Standard Operating Procedures

Responding to a poliovirus event and outbreak

Part 1: General SOPs

April 20, 2016

Effective 1st May 2016 till 30 April 2017

World Health Organization

Contents

Table and figures

Revisions

Document version (date)	Description of substantive revisions
Version 2 (April 2016)	• Emphasise national government ownership and role in leading notification and response to event and outbreak • Update following entering in post-switch era: global tOPV withdrawal and new response strategies for type 2 events and outbreaks. • Introduce fact that poliovirus "events" require initiation of risk assessment and response; and for some of them an immunisation response (SIA). • Type 2 events are managed operationally in a manner similar to outbreaks, with greater discretion while field investigation and VDPV classification underway. GPEI performance standards apply to type 2 events. • Introduce new definitions and classification of VDPVs: circulating, immuno-deficiency, and ambiguous terminology • Revised timeline to reflect that "Day 0" is the date of laboratory result notification (and not outbreak confirmation). • Generic SOPs for all poliovirus and specific type 2 poliovirus protocol merged in an aligned SOP. • Revisit polio risk and response grading concept to allow post switch a more adaptable and fit-for-purpose outbreak response in a more diverse and evolving country and global context. Aligning it with global WHO risk assessment tools (introduction of the risk matrix) • Specify new choice of vaccine for SIAs post-switch and introduce use of IPV in event and outbreak response. • Introduce steps to request mOPV2 vaccine from global stockpile • Introduce criteria and flowchart for outbreak closure • Clarify IHR notification requirements and timeframe

List of acronyms

AEFI	Adverse event following immunization
AFP	Acute flaccid paralysis
aVDPV	Ambiguous vaccine-derived poliovirus
C4D	Communications for development
CDC	US Centers for Disease Control and Prevention
cVDPV	Circulating vaccine-derived poliovirus
cVDPV1	Circulating type 1 vaccine-derived poliovirus
cVDPV2	Circulating type 2 vaccine-derived poliovirus
cVDPV3	Circulating type 3 vaccine-derived poliovirus
EOMG	Eradication and Outbreak Management Group
EOC	Emergency Operation Center
ERC	Expert Review Committee
ERF	Emergency Response Framework
ES	Environmental surveillance
GPEI	Global Polio Eradication Initiative
GPLN	Global Polio Laboratory Network
IEC	Information, education and communication
IHR	International Health Regulations
IM	Independent Monitoring
IPC	Interpersonal communication
IPV	Inactivated poliovirus vaccine
iVDPV	Immunodeficiency-associated vaccine-derived poliovirus
KAP	Knowledge, attitude and practice
NID	National Immunization Day
NPAFP	Non-polio acute flaccid paralysis
OPV	Oral polio vaccine
OB	Outbreak
OBRA	Outbreak Response Assessment
OPRTT	Outbreak Preparedness and Response Task Team
bOPV	Bivalent OPV (contains Sabin types 1 and 3)
tOPV	Trivalent OPV (contains Sabin types 1, 2 and 3)
mOPV2	Monovalent OPV (contains Sabin type 2)
PAS	Polio Access and Support
PHEIC	Public health emergency of international concern
RO	Regional Office
RRT	Rapid Response Team
SIA	Supplementary immunization activity
SITREP	Situation report
SNID	Subnational Immunization Days
SOP	Standard Operating Procedure
STOP	Stop Transmission Of Polio programme
TAG	Technical Advisory Group
UN	United Nations
UNICEF	United Nations Children's Fund
VDPV	Vaccine-derived poliovirus
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus

Executive summary

Introduction

These Standard Operating Procedures facilitate timely and effective response to poliovirus events and outbreaks, and incorporates lessons learned from previous outbreak response efforts. It summarises roles and responsibilities of countries and GPEI partners, and describes standards for polio events and outbreaks response.

The objectives are: (1) to establish standards and timeline for response; (2) to guide national governments and GPEI partners in key support functions.

This new version of the SOP lays out overall response requirements for dealing with type 1, 2 and 3 poliovirus for the first 12 months following OPV2 cessation (1st May 2016 till 30 April 2017).

Poliovirus events and outbreaks

Emergence of polioviruses is considered to be defined as an 'event' or an 'outbreak' based on a range of criteria (Table 1) for the purpose of determining the appropriate response.

The GPEI Standard Operating Procedures recommend that supplemental immunization activities be implemented within 14 days of identification of a poliovirus that requires an immunization response. For the purpose of response performance monitoring, notification of the laboratory result is defined as 'Day 0' so that progress of the event or outbreak response can be monitored against the standards set in these SOPs. Outbreak confirmation is the responsibility of the WHO Regional Office.

Obligation to notify positive poliovirus isolates

All instances of poliovirus isolation in a previously polio-free country – and other notifiable polioviruses such as VDPV2 in countries still endemic for wild poliovirus – must be reported immediately by the country to WHO, regardless of type of isolate (WPV, VDPV), or source (clinical case, environmental sample, other).

Responding to a polio event

Country, WHO and GPEI partners conduct a risk assessment for every event based on the findings of the epidemiologic and laboratory investigations and the strength of evidence. A polio event may be escalated to an outbreak at any point in the investigation.

The scope of the response to a detected event depends on the poliovirus type, classification, and in some circumstances, the local situation (Tables 5a and 5b). The initial general steps includes: case and contact investigation, community case finding, assessment of population immunity, enhanced active surveillance. In addition, specific steps are defined according to the isolate identified and its source.

All poliovirus type 2 events will be generally managed as outbreaks, while awaiting results of field investigations and final classification.

Responding to a polio outbreak

The recommended general steps to respond to all polio outbreaks are the same as for an event, but complemented with additional activities or standards (Tables 6a and 6b), such as: outbreak risk assessment and subsequent grading by EOMG, deployment of rapid response team and surge team by OPRTT, Independent Monitoring of SIAs, immunization coverage assessment with Clustered Lot Quality Assurance Sampling. Specific steps for the immunisation response are defined according to the isolate identified, in addition to the general steps above (Table 6b).

Selection of the most appropriate vaccine is made with WHO technical support. It is based on the type of poliovirus, the underlying population immunity, and projected timeframe (Table 7).

The risk assessment aims to characterize the virus transmission and the implications for further spread. It assesses the critical factors which will influence the type and scale of response and make recommendations for appropriate actions. EOMG based its risk assessment on the combination of two

sets of criteria: (1) Potential for transmission in country and spread beyond national borders and (2) Strength of the country's capacity to respond and contain the outbreak. As a result of this assessment, the EOMG assigns a grade to the outbreak (grades 1, 2 or 3). The grading system is used to prioritize or rank the level of outbreak response activities needed to manage the risk identified. The higher the grade, the more GPEI support will be needed for the response.

Strategic response framework for polio outbreak

Five strategic pillars for interrupting transmission in an outbreak setting outline what is needed for an effective response: (1) a fully engaged national government, (2) a rapid risk assessment and identification of transmission risk zones, (3) a robust immunization response, (4) an effective communication and social mobilization, (5) enhanced surveillance.

End of outbreak: closure

Criteria and decision trees for declaring closure of an outbreak differ according to poliovirus type (Figures 2a and b).

GPEI partnership support to countries outbreak response

Countries have ultimate ownership of the response, and maintain leadership throughout the process. GPEI partners support the countries in six key functions: (1) Outbreak response and assessment, (2) Coordination and advocacy, (3) Technical and human resources, (4) Information management, (5) Communication, social mobilization and behaviour change, (6) Finances and logistics.

The GPEI performance standards describe the expected outputs from each level of GPEI partners, in each of the six key functions (Table 11). Concrete deliverables and timelines are provided as well.

1- Introduction

The Global Polio Eradication Initiative (GPEI) seeks to ensure that future generations of children will be free from the threat of paralysis due to poliomyelitis. Critically important to successful eradication is ensuring rapid and effective response to polioviruses from any source if reintroduced or emerging in the remaining endemic and non-endemic countries. Countries and GPEI partners must aim to stop transmission of poliovirus within 120 days of confirmation of any new outbreak.

Wild poliovirus (WPV) and vaccine-derived polioviruses[1] (VDPVs) can both cause clinical illness, including acute flaccid paralysis (AFP), and lead to outbreaks[1]. There are three types of WPV, but only type 1 (WPV1) continues to circulate. The last type 3 poliovirus (WPV3) was isolated in 2012. The last type 2 WPV (WPV2) was isolated in 1999 and declared eradicated in September 2015[2]. There are only two endemic countries where WPV1 continues to paralyse children – Afghanistan and Pakistan. These countries continue on the path to eradication, strongly supported by the GPEI partners.

However, VDPVs capable of causing paralysis also continue to emerge and circulate. In May 2014 and in November 2015 in conjunction with the World Health Assembly (WHA), the World Health Organization (WHO) Director-General (DG) declared the ongoing spread of polioviruses — WPV and circulating vaccine-derived polioviruses (cVDPV) — to be a public health emergency of international concern (PHEIC). In response, the Emergency Committee for polio, convened under the International Health Regulations (IHR), included cVDPVs in their remit for monitoring action and progress. In under-immunized populations, cVDPVs represent a particular risk and in recent years, most cVDPV cases and outbreaks have arisen from oral polio vaccine containing the type 2 component (OPV2).

In response to the rising concern regarding VDPV2 outbreaks at the time, the May 2014 WHA endorsed a strategy to reduce the risk associated with attenuated poliovirus (Sabin strains) used in oral polio vaccine (OPV). In line with the *Polio Eradication and Endgame Strategic Plan 2013-2018*[3], all countries ceased using type 2-containing oral polio vaccine (OPV2), in their routine immunization programmes between 17 April to 1st May 2016, thus participating in the largest globally-coordinated vaccine introduction in history, as all OPV-using countries switched from using trivalent OPV (tOPV, containing Sabin 1, 2, and 3) to a bivalent form (bOPV; containing Sabin 1 and Sabin 3). All existing stocks of tOPV are being removed from circulation, to further reduce the likelihood of cVDPV type 2 virus emergence.

The GPEI is a public-private partnership, led by national governments and spear-headed by key partners[4]. GPEI partners support countries for polio eradication activities and outbreak response.

[1] strains of poliovirus mutated from the live attenuated oral polio vaccine

Scope

This document is intended to facilitate timely and effective response to interrupt poliovirus transmission in non-endemic countries, and incorporates lessons learned from previous outbreak response efforts. It summarise roles and responsibilities of countries and GPEI partners and standards for polio outbreak and event response. It updates and establishes standard operating procedures for the post-switch era [5] in alignment with the more detailed protocol for type 2 poliovirus events and outbreaks after global tOPV withdrawal on May, 1st 2016.

Objectives

The objectives of this document are:

- To establish standards and timeline for response to any polio events and/or outbreaks.
- To guide national governments and GPEI partners in key support functions to fulfill in response to any polio outbreak or event.

To be noted: this document is a revision of the SOP first made available in February 2015.

Target audience

The proposed audience for this document is national government and GPEI partners who will coordinate the national response to polioviruses events and outbreaks.

Companion documents

Additional information that may be useful to users of this document includes:

- *GPEI Reporting and classification of vaccine-derived polioviruses guidance.* [6]
  This guidance describes additional laboratory analysis and field epidemiological investigation prior to confirming classification of a VDPV sample.
- *Operational tools for outbreak response.* [7] [8]
  The SOPS do not provide specific tools for outbreak response, planning of supplemental immunization activities (SIAs) or methods for enhanced surveillance. The tools can be found in GPEI website[9] [10].

2- Poliovirus events and outbreaks

2.1-Poliovirus events and outbreaks defined

Table 1 classifies all polio isolates according to whether their appearance is currently deemed to represent an 'event' or an 'outbreak' for the purpose of describing the extent of person-to-person transmission and determining the appropriate response. In annex 1, the figure 3 describes it visually.

Table 1: Definition of poliovirus events and outbreaks

Typology	Definition
Event (as yet, no evidence of transmission)	Human
	Detection of 1) **VDPV** in: • Single AFP case or asymptomatic person (e.g. contact) or • One or more persons,[a] with no evidence of further community-level circulation (**iVDPV** or an **aVDPV** isolates) OR 2) **Sabin like 2** isolate from individual sample(s) OR 3) **WPV2** infected individual <u>with</u> documented type 2 virus exposure in a laboratory or vaccine production facility
	Environmental
	Detection of 1) **WPV** single environmental sample <u>without</u> follow-up evidence of virus excretion [b] OR 2) **VDPV** <u>without</u> evidence of further transmission, such as • single environmental sample without evidence of prolonged circulation of >1.5 years or • an aVDPV OR 3) **Sabin like 2** isolate from environmental sample(s)
Outbreak (evidence of transmission)	Human
	Detection of 1) Any **WPV** infected individual(s) [a] (an addition for type 2: "without documented exposure to a type 2 virus in a laboratory or vaccine production facility") OR 2) Any **cVDPV** infected individual(s) [a]
	Environmental
	Detection of 1) Two or more separate[c] environmental samples positive for **WPV** <u>with</u> genetic sequencing information indicating sustained local transmission OR 2) A single environmental sample positive for **WPV** <u>with</u> follow-up evidence of virus excretion [b] OR (an addition for type 2: "no documented exposure in a laboratory or vaccine production facility") 3) Any **cVDPV** positive environmental sample(s)

[a] Infected person can be an AFP case or an asymptomatic/healthy person

[b] Evidence of virus excretion is defined by identification during follow-up investigation of WPV or VDPV infected individual(s)

[c] "separate" means that:
- sample were collected at more than one distinct ES collection site (no overlapping of catchment areas), OR
- sample were collected from one site, but collection was more than two months apart

2.2-Vaccine-derived polioviruses

Vaccine-derived polioviruses (VDPVs)[11] [12]are identified based on their degree of genetic divergence from the parent OPV viral strain. Strains that are > 1% divergent (or >= 10 nt changes, for types 1 and 3) or > 0.6% divergent (>= 6 NT changes, for type 2) from the corresponding oral vaccine strain are labelled as VDPVs.[13] VDPVs are classified into 3 categories:

1. **Immunodeficiency-related vaccine-derived polioviruses (iVDPV)** are a special case of VDPVs arising in the gut of persons with a primary immunodeficiency (PID). Unlike immunocompetent persons, who excrete the vaccine virus for a limited period of time, some immunodeficient persons are unable to clear intestinal replication of the vaccine virus after receiving OPV. In this regard, iVDPVs pose a threat to eradication, as individuals who excrete the vaccine virus for prolonged periods could serve as sources of poliovirus reintroduction after polio eradication.
2. **Circulating vaccine-derived polioviruses (cVDPV)** occur when there is evidence of person-to-person transmission in the community.
3. **Ambiguous vaccine-derived polioviruse (aVDPV)** is a classification of exclusion when investigation does not support classification as cVDPV or iVDPV. Isolates may be from persons with no known immunodeficiency or from an environmental sample, without evidence for circulation.

The GPEI Reporting and classification of vaccine-derived polioviruses guidance[14] describes definitions, laboratory and field epidemiological investigation processes needed to classify a VDPV isolate.

2.3-Laboratory results and initiation of response

When one or more laboratories of the Global Polio Laboratory Network (GPLN) isolate a poliovirus from a biological (human) or environmental sample (through culture, intratypic differentiation and genetic sequencing), the GPLN rapidly notifies the Ministry of Health in the affected country and the World Health Organization at country office, regional and global levels of the identification of a poliovirus and whether the virus is wild polio or vaccine-derived, type 1, 2 or 3, and Sabin (vaccine) or non-Sabin like.

This notification is provided so that authorities can initiate case and community investigation to assess the affected child/adult and his/her family and community contacts (or circumstances of the environmental sample), and explore whether there is any evidence of person-to-person transmission. WHO provides this information to GPEI partners as soon as it is received. Investigations will also provide the information necessary to classify the isolate as outlined in the previous section. Investigation and classification can take days or weeks. The laboratory result notification is not shared beyond GPEI until WHO regional office, in collaboration with laboratory and other colleagues, confirms it as an event or an outbreak.

2.4-Defining Day Zero for event and outbreak monitoring

The GPEI Standard Operating Procedures recommend that supplemental immunization activities be implemented within 14 days of identification of a poliovirus that requires an immunization response, as detailed in tables 5 and 6 for each type of isolate.

For the purpose of performance monitoring, **notification of the laboratory result is defined as 'Day 0'** so that progress of the event or outbreak response can be monitored against the standards set in these SOPs. This is true for as-yet unclassified VDPV type 2 events and for cVDPV2 outbreaks. For VDPV type 1 and 3 events pending classification, rapid investigation is expected, but will not at this time be measured against the SOP standards unless they are confirmed to be, or become, a type 1 or type 3 outbreak.

2.5-Outbreak confirmation

The confirmation of an **outbreak** is the responsibility of WHO RO (table 2).

Table 2: Operational requirements for confirming an outbreak

Terminology	Definition
Outbreak confirmation **(**Day 0 for performance monitoring for types 1 and 3 polioviruses)	**WHO RO confirms** an outbreak in consultation with the national authority as well as GPLN laboratory experts and WHO/HQ, and after having taken into account the criteria below : • laboratory result (genetic sequencing) AND • final case investigation (to rule out iVDPV) AND • event investigation (especially for type 2 to rule out laboratory or vaccine production facility contamination)

2.6-Outbreak transmission risk zones

Factors such as past epidemiologic history, location, and population characteristics may determine three general "transmission risk zones" which reflect the risk for polio transmission (see table 3).

Table 3: Definition of "transmission risk zones" based on population risk for poliovirus transmission

Zone	Country/area and Population Characteristics	Risk for further transmission
1	Clear history of sustained WPV or reported cVDPV since 2005; OR affected community with other risks for low immunity* or high mobility links to susceptible communities	High
2	Consistently low DTP3 coverage <80% in the previous 3 years; OR history of imported WPV or any cVDPV or aVDPV in the previous 3 years; OR with DTP3 coverage <90% and adjacent to affected area	High-Medium
3	DTP3 coverage consistently >80%; affected community with few risk factors for sustained transmission	Low

*E.g. high birth rate, high population size and density, low routine immunization coverage, failure to reach unvaccinated children in pre-switch SIAs, and other conditions associated with high levels of fecal-oral transmission

2.7-High quality SIAs for event and outbreak response

Polio outbreaks and most type 2 polio events will require implementation of vaccination campaigns within 14 days to stop any further circulation of the virus.

Rapid SIA campaign for event and outbreak response is defined as first SIAs within 14 days of laboratory result notification (Day 0).

Short Interval additional dose SIAs (SIAD) interval between SIA rounds can be as short as one week.

Large scale SIAs are defined as at least 500,000 children for 1st SIA round and approximately 2 million for subsequent rounds. Where 2 million children do not exist within a reasonable radius, all children, or children of 10 million total populations could be targeted. It is possible to consider increasing the scope further in densely populated areas or if there is evidence of extensive circulation or if there is potential for extensive circulation (e.g. outbreak population well-connected to a major urban area). However, in

all situations, the target population should not be increased beyond the capacity of the program to attain high coverage.

Targeted age group for SIAS are all < 5 years old children. An **expanded age group** considers <10 years old children, < 15 years old or the whole population depending on the local context. Expanded age group vaccination is recommended if there is evidence of virus circulation among older age groups.

3- Obligation to notify positive poliovirus isolates

All instances of poliovirus isolation in a previously polio-free country – and other notifiable polioviruses such as VDPV2 in countries still endemic for wild poliovirus – must be reported immediately by the country to WHO, regardless of type of isolate (WPV, VDPV), or source (clinical case, environmental sample, other).

Notification should occur at the first indication of a positive sample; for example an unclassified VDPV should be notified immediately to WHO by the country prior to final classification. This applies to both environmental and clinical isolates. Countries should not rely on the lab notification to inform WHO but institute their own formal rapid notification procedure.

Background: In 2012, the WHA adopted a landmark resolution declaring that the completion of polio eradication is a programmatic emergency for global public health, as outlined in the Emergency Response Framework. The resolution called for an intensification of efforts to eradicate polio.

Notification: Countries should **notify WHO about any detection of WPV or VDPV poliovirus** immediately on the grounds that it could be an "event that may constitute a public health emergency" in accordance with IHR [15]. This holds true regardless of source or precise classification of source of the poliovirus. WPV isolated from an AFP case or case contact meets the criterion for "notification in all circumstances" under IHR Annex 2 (2005)[16]. Identification of a WPV or VDPV from any source (environmental or human) meets the criteria for notification to WHO under the following criteria from IHR Annex 2 (2005)[17]:

i) serious public health impact; and
ii) unusual or unexpected event. The final two criteria may also be met:
iii) significant risk of international spread of disease;
iv) significant risk of international trade or travel restrictions.

In addition, the isolation of Sabin 2 virus will be notifiable under IHR from 1 September 2016, as beyond that time, there should be no further Sabin 2 vaccine being used, except in the context of outbreak response with mOPV2.

Steps to notify:

- The **country polio focal** point notifies the polio advisor at the WHO Regional Office within 24 hours of receiving the laboratory notification of a poliovirus isolate. The Ministry of Health and WHO HQ must be copied on correspondence; WHO HQ then informs GPEI partners immediately.
- The **WHO Regional Office** confirms the notification with the country and the GLPN-affiliated laboratory. It then becomes an official IHR notification and is reported onwards to WHO HQ IHR.

Further details of notification under IHR are provided in Annex 2.

4- Responding to a polio event

The country will investigate and monitor any polio event to determine if an outbreak is occurring with support from GPEI partners where requested. Timely, clear and effective communication between all partners and levels is crucial to ensure appropriate response to events.

Table 5 describes the minimum response requirements to the different possible polio events.

NB: All poliovirus type 2 events will be managed as outbreaks for the purpose of implementing and monitoring the operational response, while, for example, waiting for results of field investigations and final classification in the case of a VDPV2.

This implies that for type 2 events, the "no-regrets" financing policy applies and the GPEI performance standards set out in these SOPs will apply. While the event response is underway, including investigation, active surveillance and vaccination campaigns according to standard, there will be more flexibility in determining the number of SIA rounds or the scale of event response assessments.

4.1-Investigation and assessment - general steps for all events

The recommended initial general steps to respond to a polio event are:

- **Case and contact investigation** [18]:
  - Conduct urgently a detailed clinical, epidemiological and social investigation of the case and contacts.
  - Investigate clinical history, including facilities visited, as well as the travel history of the case and social environment and the community context of the case
  - Sample contacts of the case/s (stool sampling): Collect one stool sample from at least 5 direct contacts (i.e. siblings, household contacts, playmates) as well as from at least 20 persons of the same age group living in the community (i.e in another part of the village or in a nearby village). Visit and document all other health-care providers in the area, including traditional healers and private practice as part of active case search.
- **Community case finding**: the community searches for unreported cases. This includes active case searching and retrospective case searching in health facilities. A positive environmental sample should also trigger active case finding in the suspected community and/or catchment area of the ES site. The cases found should be sampled.
- **Assessment of population immunity**: from the AFP database and routine immunization coverage, as well as a quick community survey of OPV/IPV status, as part of the case investigation
- **Enhanced active surveillance**: the surveillance system is put on high alert to detect any signs of poliovirus transmission in the affected country and any potentially impacted neighbouring countries (AFP surveillance supplemented by environmental surveillance):
  - In order to maximize quality and sensitivity of the AFP surveillance system, ensure strict attention to completeness and timeliness of all AFP reporting. Consider routinely doing contact sampling for AFP cases (3 contacts for every AFP case) coming from the geographical area for a period of time.
  - For the immediate investigation period, increase frequency of environmental surveillance, if available. For the longer term, investigate with the GPEI partnership about establishing or expanding local environmental sampling sites.

4.2-Risk assessment

Country, WHO and GEPI partners conduct a risk assessment for every event based on the findings of the epidemiologic and laboratory investigations and the strength of evidence. It aims to characterize the virus transmission and the implications for further spread. This is especially important following discovery of a type 2 isolate (please refer to part 2 of this SOP (Specific type 2 protocol).

The ultimate decision of whether to designate a poliovirus isolate as an event or outbreak, for the purposes of the response described in this SOP, rests with WHO in dialogue with the affected country.
A polio event may be escalated to an outbreak at any point in the investigation (following definitions in table 1), as deemed necessary by WHO in consultation with the country and other GPEI partners.

4.3-Specific steps

The scope of the response to a detected event will depend on the poliovirus type, classification, and, in some circumstances, the local situation. Post-switch, detection of even a type 2 event requires a more aggressive response than recommended for the other poliovirus types.

Specific steps are defined according to the isolate identified, in addition to the steps outlined in Table 5.

- **For all type 2 events**, the type 2 response protocol in part 2 of this SOP describes the full details on which situations require a vaccination response.
- **For VDPV1 or VDPV3 pending classification**, the approach will follow the same initial response steps. However, SIA activities are not required unless the isolate is classified as a cVDPV which will invoke a full outbreak response.
- Isolates classified as **aVDPV and iVDPV** will not likely lead to an outbreak. The general response approach is simplified to usual case and contact investigation, in addition to specific SIAs (for type 2) or no SIAs at all (for type 1 and 3) depending on local context and risk assessment.
- The investigation into an **environmental WPV isolate in a non-endemic country** must consider possible importation (e.g. incoming travel) or release from a laboratory facility. For type 1 and 3, the necessary response, including the implementation of SIAs, will be determined on a case by case basis, with careful consideration of the country (e.g. proximity to endemic regions), population immunity characteristics, and outcome of investigation.

Rapid response to types 1 and 3 outbreaks (WPV or cVDPV1 or 2) will be undertaken with bivalent OPV (Sabin vaccine types 1 and 2) and requests will follow the usual procedures for campaign support through WHO and UNICEF country offices.

Table 5a: Minimum response requirements to polio events

Isolate	Source	General response	Immunisation response	Timeframe **
WPV				
WPV 1 or 3	environment	• Case finding: community search for cases • Assessment of population immunity • Enhanced active surveillance	• **SIAs** plan and their implementation based on local situation, as advised by WHO & GPEI Partners	-
WPV 2	environment (with no evidence of individual excreting virus)	• Case finding: community search for cases • Assessment of population immunity • Enhanced active surveillance • Refer to part 2 of this SOP (poliovirus type 2 protocol)	• Refer to part 2 of this SOP (poliovirus type 2 protocol). SIAs plan and implementation depends on local situation. Especially for risk zone 1, **consider 1 round of SIA** ○ Target age: 0-5 years ○ Population size: in rapid response area (min 500,000 children) ○ Vaccine of choice - Post-switch: mOPV2+/- IPV • Vaccine request to WHO DG for mOPV2	first SIAs within 14 days
Sabin like 2				
Sabin like 2	• environment or • human	• Refer to part 2 of this SOP (specific poliovirus type 2 protocol	• Refer to part 2 of this SOP (poliovirus type 2 protocol). **SIA are not required**	-

** Timeframe :
-from lab result notification for type 2 events
-for VDPV type 1 and 3 events pending classification, aVDPV 1 or 3 , iVDPV 1 or 3, rapid response is expected, but will not at this time be measured against the SOP standards unless they are confirmed to be, or become, a type 1 or type 3 outbreak.

4.4-Release of mOPV2 from the global stockpile

In line with the World Health Assembly resolution, new procedures have been put in place for countries to request monovalent type 2 oral polio vaccine (mOPV2) from the global vaccine stockpile. The country will prepare and submit a vaccine request within 48 hours of lab result notification of a type 2 poliovirus requiring a vaccination response. Only the WHO Director General has the authority to release mOPV2 vaccine upon the recommendation of an international coordinating group (ICG) composed of the GPEI's Eradication and outbreak management group (EOMG) and selected additional laboratory and technical experts. Whereas IPV release does not require the DG's approval, due to the extremely constrained global IPV supply, the same vaccine request mechanism will be used to request IPV supplies through the ICG/EOMG.

4.5-Event response assessment

The concept of outbreak response assessment can be applied to events, particularly those for which an immunization response and surveillance strengthening are implemented. The event response assessment can be scaled appropriately or focussed to meet the needs of the local context and circumstances. The purpose of the event assessment will be to review the quality of the response, the need for further surveillance, and to recommend further SIAs that may be needed, particularly in the case of type 2 and plans to deploy further mOPV2, for which a full justification must be provided.

Table 5b: Minimum response requirements to polio events (continuing)

Isolate	Source	General response	Immunisation response	Timeframe **
VDPV				
VDPV 1 or 3 (waiting classification) *	• human • environment	• Case and contact investigation (clinical and epidemiological) • Case finding: community search for unreported cases • Assessment of population immunity • Enhanced active surveillance	• **SIAs are not required**	-
aVDPV 1 or 3	• human or • environment	• Case and contact investigation (clinical and epidemiological) • Strengthened environmental surveillance	• **SIA are not required**	-
iVDPV 1 or 3	uman	• Case and contact investigation (clinical and epidemiological)	• **SIA are not required**	-
VDPV 2 (awaiting classification, "new" VDPV: probable transmission)	• human or • environment	• Case and contact investigation (clinical and epidemiological) • Case finding: community search for unreported cases • Assessment of population immunity • Enhanced active surveillance • Refer to part 2 of this SOP (poliovirus type 2 protocol)	• Refer to part 2 of this SOP (poliovirus type 2 protocol). **Plan for ≥3 round(s) of SIAs** ○ Implement first SIA with mOPV2 in rapid response area (min 500,000) unless very low risk ○ other rounds: implementation depending on local situation ○ Vaccine of choice mOPV2 +/- IPV • Vaccine request to WHO DG for mOPV2	first SIAs within 14 days
aVDPV 2	• human or • environment	• Case and contact investigation (clinical and epidemiological) • Strengthened environmental surveillance • Refer to part 2 of this SOP (poliovirus type 2 protocol)	• Refer to part 2 of this SOP (poliovirus type 2 protocol). **Consider a maximum of 3 round(s) of SIAs** ○ Implement first SIA with mOPV2 in rapid response area (min 500,000) if high risk area ○ other rounds: implementation depending on local situation ○ Vaccine of choice - mOPV2+/- IPV • Vaccine request to WHO DG for mOPV2	first SIAs within 14 days
iVDPV 2	human	• Case and contact investigation (clinical and epidemiological) • Refer to part 2 of this SOP (poliovirus type 2 protocol)	• Refer to part 2 of this SOP (poliovirus type 2 protocol). **SIA are not required** ○ IVIG for case (+ monoclonal antibodies or anti-virals if available) PLUS ○ IPV for household members and close community contacts	-

* if a VDPV is classified as a *circulating* strain, reflecting evidence of ongoing transmission, an outbreak will be declared

** Timeframe :

-from lab result notification for PV type 2 events

-for PV type 1 and 3 events, rapid response is expected, but immunisation response will not at this time be measured against the SOP standards unless they are confirmed to be, or become, a type 1 or type 3 outbreak.

5- Responding to a polio outbreak

5.1-Minimum response requirements to all polio outbreaks

The scope of the response to a detected outbreak will be determined by the poliovirus type and classification, underlying population immunity, local situation, and findings of the initial epidemiologic investigation. The key to a successful response is for partners to adapt their strategies as the situation evolves over the course of the investigation.

Table 6 describes the minimum response requirements to all polio outbreaks.

The recommended **general steps to respond to all polio outbreaks** (table 6a) are the same as for an event (see paragraph 4.1) but complemented with additional activities or standards levels:

- An addition for enhanced active surveillance, where the minimum standards in AFP surveillance is increased to "three non-polio AFP cases per 100,000 children under 15 years of age in every first subnational divisions (province or state), for the duration of the outbreak and for at least 12 months after the last case".
- Addition of activities, such as:
    - Outbreak grading (by EOMG),
    - Deployment, where applicable (by OPRTT) of rapid response team (Team A) and surge team (Team B)
    - Independent Monitoring (IM) of SIAs
    - Immunization Coverage Assessment with Clustered Lot Quality Assurance Sampling (LQAS)
    - Independent outbreak response assessments (OBRA)

Specific steps for the immunisation response are defined according to the isolate identified, in addition to the general steps above (Table 6b)

Table 6a: Minimum response requirements to polio outbreaks.

Isolate	Response	Timeframe (from lab result notification)
	1- General response	
All isolates		
All isolates	Case and contact investigation	24 hrs to initiate
	Community case-finding	24 hrs to initiate
	Assessment of population immunity	24 hrs to initiate
	Enhanced active surveillance****	72 hrs to initiate
	Outbreak risk assessment and subsequent grading (by EOMG)	72 hrs to complete
	Initiate and deploy, where applicable (by OPRTT): • rapid response team (Team A) and • surge team (Team B)	• 72 hrs to initiate for Team A • Within 3 weeks for Team
	Independent Monitoring (IM) of SIAs[19] **	- IM in conjunction with all SIAs to be implemented **within 1 month** - Results of IM data to be internationally posted on GPEI Global website within 14 days of end date of each campaign
	Assessing Immunization Coverage with Clustered Lot Quality Assurance Sampling (Clustered-LQAS)[20]	LQAS to be started as soon as possible in conjunction with SIAs
	Independent outbreak response assessments (OBRA) [21]	1) **First independent 3-month assessment:** to be implemented 3 months after the detection of the first case of a polio outbreak 2) **Follow-up quarterly assessments:** 3 months after the first quarterly assessment, to be repeated every 3 months as long as outbreak continues 3) **End-of-outbreak assessment:** 6 months or 12+2 months after the most recent case.

* OPRTT are Outbreak Preparedness and Response Task Team

** Independent monitoring does not replace, nor equal supervision

**** including AFP surveillance to be enhanced to an annualized rate of greater than **three non-polio AFP cases per 100 000 children** aged under 15 years in every first subnational divisions (province or state), for the duration of the outbreak and for at least 12 months after the last case. Also, for the immediate assessment period, increase frequency of environmental surveillance if available

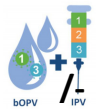
Table 6b: Minimum response requirements to polio outbreaks (continuing)

Isolate	Response	Timeframe (from laboratory result notification)
	2- Immunisation response	
WPV		
WPV 1 or 3 • human or • environment	**Plan+ implement ≥3 round(s) of SIAs**, as advised by WHO & GPEI partners ○ target age: 0-5 years + an expanded age group in ≥1 SIAs ○ population size: - SIA1: minimum 500 000 children. - SIA 2 and SIA 3: approximately 2 million children ○ Vaccine of choice bOPV	- 1st round within 14 days - First 3 rounds to be short interval SIAs (2-3 weeks apart)
WPV 2 • human	Refer to part 2 of this SOP (poliovirus type 2 protocol) **Plan for a maximum of 5 round(s) of SIAs**, as advised by WHO & GPEI partners ○ target age: 0-5 years ○ population size: - SIA1: in rapid response area, minimum 500 000 children - SIA 2 to 5: in outbreak affected area, minimum 2 million children ○ Vaccine of choice -mOPV2 +/- IPV Vaccine request to WHO DG for mOPV2	Refer to part 2 of this SOP (poliovirus type 2 protocol)
WPV 2 • environment	Refer to part 2 of this SOP (poliovirus type 2 protocol) Depends on local situation. Especially for transmission risk zone 1, **consider 1 round of SIA** ○ target age: 0-5 years ○ population size: in rapid response area minimum 500 000 children. ○ Vaccine of choice - mOPV2 +/- IPV Vaccine request to WHO DG for mOPV2	Refer to part 2 of this SOP (poliovirus type 2 protocol)
cVDPV		
cVDPV1 or 3 • human or • environment	**Plan+ implement ≥3 round(s) of SIAs**, as advised by WHO & GPEI partners ○ target age: 0-5 years + an expanded age group in ≥1 SIAs ○ population size: - SIA1: minimum 500 000 children. - SIA 2 and SIA 3: approximately 2 million children ○ Vaccine of choice bOPV	- 1st round within 14 days - First 3 rounds to be short interval SIAs (2-3 weeks apart)
cVDPV 2 • human or • environment	Refer to part 2 of this SOP (poliovirus type 2 protocol) **Plan for a maximum of 5 round(s) of SIAs**, as advised by WHO & GPEI partners ○ target age: 0-5 years ○ population size: - SIA1: in rapid response area, minimum 500 000 children - SIA 2 to 5: in outbreak affected area, minimum 2 million children ○ Vaccine of choice - mOPV2+/- IPV Vaccine request to WHO DG for mOPV2	Refer to part 2 of this SOP (poliovirus type 2 protocol)

Selection of the most appropriate vaccine is made with WHO technical support. It is based on the type of poliovirus, the underlying population immunity, and projected timeframe (Table 7).

As an alternative to the intramuscular injection of a full dose of IPV, countries may consider using **fractional doses** (1/5 of the full IPV dose) via the **intradermal route** for routine immunisation [22],and event/ outbreak response, considering the programmatic logistic implications of this option.

Table 7: Summary of typical vaccination strategies recommended for event or outbreak response, by type of poliovirus. NOTE: In all cases, WHO must be consulted regarding choice of vaccine.

Type of outbreak	Post-switch (May 2016 onwards)
Type 1 or 3 poliovirus (WPV)	bOPV +/- IPV adjunct 
Type 1 or 3 poliovirus (cVDPV)	bOPV 
Type 2 poliovirus (Post-switch: any type 2, as advised by WHO)	mOPV2 (released by WHO DG) +/- IPV adjunct 

5.2-Upon confirmation of an outbreak

- The **national government**, supported by GPEI partners, declares the outbreak and declare it as a *National Public Health Emergency*. The national government notifies it to WHO as an *Public Health Emergency of International Concern (PHEIC)* in accordance with IHR, wherever relevant
- The **national government** establishes an emergency operation center to lead the development of a comprehensive response plan including surveillance strengthening, communication and mobilization, and ensures the implementation of quality SIA strategies
- The **Outbreak Preparedness and Response Task Team (OPRTT)** will submit to EOMG adequate information to grade the outbreak within 72 hours of laboratory result notification
- The **GPEI Eradication and Outbreak Management Group (EOMG)** must meet within 72 hours of laboratory result notification to grade the outbreak
- **WHO and GPEI partners** offer technical support for all activities, as appropriate to the grade of outbreak and the requirements of the health system support in the affected country

5.3-Risk assessment and grading of an outbreak

While laboratory and epidemiologic investigative steps correspond in general to standardized processes for following-up any poliovirus detection, a risk assessment aims to characterize the virus transmission and the implications for further spread. It assesses the critical factors which will influence the type and scale of response and make recommendations for appropriate actions.

For type 2 poliovirus, the risk assessment focuses specifically on addressing three core questions (refer to part 2 of this SOP-specific type 2 poliovirus protocols):

- What is the nature of the virus (e.g. WPV, Sabin, or VDPV)?

- Is there evidence of circulation?
- What is the risk of further spread?

The EOMG performs a **risk assessment** based on the combination of **two sets of criteria**:

1) **Potential for transmission in country and spread beyond national borders.**
   Assessment of the risk of transmission takes into account the following aspects:
   a. Risk of international spread (especially for type 2 poliovirus post-switch) including multi-country/ cross border risk, through travel links and transmission routes
   b. Type and classification of poliovirus (e.g. type 1, 2, or 3; WPV or VDPV classification)
   c. Population immunity in the affected area (from the AFP database and routine immunization coverage, as well as a quick community survey of OPV/IPV status);
   d. Existence of vulnerable populations (refugees, internally displaced persons, significant nomadic groups, access-compromised population groups, etc.))
   e. Risk of intentional spread (especially for type 2 poliovirus post-switch) or breach in containment (from laboratory, research, vaccine production facilities)

2) **Strength of the country's capacity to respond and contain the outbreak.**
   Assessment of the national response capacity includes the following elements:
   a. Country health infrastructure level
   b. Capacity to mobilise human resources
   c. Security situation, including the presence of armed conflict or significant areas of insecurity or inaccessibility

This risk assessment ultimately determines the risk of further transmission and directly influences the required type and scale of response (from **grade 1 to 3**).

As a result of the risk assessment, the **EOMG** assigns a grade to the outbreak within 72 hours of confirmation of the outbreak to:

- Inform partners of the extent, complexity and likely duration of support required;
- Prompt all GPEI partners at all levels to be ready to repurpose and mobilize appropriate resources in order to provide support, including the human resources required to constitute rapid (Team A) and surge (Team B) response teams, if necessary;
- Trigger outbreak response activities and policies in the concerned country.

Table 8 outlines the 3 grades and their definitions according to the 2 sets of criteria.

Table 8: Polio outbreak grades and definitions

Grading	Criteria	Definition
Grade 1	**Potential for transmission and international spread**	Low to medium risk of transmission including international spread due to good population immunity and no major vulnerable population cluster
	Strength of country capacity	Strong to moderate country response capacity due to robust health infrastructure and no security threat or access challenges
Grade 2	**Potential for transmission and international spread**	Low to high risk of transmission including international spread
	Strength of country capacity	Strong to weak country response capacity
Grade 3	**Potential for transmission and international spread**	Medium to high risk of transmission including international spread due to significant gaps in population immunity, history of multi-country/cross-border propagation and major vulnerable population clusters
	Strength of country capacity	Moderate to weak country response capacity due to serious deficiencies in local in-country health infrastructure ,high security threats and access challenges, or a complex humanitarian emergency

The **risk profile matrix** in Table 9 provides a visual tool to illustrate the decision making process underlying the classification of an outbreak according to grade 1, 2 or 3. It highlights the fact that the level of the response needed (the grade) to a polio outbreak with a low risk of transmission can vary between grades 1 and 3, depending on the country's response capacity. The grading system is used to describe the actions necessary to manage the risk identified. Moreover the polio grading system is flexible enough to allow adaptation to every polio outbreak context as well as changes in global strategy, which will be of paramount importance after global tOPV withdrawal

Table 9 : Risk profile matrix for grading a polio outbreak

Country response capacity / **Risk transmission and international spread**	Strong	Moderate	Weak
Low	Grade 1	Grade 1	Grade 2
Medium	Grade 1	Grade 2	Grade 3
High	Grade 2	Grade 3	Grade 3

The grade will be updated at least once every three months **or** whenever a significant change in the outbreak evolution requires a re-evaluation of the assigned grade. Flexibility is embedded in the grading, so that shifts between response activity categories in Table 10 can be tailored on a nearly real-time basis to reflect the national situation and meet local needs

The grade will serve as the basis for prioritizing or ranking the level of outbreak response activities (Table 10) from the "green light" grade 1 to the "orange light" grade 2, and finally to the "red light" grade 3. The higher the grade, the more GPEI support will be needed for the response.

Table 10: Outbreak response scale-up supports according to grade

Grading / Type of support	Grade 1	Grade 2	Grade 3
Response Leadership*	National coordinator	GPEI nominated coordinator	GPEI nominated coordinator
Technical liaison*	Polio **expert mission** from the GPEI partners to support the development of the outbreak response plan	Deployment of a Rapid Response Team: **Team A *** (multidisciplinary outbreak response team).	Deployment of a Rapid Response Team: **Team A *** (multidisciplinary outbreak response team).
Surge*	**Stop Transmission Of Polio (STOP)**[23] programme support if needed	• Deployment of surge team : **Team B** * (multidisciplinary consultant team for minimum 6-month deployment) • **STOP** support	• Deployment of surge team : **Team B *** (multidisciplinary consultant team for minimum 6-month deployment) • **STOP** support
Financial	Standard financing for outbreak response immunization activities (an advance of up to US$ 500 000)**	"No-regrets" financing policy (an advance of up to US$ 500 000)	• "No-regrets" financing policy (an advance of up to US$ 500 000) • Financial support for security measures, if required
Security and access	NA ***	NA ***	• Support from Polio Access and Support (PAS) group of WHO HQ, coordination with other United Nations and humanitarian agencies on the ground • Deployment of field security officer(s) where necessary

* ToR of Team A and B can be found in Annex 4. Composition of supports, particularly the size and number of experts deployed in the rapid response team (Team A) and the surge team (Team B) will be scaled to meet the needs of the country

** Standard financing is subject to re-payment conditions, as determined on a case by case basis.

*** Not Applicable

6- Strategic response framework for polio outbreak

A strategic response framework is needed to guide the international response to a polio outbreak. This framework provides the basis for close partners coordination and collaboration in addressing the outbreak to ensure that national response activities are supported to the fullest extent possible.

Five strategic pillars for interrupting transmission in an outbreak setting are needed and have to be implemented in a coordinated manner:

1. **A fully engaged national government:** The key to a successful outbreak response is a high level of government engagement. National governments should make sure their actions meet the IHR provisions and ensure rapid notification to WHO of any suspect AFP cases or any specimens found positive for poliovirus.
   - the government's response should engage the senior leadership of GPEI partners and request guidance and outbreak response assistance as required
   - the highest level of government should declare a public health emergency
   - an Emergency Operations Centre (EOC) type-mechanism should be formed to guide and oversee the outbreak response
   - the national government should appoint a senior focal person to lead the outbreak response and the EOC
   - all key departments or ministries should be engaged to ensure a multi-sectorial response

2. **Rapid risk assessment and identification of transmission risk zones**: Affected countries must work closely with GPEI partners to conduct a rapid risk assessment to identify the outbreak-affected and high-risk zones with defined areas of ongoing circulation and areas of high risk. This should take into account sub-national areas of vulnerability given geographic contiguity and/or other criteria (e.g., underserved populations).

3. **Robust immunization response:** Upon confirmation of a poliovirus outbreak, countries should plan a coordinated immunization response, including the rapid launch of the first SIAs covering all children younger than 5 year in affected and adjacent geographic area - or a minimum of 500 000 children in large population countries. Subsequent SIAs need to be larger scale to target a minimum of 2 million children of age less than 5 years, if the risk of further spread of poliovirus justifies this strategy choice. Strategies will change with time elapsed after global tOPV cessation. Oral polio vaccine will be preferred in outbreak response because it boosts intestinal mucosal immunity. Key components of the response include:
   - First SIA launched within 14 days from confirmation of the poliovirus outbreak;
   - Selection of the most appropriate vaccine based on the type of poliovirus and underlying population immunity (see table 7). Selection should be made in consultation with WHO technical support;
   - Incorporation of IPV into at least one SIA round as a helpful adjunct to outbreak response;
   - Minimum of three SIAs planned and implemented: the first three rounds should be short interval (2-3 weeks apart); for the number of SIAs for type 2 post-switch, please refer to type 2 protocol in part 2 of this SOP
   - Expanded age group included in at least one SIA. The specific upper limit of the expanded age-group will be advised by WHO and GPEI partners in consultation with WHO and UNICEF regional and country offices based on epidemiology, susceptibility profile of the population and underlying population immunity (consider the time since last virus isolation/last SIA)
   - Oversight and release of the post-switch global stock of mOPV2 by the WHO Director General. Stocks of mOPV2 released in such responses must be tightly managed, monitored, retrieved and disposed at the end of activity

- Vaccine supplies secured through UNICEF Supply Division or other mechanisms (for self-procuring countries) immediately upon declaration of the outbreak
- Special attention given to populations at highest risk; implementation of strategies to target vaccination efforts specifically to these groups
- Independent monitoring implemented to assess whether at least 95% of children interviewed have been vaccinated.
- Involvement of the Polio Access and Support (PAS) to provide additional support if there are concerns about the security and access to immunize children in affected regions

4. **Effective communication and social mobilization:** To maximize effectiveness, the government should prioritise communication and social mobilization to ensure that populations at greatest risk are vaccinated and that chronically missed children are reached. GPEI partners will assist the government in achieving these goals. Strategies for building polio vaccine demand and mitigating the risk of population fatigue during repeated campaigns include:
   - Rapid analysis of the knowledge, attitudes and community practices around vaccination, and barriers to reaching every member of the target population
   - Design of strategic messages and key strategies based on social profiling of polio-confirmed and zero-dose non-polio AFP cases or contact cases, as well as any other available social research
   - Mass communication messages informing the population of the outbreak, the risks and implications of contracting polio, and the need to take multiple doses of polio vaccine for individual protection and to stop the outbreak
   - Engagement with the existing humanitarian or development organizations, UN country team and/or government community social networks to ensure the coordinated and coherent dissemination of messages
   - Systematic reporting of identified social indicators, especially for missed children, refusals and absences, as part of the overall national outbreak reporting mechanism
   - Adjustment of communication interventions based on outcomes of monitoring data to scale and refine C4D intervention targeting.

5. **Enhanced surveillance:** AFP surveillance should be enhanced to an annualized rate greater than *3 non-polio AFP cases per 100 000 children younger than 15 in every first subnational division (province or state), for the duration of the outbreak and for at least 6 to 12 months+2 months after the last case (see outbreak closure criteria in chapter 6 of this SOP)*. Countries should:
   - Immediately notify all subnational surveillance units of the outbreak's detection
   - Activate AFP case-finding strategies at the subnational levels and conduct a retrospective record review
   - Provide sensitization training on AFP surveillance to all health-care workers
   - Develop an outbreak monitoring system for weekly surveillance reporting from all subnational-level reporting units
   - Expand contact sampling for all AFP cases in all "infected" and "immediate" transmission risk zones (Section 3.1) until the end of the outbreak.
   - Ensure that AFP active case search is integrated into SIA activities
   - Ensure that laboratory services are strengthened to handle the additional workload and are able to maintain rapid result turn-around throughout the outbreak
   - Consider whether environmental surveillance can be launched; in areas where it exists already, increase the frequency of sampling

7- End of outbreak: closure

External assessments performed by the *OBRA team* will be conducted every three months, to determine when transmission of the outbreak virus (wild poliovirus - WPV, or circulating vaccine-derived poliovirus - cVDPV) has been interrupted.

An Expert Committee (EC) on Polio under the International Health Regulations (IHR) has held regular 3-monthly meetings since May 2014 to assess the current status of polio eradication. The IHR EC has established processes and criteria[24] to be used when assessing the poliovirus infection status of a country.

Based on the processes and criteria used by IHR EC for categorizing a country infected status, the following criteria applies for declaring the closure of an outbreak in a country.

7.1-Type 1 or 3 poliovirus

The transmission of the type 1 or 3 virus outbreak has been interrupted and so outbreak can be closed if:

a) At the 6 month OBRA visit, outbreak can be closed if
-at least 6 months have passed without detecting the outbreak virus from any source (inside or outside the country),
AND
- there is documentation that 'eradication activities were conducted at high quality' in all infected and high-risk areas; for the purposes of the OBRA, this includes that AFP surveillance should be of 'high quality' which is defined as a non-polio AFP rate of at least 3 non-polio AFP cases per 100 000 children aged under 15 years in every first subnational divisions (province or state), from the last case

In the absence of 'high quality eradication activities', particularly if surveillance is not 'high-quality', the OBRA team cannot yet declare the outbreak to be controlled. The OBRA team should provide pertinent technical recommendations to the country, and announce its return for a follow-up assessment 3 months later (at 9 months).
At the 9-month OBRA visit, the OBRA team returns when complete laboratory results are available from all AFP cases with onset of paralysis within 12 months following the last polio case

b) **After the 12-month OBRA visit**, outbreak can be closed if
- at least 12 months passed after the onset date of the last case plus two months (to account for case detection, investigation, laboratory testing and reporting period) without detecting the outbreak virus from any source (inside or outside the country)

The IHR EC no longer requires 'high quality AFP surveillance in all infected and high risk areas' to classify a country as not infected. So the OBRA team has the option to declare that outbreak-related poliovirus transmission has been interrupted (i.e. the outbreak can be closed), even if there still are deficiencies in implementing polio eradication strategies, particularly in the quality of AFP surveillance (i.e. not all provinces have reached non-polio AFP rates of 3/100.000).

The "plus two months" period ensures that :

- all stool specimens from individuals (reported AFP cases or contacts or individuals) that had onset or collection date during the past 12 months have been tested negative for polioviruses

and

- all environmental samples (if applicable for the country) that were collected during the past 12 months have been tested negative for polioviruses.

The decision trees (figures 2a) present a graphical summary of the guidance.

7.2-Type 2 poliovirus

For type 2 virus, an outbreak cannot be considered closed until 12 months after the onset date of the last case plus two months to account for case detection, investigation, laboratory testing and reporting period. IHR EC must confirm closure status.

The decision trees (figures 2b) present a graphical summary of the guidance.

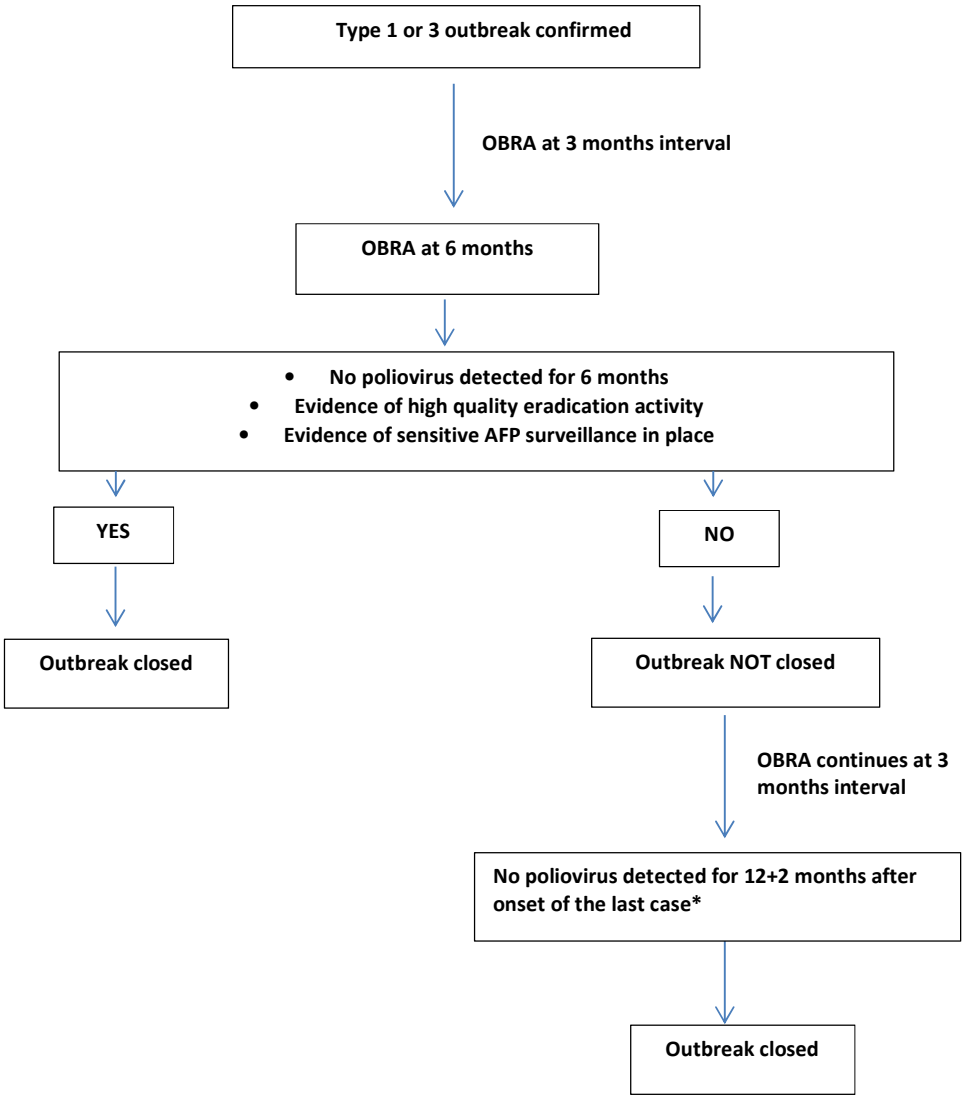
7.3-Final closure decision

Based on their overall assessment (i.e. primarily of surveillance quality, but also other considering parameters such as quality of immunization activities), an *expert review* (OBRA team or in-country expert committee or National certification committee, as applicable and feasible) may decide that it is still not possible to confidently assume transmission was interrupted.

The *EOMG* will regularly consider the reports of the expert review and is ultimately responsible for endorsement of the findings and declaring an outbreak closure.

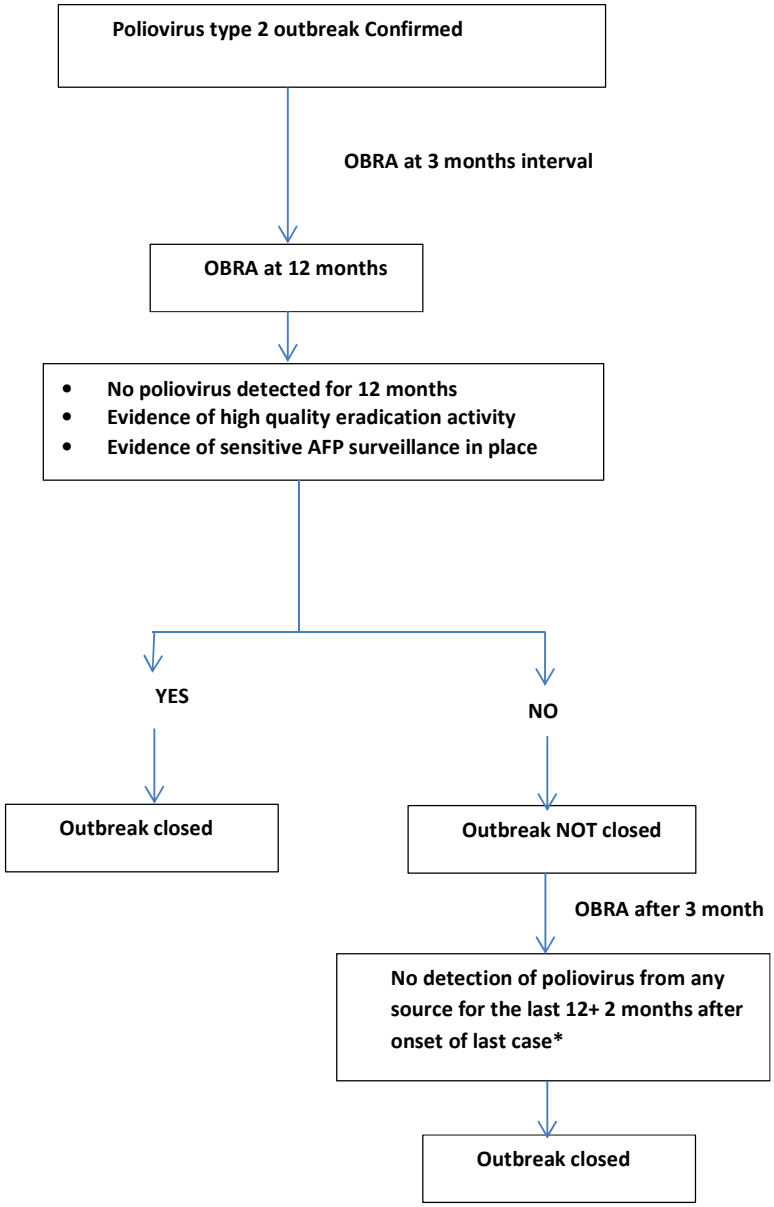
Ultimately, the *Emergency Committee (EC)* on polio, as convened under IHR may request a longer follow-up period depending on the context to declare a country not anymore infected. And for type 2 outbreak, the IHR EC must confirm outbreak closure status.

Figure 2a: Decision tree for duration <u>for type 1 or 3</u> WPV and cVDPV outbreaks



*No poliovirus detected during the past 12 months after the onset date of the last case PLUS two months to account for case detection, investigation, laboratory testing and reporting period
OR
No poliovirus detected from stool specimens from reported AFP cases or contacts or human or environmental surveillance samples that had onset or collection date during the past 12 months have been tested negative for polioviruses

Figure 2b: Decision tree for duration <u>for type 2</u> WPV and cVDPV outbreaks



*No poliovirus detected during the past 12 months after the onset date of the last case PLUS two months to account for case detection, investigation, laboratory testing and reporting period
OR
No poliovirus detected from stool specimens from reported AFP cases or contacts or human or environmental surveillance samples that had onset or collection date during the past 12 months have been tested negative for polioviruses

8- GPEI partnership support to countries outbreak response

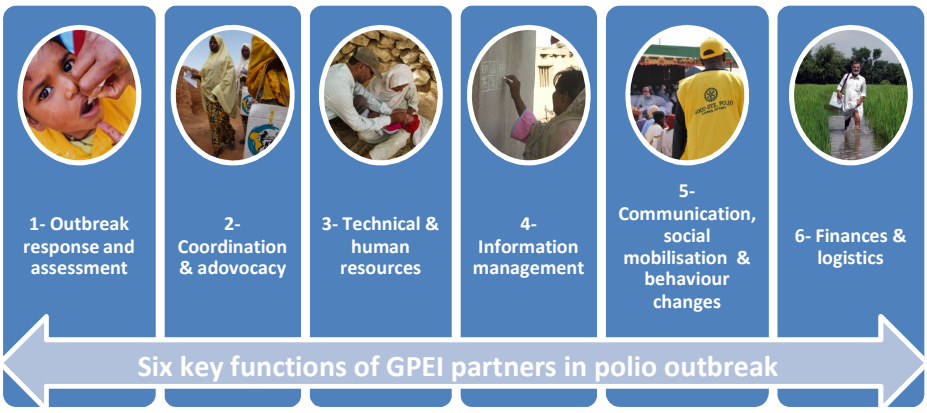
8.1-Six key functions of GPEI

Countries have ultimate ownership of the response, and have to maintain leadership throughout the process.
GPEI partners have to support the countries to complete a robust risk assessment and response to poliovirus outbreaks.

To deliver on their commitments described in the *Polio Eradication and Endgame Strategic Plan 2013-2018*[25], the GPEI partners support **six key functions** in the outbreak response (Figure 1):

1) Outbreak response and assessment
2) Coordination and advocacy
3) Technical and human resources
4) Information management
5) Communication, social mobilization and behaviour change
6) Finances and logistics

Figure 1: The six key functions of the GPEI Partners in polio outbreak response



8.2-Essential policies for optimizing GPEI response

The EOMG's outbreak grading will activate the full GPEI surge response and the "no-regrets" policy for financial support, where deemed necessary. These functions will be supported through the Outbreak Preparedness and Response Task Team (OPRTT). OPRTT will ensure that the six key support functions of GPEI are coordinated between all partners and the different levels of each organisation.
Surge policy
The GPEI mobilizes and rapidly deploys experienced professionals to the affected country so they can join the national response team and perform the six key functions in outbreak response described above.

This deployment follows the initial investigation, assessment and grading of an outbreak by the EOMG. Therefore the earliest activation of the surge policy would be 72 hours after of laboratory result notification. The activation of the surge policy is accomplished using a partner-wide interregional surge mechanism, which involves qualified staff from partner organizations or the engagement of qualified consultants.

The objective of the surge policy is to strengthen the agencies' ability to immediately staff key positions of the response and to ensure a smooth transition to longer-term staffing.

The surge policy is based on the following **principles**:

- Identification of key roles (including technical, operational, and communications coordination) to be staffed for immediate- and long-term positions, according to outbreak grade
- Establishment of a rotating interagency list of "on-call" staff who can be deployed to the risk zone within 72 hours (rapid response team called Team A)
- Active management of the interagency "on-call" roster for longer-term deployments using a centralized management platform for ease of visibility/reporting (surge team called Team B)
- Rapid training of personnel listed on the roster to ensure understanding of the SOPs and the critical standards to be met in all phases of the outbreak
- Assurance that the deployment processes allow "longer-term" personnel to be in place within 3 weeks of an outbreak, allowing at least one week of overlap between the Team A and Team B to ensure complete and detailed handover

Recognizing the challenges of meeting surge requirements, the GPEI partners will follow a **two-phase surge process** and maintain **two types of experts' rosters**:

1. *Rapid Response Phase* (Rapid Response Team A): this rapid response roster consists of pre-identified, trained and experienced professionals with multiple expertise, deployable within 72 hours for up to one month. Key roles include: technical, operational, and communication liaisons. The technical liaison is typically designated as the outbreak coordinator and should receive priority for first deployment in an urgent response. ToR are available in Annex 4.
2. *Surge Response Phase* (Surge Team B): this surge roster lists trained experts across multiple disciplines, who can be deployed within three weeks of the of laboratory result notification. The roster ensures the continuous availability of staff/consultants to support national-level and sub national-level response activities. ToR are available in Annex 4.

The **composition of the 2 teams** (the Rapid Response Team and the Surge Team) can be scaled up or down to meet the needs of the country and grade of response. Key roles and level of activities may include:

- *outbreak coordinator* where required (GPEI-nominated staff)
- *operations manager*: coordination of operations, budget, activity tracking, human resource and administrative support (national staff)
- *communications officer*: lead key external communications and C4D initiatives, assist development of communications plan (national staff)
- additional experts for polio SIAs and enhanced surveillance (national staff based at district level)
- additional communications and C4D[26] experts (national staff based at district level), to be considered as needed

ToR are available in Annex 4.

8.3-"No-regrets" policy

At the onset of emergencies, the GPEI ensures that an appropriate release of staff and funds is made to the country, even if it is later realized that a smaller contribution was required. This approach must be maintained from the initial investigation and confirmation of outbreak until the end of the outbreak. This policy affirms that it is better to err on the side of over-resourcing critical functions than to risk failure by under-resourcing.

8.4- GPEI performance standards according to timeline and key functions

GPEI partners will undertake a range of activities to support a country-led response. To ensure timely and effective outbreak response, the actions stated below comprise the essential indicators required by the country and GPEI partners. These standards are not exhaustive and may be modified as required to fit the context specific to the country and the outbreak. The Outbreak Preparedness and Response Task Team (OPRTT) will provide support to coordinate and monitor outbreak response.

These performance standards apply to polio outbreaks of all grades. The timeframe for expected response is counted forward from the date of the laboratory results. Each task is associated with the country and GPEI partners responsible for its completion.

GPEI outbreak response performance standards are described in Table 11. They describe the expected outputs from each level of GPEI partners in each of the six key functions. Concrete deliverables and timelines are provided as well.

Table 11: GPEI poliovirus outbreak response performance standards according to 6 key functions and response timeline

1-Outbreak response and assessment

Activities	Country	Regional/Global
Upon notification of a polio event		
Develop an initial immunization response plan with identified risk zones and send to GPEI's EOMG to guide grading, funding, and vaccine approval	Ministry of health to lead; WHO country office and UNICEF country offices to support.	WHO regional office/headquarters and UNICEF regional office/headquarters to provide technical support
Plan for WHO DG mOPV2 +/- IPV vaccine request to WHO DG, as well as syringes and safety boxes if IPV is needed	Ministry of health with support from WHO and UNICEF	WHO and UNICEF regional and HQ office
Within 24 hours of laboratory result notification		
Outbreak investigation and response		
Ensure ministry of health and other relevant government officials are fully aware of the status of the outbreak	WHO and UNICEF country offices	WHO headquarters/regional office liaise with laboratory network (GPLN) to ensure WHO country office has necessary information to feedback country stakeholders
Initiate full epidemiological and social investigation of the outbreak, including a field investigation and community survey to understand the community perceptions regarding immunization. Should include a social assessment of the case(s) KAP indicators and a rapid community assessment of the main social issues;	Ministry of health with support from WHO country office and UNICEF	GPEI partners will provide external technical support in field investigation
Ensure notification of the GPEI's EOMG and relevant staff who will be involved in supporting the outbreak response		WHO headquarters
Surveillance response		
conduct a rapid analysis of AFP surveillance and laboratory databases	WHO country office to analyse and share the information with headquarters	WHO headquarters to perform additional analysis and share it with all stakeholders
Within 72 hours		
Outbreak investigation and response		
Finalize and share the report on the initial epidemiological and social investigation of the outbreak and the assessment of the case or case cluster's social profile	Ministry of health with support from WHO country office and UNICEF	GPEI partners will provide external technical support EOMG must be provided report
Ensure outbreak grading by the EOMG		EOMG chairperson
Provide the country office with updated materials and guidelines on outbreak response (the Short Interval Additional Dose strategy, expanded age group, etc.)[27]		WHO and UNICEF HQ and regional office
initiate the development of a six-month outbreak response plan document that includes details for subnational implementation in high-risk areas on vaccine and other required supplies, social mobilization field activities and the budget needed	First surge outbreak coordinator to plan with support from WHO and UNICEF country team and ministry of health	Regional office and headquarters to provide technical support

to cover the activities		
Immunization response		
Begin planning to establish an EOC for first immunisation round at the national and subnational levels to develop microplans with vaccines, logistics as well as a social mobilization component;	Ministry of health with support from WHO and UNICEF; surge staff to provide close guidance in field	WHO and UNICEF regional office
Prepare mOPV2 +/- IPV vaccine request to WHO DG, as well as syringes and safety boxes if IPV needed	Ministry of health with support from WHO and UNICEF	WHO and UNICEF regional and HQ office
Surveillance response		
Initiate enhanced surveillance activities, including actively looking for AFP cases, retraining health workers and taking samples from contacts of all AFP cases (≥ 30 contacts according to context); increase the frequency of environmental sampling where appropriate; review genetic sequencing of isolates to map spread of the virus	MoH with support from WHO.RRT staff to provide close guidance in the field	
Within 14 days		
Outbreak investigation and response		
Finalize the six-month outbreak response plan document and make it available to all partners	RRT and Surge Team(Teams A and B), with repurposed country staff	
Immunization response		
Establish EOC at the national and subnational levels to develop microplans with vaccines, logistics as well as a social mobilization	Ministry of health with support from WHO and UNICEF; surge staff to provide close guidance in field	WHO and UNICEF regional office
Send to WHO DG mOPV2 +/- IPV vaccine request to WHO DG, as well as syringes and safety boxes	Ministry of health with support from WHO and UNICEF	WHO and UNICEF regional and HQ office
Conduct training of front-line workers (vaccinators, supervisors and social mobilizers) and monitor activities	RRT and Surge Team (Teams A and B), with repurposed country staff	WHO and UNICEF regional office and headquarters to provide technical support
Implement the first rapid-interval (2-3 weeks apart) SIAs immunization response campaigns, considering an expanded age range (for Type 2 post switch, please refer to Type 2 protocol)	Ministry of health with support from WHO and UNICEF under overall coordination of first surge coordinator	WHO and UNICEF regional office and headquarters to provide logistics and technical support
Establish campaign monitoring for the SIAs (Independent Monitoring (IM)), ensuring that the results to be internationally posted on WHO Global website within 14 days of end date of each campaign	WHO country office	WHO headquarters to provide technical support
For mOPV2 response ensure comprehensive management of doses deployed including recording, retrieval and disposal of balance stocks at end of response.	RRT and Surge Team (Teams A and B), with repurposed country staff	
Surveillance response		
Liaise with in-country data managers to identify and resolve data format and completeness issues, if any.	RRT and Surge Team(Teams A and B), with	

	country staff	
Within 14 days to outbreak closure		
Outbreak investigation and response		
Fully implement the comprehensive six-month outbreak response plan	RRT and Surge Team(Teams A and B), with repurposed country staff to coordinate the implementation with ministry of health	WHO and UNICEF headquarters and regional office to provide technical, logistics and monitoring support
Immunization response		
Conduct SIAs according to the response plan: ・conduct activities to improve the quality of SIAs including detailed microplanning with special attention to high-risk populations, and tailor social and community mobilization interventions; ・conduct vaccinator and supervisor training, using local language modules and including interpersonal communication skills; ・establish/strengthen supervision, monitoring and review meetings; ・fully implement independent monitoring, including relevant social data on refusals and reasons for missed children and other social barriers; ・initiate vaccination and communication strategies to reach missed children.	RRT and Surge Team(Teams A and B), with repurposed country staff to coordinate the implementation with ministry of health	WHO and UNICEF headquarters and regional office to provide technical, logistics and monitoring support
Surveillance response		
Maintain enhanced surveillance activities, including actively search for AFP cases, retraining health workers and taking stool samples from contacts of all AFP cases cases (≥ 30 contacts according to context); consider commencing environmental surveillance	RRT and Surge Team(Teams A and B), with repurposed country staff to coordinate the implementation with ministry of health	WHO headquarters and regional office to provide technical, logistics and monitoring support
At one month after of laboratory result notification		
Assess the initial response activities (by the outbreak response team OBRA) against established metrics, and report the results to regional directors and GPEI partners	Lead: GPEI coordinator	Regional office and headquarters to provide technical support
Review and adapt the outbreak response plan, including communications plans for subsequent phases, and track progress made and/or support needed to close any remaining gaps	Lead: GPEI coordinator	Regional office and headquarters to provide technical support
At three months and thereafter quarterly (from 6 to 12 months after identification of the last case)		
At three-month intervals, conduct external outbreak assessments (OBRA) from 6 to 12 months (according to outbreak closure criteria) have passed after the last case	GPEI outbreak coordinator to facilitate this assessment. Who conducts?	Lead: WHO regional office, on coordination and implementation
Reassessment of the grade of the outbreak, based on outcome of OBRA assessment, if grade changes, response will be adapted accordingly		EOMG responsible for re-assessment of grade
After 6 months or 12+1 months of the most recent case (according to outbreak closure criteria), conduct an end-of-outbreak assessment focusing on surveillance and eradication activities to advise EOMG and IHR EC on outbreak closure	WHO country office and UNICEF country office to finalize dates and approval with ministry of health	Lead: EOMG GPEI partners to coordinate assessment team through WHO regional offices

Report on any gaps in quality of eradication	Outbreak coordinator to facilitate OBRA team to list all gaps	GPEI partners to coordinate assessment team through WHO regional offices
Ensure ongoing high quality surveillance prior to closure	Outbreak coordinator to facilitate	GPEI partners to support
Document the response process and share the lessons learnt	Outbreak coordinator to facilitate the documentation	Lead: WHO regional office, on coordination and documentation

2-Coordination and advocacy

Activities	Country	Regional/Global
Within 24 hours of laboratory result notification		
Advocacy:		
Ensure all relevant government officials are duly notified of the outbreak. WHO and UNICEF Country Representatives will brief the Minister of Health and other relevant officials on the steps required for an urgent response to stop the outbreak. The Minister in turn should brief the Office of the Head of Government or Head of State on the following specific tasks: – need to declare polio a national public health emergency; – need to establish an EOC, led by a very senior government official as the designated outbreak focal point, supported by technical staff from partners, and including staff for strategic communication, logistics and supply management, and finance; – the need to conduct the minimum needed (as per this SOP standards) consecutive, high quality vaccination campaigns (SIAs) , and ensure that over 95% of all children are consistently reached; Subsequent number of rounds after the 3 minimum ones to be determined based on type of poliovirus; – need to closely monitor progress and establish a systematic oversight mechanism at all levels (National, Regional and District); – need to report back on the results of vaccination campaigns to the Office of the Head of Government or Head of State.	WHO and UNICEF Country Representatives brief Minister of Health and relevant officials MOH to brief Head of State Government	WHO and UNICEF regional office and headquarters to monitor and facilitate
Coordination:		
Establish an EOC in the country with designated outbreak focal point(s) from government and partners, including strategic communication, logistics and supply management, and finance members/staff	MOH to coordinate with WHO country office and UNICEF WHO to facilitate coordination with UNICEF	WHO and UNICEF regional office and headquarters to monitor and facilitate
Establish conference calls with GPEI partners and the regional and country offices (the call should take place daily in the first week, and weekly thereafter)	Regional and Country WHO Offices to participate	Lead: WHO regional office/headquarters, GPEI partners to participate as desired
Request expedited procedures for visas at the port of entry for initial outbreak responders	Country to facilitate. WHO country office and UNICEF country offices to assist	WHO regional office/headquarters and UNICEF regional office/headquarters to rapidly provide the required documents
Within 72 hours		
Advocacy:		
Write to the health minister on behalf of WHO and UNICEF regional directors to highlight the “emergency” and the full support of the country representatives and organizations	WHO/UNICEF Regional Directors	Lead: WHO/UNICEF regional offices
Develop an “Internal Advocacy Plan” to engage all relevant stakeholders at the national and sub-national level (Head of Government, relevant Ministries, sub-national authorities, parliamentarians and other key stakeholders);	WHO and UNICEF Country Offices	
Upon request of the country team and if external advocacy is needed to further secure high-level political commitment from the affected country, develop an “External Advocacy Plan” to complement the in-country advocacy efforts. Coordinate its implementation of		GPEI Political Advocacy Focal Points
Using the SITREP develop as well a media brief and other communication and advocacy products		

Coordination:		
Support country in IHR related actions required after IHR official notification (ex: Responses to WHO IHR requests for verification)	WHO and UNICEF to provide support to ministry of health for the implementation	WHO headquarters to provide technical support
Communicate the assessment on the risk of international spread through IHR to WHO		WHO headquarters
Convene meeting of all the key stakeholders at national level on the initial outbreak response plan with feedback from subnational teams, and communicate it to the provinces and districts involved in outbreak response	Ministry of health with support from GPEI outbreak coordinator, WHO and UNICEF country teams	
Initiate communication on the outbreak with the broader donor community as well as a media response	WHO country office and UNICEF country offices with in-country donors and media	GPEI Polio Advocacy and Communications Team with global donors and media
Within 14 days		
Advocacy:		
Establish a mechanism to track the implementation of the "Internal Advocacy Plan" and communicate any further external advocacy needs (through outbreak calls and SitReps);	WHO/UNICEF Country Offices	Lead: Outbreak Coordinator (through SITREP and outbreak calls)
Track the implementation of the "External Advocacy Plan", regularly reporting on status and outcome of activities (through Outbreak calls and monthly advocacy tracker)		GPEI Political Advocacy Focal Points (through outbreak calls and monthly advocacy tracker)
Coordination:		
Establish a weekly meeting with key stakeholders in the country (the outbreak response cell) to coordinate and implement the outbreak response plan	Ministry of health with support from WHO and UNICEF country team	Headquarters/regional office to provide support needed
Inform governments in risk zone, if any, about the outbreak, the initial response plan and the actions required	Lead: WHO country office and UNICEF country offices	WHO and UNICEF headquarters /regional offices to support
Align with health clusters among other partners to conduct additional interventions alongside OPV whenever possible	WHO country office and UNICEF country office with in-country partners	EOMG with headquarters of relevant international organizations and institutions
Develop microplans, with vaccine logistics as well as social mobilization at national and subnational level	RRT and Surge Team (Teams A and B), with repurposed country staff	WHO and UNICEF regional office and headquarters to provide technical support
Develop tools and training manuals for microplanning, and monitoring, and ensure all tools have an integrated strategic communication component	RRT and Surge Team (Teams A and B), with repurposed country staff	WHO and UNICEF regional office and headquarters to provide technical support

From 14 days to outbreak closure		
Conduct weekly meetings with all key stakeholders on the outbreak response plan and coordination	Ministry of health with support from WHO and UNICEF, monitored and supported by the GPEI outbreak coordinator	WHO/UNICEF headquarters/regional office to provide support needed
Hold weekly conference calls with GPEI partners and regional and country offices	RRT and Surge Team (Teams A and B), with repurposed country staff	Lead: WHO regional office to set a weekly call with country and headquarters, WHO headquarters to coordinate partner outbreak call
Conduct regular donor meetings and advocacy activities	RRT and Surge Team (Teams A and B), with repurposed country staff	WHO and UNICEF headquarters develop funding appeal and share with the regional office and country office
Ensure alignment with other partners health clusters to conduct additional interventions alongside OPV, such as providing Vitamin A and deworming tablets, whenever possible;	RRT and Surge Team (Teams A and B), with repurposed country staff	WHO and UNICEF regional office and headquarters to provide technical support

3-Technical and human resources

Activities	Country	Regional/Global
Within 24 hours of laboratory result notification		
Activate the GPEI's RRT, share the contact details with relevant staff throughout the partnership and have the RRT leader communicate with GPEI partners, regional offices and country offices to identify focal points	WHO country office and UNICEF country offices to send approval for travel of RRT	WHO/headquarters and UNICEF headquarters to activate RRT in coordination with regional offices
Assess the on-the-ground human resource capacity of WHO, UNICEF and other partner in-country staff	WHO and UNICEF country offices to share information with WHO headquarters	
Within 72 hours		
Deploy the RRT for coordination and development of the outbreak response plan, along with other identified staff as needed (technical, operations, communications and data)	WHO country office and UNICEF country offices to make in-country arrangements	WHO/headquarters and UNICEF/headquarters in coordination with regional offices to send travel details for deployment
Ensure all technical and human resources issues are well addressed in the development of a six-month outbreak response plan document	First surge outbreak coordinator to plan with support from WHO and UNICEF country team and ministry of health	Regional office and headquarters to provide technical support
Identify the human resource surge capacity Team B (technical, operations and communications staff) from the pre-identified pool for deployment to the country	WHO country office and UNICEF country offices to send clearly identified needs requests with support from outbreak team leads	WHO headquarters to coordinate with GPEI partners
Evaluate country office administrative capacity and gaps, and find solutions	WHO country office and UNICEF country office to provide information on current capacity and perceived needs	WHO and UNICEF regional offices/headquarters to evaluate needs
Within 14 days		
Prepare to be able to deploy (after 3 weeks of the laboratory result notification), surge staff-Team B (national and international technical, operational and communications) to support the national, subnational and field sites	Ministry of health, WHO country office and UNICEF country office to facilitate arrival and plan for deployment under guidance of first surge coordinator	WHO headquarters to coordinate with GPEI partners (including UNICEF, CDC, government) and complete the deployment process
Support the finalisation of the six-month outbreak response plan document in regard to technical and human resources issues and make it available to all partners	RRT and Surge Team(Teams A and B), with repurposed country staff	
Prepare for smooth transition and handover from Team A to Team B. Team B being deployable within 3 weeks of the laboratory result notification (Annex 2)	outbreak coordinator	WHO and UNICEF regional office and headquarters
From 14 days to outbreak closure		
Follow-up and support the implementation of the comprehensive six-month outbreak response plan	RRT and Surge Team(Teams A and B), with repurposed country staff to coordinate the implementation with ministry of health	WHO and UNICEF headquarters and regional office to provide technical, logistics and monitoring support

4-Information management

Activities	Country	Regional/Global
Upon notification of a polio event		
Initiate an assessment of the security and access situation in the outbreak and high-risk zones	Country field security officer	Global field security officers for polio
Complete a full, detailed situational data analysis and make it available to EOMG for outbreak grading	WHO country office and UNICEF country offices to send analysis to headquarters	WHO and UNICEF regional office/headquarters to finalize EOMG situational analysis
Within 24 hours of laboratory result notification		
Using data from the rapid analysis of AFP surveillance and laboratory data, update maps with WPV cases and SIAs activities, and share the information with all relevant stakeholders	WHO country office to analyse and share the information with headquarters	WHO headquarters to perform additional analysis and share it with all stakeholders
Within 72 hours		
Compile and produce a Situation Report (SITREP) using a standard format, as well as a media brief and other communication kits and products	WHO country office in conjunction with MOH and UNICEF to produce SITREP	WHO headquarters to provide support
Within 14 days		
Establish a system to produce weekly SITREPs, a media brief and other communication kits and products	WHO country office in conjunction with MOH and UNICEF to produce SITREP	WHO headquarters to provide support
Liaise with in-country data managers to identify and resolve data format and completeness issues, if any		WHO regional office/headquarters and UNICEF regional office/headquarters
From 14 days to outbreak closure		
Continue producing a weekly SITREP using a standard format, with epidemiological and social data, as well as a media brief and other communication kits and products	WHO country office in conjunction with MOH and UNICEF to produce SITREP	WHO headquarters to provide support for media brief, communication and advocacy material
Ensure surveillance, SIA and monitoring data are completed and sent to WHO regional offices/headquarters and UNICEF regional offices/headquarters according to agreed timelines (within 14 days for all SIAs, and at least weekly for AFP data)	WHO country office to ensure timely data transmission	

5-Communication, social mobilization and behaviour change

Activities	Country	Regional/Global
Within 72 hours after of laboratory result notification		
Share the C4D polio toolkit and list of long-term agreements that the country office can immediately use to accelerate the response		UNICEF regional office/headquarters
Identify the C4D and External Communication HR needs	UNICEF country team	UNICEF regional office and headquarters to provide technical support
Initiate media monitoring and conduct a media landscape analysis if it does not exist.	UNICEF country team	UNICEF regional office and headquarters to provide technical support
Identify a media focal person and spokesperson from the government, WHO and UNICEF	UNICEF country team	WHO and UNICEF country offices
Finalize the media protocol and kit with key messages, and produce media briefs and other communications relevant to the outbreak for local use and regional/global outlets	UNICEF country team	WHO headquarters and UNICEF regional office / headquarters to provide technical support
Work with partners and government counterparts to conduct a press brief/media release, if appropriate	UNICEF country team	WHO headquarters and UNICEF headquarters provide technical support
Receive and review all media releases/news feeds related to the outbreak and share with focal points; target other non-media communication channels that may be effective in certain settings	UNICEF country team	UNICEF regional office and headquarters to provide support
Ensure the completion of the social profiling of the case using the special investigation tools to guide the design of C4D interventions.	Government and UNICEF country team	
Within 14 days		
Finalize C4D community engagement and information dissemination strategies	UNICEF country office team with technical support from regional office	UNICEF regional office and headquarters to provide technical support
Finalize key C4D messages to communicate through various channels, including mass media	UNICEF country team in partnership with ministry of health	UNICEF regional office and headquarters to provide technical support
Facilitate and lead the reinvigoration of a social mobilization and/or communications plan in areas where polio has not been present for a long time so communities and health workers are sensitized to the dangers of the disease and the benefits of the vaccine	UNICEF country offices and C4D technical liaison	Regional office/headquarters to provide support
Develop a media response plan and conduct briefings with political, religious and community leaders and other stakeholders	UNICEF team under guidance of GPEI outbreak coordinator	UNICEF and WHO regional office and headquarters to provide technical support
Develop a special crisis communication plan to address rumours in case of resistance to vaccination and to respond to AEFI.	UNICEF with ministry of health	UNICEF country offices/regional office to provide support
Support national and local partners to conduct mass and/or community strategic communication campaign(s)	UNICEF with ministry of health	UNICEF country office with support from regional office
Ensure the availability of IEC materials for use at the community level, based on the key messages identified	UNICEF with ministry of health	UNICEF headquarters to provide support
Begin interpersonal communication (IPC) training all categories of health and social mobilizers	UNICEF supports ministry of health in coordination with WHO	UNICEF country office with support from regional office
Ensure microplanning, and that monitoring tools and training manuals include strategic communication activities	Ministry of health, supported by WHO and UNICEF; Surge staff to provide close guidance in field	WHO and UNICEF country office with support from regional office and headquarters
Ensure inclusion of a communication budget and communications plan in the six-month outbreak response plan ;	UNICEF supports ministry of health in coordination with WHO	UNICEF country office with support from regional office

From 14 days to outbreak closure		
Implement a strategic communication response plan: ・launch a public mass communication campaign as appropriate; ・disseminate IEC & IPC products and tools in the local language, based on identified barriers to immunization; ・mobilize other sectors, especially influencers such as religious leaders, to provide access to hard-to-reach communities; ・train vaccinators and mobilizers on communication messages and IPC skills; ・engage the media, monitor and apply the AEFI protocol to address rumours immediately; ・conduct pre-campaign awareness sessions of high-risk and hard-to-reach areas; ・undertake in-depth reviews of potential vaccine refusals or issues of mistrust that must be addressed.	UNICEF to support ministry of health in coordination with WHO	Regional office and headquarters to provide technical and monitoring support
Ensure measurement of the communication interventions with a special monitoring of missed children.		

6-Finances and logistics

Activities	Country	Regional/Global
Within 24 hours from laboratory result notification (aim for earlier if possible)		
Alert the UNICEF supply division or other vaccine suppliers to the outbreak and imminent need for the rapid delivery of vaccines and associated logistics (finger-markers, etc.)	WHO country office and UNICEF country office to communicate initial plans to WHO and UNICEF regional office/headquarters	WHO region/headquarters to communicate need to UNICEF supply division, in coordination with UNICEF headquarters
For response to type 2 poliovirus, post-switch, mOPV2 (and IPV) releases on WHO DG approval		WHO headquarters
Within 72 hours		
Allocate lump-sum funding to regional and country offices to cover the initial outbreak response activities		WHO and UNICEF headquarters
Check the availability, and order and initiate the transport of vaccines per the initial estimate and outbreak response plan		UNICEF headquarters
Within 14 days		
Review and release a budget consistent with the six-month outbreak response and communications plan	RRT and Surge Team(Teams A and B), with repurposed country staff to coordinate the implementation with ministry of health	WHO and UNICEF regional office and headquarters
Assess cold-chain capacity and take steps to fill gaps in capacity	Country team to assess and express need	UNICEF headquarters to order to fill gap
Order vaccine and finger-markers for additional campaigns according to the outbreak response plan	Country team to assess and communicate need	UNICEF and WHO headquarters to order
Review additional administrative and logistical support budget	Country team to assess and share budget	WHO headquarters to review budget and release funds
Initiate process to fill vacant positions in infected/high-risk areas	Country team	WHO and UNICEF regional office to track and support

7-Special circumstances (complex emergency settings)

Activities	Country	Regional/Global
Upon notification of a polio event		
Assess the security and access situation in the outbreak and high-risk zones	Country team to gather and provide information to WHO and UNICEF headquarters	WHO and UNICEF HQ to summarize and incorporate information available at their level
Within 72 hours of laboratory result notification		
Have the polio security adviser conduct a field-level assessment	Country team to facilitate	WHO/UNICEF headquarters security adviser to coordinate
Deploy an international outbreak coordinator (if required for a multi-country response) and other staff (technical, operations, communications and data) with experience working in complex humanitarian emergencies	Country teams to provide all required information support	WHO headquarters to identify and deploy such person for initial surge
Initially identify the key stakeholders/influencers group working in the area	Lead: Country teams to collect this information	WHO and UNICEF HQ to support
Inform the United Nations Resident Coordinator and the Humanitarian Country Team	WHO representative	
Coordinate with the United Nations Department of Safety and Security on field missions	WHO and UNICEF country teams, with advocacy from their Representative level	
Initiate the development of an access plan including the C4D component	WHO country team in coordination with UNICEF and ministry of health	WHO and UNICEF headquarters to provide technical support
Initiate coordination with other UN and humanitarian agencies on the ground	WHO representative	WHO HQ to facilitate from high level
Collect information on public sentiment to vaccination and identify any possible behavioural barriers or anti vacation groups.	WHO and UNICEF country teams,	
Within 14 days		
Finalize and implement the access plan: ・negotiate access through key players, influencers and stakeholders; ・plan for opportunistic vaccination strategies to reach populations in inaccessible areas; ・plan and conduct protected campaigns; ・engage the community.	WHO country team with support from UNICEF country team for engagement	WHO and UNICEF headquarters to provide technical support
Deploy a pre-identified field security officer	Country team to identify the candidate	WHO headquarters to facilitate and provide contract
Plan and implement a permanent vaccination point strategy surrounding the inaccessible areas	WHO and UNICEF country team with ministry of health	WHO headquarters to provide technical support
From 14 days to closure of the outbreak		
Continue to implement the access plan and modify as needed to achieve: ・access through negotiation with key players, influencers and stakeholders; ・continued opportunistic vaccination strategies to reach populations in inaccessible areas; ・plan and conduct protected campaigns;	Country office to explore options at local level	WHO and UNICEF headquarters to explore and implement at higher level, including advocacy with headquarters of other agencies as necessary

Annexes

Annex 1: SOP at a glance

Figure 3a: SOP at a glance: from event to outbreak according to poliovirus isolates

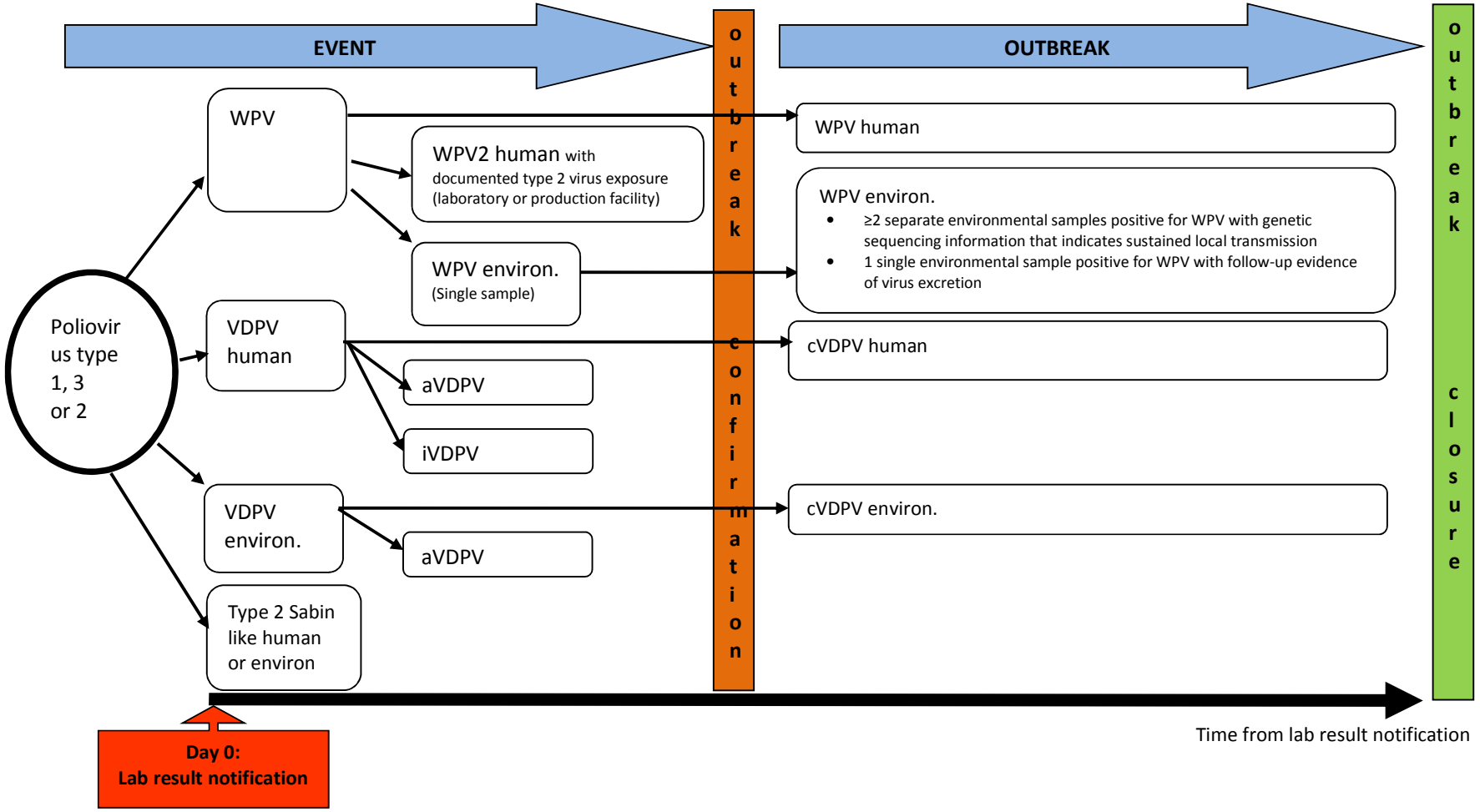
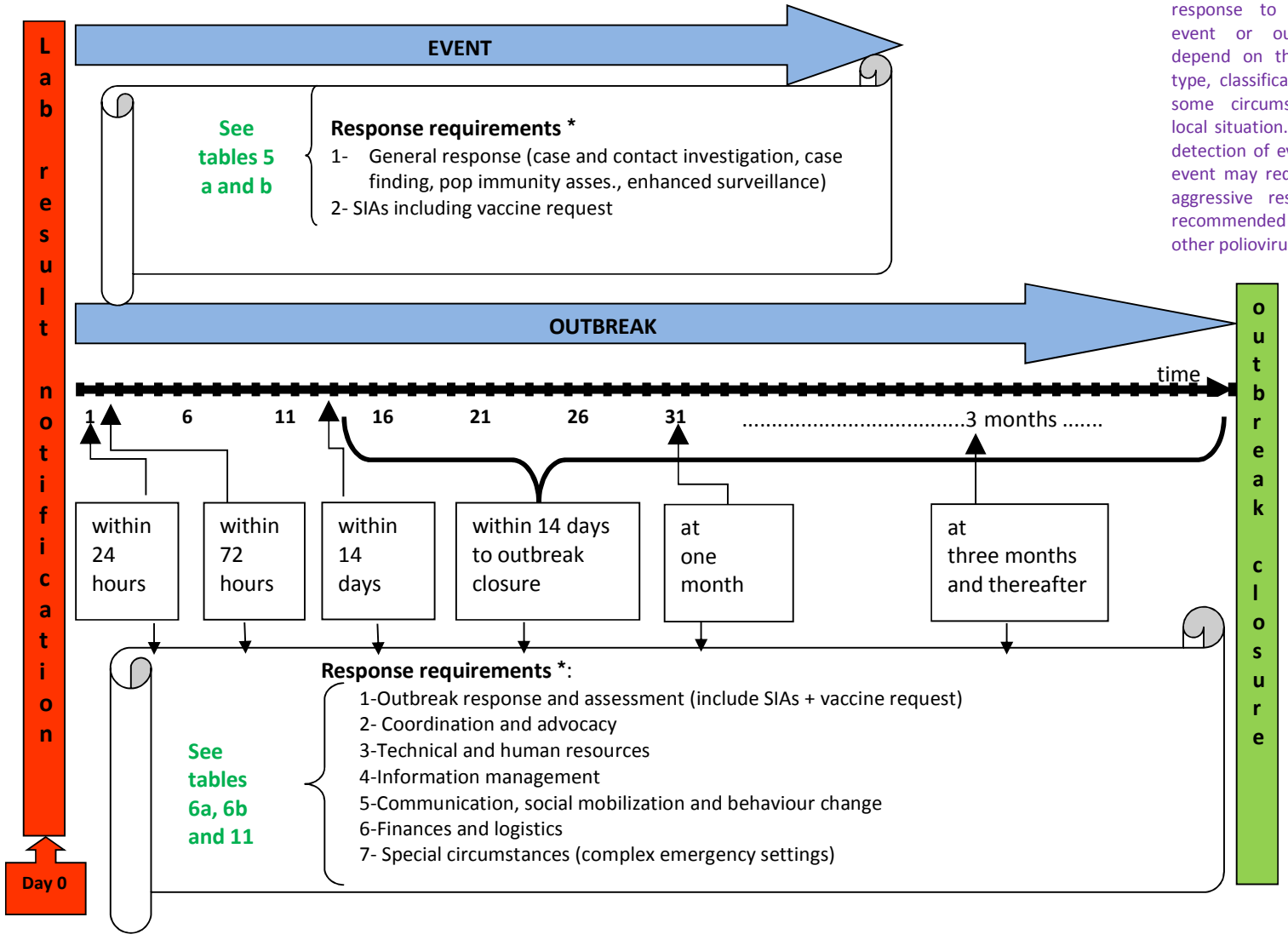


Figure 3b: SOP at a glance: Timeline and response requirements for polioviruses event and outbreak



* The scope of the response to a detected event or outbreak will depend on the poliovirus type, classification, and, in some circumstances, the local situation. Post-switch, detection of even a type 2 event may require a more aggressive response than recommended for the other poliovirus types.

Annex 2: International Health Regulations notification for polio

The main governing documents for this chapter are:

- WHO Guidance for the use of Annex 2 of the International Health Regulations (2005) [28]
- Statement on the Seventh IHR Emergency Committee meeting regarding the international spread of poliovirus. WHO statement 26 November 2015. [29]
- IHR case definition, IHR Annex 2. [30]

a- Notifiable polio conditions and events [2]

Countries must notify WHO about three conditions or events listed on the grounds that it could be an "event that may constitute a public health emergency" in accordance with IHR:

1. **WPV isolated from an AFP case or a case contact** is one of the 4 critical diseases entities under IHR, which must always be notified to WHO irrespective of the context in which they occur. [31]
2. **WPV or VDPV isolated from source other than AFP cases (environmental sample or human without paralysis)** must also be notified to WHO as they fulfill at least two of the four criteria for notification from IHR Annex 2 (2005)[32]: i) serious public health impact; and ii) unusual or unexpected event. The final two criteria may also be met: iii) significant risk of international spread of disease; iv) significant risk of international trade or travel restrictions
3. (proposed[3]) **Sabin-like type 2 virus** post-switch must also be notified to WHO if more than 4 months have passed since switch from tOPV to bOPV; as they fulfill at least two of the four criteria for notification from IHR Annex 2 (2005).

b- Timing of assessment and official notification [33]

Within a country, all public health events which may meet any one of the four IHR criteria have to be **assessed** for potential notification within 48 hours of the country becoming aware of it at the national level. This regular and routine assessment of national events should be based upon the public health information available and the application of established epidemiological principles by experienced public health professionals. The same event may be reassessed over time as necessary as further relevant information about the event becomes available.

If a country assesses an event and finds it notifiable using the IHR decision instrument[34], it is required to **notify** it within 24 hours to the WHO. Where an initial assessment of an event is negative but a subsequent assessment meets the notification requirement, then it has to be notified to WHO within 24 hours following this positive re-assessment.

c- Special note on event identified outside of country territory

Under IHR Article 9.2 "other reports", country must inform WHO a public health risk identified outside their territory that may cause international disease spread, as manifested by imported or exported human polio cases, infected or contaminated goods (environmental polio); within same timeline as an in-country IHR notifiable event (so within 24 hours of receipt of the evidence).

[2] Notification for Type 2 Sabin-like virus 4 months after the switch so from September 2016 onward

[3] A proposal to amend the IHR WHO polio case definition based on GAPIII containment criteria, has been done to include type 2 Sabin in addition to WPV and VDPV with the same IHR criteria being met (unexpected and serious impact), with an effective date from 1 August 2016 being 3 months after the last possible date for the switch. The proposal still needs to be validated by the IHR EC.

Table 4 summarize the different timeframe for IHR official notification and activities for polioviruses

Table 4: Timeframe for IHR activities and official notification of polioviruses

Notifiable polio conditions and events	Timeframe	Action	Description	Responsible body
1- WPV isolated from an AFP case or a case contact 2- WPV or VDPV isolated from source other than AFP cases 3- Sabin-like type 2 virus post-switch	within 48 hours of the country becoming aware of it at the national level	**IHR event assessment**	Within a country all public health events which may meet any one of the four IHR criteria have to be assessed for potential notification	**National authorities** +/- in consultation with WHO
	within 24 hours of the assessment	**IHR official notification** to WHO	a country assesses an event (inside or outside country territory) and finds it notifiable using the IHR decision instrument.	**Country polio focal point** and/or national IHR focal point, to the **WHO Country Office** (with copy to WHO RO/HQ and relevant national authorities)

Steps to notify:

- The **country polio focal point** notifies the polio advisor at the relevant WHO Regional office within 24 hours of receiving laboratory result of polio positive isolate (sequencing results). The country's Ministry of Health, WHO and GPEI partners must be copied on correspondence.
- The **WHO Regional Office** confirms the notification with country and the GLPN affiliated laboratory. It becomes then an *official IHR notification* and reports to WHO HQ.

Other types of IHR reporting to WHO

In addition to notification, other provisions in the IHR require reporting to WHO. An additional important option for country assessing events is to **consult** with WHO in circumstances not at the time requiring notification or where related guidance is needed (Article 8). This consultation process can be appropriate when there is insufficient available information to complete the decision instrument assessment, or if a country seeks advice on appropriate public health investigative or response measures, or otherwise wishes to keep WHO informed.

Annex 3: Handover of Rapid Response Team (Team A) to Surge Response Team (Team B)

Rationale and guiding principles

Effective handover from the outgoing Team A to the incoming Team B is crucial to continuity of outbreak response and the best use of resources. Key components to successful handover include:

- Detailed in-person handover briefings;
- Handover documents with checklist containing essential information - background; response plans; successes and challenges encountered; key reference materials; list of key contacts;
- Initial response assessment report, agreed objectives to be achieved within 30 days and "Next Steps" to get there, priority areas to support, best practices in the context.

Ensure overlap between the two teams

Allow time to handover properly, e.g. ideally at least 3 to 7 days. If there is no overlap, employ alternate means of communication (e.g. video- or teleconferences) to ensure handover.

If all incoming Team B members arrive at the same time, a complete briefing of the whole team is expected. Conversely, a staggered handover will allow for continuity between the teams when Team A members depart and Team B members arrive at different times. It may be good for one Team A person to remain for an extended period of one or two weeks (e.g. the Team A leader or another of the 3 key positions: Operations, Technical, Communications).

Overview of handover process

Every handover should include: key introductions; thorough face-to-face discussions; briefings (including media); and a field visit. Use a semi-structured handover checklist as a guide (see below).

Team introduction and desk discussion

Introductions should aim to:

- Provide a group briefing followed by a one-on-one briefing of Team A to Team B members;
- Introduce Team B to other partners involved in the outbreak response.

Internal Introductions: Focus one-on-one meetings on the operations action plan, a comprehensive list of partners and what they bring to the outbreak response; the lessons learned and the landmark issues to consider; include key office staff to connect incoming team members to necessary administrative supports

External Introductions: Introduce Team B members, particularly the technical lead, to key outbreak response partners. The list of partners will vary, but generally include government officials; key staff members; focal points within the national rapid response team; and key partners or focal points within the partnership from all relevant levels (e.g. country, regional office, HQ). Key partners include Ministry of Health, WHO, UNICEF at minimum.

Teams A and B should attend key meetings together, to facilitate building relationships. To enable clear expectations for all, explain the TORs of Team B early in meetings with partners.

Share all key documents during handover

Share all documents by various means such as on share-point, cloud, USB key to avoid loss. Documents should cover the following categories:

- List of persons and key contacts, most current outbreak response plan, list of activities (completed, ongoing, and planned), the organisational structure (human resources (HR), meetings), challenges, opportunities, recommendations, etc.

- Orientation on practical questions, such as travel authorization, transports, security issues, car rental, hotel reservation in the field, etc.
- An explanation of the hierarchical lines of all partner agencies, including names and contacts for the persons who manage logistic and finance.
- All challenges, constraints, pending issues, bottlenecks, expectations regarding all fields of activities (HR, vaccines, vaccination, surveillance, etc.)
- Raw data on SIA and monitoring activities in addition to any shared reports

General Documents	Yes	No
Government notification of the outbreak		
EOMG grading		
Communication lettre with IRH		
Letter to the Health Minister to highlight the emergency		
Initial epidemiological and social investigation report		
Rapid community assessment report		
Risk analysis report		
Vaccine, other items and log requirements and dates of delivery		
Outbreak response plan		
Outbreak response Budget		
HR surge plan		
Revision of the outbreak response plan if already done, including communications plans for subsequent phases		
Ongoing outbreak investigation, lab reports,…		
SIAs: rounds, target population, microplans, vaccination and social mobilization teams, timing, type of vaccines, special strategies, etc.		
Vaccinator and supervisor training manuals, using local language modules and tools		
Independent monitoring report of the last round, including relevant social data.		
Independent monitoring training manual and tools		
Special vaccination and communication strategies to reach missed children.		
Detailed micro-plans with special attention to high risk populations		
Plan for opportunistic vaccination strategies to reach population in inaccessible areas		
Permanent vaccination point strategy surrounding the inaccessible areas		
Plan for AFP surveillance		
Surveillance data updated and available, including Active surveillance visit completeness, AFP cases with contact sampling, AFP cases found during SIA, ES if available, etc.		
AEFI surveillance document and protocol		
Plan for strenghtening routine immunization		
SITREPs, bulletins, newsletters,…		
Security reports		

Communication	Yes	No
Overall outbreak response communication plan		
IEC and IPC products and tools in local language		
Vaccinators and mobilizers training module on communication messages and skills		
Appropriate content for advocacy and messaging strategies		
Media landscape		
Review on potential vaccine refusals or issues of mistrust or rumours to be addressed		

Contacts	Yes	No
List of contacts persons (e-mail, phones, address) : MOH, UNICEF, WHO, partners, agencies, NGOs, security contacts, journalists, etc.		

Conference calls, Meetings	Yes	No
Conference calls with who, when, objectives,… and minutes		
Outbreak response cell: who, when, where, … and minutes		
Donor meetings and advocacy activities		
Supervision and review meetings;		

Calendar	Yes	No
Chronogram of activities, meetings and calls		
Country Outbreak Dashboard		
Tracking sheet of progress made and/or support needed to close any remaining gaps		
Periodic external outbreak response assessments		
Technical documents	Yes	No
List of technical guidelines that should be available in the field as well as templates and tools to develop		
Closure	Yes	No

Although outbreak closure should occur within a matter of months, Teams A and B should already plan for the post-outbreak period from the beginning. As such some activities need to be proposed or identified during the hand-over ; for example, focus on surveillance activities to maintain polio-free status, documentation of interruption, etc.

Annex 4: ToR Rapid Response Team (Team A) and Surge Response Team (Team B)

TERMS OF REFERENCE: OUTBREAK TECHNICAL LEAD (National Level)

Introduction:
The Global Polio Eradication Initiative (GPEI) seeks to ensure that future generations of children will be free from the threat of polio paralysis. Achieving this goal depends on interrupting poliovirus transmission in the remaining endemic countries and on ensuring rapid and effective responses to poliovirus outbreaks occurring in polio-free countries. The GPEI has recently revised its Standard Operating Procedures (SOPs) for the response to new polio outbreaks.

This document describes the Terms of Reference for the Outbreak Technical Lead in the context of this SOPs.

Purpose of the position:
The Outbreak Technical Lead is responsible for the overall management of the operational response to the poliovirus outbreak, working under the supervision of the head of WHO/UNICEF offices and in collaboration with health authorities and other health partners.
The technical lead will be deployed to countries as part of the Rapid Response Team (A) or the Surge Team (B).

Summary of assigned duties:

- Support heads of WHO/UNICEF country offices with strategic and operational oversight of polio outbreak response operations, ensuring that they address the needs of the population and are aligned with the government/Ministry of Health (MOH) plans and strategies and the polio outbreak response SOPs.
- Lead and guide Team A and Team B on outbreak response strategies and technical oversight of the response activities.
- Foster close coordination with MOH, in-country health and other partners, and regional offices and HQs and assist in the organization of regular coordination meetings, teleconferences, and updates.
- Work with MOH/WHO/UNICEF teams to develop a national outbreak response plan, including a budget, chronogram of activities, and human resources (HR) surge plan, periodically adjusting and adapting the plan, as needed.
- Collaborate with MOH/WHO/UNICEF teams to establish outbreak response structures that include the four components of outbreak response: outbreak investigation, outbreak response immunization, strengthening AFP surveillance, and strengthening routine immunization.
- Collaborate with MOH/WHO/UNICEF teams to produce updates of outbreak response activities (e.g., SITREPS, bulletins, and newsletters) for distribution to relevant partners.
- Collaborate with MOH/WHO/UNICEF teams to organize periodic external outbreak response assessments.
- Collaborate with MOH/WHO/UNICEF teams to document the closure of the outbreak.
- Collaborate with MOH/WHO/UNICEF teams to assess the security situation in the geographic areas included in the response; as necessary, engage appropriate partners to discuss special strategies and resources for insecure areas.
- Collaborate with the communications team to ensure the preparation of an overall outbreak response communication plan and the appropriate content of advocacy and messaging strategies.
- Collaborate with the Outbreak Operations Manager to ensure that the logistical aspects of the outbreak response, especially financing and HR, are managed with optimal efficiency.
- Review and clear donor products and provide strategic guidance on resource mobilization and proposal development.
- Undertake other assignments and responsibilities as requested by heads of country offices, regional directors, and other partners to support the successful response to the outbreak.

TERMS OF REFERENCE: OUTBREAK OPERATIONS MANAGER (National level)

Introduction
The Global Polio Eradication Initiative (GPEI) seeks to ensure that future generations of children will be free from the threat of polio paralysis. Achieving this goal depends on interrupting poliovirus transmission in the remaining endemic countries and on ensuring rapid and effective responses to poliovirus outbreaks occurring in polio-free countries. The GPEI has recently revised its Standard Operating Procedures (SOPs) for the response to new polio outbreaks.

This document describes the Terms of Reference for the Outbreak Operations Manager in the context of the new SOPs.

Purpose of the position:
The Outbreak Operations Manager is responsible for assessing operational needs and existing infrastructure for polio outbreak response at the country level, and contributing to the development of operational response plans to ensure the availability of flexible operational platforms to support the technical response.

- To provide operational inputs to the overall response strategy, including the implementation of the operational work plans, provision of authoritative advice/support to operational units, and collaboration with national/international partners to ensure adequate operational resources.

The operations manager will be deployed to countries as part of the Rapid Response Team (A) or the Surge Team (B).

Summary of assigned duties:

- Support the operations officers at WHO/UNICEF country offices with operational oversight of polio outbreak response operations, ensuring that the response is aligned with the government/Ministry of Health (MOH) plans and strategies and the polio outbreak response SOPs.
- Liaise with regional and HQ counterparts to report and resolve operational issues that could affect the outbreak response.
- Collaborate with MOH/WHO/UNICEF teams to catalogue existing infrastructure and human resources (HR) and assess operational/logistical gaps at the country level to identify what is needed to conduct all aspects of an effective and efficient polio outbreak response.
- Collaborate with MOH/WHO/UNICEF teams and the Outbreak Technical Lead to develop operational aspects of the outbreak response plan, including budget (and a mechanism for financial tracking), chronogram of activities, HR surge plan, and administrative support that feeds into the overall national outbreak response plan. Work with partners and the technical lead to periodically review, adjust, and adapt the plan.
- Direct the implementation of the operational outbreak response plan and provide authoritative advice and support to the heads of the different operational units. In particular and as a priority, ensure that needed financial, human (including consultants and other surge team staff and their logistics), and material resources (including vaccines, cold chain equipment, transport, and surveillance tools) are requested, received via expedited procedures, and distributed so that the outbreak response can occur in the time frame indicated in the SOPs.
- Collaborate with national and international partners to pool operational resources to establish common operational hubs to maximize efficiency and cost-effectiveness.
- Provide frequent and regular reports to the Outbreak Technical Lead on all aspects of operations and contribute updates on operations for SITREPS, bulletins, and newsletters.
- Oversee the logistics related to the periodic external outbreak assessments.
- Work with the security partners to assess the security situation in the geographic areas included in the outbreak response; as necessary, engage appropriate partners to discuss logistical aspects of special strategies and resources for insecure areas.
- Collaborate with MOH/WHO/UNICEF teams to fill their vacant positions in the geographic area of the outbreak response.
- Monitor and manage the transparent and effective use of resources, developing detailed lessons learned reports, documenting achievements and obstacles to project implementation, and recommending improvements for future field operations.
- Undertake other assignments and responsibilities as requested by heads of country offices, regional directors, and other partners to support the successful response to the outbreak.

TERMS OF REFERENCE: OUTBREAK COMMUNICATION OFFICER (C4D and External Communication) (National level)

Introduction:
The Global Polio Eradication Initiative (GPEI) seeks to ensure that future generations of children will be free from the threat of polio virus infection and paralysis. Achieving this goal depends on interrupting poliovirus transmission in the remaining endemic countries and on ensuring rapid and effective responses to poliovirus outbreaks occurring in polio-free countries. The GPEI has recently revised its Standard Operating Procedures (SOPs) for the response to new polio outbreaks

This document describes the Terms of Reference for the Outbreak Communication Officer in the context of the new SOPs.

Purpose of the position:
The Outbreak Communication Officer will lead the polio communication support provided to the country during the response to a poliovirus outbreak, working under the supervision of the Head of the WHO/UNICEF Country Offices and in collaboration with the communication teams of those organizations.

The communication officer's support to the team at the country office will ensure that the response is:
1. Aligned with the government/Ministry of Health (MOH) plans and strategies, and
2. Aligned with the latest outbreak response SOPs.

The communication officer will be deployed to countries as part of the Rapid Response Team (A) or the Surge Team (B).

Summary of assigned duties:
<u>General</u>:

- Assess communication needs and existing capacity at the country level.
- Report to WHO/UNICEF headquarters on progress, achievements, and where additional assistance is required.
- Contribute to the development of a communication plan to underpin the technical response, in collaboration with the WHO/UNICEF offices.
- Provide technical input to the overall response strategy, including the implementation of the operational work plans and provision of authoritative advice and support to operational units.
- Provide leadership and strengthen the existing communication teams by emphasizing team building and collaboration as daily routine with national/international partners.

<u>Communication for Development (C4D)</u>:

- Ensure conduct of the required social investigation of polio cases as part of the early outbreak response.
- Develop/update/review data on immunization knowledge and attitudes and behavior of the target audience, especially for high-risk and mobile populations.
- Facilitate and lead the reinvigoration of a social mobilization and/or communication working group or the expansion of an existing one.
- Initiate the development of the social mobilization component of the 6-month outbreak response plan document, including details for subnational implementation in high-risk areas and mobile populations, as well as the means for monitoring field activities and budget to cover those activities.
- Finalize C4D community engagement and information dissemination strategies to promote polio and routine immunization.
- Develop and tailor health information products for various target populations/audiences, based on careful assessment of community knowledge, practices, and behaviors.
- Ensure that polio microplans (at least in priority areas) include social data and information on social mobilizers and leaders by the time of the first response.
- Provide support for the training of health workers.
- Help implement the strategic communication response plan, including mass communication plans, as appropriate.
- Undertake in-depth reviews of potential refusals of vaccines or issues of mistrust to be addressed.

- Conduct regular analyses of independent monitoring data and other available resources to identify priority areas and devise social mobilization microplans targeting those areas that incorporate social mobilization indicators within program monitoring indicators.

- Set up social mobilization teams with delegated authorities at the sub-national level, as needed, and oversee the structure until the end of the outbreak with performance monitoring.

External Communication:

- Conduct a media landscape analysis.

- Support the outbreak response team to prepare an external communications strategy, including the engagement with political, religious, and community leaders and other stakeholders.

- Develop polio-related media and external communication packages.

- Identify a media focal person and spokesperson from the government, WHO, and UNICEF.

- Work with partners and government counterparts to conduct a press brief/media release, if appropriate, and update donors and partners on work progress.

- Host weekly calls with WHO polio communications counterparts in country offices, regional offices, and HQ.

- Receive and review all media releases/news feeds related to the outbreak and share with focal points. Target other non-media communication channels that could be more effective in certain settings.

- Update talking points and FAQs, as needed (e.g., with changing epidemiology and ahead of vaccination rounds).

Other:

- Undertake other assignments and responsibilities as requested by heads of country offices, regional directors, and other partners to support the successful response to the outbreak.

List of main additional reference documents

- GPEI Outbreak response: a package of guidelines and materials. http://www.polioeradication.org/Resourcelibrary/Resourcesforpolioeradicators/Technicalguidelines.aspx
- GPEI Reporting and classification of vaccine-derived polioviruses. GPEI guidelines. http://www.polioeradication.org/Portals/0/Document/Resources/VDPV_ReportingClassification.pdf
- Polio Eradication and Endgame Strategic Plan 2013-2018. http://www.polioeradication.org/resourcelibrary/strategyandwork.aspx
- WHO Guidance for the use of Annex 2 of the International Health Regulations (2005) http://www.who.int/ihr/revised_annex2_guidance.pdf
- IHR case definition, IHR Annex 2. http://www.who.int/ihr/Case_Definitions.pdf?ua=1
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Standard Operating Procedures

Responding to a poliovirus event and outbreak

Part 2: Protocol for poliovirus type 2

April 20, 2016

Effective 1st May 2016 till 30 April 2017

World Health Organization

Contents

Tables and figures

List of acronyms

AFP	Acute flaccid paralysis
aVDPV	Ambiguous vaccine-derived poliovirus
bOPV	Bivalent OPV (contains Sabin 1 and 3)
cVDPV	Circulating vaccine-derived poliovirus
EOMG	Eradication and Outbreak Management Group
EOC	Emergency Operations Center
ES	Environmental surveillance
GAPIII	Third edition of the Global Action Plan to minimize post-eradication poliovirus facility-associated risk
GCC	Global Commission for Certification of the Eradication of Poliomyelitis
GPEI	Global Polio Eradication Initiative
GPLN	Global Polio Laboratory Network
ICG	Interagency Coordinating Group
IHR	International Health Regulations (2005)
IPV	Inactivated polio vaccine
ITD	Intratypic differentiation
iVDPV	Immunodeficiency-associated vaccine-derived poliovirus
mOPV2	monovalent oral polio vaccine type 2
NRA	National Regulatory Authority
OPV	Oral polio vaccine
OPV2	Oral polio vaccine type 2
OBRA	Outbreak Response Assessment
OPRTT	Outbreak Preparedness and Response Task Team
PHEIC	Public health emergency of international concern
RO	Regional Office
RRT	Rapid Response Team
SIA	Supplementary immunization activity
SL	Sabin like poliovirus
tOPV	Trivalent oral polio vaccine (contains Sabin 1, 2 and 3)
VAPP	Vaccine-associated paralytic poliomyelitis
VDPV	Vaccine-derived poliovirus
VDPV2	Vaccine-derived poliovirus type 2
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus
WPV2	Wild poliovirus type 2

Executive summary

Following the switch from tOPV to bOPV, the detection of any poliovirus type 2 (wild, vaccine derived, or Sabin) in any sample of any source will be considered a global public health emergency. Three main outbreak threats following OPV2 cessation are: a higher, but primarily short-term risk of the emergence of a VDPV2; a lower, long term risk of poliovirus re-introduction from a manufacturing site or laboratory; and a small, but potentially larger threat in the future posed by prolonged or chronic poliovirus infection in individuals with B-cell related primary immunodeficiencies (e.g. iVDPV).

Key objectives of the Protocol: 1. To outline the main elements of the strategy to detect and respond appropriately to any type 2 polioviruses; and 2. To provide guidance to global, regional and national public health officials and policy makers for the necessary steps required

The strategic actions following detection of a type 2 poliovirus isolate after OPV2 cessation have the same basic approaches and principles to those currently required for investigating and responding to any polio outbreak as outlined in the Standard Operating Procedures (see Part 1). Features which are specific to the response following a type 2 outbreak/event are summarized in **Table 4.**

Timeframe and target audience: While this version of the protocol lays out overall strategic imperatives for dealing with all future type 2 outbreaks, the recommendations focus only on the response required within in the first 12 months following OPV2 cessation (e.g. May 2016 to April 2017) and are aimed primarily for those countries which have used tOPV within the last 12 months prior to the switch.

Key strategic principles for responding to a type 2 poliovirus:

- Prompt response in a sufficiently large population to lead to rapid cessation of type 2 poliovirus circulation;
- Utilization of vaccines from a global stockpile for the outbreak response for all countries whether or not they have previously received vaccines through UNICEF;
- Limit exposure to Sabin 2 poliovirus (e.g. from mOPV2) among populations not directly affected by the outbreak to prevent emergence of a new cVDPV2;
- Validate the absence of poliovirus type 2 in the population and the environment following the outbreak response.

Detection: Detection of a type 2 poliovirus will continue to depend on sensitive AFP surveillance as well as an expansion of environmental surveillance sites targeted especially in areas of high risk for cVDPV emergence, areas where there is a risk of silent transmission and circulation of poliovirus, and areas at risk due to vaccine production.

Notification: Detection of any poliovirus type 2-wild, vaccine derived, or even Sabin (4 months post switch) will require notification under IHR (2005).

Investigation & Risk Assessment: Following detection of any type 2 polio virus, primary actions required include: conducting enhanced virologic investigation, enhanced surveillance, and a rapid field investigation and risk assessment. The nature of the virus (e.g. WPV, VDPV, or Sabin) and strength of

evidence of circulation (e.g. confirmed, probable, or possible) will determine the potential risk of further poliovirus type 2 transmission (see **Table 1**). Unlike type 1 or 3 isolates, for type 2 isolates, the transmission classification (not typology) determines response.

Factors such as past epidemiologic history, location, and population characteristics determine three general "transmission risk zones" that reflect the risk for any type 2 transmission (see **Table 3**). The risk zone designation will also help determine the appropriate response.

Response: Preparations for a vaccination response should begin upon receiving initial sequencing results and should not wait for a complete epidemiologic investigation or final classification of an isolate. In most all situations, any VDPV2 or WPV2 (without a confirmed exposure) will require an initial vaccination response using mOPV2 (from a global stockpile), should target 500,000 children under 5 years of age, and be implemented within 14 days of receiving the initial sequencing results. Additional SIAs should each target a minimum of 2 million children approximately every 2-3 weeks. The number additional SIAs will depend on the further classification of the virus and transmission risk zone. (See **Figures 3a and 3b**). Situations of confirmed transmission require that one SIA should target use of IPV in combination with mOPV in the outbreak area plus IPV alone for an expanded high risk sub-population. Depending on supply and operational issues, fractional dosing of IPV will most likely be recommended.

Countries will need to apply to WHO in order to access mOPV2 from the global stockpile. Release of the vaccine will require authorization from the WHO Director General. Countries will also be able to obtain IPV for an outbreak response through a similar request mechanism. (For details on the stockpile and the request process see **Annex A and Annex B)**

Detection of a Sabin type 2 isolate in either an AFP/human case or environmental sample >4 months post switch (or post use of mOPV2 in an outbreak) should prompt a full investigation to determine whether tOPV (or mOPV2) are still being utilized or the potential of a containment breach.

Travelers & quarantine: Strict quarantine of individual polio cases will have limited impact on stopping the outbreak unless there is a documented exposure to a type 2 poliovirus. On a population wide basis, travel and migration patterns in and out of affected communities can have a significant impact on the risk and extent of poliovirus circulation, but the potential for enforcing local travel restrictions and vaccination requirements will depend on local circumstances.

Outbreak/event response assessment and follow-up steps: Conduct Independent Monitoring at least by SIA2. Also conduct outbreak/event response assessments by the third month from day 0 and continuing quarterly thereafter until 12 months have passed without a type 2 poliovirus identification. It is critically important to confirm the end of the outbreak by validating the absence of poliovirus type 2 in the population and the environment 12 months after the onset date of the most recent case plus 2 months.

1- Introduction

The last detected case of wild poliovirus (WPV) type 2 (WPV2) anywhere in the world occurred in 1999. On 20 September 2015, the Global Commission for the Certification of Poliomyelitis Eradication (GCC) formally declared that WPV2 has been eradicated.[1] However, the continued use of oral polio vaccine (OPV) type 2 component (OPV2) remains responsible for the vast majority of circulating vaccine-derived poliovirus (cVDPV) cases and a substantial portion of vaccine associated paralytic poliomyelitis (VAPP) cases. In order to address this situation and the wider implications of OPV use after global wild poliovirus eradication, Objective 2 of the *Polio Eradication and Endgame Strategic Plan 2013-2018*[2] proposes an endgame strategy of three sequential steps: 1. Introduce at least one dose of inactivated polio vaccine (IPV) into routine immunization in all countries; 2. Cease using type 2-containing oral polio vaccine (OPV2) by a globally-coordinated switch from trivalent OPV (tOPV) to bivalent OPV (bOPV); and 3. Eventually globally-coordinate withdrawal of all OPV.[3]

As of April 2016, all 156 countries and territories using tOPV have either already introduced or made formal commitments to introduce at least one dose of IPV into their routine immunization programs. Consequently, step 2, the globally coordinated switch from tOPV to bOPV (e.g. OPV2 cessation), is on track to proceed between 17 April and 1 May 2016.

Following OPV2 cessation, population immunity and especially intestinal immunity and secondary spread of type 2 OPV-related viruses will decline, which will increase the risk of an outbreak if exposure to a type 2 poliovirus occurs.[4] Three main outbreak threats following OPV2 cessation are: a relatively higher, but primarily short-term risk of the emergence of a cVDPV; a lower, long term risk of poliovirus re-introduction from a manufacturing site or laboratory; and a small, but potentially larger threat in the future posed by prolonged or chronic poliovirus infection in individuals with B-cell related primary immunodeficiencies (e.g. immunodeficiency-related vaccine-derived poliovirus [iVDPV]).[5] Since WPV2 has been declared eradicated and OPV2 should no longer be in use after the tOPV to bOPV switch, the detection of any poliovirus type 2 (wild, vaccine derived, or Sabin) in any sample of any source after the switch will be considered a global public health emergency that requires a concrete strategy with rapid and high-quality coordinated action from the Global Polio Eradication Initiative (GPEI) and national and sub-national health agencies.

There is a high probability that at least one cVDPV2 and possibly multiple other VDPV2s will emerge within 12 months of the global switch from the use of tOPV to bOPV. The strategic actions following detection of a type 2 poliovirus isolate after OPV2 cessation have the same basic approaches and principles to those currently required for investigating and responding to any polio outbreak as outlined in the Standard Operating Procedures. However, the post-OPV2 era will require a heightened urgency, vigilant surveillance, a carefully planned risk assessment, and usually a specific vaccine response due to the world entering truly new territory with associated uncertainties surrounding the consequences of re-introducing an eradicated pathogen. **(see Table 4 for a summary of features specific to a type 2 outbreak response).**

2- Protocol objectives and scope

The objectives of this document are:

1. Outline the main elements of the strategy to detect and respond appropriately to any type 2 polioviruses from environmental sources or circulating in the population post OPV2 cessation.
2. Provide guidance to global, regional and national public health officials and policy makers for the necessary steps required to rapidly notify the proper authorities, conduct an initial risk assessment, and develop an effective response to promptly curtail any type 2 poliovirus outbreaks.

This proposed strategy is based on evidence from past and current program experience dealing with polioviruses as well as existing models projecting possible scenarios.[6] Development of these guidelines is an iterative process that will evolve as further evidence and experience are generated. **While this version of the protocol lays out overall strategic imperatives for dealing with all future type 2 outbreaks**, **the recommendations focus only on the response required within in the first 12 months following OPV2 cessation (e.g. May 2016 to April 2017).** Further recommendations will be developed in 2017.

These guidelines are intended to provide concrete parameters for decision making, yet they cannot address every possible scenario. Decision makers should flexibly interpret the protocol and actively consider their specific epidemiologic circumstances. In particular, the protocol's recommendations for vaccine use in an outbreak response are targeted specifically to countries which have used OPV within 1 year of the switch. However, any WPV2 or VDPV2 detected in the post-switch era in any country (even in those with exclusive IPV use) must be considered a potential global risk. Given the potential for Sabin type 2 polioviruses to evolve into cVDPV2s, detection of Sabin type 2 polioviruses more than 4 months after the switch and/or use of mOPV2 in responding to a type 2 event or outbreak in any country must also be considered a potential global risk. While detection of a type 2 poliovirus in one location may not generate sufficient concern of further transmission to necessitate an immediate local vaccination campaign, an urgent and aggressive investigation may still be required to trace the origin of the virus in order to rapidly determine an appropriate response at the initial source of the outbreak.

2- Background -preparation for type 2 OPV withdrawal

In May 2014, the World Health Assembly (WHA) adopted criteria which the Strategic Advisory Group of Experts on Immunization (SAGE) recommended to gauge global readiness for OPV2 cessation.[7] OPV2 withdrawal is dependent on satisfying these readiness criteria and the global interruption of persistent cVDPV2 transmission.

Primary actions required at the global level by GPEI:

- Establish a global stockpile of monovalent oral polio vaccine (mOPV) type 2 (mOPV2) for outbreak use (See **Annex A** for details on stockpile operations)
- Provide global guidelines and technical assistance as required to implement Objective 2[8]
- Verify global eradication of wild poliovirus type 2 (completed in September 2015)

Primary actions required at the national level by public health authorities:

- Introduce at least one dose of IPV into routine immunization in OPV-only using countries[9]
- Conduct one or more tOPV campaigns just prior to OPV2 cessation (if OPV coverage levels indicate population could be at risk for type 2 outbreak)
- Strengthen outbreak response capacity and ensure that all relevant public health officials are aware of the recommendations outlined in this protocol in the case of a type 2 outbreak.
- Institute appropriate containment measures as required under the Global Action Plan III (GAPIII)[10]
- Ensure that bOPV is licensed for routine immunization

3- Poliovirus type 2 outbreak response strategy

The overall principles of the strategy to deal with detection of any type 2 poliovirus include:

- Prompt detection and notification of all type 2 poliovirus strains;
- Prompt response in a sufficiently large population to lead to rapid cessation of type 2 poliovirus circulation;
- Utilization of vaccines from a global stockpile for the outbreak response for all countries whether or not they have previously received vaccines through UNICEF;
- Limit exposure to Sabin 2 poliovirus (e.g. from mOPV2) among populations not directly affected by the outbreak to prevent emergence of a new cVDPV2;
- Validate the absence of poliovirus type 2 in the population and the environment following the outbreak response.

In addition to incorporating the several preparatory steps which are required for initiating Sabin type 2 withdrawal , the strategy for addressing the risks associated with withdrawal of OPV2 includes six components: detection, notification, investigation/risk assessment, response, traveler considerations (internal, and international), and follow-up. The proposed guidelines for each component are based on risk factors and epidemiological contexts. Although presented separately, some components should proceed simultaneously.

3.1 Detection

Poliovirus surveillance includes multiple components.[11] Acute Flaccid Paralysis (AFP) surveillance has been the gold standard for global polio eradication and will remain the primary method for detecting any type 2 virus in the post cessation era.[12] AFP surveillance is linked to global, regional, and national laboratories which are part of the Global Polio Laboratory Network (GPLN) with comprehensive, standardized guidelines to distinguish poliovirus as a cause of AFP from diseases other than poliovirus.[13]

Environmental surveillance (ES) will provide an increasingly important adjunct to AFP surveillance. While environmental sampling is already being utilized in key countries to supplement polio eradication efforts, the GPEI is working jointly with specific countries on a strategic expansion plan to markedly increase the number of sites and role of ES between now and 2018.[14] To address surveillance needs in the post OPV2 era ES will be targeted especially in areas of high risk for cVDPV emergence (e.g. low routine coverage and historical cVDPV cases), areas where there is a risk of silent transmission and circulation of poliovirus (e.g. high force-of-poliovirus-infection), and areas at risk due to vaccine production. ES can also be instrumental in tracking the disappearance of Sabin 2 strain polioviruses, detecting any Sabin 2 strain polioviruses that subsequently might surface, and identifying any continued use of tOPV. Establishing ES as a fundamental part of the surveillance strategy for OPV2 withdrawal requires sufficient laboratory and staff resources as well as operational procedures following current WHO guidelines[15] and should be instituted through a collaborative strategic global effort to enhance detection capacity for type 2 polioviruses.

Polioviruses may also be detected as an incidental finding in a non-AFP clinical specimen or through a stool survey. Currently, this detection method is not an important surveillance source. Nevertheless,

any incidental findings of type 2 poliovirus should be reported through the standard notification system (See ***Notification***).

Primary actions required at the global/regional level by the GPEI/GPLN:

- Assist countries with implementation of the ES global expansion plan
- Adequately support national polio laboratories to ensure rapid and sensitive poliovirus isolation and characterization of polioviruses through intratypic differentiation (ITD). As a global priority, all essential laboratories should expedite processing and sequencing of any type 2 isolates.

Primary actions required at the national level by public health authorities:

- Regularly monitor and evaluate AFP surveillance and laboratory networks to ensure global quality standards are maintained even as wild poliovirus cases disappear.[16]
- Collaborate with GPLN and GPEI to implement the global ES Expansion Plan. At this time countries not already engaged in ES for polioviruses do not need to independently start performing environmental sampling for polioviruses solely for the purpose of detecting Sabin type 2 polioviruses as markers for post-switch use of tOPV.

3.2 Notification

Treaty obligations under the International Health Regulations (2005) [IHR (2005)] specifically designate detection of a WPV from a suspected case or from a close contact to be a notifiable event. Additionally, the isolation of any WPV or cVDPV from other human or non-human sources must also be notified to WHO under the separate notification requirement for 'events which may constitute a public health emergency of international concern'.[17] Post cessation of OPV2 and confirmation of the elimination of cVDPV2 the interpretation of this criterion is expanded to include detection of any poliovirus type 2 (wild, vaccine derived, or Sabin[18]) in any sample (from clinical case or environment) of any provenance as a notifiable event under IHR (2005). The *IHR Emergency Committee* regarding the international spread of poliovirus will advise the WHO Director-General as to the appropriate risk category of the affected country.[19]

Primary actions required by national and/or regional laboratories:

- Promptly provide notification to national health authorities and WHO (and to other GPEI partners) within 24 hours of obtaining results.

***Primary actions required by national health authorities*:**

- The National IHR Focal Point should notify WHO of any type 2 poliovirus detection within 24 hours as specified in the IHR (2005). The Ministry of Health should likewise inform relevant national officials.
- Non-laboratory confirmed cases, contradictory laboratory results, an unexpected cluster of AFP cases, or clusters of clinically compatible AFP cases would not trigger global actions or notification under IHR (2005). However, these situations, as well as concerns about suboptimal surveillance should be thoroughly investigated at the appropriate national/sub-national level.

3.3 Investigation and risk assessment

a- Initial investigation

Discovery of any type 2 poliovirus isolate from either AFP or environmental surveillance should initiate an immediate field investigation to: 1) confirm the outbreak/event; 2) determine number and characteristics of the case(s); 3) identify the origin/causes for the outbreak/event; and 4) assess the risk for occurrence and geographic extent of transmission.

Several steps may take place simultaneously. **Figure 1** (see page26) provides an overall timeline of required activities, the agency or persons with primary responsibility, and the expected time frame for completing the action. (For further details see general *Standard Operating Procedures* for responding to any poliovirus outbreak.[20])

Primary actions required by all relevant GPLN laboratories:

- Enhance virologic investigation: Further sequencing analysis beyond initial testing can aid in estimating the duration of poliovirus circulation. Laboratories responsible for covering the area where the poliovirus was detected should also carefully review relevant laboratory indicators (cell-sensitivity testing results, proficiency testing for viral isolation and ITD, accuracy of detection and testing, etc.) to ensure that the laboratory met recommended standards before and at the time of type 2 detection.

***Primary actions required by national public health authorities*:**

- Enhance surveillance: In order to maximize quality and sensitivity of the surveillance system, ensure strict attention to completeness and timeliness of all AFP reporting. Note that minimum standards for the affected country and first administrative level should be increased to three non-polio AFP cases per 100,000 children under 15 years of age for 12 months following outbreak confirmation. Also, for the immediate assessment period, increase frequency of environmental surveillance if available. For the longer term, if any WPV2 or VDPV2 is detected, investigate with the GPEI about establishing or expanding local environmental sampling sites.
- Conduct an epidemiologic investigation: A prompt field investigation of any AFP case should include specific case characteristics as well as active case finding in the community and local reporting sites. A positive environmental sample should also trigger active case finding in the suspected community and/or catchment area of the ES site.
- Conduct a risk assessment: Based on the findings of the epidemiologic and virologic investigations and the strength of evidence, characterize the virus transmission and the implications for further spread. Assess the critical factors which will influence the type and scale of response and make recommendations for appropriate actions (see ***Key Questions and Determinations*** below). Identify sub-populations outside the primarily affected area which are at-risk for possible transmission.

b- Key questions and determinations for the risk assessment

While laboratory and epidemiologic investigative steps correspond in general to standardized guidelines for following-up any poliovirus detection, the risk assessment following discovery of a type 2 isolate should focus specifically on addressing three core questions:

1. *What is the nature of the virus (e.g. WPV, Sabin, or VDPV)?*
2. *Is there evidence of circulation?*
3. *What is the risk of further spread?*

Following Initial detection, ITD, and sequencing, a poliovirus isolate may be grouped into one of three categories: 1) WPVs, 2) Sabin [e.g. OPV strain], and 3) VDPVs (>1% divergent [PV1 and PV3] or >0.6% divergent [PV2] from the corresponding OPV strain). A thorough risk assessment is required regardless of isolate category.

WPV2. Given the extended period since a circulating WPV2 has been detected, the possibility of further emergence of this virus is very remote. However, if an individual WPV2 infection is detected, rapid case investigation is mandatory since transmission could rapidly take place depending on local population immunity. A WPV2 infected individual without a known exposure to a poliovirus in a laboratory or vaccine production facility should be treated as evidence of *confirmed transmission*. A WPV2 infected individual with a known exposure to a breach in containment is most likely an isolated event but is a risk for *possible future transmission*. Likewise, a WPV2 isolate from an environmental sample is, in all probability, due to a containment breach in a laboratory or research facility. Nevertheless, a thorough investigation is warranted in the community catchment area surrounding the ES site as well as in any nearby laboratory or research facility in order to identify an AFP case or rule out an individual with ongoing sub-clinical infection who is excreting poliovirus. A cautionary approach dictates that discovery of a WPV2 in an ES sample should initially be considered evidence of *probable transmission*.

Sabin 2. While there will be considerable variability depending on the local environment, empirical evidence as well as modeling indicate that Sabin type 2 polioviruses can be expected to remain detectable for approximately 3 months in stool and 4 months in sewage samples after the last use of tOPV (and/or use of mOPV2).[21] While this detection should prompt increased vigilance through AFP and environmental surveillance, the risk for this occurrence should rapidly diminish with time.[22] Detection of Sabin type 2 polioviruses after this 4-month period following the switch (i.e. from September 2016 onwards) or last use of mOPV2 in a type 2 outbreak/event response could be evidence of continued use of OPV2-containing vaccine, and as such would represent a risk for *possible future transmission*. A single individual AFP case with a Sabin type 2 poliovirus could also indicate a rare isolated exposure in a vaccine production facility or research laboratory.[23] This situation warrants a thorough case investigation, including checks for any remaining local stocks of tOPV and review of containment procedures and good manufacturing practices at nearby facilities.

VDPV2. Aside from Sabin 2 isolates in the immediate post-switch era, the most common poliovirus to be detected following withdrawal of tOPV will likely be a VDPV.[24] Genetic sequencing of the detected poliovirus through a combination of molecular and antigenic methods or real-time reverse transcription–polymerase chain reaction (rRT-PCR) targeting sequences within the VP1 capsid region that are selected for during replication of OPV in the human intestine will provide more specific categorization. VDPVs are further classified as: 1) cVDPVs when there is evidence of person-to-person transmission in the community; 2) iVDPVs, which are isolated from persons with primary, B-cell immunodeficiencies; and 3) ambiguous VDPVs (aVDPVs), which do not fit into the other two categories.

As an isolate linked either to known cVPDVs or a previously detected aVDPV demonstrates ongoing circulation and *confirmed transmission* in the community it represents the same public health threat as a WPV.[25] Given the critical importance of detecting and stopping cVDPV transmission during the endgame, in July 2015 WHO increased the sensitivity of surveillance to include the following expanded definition:

cVDPV

- genetically linked VDPVs, isolated:

i) from at least two individuals (not necessarily AFP cases), who are not household contacts,
ii) from one individual and one or more environmental surveillance (ES) samples, or
iii) from two or more ES samples if they were collected at more than one distinct ES collection site (no overlapping of catchment areas), or from one site if collection was more than two months apart *or*

- a single VDPV isolate, with genetic features indicating prolonged circulation (i.e. a number of nucleotide changes suggesting > 1.5 yrs of independent circulation).[26]

A sample that does not initially meet the above definition should be considered a "New VDPV," which requires more intensive investigation to determine if additional infections are occurring in the community (See **Figure 2**). A single VDPV2 without evidence of prolonged circulation or a single VDPV2 case not linked to a previously detected aVDPV may only represent an isolated event without any other consequences. However, given the large risks inherent in failing to promptly respond to even low level type 2 spread, initial discovery of these scenarios should be treated as evidence of *probable transmission*.

Further active surveillance in the catchment area of an environmental sample or community search and contact tracing of a human case may find additional case(s) linked to the new VDPV, which would lead to classification of the cases as cVPDVs.

The case investigation should also determine whether an individual VDPV case represents a long-term, immunodeficient carrier for poliovirus (i.e. an iVDPV). Classification of iVPDV should be made only after a thorough investigation including: a) detailed history, b) competently performed physical examination, and c) results of quantitative immunoglobulin (IG) testing.[27] Acute or chronic malnutrition, which may cause a form of secondary depression of the immune system, should not be confused with serious

primary immune deficiency (such as a- or hypo-gammaglobulinemia, common variable immunodeficiency, x-linked agammaglobulinemia, other antibody deficiency; or some form combined immunodeficiencies - most commonly severe combined immunodeficiency (SCID)).

Detection of iVDPVs is rare (e.g. ~100 known cases worldwide since 1961) and these cases have predominantly been found in developed countries.[28] Recent studies in developing and middle income countries have demonstrated that such cases may occur more frequently than previously thought; however, the survival rates for persons with primary immune deficiencies are probably very low in areas with the highest risk for polio transmission.[29] With one possible exception,[30] there is no evidence that iVDPV excretors have triggered substantial cVDPV transmission or outbreaks to date. However, all known iVDPV excretors have lived in settings of very high population immunity to poliovirus transmission and/or high hygiene and sanitation settings with reduced transmission potential of polioviruses. Therefore, especially in the first year following OPV2 cessation while type 2 immunity remains relatively high, the potential of further transmission from an iVDPV is deemed low in most countries but still *possible*. Modelling indicates that the future risk of live poliovirus reintroduction into the population from iVDPVs may rise considerably after global wild poliovirus eradication and subsequent OPV cessation.[31]

3.4 Response

a- Classification of poliovirus events/outbreaks, type 2 transmission, and further risk of post-switch transmission

Based on the nature of the virus and strength of evidence of circulation (e.g. confirmed, probable, or possible), three scenarios emerge reflecting the potential risk of further poliovirus type 2 transmission: high, medium, and low (see **Table 1**). Note that unlike type 1 or 3 isolates, for type 2 isolates post switch, the transmission classification (not typology) determines response. The level of concern should increase with the higher likelihood of further transmission.

Table 1: Definitions of poliovirus events/outbreaks and classification of type 2 transmission during Phase 1

Typology	Sample source	Classification	Type 2 transmission	Potential risk for further transmission[a]
Event	*Human/AFP*[b]	"new VDPV2" awaiting classification	Probable	Medium
		aVDPV2	Probable	Medium
		iVPDV2	Possible	Low
		Sabin2	Possible	Low
		WPV2 with documented exposure in a laboratory or vaccine production facility	Possible	Low
	Environmental	VDPV2 single sample without evidence of prolonged circulation of >1.5 years	Probable	Medium
		WPV2 single sample without follow-up evidence of virus excretion[c]	Probable	Medium
		Sabin2	Possible	Low
Outbreak	*Human/AFP*[b]	cVDPV2	Confirmed	High
		WPV2 without documented exposure in a laboratory or vaccine production facility	Confirmed	High
	Environmental	cVDPV2	Confirmed	High
		≥2 separate WPV with genetic sequencing indicating sustained local transmission[d]	Confirmed	High
		WPV2 single sample with follow-up evidence of virus excretion[c] & no documented exposure	Confirmed	High

[a] Additional factors (e.g. force-of-infection, population density, season of the outbreak, indigenous vs. imported virus, etc.) will ultimately determine the risk of further transmission and directly influence the required type and scale of response.

[b] Infected individual can be an AFP case or an asymptomatic/healthy person

[c] Evidence of virus excretion = identification of polio compatible AFP case or WFP infected individual

[d] Collected at more than one distinct ES collection site (no overlapping of catchment areas), or from one site if collection was more than two months apart

b- Factors influencing type and scale of response

If the initial investigation and risk assessment indicate that either confirmed or probable type 2 poliovirus transmission has been detected, an immunization response will mostly likely be required even before waiting for final classification. Further assessment to determine an appropriate type and scale of response is critical given the potential risks associated with mOPV2 use following OPV2 withdrawal and the need to balance this risk with the necessity to stop the type 2 transmission.

The risk for emergence of any type 2 poliovirus following withdrawal of OPV2 is not homogenous across countries or even within large countries. A significant factor will be the predominant polio vaccine in use within a country.

Countries exclusively using IPV

For countries that exclusively use IPV, the risk for cVDPVs (detected in either an ES sample or an individual case) depends on their relatively limited risk of exposure to imported OPV through travelers or migrants. Even the definitions of confirmed or probable transmission for their situation may depend on whether the type 2 poliovirus isolates demonstrates genetic features consistent with local transmission vs. importation. These countries may still be at risk, albeit at a low level, for discovery of WPV2 or Sabin2 virus traced to a breach in containment from a laboratory or vaccine production facility. Given the generally high vaccination coverage and levels of sanitation found in these countries, the risk of type 2 transmission is relatively low in all these circumstances but poliovirus may still spread to under-vaccinated sub-populations.[32] The level of concern (and associated degree of response) in these countries will thus depend on a thorough virologic and epidemiologic investigation and tailored to the individual situation.

However, from a global perspective, detection of any type 2 poliovirus should be a cause of concern. An attempt to identify the origin of any outbreak, including those due to importations, will be important in order to determine an appropriate response at the source. Nevertheless, the recommendations below regarding a vaccination response following detection of a type 2 poliovirus are focused on countries with use of tOPV within the 12 months prior to the switch.

Countries using tOPV in the last 12 months prior to type 2 OPV withdrawal

For countries with prior recent use of OPV, two dynamically inter-related trends determine post-cessation risk of cVDPV emergence: decreasing population immunity to transmission and decreasing OPV-related virus presence. These same factors that predispose for the emergence of a new poliovirus type 2 will also be critical in determining the potential risk for further transmission and the extent of any transmission which might occur.

NOTE: Risk factors and response strategies presented below apply to countries using tOPV within the last 12 months prior to the switch.

Critical factors for countries to consider in reaching response decisions include time, place, and characteristics of the affected population.

i) Time

How many months/years have elapsed between OPV2 cessation and detection of poliovirus type2?

Multiple high quality SIAs (i.e. ≥3 SIAs with ≥ 80% coverage) in the 4-6 months before the switch will significantly reduce the risk of emergence.[33] However, modelling suggests a high probability that at least one cVDPV will emerge within 12 months of the switch.[34] While specific cutoff dates cannot be determined, three broad phases –based on the time elapsed since tOPV cessation shown in Table 2-- can be identified, which reflect the exposure to type 2 poliovirus and the risk for initial VDPV occurrence and further transmission.[35] Phase 1 (within 1 year of cessation of tOPV) has the highest risk of initial occurrence of a type 2 virus detection; however, assuming pre-cessation mitigation activities (i.e., tOPV SIAs) have taken place prior to withdrawal of tOPV, this phase should have the lowest risk of further transmission. Phase 2 (2-3 years post-cessation) reflects medium risks of occurrence and further

circulation. Similarly, Phase 3 (4+ years since cessation of OPV2) will have the lowest exposure risk to type 2 virus, but will have an accelerating risk of further transmission due to waning mucosal immunity in the population.

Table 2. Phases of risk for type 2 poliovirus emergence and circulation

Phase	Time after cessation of OPV2	Comment	Relative Risk for initial type 2 occurrence	Risk for further circulation
1	≤1 year	General population immunity remains high if mucosal immunity is boosted in <5 population by pre-switch tOPV SIAs	High	Low
2	2-3years	General immunity still reasonably high, but overall mucosal immunity declining and absent in new birth cohorts	Medium	Medium
3	≥4 years	Mucosal immunity declines sharply	Low	High

Occurrence of aVDPV2s is historically less responsive to immunity conditions and may be more difficult to predict in the context of rapidly decreasing population immunity to transmission after OPV2 cessation; however, a minimum of four aVDPVs could be expected in the first year following OPV2 cessation.[36]

ii) Place—(country or sub-national region w/ >10 million population)
What is the scope of the outbreak affected area and extent of epidemiologically linked populations?

The geographic scope under consideration for a response should take into account epidemiologically-linked populations, including defined areas of ongoing circulation as well as other areas of high risk. The scope may include an entire country, or for large countries, could include a sub-national region/urban area with at least 10 million population. Note that in some situations, epidemiologic links may include homogenous populations who regularly inter-mix and cross international borders so that areas of multiple countries may need to be included in the scope of the response.

The scope and scale of response may also be influenced by characteristics of the place such as environmental factors (e.g. poor sanitation and high force-of-infection), geo-political challenges (e.g. insecurity) and other geographic factors (e.g. transport links to high risk communities with immunity gaps).

iii) Characteristics of the affected population.
What are the estimated immunity levels of the population in the area where the poliovirus was detected? Does the community in which the virus was discovered have particular characteristics which may signal low immunity and/or an increased risk for transmission?

Although the greatest risk factor for emergence of a VDPV2 is low overall population immunity to type 2 poliovirus transmission, other risk factors include high birth rate, high population size and density, low routine immunization coverage, failure to reach unvaccinated children in pre-switch SIAs, and other conditions associated with high levels of fecal-oral transmission.

Vaccination coverage rates from both routine immunization programs and any SIAs in the area can be useful input, but this data must be analyzed in the context of any known information on the immunogenicity of OPV in order to provide an indication of population immunity. In many situations, vaccination coverage may be unknown but other population characteristics *(*e.g. marginalized or underserved, conflict-affected, history of immunization refusal, etc.) in the affected community may be indicative of low immunity. Detection of poliovirus in a mobile community or conflict zone may be of special concern for further spread.

Factors such as past epidemiologic history, location, and population characteristics may determine three general "transmission risk zones" that reflect the risk for any type 2 transmission (see **Table 3**).

Table 3. "Transmission risk zones" based on population risk for type 2 poliovirus transmission

Zone	Country/area and Population Characteristics	Risk for further transmission
1	Clear history of sustained WPV or reported **cVDPV2** since 2005; OR affected community with other risks for low immunity* or high mobility links to susceptible communities	High
2	Consistently low DTP3 coverage <80% in the previous 3 years; OR history of imported WPV or **any cVDPV or aVDPV2** in the previous 3 years; OR with DTP3 coverage <90% and adjacent to affected area	High-Medium
3	DTP3 coverage consistently >80%; affected community with few risk factors for sustained transmission	Low

*E.g. high birth rate, high population size and density, low routine immunization coverage, failure to reach unvaccinated children in pre-switch SIAs, and other conditions associated with high levels of fecal-oral transmission

c- Response strategies for phase 1

See **Table 4** for a summary comparison of the standard strategies for responding to any polio outbreak and steps required following detection of a type 2 isolate post-cessation of OPV2. Further details and comments on these strategies are provided below.

- **Vaccine choice:** Utilize mOPV2 as the vaccine of choice for response to stop type 2 poliovirus circulation during Phase 1, but there are specific targeted roles for the use of inactivated polio vaccine (IPV).

Special circumstances: Although tOPV and mOPV2 have similar immunogenicity against type 2,[37] use of tOPV in the post-switch era is not feasible due to logistical concerns and containment imperatives. Simultaneous bOPV and mOPV2 might be considered in areas at risk for WPV1 or WPV3. If an outbreak response to cVPDV2 requires multiple SIAs that overlap the switch, initiate any pre-switch SIAs with tOPV and request release of mOPV2 from the global stockpile to implement any SIAs planned post-switch.

mOPV2. Modeling suggests that a mOPV2 response sufficient to interrupt the live poliovirus transmission that caused the outbreak will not create new cVDPVs within the same population.[38] However, exportation of the OPV-related virus to other susceptible neighboring populations remains a concern. In addition, an inadequate response with mOPV2 long after initial SIAs have controlled an

outbreak also creates the potential for vaccine virus transmission. Nevertheless, the risk of remaining cVPDV2 circulation far outweighs the risk of seeding type 2 virus through mOPV2 SIAs.

IPV. While modeling has shown that a single IPV dose (such as given during routine immunization) may have only a modest impact on the probability of cVDPV emergence, a second IPV dose given in an outbreak response is expected to rapidly boost individual antibody titers.[39] Further indication of the potential role for IPV was demonstrated by a recent field study showing that one dose of IPV given to OPV-primed children significantly boosted intestinal mucosal immunity for types 1 and 3 compared to no vaccine and this boost was higher than what was achieved with an additional dose of bOPV.[40] The full impact on transmission of these clinical trial findings demonstrating an increase in mucosal immunity remains to be determined. However, preliminary analyses of polio case data in both Pakistan and Nigeria from March 2014 to October 2015 promisingly suggest that combined use of IPV + tOPV in endemic settings is associated with a measurable decrease in incidence of both wild and vaccine-derived poliovirus.[41]

Based on the evidence of IPV boosting of previously-OPV immunized individuals, IPV use along with mOPV2 in the outbreak response area may aid in preventing paralytic cases and limiting transmission--particularly within the first 12 months after the switch from tOPV. Additional use of IPV alone can boost individual immunity in surrounding high risk populations to mitigate the risk of mOPV2 exportations beyond the initial outbreak zone. On a smaller scale, IPV may also be utilized in selected individuals to provide protection for long distance travelers to infected areas (see section on IHR below) or close contacts of iVDPV or WPV2 cases.

Due to the projected limited global IPV supply through at least the end of 2017, full dose IPV will most likely not be available for outbreak response. Multiple studies have demonstrated the efficacy and operational feasibility of using fractional dosing through intradermal (ID) administration for IPV.[42] Therefore, full or fractional dose IPV (preferably administered with an ID device rather than a needle and syringe) may be used depending on vaccine availability.

***Other tools*.** The most common form of treatment for persons with primary immune deficiency disorders that may lead to an iVDPV is replacement therapy with intravenous immunoglobulin (IVIG). Polio anti-viral compounds and monoclonal antibodies have demonstrated therapeutic value in limited studies, but additional research is being conducted urgently to make these options widely available as potentially useful prevention measures.[43]

- **Vaccine Stockpile**. Request mOPV2 for type 2 outbreak response through WHO for allocation from the global stockpile managed in collaboration with UNICEF Supply Division. Member States that decide to establish a national poliovirus vaccine stockpile should maintain the stockpile in conditions of containment that are verified by the Regional Certification Commission for Polio Eradication to be compliant with the containment Global Action Plan and also seek authorization of the Director-General (DG) of WHO before release and use of mOPV2 [44] (See **Response Scenarios** and **Annex A** for further details).

In order to maximize the containment of type 2 poliovirus, the WHA has urged countries to rely on a global stockpile of mOPV2 managed under the authority of the WHO Director-General. Accordingly, WHO, in collaboration with UNICEF Supply Division and vaccine manufacturers, has established a stockpile of mOPV2 which can be rapidly provided to Member States based on an established request procedure in case of a type 2 outbreak. In line with the guidelines for a type 2 outbreak response in this protocol, countries should file a request for mOPV2 (and IPV if indicated for a SIA)[45] to WHO. A global advisory body will review the request and make a recommendation to the WHO Director-General who can authorize the release of mOPV2. Due to global supply constraints of IPV, UNICEF will coordinate shipments from available supplies of IPV when targeted to an outbreak response. Appropriate syringes and intradermal delivery devices will also be provided for fractional dosing of IPV.

- **Optimal number of Supplemental Immunization Activities (SIAs):** Conduct a minimum of four SIAs in response to *confirmed type 2 transmission*; however five (or more) SIAs may be needed in high risk settings (e.g. Transmission Risk Zones 1 or 2). Evidence of *probable transmission* will require a more situational response, but in most circumstances at least one initial SIA should be conducted while further investigation continues (See **Response Scenarios** below for further details and recommended SIAs).

- **Speed of Supplemental Immunization Activities (SIAs):** Conduct the first 'rapid response' SIA (e.g. SIA1) within 14 days of initial sequencing results provided by the GPLN.

Modeling[46] and multiple years of experience in responding to prior outbreaks of WPV and cVDPV have demonstrated that conducting an immunization response quickly even with moderate coverage for the first round will stop transmission in fewer rounds than waiting to intervene later in hopes of maximizing coverage through better organization. The implications are even greater in responding to an emergence of type 2 poliovirus given the potential ramifications of spread.

- **Interval of SIAs:** After SIA1, conduct subsequent SIAs (if required) within 2-3 week intervals as long as coverage is not compromised. Plan to begin the combined mOPV + IPV SIA (if required) no later than 45 days post outbreak confirmation. If additional time for planning or logistics is required, continue with mOPV2 alone in SIA2 and add the IPV to SIA3 in order not to delay any of the outbreak response. Local operational feasibility based on environmental, infrastructure, security, and programmatic factors should ultimately determine the intervals required to ensure safety and effectiveness.

- **Target age group:** During the first year after tOPV cessation, target **all** children under 5 years of age. To minimize the use of mOPV2 in the population, expanded age groups are not routinely recommended for a type 2 immunization response unless there is evidence of circulation among older persons.

- **Target population:** Target 500,000 children for SIA1 in the "rapid response area." Subsequent SIAs should include this group and increase the full "outbreak affected area" to cover a minimum of 2 million children. Where 2 million children do not exist within a reasonable radius, all children, or children of 10 million total population could be targeted. Consider increasing the scope further in densely populated areas or if there is evidence of extensive circulation (e.g. higher number of nucleotide changes) or if there is potential for extensive circulation (e.g. outbreak population well-connected to a major urban area). However, in all situations, the target population should not be increased beyond the capacity of the program to attain high coverage.

A global retrospective analysis in 13 countries with recent VDPVs found an average of 100,000 potentially exposed children (and likely less than 300,000 children) under 5 years of age prior to detection.[47] For the initial response to a VDPV after tOPV cessation, most of which will likely have 6-10 nucleotide changes, a conservative vaccination target up to 500,000 children should maximize the chances of containing transmission. Practical field experience to date has also demonstrated that this target represents the upper boundary of the number of children that can be effectively vaccinated through a rapidly organized SIA. Even if a cVDPV shows evidence of prolonged circulation, the priority for the initial SIA is to begin vaccination within 14 days of sequencing results using the 500,000 target, unless circumstances clearly suggest otherwise.

The minimum target for the second and subsequent SIAs needs to balance the requirement to stop transmission while minimizing the chances of reseeding the vaccine virus elsewhere. Related modeling shows that the exportation risk is very low during the period that population immunity remains high (e.g. during Phase 1) in most countries.[48] The target of 2 million reflects successful experience in the pre-cessation era. With high coverage, this target should be adequate to stop transmission in most areas, but could be expanded based on analysis of local risk factors.

Supplies permitting, the recommended target for the use of IPV in the expanded high risk area surrounding the outbreak is also 2 million children. While in general this intervention should target geographic areas adjacent to the outbreak affected area, the key objective is to raise individual immunity levels in populations that mix with or surround those receiving mOPV. Therefore, the size and location of the expanded high risk area to vaccinate may vary depending on the assessed risk of neighboring populations and degree of interaction with the affected community. Especially for highly mobile populations such as migrants, the targeted area may include non-adjacent pockets or transmission corridors.

d- Response scenarios for phase 1

The general GPEI performance standards and planning steps for any poliovirus outbreak response are detailed elsewhere.[49] **Figure 1** summarizes these steps and includes the specific measures required for a type 2 outbreak response. Depending on the situation, an outbreak or an event may trigger a vaccination response.

VDPVs (See **Figure 3a,** page 28)**.** Initial sequencing results of a **cVDPV** should prompt a rapid, small scale SIA response (e.g. SIA1) in all risk zones. For Transmission Risk Zones 1 or 2 one SIA after the first round (SIA2 if logistically practical) should use mOPV2+IPV in the outbreak affected area, and if IPV supply is adequate[50], target an additional 2 million children with IPV only in an "extended area" for high-risk populations. Other SIAs in the outbreak affected area should use mOPV2. For Transmission Risk Zone 3, target 2 million children with mOPV2 for SIAs 2 to 4.

Given the risks involved with a delayed response, proceed with an initial SIA following detection of a **'new VDPV'** even before final classification can be obtained.[51] **NOTE: implementing a rapid response SIA should not wait for full case or community investigation or for laboratory testing to rule out an iVDPV.**

If further contact tracing finds additional VDPV cases linked to the original isolate, classify as a '**new cVDPV'** and continue with *confirmed transmission* response SIAs for the appropriate transmission risk zone. If an **iVDPV** individual is discovered, treat the individual with IVIG and/or antivirals (when available) plus give IPV for any household members or close contacts. SIAs are not routinely recommended in response to iVPDVs whether the classification is made based on initial sequencing or after identification of an immunocompromised individual. However, one to three SIAs (each with a target of 500,000 children) may be considered in high-risk areas around the immunodeficient case, especially if the iVDPV is detected late in Phase 1 when type 2 immunity will have declined.

If further investigation does not discover either a new cVDPV or iVDPV, consider the isolate an **aVDPV**. Historically, most aVDPVs have occurred in isolation, but in the context of decreasing population immunity a higher fraction of aVDPVs may go on to become cVDPVs . Therefore, classification of an aVDPV should lead to close monitoring of surveillance performance standards for the next 3-6 months. Additionally, a more aggressive vaccination response to an aVDPV may be required if it meets one of several criteria: i) interval from the switch is >6 months; or ii) occurrence in an area with prior cVDPV emergence; or iii) substantial genetic deviation from a parent Sabin virus (e.g. evidenced by nucleotide deviations or recombination with class C enterovirus). In these situations or in an area otherwise considered high risk for transmission, after the initial rapid response SIA, proceed with at least two more SIAs each targeting 2 million children with mOPV2.

WPV (See **Figure 3b,** page 29)**.** In the unlikely event of detecting a **WPV2 human/AFP case**, promptly determine whether the individual has a known type 2 exposure due to a containment breach. In the instance of known, documented exposure, vaccinate close contacts with IPV; but no further vaccination response is required unless active surveillance provides evidence of other cases. If no exposure can be documented, respond aggressively according to the *confirmed transmission* scenarios for a cVDPV.

For a single **WPV2 ES sample**, rapidly assess the community for evidence of an individual excreting virus (e.g. a polio compatible AFP case or a WPV case). Multiple ES samples with sequencing which indicates >1 infected individual[52] may also demonstrate virus excretion in the community. If evidence of excretion is found, respond according to the WPV2 case scenario. If no evidence is found, consider at

least one rapid response SIA especially in Transmission Risk Zone 1 or any area deemed to be at high risk.

Sabin ES sample or individual (See **Figure 3c,** page 30). Detection of Sabin type 2 poliovirus in stool within 3 months or in sewage within 4 months of the switch (and/or mOPV2 response immunization) should encourage continued monitoring for Sabin type 2 poliovirus, but does not need to automatically trigger a search for OPV2-containing vaccine in the community. However, if there are any nearby laboratories or vaccine production facilities, prompt investigation should be undertaken to discover any breach in containment, to test workers as possible sources of poliovirus, and to review safety protocols, particularly in light of the deadline for all Sabin type 2 polioviruses globally to be contained or destroyed within 3 months of the switch.[53]

Detection of Sabin type 2 poliovirus more than 3 months after the switch in stool and more than 4 months of the switch in sewage suggests possible containment breach or continued use of tOPV after the switch. The sequencing of the isolated Sabin type 2 poliovirus and, if there are multiple isolates, analysis of trends in the detection of Sabin type 2 polioviruses, should guide further action. If the detected isolate sequence is ≥99.7% similar to the parent Sabin type 2 poliovirus sequence, the isolate probably originated from tOPV administered after the switch or a breach in containment and a search should be conducted for tOPV in use or storage in the area in which the Sabin type 2 poliovirus was found. If the detected isolate sequence is <99.7% similar to the parent Sabin type 2 poliovirus sequence, the isolate may have originated from tOPV administered prior to the switch and may represent an outlier in excretion descended from polio vaccine viruses. A search for tOPV may still be warranted unless sequencing results compared to prior Sabin type 2 samples demonstrate a continued decline in similarity to the parent Sabin strain.

Primary actions required by national public health authorities:

- Based on the risk assessment (Tables 2 and 3) and strategies noted above, implement the recommended response according to the appropriate scenario of type 2 virus classification (Table 1).
- If indicated, request mOPV2 (and IPV) for type 2 outbreak response through WHO for allocation from the global stockpile. Requests should be submitted in two stages. Submit the Stage 1 request for vaccines required for SIA1 within 24 hours of validation of sequencing results. The Stage 2 request covering vaccines needed for all subsequent SIAs should be submitted within the two weeks following outbreak/event confirmation. (See **Annex A** for details.)

3.5 Travelers and quarantine

Due to the high likelihood of ongoing undetected poliovirus circulation in the situations of confirmed or probable poliovirus type 2 transmissions, strict quarantine of individual polio cases will have limited impact on stopping the outbreak unless there is a documented exposure to a type 2 poliovirus. On a population wide basis, travel and migration patterns in and out of affected communities can have a significant impact on the risk and extent of poliovirus circulation, but even in the face of major epidemics enforcing local travel restrictions has proved challenging. Nevertheless, in the situation of a type 2 poliovirus outbreak, local epidemiologic, geographic, and population mobility factors should be used to determine the specific boundaries of the outbreak affected area.

***Primary actions required by national public health authorities*:**

- Consider imposing a local quarantine in situations where a single individual has a documented exposure to poliovirus type 2 (e.g. in a laboratory or vaccine production facility). Continue further investigation and close surveillance of family members and/or co-workers for at least 60 days post initial case detection.
- Based on local feasibility and assessed risk, consider implementing local travel restrictions and/or proof of polio vaccination for travelers of any age into/out of the outbreak area. This is in addition to the IPV SIA recommended for adjacent high risk populations in the scenario of confirmed transmission. Community organizers may be mobilized to engage the population in risk reduction behaviors, including vaccination and voluntarily restricting travel.

On 5 May 2014, the Director-General declared the international spread of wild poliovirus a public health emergency of international concern under the International Health Regulations (2005).[54] Since then, The *IHR Emergency Committee* has met regularly to issue advisories to polio-affected countries regarding measures they should undertake to restrict the international spread of poliovirus, including heightened surveillance and traveler vaccination. [55]

Primary actions required by WHO and national public health authorities:

- In accordance with national regulations and IHR (2005) Articles 30-32[56] WHO and national health authorities should collaborate to implement international travel restrictions as necessary. International traveler verification of IPV vaccination should follow guidance in the IHR (2005).

3.6 Outbreak/event response assessment and follow-up steps

The urgency of stopping any type 2 poliovirus transmission as soon as possible underscores the need to follow up the initial response steps with ongoing evaluation of the impact. Since poliovirus transmission has been declared a public health emergency of international concern, specific oversight and reporting requirements will be required under IHR (2005).

***Primary actions required by national public health authorities*:**

- As with any SIA, institute adequate supervision, lot quality assurance, and independent monitoring of immunization activities to ensure the quality of the interventions.[57]
- Submit regular updates to the *IHR Emergency Committee* as requested.

Primary actions required by GPEI[58]:

- Conduct Independent Monitoring at least by SIA2. Also conduct outbreak/event response assessments by the third month from day 0 and continuing quarterly thereafter until 12 months have passed without a type 2 poliovirus identification.
- Confirm the end of the outbreak by validating the absence of poliovirus type 2 in the population and the environment 12 months after the onset date of the most recent case plus one month to account for case detection, investigation, laboratory testing and reporting period.[59] The final assessment should be submitted to the GCC for final verification that the outbreak has ended.
- Develop a six month plan for strengthening surveillance which should be monitored quarterly.
- Provide 'surge' technical support graded to risk of transmission and local response capacity.

Additional tables and figures

Table 4: Comparison of the standard strategies for responding to any polio outbreak and steps required post detection of a type 2 isolate post-cessation of OPV2

	Standard ***(e.g. response to detection of any type 1 or 3)***	***Response to detection of type 2***
General		
Objective	To provide standard operating procedures to respond to any polio outbreak or event	To provide strategy and guidance for detecting, notification, and response specifically to a type 2 poliovirus after OPV2 cessation
Target application	Any non-endemic country (previously free from polio for at least 6 months)	General strategies apply to any country. Response guidelines are directed to countries with prior use of tOPV within 1 year prior to OPV2 cessation.
Time frame	Ongoing	Begins with OPV2 cessation-1May 2016. Response guidelines limited to Phase 1 (e.g. ≤12 months post OPV2 cessation).
Detection	AFP surveillance supplemented by environmental surveillance (ES). If outbreak, enhance target to >3 NPAFP/100,000 pop <15yrs for 12 months in every 1st level sub-national area.	In addition, polio laboratories should prioritize processing any type 2 isolate.
Notification	Report all poliovirus isolation to WHO w/in 24 hours regardless of isolate (WPV, VDPV) or source (clinical case or ES sample).	Detection of any type 2 poliovirus (including Sabin2 >4 months post OPV2 cessation and/or mOPV2 response) reportable under IHR.
Rapid Assessment	Conduct rapid clinical and epidemiologic investigation of case and affected community.	In addition, investigate possible containment breaks for any Sabin2 isolation or post-switch use of tOPV (>4 months post OPV2 cessation).
Response		
Classification of response scenarios	Event (no evidence of transmission) or Outbreak (evidence of transmission).	Further classifies by status of type 2 transmission (See Table 1); -Outbreak=confirmed transmission; -Event= probable or possible transmission (includes detection of Sabin2 poliovirus)
SIAs	Required for outbreaks; typically not required for events (e.g. VDPV1 or 3) -SIA for WPV in ES based on situation	Required for outbreaks and some events. Based on all confirmed and most situations of probable type 2 transmission (e.g. VDPV2); -SIA for WPV2 depends on +/- known exposure and local situation
Vaccine of choice	Vaccine choice based on consultation with WHO; bOPV for WPV1 or 3 bOPV for cVDPV1 or 3	mOPV2 (+ IPV for confirmed transmission in a high risk area). Country must submit application to WHO for release of mOPV2 from global stockpile under authority of WHO DG
Number of rounds	≥3 SIAs	Confirmed transmission: min 4 SIAs, 5+ in high risk areas; Probable transmission: 1-3 SIAs depending on situation

Initial SIA	Within 14 days from sequencing results	Within 14 days from sequencing results
Interval between SIA rounds	First three rounds should be 2-3 weeks apart	2-3 week intervals; if SIA2 includes mOPV2 + IPV may require up to 4 weeks
Target age	All children under 5 years of age + an expanded age group in ≥1 SIAs	All children under 5 years of age unless there is evidence of circulation among older persons
Target population scope	Based on local situation, as advised by WHO and GPEI partners	500,000 for SIA1; minimum of 2 million for subsequent SIAs
Travellers	Travel restrictions and quarantine may be recommended by IHR EC.	In addition, consider quarantine of polio cases + possible local traveller vaccination requirements
Follow-up	Independent Monitoring (IM) within 1 month; outbreak response assessments (OBRA) every 3 months and continuing quarterly thereafter until 6 months without any further detection of the outbreak virus, with documentation of high quality eradication activities, and with evidence of sensitive and enhanced surveillance. In the absence of such activities, the outbreak is not considered closed until at least 12+2 months pass without detection of the outbreak virus. IHR EC may request longer follow-up.	Institute IM and OBRA. Outbreak cannot be considered closed until 12 months after the onset date of the most recent case PLUS 2 months to account for case detection, investigation, laboratory testing and reporting period. IHR EC must confirm closure status.

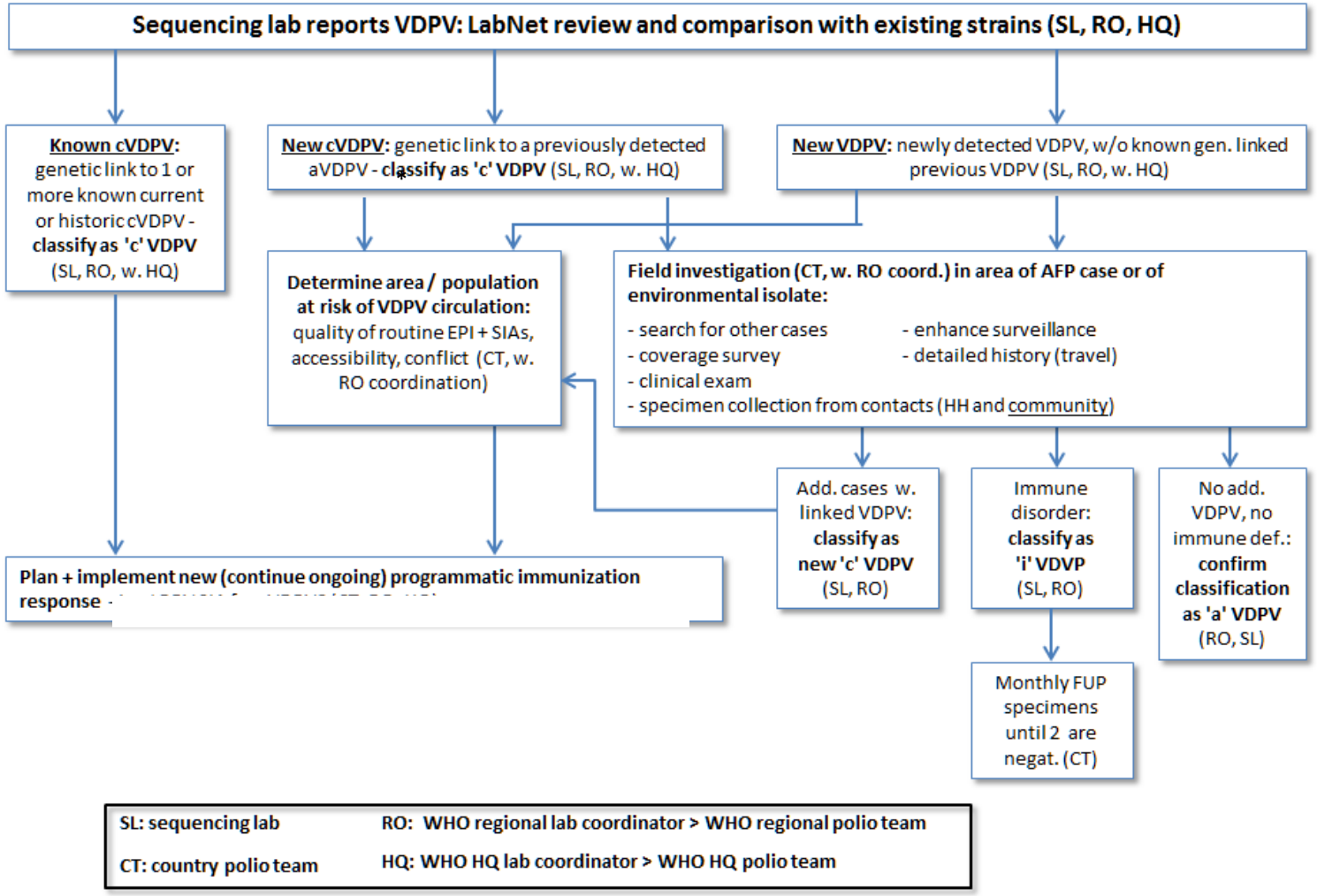
Figure 1: Timeline and responsibility for actions following detection of type 2 poliovirus

Action Steps	Days post sequencing results																	
	<0	**0**	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15-30	30
Detection																		
Virus isolation; ITD, sequencing by GPLN																		
Notification																		
Sequencing results notification to all GPEI by GPLN																		
Notification to WHO/HQ under IHR																		
Confirmation																		
Initial outbreak/event confirmation by MoH																		
Further confirmation by WHO RO as required																		
Final classification if required																		
Investigation and Risk Assessment																		
Enhance virologic investigation																		
Enhance AFP and environmental surveillance (ES)																		12mo.
Field investigation and/or active case search in area of ES																		
Conduct risk assessment																		
Response																		
Prepare SIA1 response plan & draft vaccine request																		
Submit vaccine request																		
EOMG prepares OPRTT response																		
Request evaluated by Advisory Group (EOMG^{+})																		
WHO DG authorizes release of mOPV2 from stockpile																		
EOMG initiates OPRTT response																		
Official notification to manufacturer																		
Manufacturer prepares shipment																		
Vaccine (& syringes) shipped to country																		
In-country processing and vaccine sent to field																		

Start of **SIA1**																	
Prepare SIA2+ response plan & submit Stage 2 vaccine request																	
Other steps as above																	
Start of **SIA2**																	
Primary responsibility																	
National MoH and/or Emergency Operations Center (EOC)																	
Global and regional partners																	
Both MoH & Global partners																	
Manufacturer																	
WHO																	
UNICEF																	

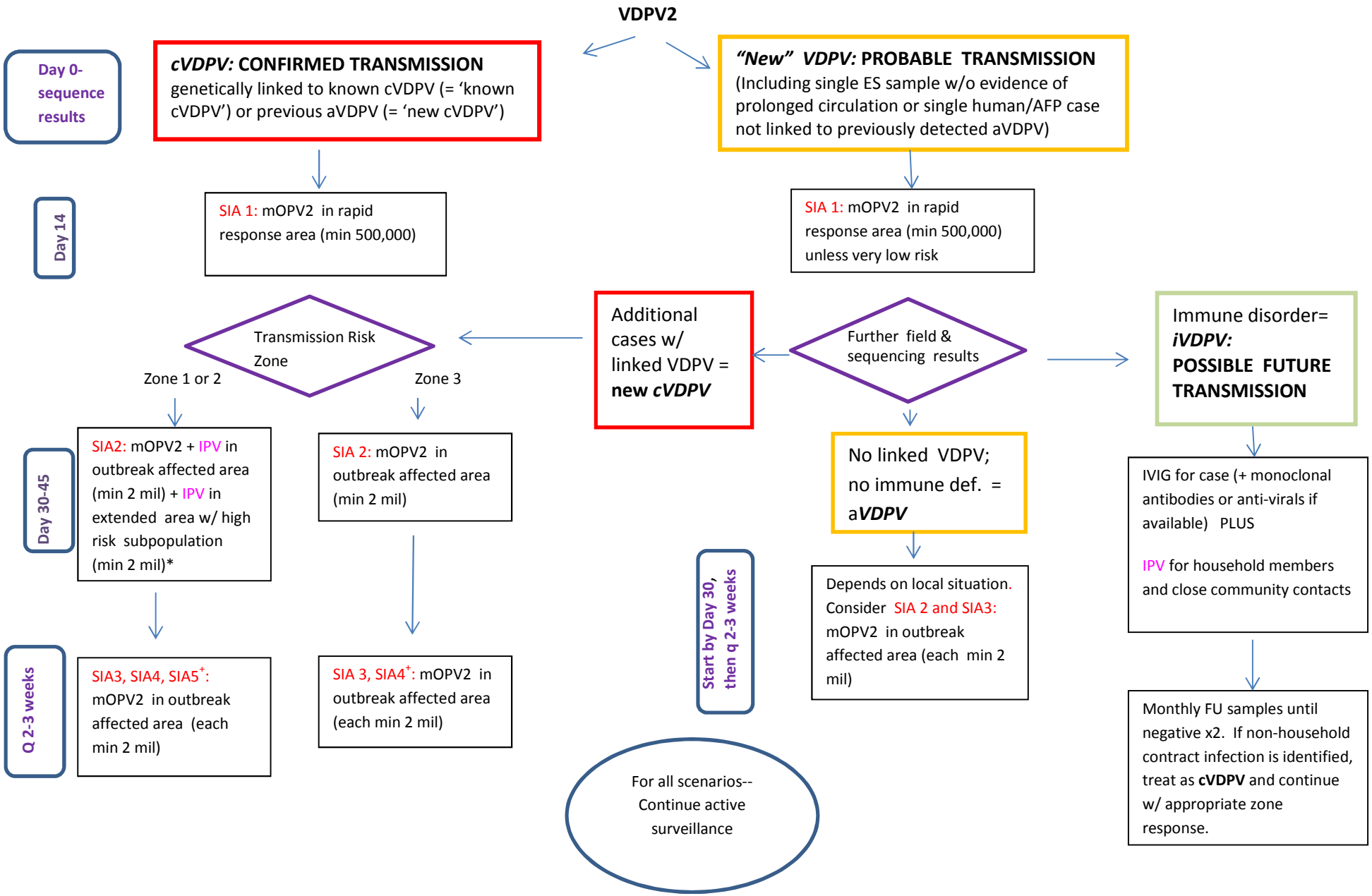
Figure 2: Classification of and response to reported VDPV isolates

Source: GPEI. Reporting and classification of vaccine-derived polioviruses. July 2015.
http://www.polioeradication.org/Portals/0/Document/Resources/VDPV_ReportingClassification.pdf



*or a single VDPV isolate with genetic features indicating prolonged circulation. .

Figure 3a: General response strategies by detection scenarios of a VDPV2 isolate during Phase 1 for countries with use of OPV within 1 year prior to type 2 OPV withdrawal



*combined mOPV2 + IPV campaign may be switched to SIA3 if there are logistical constraints

Figure 3b: General response strategies by detection scenarios of a <u>WPV2</u> isolate during Phase 1 for countries with use of OPV within 1 year prior to type 2 OPV withdrawal

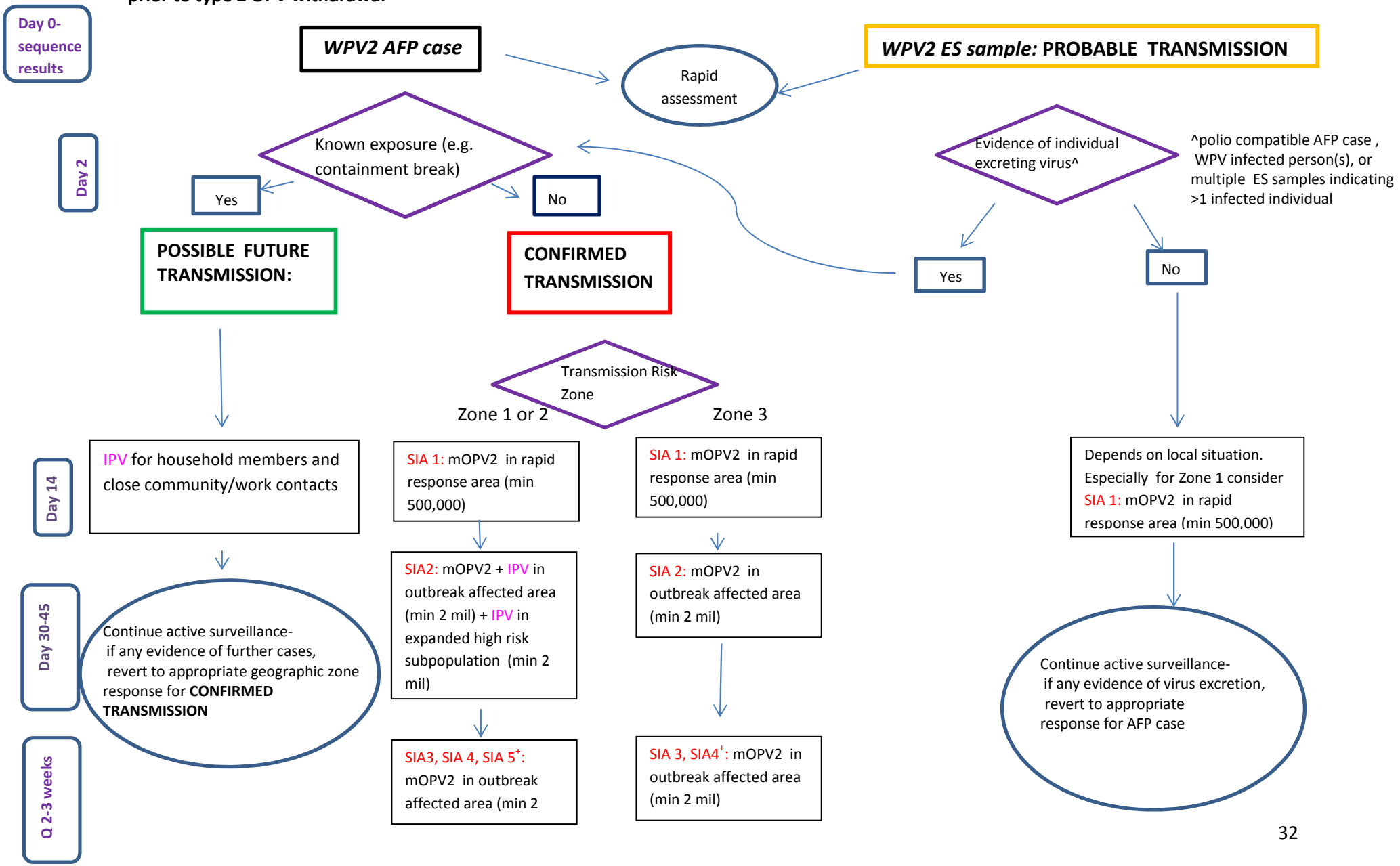
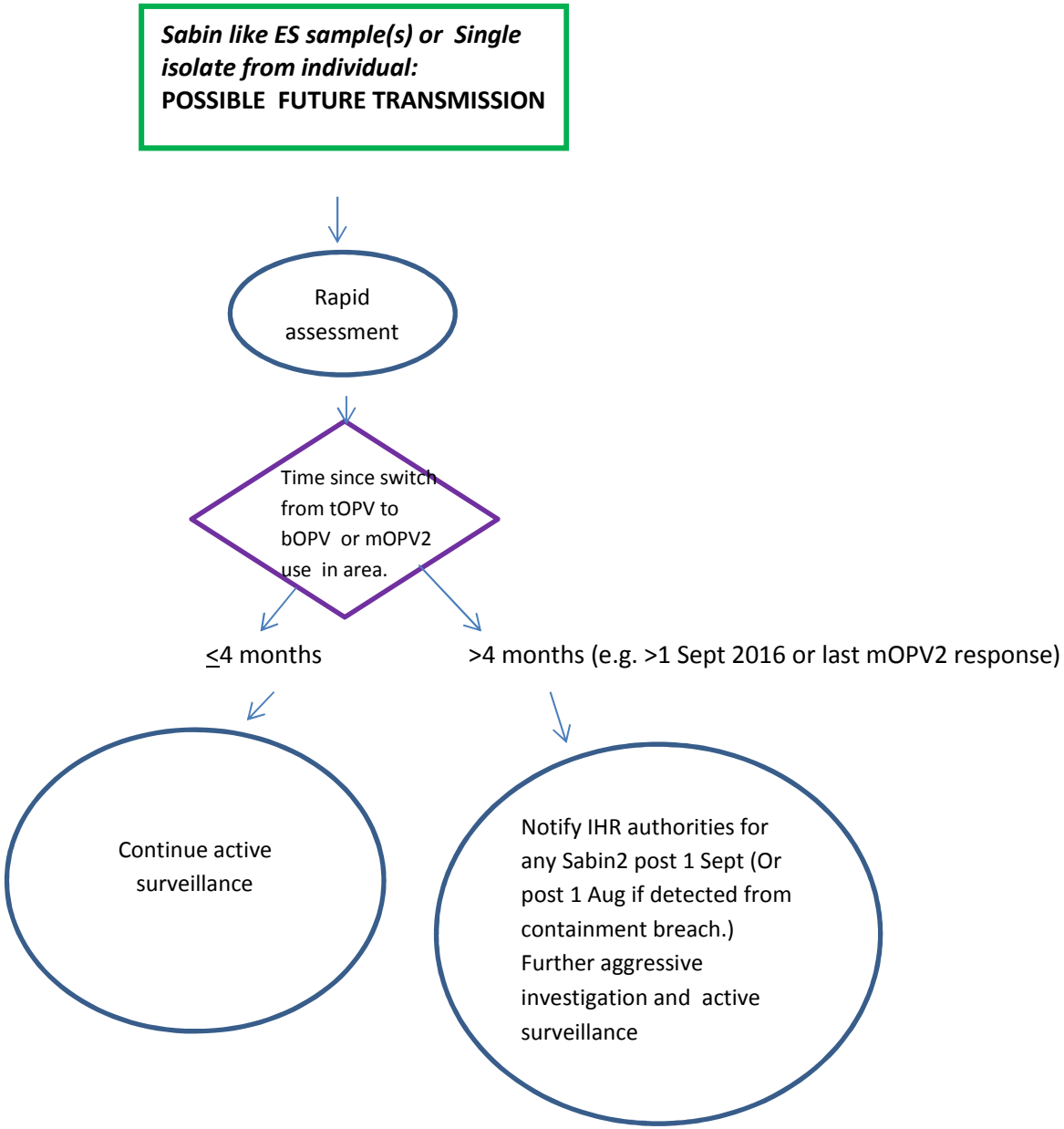


Figure 3c: General response strategies by detection scenarios for a Sabin2 isolate during Phase 1 for countries with use of OPV within 1 year prior to type 2 OPV withdrawal



Annexes

Annex A. Operational framework for monovalent oral poliovirus type 2 (mOPV2) stockpile deployment and replenishment after OPV2 cessation

1 Stockpile Objectives

In May 2014, the WHA endorsed the SAGE recommendation to establish a global stockpile of mOPV2 for responding to type 2 outbreaks post OPV2 cessation.[60] The primary objectives of the stock pile are: 1) to ensure rapid, universal supplies of mOPV2 for countries experiencing outbreaks of VDPV2 or WPV2; and 2) to maximize the containment of Sabin type 2 poliovirus. Specific quantities of vaccine will be released upon authorization of the WHO Director General.

2 Eligibility

All countries, whether or not they have previously received vaccines through UNICEF, are eligible to access the stockpile.

The SAGE has strongly advised that all countries should rely on this global stock. In May 2015, the WHA directed that any country that decides to establish their own national stock of mOPV2 should maintain the stockpile in conditions of containment that are verified by their Regional Certification Commission for Polio Eradication to be compliant with the GAPIII guidelines[61] and to seek authorization from the Director-General of WHO before its release and use.[62]

3 Stockpile content

WHO and the UNICEF Supply Division have collaborated with two vaccine manufacturers to establish a stockpile of bulk mOPV2. Both manufactures of mOPV2 vaccines have been licensed in the country of origin and their vaccines are pre-qualified by WHO.[63]

As of March 2016, the stockpile contains 519 million doses of mOPV2: 419 million doses of bulk vaccine (shelf life of 20 years), 50 million doses finished product ready for deployment by April 2016 and 50 million doses in semi-finished product (vials without labels) available by July 2016 which can be converted to finished product between September and December 2016. Vaccine will be processed to replenish the supply of finished product upon request from the GPEI to maintain stock levels.

4 Stockpile location, management, and governance

The roles and responsibilities of each party (e.g. manufacturers, WHO, UNICEF) are outlined in a contract for services with the manufacturers which builds on a Letter of Agreement between WHO and UNICEF. WHO maintains ownership of the stockpile. The manufacturers are responsible for storing and maintaining the stockpile under appropriate containment and quality assurance standards as well as preparing the vaccine for delivery in line with the agreed lead times. UNICEF has responsibility for procuring and coordinating the delivery of the vaccine to recipient countries when authorized by the WHO Director General based on national requests.

5 Decision making for release of vaccine

The objective of establishing the stockpile is to manage stocks of mOPV2 which will be required in all vaccination responses. (See **Response Strategies for Phase 1**, page 16). Countries (even those with their own national stocks) should submit a request for mOPV2 to a global advisory committee (the Eradication and Outbreak Management Group (EOMG) plus other technical experts) who will make a recommendation to the Director-General of WHO (DG). The DG's authorization permits release of mOPV2 from a national or global stockpile and initiates the process for shipping the vaccine to the requesting country as necessary.

Evidence of confirmed type 2 transmission in high risk countries will also require a response with IPV. Due to severe constraints in the global availability of IPV vaccine through at least the end of 2017 use of this vaccine for a type 2 outbreak response will need to be closely monitored and managed. Countries may use the same form to request both mOPV2 and IPV. As it does for IPV used for routine immunization, UNICEF in close coordination with global partners will manage the procurement and supply of IPV targeted for response to a type 2 outbreak in any non-producing country. If only a very limited number of doses of IPV are required (i.e. to vaccinate household contacts) countries should use their own national stocks.

See **Table 5** for a summary of the steps required for notification, confirmation, and response to a type 2 outbreak/event. Note that the steps and time frame may be revised based on experience and implementation of new laboratory procedures.

6 Stages in Accessing Vaccine Stockpile *(See also Figure 2)*

Vaccine will be requested in two stages: Stage 1 covers only the mOPV2 vaccine required for SIA1; Stage 2 covers vaccines (mOPV2 and if necessary, IPV) for all further planned SIAs.

Stage 1: In order to ensure a rapid response, the initial request (**see Annex B**) should be prepared within 24 hours of validation of sequencing results and include:

- Relevant laboratory and epidemiologic information of the investigation to date
- Basic profile of the affected population (e.g. vaccination coverage rates, summary of other risk factors, etc.)
- General response plan for SIA1 only, including requested quantities of mOPV2 vaccine
- Authorization for emergency use of mOPV2 based on WHO prequalification (See **Regulatory Considerations** below.)

Stage 2: Planning for subsequent response strategies will usually require further field investigation. Submit request for all subsequent SIAs together. Stage 2 request form should contain:

- Results of any further laboratory and epidemiologic investigation
- Response plan for all further SIAs (including specific number of vaccine doses required) and number of doses of any existing stocks of mOPV2 from SIA1
- If IPV is required (and not already licensed in the country), confirmation that the recipient country will accept the vaccine and has the regulatory procedure in place to authorize its anticipated use.

Table 5. Steps for notification, confirmation, and response to a type 2 outbreak/event [+]

Step	Action	Comments	Responsibility	Time frame@	Data or decision reported to	Days > Notification of Sequencing Results
Notification and Response Preparation						
1	Laboratory Notification of type 2 poliovirus isolate sequencing results		Global Polio Laboratory Network (GPLN)	-Complete w/in 14 days of initial isolation -Report w/in 24 hours of results	Notification to MoH, GPEI partners (including UNICEF SD)	Day 0
2a	Initial confirmation of outbreak/event & risk assessment *-national level*	Conduct rapid case confirmation and risk assessment. Further investigation should continue to aid in final classification (*see step 14*)	-MoH/EOC*(with local GPEI support if needed and available). -If outbreak/event is confirmed, IHR focal point has reporting responsibility	-Complete in <48 hours; report findings asap. -If outbreak/event is confirmed to meet IHR criteria, report in <24 hours of completing assessment through IHR protocol	-Report initial findings to WHO country and Regional Office. - Report to WHO IHR contact point	Day 0-2
2b	Confirmation of outbreak/event - *regional-global level*	Follow-up with MoH upon receiving lab notification. If any concerns, verify lab results with GPLN regional reference lab	WHO Regional Office polio focal point	Report immediately or in <24 hours of completing assessment	Notification to regional & global GPEI partners	Day 2
3a	Response preparation *-global level*	Prepare OPRTT^ response -Identify potential TA -Prepare funding	EOMG **	Begin <24 hours from lab notification		Days 0-2
3b	Response preparation *-national level*	Draft response plan & vaccine request simultaneously with rapid investigation	MOH/EOC (with GPEI if needed & available)	Begin <24 hours from lab notification; complete within 48 hours		Days 1-2
Stage 1 – Response Implementation						
4	Submit SIA1 vaccine request upon confirmation of outbreak/event	Complete initial risk assessment; finalize vaccine requirements per response plan	MoH/EOC (consult with WHO/UNICEF in-country)	<24 hours from confirmation of outbreak or event	EOMG**	Day 2
5	Vaccine request evaluated at global level	Assisted by WHO/POL as secretariat	Advisory Group (EOMG[+])	<24 hours	WHO Director General (DG)	Day 3
6	Vaccine stockpile release authorized	DG reviews Advisory Group recommendation	WHO DG	<24 hours	Authorization sent to UNICEF, MoH	Day 4

7	GPEI Response initiated	OPRTT^ support implementation -Grading -TA staff deployed -No regret funds released	EOMG**/OPRTT^	<72 hours from DG authorization	Communicates w/ other GPEI partners at all levels & MoH	Days 4-6
8	Official notification to prepare vaccines for delivery	Purchase Order issued to manufacturer	UNICEF Supply Division (SD)	<24 hrs from receipt of DG's authorization	Vaccine manufacturer	Day 4
9	Prepare shipment		Manufacturer-vaccine; UNICEF (or WHO)-syringes and safety boxes if required	3 working days	UNICEF	Days 4-6
10	Ship to recipient country		UNICEF SD (or WHO)	≤72 hours	Recipient MoH	Days 7-9
11	In-country processing and transport	Includes customs clearances; delivery to field level	MoH/EOC	≤5 days		Days 10-14
12	**SIA 1**		MoH/EOC +EOMG Rapid Response Team	3-5 days		Day 14+
Stage 2 - Response Preparation and Implementation						
13	Conduct further field + laboratory investigation to reach final classification	Simultaneous with Stage 1. Includes contact tracing, further labs to rule out immunodeficiency.	MoH/EOC + EOMG Rapid Response Team	7-14 days; further time may be required in some circumstances		Day 0-13
14	Prepare further response plans (SIA2+) & Stage 2 vaccine request	Simultaneous with Stage 1. Request should include vaccines required for all additional planned SIAs.	MoH/EOC + EOMG Rapid Response Team	7-14 days	WHO HQ	By day 14
	Repeat steps 4-12	Delivery may take longer than in Stage 1 when syringes required.	All	16 Days		Days 15-30
	Implement **SIA 2 and additional SIAs**		MoH/EOC + EOMG support as necessary			By day 30-45; then q2-3 wks
	Proper containment & disposal of mOPV2	Should take place after each SIA w/ validation after last SIA.	MoH w/ assistance of GPEI	Final stock report w/in 2 weeks of last SIA		

+NOTE: Steps and time frame may be revised based on experience and implementation of new laboratory procedures

@: All time frames indicate intended targets. Some steps may be accomplished quicker; others, particularly for logistics, may take longer depending on local conditions, flight schedules, etc. *EOC-Emergency Operations Center; **EOMG-Eradication & Outbreak Management Group; ^OPRTT-Outbreak Preparedness and Response Task Team; ^^NRA-National Regulatory Authority

7 Logistics

a. Shipping

UNICEF will coordinate with the supplier to organize shipment of mOPV2 and IPV. Depending on supplier, UNICEF or WHO will organize shipment of and syringes/ID devices and safety boxes as appropriate for the outbreak response.

b. Documentation

The list of documents in the packing list to accompany each vaccine consignment is listed in the contract for services with the manufacturer and includes: (a) Invoice; (b) Air Waybill; (c) Release certificate issued by the National Regulatory Authority of the country of manufacture for each lot of vaccine supplied; and (e) Vaccine Arrival Report (VAR). Temperature recorders will be including in the consignment as per guideline for international shipping of vaccine. A vaccine vial monitor (VVM) will be placed on each vaccine vial as for any WHO pre-qualified OPV vaccine. Any additional documentation requirements from recipient countries will not be accommodated and will need to be waived to ensure timely delivery.

c. Vaccine specifications and storage at country level

WHO and UNICEF will work closely with the recipient country to assess the storage volume required for the outbreak response vaccine and ensure sufficient cold room space at -20°C or 2°C to 8°C at the national level as well as adequate capacity at all relevant links of the cold chain. Vial sizes will depend on available supply. Refer to the request form for estimated volumes and storage requirements for both mOPV2 and IPV.

d. Management of unused stocks

The program should rigorously manage and monitor utilization of mOPV2 stocks.[64] After each SIA, all vaccine doses utilized and balance stock remaining (unopened vials) should be reported to district level within 2 days of completion of round. These unopened vials should be retrieved by the district level cold store within 5 days of completion of round. The district level cold store should report mOPV2 stock levels to the national EPI manager within one week of SIA completion. Supplies to the district for the next mOPV2 SIA round should be adjusted against these available stocks.

The district level cold chain manager should clearly segregate and store any retrieved mOPV2 vials separately from bOPV stocks. Open vials of mOPV2 remaining after each SIA should be securely disposed at the local level using the same guidelines issued for disposal of tOPV.[65]

Within two weeks of completing the last SIA required in the response plan, countries must report their remaining stock levels of mOPV2 to WHO and UNICEF as outlined in the revised Standard Operation Procedures for Vaccine Management (SOP-VM2).[66]

All district stores should take remaining unopened mOPV2 vials out of the cold chain, label, and mark them clearly as explained in tOPV-bOPV switch guidelines. These vials should then be collected at regional stores and disposed of properly as per national regulatory procedures.

Further detailed guidance for country programs is being developed by GPEI.

8 Regulatory Considerations

a. Role of National Regulatory Authorities (NRA) in licensing and oversight

The 68th WHA urged all member states to establish procedures to authorize the importing and use of mOPV2 in the event of a type 2 outbreak. Since the procedure to license vaccine even in the case of a fast track procedure may be time consuming, high risk countries (e.g. those in transmission risk zones 1 and 2) should take steps in advance to ensure that mOPV2 can be rapidly deployed if necessary. WHO will provide technical support for these countries to facilitate implementation of this authorization procedure. Recipient countries may preemptively authorize use of mOPV2 based on licensure issued by the stringent NRA process in the producing country and the knowledge that the vaccine is prequalified by WHO. If not already completed, this authorization should be included as part of the vaccine request and will confirm that the recipient country will accept the vaccine and has the regulatory procedure in place to sanction its intended use.

If IPV response is recommended, the recipient country will also need to confirm it will accept the vaccine and has the regulatory procedure in place to authorize its intended use.

b. Prequalification

The mOPV2 products in the stockpile and IPV provided for outbreaks are licensed in the country of origin and WHO-prequalified. As for any vaccine supplied through UNICEF, the manufacturers are responsible for submission for WHO prequalification and for maintaining the prequalification status to cover the period of the stockpile contract.

Annex B: Vaccine request form

Refer to GEPI website (under publication)

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[50] In the face of limited IPV supply, the first priority for use of IPV is to target children in the outbreak affected area.
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