Outbreak SOPs can be found at <http://polioeradication.org/wp-content/uploads/2020/04/POL-SOP-V3.1-20200424.pdf>

Tools and SOPs must be developed, and readily available.



*A standard SOP document on collecting age matched randomly selected community members can be found in Annex 3. The program must present evidence that it has been adapted to the local context, and planned for.*

## Adapting data management and data collection tools

### Updated Case Investigation Form (CIF):

An updated case investigation form (CIF) has been developed to record separately polio vaccines received through RI and SIAs, as well as date of last OPV received through SIAs. All CIFs must be updated with those new variables. An example of the ‘vaccine history requirements’ can be found in Annex 2.

### New Adverse Events of Special Interest (AESI) tool

WHO has established global guidelines for all countries on how to set up a functional passive AEFI surveillance system to report adverse events following immunization (AEFI), as well guidance on how to investigate, analyze surveillance data, and conduct causality assessment on AEFI<sup>10</sup>.

To compliment this system, active surveillance for a focused list of adverse events of special interest (AESI) has been developed<sup>11</sup>. Polio surveillance officers may provide support in detecting and possibly investigating AESIs (see Section 1.e for list of AESI) depending on the country. Some AESI are already detected through AFP surveillance (e.g., VAPP, transverse myelitis, Guillain Barre Syndrome), while others are not (e.g., Anaphylactic reaction, Aseptic meningitis/ encephalitis, Acute disseminated encephalomyelitis).

For initial use countries, active surveillance for AESI will be combined with active surveillance for AFP for the duration of nOPV2 use, up to three months after the last nOPV2 SIAs. Surveillance officers will need to be trained on AESI case definitions and data collection tools<sup>10</sup>. For other countries using nOPV2 under EUL, active surveillance for AESI is recommended but is not a requirement.

AESI data management may fall under the responsibility of the polio surveillance and/or EPI data manager depending on the country. AFP and AESI active surveillance data will flow to the central level per the AFP data flow process. After compilation of AESI data from multiple data streams, AESI data will be submitted to the expert review group and causality committee who, after thorough investigation, will decide whether the AESI are indeed AEFI and conduct a causality assessment for conditions identified.

A report to RO/nOPV2 working group on AEFI is expected: (1) on a monthly basis for three months for initial use countries which will then shift to quarterly reports; (2) on a quarterly basis for all other countries using nOPV2 under EUL for a 12-month period (no monthly reporting required).

<sup>10</sup> [https://www.who.int/vaccine\\_safety/publications/aeifi\\_surveillance/en/](https://www.who.int/vaccine_safety/publications/aeifi_surveillance/en/)

<sup>11</sup> nOPV2 AESI Surveillance Guide (soon to be posted under the GPEI website)



*The program must present evidence that tools are updated, and available and data flow processes and roles and responsibilities have been clarified.*

### Specific activities for initial use countries

Initial use countries will face more stringent criteria as nOPV2 starts to be used on such a large scale. In addition to what has already been listed, initial use countries will be required to:

- carry out a desk review and develop a readiness/surveillance strengthening plan
- carry out systematic contact sampling of all AFP cases at national level for the duration of nOPV2 use, and at least six months following the last nOPV2 SIAs.
- ensure one functional ES site in areas where nOPV2 will be used
- collect ES samples twice per month for six months after nOPV2 use (then monthly for additional six months)
- ensure NPAFP rate  $\geq 2$  at national level and in  $\geq 80\%$  of all districts with more than 100,000 under 15 population
- ensure stool adequacy  $\geq 80\%$  at national level and in at least 80% of all districts reporting AFP cases
- if appropriate<sup>12</sup>, establish active surveillance for AESI using the AFP active surveillance network infrastructure: active AESI surveillance will be implemented for the duration of nOPV2 use, and for a minimum of three months after the last nOPV2 vaccination campaign.

### Additional requirements for initial use countries

- Systematic contact sampling for all AFP cases
- One functional ES sites in nOPV2 used areas.
- Twice a month sampling for 6 months after nOPV2 use from all ES sites.
- Ensure NP AFP rate  $\geq 2$  and  $\geq 80\%$  stool adequacy at national level, and in populated districts
- Active surveillance for AESI

## Step 3: Submitting Readiness Status

Once the country is ready to use nOPV2, the program should submit its readiness checklist, and its supporting documents, to the regional office for the nOPV2 Readiness Verification Team to review, demonstrating the surveillance readiness requirements have been met. If the country has a WHO-accredited polio laboratory, readiness status for both field and laboratory surveillance must be submitted jointly. The readiness checklist can be submitted at regular intervals to assess the progress of the country (monthly intervals or otherwise defined by the regional offices).

The country will need to demonstrate that all the surveillance requirements are met. All documents generated by activities listed in the checklist as D1-D3 and F1-F2 for countries under EUL, in addition to activities D4-D7 and E1-E2 for initial use countries, should be part of the readiness status dossier. Selected variables and thresholds are highlighted in the surveillance

<sup>12</sup> Some countries may not have an active AFP surveillance system; in that case, active AESI should be set up as a stand-alone system or integrated with another program, as deemed appropriate by the country team.



tab of the readiness checklist as a guide to countries on what is considered a sensitive polio surveillance system.

## Step 4: Post-deployment Monitoring

Once nOPV2 has been used in a country, the following post-deployment monitoring activities need to be implemented and documented based on the readiness plan. The program must be able to contribute to the documentation on safety and efficacy of nOPV2. The documentation and reporting are therefore essential.

**Table 2. Summary of Post-deployment Monitoring activities and reporting timelines**

Activity	Description	Documentation	Reporting milestones <sup>13</sup>
<b>Enhanced AFP surveillance</b>	<p>Retrospective &amp; active case search</p> <ul style="list-style-type: none"> <li>All countries must conduct one-time retrospective case search one month after the first campaign reviewing the previous 6 months, and ongoing AFP active case search via active surveillance.</li> <li><b>For initial use countries only:</b> systematic contact sampling of AFP cases (2 contacts), for 6 months after the last nOPV2 SIA rounds</li> </ul>	<ul style="list-style-type: none"> <li>Narrative report on retrospective one-time case search, within a month of the activity taking place</li> <li>Evidence of monitoring of active surveillance visits</li> <li>Data on AFP &amp; contact sampling (as per AFP regular analysis)</li> </ul>	<ul style="list-style-type: none"> <li><b>For initial use countries,</b> monthly report for first 3 months then quarterly reports for initial use countries.</li> <li>For other countries using nOPV2 under EUL, quarterly reports</li> </ul>
<b>Enhanced environmental surveillance</b>	<ul style="list-style-type: none"> <li><b>For initial use countries:</b> all sites shift to twice a month sampling for up to 6 months after the last nOPV2 SIAs, then monthly sampling</li> <li>For countries under EUL: twice a month sampling for 6 months for ad hoc sites only, routine sites continue monthly sampling.</li> </ul>	<ul style="list-style-type: none"> <li>Data on ES (as per SOPs<sup>14</sup>)</li> </ul>	<ul style="list-style-type: none"> <li><b>For initial use countries,</b> monthly report for first 3 months then quarterly reports for initial use countries.</li> <li>For other countries using nOPV2 under EUL, quarterly reports</li> </ul>
<b>Enhanced AESI surveillance<sup>15</sup></b>	<p>Retrospective &amp; active case search</p> <ul style="list-style-type: none"> <li><b>For initial use countries:</b> one-time retrospective AESI case search (could be combined with AFP retrospective case search), and AESI active surveillance for 3 months following last nOPV2 use.</li> <li>For other countries using nOPV2 under EUL, the above-mentioned activities are</li> </ul>	<ul style="list-style-type: none"> <li>Narrative report on retrospective case search, within a month of the activity taking place</li> <li>Evidence of monitoring of active surveillance visits</li> <li>Data on AESI/AEFI</li> </ul>	<ul style="list-style-type: none"> <li><b>For initial use countries,</b> monthly report for first 3 months then quarterly reports for initial use countries.</li> <li>For other countries using nOPV2 under EUL, quarterly reports</li> </ul>

<sup>13</sup> A detailed reporting timeline will be provided by the nOPV2 working group once nOPV2 is rolled out.

<sup>14</sup> Guidelines on environmental surveillance for detection of polioviruses. March, 2015. Available at [http://polioeradication.org/wp-content/uploads/2016/07/GPLN\\_GuidelinesES\\_April2015.pdf](http://polioeradication.org/wp-content/uploads/2016/07/GPLN_GuidelinesES_April2015.pdf)

<sup>15</sup> nOPV2 AESI Surveillance Guide (soon to be posted under the GPEI website)

	<p>recommended but are not a requirement.</p> <p>Classification of cases</p> <ul style="list-style-type: none"> <li>For all countries - review of AESI data by the Causality Committee (with the support of the NPEC)</li> </ul>		
<b>Data to inform nOPV2 effectiveness against paralytic polio</b>	<p>For all countries, collect vaccination coverage data from age-matched, randomly selected community members of VDPV2 cases (See Annex 3)</p>	<ul style="list-style-type: none"> <li>Data and narrative report within a week of activity completion</li> </ul>	<p>Quarterly reports for all countries</p>

## PART II: Laboratory Surveillance

### Laboratory Surveillance Requirements

To meet EUL requirements, all countries must meet the following requirements as described in the nOPV2 Readiness Checklist:

H1: A plan has been developed to prepare the national lab for nOPV2 use, including updating the isolation algorithms and stocking/training on the ITD testing kits for both AFP and ES along with modifications to the reporting mechanism.

H2: Relevant laboratories are prepared to ship samples to the United States Centers for Disease Control and Prevention (CDC) or National Institute for Biological Standards and Control (NIBSC) for complete genome sequencing for post-response monitoring

To meet these requirements, a list of enabling activities to be conducted by the laboratory serving the country which will use nOPV2 has been identified:

- laboratory to submit a desk-review for the previous 12 months using checklists available in the web-based [Global Polio Laboratory Network \(GPLN\) management system](#)<sup>16</sup>
- current workload is calculated and expected increase is estimated based on field surveillance strengthening plan (refer to Part I: Field Surveillance)
- one-year stock of consumables and reagents is secured at least one month before nOPV2 use in the country
- laboratory staff for all polio laboratories are formerly trained on ITD 6.0 and new algorithm for ES VI.
- Standard Operating Procedures and worksheets for (i) ITD testing and sequencing, and (ii) for virus isolation from environmental samples are updated.
- laboratory databases (AFP and ES) have been updated to reflect new testing algorithm outcomes
- A specific SOP for nOPV2 data management and reporting is developed and shared

<sup>16</sup> Note that this site is restricted access. Contact GPLN if you don't have access and require it.

## Implementation

### First Step: Getting ready

The National Polio laboratory (NPL) in charge of polio diagnosis in countries where nOPV2 is being considered for use should develop and implement a plan to meet the readiness requirements, in close collaboration with the GPLN at regional and global levels.

#### Review of NPL performance and capabilities

A review of status update and performance of the NPL over the 12 months immediately preceding the expression of interest to use nOPV2 should be carried out by the regional polio laboratory coordinator using the appropriate online checklists accessible through the web-based GPLN Management System (GPLNMS). Specific attention should be paid to Part IV of the online checklist on GPLNMS, i.e. laboratory operating procedures and work practices.

Whenever and wherever possible, onsite review of the NPL serving countries using nOPV2 under EUL should be conducted to allow for development of a comprehensive strengthening plan to address main identified gaps. If an onsite visit cannot be envisioned due to the COVID-19 situation, a desk-review completed via an interview with the laboratory head of the NPL should be conducted to ensure a comprehensive assessment of the capacity and the capability of the NPL to fulfill all key requirements.

**Deliverable/output:** Once the assessment is completed, a report validated by WHO regional and global polio laboratory coordinators will be shared with the country program and relevant regional and global reference sequencing laboratories to confirm readiness.

#### Training of laboratory staff on updated testing algorithms

The GPLN has validated a new intra-typic differentiation (ITD) algorithm and viral isolation (VI) algorithm for ES samples to ensure sensitive detection and characterization of nOPV2 and nOPV2-related viruses in both AFP specimens and ES samples.

Since all laboratories may come across nOPV2 isolates during the EUL period, the staff of all polio laboratories will be trained on performing and interpretation of amended algorithms for testing, described above, through regional webinars. These training sessions will be remotely organized for all GPLN laboratories and conducted by WHO and the Polio Global Specialized Laboratory (GSL) at US CDC. Polio laboratories in the AFR and EMR will be prioritized (training in August 2020). For other regions (WPR, EUR, EMR, SEAR) trainings were organized in September 2020.

For NPLs serving initial use countries, an additional advanced training curriculum including reporting mechanisms will be designed and delivered. Wherever possible, an onsite visit should be organized; training can be done remotely, if necessary. Following the training sessions, these NPLs will receive a panel of samples containing nOPV2 (alone or in a mixture) to evaluate *in situ* capacity to detect nOPV2 from clinical samples.

**Deliverable/Output:** The NPL has successfully passed the proficiency testing.

#### Update Standard Operating Procedures (SOPs) and worksheets

To ensure that specimens which may contain nOPV2 are properly processed and results are correctly captured, all relevant SOPs and worksheets (related to ITD testing, sequencing and viral isolation from sewage samples) should be updated by the NPL and shared with Regional

and Global Polio Laboratory Coordinators for validation at least one month prior to nOPV2 use in that country.

Deliverable/Output: Updated SOPs for ITD testing and reporting have been validated by WHO Coordinators.

### Update laboratory data system and develop a clear reporting mechanism.

To ensure standardization of data collection, analyses and reporting, WHO Polio laboratory coordinators and data managers at WHO regional offices, in coordination with WHO HQ, should make necessary adjustments in current databases in order to capture nOPV2 testing results. Pilot testing and implementation of amended laboratory databases and reporting mechanisms should take place at least one month prior to initial nOPV2 use in the Region. Laboratories should then update their specific data management and reporting SOP to incorporate changes.

Deliverable/Output: Updated laboratory data system is validated by the WHO regional polio laboratory coordinators.

### Develop a referral plan for biological materials

The NPL in collaboration with WHO Laboratory Coordinators should propose a comprehensive and detailed referral plan for biological materials which will be shipped in a timely manner to global and regional reference sequencing laboratories. Due to the COVID-19 situation, it is important that the plan include all logistics arrangements as well as contingency measures to be implemented when required.

Deliverable/Output: Referral plan submitted by the laboratory is validated by WHO regional and global coordinators.

## Second Step: submission of readiness status

All documents generated by activities described in sections 1a. to 1e. should be part of the readiness-status dossier to be submitted by the country to the nOPV2 Readiness Verification Team to confirm readiness requirements are met.

## Third step: 'Post deployment Monitoring' (PDM) phase

This phase starts once nOPV2 has been used and will last for six months after the last nOPV2 SIA in the country.

### Monitoring laboratory performance

It is imperative that the program through the GPLN closely monitor laboratory performance during the post-deployment phase. A report on the workload, timeliness and accuracy of results is expected from the laboratory on a bi-weekly basis for six months after the initial use of nOPV2. This will then shift to quarterly reports. Reports are expected from all laboratories serving countries using nOPV2 under EUL for at least six months after the last SIA.

### Monitoring consumables and reagents

Even though, as part of readiness criteria, a one-year stock of consumables and reagents is secured before initial use in the relevant country, the NPL should update and share with the national and regional offices the existing monitoring sheet on a monthly basis during the initial-use and post-deployment periods. As part of contingency planning, the WHO Regional Office should ensure that an easily accessible buffer stock is available.

### Data management and reporting

GPLN has a well-established process to share data within its laboratories and with the GPEI. However, the process to introduce nOPV2 under EUL dictates creation of specific pathways to manage, review and report data to GPEI and the vaccine manufacturer.

While laboratory result reporting schemes for all detected viruses, including Sabin-like 2 and VDPV2 will be maintained, the GPLN has proposed the creation of a “nOPV2 genetic characterization sub group” who will oversee sequencing of nOPV2 isolates and reporting of results post deployment (refer to the Subgroup terms of reference)

ANNEX 1a

Summary of field surveillance related activities and available support

Topic	Activity/Element (nOPV2 checklist reference <sup>17</sup> )	Requirement	Description	Timeline	Support
AFP Surveillance	Complete Desk Surveillance Review; develop surveillance strengthening plan (D4)	Initial use countries *	Baseline assessment of the polio surveillance system in the country +3 months plan to get the country ready for nOPV2 use	Desk review and surveillance plan to be done within 2-3 weeks of expression of interest by the country to use nOPV2	RO/STT-Template available
	Adapt new Case Investigation Form – CIF (D3)	All countries	Adjust the CIF to record separately routine and SIA Polio vaccines	Within 1-2 months of expression of interest	Template included in Annex 2
	Carry out retrospective AFP/AESI case search in all priority sites where nOPV2 was used, one month after first nOPV2 campaign (D1)	All countries	One-time retrospective case search one month after the first campaign reviewing previous 6-months	One month after the first nOPV2 SIA round	SOPs available in GPSAP <sup>18</sup>
	Systematic contact sampling of all AFP cases for 6 months after nOPV2 use (D5)	Initial use countries	Systematic contact sampling of all AFP cases – 2 contacts per case	For the duration of nOPV2 use until 6 months after the last nOPV2 SIA round.	SOPs available in GPSAP <sup>16</sup>
	Ensure NPAFP rate $\geq 2$ at national level and in 80% of all districts with more than 100,000 u15 (D6)	Initial use countries*			
	Ensure stool adequacy $\geq 80\%$ at national level and 80% of all districts reporting AFP cases (D7)	Initial use countries*			
	Collect data to inform nOPV2 effectiveness against paralytic polio (D2)	All countries	Collect vaccination coverage data from age-matched, randomly selected community members of VDPV2 cases. (see Annex 3)	Adjust the SOPs and make tool readily available. Implement around any VDPV case for the duration of the EUL period	SOPs available <sup>19</sup>

<sup>17</sup> ‘nOPV2 vaccine deployment checklist’ under <http://polioeradication.org/wp-content/uploads/2020/08/nOPV2-Vaccine-Deployment-Readiness-Checklist-July-2020-FINAL.xlsx>

<sup>18</sup> <http://polioeradication.org/wp-content/uploads/2020/03/AFP-contact-sampling-and-targeted-healthy-children-stool-sampling-20200327.pdf>

<sup>19</sup> SOPs will soon be available under the nOPV2 section of the GPEI website

ES	Ensure one functional ES site in areas where nOPV2 will be used (E1) Collect ES samples twice per month for 6 months after nOPV2 use -then monthly for additional 6 months (E2)	Initial use countries* - (E2) applies for new ad hoc sites in countries under EUL too	Review performance of all current ES sites & explore feasibility of opening new sites in nOPV2 use areas.  Increased sampling frequency.	Within 3 months of expression of interest  Twice a month ES sampling for 6 months after last nOPV2 use for initial use countries; Monthly for other countries under EUL	Guidelines on ES (draft) from STT. Desk review on ES available from STT
	Support training on data collection tools and modification of information system for nOPV2 AESI (F1-F2) – Carry out active AESI surveillance with the support of the AFP network and possibly AESI retrospective case search	Initial use countries	Print the AESI tools; Agree on responsibilities re- data management Set up Database/Information system for AESI Active AESI surveillance is a complement to AEFI and aims to detect signals; the retrospective AESI search can be combined with the AFP retrospective case search (see above)	Within 2-3 months of expression of interest.  Active AESI surveillance is implemented for the duration of nOPV2 use and at least for 3 months following the last nOPV2 use Retrospective case search is a one off activity one month after the first round of nOPV2 SIAs	Tools available from nOPV2 safety team and STT
Support to Safety	Train all AFP officers on nOPV2 variables and collection of safety monitoring data (F2)	All countries	Train all SO on AFP surveillance and nOPV2 related activities and AESI: Train NPEC on AESI/AEFI, and VAPP	Within 3 months of expression of interest	Training materials (methodology and content) available from nOPV2 safety team and STT. Online (webinars) training available from nOPV2 safety team and STT

## Annex 1b

### Summary of laboratory surveillance-related enabling activities and available support

Activity/Element	Description	Timeline	Support
Desk review (if possible onsite review)	Baseline assessment of the performance of the first-line laboratory for the period of last 12 months	Within 1-2 weeks of expression of interest by the country to use nOPV2	GPLNMS website
Workload estimation and stockpiling	Estimate expected AFP and ES workload for the first six months after nOPV2 use. Place an order to RO.	Within 1 week of expression of interest by the country to use nOPV2; this should be done proactively for first use countries.	AFP and ES Surveillance strengthening plan. Dynamics or workload, consumables and reagents consumption during latest three years.
Training workshops for Laboratory personnel	1. Train all laboratories on performing and interpreting (i) nOPV2 rRT-PCR assay and (ii) new ES diagnostic algorithm. 2. Priority will be given to (i) AFR and EMR, (ii) WPR, SEAR, EUR and AMR	By end of August 2020 for AFR, EMR For other regions by end of Sep.	Webinar training modules designed by US CDC and WHO and validated by GPLN.
Standard Operating Procedures and worksheets	All relevant SOPs and Worksheets describing/supporting VI, ITD procedures, sequencing and ES; this includes (i) referral pattern for isolates and original specimens as needed and (ii) specific SOP for nOPV2 data management and reporting.	Within a month after the training workshop.	WHO Polio Laboratory Coordinators and data managers. .
Monitoring of supplies and laboratory performance	Proactive monitoring of laboratory consumption and key performance indicators (timeliness, accuracy)	Monitoring sheets to be shared with RO on a monthly basis	Supplies ordering/monitoring sheet, and performance monitoring sheet
Laboratory data management and reporting	Laboratory databases (AFP and ES) have been updated to reflect new testing algorithm outcomes	Weekly updated databases to be shared with WHO as per GPLN rules.	Regional Laboratory databases



Annex 2

## CASE INVESTIGATION FORM - - ACUTE FLACCID PARALYSIS

Recognizing that CIF are usually region specific, it is requested that the following section on immunization history be adapted to reflect the following variables in addition to (or to replace) existing ones.

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### IMMUNIZATION HISTORY

Total OPV (bOPV/mOPV2/nOPV2) doses received through SIA:  99=Unknown      Total OPV doses received through RI:  99=Unknown

Date of last OPV dose received (SIA) : \_\_\_\_/\_\_\_\_/\_\_\_\_

Total IPV doses received through SIA:  99=Unknown      Total IPV doses received through RI:  99=Unknown

Date of last IPV dose received (SIA) : \_\_\_\_/\_\_\_\_/\_\_\_\_      Source of RI vaccination information: Card  Re

Choose one

---

## Assessing nOPV2 vaccine effectiveness through the collection of vaccination coverage data from community healthy controls

Post-deployment monitoring following the use of novel oral poliovirus vaccine 2 (nOPV2) includes assessment of vaccine effectiveness against paralytic disease caused by vaccine derived polio virus 2 (VDPV2).

Vaccine effectiveness of trivalent OPV, bivalent OPV and monovalent OPV (types 1 and 3) against poliomyelitis has been estimated from vaccination history data reported by caregivers of poliomyelitis cases and non-polio acute flaccid paralysis (AFP) cases (controls)<sup>20,21</sup>. These estimates were based on 10 years of polio surveillance data. There is a need to estimate nOPV2 vaccine effectiveness quickly and dose reporting from AFP cases alone cannot be conducted in a timely manner. Obtaining dose reporting data from age-matched community controls will be an efficient way to accrue more data quickly.

This document presents the SOP to be followed by surveillance officers to collect data on vaccination histories from randomly chosen age-matched healthy community controls of VDPV2 cases. Vaccination histories from VDPV2 cases will be obtained during routine case investigation and recorded in the Case Investigation Form (CIF). We will provide a similar form to obtain vaccination history data from community controls.

Depending on the country data collection methods and availability, a data collection system will be established to ensure data flows from CO, RO to HQ. Where mobile data collection can take place, an Open Data Kit (ODK) form will be made available for country offices. Where electronic data collection is not possible, paper-based methods will be used. Details on these procedures are out of scope for this particular SOP and will be provided separately.

This SOP should be followed for any VDPV2 case detected in an area where nOPV2 has been used and should be immediately implementable from the first introduction of nOPV2.

Note this SOP is Annex 3 of the *Field and Laboratory Surveillance requirements in the context of nOPV2 use*

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<sup>20</sup>Mangal, T. D. *et al.* Key issues in the persistence of poliomyelitis in Nigeria: a case-control study. *The Lancet. Global health* **2**, e90-97, doi:10.1016/S2214-109X(13)70168-2 (2014).

<sup>21</sup>O'Reilly, K. M. *et al.* The effect of mass immunisation campaigns and new oral poliovirus vaccines on the incidence of poliomyelitis in Pakistan and Afghanistan, 2001-11: a retrospective analysis. *Lancet* **380**, 491-498, doi:10.1016/S0140-6736(12)60648-5 (2012).

## SOP to collect vaccination coverage data from age-matched, randomly selected community controls of VDPV2 cases

This SOP should be followed by surveillance officers to find community controls for each VDPV2 case. Twelve community controls will be age-matched to each VDPV2 case and vaccination histories of these community controls will be obtained.

This SOP must be commenced within two weeks of confirmation of a VDPV2 case and data from the twelve community controls must be collected within a month of confirmation of the VDPV2 case.

### **For the purposes of this activity, VDPV2 cases are defined as:**

- AFP cases with a laboratory isolation of VDPV2 in their stool sample (or isolation of VDPV2 from stool of his/her contact if the AFP case has inadequate stool)
- who resides or was in an area that used nOPV2 in outbreak response at least once, with date of paralysis onset after the first nOPV2 outbreak response campaign, and
- with polio vaccination histories (both routine and SIA) recorded as part of the Case Investigation Form (CIF).

### **Definition of community control:**

Children who:

- likely had the same VDPV2 exposure as the VDPV2 case
- resided in the same community as the VDPV2 case at the time of paralysis
- are of similar age (+/- 1 year)

### **Inclusion criteria for community controls:**

- Age: +/- 1 year of age of the current age of the VDPV2 case
- Residence:
  - Their household is in the same community as the VDPV2 case.
  - They resided in this household at the time of paralysis onset of the VDPV2 case.
  - The child and primary caregiver must both be present at the time of the interview (allow for two re-visits before choosing a new household due to absence of child and primary caregiver).
  - Only one child per household will be included as a community control.
  - When VDPV2 cases are reported in small villages there may not be enough households to collect enough community controls, therefore households from adjacent villages in the same district can be included.

### **Definition of household:**

- People who share a kitchen and eat from the same pot

### **Definition of a primary caregiver:**

- The mother, grandmother, father, or guardian who is aware about the child's health status
- No siblings of children < 15 years
- No distant family members or neighbours

### **Random selection of households:**

A total of 12 households will have information recorded on 12 community controls (1 control per household).

- Four households will be selected from each of three randomly selected directions of the VDPV2 case.
- In each direction, every fourth household will be sampled.

- When a household does not contain children meeting the inclusion criteria, or the child and primary caregiver are not present at two additional attempted visits, the next adjacent households will be visited until a suitable household is reached.

## Annex 3b

# Steps for collecting Vaccination History of age matched, randomly selected community controls of VDPV2 cases

### Materials needed

- A pen or pencil
- Either a smartphone with the ODK household screening form and data collection form installed or the paper household screening tool and paper investigation form to record data on each community control
- A calendar/list of dates of previous polio SIAs in the community (please remove any information of the type of OPV administered to avoid bias)

*A flow diagram illustrating the process is given in Figure 1 and a visual for randomly selecting households is given in Figure 2. A flow diagram illustrating the screening process for selecting households is given in Figure 3.*

### Steps to follow

1. Obtain the address of the VDPV2 case where s/he was residing when paralysis onset occurred.
2. Generate three random directions to walk from this location by spinning a pen on the ground outside the home of the VDPV2 case.
  - If a street or household is not directly in the direction of where the pen points, choose the closest street or household to go in from that direction.
  - Local information should be considered in selecting households in a certain direction. For example, if a VDPV2 case resides on the edge of a village. If feasible, another direction should be randomly selected.
3. For each of these directions, visit the first household in this direction from the VDPV2 case.
  - In cities with multi-level buildings, the first household in a such a building will be the nearest household on the ground floor.
4. When contacting a new household, introduce yourself and explain the purpose of the visit.
5. Ask to speak with the primary caregiver and use the household screening tool to determine if a child resides in the household who fits the matching criteria (+/- 1 year of age of the VDPV2 case).
  - Begin by explaining how the primary caregiver can help.
  - Include children only who are physically present at the time of visit and were living in the household at the time of paralysis onset of the VDPV2 case.
  - **Do not** include visiting children or the children of relatives who were not present in the household at the time of paralysis onset of the VDPV2 case.
  - If there is more than one child who fits these criteria, choose the child who is closest in age to the VDPV2 case.
6. If the primary caregiver and / or child is not present at the time of the initial visit, re-visit up to two more times before choosing an alternative household to collect information from.

- When selecting an alternative household visit adjacent households in the same direction until a suitable household is reached (or in multi-level buildings, visit adjacent apartments and then move up floors before moving on to the adjacent building in the street).
7. If a suitable child does live in this household:
    - Record the GPS coordinates of the household (if applicable).
    - Ask the primary caregiver to:
      - retrieve the vaccination record of the community control child
      - provide demographic of the child as required by the investigation form
      - provide details on the child's vaccination status (by both vaccination card and verbal recall of SIAs) as required by the investigation form.
    - Then thank the primary caregiver for their time and continue in the same direction, count four households and at the fourth household determine if a child resides within the matching criteria. (In multi-level buildings count households by moving up the building before visiting the adjacent buildings.)
  8. If no suitable children live in this household, thank the primary caregiver for his/her help and continue in the same direction to the next adjacent household until a suitable household is reached (or in multi-level buildings visit adjacent apartments and then move up floors before moving on to the adjacent building in the street)..
  9. Repeat steps 4 – 8 until data from four children from four households in each direction have been collected. If the village is too small to find enough households, visit adjacent villages in the same district.
  10. Ultimately 12 children per VDPV2 case should be selected from 12 different households that are in three different directions from the VDPV2 case residence (i.e., four households per direction)

**Figure 1** Flow chart of sampling process

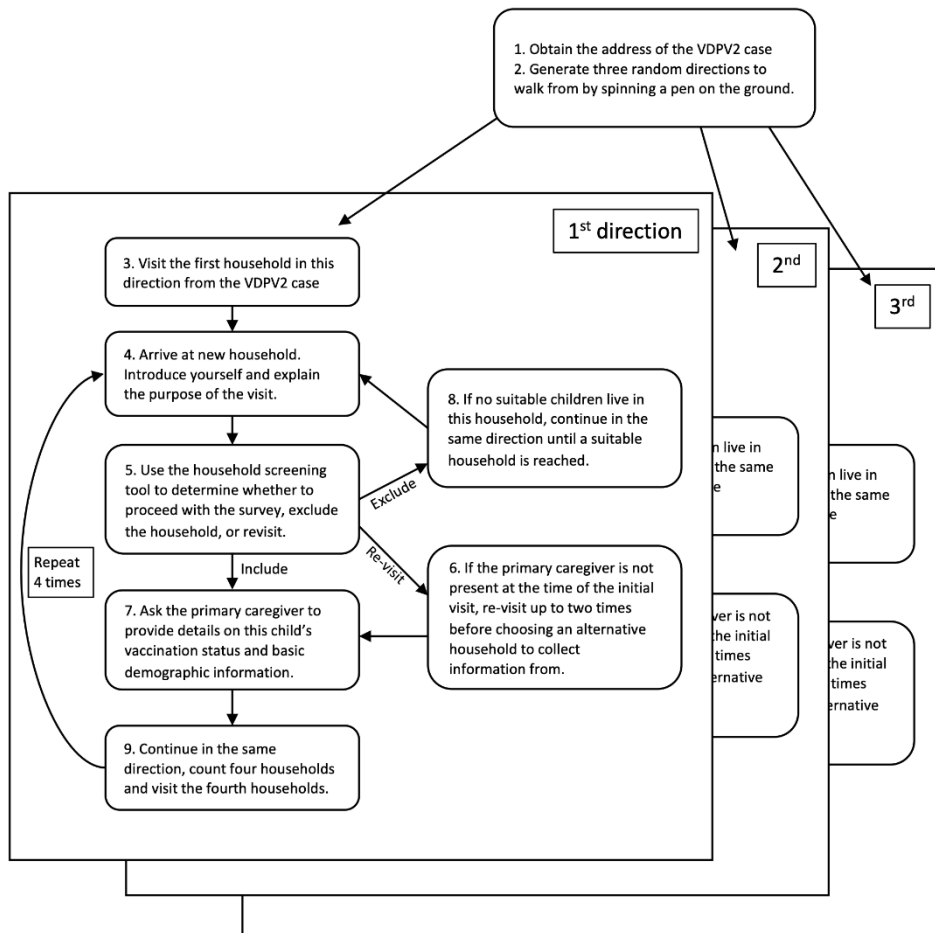
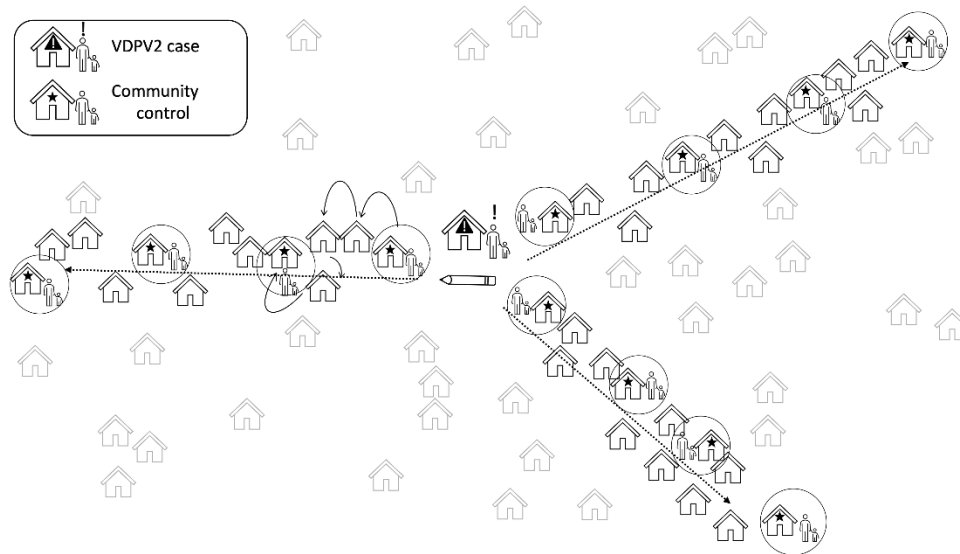


Figure 2 Diagram for randomly choosing households

A) Rural setting



B) Urban setting

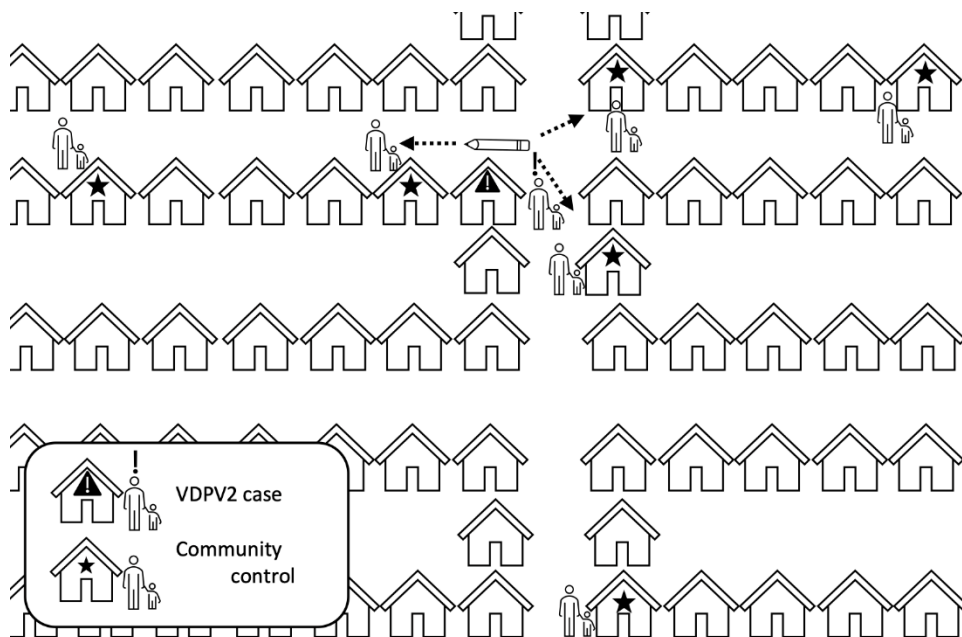
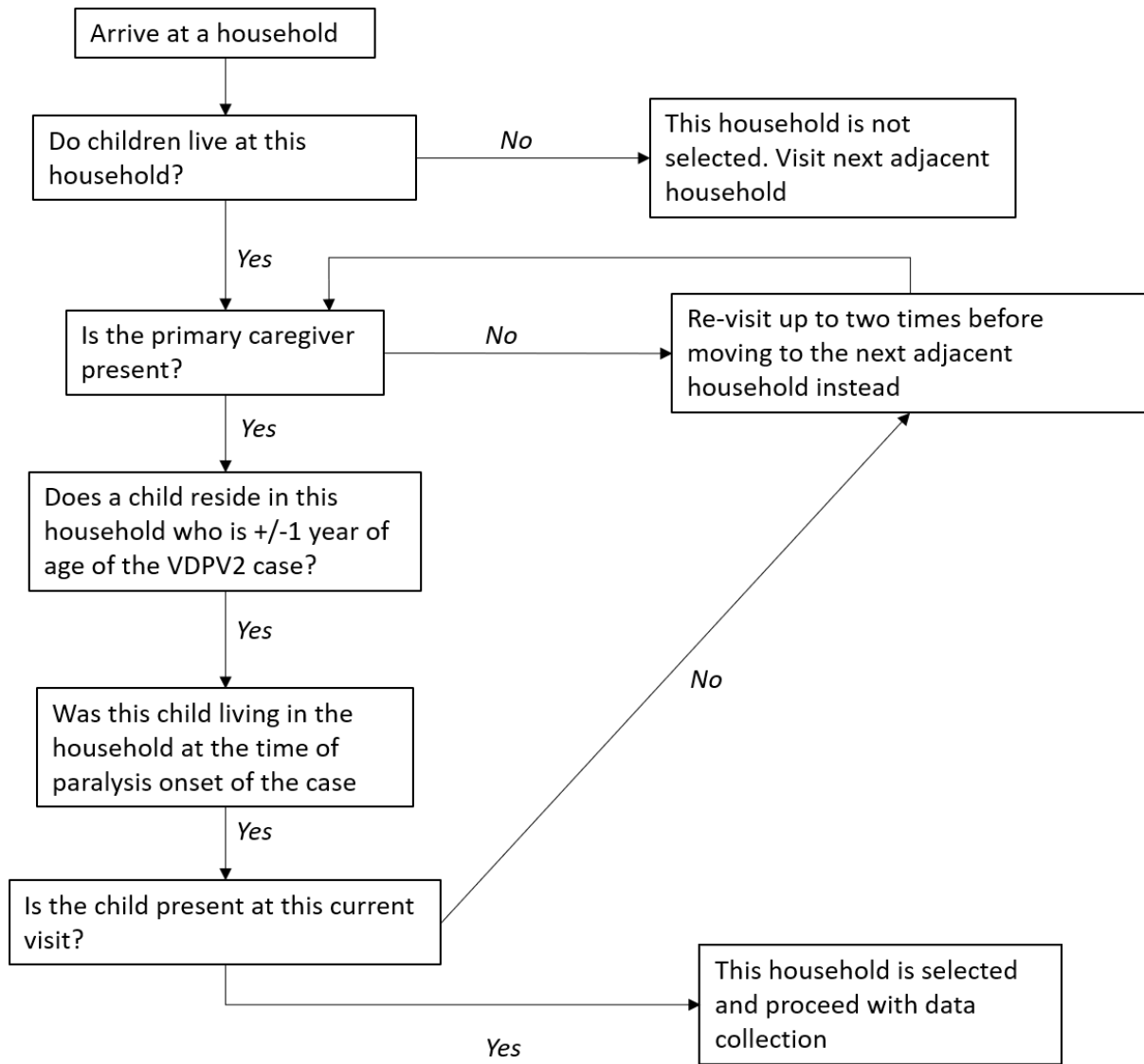




Figure 3 Household screening illustration



# Household Screening: *(dates = dd.mm.yy)*

## Investigation details

Surveyor's Name \_\_\_\_\_ Surveyor's mobile number \_\_\_\_\_

Date of interviews \_\_\_\_\_

## Case details

EPID \_\_\_\_\_ Name \_\_\_\_\_ Sex \_\_\_\_\_

Date of birth \_\_\_\_\_ (dd.mm.yy) Age in months \_\_\_\_\_ Date of Onset \_\_\_\_\_

Region/Province \_\_\_\_\_ District \_\_\_\_\_ City/Village \_\_\_\_\_

Address \_\_\_\_\_

Repeat the following sections for each control (x12)

## Community Control 1

Region/Province \_\_\_\_\_ District \_\_\_\_\_ City/Village \_\_\_\_\_

Address \_\_\_\_\_

Coordinates (House) (WGS 1984 format)

Longitude \_\_\_\_\_ Latitude \_\_\_\_\_

Name \_\_\_\_\_ Primary caregiver name \_\_\_\_\_ Father/Mother/Guardian

Date of Birth \_\_\_\_\_ Age in months \_\_\_\_\_ Sex \_\_\_\_\_

## Immunization History 1

Total OPV doses received through SIA \_\_\_\_\_ 99 = Unknown

Date of last OPV doses received (SIA) \_\_\_\_\_

Total OPV Doses received through RI \_\_\_\_\_ 99 = Unknown

Total IPV doses received through SIA \_\_\_\_\_ 99 = Unknown

Date of last IPV dose received SIA \_\_\_\_\_

Total IPV doses received through RI \_\_\_\_\_ 99 = Unknown

Source of RI Vaccination information *Choose one*

Card \_\_\_\_\_

Recall \_\_\_\_\_

Number of OPV doses received through SIA since the date of onset (paralysis) of the case \_\_\_\_\_

In order to assess the safety of the nOPV2 vaccine, the post-deployment monitoring framework includes surveillance of poliovirus among individuals with primary immunodeficiency disorder (PID) – see EUL in box 1.

Prolonged replication of VDPVs has been observed in a small number of people with rare immune deficiency disorders. As they are not able to mount an immune response, these individuals are not able to clear the intestinal vaccine virus infection, which is usually cleared in an immunocompetent individual within six to eight weeks. Through prolonged replication in the immunodeficient individual, reversion of these attenuated vaccine polioviruses may occur leading to neurovirulence and transmission characteristics of wild poliovirus. When this occurs, these polioviruses are referred to as immune-deficiency associated vaccine-derived polioviruses (iVDPV). PID patients can therefore excrete iVDPVs for prolonged periods.

PID patients at known risk of poliovirus infection are individuals of any age who have a primary antibody disorder; humoral (B-cell) or combined humoral (B-cell) and cellular (T-cell) immunodeficiency disorder, confirmed by levels of immunoglobulin below standards for age. A list of PIDs with known risk of prolonged poliovirus excretion is available in Box 2. It is important to note that T-cell only immunodeficiencies, such as HIV, is not a known risk factor for iVDPV.

Under EUL requirements for nOPV2 use, there is an obligation to estimate nOPV2 vaccine safety among PID individuals. Furthermore, there is also a clear recommendation from SAGE<sup>22</sup> to expand poliovirus surveillance among PID individuals as part of the polio post-certification strategy, regardless of nOPV2 use. The GPEI has therefore developed guidelines for implementing polio surveillance among patients with PIDs. However, not all countries have the capacity to diagnose and treat patients with immunodeficiency disorders, including PID. This document presents the steps to be followed by surveillance officers to assess whether a country has the required infrastructure to implement poliovirus surveillance among PID individuals, and an overview of what is required to implement this surveillance system.

### Step 1- Assessing country's capacity

The objective of this assessment is to document if the country has the capacity to diagnose PID patients and has a system in place to continuously follow them. If the country has this capacity, a list of PID patients should already be available, even if incomplete, in the relevant institutions, such as university hospitals and tertiary hospitals,

#### Box 1 – extract from Emergency Use Listing text on nOPV2

“Active surveillance will be set up to identify PID cases that may have been exposed during the vaccination campaigns. The PID monitoring will be implemented in the first countries or regions where nOPV2 vaccination campaigns take place and the necessary infrastructure exists and access can be reasonably achieved for a sustained period after the vaccination campaign. The necessary infrastructure refers to tertiary care centers with capacity to diagnose PIDs.

Regular visits will be made to existing immunology departments in major/university hospitals to register known and new PID patients that were vaccinated with nOPV2. Reported PID cases will be documented in a dedicated registry.

The PID monitoring efforts will be sustained until a sufficient number of PID cases has been collected that would allow for an assessment on the safety of nOPV2 in PID cases with regards to the progression of the disease or the prolonged shedding of nOPV2”

<sup>22</sup> [https://www.who.int/immunization/sage/meetings/2019/april/2\\_SAGE\\_April\\_2019\\_polio\\_Mach.pdf?ua=1](https://www.who.int/immunization/sage/meetings/2019/april/2_SAGE_April_2019_polio_Mach.pdf?ua=1)

specialized laboratory or immunology centers, specialized pediatric wards. This assessment should be carried out as part of the country nOPV2 readiness verification assessment.

The surveillance officer will need to

1. Identify all hospitals and facilities that may diagnose and treat patients with PID (e.g., tertiary or University hospitals, immunologic centers, Specialized pediatric clinics, etc...)
2. Visit these institutions and discuss with the head of each institution or ward (e.g., hospital and/or medical director, clinician in charge of the immunological and pediatric ward) to determine if a list of PID patients already exists and if there is an existing system for their follow-up. Refer to Box 2 for a list of the PID with known risk of prolonged poliovirus excretion, and Annex A for the PID checklist that should be used to document the visits.
3. Report and document the findings of the institutional visits:
  - a. If there is no capacity to diagnose PID patients, no list of PID patient, or no existing system to conduct follow-up, the surveillance officer will document this finding in the PID checklist (Annex A) and report this finding to the national nOPV2 focal point. This report should include the date of visit to the relevant institutions and the name and contact information of person interviewed.
  - b. If there is capacity to diagnose PID patients and a system exists for follow-up, the surveillance officer will document this finding in the PID checklist and report this finding to the national nOPV2 focal point.
  - c. The surveillance officer and the national nOPV2 focal point should fill and sign the PID checklist and **include in the country readiness report as part of the EUL process.**
4. If there is capacity to diagnose PID patients, proceed to Step 2 – Setting up PID Surveillance.

#### Box 2 - PIDs with known high risk of prolonged poliovirus excretion

1. Predominant antibody disorders:
  - Common variable immunodeficiency disorder (CVID) and other primary hypogammaglobulinemia
  - Agammaglobulinemia including X-linked agammaglobulinemia,
2. Immunodeficiencies affecting cellular and humoral immunity including:
  - Severe combined immunodeficiency disorder
  - Combined immunodeficiencies, including major histocompatibility complex deficiencies, immunodeficiency, centromeric instability and facial anomalies syndrome (ICF)
3. Other immunodeficiencies with hypogammaglobulinemia

## Step 2- Setting up PID surveillance

If the country has the capacity to set up Poliovirus surveillance among PID patients, as documented in the PID checklist, the nOPV2 focal point and surveillance team should request WHO RO/HQ for support to set up this surveillance system.

This will be a gradual process starting with initiating poliovirus surveillance among PID patients in one or several key facilities and incrementally expanding to other relevant facilities (e.g., provincial health facilities) as appropriate. Several tools are available from the GPEI (e.g., Guidelines, training material and information system). This SOP highlights the first steps, but the “GPEI Guidelines for Implementing Poliovirus Surveillance among patients with Primary Immunodeficiency Disorders (PIDs)” describes the system in further details (available at: [www.polioeradication.org](http://www.polioeradication.org))

The following steps are recommended:

1. Country to request support from WHO to initiate Poliovirus surveillance among PID patients, as part of the readiness process.
2. WHO RO/HQ and GPEI will provide an initial briefing to the national surveillance team within a month of the request (this may be done virtually)
3. As per the PID surveillance guideline the country will then have to implement the following steps:

- Sensitize public health officials on the importance of poliovirus surveillance among PID patients and its role as part of the EUL process for nOPV2, using results of the global risk assessment model and if available national data.
- Based on the initial capacity assessment (Step 1), enrol as ‘reporting sentinel site’ those institutions that were identified with capacity to diagnose and follow PID patients. In each sentinel reporting site, identify a focal point, preferably a specialized physician. Include the sentinel reporting site in the active surveillance site network.
- Train national surveillance officers and specialised physicians/focal points in the sentinel reporting site about PID surveillance, using available training modules.
- Assess the country’s PID data system to explore how it could be linked up electronically with the Polio PID information system (as per global standard),
- Once the PID surveillance system has been established (e.g., national registry, information system linkage),
  - Collect and test stool specimens for all known and newly diagnosed PID patients that meet the case definition of ‘PID patient at high risk of excreting poliovirus’. Please refer to Box2.
  - Plan for an annual follow-up visit and testing of stool specimens; the frequency of testing will increase for those with positive polio results; refer to the PID surveillance guideline for further details ([www.polioeradication.org](http://www.polioeradication.org))
  - As part of the EUL process for nOPV2, all PID patients at high risk of excreting poliovirus (refer to box 2) should be tested one month after the last nOPV2 SIA in the country.
    - For PID patients that have a positive result, monthly follow-up for specimen testing should be conducted until two consecutive negative results are obtained.
    - For PID patients that a have a negative result, annual follow-up for specimen testing should be conducted.
    - Excretion of nOPV2 related virus among PID patients will be detected through laboratory testing similar to current methods for detection of Sabin related viruses.

**In the context of nOPV2, all PID patients ‘at high risk of excreting poliovirus’ should be tested one month after the last nOPV2 SIA.**

**Annex A:**

**PID surveillance checklist**

Information below should be systematically documented during each institution visit

**Investigation Facility 1**

Name and position of interviewer \_\_\_\_\_

Date of interview \_\_\_\_\_

Province \_\_\_\_\_ District \_\_\_\_\_ City \_\_\_\_\_

Name of Health facility visited \_\_\_\_\_

Type of health facility (university hospital, immunology center, etc...) \_\_\_\_\_

Name, position and title of person interviewed \_\_\_\_\_

Contact details of person interviewed \_\_\_\_\_

*After the interview, and visit of the ward, please answer the following questions:*

Is there capacity to diagnose PID patients? **YES/NO**

if YES, How is the PID diagnostics established:

Ig levels  Jeffrey Modell Signs  others (pls specify) \_\_\_\_\_

Is there an existing list or registry of PID patients? **YES/NO** Did you see it? **YES/NO**

Is there an established system for patient follow-up **YES/NO**

(i.e. maintain updated contact information, regular visits, etc.)

What are the most frequent diagnosis registered/listed : \_\_\_\_\_  
 \_\_\_\_\_

**Investigation Facility 2**

Name and position of interviewer \_\_\_\_\_

Date of interview \_\_\_\_\_

Province \_\_\_\_\_ District \_\_\_\_\_ City \_\_\_\_\_

Name of Health facility visited \_\_\_\_\_

Type of health facility (university hospital, immunology center, etc...) \_\_\_\_\_

Name, position and title of person interviewed \_\_\_\_\_

Contact details of person interviewed \_\_\_\_\_

*After the interview, and visit of the ward, please answer the following questions:*

Is there capacity to diagnose PID patients? **YES/NO**

if YES, How is the PID diagnostics established:

Ig levels  Jeffrey Modell Signs  others (pls specify) \_\_\_\_\_

Is there an existing list or registry of PID patients? **YES/NO** Did you see it? **YES/NO**

Is there an established system for patient follow-up **YES/NO**

(i.e. maintain updated contact information, regular visits, etc.)

What are the most frequent diagnosis registered/listed : \_\_\_\_\_  
 \_\_\_\_\_

*Please continue and add additional investigations (facility 3, 4, etc) if appropriate*

How many facilities have been visited?	
Does the country have a system in place to diagnose and follow PID patients?	YES/NO
<b>Name and signature of the surveillance focal point</b>	<b>Name and signature of the nOPV2 focal point</b>
<b>Name:</b>	<b>Name:</b>
<b>Signature</b>	<b>Signature</b>
<b>Date</b>	<b>Date</b>