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Photo: WHO Nigeria

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

EVERY
LAST CHILD



Objective

The novel oral polio vaccine type 2 (nOPV2) is available for outbreak response through an Emergency Use Listing (EUL) of the World Health Organization (WHO). The EUL procedure provides a rigorous analysis of efficacy and safety data to address all Public Health Emergencies of International Concern, which polio has been since 2014.

Countries wishing to use nOPV2 under an EUL will only be able to introduce the vaccine by meeting established criteria, which include detailed evidence of a robust and sensitive surveillance system (see

Annex A for the full list of requirements). In addition to polio surveillance activities as described in the *Global Polio Surveillance Action Plan*,¹ field and laboratory surveillance in countries with nOPV2 use will need to be further enhanced to:

- rapidly detect and characterize any nOPV2-related virus or vaccine-derived poliovirus (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); and
- contribute to the documentation on safety and efficacy of nOPV2, as required under the new vaccine's EUL status.

As countries prepare to meet EUL requirements for nOPV2 use, they are encouraged to regularly update WHO regional offices (ROs) on their progress to avoid delays that could impede potential future release of vaccine, in the event of there is a notification of an outbreak. Focal points within WHO ROs will support countries as they prepare and complete their readiness requirements, providing input and guidance to ensure that the country's submission is complete and meets the requirements prior to review.

The Global Polio Eradication Initiative (GPEI) has prepared this document to highlight what is required for all countries using nOPV2 under EUL and what is recommended by the GPEI to ensure surveillance systems of the highest quality.²

This document should be read in conjunction with Preparing for nOPV2 Use: An overview on requirements for countries.³

Countries must be able to document the safety and efficacy of nOPV2 through sensitive and robust acute flaccid paralysis (AFP) surveillance, environmental surveillance (ES), where possible, and support for adverse events following immunization (AEFI).

¹ Global Polio Surveillance Action Plan, 2018-2020. Geneva: World Health Organization; 2019 (<https://polioeradication.org/wp-content/uploads/2016/07/GPEI-global-polio-surveillance-action-plan-2018-2020-EN-1.pdf>). Revisions to the GPSAP will be forthcoming in January 2022.

² Countries that introduced nOPV2 during its initial use phase must continue to follow initial use requirements until they have fulfilled the terms and related timelines.

³ Preparing for nOPV2 Use: An overview on requirements for countries. Geneva: World Health Organization; 2021 (<http://polioeradication.org/wp-content/uploads/2021/10/nOPV2-Requirements-Overview-for-Countries.pdf>.) All documents and guidance on nOPV2 can be found at <http://polioeradication.org/nOPV2>

Steps toward nOPV2 use in a country

All countries at risk of circulating vaccine-derived poliovirus type 2 (cVDPV2), or countries looking to safeguard against a type 2 polio event, are encouraged to begin preparations now to be verified for nOPV2 use.

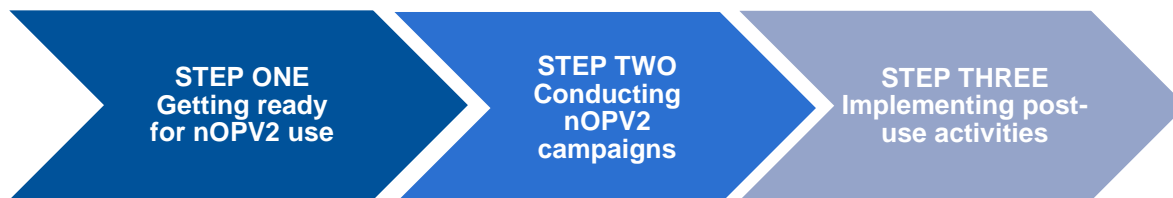
Once a country confirms its interest in using nOPV2 for cVDPV2 outbreak response, the following steps outline the field and laboratory surveillance activities that need to take place to prepare for nOPV2 use in-country (see **Fig. 1**).

Step 1: Getting ready – The country develops and implements a plan to meet nOPV2 readiness requirements. While the duration of this step may vary, it is expected that preparations will take one to three months. A country's readiness documents can be submitted to the WHO RO to review for completeness and to advise on final documentation.

Step 2: Conducting nOPV2 campaigns – Country documentation will be verified before nOPV2 is released for use. For surveillance, verification is done at the global level; for laboratories, it is done at the regional level. Once the country has been verified for nOPV2 use, specific field surveillance activities will need to be implemented for nOPV2 campaigns.

Step 3: Implementing post-use activities – Post-deployment monitoring (PDM) begins once nOPV2 has been used for the first time, and some PDM activities will last for up to 12 months after the last nOPV2 supplementary immunization activity (SIA). While nOPV2 is under EUL, PDM requirements will be in place for all countries using nOPV2.⁴

Fig. 1. Steps toward nOPV2 readiness verification, use and implementation



Countries interested in using nOPV2 should review the required and recommended activities for nOPV2 readiness, as each country will be asked to report on the implementation status of these activities. Activities are reviewed in detail for both field and laboratory surveillance (see **Parts 1 and 2**).

Dedicated nOPV2 focal points within each WHO regional office and at WHO headquarters (nopv2@who.int) are available to provide resources and guidance to inform country-level decisions on whether and when to begin preparations.

⁴ The PDM requirements have been proposed by Bio Farma and submitted to the WHO prequalification (PQ) team.

PART I: Field surveillance

Step 1: Getting ready for nOPV2 use

Using a new vaccine in an outbreak setting is a challenge that requires coordination at all levels of the Ministry of Health (MoH), from the central to district levels. Before initiating the process, a briefing of the national surveillance and laboratory teams should take place, along with the Expanded Programme on Immunization (EPI) or AEFI team and the GPEI outbreak team, to ensure everyone is aligned on the process, required commitment and timeline. This briefing can be organized by the nOPV2 national lead, with regional and global teams available to support, as needed.

Documentation to meet the requirements for field surveillance is summarized below (see **Table 1**) and detailed throughout this guidance.

Table 1. Summary of field surveillance requirements for nOPV2 use

Req #	Requirement	What needs to be submitted
D1	Update national surveillance guidelines and supporting documents to include: (1) plans for active case search at priority sites; (2) plans to carry out 60-day follow-up for all acute flaccid paralysis (AFP) cases with nOPV2 detected in stool samples; and (3) plan for collecting vaccination coverage data from community members around AFP VDPV2 cases.	National surveillance guidelines for <ul style="list-style-type: none"> • active case search; • 60-day follow-up; and • age-matched community controls for VDPV2 cases.
D2	Provide evidence that the Case Information Form (CIF) has been adapted (if needed) to record polio routine and SIA doses by submitting three (3) filled in CIFs.	Adapted national CIF and three (3) filled-in CIFs.
D3	A primary immunodeficiency disorder (PID) diagnostic capacity checklist has been completed.	PID diagnostic capacity checklist

Once a country has proof of completion for the EUL requirements, its readiness checklist and supporting documents can be submitted to the RO who will review and share with the global nOPV2 Readiness Verification Team (RVT). Subject matter experts then evaluate submissions to confirm that all requirements have been met. A report will be shared with countries on any issues that need to be addressed, with GPEI support, prior to nOPV2 use.

Should critical gaps be identified, either global or regional teams may request a call with the country to align on next steps. If the country has concerns, they can also request a call. Once it has been confirmed that all requirements, including surveillance, have been met, the country receives its nOPV2 readiness verification and is eligible for the dose release process.

Required field surveillance activities

- ✓ Plan for retrospective case search
- ✓ Plan to carry out 60-day follow-ups for cases where nOPV2 is detected in the stool
- ✓ Plan to collect data around VDPV2 cases
- ✓ Updated and adapted CIF tool
- ✓ Completed PID checklist to assess capacity to diagnose PID patients
- ✓ Plan to lend support to safety monitoring through trainings for surveillance & AESI

D1. Update national surveillance guidelines and supporting documents

Plan for retrospective case search (post-nOPV2 use)

Under the EUL requirement, a retrospective case search must be performed by searching in health facility records to detect any missed AFP cases. Retrospective case searches focus on all key facilities in the nOPV2 area-of-use (priority 1 and 2), through a review of the previous six months of data in health facility records.⁵ The retrospective case search is conducted in addition to regular active AFP surveillance visits. It should be planned for implementation within six weeks after the first nOPV2 campaign – though the earlier, the better.



Required

Countries must 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.

Plan for 60-day follow-up exams for all AFP cases with nOPV2 detected in their stool

In the context of nOPV2 use, the current 60-day follow-up protocol must be adapted to facilitate examination of possible vaccine-associated paralytic poliomyelitis (VAPP) among those with nOPV2 detected in their stool and to meet the EUL safety requirements for monitoring nOPV2 use. This modification, however, is required for all countries, not just those that used nOPV2, due to population movement and the need to detect any VAPP that may be related to nOPV2 use (see **Annex B**).



Required

Countries should update national surveillance guidelines to ensure all AFP cases with nOPV2 detected in their stool receive a 60-day follow-up examination, with case files submitted to the Expert Review Committee, and databases updated accordingly.

Plan for collecting additional data around VDPV2 cases

Based on the current standard operating procedures (SOPs) on investigating VDPV2 cases,⁶ stool specimens from healthy children within the community who have not been in close contact with the VDPV2 case are collected to detect evidence of circulation of the VDPV2.

In the context of nOPV2 use, 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 C**). The data collected will help estimate the effectiveness of nOPV2 against paralytic disease caused by VDPV2. For all VDPV2 cases and select community members, a complete and detailed polio vaccination history will be required.



Required

Countries must present evidence that the SOP on age-matched, randomly selected community member sampling has been updated, adapted to the local context, and made available to surveillance officers.

⁵ Priority 1 refers to 'very high' and 'high-priority sites' with twice weekly or weekly visits; priority 2 refers to 'medium-priority sites' with twice monthly visits.

⁶ Polio outbreak SOPs can be found on the GPEI website (<http://polioeradication.org/wp-content/uploads/2020/04/POL-SOP-V3.1-20200424.pdf>).

D2. Adapt the Case Investigation Form

Provide evidence by submitting three completed forms

In the context of nOPV2 use, the AFP case investigation form (CIF) must separately record polio vaccines received through routine immunization and SIAs, as well as the date of last OPV received through SIAs, as part of the case immunization history (see **Annex D**). All CIFs must include these variables. Country CIFs that do not currently include this information must be updated prior to nOPV2 use.



Required

Countries must provide evidence that the AFP Case Investigation Form (CIF) has been adapted to record routine and SIA OPV doses by submitting three filled in CIFs.

D3. Complete the PID diagnostic capacity checklist

Under EUL requirements for nOPV2, the programme must estimate vaccine safety among primary immunodeficiency disorder (PID) patients. The GPEI has previously developed guidance for implementing poliovirus surveillance among PID patients,⁷ based upon a recommendation from the Strategic Advisory Group of Experts (SAGE) that such guidance be developed as part of the *Post-Certification Strategy*.⁸ However, not all countries have the capacity to diagnose and treat patients with immunodeficiency disorders, including PIDs.

Using the background offered in **Annex E**, national surveillance officers must assess whether a country has the required infrastructure to implement poliovirus surveillance among PID patients.

Assessing PID diagnostic capacity

1. Identify all hospitals and facilities that may diagnose and treat patients with PID (e.g., tertiary or university hospitals, immunologic centers, specialized paediatric clinics, etc.).
2. Visit these institutions and discuss with the head of each institution or ward (e.g., hospital and/or medical director, clinicians in charge of the immunological and paediatric ward) to determine if a list of PID patients already exists and if there is an existing system for their follow-up. Refer to the list of PIDs with known risk of prolonged poliovirus excretion (see **Annex E**) and use the **PID checklist (Annex E)** to guide the visit.
3. Document and report the findings of the institutional visits:
 - If there is no capacity to diagnose PID patients, no list of PID patients, or no existing system to conduct follow-up, the surveillance officer will document this finding in the PID checklist and report this finding to the national nOPV2 focal point.
 - 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.

⁷ GPEI. Guidelines for Implementing Poliovirus Surveillance among Patients with Primary Immunodeficiency Disorders (PIDs). April 2019. (https://www.who.int/immunization/sage/meetings/2019/april/2_Guidelines_Implementing_PID_Suveillance.pdf).

⁸ Strategic Advisory Group of Experts (SAGE). Poliovirus Surveillance among patients with Primary Immunodeficiency Disorders (PIDs): Introduction of new guidelines. 3 April 2019. (https://www.who.int/immunization/sage/meetings/2019/april/2_SAGE_April_2019_polio_Mach.pdf?ua=1)

4. Complete and sign the PID checklist with the national nOPV2 focal point. The PID checklist should include the date of visit to the relevant institutions and the name and contact information of person interviewed.



Required

The surveillance officer and the national nOPV2 focal point must complete and sign the PID capacity diagnostic checklist (Annex E) and include it in the country's readiness documentation.

Safety surveillance trainings

The AFP surveillance system plays an active role in nOPV2 safety monitoring. AFP surveillance officers are well-poised to support AESI surveillance, as AFP reports make up a significant number of AESI investigations. Furthermore, in nOPV2 safety monitoring, type 2 isolates from AFP stool samples, contact sampling and environmental samples are all sent for whole genome sequencing to monitor the genetic stability of the new vaccine.

For these reasons, AFP surveillance officers should be trained on changes in their surveillance functions to support nOPV2 safety monitoring.⁹

Trainings of surveillance officers

Trainings in country offices will help to refresh knowledge of AFP surveillance and to brief surveillance officers on nOPV2 surveillance requirements. Ideally, all districts nationwide should receive training; at a minimum, training should be held in all districts using nOPV2 and their neighbouring districts. Content can be adapted to local needs but must include a module on AFP case investigation and active case search.

In addition, a module on AESI will be necessary to train surveillance officers on the identification, reporting and monitoring of AESI. Some examples of AESI conditions that will need to be actively monitored under enhanced safety surveillance measures for six months are listed below; the full list can be found in the AESI surveillance guide.¹⁰

- Anaphylactic reactions
- Aseptic meningitis / encephalitis
- Acute disseminated encephalomyelitis
- Guillain-Barré Syndrome / Miller Fisher Syndrome
- Myelitis / transverse myelitis
- AFP due to VDPV or VAPP
- Unexplained deaths

Training of National Polio Expert Committee

The National Polio Expert Committee (NPEC) will need to be briefed on nOPV2 and related AEFI and AESI activities. A refresher training must be provided to the NPEC on diagnosing VAPP 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, the committee will be requested to support the AEFI Causality Assessment Committee. As such, the NPEC training should also include a significant component on AESI/AEFI.

⁹ Global Polio Eradication Initiative. Vaccine Safety Requirements in the Context of nOPV2 Use. October 2021 (<http://polioeradication.org/wp-content/uploads/2021/10/nOPV2-Safety-Guidance.pdf>).

¹⁰ Guide for Surveillance of Adverse Events of Special Interest (AESI) during Novel Oral Polio Vaccine Type 2 (nOPV2) Use. Last updated: October 2021. (<http://polioeradication.org/wp-content/uploads/2021/10/nOPV2-AESI-surveillance.pdf>).

Recommended activities

In addition to the EUL requirements, the GPEI recommends surveillance activities to strengthen the sensitivity of the national polio surveillance system for nOPV2 use. Since these are not required, no submissions are needed for the activities detailed below.

1. Complete a surveillance desk review.
2. Develop a surveillance strengthening plan.
3. Achieve and maintain key performance indicators for AFP surveillance:
 - Ensure non-polio acute flaccid paralysis (NPAFP) rate ≥ 2 at the national level and in at least 80% of all districts with more than 100,000 children under 15 for the last 12 months.
 - Ensure stool adequacy $\geq 80\%$ at the national level and in at least 80% of all districts reporting AFP cases for the last 12 months,
4. For countries with environmental surveillance (ES) systems:
 - Ensure one functional ES site in areas where nOPV2 will be used.
 - Collect ES samples twice per month from new ad hoc sites for six months after nOPV2 use, and then monthly for an additional six months.

Desk review

Although not required, a desk review of the polio surveillance system is recommended as soon as the country expresses interest in using nOPV2, preferably within the first two weeks. In a desk review, detailed analyses of different surveillance elements provide a comprehensive picture of the country's polio surveillance system and its performance, alongside the broader immunization and public health context that can inform surveillance strengthening activities.¹¹ Desk reviews capture strengths and weaknesses of the current surveillance system and highlight gaps that may hamper the rollout of nOPV2. Not every gap in the surveillance system may be addressed for nOPV2 rollout; but understanding the weaknesses and strengths of the system behind the reported data is essential to reliably assess polio surveillance sensitivity.



Recommended

Desk reviews are most valuable if completed within two weeks following the country's decision to use nOPV2. Global guidance on desk reviews is available online.¹¹

Surveillance strengthening plan

If a country chooses to conduct the desk review, a surveillance strengthening plan is recommended to address gaps identified in the desk review. The plan should cover nOPV2-specific surveillance activities for the next three- to six-month period, prior to nOPV2 use.

In the surveillance strengthening plan, countries should:

- review the prioritization of the active surveillance network, with a focus on hard-to-reach and special populations and community-based surveillance (CBS);
- review and address surveillance shortcomings in underperforming first-level administrative areas (i.e., first subnational level);

¹¹ A template for the desk review, with recommended areas to capture as part of the review, is available online. See Desk/Field Surveillance Reviews for nOPV2 Use, October 2021 ([nOPV2 field surveillance desk review template](#))

- review and address any additional gaps identified (data management, cold chain, logistics, supervision, etc.); and
- plan for nOPV2-specific surveillance activities.



Recommended

Surveillance strengthening plans, if pursued, should be developed within a week of finalizing the desk review.

Environmental surveillance expansion

While the presence of environmental surveillance (ES) is not a requirement for nOPV2 use, in countries where it is established, ES can generate complementary information for action to support case-based AFP surveillance.

Assessing current and potential ES sites

For countries with ES in place, the programme, with the support of the WHO RO and the GPEI, will review the performance of all current ES sites in-country with a focus on outbreak areas and areas with nOPV2 use.¹² If ES sites do not exist in nOPV2-use areas, the programme should explore the feasibility of ad hoc sites to target large population centers (100 000 people).

Opening ad hoc sites in nOPV2 areas

While most ES sites are permanent sites for routine poliovirus surveillance, ad hoc sites can be opened in response to an outbreak or due to increased risk of transmission in a certain area.

- Any new ad hoc site opened for nOPV2 outbreak response will collect specimens every two weeks for the first six months of implementation. The frequency may revert to monthly for the remainder of the assessment period.
- Ad hoc sites will be assessed at the end of the 12 months to determine if sample collections should continue for an additional six months.
- Existing (permanent) ES sites will be monitored as per their current sampling schedule for 12 months.



Recommended

Expanding the ES network to support nOPV2 surveillance through ad hoc sites should be discussed between the country programme, the laboratory and the WHO RO to determine feasibility.

¹² [Concept Note] Polio Environmental Surveillance Enhancement Following Detection of Vaccine-Related Type-2 Poliovirus. June 2020. (<http://polioeradication.org/wp-content/uploads/2020/06/ES-OBR-nOPV2-revision-20200601.pdf>)

Step 2: Conducting nOPV2 campaigns

When conducting an outbreak response using nOPV2, the following additional field surveillance activities should be implemented, as per the plans outlined in preparation for use.

- ❑ Confirm all regions, districts and states participating in the nOPV2 response are using an adapted and revised CIF.
 - A random check of health facilities should be conducted to confirm that the new CIF has been thoroughly distributed and surveillance officers are completing it properly, with corrective measures and refresher trainings implemented, as needed.
- ❑ Confirm all necessary elements – operational plans, training materials, budget distributions – are in place to support the following critical activities:
 - During supervisory visits, ensure all AFP officers are up-to-date on nOPV2 variables and plans, timelines and processes for the collection of safety monitoring data.
 - Ensure the plan outlined as part of verification process is fully implemented.
- ❑ Ensure plans, resources and budget are in place to enable implementing the following post-campaign activities:
 - Collect vaccination coverage data from age-matched, randomly selected community members around AFP VDPV2 cases.
 - Conduct 60-day follow-up exams for any case with nOPV2 isolated in the stools.
 - Conduct retrospective AFP case searches within six weeks after nOPV2 use.

AFP officers play a key role in safety monitoring for nOPV2. It is important they are clear on the requirements of this role and have been well trained prior to the start of the campaign. This is an activity best conducted jointly with the national nOPV2 safety focal point. Support is available from your regional nOPV2 focal point or by contacting nOPV2@who.int.

A full pre-campaign checklist across all nOPV2 readiness categories can be found online.¹³

¹³ nOPV2 pre-campaign checklist: Activities to complete prior to launch of nOPV2 response. ([nOPV2-pre-campaign-checklist](#)).

Step 3: Implementing post-use activities

Post-deployment monitoring (PDM) is an essential requirement, as countries must be able to contribute to documentation on the safety and efficacy of this new vaccine by tracking its performance in the field.

All countries using nOPV2 will need to fulfill commitments agreed upon in the readiness verification process. Monitoring these commitments following nOPV2 use is an essential step to ensuring countries meet the WHO EUL requirements.

The WHO Regulation and Prequalification Department will carefully examine reports on safety, effectiveness and other relevant data that may impact the validity of the EUL status. Such information will be primarily based on existing polio and vaccine safety surveillance mechanisms in polio outbreak-affected countries and on nOPV2 post-deployment surveillance commitments of the manufacturer, set as conditions for the listing.

Once nOPV2 has been used in a country, the following surveillance activities need to be implemented and documented based on the commitments in the readiness plan.

Table 2. Summary of post-deployment monitoring activities and reporting

Activity	Description	Documentation
Enhanced AFP surveillance	<p>Retrospective and active case search</p> <ul style="list-style-type: none"> Conduct one-time retrospective case search within 6 weeks after the first campaign reviewing the previous six (6) months, and ongoing AFP active case search via active surveillance. Note that retrospective AESI case search is not required, but may be combined with AFP retrospective case search 	<ul style="list-style-type: none"> Narrative report on retrospective one-time case search, within a month of the activity taking place Evidence of monitoring of active surveillance visits Data on AFP and contact sampling (as per AFP regular analysis)
60-day follow-up of AFP cases	<p>60-day follow-up</p> <ul style="list-style-type: none"> 60-day follow-up exams should be conducted for all AFP cases or as a minimum practice for (1) all AFP cases with inadequate stools specimen and (2) for AFP cases with nOPV2 detected in their stools.¹⁴ 	<ul style="list-style-type: none"> AFP data
Data to inform nOPV2 effectiveness against paralytic polio	<p>Collect vaccination coverage data from age-matched, randomly selected community members of VDPV2 cases (See Annex D)</p>	<ul style="list-style-type: none"> Data and narrative report within a week of activity completion

¹⁴ This applies for ALL AFP cases with nOPV2 in the stool, regardless of the adequacy of the stool specimen (i.e., include adequate and inadequate specimen). If regions adopt the minimum practice and are concerned about delay in sequencing results, regions could decide to carry out 60-day follow-up examinations for ALL cases with type 2 poliovirus isolates.

Tracking and reporting on progress

The GPEI has developed a tool to help countries to track and report on surveillance activities that must be completed by countries implementing nOPV2 campaigns. The tool will be used to assess whether a country has successfully met the post-deployment requirements after nOPV2 use and to identify plans to address any gaps.

>> **[Access the nOPV2 monitoring tool](#)** <<

To support managers and coordinators in tracking progress, the GPEI has also published online an nOPV2 post-campaign checklist, which summarizes post-nOPV2 campaign activities across all categories of the EUL requirements.¹⁵

¹⁵ nOPV2 post-campaign checklist: Activities to complete after an nOPV2 response. ([nOPV2-post-campaign-checklist](#)).

PART II: Laboratory surveillance

Step 1: Getting ready for nOPV2 use

As countries begin to explore the option of nOPV2 use, they should actively dialogue with the national laboratory in review of laboratory requirements in the nOPV2 readiness checklist (see **Annex A** for the full list of the requirements).

Table 3. Summary of laboratory surveillance requirements for nOPV2 use

Req #	Requirement	What needs to be completed
H1	A plan has been developed to prepare the national lab for nOPV2 use, including updating the isolation algorithms and stocking and training on ITD testing kits for both AFP and ES, along with modifications to the reporting mechanism.	<ul style="list-style-type: none">• A report validated by WHO regional polio laboratory coordinators confirming readiness.• Documented staff training on testing algorithms.• Updated SOPs for ITD testing and reporting.
H2	Relevant laboratories are prepared to ship samples to the U.S. Centers for Disease Control and Prevention (CDC) or National Institute for Biological Standards and Control (NIBSC) for complete genome sequencing for post-deployment monitoring.	<ul style="list-style-type: none">• A referral plan for biological materials validated by WHO regional and global coordinators.

To meet these requirements, enabling activities have been identified for implementation by the laboratory serving the country which will use nOPV2, including laboratories in the Global Polio Laboratory Network (GPLN).

Laboratories should:

- conduct and submit a desk review for the previous 12 months using checklists available in the web-based GPLN management system (GPLNMS);¹⁶
- calculate current workload and estimate expected increase based on the extent of nOPV2 campaigns, the field surveillance strengthening plan and new ad hoc ES sites, if applicable (refer to **Part I: Field surveillance**);
- aim to build one-year stock of consumables and reagents secured at least one month before nOPV2 use in the country;
- update SOPs and worksheets for (1) intratypic differentiation (ITD) testing and sequencing, and (2) virus isolation (VI) from environmental samples;
- train laboratory staff for all polio laboratories on new testing algorithms for ITD and VI;
- update laboratory databases (AFP and ES) to reflect new testing algorithm outcomes; and
- develop and share a specific SOP for nOPV2 data management and reporting.

¹⁶ The GPLNMS can be found online (<https://extranet.who.int/gpln/en/Home/HQ>). Note: this site is restricted to registered users. Access can be requested via the link. If issues arise in securing access, contact the GPLN through nOPV2@who.int.

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

Review laboratory performance and capabilities

A review of the 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 online checklists accessible through GPLNMS. Specific attention should be paid to laboratory operating procedures and work practices (part IV of the online checklist). Whenever and wherever possible, onsite review of the NPL-serving countries using nOPV2 should be conducted to allow for the development of a comprehensive strengthening plan to address identified gaps. If an onsite visit cannot be planned due to COVID-19, a desk review should be conducted by interviewing the laboratory head to ensure a comprehensive assessment of the capacity and the capability of the NPL to fulfill all key requirements.



Required

To confirm readiness, a report validated by WHO regional and global polio laboratory coordinators will be shared with the country programme and relevant regional and global reference sequencing laboratories.

Train laboratory staff on updated testing algorithms

The GPLN has validated a new ITD algorithm, called ITD 6.0, and 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, all polio laboratory staff will be trained through regional webinars on performing and interpreting the updated testing algorithms. These trainings will be remotely organized for all GPLN laboratories and conducted by the WHO and the Polio Global Specialized Laboratory (GSL) at the CDC.



Required

The NPL has successfully passed the proficiency testing.

Update standard operating procedures and worksheets

To ensure that specimens that may contain nOPV2 are properly processed and results are correctly captured, all relevant SOPs and worksheets (related to ITD testing, sequencing and VI from sewage samples) should be updated by the NPL and shared with regional and global polio laboratory coordinators for validation, with a target of at least one month prior to nOPV2 use in that country.



Required

Updated SOPs for ITD testing and reporting have been validated by 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 that will be shipped in a timely manner to global and regional reference sequencing laboratories. Due to the impact of COVID-19, it is important that the plan include all logistics arrangements, as well as contingency measures to be implemented, as needed.



Required

Referral plan submitted by the laboratory is validated by WHO regional and global 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 RO data managers, in coordination with WHO headquarters, should make necessary adjustments in current databases in order to capture nOPV2 testing results. Laboratories should then update their specific data management and reporting SOP to incorporate changes.



Recommended

Updated laboratory data system is validated by the WHO regional polio laboratory coordinators.

Step 2: Submitting for verification

All documents generated by activities described in Step 1 should be part of the readiness documents submitted by the country to the nOPV2 Readiness Verification Team (RVT) to confirm readiness requirements are met. This includes:

- a report validated by WHO regional polio laboratory coordinators confirming readiness;
- documentation that provides evidence of staff training on the updated testing algorithms;
- updated SOPs for ITD testing and reporting;
- a referral plan for biological materials; and
- and an updated laboratory data system, if applicable.

Review of laboratory readiness is done at regional level. Once its documentation is completed, the country should submit its readiness checklist and supporting documents to the RO for the nOPV2 RVT for regional-level review. **If the country has a WHO-accredited polio laboratory, readiness status for both field and laboratory surveillance must be submitted jointly** (see **Part I**). Should critical gaps be identified, either global- or regional-level teams may request a call with the country to align on next steps.

Once it has been confirmed that all requirements for nOPV2 use have been met, the country receives its nOPV2 readiness verification and is eligible for the dose release process.

Step 3: Implementing post-use activities

Post-deployment monitoring (PDM) starts once nOPV2 has been used and will last for six to twelve months after the last nOPV2 SIA in the country.

Monitoring laboratory performance

It is imperative that the programme, in coordination with 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 quarterly basis for 12 months after use of nOPV2. Reports will be 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 a one-year stock of consumables and reagents is secured as part of readiness criteria 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 post-deployment period. As part of contingency planning, the WHO regional office should ensure that an easily accessible buffer stock is available.

Data management and reporting

The 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 the 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 type 2 and VDPV2, will be maintained, the “nOPV2 genetic characterization subgroup” is monitoring sequencing results of nOPV2 isolates and reporting of results post-deployment.

Annex A: Readiness Requirements

For further guidance and details, see: [Preparing for nOPV2 Use: An overview on requirements for countries](#)

Category	Ref #	Requirement
Coordination	A1	Confirmation that a national coordinating mechanism/body has been created and technical committees have been established to oversee preparations for nOPV2 across the following critical areas: a) cold chain, logistics and vaccine management; b) safety/causality; c) advocacy, communications and social mobilization; d) surveillance; and e) laboratory.
Approvals	B1	Official documentation (letter, meeting minutes) confirming national decision by the relevant national immunization body to use nOPV2 for outbreak response.
	B2	Documentation from the NRA confirming approval for the import and use of nOPV2.
Cold Chain / Vx Mgmt	C1	National logistics plan is updated to include: a) cold chain equipment inventory and gap analysis; b) updated vaccine management tools for nOPV2 (50-dose vial); and c) vaccine management plans, outlining how vial tracking and disposal will be handled.
Surveillance	D1	National surveillance guidelines and supporting documents are updated to include: a) plans for active case search at priority sites; b) plans confirming 60-day follow-up for all AFP cases with nOPV2 detected in stool samples; and c) plan for collecting vaccination coverage data from community members around AFP VDPV2 cases.
	D2	Provide evidence that the CIF has been adapted (if needed) and records polio routine and SIA doses by submitting 3 filled in CIFs.
	D3	A primary immunodeficiency disorder (PID) diagnostic capacity checklist has been completed.
Safety	F1	Confirmation of nOPV2 safety surveillance monitoring activities including: a) active AESI safety monitoring protocol for nOPV2; and b) national AEFI surveillance manual or abridged guide and key forms.
	F2	An operational plan for implementing nOPV2 safety surveillance is developed, which includes plans for implementing AEFI and AESI surveillance, along with plans for managing a vaccine-related event (VRE) and confirmation of data sharing processes and timelines.
	F3	Key nOPV2-related safety trainings have been completed or are planned.
	F4	Causality assessment committee is oriented on nOPV2 and equipped to conduct AEFI/AESI causality assessments as demonstrated through: a) terms of reference along with list of members (noting their specialty); b) training plans; and c) if applicable, previous meeting minutes.
Advocacy, Communications and Social Mobilization (ACSM)	G1	Finalized advocacy strategy for key in-country stakeholders (e.g., medical practitioners, religious and community leaders).
	G2	C4D action plan that includes: a) nOPV2 communications and messaging adapted to the local context; b) key actors, including frontline workers, have been trained or plans are detailed to provide training; c) all stakeholders have been mapped and plans for sensitization outlined; d) concrete plans for digital platforms have been developed; e) all necessary messaging, tools and products and f) the outline of how the country will meet the communication-specific EUL commitments.
	G3	A crisis communications plan that addresses possible VREs and possible public controversy. Detailed digital and misinformation management plan and implementation structure description. The plan should include tailored social listening approaches, content to respond to misinformation on-line and offline, and plan on how crisis communications training was/will be conducted.
Lab	H1	A plan has been developed to prepare the national lab for nOPV2 use, including updating the isolation algorithms and stocking/ training on the ITD testing kits for both AFP and ES along with modifications to the reporting mechanism.
	H2	Relevant laboratories are prepared to ship samples to CDC or NIBSC for complete genome sequencing.

Category E, which related to environmental surveillance requirements under the initial use phase, is now a recommended but not required activity in the EUL period. No documents/data need to be submitted for verification under category E.

Annex B

Guidance on the 60-day follow-up in the context of nOPV2 use

Rationale

To document potential vaccine-associated paralytic polio (VAPP) cases due to nOPV2.

Context

The current best practice for AFP surveillance is to apply the 60-day follow-up examinations to ALL AFP cases.¹⁷ However due to observed realities on the ground and in the field (e.g., case workload, competing health program priorities, limited human resources and logistics available), the programme has recognized it's not feasible to conduct the 60-day follow-up for all AFP cases in all WHO regions, and has recommended the 60-days follow-up for all AFP cases with inadequate stool specimens, at a minimum.¹⁸

However, in the context of the nOPV2 rollout, there is a need to adapt the current 60-day follow-up recommendation to ensure appropriate safety monitoring of nOPV2 use. This modification is necessary for all countries, not just countries that have used nOPV2, due to population movement and the need to detect any VAPP that may be related to nOPV2 use.

Recommendation

60-day follow-up examinations should be conducted:

- **Recommended best practice:** for all AFP cases
- **Recommended minimum practice:** all AFP cases with inadequate stools specimen and for AFP cases with nOPV2 detected in their stools.¹⁹

WHO regions are highly encouraged to adopt the recommended best practice in order to ensure that 60-day follow-up examinations are conducted within the 60- to 90-day time period in which examinations should be conducted.²⁰

Duration

This guidance will be effective immediately and for the duration of the nOPV2 EUL process, or until superseded by new guidance. For countries that have already used nOPV2, 60-day follow-up examinations must be done for all AFP cases with nOPV2 in the stools, submitted to the Expert Review Committee (ERC), with databases updated accordingly.

Note

- 60-day follow-up examinations must be carried out between 60 to 90 days after paralysis onset (as per existing guidance); if this cannot be done, the “60-day FUP exam” must still be done as soon as possible after that date, to document whether there is residual paralysis for those cases with nOPV2 detected in their stools.
- This guidance is specific for AFP cases with nOPV2 isolated from stools. 60-day follow-up examinations are not required for AFP contacts or healthy children who have nOPV2 isolated from their stools.

¹⁷ See GPEI. Best Practices in Active Surveillance for Polio Eradication. (<https://www.who.int/polio-transition/documents-resources/best-practices-active-surveillance.pdf>).

¹⁸ Surveillance standards for vaccine-preventable diseases, second edition. Geneva: World Health Organization; 2018 (<https://apps.who.int/iris/handle/10665/275754>). Licence: CC BY-NC-SA 3.0 IGO.

¹⁹ For ALL AFP cases with nOPV2 in the stool, regardless of the adequacy of the stool specimen (i.e., include adequate and inadequate specimen).

²⁰ If regions adopt the minimum practice and are concerned about delay in sequencing results, regions could decide to carry out 60-day follow-up examinations for ALL cases with type 2 poliovirus isolated.

Annex C

Introducing a new SOP to assess nOPV2 vaccine effectiveness

Vaccine effectiveness of the trivalent OPV (tOPV), bivalent OPV (bOPV) and monovalent OPV types 1 and 3 (mOPV1 and mOPV3) has been estimated based on 10 years of vaccination history data reported by caregivers of poliomyelitis cases and non-polio AFP cases (controls).^{21,22}

With the novel vaccine, there is a need to estimate nOPV2 vaccine effectiveness quickly, and dose-reporting data from AFP cases alone cannot be conducted in a timely manner. Obtaining dose-reporting data from age-matched community controls as a new SOP will be an efficient way to accrue more data, more quickly.

Age-matched, randomly selected community controls of VDPV2 cases

Under this new SOP, surveillance officers will collect data on the vaccination histories of randomly chosen and age-matched healthy community controls of VDPV2 cases in an area where nOPV2 has been used. Twelve (12) community controls will be age-matched to each VDPV2 case, and the vaccination histories of these community controls will be obtained. This SOP must be commenced within two (2) weeks of confirmation of a VDPV2 case, and data from the 12 community controls must be collected within a month of confirmation of the VDPV2 case. Surveillance officers should be tasked with finding community controls for each VDPV2 case. Vaccination histories from VDPV2 cases will be obtained during routine case investigation and recorded on the CIF; a similar form will be provided to obtain vaccination history data from community controls.

This new 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 rollout of nOPV2.

Depending on the country data collection methods and availability, a data collection system will be established to ensure data flows from the country office, to the regional office, and finally to headquarters. 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. Please contact your regional surveillance focal point to discuss your country-specific context.

²¹ 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).

²² 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).

Table D1. Definitions for randomly selected community controls of VDPV2 cases

Term	Definition
VDPV2 case	<ul style="list-style-type: none"> • An AFP case 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 immunization histories (both EI and SIA) recorded as part of the CIF.
Community control	<p>Children who:</p> <ul style="list-style-type: none"> • likely had the same VDPV2 exposure as the VDPV2 case; • resided in the same community as the VDPV2 case at the time of paralysis; and • are of similar age (+/- one year).
Inclusion criteria for community controls	<ul style="list-style-type: none"> • Age: +/- one year of the current age of the VDPV2 case • Residence: <ul style="list-style-type: none"> ○ 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.
Household	<ul style="list-style-type: none"> • People who share a kitchen and eat from the same pot.
Primary caregiver	<ul style="list-style-type: none"> • The mother, grandmother, father, or guardian who is aware of the child's health status. • No siblings of children < 15 years. • No distant family members or neighbours.

SOP process for age-matched, randomly selected healthy community controls

Random selection of households

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

- Four (4) households will be selected from each of three (3) 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

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.²³
- 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 Fig. 1 and a visual for randomly selecting households is given in Fig. 2. A flow diagram illustrating the screening process for selecting households is given in Fig. 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 direction, 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 greeting 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 (+/- one year of age of the VDPV2 case).
 - Begin by explaining how the primary caregiver can help.

²³ A blank paper household screening tool can be found online. See: [polio surveillance household screening tool](#)

- Include only children 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).

Fig. D1. Flow chart of sampling process

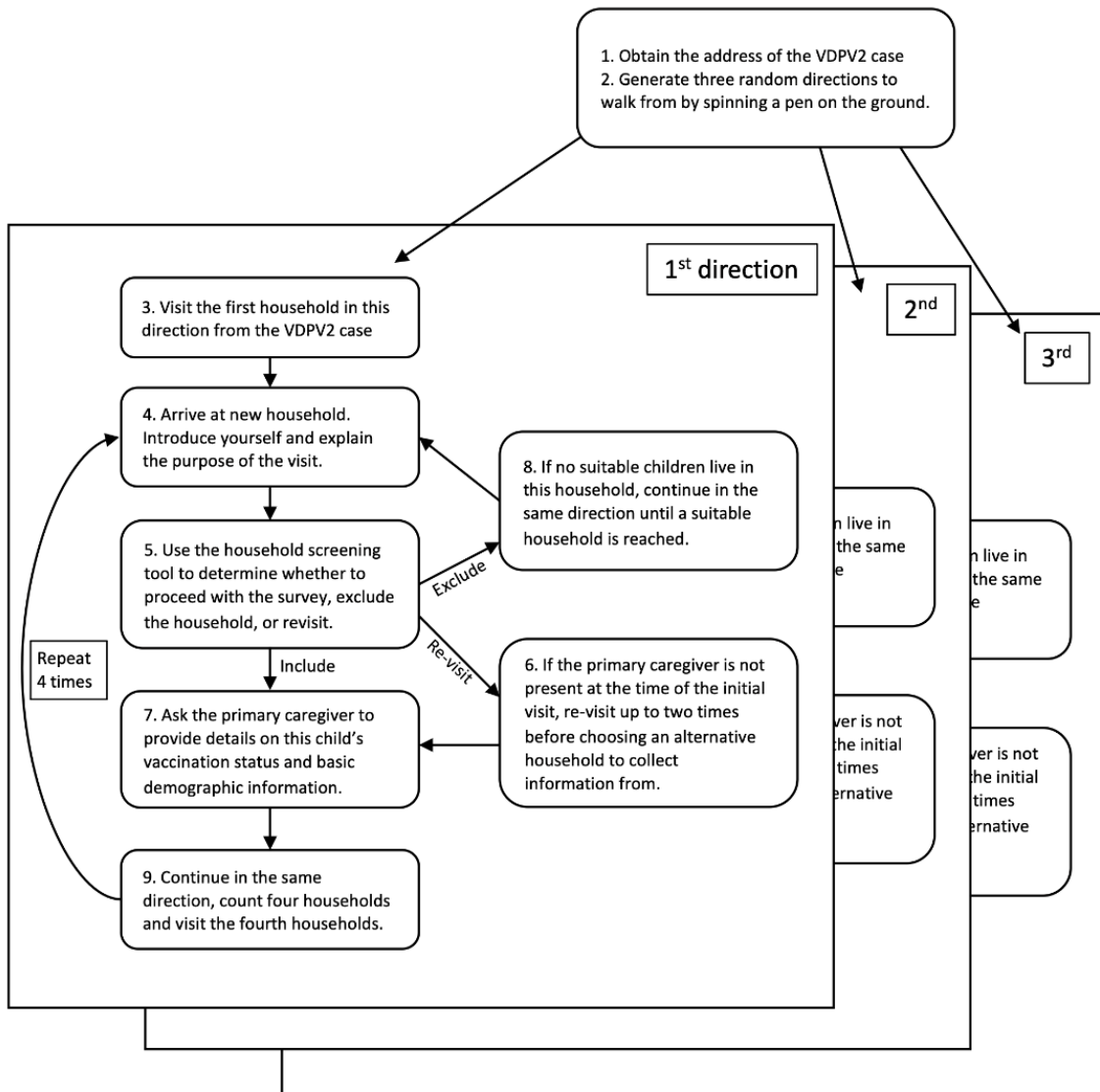
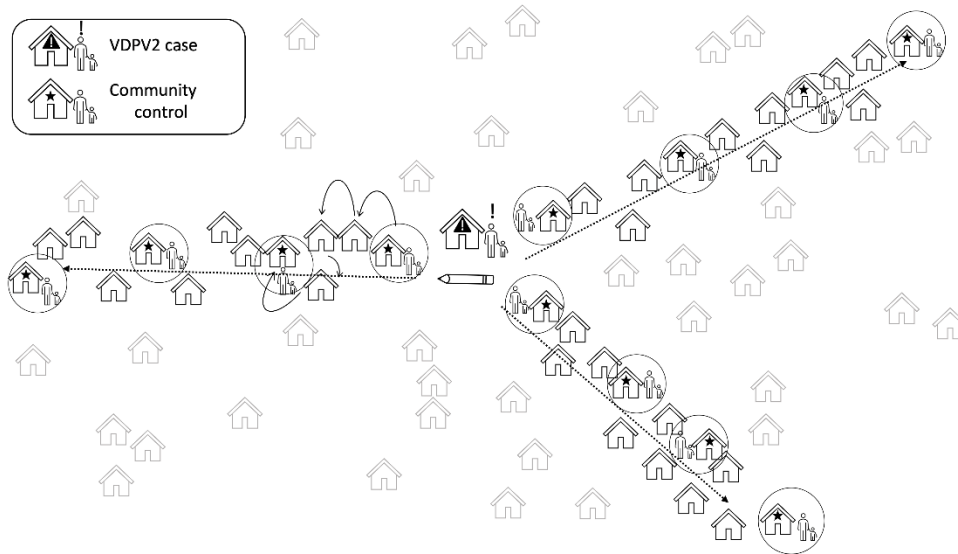


Fig. D2. Diagram for randomly choosing households

A) Rural setting



B) Urban setting

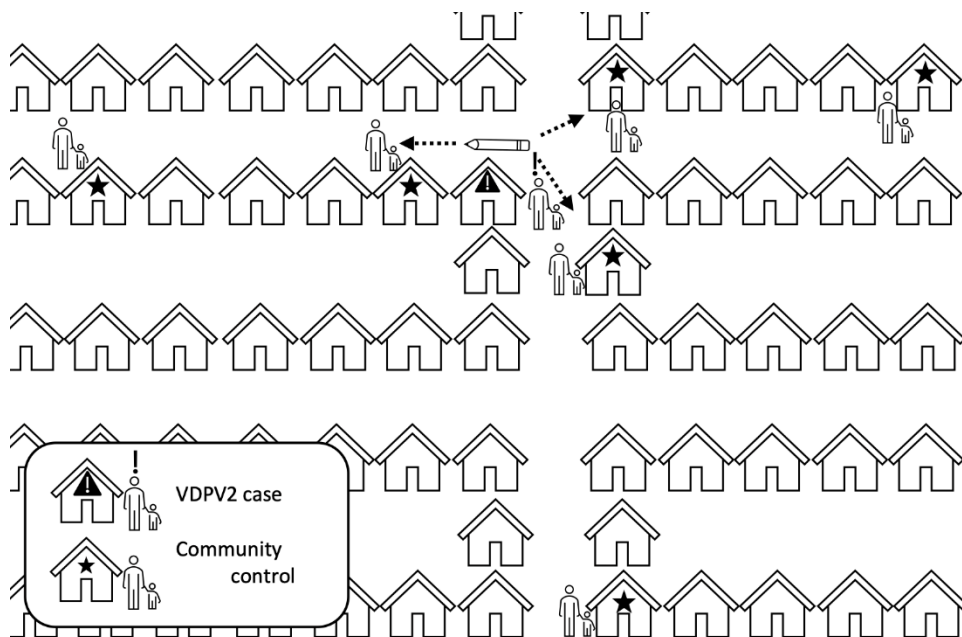
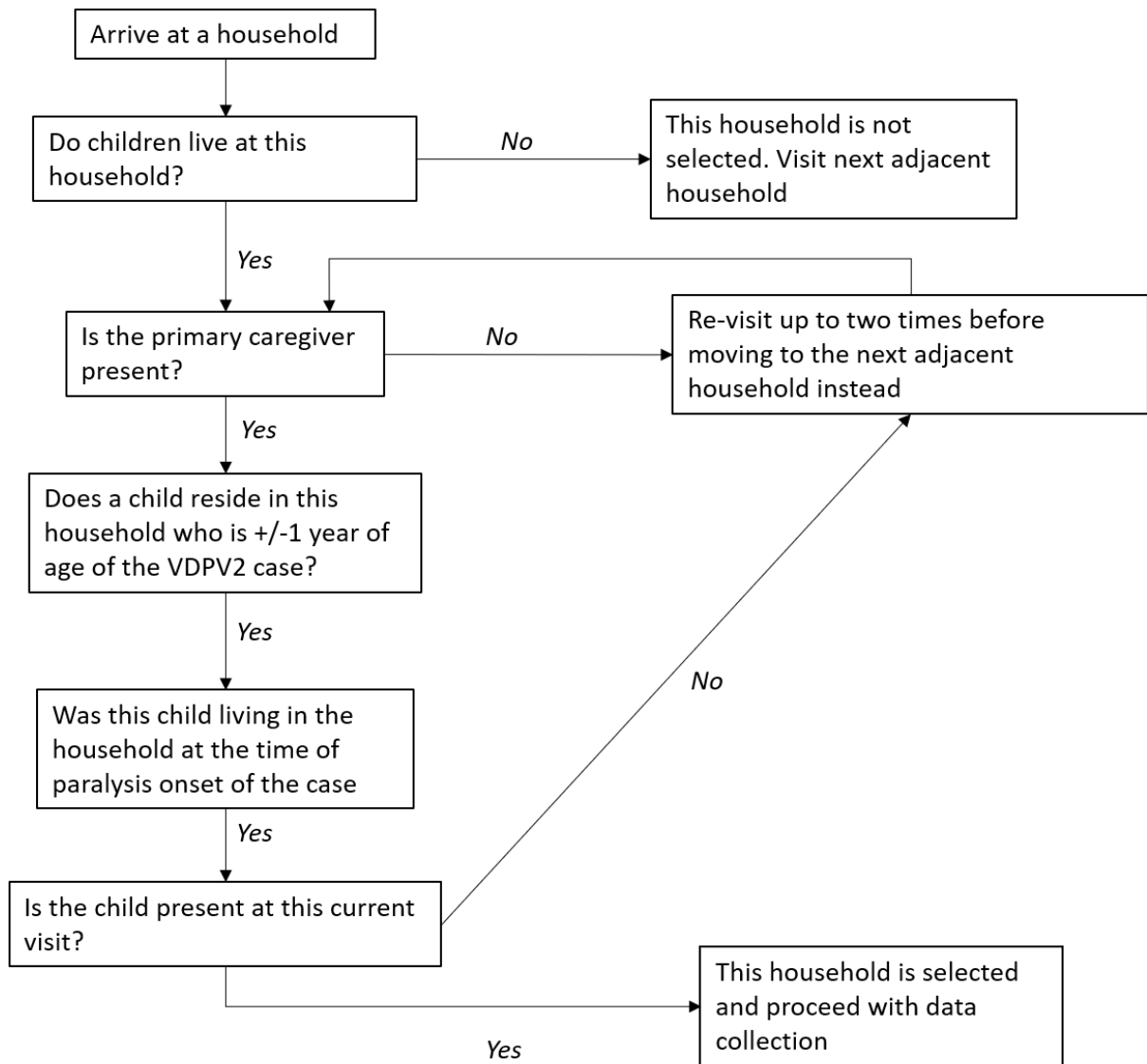


Fig. D3. Household screening illustration



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:
(bOPV/mOPV2/nOPV2)

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 info:
(Choose one)

Card

Recall

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

Annex D

Case Investigation Form for acute flaccid paralysis

Recognizing that CIFs 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.

A sample CIF with updated immunization history can be found online:
[Case Investigation Form](#).

IMMUNIZATION HISTORY

Total OPV doses received through SIA:
(bOPV/mOPV2/nOPV2)

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 info:
(Choose one)

Card

Recall

Annex E

Poliovirus surveillance among PID patients in the context of nOPV2 use

To assess the safety of nOPV2, the post-deployment monitoring (PDM) framework includes poliovirus surveillance among individuals with primary immunodeficiency disorders (PIDs). Prior to use of nOPV2, countries must complete the [PID diagnostic capacity checklist](#).

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 are referred to as immunodeficiency-associated vaccine-derived polioviruses (iVDPVs). PID patients can 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 (see panel at right). T-cell only immunodeficiencies, such as HIV, are not a known risk factor for iVDPV.

nOPV2 and PIDs:

Excerpt from the Emergency Use Listing

“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”

PIDs with known high risk of prolonged poliovirus excretion

- Predominant antibody disorders:*
 - Common variable immunodeficiency disorder (CVID) and other primary hypogammaglobulinemia
 - Agammaglobulinemia including X-linked agammaglobulinemia
- 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)
- Other immunodeficiencies with hypogammaglobulinemia or increased susceptibility to viral infections*

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
Name and signature of the surveillance focal point	Name and signature of the nOPV2 focal point
Name:	Name:
Signature	Signature
Date	Date

An editable version of this form can be found online: download [PID diagnostic capacity checklist](#)

Field and laboratory surveillance resources

Resource	Description	For more information
Environmental Surveillance in Outbreak Settings	Provides SOPs to enhance environmental surveillance following investigation of any polio event or outbreak (type 1, 2 or 3) and to monitor, on a short-term basis, the presence or absence of vaccine-related virus following VDPV detection.	Link
Global Polio Surveillance Action Plan (2018-2020)	Supports endemic, outbreak and high-risk countries in evaluating and increasing the sensitivity of their surveillance systems. Provides supplemental strategies that may help in closing gaps in detecting polioviruses. Aims to strengthen coordination across surveillance field teams, the GPLN and POLIS.	Link Note: The GPSAP is being updated and a new version is expected in early 2022.
Field Guidance for the Implementation of Environmental Surveillance for Poliovirus	Provides detailed guidance on the preparation and implementation of a National Poliovirus Environmental Surveillance Plan. Focuses on site selection, sample collection and transport, and the use of data for action.	Forthcoming publication. Contact the Surveillance Task Team for the guidance document or to access the publication online.
Global Guidelines for Acute Flaccid Paralysis (AFP) and Poliovirus Surveillance	Provides updated guidance on AFP surveillance. These guidelines revisit the basics of AFP surveillance while also incorporating new strategies to enhance surveillance quality for special populations, such as those who live in areas with access limitations.	Forthcoming publication. Contact the Surveillance Task Team for the guidance document or to access the publication.
Guidelines for Implementing Poliovirus Surveillance among Patients with Primary Immunodeficiency Disorders (PIDs)	Provides detailed guidance on establishing a PID surveillance system by detailing steps to set up the system, notes on the role of the laboratory and information management, and details on case detection, investigation and management.	Link
Pre-campaign checklist	Details activities that should be completed across all categories of the EUL requirement or areas of work before nOPV2 use.	nOPV2 pre-campaign checklist
Post-campaign checklist	Details activities that should be completed across all categories of the EUL requirement or areas of work before nOPV2 use.	nOPV2 post-campaign checklist