Standard
Operating
Procedures

Responding to a poliovirus event and outbreak

Updated according to WHO guidelines from May 2017

This is a version of the original two-part document drawn up by the WHO and adapted by the Pan American Health Organization for the Region of the Americas.

Further information on responding to polio events and outbreaks is available at:

www.paho.org/immunization/polio

Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

Contents

List of abbreviations

AFP	Acute flaccid paralysis
aVDPV	Ambiguous vaccine-derived poliovirus
bOPV	Bivalent oral polio vaccine (contains Sabin types 1 and 3)
cVDPV	Circulating vaccine-derived poliovirus
EOMG	Eradication and Outbreak Management Group
EPI	Expanded Program on Immunization
ES	Environmental surveillance
GAPIII	WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of routine OPV use (third edition)
GPEI	Global Polio Eradication Initiative
GPLN	Global Polio Laboratory Network
IHR	International Health Regulations (2005)
IPV	Inactivated polio vaccine
iVDPV	Immunodeficiency-associated vaccine-derived poliovirus
mOPV2	Monovalent oral polio vaccine (contains Sabin type 2)
OBRA	Outbreak response assessment
OPRTT	Outbreak Preparedness and Response Task Team
OPV	Oral polio vaccine
OPV2	Oral polio vaccine that contains type 2
PAHO	Pan American Health Organization
SOP	Standard Operating Procedure
tOPV	Trivalent oral polio vaccine (contains Sabin types 1, 2 and 3)
VDPV	Vaccine-derived poliovirus
VDPV2	Vaccine-derived poliovirus, type 2
WHO	World Health Organization
WPV	Wild poliovirus
WPV2	Wild poliovirus, type 2

1. Foreword

Ensuring a rapid and effective response to any poliovirus event or outbreak, following the importation of the virus or the emergence of a vaccine-derived poliovirus, is crucial to the success of polio eradication.

The World Health Organization (WHO) has drawn up some standard operating procedures (SOPs) to guide countries in developing their respective plans on how to respond to a poliovirus event or outbreak. They encompass lessons learnt from previous outbreak response efforts and outline the steps to be followed in cases of a (type 1, 2 or 3) poliovirus event or outbreak.

Based on these SOPs, the Pan American Health Organization (PAHO/WHO) has developed this document to cover all key elements to be considered in such a response plan. It is designed for the technical teams in the countries of the Region responsible for coordinating the national response to a poliovirus event or outbreak.

This document establishes some strategic guidelines on how to respond to events or outbreaks caused by any type of poliovirus. However, the recommendations focus primarily on type 2 virus detection response during the first 12 months after withdrawal of the type 2 component from the oral polio vaccine (OPV), which is taking place between May 2016 and April 2017. The recommendations are mainly for countries that used the trivalent oral polio vaccine (tOPV) in the 12 months prior to the switch to the bivalent vaccine (bOPV).

In responding to a poliovirus event, some common steps must be taken irrespective of the type of poliovirus, as well as some more specific steps depending on the strain detected and its origin. Accordingly, this document has been structured into three large sections based on the type of poliovirus detected and the origin of the sample:

- Type 2 poliovirus detection
- Type 1 or 3 poliovirus detection
- Poliovirus detection in environmental samples.

We hope that this document will serve as a useful tool so that countries may be timely and effectively prepared to respond to any poliovirus event or outbreak.

Note: Further adjustments to type 2 polio response may be necessary after 30 April 2017, which marks one year after the tOPV/bOPV switch.

2. Introduction

The Region of the Americas was certified polio-free in 1994. This was achieved with the use of trivalent oral polio vaccine (tOPV) in routine vaccination programs and major vaccination campaigns.

The last poliomyelitis case caused by the wild type 2 poliovirus (WPV2) worldwide was detected in 1999. However, since 2000 the Sabin type 2 poliovirus has been responsible for most circulating vaccine-derived poliovirus (cVDPV) cases, and for a large proportion of vaccine-associated paralytic poliomyelitis cases.

In response to this situation and with the broader implications of OPV use following the global eradication of poliomyelitis, the Polio Eradication & Endgame Strategic Plan 2013–2018 guided countries using only tOPV in their vaccination schedules toward introducing at least one IPV dose into their routine vaccinations before the withdrawal of the type 2 component from the oral polio vaccine (OPV). This was achieved through a synchronized worldwide switch from tOPV to bivalent oral polio vaccine (bOPV), which contains only types 1 and 3.

As a result of the OPV2 withdrawal (the switch), between 17 April and 1 May 2016, there will be a gradual decline of type 2 population immunity, especially intestinal immunity, thus increasing the risk of an epidemic outbreak following exposure to the type 2 poliovirus. Therefore, the detection of any type 2 poliovirus (wild, vaccine-derived or Sabin) in any sample of any origin is therefore considered a global public health emergency warranting a rapid and coordinated response, at international, national and subnational levels. At least one cVDPV2 and several VDPV2 cases are likely to emerge within 12 months of the global switch from tOPV to bOPV.

A critical factor to the successful eradication of polio is ensuring a rapid and effective response to type 2 poliovirus, as well as type 1 and 3, following virus importation, reintroduction due to containment breaches, or VDPV emergence.

3. Objectives

The objectives of this document are:

a. To establish standards and timelines for the notification, investigation, risk assessment, response, and response assessment following any confirmed wild, VDPV type 1, 2 and 3, or Sabin type 2 poliovirus detection.
b. To provide national governments and partners with guidance on the key coordination and support actions that must be taken in response to any polio event or outbreak.

4. Preparation

In order to provide a rapid and effective response to a polio event or outbreak, several activities must already be prepared before any such event or outbreak is detected. The actions recommended in this section should be developed in advance, so that countries are duly prepared for any eventuality.

4.1 Management structure

- Devise a polio event/outbreak management mechanism; identify who is responsible for the overall coordination and members of the team responsible for planning, investigation, intervention and communication, etc.
    - The management team should include, at least, the person responsible for the immunization program, for epidemiological surveillance, communication and social mobilization, and logistics and finances; to guarantee proper implementation of the intervention strategies should a poliovirus outbreak or event occur.
- Define the management teams at decentralized levels.

- Identify other partners and institutions that should be involved in the response, for example the Ministry of Education, Social Security, and UNICEF.
- Draw up a list of the names and contact details of all members of the management team and of the partners involved.

4.2 mOPV2 use

Countries should ensure that they can rapidly obtain mOPV2 supplies if needed in the event of an outbreak. These vaccines are obtained from the global outbreak response stock pile and are delivered through UNICEF (Annex 1).

4.3 IPV use

As of May 2017, the use of IPV is no longer recommended to respond to outbreaks caused by poliovirus type 2, even in fractionated doses. IPV is only recommended for contact vaccination of an iVDPV2 case.

4.4 Preliminary Training Plan

A preliminary training plan on outbreak response should be developed, which can then be adapted accordingly.

4.5 Preliminary Communications Plan

For the purpose of facilitating rapid and effective communication, the country should prepare in advance key messages addressing health workers, which can be adapted depending on the type of event. Also, the country should formulate messages to be transmitted to the community, clarifying the meaning and importance of the event. Model press releases should also be drafted.

4.6 Preliminary Supervision Plan

Prepare a preliminary supervision plan for the event/outbreak response, including the removal of all mOPV2 and the safe destruction of opened and unopened vials.

4.7 Preliminary Budget Plan

Key components for the preparation of the response budget should be identified in advance.

4.8 Familiarization with the information required for the risk analysis (Annex 3)

If a poliovirus event or outbreak is detected, the country will have to conduct a risk analysis and submit it to WHO within 24 hours. Although this risk analysis cannot be completed until the actual event unfolds, the country should be familiar with the information that will be required and be able to identify the source of this information. This will facilitate the data collection process, should this be necessary (Annex 3—Information necessary for the transmission risk analysis).

4.9 Preparation for the Rapid Response Team (Team A)

The Global Polio Eradication Initiative (GPEI) will offer the country support for the event/outbreak response (see section 9 for more information). This includes deploying a Rapid Response Team (Team A) within 72 hours, whose members may require visas to enter the country. The country should implement mechanisms to expedite the visa application process for those participating in the initial outbreak response.
A second Surge Response Team (Team B) will also be deployed within a period of 3 weeks.

5. Definitions

5.1 Definition of poliovirus events and outbreaks

Table 1 classifies all poliovirus strains according to whether their appearance is regarded as an "event" or an "outbreak" for the purpose of describing the extent of person-to-person transmission and defining the appropriate response.

Table 1: Epidemiological definitions of poliovirus events and outbreaks

Typology	Definition
Event (as yet, no evidence of transmission)	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 (immunodeficiency-related **VDPV [iVDPV]** or ambiguous [**aVDPV]** strains) OR 2) **Sabin type 2** in one or more clinical samples OR 3) **WPV2** infected individual with documented type 2 virus exposure in a laboratory or vaccine-production facility
Outbreak (evidence of transmission)	Detection of 1) Any **WPV** infected individual(s) [a] (in 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]

[a] An infected person could be an AFP case or an asymptomatic/healthy person.

5.2 Vaccine-derived polioviruses

The following definitions have been developed, taking into account virological and epidemiological considerations, and should be used when referring to vaccine-derived poliovirus:

a) Vaccine-derived poliovirus (VDPV)

- OPV strains that are >1% divergent (> = 10 nucleotide (NT) changes for types 1 and 3) in the VP1 genomic region
- OPV strains that are > 0.6% divergent (> = 6 NT changes for type 2) in the VP1 genomic region.

b) Circulating VDPV (cVDPV)

VDPV isolates for which there is evidence of person-to-person transmission in the community:

i) From at least two individuals (not necessarily AFP cases) who are not household contacts

ii) From one individual and one or more environment samples.

iii) A single isolated VDPV, with genetic characteristics indicating a prolonged circulation (ie, a number of nucleotide changes indicating ⩾1.5 years of independent circulation).

c) Immunodeficiency-associated VDPV (iVDPV)

VDPV isolate from persons with primary immunodeficiency evidence.

d) Ambiguous VDPV (aVDPV)

VDPV isolates from individuals with no known immunodeficiency or from the environment, without evidence of circulation.

A VDPV isolate should only be classified as "ambiguous" if additional investigations have excluded that it is derived from a person with primary immunodeficiency of B lymphocytes (iVDPV) or that it is part of an ongoing chain of transmission, i.e. a circulating VDPV (cVDPV).

6. Poliovirus 2 detection

6.1 Notification

The timely reporting of any type 2 poliovirus detection is key to triggering the response measures and avoiding the spread of the virus. Notification is carried out at both national and international levels.

In accordance with International Health Regulations (IHR) obligations:

- Laboratory isolation of a type 2 poliovirus (wild, vaccine-derived or Sabin) in the country where the sample was obtained must be reported immediately to the competent authority of the country, to the PAHO IHR Focal Point (via the National IHR Focal Point) and the PAHO country office at the same time
- When a positive type 2 poliovirus sample is detected in an international reference laboratory, the authority of the country where the sample was obtained will be notified. If this country fails to issue the international notification within 24 hours, the National IHR Focal Point in the country that isolated the poliovirus should notify WHO and PAHO country office at the same time.

The national government, with PAHO/WHO support and backed by the GPEI partners, will declare the poliovirus type 2 event or outbreak as a potential “national public health emergency”.

The national government will report it to WHO as a potential "public health emergency of international concern", in accordance with IHR (Annex 2).

6.2 Investigation

The detection of any type 2 poliovirus should trigger an immediate investigation with the aim of gathering all the information necessary to determine whether it is an event or outbreak; to determine the number and characteristics of the case(s); to identify the origin and causes of the event or outbreak; and to evaluate the geographic extent of the transmission.

Table 2: Definition of poliovirus events/outbreaks and classification of type 2 transmission

Typology	Sample source	Classification
Event	*Human/AFP* [b]	VDPV2 under investigation
		aVDPV2
		iVDPV2
		Sabin 2
		WPV2 with documented exposure in a laboratory or vaccine-production facility
Outbreak	*Human/AFP* [b]	cVDPV2
		WPV2 without documented exposure in a laboratory or vaccine-production facility

[a] Other factors (e.g. force-of-infection, population density, season of outbreak, indigenous versus imported virus, etc.) will ultimately determine the risk of further transmission and will directly influence the type and scale of the response required.
[b] An infected individual may be an AFP case or asymptomatic/healthy person.

The final decision on defining the isolation of a poliovirus strain as an event or an outbreak is made following discussions between the country where strain was detected and PAHO/WHO, after having conducted the risk assessment.

a. Case and contact investigation

An immediate field investigation of every AFP case should determine the specific characteristics of the case and trigger active case searching in the community and at local notification centers.

The following activities will be undertaken to characterize the situation.

- **Case investigation**
  Investigate the medical history including immunodeficiency history or signs, vaccination history, travel history, history of contact with travelers from abroad, social environment, community context, or whether or not the person is a clinical laboratory or vaccine-production facility employee/contact.

- **Contact investigation**
  Sampling: A stool sample should be collected from at least five direct contacts (i.e. siblings, household contacts, or playmates) and from at least 20 persons of the same age group living in the community of the affected area[1] to determine if there is circulation.

b. Active institutional and community case finding

- Active institutional search for AFP cases in public and private hospitals.
- Active community case finding in the area of residency, using different search strategies (in educational centers, day-care centers, and residences).

c. Immunization coverage analysis

The analysis of the coverage of routine vaccination programs and vaccination campaigns in the affected area (to the most disaggregated level of coverage available) provides key information that should be considered together with known epidemiological information in order to identify the population's susceptibility and the risk of transmission.

d. Laboratory

In addition to identifying if the isolated poliovirus is a wild, vaccine-derived or Sabin poliovirus, genetic analysis also helps identify if the virus has been imported or if there has been a containment breach. It also reveals if it concerns a vaccine-derived poliovirus, the length of time the virus may have been circulating, or excreted in the case of an iVDPV isolate.

6.3 Risk assessment

The country, with the support of PAHO/WHO and GPEI partners, will carry out a risk assessment whenever there is an event or an outbreak. The aim of this assessment is to characterize the viral transmission and the risk of further spreading. It assesses critical factors that will influence the type and scale of the response, and help formulate the recommendations on the measures to be taken. It will also identify sub-populations outside the affected area that could be at risk of possible transmission.

It is essential to evaluate the virological and epidemiological risk factors for risk assessment in a given context. For each type of virus detected, it must be determined if this finding represents a high or medium-low risk of subsequent transmission, based on multiple factors in three areas (virology, local context and risk of international spread). Instead of specific quantitative parameters, the evaluation should reflect a general assessment of the situation. The relative "weight" of each category will depend on the situation and any attenuating factors taken into consideration.

[1] Affected area is considered at the third geopolitical administrative level; the site or place where the poliovirus was isolated

Table 3. Elements to assess risk for further type 2 poliovirus transmission and that will influence type and scale of response

Critieria	Sample of elements considered (not exhaustive)
Virologic risk	degree of genetic deviation from parent Sabin, virologist assessment / interpretation of types of nucleotide changes etc.
Contextual risk	limited access due to conflict, recent poliovirus detection, high force of infection, population movement etc.
Risk of international transmission	border area with high population mobility, nomadic or refugee populations etc.

The risk assessment should focus specifically on addressing three core questions:

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

Following initial detection, intratypic differentiation and sequencing, a poliovirus isolate may be grouped into one of three categories: 1) WPVs, 2) Sabin (OPV strain), and 3) VDPVs (>1% divergence [PV1 and PV3] or >0.6% [PV2] from the corresponding OPV strain).

1. Nature of the virus (WPV, Sabin or VDPV) and evidence of circulation

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 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 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 environmental surveillance (ES) site as well as in any nearby laboratory or research facility in an attempt to identify AFP cases or rule out individuals with ongoing subclinical infection excreting the poliovirus. A cautionary approach dictates that discovery of a WPV2 in an environmental 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 tOPV use (and/or mOPV2 use).[2] While this detection should prompt increased AFP surveillance, this risk should rapidly diminish with time.[3] Detection of Sabin type 2 polioviruses after this 4-month period following the switch (i.e. from September 2016 onwards) or last mOPV2 use in an outbreak/event response could be evidence of continued use of OPV2 and as such would represent a risk for *possible future transmission*. A single AFP case with a Sabin type 2 poliovirus could also indicate isolated exposure in a vaccine-production facility or research laboratory.[4] This situation warrants a thorough case investigation, including checks for any remaining local tOPV stocks and a review of containment procedures and good manufacturing practices at nearby facilities.

VDPV2. In the immediate post-switch era, the most commonly detected poliovirus, aside from Sabin 2 isolates, will most likely be VDPV.[5] Since a known cVDPV or a previously detected aVDPV is evidence of active circulation and *confirmed transmission* in the community, its isolation represents the same threat to public health as the isolation of WPV.[6]

VDPV2 under investigation. A single VDPV2 sample without evidence of prolonged circulation, or a single VDPV2 case unrelated to a previously detected aVDPV could only suggest an isolated episode without further consequences. However, given the enormous implications of failure to provide an immediate response to any type 2 virus transmission, even at low levels, the identification of these cases should initially be considered evidence of *probable transmission*.

iVDPV. Case investigation should determine whether an individual VDPV case might constitute a long-term immunodeficient poliovirus carrier (i.e. an iVDPV).
The initial iVPDV classification 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.
Acute or chronic malnutrition, which may cause a type of secondary immunosuppression, should not be confused with a serious primary immune deficiency (such as agammaglobulinemia or hypogammaglobulinemia, common variable immunodeficiency, x-linked agammaglobulinemia, other antibody deficiencies; or some combined immunodeficiency - most commonly severe combined immunodeficiency).

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[2] An example of empirical evidence can be consulted: in: Wahjuhono G, et al. *Switch from oral to inactivated poliovirus vaccine in Yogyakarta Province, Indonevaccination campaign: summary of coverage, immunity, and environmental surveillance*. J Infect Dis. (2014) 210 (suppl 1): S347-352.
Modeling indicates that the mean time until OPV-related viruses die out is approximately four months (range 2–12 months). See Thompson KM and Duintjer Tebbens RJ. *Modeling the dynamics of oral poliovirus vaccine cessation*. J Infect Dis. (2014) 210 (suppl 1): S475-484.

[3] Tebbens, R. J. D et al. *Risks of Paralytic Disease Due to Wild or Vaccine-Derived Poliovirus after Eradication. Risk Analysis*, 2006. 26: 1471–1505.

[4] GAPIII requires that all research laboratories or production centers have containment procedures implemented and adapted for the Sabin type 2 poliovirus strain by 1 August 2016 at the latest.

[5] There is an exhaustive review of VDPV in Burns C, Diop OM, Sutter RW, and Kew OM. *Vaccine-derived polioviruses*. J Infect Dis 2014:210 (Supl 1):S283-293.

[6] See Kew O et al. Vaccine-derived polioviruses and the endgame strategy for global polio eradication. Annu Rev Microbiol. 2005; 59:587-635.

After OPV2 withdrawal, and as long as type 2 immunity remains relatively high, the *possibility of transmission* and circulation in the community is considered low in most countries.

Regardless of the type of virus isolated, a detailed risk assessment is imperative

NOTE: In cases of **iVDPV** infections, intravenous immunoglobulins or antivirals (when available) should be administered, as well as IPV for household members and close contacts.

2. Evaluating the geographic extent of the transmission and the risk of spread

In order to determine the geographic extent and the risk of spread, three factors should be taken into account: epidemiological background, location, and population characteristics.

6.4 Classification of the risk for further type 2 poliovirus transmission

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

The purpose of risk assessment in an outbreak is to characterize the transmission of the virus and its implications for possible spread.

6.5 Factors influencing the response type and scale

The risk for the emergence of any type 2 poliovirus following OPV2withdrawal is not homogenous across countries or even within large countries. A significant factor will be the predominant polio vaccine in use within a country.

Table 4. Risk phases for the appearance and circulation of type 2 poliovirus

Phase	Time since OPV2 withdrawal	Comment	Relative risk for initial type 2 virus	Risk for further circulation
1	≤ 1 year	General population immunity remains high if mucosal immunity is boosted with pre-switch vaccination campaigns	High	Low
2	2-3 years	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

Independent of the risk of further circulation, the control response should always be immediate.

Countries exclusively using IPV

For countries exclusively using IPV, the risk for cVDPVs (detected in either an individual case or ES sample) depends largely on the relatively limited risk of exposure to the vaccine virus namely via travelers or migrants. These countries may still be at risk, albeit at a low level, for discovery of WPV2 or Sabin 2 virus which may be 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. However, the poliovirus may still spread among under-vaccinated sub-populations.

The level of concern (and thus associated response) in these countries will thus depend on a thorough virologic and epidemiologic investigation tailored to the individual situation. However, from a global perspective, detection of any type 2 poliovirus should be cause for concern. Attempts to identify the origin of any outbreak, including those due to virus importations, are paramount to determine the appropriate response at the source.

Nevertheless, the recommendations below regarding the type of vaccination response following a type 2 poliovirus detection focus on countries which used tOPV in the 12 months prior to the switch.

Countries that used tOPV in the 12 months prior to OPV2 withdrawal

For countries that used tOPV in the 12 months prior to OPV2 withdrawal, reduced population immunity and the decreasing presence of the vaccine virus in the environment increase the risk of type 2 VDPV emergence.

Critical factors to be considered in reaching response decisions include time, place, and the characteristics of the affected population, which will consequently determine the necessary resources.

a) Time

The risk of type 2 poliovirus emergence and circulation will vary depending on the time since OPV2 withdrawal (Table 4).

b) Place

The geographic scope should consider epidemiologically-linked populations due to the proximity of national or international borders, high flow of people for trade, tourism, or work, environmental factors (e.g. poor sanitation), geopolitical challenges (e.g. insecurity) and other geographic factors (e.g. transport links to high-risk communities with low vaccination coverage).

c) Characteristics of the affected population

Although the greatest risk factor for VDPV2 emergence is low vaccination coverage in the general population, other risk factors include high birth rates, high population size and density, and other conditions associated with high levels of fecal-oral transmission such as

marginalized or neglected populations, communities affected by conflict or with a history of immunization refusal, etc.
Once the population to be vaccinated has been defined, planning the outbreak response can commence.

National authorities with the support of PAHO/WHO and GPEI partners will determine whether it is an event or an outbreak and estimate the transmission risk and the type and scale of the response required. It will submit this information to the WHO Eradication and Outbreak Management Group (EOMG), who will issue the final ruling.

6.6 Decision-making

- **With the support of PAHO/WHO, the Outbreak Preparedness and Response Task Team (OPRTT) in the country** will present the information required (Annex 3) by EOMG so that the outbreak can be graded, according to the risk of transmission and the response capacity, within 72 hours of the laboratory result notification.
- **The EOMG** will convene within 72 hours of the laboratory result notification to grade the outbreak.
- **WHO and GPEI partners,** will provide technical support for all activities as required based on the outbreak grade and the support needs of the country's health system.

Based on the risk classification, these teams together with the GPEI partners will make a decision regarding the response, and present it to the EOMG who will issue the final ruling.

6.7 Responding to a confirmed polio event or outbreak

When a polio event or outbreak is confirmed, a response is triggered. This comprises a thorough investigation, active surveillance, and standard vaccination campaigns. Later, the number of vaccination rounds necessary or the scale of the event response assessments will be evaluated (Annex 4).

When type 2 events are detected, the WHO "*no-regrets*" financing policy will apply and the GPEI performance standards set out in these SOPs will be followed.

a. Vaccination

Once it has been decided to carry out vaccination strategies, either for a poliovirus type 2 event or outbreak, the following should be defined:

- **Number of rounds and intervals (Annex 8)**
  Up to four vaccination rounds may be carried out in each target group.
  The type of vaccine to be used is shown in the following table:

Table 5: Round number and period between rounds

Round number	Type of vaccine	Periods between rounds (days)
First	mOPV2	Zero
Second	mOPV2	14 -21 days

- **Target group**
  Efforts will focus on all children under 5 years.
  Other groups: Other age groups will be vaccinated only if there is evidence of circulation in children of 5 years or over.

- **Areas to cover**
  Vaccination has to begin in the affected area immediately, and then the need to vaccinate in the expanded area will be evaluated.

Table 6: Vaccination intervention and priority areas

Area	Vaccination
Affected	Immediately
Expanded (border, flow of trade, work, etc.)	According to EOMG recommendations

b. Vaccine request

Once the vaccination strategies have been determined, either in response to a type 2 poliovirus event or outbreak and the scale of the intervention, the age groups to vaccinate, the areas to cover and intervals between doses are defined, countries should submit their request to WHO for mOPV2 within 72 hours of the laboratory type 2 result. The EOMG will examine the request and submit its recommendation to the WHO Director-General who will authorize the mOPV2 release.

The Vaccine Request Form is available at: http://polioeradication.org/tools-and-library/field-resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/

c. Organizing vaccination rounds

- Set up a situation room for the duration of the outbreak
- Define vaccination teams
- Training for human resources
- Budget planning and programming (per diem, transportation, purchase of equipment and supplies)
- Communications plan (dissemination of information on action to be taken by the population and progress reports for authorities and community)
- Develop registry and information tool
- Logistics and cold chain (transport for the external advisory team should be included under logistics)
- Preparation of supervision team
- Timetable
- Monitoring and assessing if vaccination targets are achieved.

d. Travelers

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 the poliovirus circulation. However, even in the face of major epidemics, enforcing local travel restrictions has proved challenging. Nevertheless, in the event 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.

Principal actions required by national public health authorities

- Consider imposing a local quarantine in situations where a single individual has documented exposure to type 2 poliovirus (e.g. in a laboratory or vaccine-production facility). Continue further investigation and close surveillance of family members or co-workers for at least 60 days post initial case detection.
- Based on local feasibility and the evaluated risk, consider implementing local travel restrictions, requesting proof of polio vaccination, or vaccination of all travelers of all ages going into or out of the outbreak area.
- Community leaders may be mobilized to engage communities in voluntarily travel restrictions.

6.8 Outbreak response assessment

Assessments will be carried out by the external Outbreak Response Assessment (OBRA) team according to the following procedures:

- Independent monitoring, at least by the 2nd vaccination campaign.
- Outbreak/event response assessment by the independent international team by the third month after day 0 (date of laboratory result notification), and continuing quarterly thereafter until 12 months have passed since a type 2 poliovirus identification.
- Confirm the end of the outbreak.
- Develop a six-month plan to strengthen surveillance, with quarterly monitoring.
- Provide “surge” technical support tailored to the transmission risk and local response capacity.

6.9 Outbreak closure and final validation

The international independent OBRA team will carry out external assessments every three months to determine when the outbreak viral transmission (WPV or cVDPV) has been interrupted. In the case of a type 2 poliovirus outbreak, this cannot be considered closed until 12 months after the onset date of the last case *or last positive environmental sample*, plus a two-month margin. The IHR Expert Committee must confirm the closure status of the outbreak. (Annex 5)

6.10 Surveillance after a polio event/outbreak

AFP surveillance will continue as the fundamental mechanism in the detection of any type 2 poliovirus.

Enhanced surveillance: surveillance rate of at least three non-polio AFP cases per 100,000 children under 15 years in all first subnational administrative levels (province or state), during the outbreak and for at least 6 to 12 months (plus another 2-month margin) after the last case.

To this end, countries should conduct the following tasks:

- Communicate the event/outbreak to all subnational surveillance units.
- Activate AFP cases finding strategies, on a subnational scale, and retrospectively review medical records.
- Promote AFP surveillance training for all health professionals.
- Develop an outbreak surveillance system to provide weekly reports on the monitoring data of all reporting units at subnational level.
- Obtain samples from contacts of all AFP cases in all affected areas and adjacent areas at risk of transmission (section 3.1), until the outbreak has been declared closed.
- Ensure that active AFP case finding is integrated into vaccination campaigns.
- Safeguard reinforcements for laboratory services so that they can cope with the additional workload and ensure expedite results delivery throughout the outbreak.

7. Poliovirus 1 and 3 detection

7.1 Poliovirus 1 and 3 notification

All instances of poliovirus isolation in a previously polio-free country 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 be made at the first indication of a positive sample; for example an unclassified VDPV should be notified immediately to WHO by the country, even before final classification. Countries should institute their own rapid notification procedure, and not rely on the laboratory WHO notification process.

Countries should **immediately notify WHO about any WPV or VDPV poliovirus detection** on the grounds that it could constitute a potential "public health emergency" in accordance with IHR. (2) This holds true regardless of the origin or the precise classification of the source of the poliovirus. Any WPV isolate from an AFP case or case contact meets the criterion for "notification in all circumstances" under Annex 2 of the IHR (2005). (*3*) Identification of a WPV or VDPV from any source (environmental or human) must also be reported as it fulfills the following criteria for notification under Annex 2 of IHR (2005): (*4*)

i) may have a serious public health impact
ii) it is an unusual or unexpected event

And the last two criteria may also be met:

iii) significant risk of international spread
iv) significant risk of international trade or travel restrictions.

In accordance with the obligations established under IHR:

- Isolation of a wild or vaccine-derived poliovirus in a laboratory of the country where the sample was obtained must be reported immediately to the competent authority of the country and to the Regional WHO IHR Focal Point (via the National Focal Point) and the PAHO country office at the same time.
- When a positive poliovirus sample is detected in an international reference laboratory, the authority of the country where the sample was obtained will be notified. If the country fails to deliver the international notification within 24 hours, the National IHR Focal Point that isolated the poliovirus should notify WHO and the PAHO country office at the same time.

7.2 Investigation

The detection of any type 1 and 3 wild or vaccine-derived poliovirus should trigger an immediate investigation to gather information to determine the number and characteristics of the case or cases, identify the origin and causes of the event or outbreak, and evaluate the geographic extent of the transmission.

a. Case and contact investigation

Prompt field investigation of every AFP case should identify the specific characteristics of each case and trigger the active search for other cases in the community and at local notification centers.

The following activities will be undertaken to characterize the situation.

- **Case investigation**
  Investigate the medical history including immunodeficiency signs, vaccination history, travel history, history of contact with travelers from abroad, the social environment and the community context, or whether or not the person is a clinical laboratory or vaccine-production facility employee/contact.

- **Contact investigation**
  Sampling: A stool sample should be collected from at least five direct contacts (i.e. siblings, household contacts, or playmates) and from at least 20 persons of the same age group living in the community of the affected area[7] to determine if there is circulation.

[7] Affected area is considered at the third geopolitical administrative level

b. Active institutional and community case finding

- Active institutional search for AFP cases in public and private hospitals.
- Active community search in area of residency, using different search strategies (educational centers, day-care centers, and residences).

i. Immunization coverage analysis

The analysis of routine vaccination coverage and campaigns, over the past five years, in the affected area (up to the most disaggregated level of coverage available) provides key information that should be considered together with known epidemiologic information in order to identify the population's susceptibility and the risk of transmission.

ii. Laboratory

In addition to identifying if the isolated poliovirus is a wild, vaccine-derived or Sabin virus, the genetic analysis helps identify if the virus was imported or if it concerns a vaccine-derived poliovirus, the length of time the virus may have been circulating or excreted in the case of an iVDPV isolate.

7.3 Risk assessment

The procedures for the conduct of a risk assessment are the same as those following type 2 detection. The aim is to characterize the viral transmission and the implications of a potential spread.

7.4 Response to poliovirus 1 and 3 detection

- **Isolation of a WPV strain in a human or an environmental sample (see chapter 8) in non-endemic countries:** the investigation must consider possible viral importation or release from a laboratory. The necessary response, including the implementation of vaccination campaigns, will be determined on a case-by-case basis depending on the characteristics of the affected area, namely regarding vaccination coverage and the outcome of investigations.

- **Isolation of VDPV1 or VDPV3 pending classification:** All clinical and epidemiologic investigation steps for cases and contacts should be carried out. However, vaccination campaigns are not necessary unless the isolate is classified as a cVDPV which will invoke a full outbreak response.

- **Strains classified as aVDPV and iVDPV:** As these strains are unlikely to lead to an outbreak, response vaccination campaigns are not recommended (Annex 6, Table 5 b).

Rapid vaccination response to type 1 and 3 (WPV or cVDPV) outbreaks will involve use of the bivalent OPV (Sabin vaccine, type 1 and 3). This vaccine is obtained following the PAHO/WHO Revolving Fund procedures.

- Enhanced AFP surveillance: minimum AFP surveillance rate of at least "three non-polio AFP cases per 100,000 children aged under 15 years in all first subnational divisions (province or state) for the duration of the outbreak and for at least 12 months after the last case."
- Additional activities:
  - ✓ Deployment by OPRTT of the Rapid Response Team (Team A), and Surge Response Team (Team B). See Chapter 9, page 34-35.
  - ✓ Independent monitoring of vaccination campaigns.
  - ✓ Independent outbreak response assessment.

7.5 Outbreak closure

The independent international OBRA team will carry out external assessments every three months to determine when the virus transmission (WPV or cVDPV) has been interrupted (Annex 7). Transmission of type 1 or 3 poliovirus outbreak is interrupted and so the outbreak can be closed if:

a. **At the 6-month OBRA**, the outbreak can be considered controlled if:
   - *at least 6 months have passed without detecting the outbreak virus from any source (inside or outside the country)*

   AND

   - *the response vaccination campaign reached high vaccination coverage (90% or over)*

   AND
   - *there is evidence of "high-quality surveillance", which is defined as a non-polio AFP surveillance rate of at least three non-polio AFP cases per 100,000 children aged under 15 years in every first subnational division (province or state) since the last case.*

b. **After the 12-month OBRA**, the outbreak can be considered controlled if at least 12 months have passed after the onset date of the last case, plus a two-month margin (to account for case finding, investigation, laboratory testing and the notification period) without detecting the outbreak virus from any source in any country involved in the outbreak.

   The OBRA team has the option to declare that the outbreak-related poliovirus transmission has been interrupted (i.e. the outbreak can be closed), even if non-polio AFP surveillance rates of 3/100,000 have not been reached provided there is documented evidence with active case searching that there are no further AFP cases.

   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 tested negative for polioviruses

   AND

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

8. Detecting poliovirus events and outbreaks in the environment

Environmental surveillance is recommended particularly in areas of high risk of cVDPV emergence, in areas where there is risk of silent poliovirus transmission and circulation, and areas at risk due to vaccine-production. At present, it is not required that countries of the Americas do environmental surveillance.

8.1 Definition of poliovirus events and outbreaks in the environment

Table 7: Definition of polio events and outbreaks detected in the environment

Typology	Definition
Event (as yet no evidence of transmission)	Detection of 1) **WPV** in 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 over 1.5 years OR • an aVDPV OR 3) **Sabin type 2** isolate in one or more environmental samples
Outbreak (evidence of transmission)	Detection of 1) Two or more separate environmental samples[c] 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] (in addition for type 2: "no documented exposure in a laboratory or vaccine-production facility") OR 3) Two or more environmental samples, if they have been obtained in more than two different collection centers (without overlapping coverage areas) or in a center if the collection was made with more than two months of interval

b. Evidence of virus excretion is defined by identification during follow-up investigation of one or more WPV or a cVDPV infected individuals.

c. "Separate" means that:

1. samples were collected at more than one ES collection site (no overlapping of catchment areas)
   OR
2. samples were collected from one site, but collection was more than two months apart.

Event

With the backing of the GPEI partners, countries will investigate and monitor each poliovirus event to determine if an outbreak is occurring.

Outbreak

The scale of the outbreak response will be determined by the poliovirus type and classification, the population immunity, the local situation, and the initial epidemiological findings. Key to an

effective response is the tailoring of measures to the situation as it evolves over the course of the investigation.

8.2 Detection

While environmental sampling is increasingly 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 this sampling between now and 2018.

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 poliovirus transmission and circulation, especially when there is low coverage, high demographic density and poor sanitation conditions, and areas at risk due to vaccine-production.

ES can also be instrumental in tracking the disappearance of Sabin 2 polioviruses, by detecting any strains that might subsequently surface after tOPV withdrawal, thus identifying any continued use of this vaccine.

Polioviruses may also be detected as an incidental finding in non-AFP clinical specimens or through stool surveys. This detection method is not currently considered an essential surveillance method.

8.3 Notification

In accordance with obligations established under IHR:

- Isolation of a poliovirus (wild, vaccine-derived, any type or Sabin type 2) in an environmental sample by a laboratory in the country where the sample was obtained must be reported immediately to the competent authority of the country, to the Regional WHO IHR Focal Point via the National Focal Point.
- When a positive poliovirus sample is detected in an international reference laboratory, the authority of the country where the sample was obtained will be notified. If the country fails to deliver the international notification within 24 hours, the National Focal Point that isolated the poliovirus should notify WHO and the PAHO country office at the same time.

8.4 Investigation

If the VDPV is of environmental origin, additional environmental samples and community stool samples will be collected.

WPV2. The detection of a WPV2 isolate in an environmental sample is, in all probability, due to a containment breach in a laboratory or research facility and warrants a thorough investigation in the community catchment area where the sample was taken, as well as in any nearby laboratory or research facility in order to identify any AFP cases, or to rule out the presence of individuals with subclinical infection excreting the poliovirus. A cautionary approach dictates

that discovery of a WPV2 in an environmental sample should initially be considered evidence of probable transmission.

Sabin 2. While there is considerable variability depending on the local environment, empirical evidence, as well as modeling, indicates that Sabin type 2 polioviruses can be expected to remain detectable for approximately 4 months in sewage samples after the last tOPV use (or mOPV2 use).[8] While this detection should prompt increased environmental surveillance, the risk for this occurrence should rapidly diminish with time. Detection of Sabin type 2 polioviruses after this 4-month period following the switch could be evidence of continued use of OPV2-containing vaccine, and as such would represent a risk for possible future transmission.

WPV 1 and 3. The investigation into an environmental WPV isolate in a non-endemic country must consider possible viral importation or laboratory release. The necessary response, including the implementation of vaccination campaigns, will be determined on a case-by-case basis, with careful consideration of the country characteristics (e.g. proximity to endemic regions), population immunity, and outcome of the investigation.

cVDPV: VDPV isolation when there is evidence of person-to-person transmission in the community:

i. Of a person and one or more environmental samples
   OR
ii. Two or more environmental samples, if obtained in more than two different collection sites (without overlapping of catchment areas) or collected from one site, but more than two months apart.

If the VDPV is of environmental origin, additional environmental samples will be collected and also community fecal samples.

VDPV1 or VDPV3 awaiting classification: the approach will follow the same initial response steps. However, vaccination campaign activities are not required unless the isolate is classified as a cVDPV which would invoke a full outbreak response.

- Isolates classified as **aVDPV** are unlikely to lead to an outbreak. The general response strategy is simplified to usual case and contact investigation, in addition to specific vaccination campaigns (for type 2) or no vaccination campaigns at all (for type 1 and 3) depending on the local context and risk assessment
- The rapid response to type 1 and 3 outbreaks (WPV or cVDPV1 or cVDPV3) will involve use of bOPV (Sabin vaccine, type 1 and 3). Requests will follow the current procedures for campaign support through WHO country offices.

[8] An example of empirical evidence can be consulted: in: Wahjuhono G, et al. *Switch from oral to inactivated poliovirus vaccine in Yogyakarta Province, Indonesia: summary of coverage, immunity, and environmental surveillance*. J Infect Dis. (2014) 210 (suppl 1): S347-352.
Modeling indicates that the mean time until OPV-related viruses die out
is approximately four months (range 2–12 months). See Thompson KM and Duintjer Tebbens RJ. *Modeling the dynamics of oral poliovirus vaccine cessation.* J Infect Dis. (2014) 210 (suppl 1): S475-484.

Community case finding (community and institutional): A positive environmental sample should trigger active case finding in the community that is presumably affected or in the catchment area of the environmental surveillance site. Fecal samples should be obtained from the cases detected.

Enhanced surveillance: For the immediate investigation period, increase frequency of environmental surveillance, if feasible. For the longer term, together with GPEI partners, investigate the possibility of establishing or expanding local environmental sampling catchment areas.

Coverage assessment: The analysis of routine vaccination coverage and campaigns over the past five years in the affected area (up to the most disaggregated level of coverage available) provides key information that should be considered together with the known epidemiological information to identify the population's susceptibility and the risk of transmission.

8.5 Risk assessment

The same risk assessment methodology used to evaluate the risk of an event or outbreak in clinical samples is applied to environmental samples.

8.6 Response to poliovirus events and outbreaks in the environment

The detection of an environmental sample calls for a complete investigation of the situation, including identifying possible errors in tOPV withdrawal and destruction after the switch, as well as containment breaches in laboratories, vaccine-production sites or research facilities.

Depending on the specific situation, an event or an outbreak could trigger a vaccination campaign (Annex 6 and 7).

WPV 1 or 3 in the environment: vaccination campaigns should be carried out depending on the local situation.

WPV 2 in the environment: in terms of vaccination, the vaccination campaign plan and implementation depends on the local context. Especially for risk area 1, consider one vaccination campaign round within first 14 days in children from 0-5 years, and in other age groups only if there is evidence of transmission in children aged 5 or over in the affected area.

Sabin type 2 in the environment: vaccination campaigns not required.

VDPV 1 or 3 awaiting classification: vaccination campaigns not required.

aVDPV 1 or 3: vaccination campaigns not required.

iVDPV 1 or 3: vaccination campaigns not required.

Systematic vaccination campaigns are not recommended in response to iVDPV if the classification is based on initial sequencing or after identifying a person with an immunodeficiency. However, one to three vaccination campaigns (in the affected area) may be considered in high-risk areas surrounding the immunodeficiency case, especially if the iVDPV is detected at the end of Phase 1, when type 2 immunity will have declined.

NOTE: In cases of **iVDPV** infections, intravenous immunoglobulins or antivirals (when available) should be administered, as well as IPV for household members and close contacts.

VDPV 2: Initial sequencing results of a cVDPV should prompt a rapid vaccination campaign (e.g. vaccination campaign 1) response in all risk zones.

A single VDPV2 without evidence of prolonged circulation or a single VDPV2, not linked to a previously detected aVDPV, may represent an isolated event with no other consequences, however, the circumstances surrounding this detection must be carefully evaluated to determine whether it represents a high risk of transmission. Field investigation must be intensified and surveillance strengthened.

Multiple emergences of VDPV in a population with significant immunity deficiencies should be considered as a red flag and be handled as a high risk situation.

aVDPV 2: If further investigation does not uncover a cVDPV or iVDPV, a possible aVDPV isolate should be considered.
A more aggressive vaccination response to an aVDPV may be required if it meets one of the following criteria:

1) Interval from the switch is >6 months

OR

2) Occurrence in an area with prior cVDPV emergence

OR

3) Substantial genetic deviation from the 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 vaccination campaign, proceed with at least one more vaccination campaign with mOPV2.

9. GPEI partnership support to countries' outbreak response

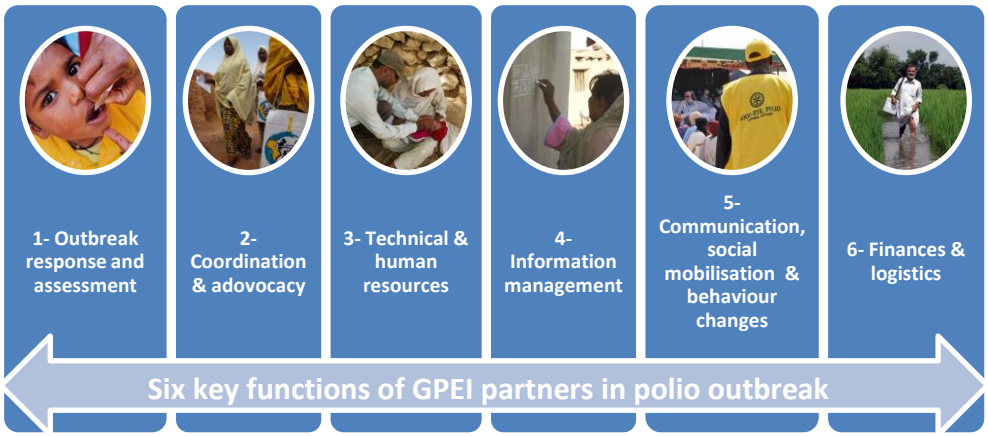
9.1 Six key functions of GPEI

Countries have ultimate responsibility for the response, and have to retain their leadership throughout the process.
GPEI partners should support countries in completing a robust risk assessment and a vigorous response to poliovirus outbreaks.

To deliver on their commitments described in the *Polio Eradication and Endgame Strategic Plan 2013-2018* (*5*), GPEI partners support **six key functions** in outbreak responses (Figure 1):

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

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



9.2 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 OPRTT. OPRTT will ensure that the six key GPEI support functions are coordinated between all partners and the different levels of each organization.

a. Surge policy

The objective of the surge policy is to strengthen the ability to immediately staff key positions of the response and to ensure a smooth transition to longer-term staffing. For this, 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 outbreak response functions described above.

This deployment follows the initial investigation, risk assessment and grading of an outbreak by the EOMG. Therefore, the earliest activation of the surge policy would be 72 hours after the laboratory result notification.

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

- Identification of key roles to be staffed for immediate- and long-term positions, according to the outbreak grade

- Establishment of a Rapid Response Team (Team A) which can be deployed to the risk zone within 72 hours
- Establishment of a Surge Response Team (Team B) for longer-term deployments
- Rapid training of personnel on SOPs
- Assurance of deployment of Team B within 3 weeks of an outbreak, allowing at least one week overlap between Team A and Team B to ensure a complete and detailed handover.

b. "*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 the outbreak until the end of the outbreak. This policy affirms that it is better to err on the side of over-resourcing critical functions rather than risk failure by under-resourcing.

10. Removal and destruction of surplus mOPV2

Stringent monitoring of the storage, distribution, usage and destruction of mOPV2 is critical for ensuring that the vaccine is not mixed up with or mistaken for another vaccine (or vaccines) and that no vials are left within the country once the SIA rounds are completed and the Outbreak Response Assessment team (OBRA) recommends mOPV2 destruction. Key considerations in managing the deployment of mOPV2 and monitoring its usage are outlined below.

Managing deployment of mOPV2 in a country

- When a VDPV2 event or outbreak is notified, there are **no mOPV2 stocks** in countries.
- In most cases, **immunization response with mOPV2 must start within 2 weeks** following laboratory confirmation of type 2 poliovirus.
- Complete the **vaccine arrival report** and provide to the PAHO/WHO country office within 24 hours of the arrival of the vaccine consignment (within 72 hours for other vaccines).
- **Label the vaccine clearly** to be easily identifiable.
- **Store and transport separately** from other vaccines in the cold chain.
- Deploy mOPV2 **only** to the outbreak-affected areas per the immunization plan and the terms and conditions in the mOPV2 request form.
- **Supply mOPV2 to outbreak zones in separate, clearly identified cold chain containers prepared with frozen icepacks.**
- At the end of each SIA round, return all **open (fully or partially used) and unopened vials** *to the health facility.*
    - Promptly inactivate and safely destroy all **open vials (fully or partially used)** at the health facility. If this cannot be done at the health facility, send open vials to the district level.
    - Safely store all **unopened vials** at the health facility if the cold chain is reliable, or return for storage to the district-level facility where the cold chain is reliable.

- At the end of the last SIA round, return all **unopened vials of mOPV2** to the central-level facility, and ensure they are safely stored, labelled and identified, until the MOH, in line with the advice from the OBRA team, instructs further use or destruction. If destruction is recommended, inactivate and safely dispose of all unopened vaccine vials in order to return to zero stock throughout the cold chain.

- **Provide full documentation of the number of mOPV2 vials used**, including the final stock balance, to the EPI/immunization program for monitoring purposes.

- **Ensure final validation of mOPV2 removal from the country is endorsed by the body entrusted with that responsibility.**

  Monitoring of mOPV2 distribution
  Most countries have an established vaccine distribution and stock monitoring system involving batch cards and vaccine stock recording books. However, because of the traceability of mOPV2 vials and their specific handling, destruction and disposal requirements, it is important to establish a recording/reporting system similar to that used for the switch from tOPV to bOPV. This can facilitate and ensure accurate accountability of the mOPV2 vials.

  A tracking system must be put in place to:

  1. manage deployment of mOPV2 to the outbreak-affected area;
  2. ensure that all vials of mOPV2 from the central store are properly distributed through the supply chain to the immunization points;
  3. monitor utilization patterns and stock balances at each level;
  4. ensure that all opened (fully or partially used) vials are returned from immunization sites to health facilities or the district level;
  5. ensure that all opened vials are inactivated and safely destroyed in compliance with national regulations for medical waste management
  6. validate the removal of all mOPV2 vials from the cold chain following completion of all SIA rounds and recommendation from an OBRA to destroy remaining unopened mOPV2 vials

Safe destruction and disposal of mOPV2

Basic principles

- The VDPV2 event or outbreak response plan should include a detailed mOPV2 collection and destruction plan for the country, both between SIA rounds and after the final SIA round.
- Destruction of mOPV2 should be in accordance with national regulations. If the national regulations do not provide clear guidance, refer to the approaches for mOPV2 destruction discussed below.
- mOPV2 should be inactivated prior to destruction. The following are the recommended methodsfor inactivation, destruction and subsequent disposal of mOPV2:
  - Inactivation by autoclaving, boiling, chemical inactivation, encapsulation or incineration
  - Destruction and disposal by transporting to the waste facility or burying.

Methods for inactivation of mOPV2, and their associated pros and cons:

- **Autoclaving**: Autoclaving uses high-temperature steam. It is the most environmentally friendly method. Unopened glass vials full of liquid should be loosened before autoclaving to avoid rupture, unless the autoclave has an integrated shredder. However, glass vials that contain little liquid do not need to be opened. After autoclaving, vials will be sterile but must still be destroyed in accordance with national or local waste management guidelines for municipal waste.

- **Boiling:** Boiling involves immersing vials in boiling water for approximately 30 minutes, which destroys pathogenic microorganisms. Glass vials can be safely boiled, and do not need to be opened prior to boiling. After boiling, the inactivated vials should be destroyed in accordance with national or local waste management guidelines.

- **Chemical inactivation:** Chemical inactivation of mOPV2 involves opening and immersing mOPV2 vials in 0.5% chlorine solution for at least 30 minutes. The solution should be nine parts clear water to one part household bleach. Immersing 20 vials in 4 litres of solution will safely inactivate mOPV2. After this treatment, vials and leftover chlorine solution must both be destroyed in accordance with national or local waste management guidelines.

- **Incineration (inactivation and destruction):** Incineration should be carried out at a temperature of ≥1100 °C for safe destruction of glass vials containing mOPV2 (for example, using rotary-kiln incinerators and industrial furnaces).
    - It is important to note that the temperatures reached in the primary waste chamber of the incinerator can vary. For instance, low-temperature burning (<800 °C) using single-chamber cement or brick-covered incinerators is not recommended because this is environmentally hazardous.
    - Additionally, medium-temperature burning (800–1100 °C) using dual-chamber incinerators may cause glass vials to explode or partially melt, and is also not recommended.
    - Co-incineration in industrial furnaces (such as cement kilns) will both inactivate and destroy mOPV2 vials and can be done in partnership with an industrial facility.
    - The resulting ash and any other post-incineration residue must be treated as toxic waste and destroyed in accordance with national or local waste management guidelines.

- **Encapsulation (sequestration and destruction):** Encapsulation destroys mOPV2 without immediate inactivation (and without opening the vials) but makes it inaccessible and unusable. This method involves filling containers three-quarters full with mOPV2 vials, adding an immobilizing material (such as sand, cement or clay) and sealing and burying the containers. The encapsulated waste must be destroyed in accordance with national or local waste management guidelines.

GPEI has drawn up comprehensive guidelines for countries, available in English at: Technical Guidance mOPV2 vaccine management, monitoring, removal and validation, October 2016|English|

ANNEXES

Annex 1: mOPV2 use in poliovirus type 2 event/outbreak response

If use of the mOPV2 is necessary in response to a poliovirus type 2 event or outbreak, the vaccine will be dispatched as a donation through UNICEF.

This vaccine, which is WHO prequalified, is unlicensed in the countries of the Region of America as it is not marketed for routine use. However, all the countries of the Region include a waiver in their licensing laws to cover such products when needed to serve a critical public health situation and/or donations in such cases. To that end, it is recommended that the EPI team begin liaising with the regulatory entity to ensure that the vaccine can be nationalized, in other words, to expedite importation permits to the shortest time possible, should this be necessary.

We should also point out that, as well as being WHO prequalified, the vaccines will be dispatched to countries with all the necessary documentation to guarantee users that they meet all recommended quality, safety, and efficacy standards. For that purpose, WHO has reported that vaccines will be delivered to countries with the following documentation:

- Summary protocol of manufacturing and control
- Lot release certificate issued by the national regulatory authority of the country of origin

Countries should define, as soon as possible, the minimum documentation they will require to ensure that the vaccine may be nationalized in the shortest time possible.

We should also stress the importance of defining a national action plan to facilitate vaccine importation and to inform all relevant actors on the documentation that will be sent.

Annex 2: International Health Regulations on polio notifications

The main governing documents for this chapter are:
- WHO Guidance for the use of Annex 2 of the International Health Regulations (2005) (*6*)
- Statement on the Seventh IHR Emergency Committee meeting regarding the international spread of poliovirus. WHO statement 26 November 2015 (*2*)
- IHR case definition, IHR Annex 2. (*3*)

a- Mandatory notification of polio events and conditions[9]

Countries must notify WHO about the three conditions or events listed below on the grounds that they could constitute a "public health emergency" in accordance with IHR:

1. **WPV or VDPV isolated from an AFP case or a case contact** is one of the four critical diseases, under IHR, which must always be notified to WHO irrespective of the context in which it occurs. (*3*)
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 according to Annex 2 of the IHR (2005) (*6*):

[9] Notification for type 2 Sabin-like virus 4 months after the switch, i.e. from September 2016 onward

i) serious public health impact, and
ii) unusual or unexpected event. The last 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 pending validation[10]) **Sabin-like type 2 virus** post-switch must also be notified to WHO if more than 4 months have passed since the switch from tOPV to bOPV; as they fulfill at least two of the four criteria for notification under IHR Annex 2 (2005).

b- Timing of assessment and official notification

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 them 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, it is required to notify it within 24 hours to 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 an event identified outside of the country territory

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

Annex 3: Information necessary for the transmission risk analysis

1. Epidemiological information

- **Case/Sample details**
  - Type of virus: [*wild/VDPV/Sabin2*]
  - Virus serotype: [*type 1, 2, 3*]
  - Source: [AFP*/Environment/asymptomatic person*]
  - Onset date or environmental sample collection date:
  - PAHO country office/PAHO regional office notification
  - WHO notification date
  - Location of onset of the case/environmental sample collection site
  - If a person: age and OPV vaccination history(including vaccine type)

[10] A proposal to amend the IHR WHO polio case definition based on GAPIII containment criteria has been submitted 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, 3 months after the last possible date for the switch. The proposal still needs to be validated by the IHR EC

- Sequencing results: Nature of the virus (number of nucleotides different from Sabin and most similar sequence if available/applicable) + Evidence of circulation

- **Brief description of last VDPV/WPV and the response**
  - Details of case/environmental sample
    - Virus type [WPV/VDPV; serotype]
    - Onset date/environmental sample collection date
    - Geographical location.
  - # of vaccination campaigns since the last case or positive isolation in the environment

2. **Map showing location of case(s)**

3. **Immunization performance**
   a. **Polio vaccination (OPV/IPV) status in non-polio AFP cases from 6-59 months [bar chart]**
      - At national level
      - Affected administrative area 1 (or 2, if applicable)
        - % zero dose
        - % 3 or more doses

   b. **vaccination campaigns**
      - Number of vaccination campaigns during the current year + type of vaccine used [indicate if affected areas were covered]
      - Information on vaccination campaigns during previous year + type of vaccine used [indicate if affected areas were covered]

   c. **Routine immunization (source: WHO/UNICEF estimates)**
      - Polio3 (OPV/IPV) and DTP3/Penta3, this year
      - Polio3 (OPV/IPV) and DTP3/Penta3, previous 5 years

   d. **Date of tOPV-bOPV switch**
      - Time after OPV2 cessation [weeks/months/years between OPV2 cessation and poliovirus detection]

   e. **Date of IPV introduction and scheme used**

   f. **Analysis and conclusions**

4. **AFP surveillance quality**
   a. **AFP surveillance quality indicators (past 5 years)**
   b. **Analysis and conclusions**

5. **Country context**
   a. **Population**
      - Population <15 and <5 years at administrative level 1 and administrative level 2
      - Population movement in country (within country—focused on affected area)
        - Internal movement of people, focused on affected area
        - Displaced populations
      - High-risk population (in affected areas, special, if applicable)
        - Characteristics (e.g. displaced populations, remote communities)
        - Reasons to consider them as “high risk”
      - International borders, neighboring country/countries, and population movement [if applicable]
        - Proximity of affected areas to borders
        - Trade and travel patterns

b. **Security [natural disasters, political instability, crime/terrorism (if applicable)**
c. **Major upcoming events in country that could affect the response** (e.g. elections, events involving key Ministry of Health personnel) [if applicable]

6. Country capacity

a. **Provision of national immunization services (as expressed by national EPI director or higher authority)**
   - Immunization service system: strong/moderate/weak (specify)
   - Human resources for management at all levels: adequate/inadequate/limited (specify)
   - Human resources for service delivery: adequate/inadequate/limited (specify)
   - Country's experience in conduct of previous polio campaigns
   - Country's experience in conduct of other previous vaccination campaigns

7. Detailed information on investigation of polio cases

[to be completed by regional and country office once the information becomes available]

a. Main conclusions of field investigation [if known/if applicable]
b. Missed AFP cases found through active case finding in community and health facilities
c. OPV/IPV coverage status evaluated through rapid community surveys
d. Number and results of laboratory testing of AFP cases and contacts/environmental samples in the community
e. Patterns in AFP case finding/missed opportunity in reporting case as early as possible (if applicable)
f. Travel connections and population movement:
   - Travel to other areas in the country: name of districts
   - Travel to other countries: name of countries, provinces, and districts

8. Proposed plan of action

[to be completed by the regional office and the country office once the information becomes available]

a. Field investigation
   - Laboratory investigation:
   - Exhaustive case investigation and case finding:
b. Improve ongoing surveillance measures (AFP, environment):
c. Improve/attain routine immunization (including bOPV and IPV):
d. Vaccination Response Plan:
   - mOPV2 requested: [YES/NO] at this point
     - Justification (briefly)
     - Target population, geographic area, age group
     - Doses requested per round
     - Proposed dates for vaccination campaign 1 and 2
e. Plans to notify neighboring countries: [who, when, how, by whom]

9. Map of proposed mOPV2 intervention area

10. Advisory Group

Discussion, conclusion, and recommendations

a. Risk assessment
   - Virological risk

- Risk of additional contextual transmission
- Risk of international spread

b. Evaluate the need for mOPV2 and evaluate vaccine request [if applicable]
   - mOPV2—and number of doses/rounds/extension/age
c. Submit recommendation to DG of WHO [if applicable]
d. Submit country recommendations
e. Instructions to UNICEF Supply Division

Annex 4: Steps for type 2 polio outbreak/event notification, confirmation, and response+

Step	Action	Comments	Responsibility	Time frame@	Data or decision reported to	Days since notification of lab sequencing results
Notification and Response Preparation						
1	Laboratory notification of type 2 poliovirus isolate sequencing results		Global Polio Laboratory Network (GPLN)	-Complete within 14 days of initial isolation -Report within 24 hours of results	Notification to MoH, IHR through the National IHR Focal Point	Day 0
2a	Initial confirmation of outbreak/event and 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 WHO/PAHO support) -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 PAHO country and Regional Office. - Report to WHO through National IHR Focal Point	Day 0-2
2b	Confirmation of outbreak/event *- regional and global level*	Follow-up with MoH upon receiving lab notification. If any concerns, verify lab results with GPLN regional reference lab	PAHO Regional Office IHR Focal Point and PAHO/WHO Immunization Unit	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 international temporary personnel (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 PAHO/WHO support	Begin <24 hours from lab notification; complete within 48 hours		Days 1-2
Stage 1 – Response Implementation						
4	Submit vaccination campaign 1 vaccine request upon confirmation of outbreak/event	Complete initial risk assessment; finalize vaccine requirements per response plan	MoH/EOC with PAHO/WHO support	<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 on vaccine provision (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 and PAHO	Day 4
7	GPEI Response initiated	OPRTT^ support implementation -Grading -TA staff deployed -Funds released	EOMG**/OPRTT^	<72 hours from WHO DG authorization	Communicates with other GPEI partners at all levels and with MoH and PAHO	Days 4-6

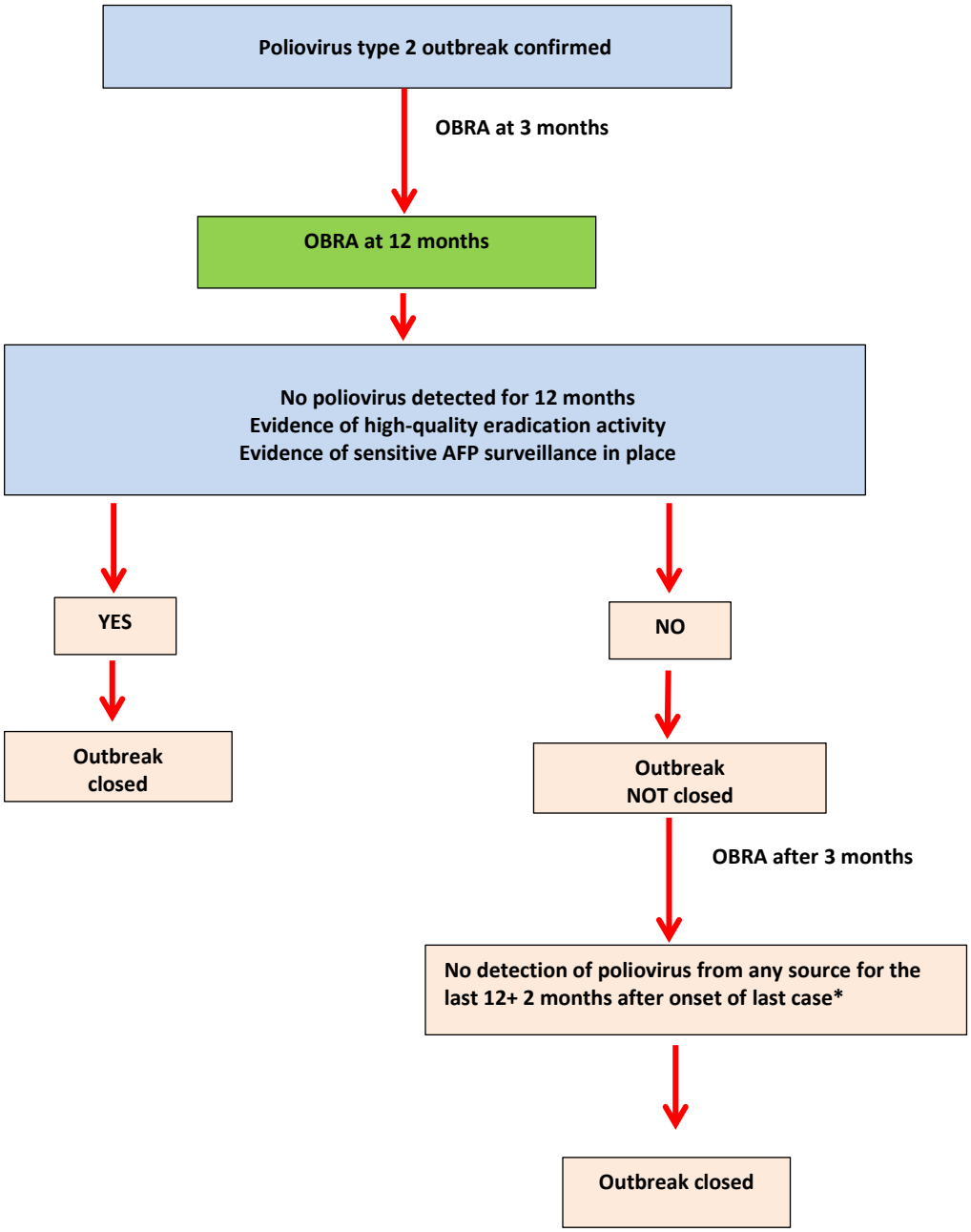
8	Official notification to prepare vaccines for delivery	Purchase Order issued to manufacturer	UNICEF Supply Division (SD)	<24 hours from receipt of DG's authorization	Vaccine manufacturer	Day 4
9	Prepare shipment		Vaccine manufacturer; UNICEF (or WHO): syringes and safety boxes if required	3 working 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	**Vaccination campaign 1**		MoH/EOC +EOMG Rapid Response Team	3-5 days		Day 14+
Stage 2 - Response Preparation and Implementation						
13	Conduct further field and laboratory investigation to reach final classification	Simultaneous with Stage 1. Includes contact tracing, further labs test 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 (vaccination campaign 2 and 3) and request Stage 2 vaccine	Simultaneous with Stage 1. Request should include vaccines required for all additional planned vaccination campaigns	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 are required	All	16 Days		Days 15-30
	Implement **vaccination campaign 2 and 3**		MoH/EOC + EOMG support as necessary			2 – 3 weeks after the first
	Proper containment and disposal of mOPV2	Should take place after each vaccination campaign with field validation after last vaccination campaign	MoH with assistance of GPEI	Final stock report within a maximum of 2 weeks of last vaccination campaign		

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; WHO/POL: World Health Organization Polio Eradication Initiative, ^OPRTT-Outbreak Preparedness and Response Task Team.

Annex 5: Outbreak termination and closure

Decisions tree for duration for <u>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 notification period.
OR
All 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 tested positive for polioviruses.

Annex 6: Minimum response requirements to a poliovirus event

Isolate	Source	General response	Vaccination response	Timeframe **
WPV				
WPV 1 or 3	Environment	• Case finding: community search for cases • Assessment of population immunity • Enhanced surveillance • Event response assessment	• **Vaccination campaigns** plan and their implementation based on local situation, as recommended by WHO and GPEI Partners	-
WPV 2	Environment (with no evidence of individual excreting virus)	• Case finding: community search for cases • Assessment of population immunity • Enhanced surveillance • Event response assessment	**Vaccination campaigns** plan and implementation based on local situation. Especially for risk zone 1, **consider 1 vaccination campaign round** ○ Target age: 0-5 years ○ Target population: in affected area ○ Vaccine of choice: mOPV2 • Vaccine request to WHO DG for mOPV2	First vaccination campaigns within 14 days
Sabin-like 2				
Sabin-like 2	• Environment • Human	• Investigate to determine if there is containment breach	**Vaccination campaigns are not required.**	-
VDPV				
VDPV 1 or 3 (awaiting classification) *	• Human • Environment	• Case and contact investigation (clinical and epidemiological) • Case finding: community search for unreported cases • Assessment of population immunity • Enhanced surveillance	• **Vaccination campaigns are not required**	-
aVDPV 1 or 3	• Human • Environment	• Case and contact investigation (clinical and epidemiological)	• **Vaccination campaigns are not required**	-
iVDPV 1 or 3	• Human	• Case and contact investigation (clinical and epidemiological)	• **Vaccination campaigns are not required**	-
VDPV 2 (awaiting classification, "new" VDPV: probable transmission)	• Human • Environment	• Case and contact investigation (clinical and epidemiological) • Case finding: community search for unreported cases • Assessment of population immunity • Enhanced surveillance	**Plan for ≥3 vaccination campaigns rounds** ○ Implement first vaccination campaign with mOPV2 in affected area ○ Other rounds: implementation based on local situation ○ Vaccine of choice: mOPV2 • Vaccine request to WHO DG for mOPV2	First vaccination campaign within 14 days
aVDPV 2	• Human • Environment	• Case and contact investigation (clinical and epidemiological) • Enhanced surveillance	• **Consider a maximum of 2 vaccination campaign rounds if there is high risk of transmission**	First vaccination campaign within 14 days

Isolate	Source	General response	Vaccination response	Timeframe **
			○ Implement first vaccination campaign with mOPV2 in affected area (in rapid response zone) if high risk area ○ Other rounds: implementation based on local situation ○ Vaccine of choice: mOPV2 • Vaccine request to WHO DG for mOPV2	
iVDPV 2	• Human	• Case and contact investigation (clinical and epidemiological)	• **In general, vaccination campaigns are not required** ○ IV immunoglobulins for case (+ monoclonal antibodies or antivirals 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 immunization 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.

Annex 7: Minimum response requirements to a poliomyelitis outbreak

1. Action to be taken	
Response: all isolates	**Timeframe (from lab result notification)**
Cases and contacts investigation	24 hours to initiate
Community case finding	24 hours to initiate
Assessment of vaccination coverage	24 hours to initiate
Enhanced surveillance ***	72 hours to initiate
Outbreak risk assessment and subsequent grading (by EOMG)	72 hours to complete
Initiate and deploy, where applicable (by OPRTT): ➢ Rapid Response Team (Team A) and ✓ Surge Team (Team B)	➢ 72 hours to initiate deployment of **Team A** ✓ 3 weeks for deployment of **Team B**
Independent Monitoring (IM) of vaccination campaigns**	- IM in conjunction with all vaccination campaigns 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 Quality Assurance	Rapid Coverage Monitoring in line with most commonly used mechanism in vaccination campaigns
Independent outbreak response assessments	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.

** Independent monitoring does not replace nor equal supervision.

*** AFP surveillance to be enhanced to an annual surveillance rate of over **three non-polio AFP cases per 100,000 children under 15 years** in all first subnational divisions (province or state) for the duration of the outbreak and for at least 12 months after the last case.

Annex 8: Minimum response requirements to a poliomyelitis outbreak (continued)

Timeframes are considered based on the laboratory results notification

Isolate	Response	Timeframe
2. Vaccination response		
WPV		
WPV 1 or 3 • **Human** • **Environment**	**Plan and implement 3 vaccination campaign rounds**, as advised by WHO & GPEI partners: ○ target age: 0-5 years and other age groups only if evidence of transmission to children aged 5 or over ○ population size: - vaccination campaign 1: affected area - vaccination campaign 2 and vaccination campaign 3: all affected area + at risk areas ○ Vaccine of choice: bOPV	• First round within 14 days • The 3 rounds to be short interval vaccination campaigns (2-3 weeks apart)
WPV 2 • **Human**	**Plan 2 vaccination campaign rounds**, as advised by WHO & GPEI partners ○ target age: 0-5 years and other age groups only if evidence of transmission to children aged 5 or over ○ population size: - vaccination campaign 1: affected area - vaccination campaign 2: area affected by the outbreak ○ Vaccine of choice: bOPV mOPV2 vaccine request to WHO DG	(Poliovirus type 2 protocol)
WPV 2 • **Environment**	Based on local situation. Especially for transmission risk zone 1, **consider 1 vaccination campaign round** ○ target age: 0-5 years and other age groups only if evidence of transmission to children aged 5 or over ○ population size: affected area ○ vaccine of choice: mOPV2 mOPV2 vaccine request to WHO DG	(Poliovirus type 2 protocol)
VDPV		
cVDPV1 or cVDPV3 • **Human** • **Environment**	**Plan and implement 3 or more vaccination campaign rounds**, as advised by WHO & GPEI partners ○ target age: 0-5 years and other age groups only if evidence of transmission to children aged 5 or over ○ population size: - vaccination campaign 1: affected area - vaccination campaign 2 and vaccination campaign 3: all at risk areas ○ Vaccine of choice: bOPV	- 1st round within 14 days - The 3 rounds to be short interval vaccination campaigns (2-3 weeks apart)
cVDPV2 • **Human** • **Environment**	**Plan two vaccination campaign rounds** as advised by WHO & GPEI partners ○ target age: 0-5 years and other age groups only if evidence of transmission to children aged 5 or over ○ population size: - vaccination campaign 1: rapid response area - vaccination campaign 2 to vaccination campaign 5: area affected by the outbreak ○ Vaccine of choice: mOP2 mOPV2 Vaccine request to WHO DG	(Poliovirus type 2 protocol)

Annex 9: National Plan Components

National Plan

All countries should develop or review their national plan on how to respond to a poliovirus event or outbreak. The preliminary plan should be ready by **December 2016** and the final plan by **February 2017**.

Key elements of this plan are listed below.

National plan for a polio event or outbreak response

Country name: _____

1 Country background ☐

A brief description of the country, including population figures, immunization programs, and acute flaccid paralysis (AFP) surveillance systems. Describe specific risk groups and other pertinent information, as appropriate.

2 Introduction ☐

Describe briefly the basis and the purpose of this document.

3 Objectives ☐

Describe the objectives of the document.

4 Preparation

- 4.1 Management structure ☐
- 4.2 mOPV2 use ☐
- 4.3 Preliminary Training Plan ☐
- 4.4 Preliminary Communications Plan ☐
- 4.5 Preliminary Supervision Plan ☐
- 4.6 Preliminary Budget Plan ☐
- 4.7 List the source of information required for the risk analysis (Annex 3) ☐
- 4.8 Preparation for the arrival of the Rapid Response Team (Team A) ☐

5 Definitions of events and outbreaks ☐

6 Poliovirus 2 detection

- 6.1 Notification ☐

6.2 Investigation (include who is responsible for each task) ☐
- a. Case and contact investigation ☐
- b. Active institutional and community case finding ☐
- c. Coverage analysis ☐
- d. Laboratory ☐

6.3 Risk assessment method
- a. Nature of the virus (WPV, Sabin or VDPV) ☐
- b. Evaluation of the geographic extent of the transmission and risk of spread ☐

6.4 Classification of risk of further type 2 poliovirus transmission ☐

6.5 Factors influencing the response type and scale ☐

6.6 Decision-making ☐

6.7 Responding to a confirmed polio event or outbreak
- a. Vaccination ☐
- b. Vaccine request ☐
- c. Organizing vaccination rounds ☐
- d. Travelers ☐

6.8 Outbreak response assessment ☐

6.9 Outbreak final validation: closing activities ☐

6.1 Post-event/outbreak surveillance ☐

7 Poliovirus 1 and 3 detection

7.1 Poliovirus type 1 and 3 notification ☐

7.2 Investigation
- Case and contact investigation ☐
- Active institutional and community case finding ☐
- Coverage analysis ☐
- Laboratory diagnosis ☐

7.3 Risk assessment ☐

7.4 Response to poliovirus 1 and 3 detection ☐

7.5 Outbreak closure ☐

8 Detecting poliovirus events and outbreaks in the environment

8.1 Definition of poliovirus events and outbreaks in the environment ☐

8.2 Detection ☐

8.3 Notification ☐

8.4 Investigation ☐

8.5 Risk assessment ☐

8.6 Response ☐

9 Removal and destruction of surplus vaccines ☐

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://polioeradication.org/wp-content/uploads/2016/07/VDPV_ReportingClassification.pdf
- The Polio Eradication and Endgame Strategic Plan 2013–2018 http://polioeradication.org/wp-content/uploads/2016/07/PEESP_EN_US.pdf
- 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
- Statement on the Seventh IHR Emergency Committee meeting regarding the international spread of poliovirus. WHO statement, 26 November 2015 http://www.who.int/mediacentre/news/statements/2015/ihr-ec-poliovirus/en/

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1. Statement on the Seventh IHR Emergency Committee meeting regarding the international spread of poliovirus. WHO statement, 26 November 2015 http://www.who.int/mediacentre/news/statements/2015/ihr-ec-poliovirus/en/
2. IHR case definition, IHR Annex 2. http:/www.who.int/ihr/Case_Definitions.pdf?ua=1
3. See also WHO Guidance for the Use of Annex 2 of the International Health Regulations (2005) http:/www.who.int/ihr/revised_annex2_guidance.pdf
4. Polio Eradication and Endgame Strategic Plan 2013-2018. http:/www.polioeradication.org/resourcelibrary/strategyandwork.aspx
5. WHO Guidance for the use of Annex 2 of the International Health Regulations (2005) http:/www.who.int/ihr/revised_annex2_guidance.pdf

[TN: I have deleted number 7-10 as they are repetitions of above and adjusted accordingly]

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