



STANDARD OPERATING PROCEDURES

RESPONDING TO A POLIOVIRUS EVENT OR OUTBREAK

Version 4

March 2022



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ACRONYMS

AFP	Acute Flaccid Paralysis	NPAFP	Non Polio Acute Flaccid Paralysis
aVDPV	Ambiguous Vaccine Derived Poliovirus	OBRA	Outbreak Response Assessment
bOPV	Bivalent Oral Polio Vaccine	OPV	Oral Polio Vaccine
COVID-19	Coronavirus Disease 2019	ORPG	Outbreak Response and Preparedness Group
cVDPV	Circulating Vaccine Derived Poliovirus	PCS	Post Certification Strategy
DG	Director General	PHEIC	Public Health Emergency of International Concern
DON	Disease Outbreak Notification	PID	Primary immunodeficiency disorder
EOC	Emergency Operation Centre	PIRI	Periodic Intensification of Routine Immunization
EPI	Expanded Programme on Immunization	POB	Polio Oversight Board
ES	Environmental Sampling	PRSEAH	Prevention of Sexual Exploitation, Abuse and Harassment
EUL	Emergency Use Listing	RED	Reach Every District
EV	Enterovirus	RR	Rapid Response
GAVI	Global Alliance for Vaccines and Immunizations	RRT	Rapid Response Team
GIS	Geographic Information System	SAGE	Strategic Advisory Group of Expert on Immunization
GPEI	Global Polio Eradication Initiative	SIA	Supplementary Immunization Activities
GPLN	Global Polio Laboratory Network	SIAD	Short Interval Additional Dose Strategy
GPS	Global Positioning System	STOP	Stop Transmission of Polioviruses
IHR	International Health Regulations	tOPV	Trivalent Oral Polio Vaccine
IM	Independent Monitoring	UNDSS	United Nations Department of Safety and Security
IMST	Incident Management Support Team	UNICEF	United Nations Children's Fund
IPC	Infection Prevention and Control	VAPP	Vaccine Associated Paralytic Polio
IPV	Inactivated Polio Vaccine	VDPV	Vaccine Derived Poliovirus
iVDPV	Immunodeficiency-associated Vaccine Derived Poliovirus	VVM	Vaccine Vial Monitor
LQAS	Lot quality Assurance Sampling	WHO	World Health Organization
mOPV2	Monovalent Oral Polio Vaccine type2	WPV	Wild Poliovirus
nOPV2	Novel Oral Polio Vaccine type2		

1. OVERVIEW

BACKGROUND

In May 2014, the Director-General of the World Health Organization (WHO) declared the international spread of wild poliovirus a Public Health Emergency of International Concern, following international spread of WPV1 in Africa and Asia. In 2021, a WPV-1 confirmed case was reported from Malawi in the African Region, genetically linked to WPV-1 transmission in Pakistan. This highlights the ongoing risk of WPV-1 international spread until the goal of polio eradication is achieved and that countries should be prepared to respond.

Global eradication of wild poliovirus type 2 was certified in 2015 as was the global eradication of wild poliovirus type 3 in 2019. The WHO African Region was certified free from WPV1 in 2020. Detection of any wild poliovirus outside a laboratory or vaccine plant should be considered as a public health emergency.

Since the withdrawal of OPV2 from routine immunization in 2016, there has been a global increase in vaccine derived poliovirus type 2 (VDPV2) related to the global fall in population intestinal mucosal immunity to type 2 polioviruses in children born after April 2016. Increasingly the circulation of VDPV2 has affected more and more countries, with international spread now occurring regularly. This situation has led to the maintenance of the polio Public Health Emergency of International Concern.

PURPOSE AND SCOPE

The purpose of these standard operating procedures (SOPs) is to offer guidance to any country that detects any type of poliovirus outbreak or event, to respond in a timely and effective manner, with the specific objective to stop polio outbreaks within 120 days (four months). This guide is aimed at national governments and public health decision-makers who coordinate responses to poliovirus events and outbreaks, and their global, regional and country-level partners. This version of the SOPs builds on the prior versions developed since 2015 and takes into account the key developments, lessons learnt and availability of new tools since the publishing of the last version in March 2020.

The development of these SOPs relies on available scientific evidence and expert consensus, while remaining grounded in operational realities and the context of waning global immunity to type 2 poliovirus. Critical aspects of the SOPs result from broad consultation with expert advisory groups, including the WHO, Strategic Advisory Group of Experts (SAGE) on immunization, and endorsement by the GPEI's relevant technical and management groups.

These SOPs establish response standards and timelines for response to WPV spread to a non-endemic country, or when VDPV events and/or outbreaks of any type

(VDPV1, VDPV2 or VDPV3) are detected in any context, whether a new emergence or previously undetected circulating vaccine-derived poliovirus (cVDPV).

These SOPs do not include response to WPV1 due to local transmission in an endemic context, field-level operational guidance or tools for planning high- quality supplemental immunization activities (SIAs), or detailed methods for enhanced surveillance.

WHAT'S NEW IN THIS VERSION

- In this version of the SOPs, the section on key definitions has been updated to include the novel oral polio vaccine virus type 2, genetic linkages and orphan viruses.
- This version of the SOPs provides updated guidance on the rapid response round (sometimes also referred to, as 'round zero'). It is recommended to implement the rapid response round within 14 days of the outbreak notification (Day 0) targeting the immediate area of the virus isolation; if it cannot be commenced within this time frame, the programme should consider proceeding directly to SIA1.
- Guidance has also been updated on the proposed target population of the response vaccination rounds, depending on the risk of spread in varying epidemiological situations. This is based on the available data and modelling for VDPV2 which shows that significant delays in notification of outbreaks and implementing vaccination response necessitate larger scoped vaccination rounds to stop the transmission.
- The definition of breakthrough transmission has been included: any WPV or cVDPV detected in an AFP case, healthy child or environmental sample with the date of onset of paralysis (for AFP cases) or the date of sample collection (for healthy child or environmental sample) more than 21 days after the first day of the last SIA in an area where at least two SIAs have been implemented is evidence of breakthrough transmission. The SOPs do provide flexibility in high-risk scenarios, when a shorter threshold (14 days rather than 21) may be considered to decide upon breakthrough transmission.
- In line with the new GPEI strategy (2022-2026), this version recommends making routine immunization coverage improvement an essential component of the overall outbreak response planning and implementation processes. There is emphasis on dedicating a section of the plan to improving routine immunization coverage as part of the EOCs (or similar coordination platforms) remit, led by the national EPI programmes and adequately supported by the immunization partners, including GAVI.
- Guidance on vaccine choices for responding to type-2 poliovirus outbreaks or high-risk events has

been updated, as the polio programme undergoes a transition away from Sabin OPV2 to the novel OPV2, as per the recommendations of the SAGE. The countries facing cVDPV2 outbreaks should prioritize rapid, high-quality outbreak response with whichever oral polio vaccine is available to them, without any delay.

- The SOPs provide general guidance on continued adaptation to the ever evolving COVID-19 Pandemic. After dealing with the emergency phase of the pandemic, it is important that the GPEI continues close coordination with national and local COVID-19 response management mechanisms while planning and implementing the polio SIAs, with special focus on putting in place infection prevention and control (IPC) measures, community mobilization and mitigation to rumors and misinformation, in order to achieve uniformly high quality vaccination coverage.
- This version of SOPs aligns the guidance on IPV use with the recommendations of the SAGE. Considering that IPV provides a high-level of individual immunity and protection against paralysis but not the intestinal mucosal immunity sufficient to stop person to person transmission of polioviruses, IPV should not be used for outbreak response. Moreover, IPV campaigns are unlikely to reach children not reached with OPV campaigns. The priority of outbreak response is to stop transmission, therefore primary focus should be on achieving high

coverage with OPV. However, concurrent concerted efforts should be made to improve the IPV coverage through enhanced EPI activities as IPV can boost mucosal immunity in populations with prior OPV vaccination.

- This version also touches upon the release mechanism for novel OPV2 and its further management, in line with other detailed documents available on this subject. Like monovalent Sabin OPV2, the release of novel OPV2 from the global OPV stockpile requires approval of the WHO Director-General, upon the recommendation of the Outbreak Response and Preparedness Group (ORPG). The ORPG review process for requests for novel OPV2 will be carried out in close coordination with the Rapid Response Teams (RRT)/ Incident Management Support Team (IMST), WHO and UNICEF regional offices as well as the national programmes.
- In the surveillance section, the target for non-polio AFP rate and performing healthy children stool sampling have been further clarified. Following the outbreak notification or identification of an event in a high-risk area, the programme will target an annualized rate of greater than three non-polio AFP cases per 100 000 children, younger than 15 years of age, in outbreak-affected and high-risk areas. At the national level, a rate of two non-polio AFP cases per 100 000 children is expected in outbreak countries. While districts with fewer than 50 000 children under 15 years of age may not detect

AFP every year, the quality of AFP surveillance should be checked for all districts that did not report any AFP case, regardless of population size. If there is already evidence of community-wide transmission, targeted healthy children stool samplings need not be conducted.

- This version of the SOPs considers the revised structure of the GPEI in line with the new Strategy (2022-2026), to support the county polio programmes. The key revisions include the formation of Rapid Response Team (RRT) in the African Region, Incident Management Support Team (IMST) in the Eastern Mediterranean Region and Outbreak Response and Preparedness Group (ORPG) and Surveillance Group (SG) at the global level. In this document, RRT, IMST and other regional outbreak response mechanisms/bodies are referred to as Regional polio response teams.
- In line with the GPEI strategy, chapters on gender mainstreaming and Prevention and Response to Sexual Exploitation, Abuse and Harassment (PRSEAH) have been included. Moreover, gender related aspects have been included in all the components of outbreak response.

RELATED GUIDANCE

- Classification of VDPVs is comprehensively set out in 'Classification and reporting of vaccine-derived polioviruses' found at https://polioeradication.org/wp-content/uploads/2016/09/Reporting-and-Classification-of-VDPVs_Aug2016_EN.pdf
- For laboratory and vaccine manufacturing related polio events, please refer to 'Public health management of facility-related exposure to live polioviruses. Guidance in managing exposed persons for countries hosting facilities that maintain live polioviruses' found at <https://polioeradication.org/wp-content/uploads/2019/02/public-health-management-of-a-facility-based-pv-exposure.pdf>
- Interim Quick Reference on Strengthening Polio Surveillance during an Poliovirus Outbreak (March 2021) found at https://polioeradication.org/wp-content/uploads/2021/12/Quick-Reference-Strengthening-Surveillance-during-Poliovirus-Outbreaks_24-March-2021.pdf
- Diagnostic procedures following an accidental exposure to poliovirus found at https://polioeradication.org/wp-content/uploads/2020/08/GP8_Diagnostic-procedures-following-accidental-exposure-to-poliovirus.pdf
- Global polio surveillance action plan 2022-2024 found at <https://polioeradication.org/wp-content/uploads/2022/02/Global-Polio-Surveillance-Action-Plan-2022-2024.pdf>.

POLIO ERADICATION STRATEGY 2022–2026, DELIVERING ON A PROMISE

Given the programmatic and epidemiological challenges, the GPEI has re-envisioned the endgame pathway with focus on collective ownership and accountability along with governments, communities and other stakeholders. The [Polio Eradication Strategy 2022–2026](#) comprises of a wide-ranging set of actions to position the GPEI for delivering on a promise that brought the world together in a collective commitment to eradicate polio. These actions target strengthening and empowering the GPEI to address challenges head-on and achieve and sustain a polio-free world.

Goal One of the new Polio Eradication Strategy sets a pathway towards permanently interrupting transmission of all polioviruses in Afghanistan and Pakistan; while Goal Two outlines strategies and tactics to put the GPEI and impacted countries on an emergency footing to stop cVDPV2 transmission.

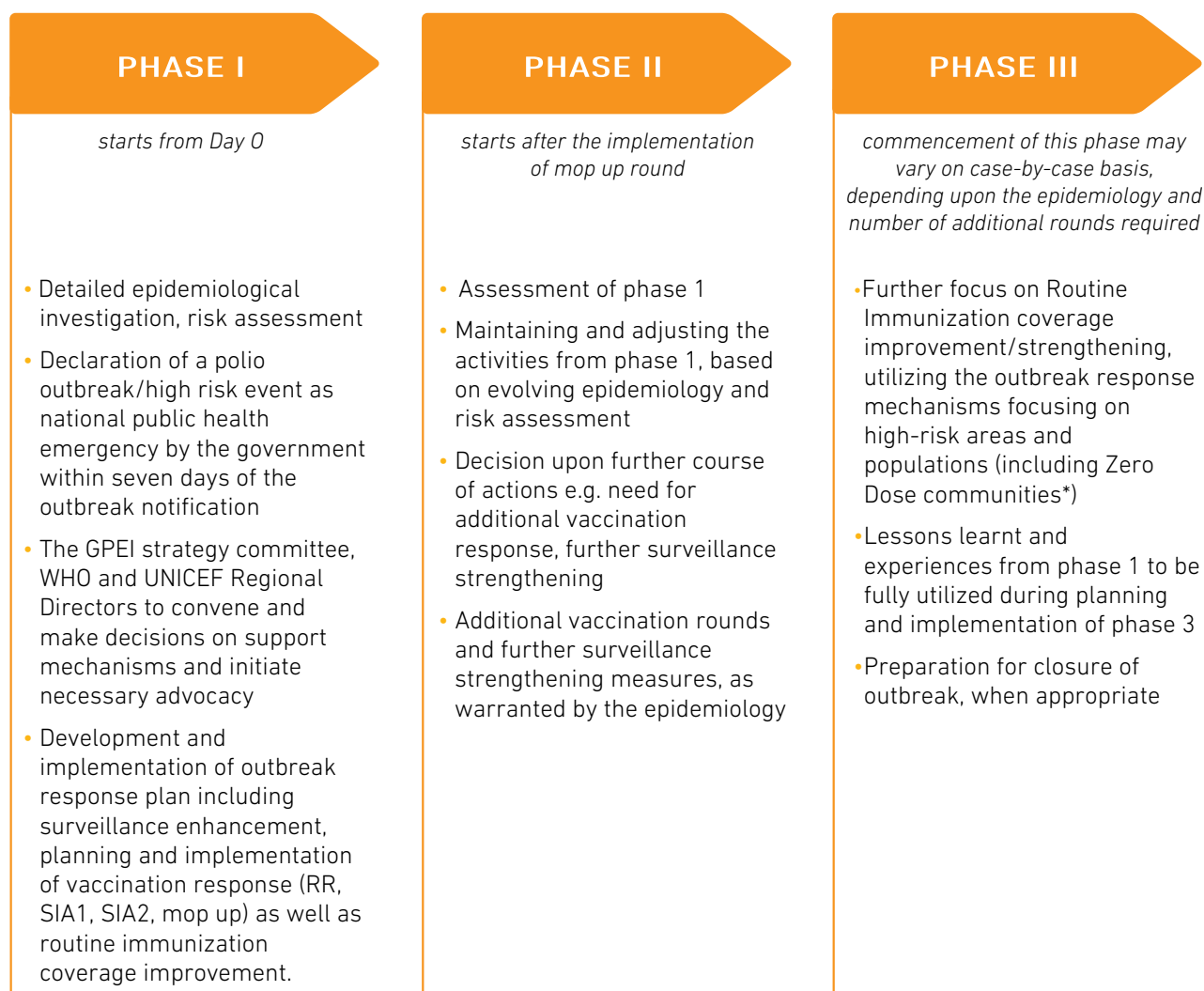
The Polio Eradication Strategy 2022–2026 sets aggressive benchmarks to measure progress towards eradication in order to interrupt the endemic transmission of WPV1 in Pakistan and Afghanistan and stop all cVDPV2 outbreaks by the end of 2023, allowing for certification of global eradication of all wild polioviruses and validation of absence of cVDPV2 in 2026.

Achieving the last milestones for WPV1 certification and cVDPV2 interruption will launch the Post-Certification Strategy (PCS), for which steps have been initiated toward long-term integrated polio surveillance, response capacity, essential immunization strengthening and containment.

The GPEI plans to achieve Goal Two of the strategy by functionalizing an emergency management structure with clearly defined roles and responsibilities, developing and implementing a comprehensive accountability framework, increasing government ownership through political advocacy, and strengthening regional and country capacities for sensitive surveillance and rapid, high-quality response. Innovative tools and methods, as well as new partnerships, will be pursued to strengthen outbreak response operations.

The new Polio Eradication Strategy also commits to an integrated approach to programme implementation that enables countries to leverage existing polio programme assets and serve the health needs of vulnerable communities. The strategy defines integration as joint efforts between the polio eradication programme and a range of partners with the objective of improving immunization outcomes in targeted geographies. The two principal means for integration mentioned in the strategy include strengthened collaboration with other immunization programmes and context-appropriate strategies for delivering vaccines alongside primary health care and other services.

Box 1: Outbreak response planning: at a glance



*<https://www.immunizationagenda2030.org/>

2. POLIOVIRUS EVENTS & OUTBREAKS

KEY DEFINITIONS:

Poliovirus isolates detected in humans or in the environment fall into three categories:

- 1. Wild polioviruses;** the natural virus that can cause paralysis particularly in young children. Wild poliovirus types 2 and type 3 (WPV2, WPV3) have been certified eradicated, and no longer circulate in human populations, but may be found in laboratories and vaccine manufacturing plants. Wild poliovirus type 1 still circulates in human populations in the remaining two WPV-1 endemic countries, Afghanistan and Pakistan.
- 2. Vaccine viruses;** these include:
 - Sabin viruses, the live attenuated poliovirus in oral polio vaccine (OPV).
 - Sabin-like polioviruses are those that have begun to diverge from the standard Sabin strain in OPV, but to a lesser degree than those that are able to cause paralysis, known as a vaccine-derived poliovirus (see below).
 - in 2020, a second attenuated virus was authorized for use in cVDPV2 outbreaks, this virus is named commonly as Novel oral polio vaccine virus type 2.

Sabin and Sabin-like viruses are commonly detected in the population and the environment when OPV is used in routine immunization (RI) or supplementary immunization activities (SIA) with OPV. Type 2 vaccine virus should no longer be detected except where monovalent OPV2,

trivalent OPV or novel OPV2 have recently been used for response to poliovirus type 2.

3. Vaccine Derived Polioviruses

(VDPV) vaccine virus strains that are >1% divergent (≥ 10 nucleotide (nt) differences) for types 1 and 3 and >0.6% divergent (≥ 6 nt differences) for type 2 from the corresponding reference Sabin strain in the VP1 gene region. VDPVs can be further categorized as follows:

- **Circulating vaccine-derived poliovirus (cVDPV)** is a VDPV demonstrating person-to-person transmission in the community, based on evidence from human and/or environmental detections of genetically linked viruses.
- **Immune-deficiency associated VDPV (iVDPV)** is a VDPV from individuals that have evidence of primary immunodeficiency (PID). Unlike immunocompetent persons, who excrete the vaccine virus for a limited period, in rare cases individuals with primary immunodeficiency may excrete a genetically diverged vaccine virus for an extended period after receiving OPV.
- **Ambiguous VDPV (aVDPV)** is a VDPV for which the VP1 sequence is not genetically linked to other previously identified VDPV sequences and there is no evidence of PID if the virus is from an individual. A VDPV sequence will be classified as ambiguous based on laboratory results and epidemiological investigation and in communication with field teams, and technical experts and laboratory staff

at WHO HQ and the WHO Regional Office. Isolates may be from persons with no known immunodeficiency or from an environmental sample, without evidence of circulation.

Genetic linkage: Genetic relationship between or among poliovirus sequences that suggests a common origin or emergence.

Orphan viruses: Viruses with less than or equal to 98.5% VP1 identity from the closest match in the sequence database at that time. Finding these viruses usually indicates that the virus has been circulating for some time without being detected by either AFP or environmental surveillance.

DEFINITION OF POLIO OUTBREAKS AND EVENTS IN THIS VERSION OF THE SOPS

Detection of WPV or VDPV (excluding iVDPV) in a previously unaffected area can be classified according to the pattern of detection and spread.

1. An Outbreak: detection of WPV or cVDPV with community level transmission as demonstrated by:

- a. detection in a human, UNLESS there is a travel history to an infected area within 35 days before onset of paralysis OR a confirmed type specific virus exposure in a laboratory or vaccine production facility;

- b. two separate detections from the environment, where separate means the samples were collected from two different sites with no overlapping catchment areas OR from the same site but at least two months apart;
- c. any newly detected cVDPV, whether in a human or environmental sample; i.e. when a VDPV isolated either in human stool or the environment can immediately be genetically linked to another VDPV thereby confirming circulation in the areas of detection.

2. An Importation Event: detection of WPV or cVDPV importation but no evidence of community transmission:

- a. Detection of WPV or known cVDPV in an AFP case or asymptomatic person with a travel history to an infected area within the 35¹ days before onset of illness.
- b. One single environmental detection of WPV or a known cVDPV in a new infected territory (or country); with no evidence of local community transmission found².
- c. Multiple environmental detections of WPV or a known cVDPV from one site over less than two months but no evidence of ongoing viral replication (isolates are genetically identical or nearly identical³).

1. The probability of a case being travel associated is the highest at 7-10 days, and decreases thereafter, minimal after 35 days (<https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization/poliomyelitis>)

2. after adequate sampling of sufficient number of healthy children in the same community and sampling of environmental sites in the area but not in the sewage catchment of the case

3. isolates show no or minor genetic variation consistent with excretion by a single human being.

3. A New Emergence Event: New VDPV emergence

- a. Detection of a newly identified VDPV in a single AFP case or asymptomatic person (such as a household contact) with no evidence of community transmission found², including from genetic sequencing (not genetically linked to another known VDPV)
- b. Multiple detections of a newly identified VDPVs from a single environmental sampling site within a two-month period but no virological evidence of multiple excretors (i.e. the genetic sequences are identical or nearly identical³).

4. Facility associated WPV or VDPV event:

Detection of WPV or VDPV in a person with suspected or documented type-specific virus exposure in a laboratory or vaccine production facility, or in the environment samples collected in the vicinity of such a facility.

5. Vaccine Event

- a. A case of vaccine associated paralytic polio (VAPP) very rarely caused by Sabin and Sabin-like polioviruses typically in the newborn, which is a clinical event rather than a public health event.
- b. Detection of a type 2 vaccine virus in an area where type-2 containing

polio vaccine has not been used in the four months prior to detection -OR- detection of type 1 or type 3 vaccine virus in an area where polio vaccine has not been used for routine immunization (countries with only IPV in their routine childhood vaccination schedules) or SIAs in the four months prior to detection

An uninfected area is defined as an administrative division of a country in which there has been no transmission of the specific poliovirus in the previous 12 months (as determined by the date of onset of paralysis for AFP cases or date of collection for other human or environmental samples). Typically, the uninfected area is either the whole country (in case of small countries e.g. population <2 million) or first sub-national administrative unit such as a state or province (in case of moderately populous countries e.g. population >2 million), but may also be a second sub-national area such as a district or prefecture or metropolitan area (for large countries with populations >10 million).

Events do not require a vaccination response unless those are high risk. Events 2b, 2c and 3a due to type 2 poliovirus are considered high risk, as is 3b if additional risk factors are present (details in section 6).

3. DETECTION, NOTIFICATION & INVESTIGATION

DETECTION

Samples collected from human or environment sources during routine surveillance or an event or outbreak investigation are sent to a laboratory of the Global Polio Laboratory Network (GPLN) to determine the presence of poliovirus. The virus is identified through culture, intra-typic differentiation and genetic sequencing. Direct poliovirus detection is being rolled out in 2022.

NOTIFICATION

As soon as poliovirus is identified, the GPLN will inform the health authorities of the affected country and WHO at the country, regional and headquarters levels. Under the *International Health Regulations (2005) (IHR)*⁴, all notifiable polioviruses (see Box 2) must also be immediately reported by national authorities to the IHR focal point at the respective WHO regional office.

WHO headquarters will inform GPEI partners when this information is received and validated. Additional details, including any genetic links to other polioviruses, will be shared by the GPLN and WHO headquarters as soon as available.

Notification to WHO may lead to publication of a disease outbreak news report on the WHO website, as appropriate, based on virus type, risk assessment and outbreak status.

Defining “Day 0” for response monitoring

For response performance monitoring, a “Day 0” is defined so that progress of all response actions can be monitored against the standards set in these SOPs. Day 0 is the day of receipt of laboratory confirmation of WPV or VDPV by genetic sequencing at WHO headquarters or relevant WHO Regional Office and is considered as the “outbreak notification day”. All timelines mentioned in these SOPs are counted from “Day 0” unless specified.

All poliovirus events should trigger the following responses:

- Public health investigation of cases and their contacts, and their local communities. In case of a positive environmental sample, the investigation should focus on the catchment area and population being sampled by the environmental surveillance site;
- Risk assessment based on the results of the public health investigation;
- Surveillance enhancement; and
- Strategic advocacy and risk communication.

For all outbreaks and some high-risk events (deemed to require a vaccination response), Day 0 remains the same for the purpose of operational response monitoring, even if new information confirming transmission becomes available at a later stage.

4. See “International Health Regulations” (2005), third Edition. Geneva: World Health Organization; (<https://www.who.int/publications/i/item/9789241580496>, accessed 15 November 2021)

In case of a low-risk event without vaccination response, genetic sequencing information for new isolates may subsequently retrospectively confirm transmission. In this case, consideration may be given by GPEI to adjust Day 0 to the date of receipt of the new sequencing information that necessitated the vaccination response.

INVESTIGATION

The country must investigate any poliovirus isolate notifiable under IHR, from any human or environmental sources. The GPEI will support the country as needed.

Box 2: International Health Regulations 2005 (IHR) and the obligation to notify

Under IHR, notification is required for all events that may constitute a public health emergency of international concern. For polio, this includes detection in human or non-human sources of:

- WPV,
- VDPV (type 1, 2, or 3), and
- and Sabin / Sabin-like type 2 viruses, from the areas where Sabin OPV2 has not been used in the previous four months (Sabin / Sabin-like viruses types 1 and 3 are not notifiable)

The national IHR focal point must notify WHO within 24 hours the IHR contact person at the respective WHO regional office of all notifiable polioviruses, without waiting for final classification.

Local health authorities should initiate the investigation within 24 hours of a poliovirus isolate report. The most effective approach is a joint epidemiological and social investigation with support from the national level of any case and affected community, as well as the gathering of relevant national data. A detailed case investigation may also be carried out for a clustering of compatibles (two cases in either a single district or two neighbouring districts in four weeks) and in some cases, a “hot” AFP case⁵ in advance of laboratory confirmation. Information from the GPLN and the

epidemiological and social investigation are used to describe the characteristics of the virus and determine if there is evidence of community transmission. This will inform the risk assessment and classification. Ominous epidemiological situations and alerts should be investigated immediately without waiting for the results of the laboratory investigation and final virus classification.

Table 1 outlines the scope and objectives of an investigation.

5. A “hot” AFP case is a case that meet at least 3 of the following criteria or the criteria as defined by the Country or Region: less than five years of age; fewer than three doses of OPV or have an unknown OPV status; 3) rapid progression of paralysis; 4) asymmetrical paralysis; 5) fever at onset. See Section 2.3 for further information on “hot” cases

Table 1: Investigation of poliovirus isolates from AFP cases, contacts or environmental surveillance

Investigation components		Objectives
Part A: Investigating the case or environmental isolate and local context	1. Detailed case investigation of a poliovirus isolate from an AFP case or a contact of an AFP case	• Gather information to confirm the event/outbreak and associated risks
	2. Investigating the site of an isolate from environmental surveillance	• Identify possible source of infection/causes of the event/outbreak
	3. Describing the community context of any detected isolate, regardless of source: <ul style="list-style-type: none"> • Population immunity • Recent SIA performance • Population characteristics, movement and migration routes • Community social mapping and determinants 	<ul style="list-style-type: none"> • Determine the number and characteristics of cases, the context for environmental isolates • Formulate control measures (immunization and surveillance) to interrupt transmission and prevent spread
Part B: Determining the geographic extent of transmission	4. Community search for additional cases of AFP and evidence of virus transmission: <ul style="list-style-type: none"> • Surveillance Data • AFP contact sampling (for inadequate AFP cases) • Targeted healthy children stool sampling (as per GPEI surveillance guidance) • Community household search • Local health facility search • Other community outreach 	<ul style="list-style-type: none"> • Determine the geographic extent and assess the risk of further transmission • Further refine and sharpen the control measures to interrupt transmission and prevent geographical spread

Part A: Investigating the case or environmental isolate and local context

1. Detailed case investigation of an isolate from an AFP case or contact

For any poliovirus isolated from a child or adult (AFP case or contact), conduct a detailed clinical and neurological history and examination. Collect a

detailed history of fever, progression of weakness, treatment, injections and vaccination (including all routine and SIA doses of any polio vaccine, date of last vaccination, and reasons for any missed doses). Clinical and family history should include any signs or symptoms of primary immunodeficiency, and a test for quantitative immunoglobulins where indicated.

An urgent epidemiological (i.e. person, place and time) and social investigation of the AFP case is required. Specimens should not be collected from close contacts if adequate stool samples have been collected from the AFP case and poliovirus has been confirmed. It is important to collect detailed information on immunization history, medical history, travel history, special population or high-risk status, socioeconomic and community context, distance to health facility or other barriers to vaccination, and other relevant information. The investigation should also consider any existing environmental surveillance sites in the vicinity of the case. The GPEI form *Detailed epidemiologic case investigation form*⁶, provides a guiding template for a joint epidemiological and social investigation⁷.

2. Investigating the site of an isolate from environmental surveillance

Describe the catchment area of the infected sampling site and other collection sites in the area, including information on population demographics (especially high-risk groups), population movement, relevant institutions (e.g. health facilities, schools, poliovirus essential facility like a poliovirus vaccine manufacturer or laboratory), and bus stations or other transportation centres.

Describe the sewage or drainage system into the collection site, complemented by geographic information system (GIS)

imagery where possible (e.g. elevation profile, links with other sites, and density of dwellings). Document the history of the site, collection schedule, number and frequency of samples collected, timeliness and completeness of collection, and proportion of samples positive for enteroviruses (EV). Record any poliovirus detected, including Sabin virus.

For Sabin 2 virus isolation, investigate immediately using the field guide and investigation template available (unless within four months of a type-2 containing OPV response in the immediate area).

Detection of novel OPV2 virus (in human or environment) in an area that has never implemented a vaccination round using novel OPV2 or implemented any such rounds more than four months before the novel OPV2 virus isolation, should also trigger an immediate investigation and risk assessment. Findings of the investigation should be shared with the Regional polio response teams, ORPG and the GPLN. An important subset of Novel OPV2 viruses will undergo full genome sequencing to determine if attenuation sites are maintained through subsequent transmissions in communities where the vaccine had been used. Any nOPV2 isolates for which the number of mutations in VP1 is >6 nucleotides may trigger investigations, risk-assessment

6. See "Detailed epidemiologic case investigation form". GPEI guidance. Geneva: Global Polio Eradication Initiative; 2011 (see document within GPEI library <http://polioeradication.org/tools-and-library/resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/>, accessed 15 November 2021)

7. Country-specific tools required to investigate a poliovirus detection should be developed during outbreak preparedness and response planning. A national team to conduct the investigation should be trained as core capacity development for implementation of IHR or Integrated Disease Surveillance and Response (IDSR).

and findings to be shared among all concerned stakeholders (e.g. Regional polio response teams, ORPG, SG, GPLN etc.) for figuring the way forward.

Investigation of WPV (in a non-endemic country) and other poliovirus isolates must consider possible release from a laboratory or other facility⁸ or importation (e.g. by an incoming traveler), particularly when genetic sequencing to ascertain origin is still pending.

3. Describing the characteristics of the community of any detected isolate, regardless of source

The information outlined below should be collected following detection of poliovirus in a previously uninfected community. For any subsequent detection in the same area, focus on significant updates to the general information previously collected.

Population immunity

- Develop an immunity profile based on available information such as type-specific vaccination status of non-polio AFP cases, routine and SIA vaccination coverage data, and community immunization surveys.
- Determine the characteristics of unvaccinated and partially vaccinated children, high-risk or special populations, and seek details of health-seeking behaviour.
- For type 2 isolates, distinguish carefully between immunity to type 2 poliovirus compared to types 1 and 3 polioviruses, and pay special attention to birth cohorts born since the switch or since last use of type 2 containing OPV.
- Estimate the population naive to oral polio vaccine or protected only by inactivated polio vaccine (IPV) for type 2 poliovirus. Collect epidemiologic evidence of any past poliovirus detections (WPV or VDPV) in the affected or surrounding communities.
- Review documented communicable disease incidence and transmission patterns, including vaccine-preventable diseases, while paying special attention to diseases with faecal–oral transmission such as cholera and acute bloody diarrhoea.

Recent SIA performance

- Use immunization coverage, independent monitoring (IM), and lot quality assurance sampling (LQAS) indicators from recent SIAs to define the following: i) number and characteristics (including sex) of missed children; ii) reasons for missing children; and iii) any interventions that worked to successfully reach missed children.
- For any type 2 poliovirus, in addition to information on any post-switch detection of Sabin 2 or previous VDPV2, collect additional details regarding last known use of tOPV, mOPV2, or novel

8. See “Public Health Management of Facility-Related Exposure to Live Polioviruses: Interim guidance in managing exposed persons for countries hosting facilities that maintain live polioviruses” on GPEI website library, <http://polioeradication.org/tools-and-library/resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/>, accessed on 15 Nov. 2021

- OPV2; quality of type 2 containing vaccine management, and steps taken to search for any remaining tOPV, mOPV2 or nOPV2 vials.

Population characteristics, movement and migration routes.

- Obtain a general overview of the affected population, including information on population density, social structure and networks, presence of minority or non-local residents, and community awareness of polio and immunization.
- Highlight any security and access constraints.
- Take note of major population movements due to economic, seasonal or nomadic migration, religious pilgrimage, insecurity, or natural disaster.

Community social mapping

- Use formal or informal sources to gain an appreciation of immunization practice and vaccine acceptance in the community, including gender related barriers to immunization (through rapid gender analysis).
- Gather general information on media reach, community influencers, and relevant social and language groups.

Part B: Determining the geographic extent of transmission

4. Community search for additional cases of AFP and evidence of virus transmission

Once a poliovirus has been detected from any source, additional steps are required to ascertain the geographic extent of possible transmission. These activities can include a review of surveillance data, investigation of AFP contacts, others in the community, and health facilities using strategies that are often part of routine poliovirus surveillance, but also useful in specific circumstances after a poliovirus has been confirmed (see also Section 8 on enhanced routine surveillance).

Surveillance data

- Conduct an in-depth polio surveillance review across the country (and bordering areas of neighbouring countries, if applicable) to analyse risk and determine the quality and sensitivity of the current surveillance system, with special focus on polio infected and bordering areas.
- Include a review of AFP surveillance indicators at the lowest applicable administrative level, including (but not limited to) AFP detection, stool adequacy, and the immunization profile for non-polio AFP (NPAFP) children 6–59 months disaggregated by sex, for the last three to five years.
- Understand and map inaccessible areas and high-risk populations to ensure there are no blind spots within the surveillance system.

- Consider evidence of implementation of recommendations for surveillance strengthening from recent programme or surveillance reviews

Further investigation in the community and health facilities are time and resource intensive, and so require close coordination with the relevant surveillance and laboratory colleagues to prepare for any surge requirements. Unless otherwise indicated, the strategies below should only be implemented as part of the field investigation following detection of a new unclassified VDPV case or newly positive environmental sample (VDPV or WPV) in an area that has not had documented transmission within the past 12 months

Possibly relevant investigation strategies include:

- **AFP Contact sampling** (also known as direct contact sampling and close contact sampling) is usually conducted, *when an AFP case has inadequate stool specimens* for laboratory confirmation of poliovirus: AFP contact sampling is used to provide laboratory evidence of poliovirus in an AFP case. Individuals in contact with AFP cases have a higher likelihood of asymptomatic infection and virus excretion than people who have not had contact. The collection of stool specimens from contacts of AFP cases provides an additional approach to determine if poliovirus is the cause of paralysis in an AFP

case. Positive laboratory results of contact specimens are used to confirm poliovirus infection in an AFP case who is not otherwise laboratory confirmed. The **AFP contact sampling should not be conducted for laboratory-confirmed cases of poliovirus**. Direct contact sampling does not provide evidence for community transmission.

- Under specific circumstances during a poliovirus outbreak, AFP contact sampling may be expanded for all AFP cases for a limited time period. Examples include AFP cases outside the outbreak zone to detect further transmission, or AFP cases within a security compromised, at-risk, or hard-to-reach area to take advantage of the limited opportunities to reach this community. Decisions on expansion should be made at the national level with laboratory colleagues. See AFP contact sampling job aid⁹ and GPEI website for more information on the process for sampling and specimen labelling.
- **Targeted healthy children stool sampling** (also known as healthy children sampling, community contact sampling, community stool sampling, or asymptomatic children stool sampling) should be conducted following a new VDPV isolation when community transmission has not been confirmed. The decision to conduct targeted healthy children stool sampling must be made in close coordination with national surveillance and laboratory teams. It is recommended to collect

9. See: Job aid (<https://polioeradication.org/wp-content/uploads/2020/03/AFP-contact-sampling-and-targeted-healthy-children-stool-sampling-20200327.pdf>, accessed on 15 Nov. 2021)

and laboratory test one stool specimen from each of 20 asymptomatic children (i.e. children without AFP) to determine if poliovirus is present and hence transmission in the community.

If there is already evidence of community-wide transmission, targeted healthy children stool samplings should not be conducted.

Children (<5 years old but preferably <2 years old) with no evidence of AFP and **have not had contact with the AFP case within the week prior to or two weeks after paralysis onset**, should be targeted for specimen collection. The objective is to identify children who reside in the same community but are not close contacts.

Any decision to do a targeted healthy children stool sampling should be made at the national level in consultation with laboratory colleagues. See AFP contact sampling job aid¹⁰ and GPEI website for more information on the process for sampling and specimen labelling.

Community household search. For any area with a newly detected VDPV or environmental surveillance (ES) sample, a house-to-house search to identify any person with sudden onset of weakness or paralysis in one or more limbs in the past 60 days can help to determine if there is any additional community transmission. The number

of households to visit will depend on local population density and other risk factors. Existing mechanisms (if available) for community based surveillance should be utilized for household search. National authorities and/or GPEI technical expert advisory bodies can provide further guidance.

Local health facility search. Conduct retrospective case searches in health facilities (formal, informal, traditional faith healers) and document findings. Include at least six-month record reviews for undetected/unreported AFP cases; and investigate unreported AFP cases. Assess clinicians' knowledge of AFP surveillance and polio immunization performance and capabilities and provide sensitization as necessary. Complete a search for vials of tOPV, mOPV2, or nOPV2 where relevant.

Other community outreach. As part of the search for any cases of AFP, including during household search, investigators should engage local leaders and influencers in the community and sensitize them to the case definition of AFP and the importance of early reporting of AFP. If the community based surveillance mechanisms already exist, investigators should interview the community informants to learn about any potential unreported AFP cases.

10. See: Use of AFP contact sampling and targeted healthy children stool sampling: GPEI Job Aid. Geneva: Global Polio Eradication Initiative 2019. [see document with GPEI library <http://polioeradication.org/tools-and-library/resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/>, accessed on 15 Nov. 2021]

4. RISK ASSESSMENT

INITIAL RISK ASSESSMENT

Isolation of a poliovirus in a previously non-infected area represents an event or outbreak that requires national authorities to complete an immediate risk assessment to inform the type and scale of response. The purpose of the risk assessment is to review virologic and epidemiologic characteristics of the newly detected virus, event or outbreak and determine the level of risk for further local or international spread as high, medium or low.

The risk assessment is presented by national authorities/country polio eradication team to Regional polio response teams and ORPG within 72 hours of receipt of a genetic sequencing result, or outbreak confirmation. The assessment reviews critical factors as well as information from the field investigation that will influence the type and scale of response and allows GPEI to recommend appropriate actions.

A risk assessment addresses three risk elements: virologic, contextual, and risk of international transmission (see Table 2).

Virologic Risk

Based on experience since the international spread of polio was declared a PHEIC, compared to the other two polio types, cVDPV2 outbreaks are the highest risk

for becoming persistent, spreading internationally and failing to be under control within 120 days. This is due to the absence of population intestinal mucosal immunity in many countries and many age groups and the greater propensity of Sabin type 2 to revert to VDPV2. Similarly, a WPV2 outbreak due to a containment breach would be very high risk particularly in areas with poor sanitation and low IPV coverage.

By definition, two genetically linked VDPVs are required to classify the virus as circulating, so the first virus detected may initially be classified as an aVDPV. However, currently a single new VDPV2 detection may also signal high risk of further transmission and cVDPV2 outbreak, depending upon the local context. The risk is higher if the VDPV2 isolation occurs in a previously uninfected area with no type-2 vaccination in the last six months; moreover, the higher the genetic divergence from Sabin type 2, the higher is the risk of the outbreak. Conversely, a new VDPV2 with fewer nucleotide changes in an area with recent Sabin OPV2 use is a much lesser risk of circulation. A recent data analysis¹¹ indicates that almost 90% of the VDPV2 detected in AFP cases since the tOPV – bOPV switch (2016), went on to circulate and classified later as cVDPV2. This proportion increased to 97% if the VDPV detection was more than six months

11. Presentation: GPEI Cessation Risk Task Team (CRTT) modelling groups (2021, April 16), quarterly meeting of the GPEI CRTT (virtual by MS Teams)

after the last use of type 2 OPV. Among the VDPVs detected through environmental surveillance, 40% were later shown to be circulating and this increased to 89% if the detection was more than six months from the last use of type 2 OPV. Isolation of new VDPV in areas with known inaccessibility for vaccination and sub-optimal surveillance also represents high risk of further transmission, geographical spread and undetected local transmission.

The overall risk of emergence and transmission of VDPV1 and VDPV3 is much less than for type 2 and is primarily related to bOPV immunization coverage. Since 2016, outbreaks due to cVDPV1 and cVDPV3 have been mostly small and localized. However, international spread of VDPV1 was detected between Malaysia and the Philippines in 2019. WPV1, the last wild poliovirus to be eradicated, is also a high-risk virus and capable of long-distance spread. However, given the higher population intestinal immunity due to bOPV use in routine immunization and SIAs, the risk is related directly to immunization coverage in the affected populations. WPV3 infection as a result of a containment breach would present a similar risk.

All type 2 virus isolations require special attention when conducting a risk assessment and determining the type and scale of response. Following the global withdrawal of type 2 containing OPV from routine immunization programmes in April and May of 2016, there is increasing risk of very rapid virus spread associated with declining mucosal immunity in children.

All type 2 poliovirus (VDPV2 or WPV2) detections require consultation with Regional polio response teams and will be considered by the Sabin OPV2 Advisory Group/ORPG nOPV2 Release Group, to review the risk assessment and assess the need for a potential vaccination response with a type 2 oral polio vaccine.

A detection of type 2 Sabin or Sabin-like virus in an area where Sabin OPV2 has not been used in the previous four months is notifiable under IHR. Such a finding may reflect ongoing and/or unauthorized use of tOPV or monovalent Sabin OPV2, as children vaccinated with OPV continue to shed Sabin virus for approximately three months. For this reason, detection of type 2 Sabin or Sabin-like virus from any source four months or more after last Sabin OPV2 use requires an investigation, risk assessment and IHR notification to WHO.

Initial risk assessment and investigation should also be initiated for a poliovirus type 2 isolate pending for genetic sequencing (PV2) in the laboratory, from an area that did not implement any OPV2 rounds in the last six months, especially if other epidemiological risk factors also exist.

If novel OPV2 virus is detected (in human or environment) in an area that has never implemented a vaccination round using novel OPV2 or implemented any such rounds more than four months before the novel OPV2 virus isolation, an investigation and risk assessment should be initiated to determine the source. The country programme should immediately share the findings with the Regional polio response teams and the Outbreak Response and ORPG.

Contextual risk

A detailed summary of elements to help countries prepare a robust risk assessment is provided, along with additional resources and tools (see Annex 1: Risk assessment overview for detailed guidance) but should include:

- detailed quantitative and qualitative analysis and mapping of population movement (e.g. trade, migration, displacement, and travel and migration routes such as roads, lakes and rivers);
- quantification of special high-risk or hard-to-reach populations (e.g. geographic or cultural inaccessibility, areas of insecurity, vaccine refusals and sentinel events);
- modelling of population immunity to relevant outbreak/event poliovirus type(s);
- detailed assessment of all surveillance indicators at subnational level;
- mapping with geographic information system (GIS), with emphasis on high-

risk populations, urban areas, border areas and regions difficult to access for any reason.

Entities such as the International Organization for Migration, the United Nations Office for the Coordination of Humanitarian Affairs, and the WHO Health Emergencies Programme can provide critical information on population migration and insecurity.

Risk of International Spread

The risk of international spread is to be considered in conjunction with the virologic and contextual risk, especially if the area affected by outbreak or high-risk event is bordering another country or has demographic links to other areas across the international borders (e.g. significant cross-border population mobility, international travel routes etc.). In such situations, it is important to initiate necessary cross-border coordination on development and implementation of joint and complementing response plans with feasible synchronization of activities.

Table 2: Elements to assess risk for further poliovirus transmission that will guide response planning

Risk element	Sample of risk factors considered (not exhaustive)
Virologic risk ¹	<ul style="list-style-type: none">• High degree of genetic deviation from parent Sabin, number and nature of nucleotide changes, and expert interpretation by virologists, etc.
Contextual risk	<ul style="list-style-type: none">• Recent poliovirus detection or other sentinel events, sensitivity of AFP surveillance system, high population density, low immunization coverage and population immunity, geographic access, conflict, inaccessible or hard-to-reach populations, and population movements, etc.
Risk of international transmission	<ul style="list-style-type: none">• Border area with high population mobility, nomadic or refugee populations, cross- border conflict, and international travel routes, etc.

¹ Virologic risk is considered high for any WPV or cVDPV

INCLUDING SENTINEL EVENTS IN THE RISK ASSESSMENT

A sentinel event is information or an occurrence of any nature, related or unrelated to polio, which suggests that the community or general geographic area may be at risk for a polio outbreak. Sentinel events can include:

- Appearance of vaccine-preventable disease (e.g. measles, diphtheria, and/or VDPV of any type) that suggests low routine immunization performance in general (e.g. measles) or
- Appearance of a disease with the similar mode of person-to-person transmission as polio;
- Rapid displacement or ongoing movement of under-immunized communities;

- Detection of type 2 polio vaccine virus from a biological or environmental source in the absence of OPV2 use;
- Finding vials of tOPV, monovalent Sabin OPV2 or novel OPV2 in the community.

Communities or administrative areas with sentinel events should be included in the investigation and risk assessment.

ONGOING RISK ASSESSMENT

Following initial investigation and risk assessment, national authorities must continue to collect detailed information to update the situation analysis and risk assessment (i.e. results from laboratory investigations, detailed information on affected communities, etc.).

5. RESPONSE STANDARDS – OVERVIEW

The scope of response to a detected event or outbreak will be determined by the type and classification of the poliovirus and the risk assessment. The key to a successful response and interrupting transmission lies in adapting strategies as the situation evolves, over the course of the investigation and response.

MINIMUM RESPONSE STANDARDS FOR POLIOVIRUS EVENTS AND OUTBREAKS

Notification of a new poliovirus, or the spread of poliovirus to a new geographic area or population, requires national authorities and GPEI partners to be strongly engaged and rapidly initiate the following elements:

1. Immediate declaration of the outbreak/ high risk event as an emergency by

the national government. This serves a very important trigger for all the subsequent steps and helps ensuring a fully committed 'all of government' approach. The highest GPEI strategic leadership (Strategy Committee) as well as the Regional Directors of the concerned WHO and UNICEF regions will also coordinate on providing necessary enabling support and advocacy for a timely and effective outbreak response.

2. Detailed investigation and risk assessment.

Details on investigation and risk assessment have been

discussed in chapters 3 and 4.

3. Enhanced surveillance

to increase sensitivity and confidence that any ongoing person-to-person transmission of poliovirus will be rapidly detected (see investigation in chapters 5 and 8).

4. Planning for a vaccination response.

Robust coordination, planning, budgeting, community engagement, and monitoring are enabling functions central to successful response. Risk communication and social mobilization efforts should be tailored to the event or outbreak context and support surveillance enhancement, vaccination response activities and routine immunization. For all polio emergency responses, it is necessary to monitor and report all interventions and enhancements for surveillance, vaccination and communication.

5. Scope of vaccination.

The scope of vaccination campaigns will vary according to the risk assessment. All polio emergencies with local transmission, whether VDPV or WPV, should preferably have a vaccination response with an appropriate type specific OPV within 14 days of laboratory notification (more details in the section on vaccination response). In some circumstances, a polio emergency without proven local transmission may warrant vaccination response, based on the risk assessment.

Isolation of an iVDPV requires careful assessment to ensure that all household members and close community contacts are immunized with IPV. Larger-scale SIAs are not required unless circulation in the community is established.

An iVDPV carrier should receive appropriate therapy for their underlying immune deficiency syndrome and be offered optimal anti-poliovirus treatment where available

6. Defining and planning high-quality outbreak response. A comprehensive outbreak response should be able to stop the polio outbreak within 120 days of notification, and includes investigation, surveillance and vaccination, all supported by communication and social mobilization activities, including cross-border coordination between countries. Coordinated and high-quality activities will ensure confidence in the country's ability to detect rapidly any poliovirus circulation and to interrupt transmission through vaccination. For surveillance, it is necessary to monitor carefully both process (e.g. AFP reporting rates, laboratory performance) and outcomes (e.g. early detection of virus through all surveillance strategies in high-risk special populations).

OUTBREAK GRADING

All polio outbreaks and in some instances, high-risk events, should be graded by the relevant WHO Regional Office as per the Health Emergency Response Framework¹².

Grading is a procedure that triggers outbreak response policies in WHO and the affected country or countries. The grading will indicate risk level and determine actions needed to manage the poliovirus event or outbreak in the country context. See Chapter 9 for outbreak response scale-up and detailed information on GPEI support according to grading.

The purpose of the grading is to:

- inform all partners of the nature of the event or outbreak, the response required and the need for mobilization of internal and external resources;
- activate GPEI response mechanisms; and
- prompt local government and GPEI partners at all levels to mobilize resources for support, including immediate human resources.

Ideally, the outbreak should be graded within the first three days of outbreak detection (day 0). Grade 1 is assigned to outbreaks that can be managed in-country, and grade 2 to those that require substantial Regional support and/or technical support from WHO Headquarters. Grade 3 emergencies are global in extent or involve multiple regions. A grade is valid for three to six months, through the first phase of outbreak response, and should be reviewed with new information and/or as response activities progress.

The criteria used to grade outbreaks include: 1) the potential for transmission within the country and beyond national borders based on the risk assessment (virologic, contextual, risk of international spread); and 2) the strength of the country's ability to respond to and contain the outbreak, including vaccine management capacity. Depending on circumstances, the risk assessment may include discussion of the urgency and complexity of the event and the reputational risk it may generate. Country capacity is a subjective assessment based on health infrastructure and current security or access challenges. Figure 1 presents a general risk matrix for grading an event or outbreak.

12. See "Emergency Response Framework (ERF)". World Health Organization; 2017 (<https://www.who.int/publications/item/9789241512299>, pg 28, accessed 15 Nov. 2021)

Figure 1: General risk matrix for grading an event or outbreak

Risk of local or international transmission	Country capacity to respond		
	Strong	Moderate	Weak
Low	Grade 1	Grade 1	Grade 2
Medium	Grade 1	Grade 2	Grade 3
High	Grade 2	Grade 3	Grade 3

STANDARD TIMELINES FOR OUTBREAK RESPONSE

Table 3 outlines key actions and timelines for event and outbreak response (see Annex 2 for a detailed list from Day 0 to close of outbreak). It is essential to rapidly establish coordination mechanisms between countries and GPEI partners at

all levels, including RRT/IMST, WHO and UNICEF Regional offices as well as the OPRG. This may include multilevel calls with sub-regional outbreak coordination offices, regional offices and global partners. Following initial consultation, operations are supported by the relevant GPEI Outbreak Response and Preparedness Group to manage coordination with all partners.

Table 3: Major steps and timelines for critical components of event and outbreak response

Timeline	Response actions for all isolates
Within 24 hours	Initiate investigation
	Country and each partner agency to initiate internal consultations
	Country to notify WHO through IHR
Within 48 hours	Initiate partner coordination via OPRG
Within 72 hours	Risk assessment and grading
	vaccine request to Sabin OPV2 Advisory Group/ORPG-nOPV2 release group (if applicable)
	Initiate development of response plan (surveillance, vaccination, social mobilization)
	GPEI to coordinate and deploy a rapid response team, as required
Within 7 days	National Government to declare the outbreak as National Public Health Emergency
Within 14 days	Rapid response round. If not implemented within 14 days, move to SIA
Within 56 days	First large-scale and second large-scale rounds (<i>mop-up to be implemented within 14 days of second large scale round</i>)
Independent monitoring and LQAS results to be shared within 14 days of each campaign	Assess immunization quality: <ul style="list-style-type: none"> • Independent monitoring • LQAS
Outbreak response assessments (OBRA's)	1. First assessment within three to four months of lab notification
	2. Follow-up quarterly assessments and desk reviews during the course of the outbreak
	3. Final assessment after at least six months without poliovirus detection
	4. Further desk reviews/OBRA's in prolonged outbreaks, as appropriate

6. VACCINATION RESPONSE

The primary objective of vaccination response is to rapidly interrupt person-to-person transmission of poliovirus and hence protect the vulnerable population. Both the timing and the quality of the vaccination response are critically important. To accomplish virus interruption, a prompt vaccination response is required in a sufficiently large population and geographic scope. High-quality vaccination will protect individuals from poliovirus infection and prevent future outbreaks if importation occurs.

The oral polio vaccine appropriate to the poliovirus strain induces intestinal mucosal immunity and remains the vaccine of choice to interrupt transmission rapidly and stop polio outbreaks. The most appropriate vaccine is selected with technical support from WHO and GPEI partners.

ORAL POLIO VACCINE (OPV) FOR OUTBREAK RESPONSE

Oral polio vaccine is the primary vaccination tool used in the fight to eradicate polio. There are different types of oral poliovirus vaccine, that may contain one or a combination of two or all three types of attenuated poliovirus. Vaccination with OPV enables individuals to mount an immune response against the poliovirus. All countries which have eradicated polio used OPV to interrupt person to person transmission of the virus.¹³

Sabin monovalent OPV2

Since the withdrawal of type 2 containing OPV from routine immunization in 2016, vaccination response to cVDPV2 outbreaks could be implemented only using Sabin-based monovalent OPV type 2 under the authorization of the Director General of WHO. Sabin monovalent OPV2 while effective in halting transmission, has a risk of reversion to neurovirulence and hence seeding new outbreaks in the areas with low vaccination campaigns coverage.

Trivalent OPV

In 2020, use of trivalent OPV was initiated under the authorization of the Director General of WHO, to respond to concurrent outbreaks of cVDPV2 and either of cVDPV1, cVDPV3 or WPV1. Trivalent OPV is currently the vaccine of choice to respond to co-circulation of type-2 poliovirus and other types of poliovirus.

Novel OPV2

After receiving Emergency Use Listing (EUL) approval in November 2020, the first outbreak vaccination response with novel OPV2 was implemented in March 2021. SAGE has endorsed a prioritization framework for type 2 vaccines for cVDPV2 outbreak response with clear distinct phases [Phase A: Pre-EUL recommendation, preparing for novel OPV2 use; Phase B: Initial novel OPV2 use under interim EUL recommendation; Phase C: Wider use of novel OPV2 under interim EUL recommendation; Phase D: novel OPV2

¹³. <https://polioeradication.org/polio-today/polio-prevention/the-vaccines/opv/>

licensed and pre-qualified]. The novel OPV2 was used in its 'initial use period' under the EUL from March to September 2021. In October 2021, the SAGE endorsed the transition of novel OPV2 to its next use phase, based on several factors, including the independent review of safety data from campaigns held in Nigeria, Liberia, Benin and Congo. Collectively, these countries used over 65 million doses of novel OPV2 during the 'initial use period'. With the transition from its initial to wider use period, novel OPV2 will be more accessible for outbreak response when supply allows. It is important to mention that the novel OPV2 will be used under EUL until 2023 and all countries planning to use novel OPV2 need to meet additional readiness requirements prior to the release of the vaccine.

As per recommendation of the SAGE, countries facing cVDPV2 outbreaks should avoid delay and prioritize rapid, high-quality cVDPV2 outbreak response with whichever oral polio vaccine is available to them. Moreover, all countries at risk of cVDPV2 outbreaks should prepare to meet the criteria for use of novel OPV2 and to complete the necessary novel OPV2 programmatic readiness assessments. Novel OPV2 can be used for vaccination campaigns at 4-week interval from other OPV campaigns (for both pre and post campaign time). There is no limitation on the time between campaign use of novel OPV2 and routine use of OPV as well as IPV, measles and other non-polio vaccines¹⁴.

Bivalent OPV

For all WPV1, cVDPV1 and cVDPV3 outbreaks (without any concurrent type2 poliovirus outbreak), bOPV remains the vaccine of choice.

INITIATION

A vaccination response is warranted in all outbreaks of any type (i.e. wild or VDPV, all types 1, 2 and 3) and high-risk type 2 events as follows (refer to chapter 2 for definitions):

- Importation event involving cVDPV2 unless travel associated;
- New emergence event involving VDPV2 in a human; and
- New emergence event involving VDPV2 in the environment plus additional risk factors (virus is highly divergent >12 nt, or in areas that implemented OPV2 SIAs more than six months ago, poor quality polio surveillance, presence of inaccessible or hard to reach populations and/or presence of displaced or highly mobile populations.

Epidemiologic data since 2016 has shown that the detection of any cVDPV2, even single detections in new areas, is evidence of either previously undetected ongoing poliovirus transmission or represents a high risk of transmission in the immediate future. Therefore, OPV SIAs are warranted after any cVDPV2 detection even in areas where reported routine immunization/IPV coverage is high¹⁵. Although IPV provides

14. See: WHO department of IVB, Strategic Advisory Group of Experts on Immunization (SAGE) meeting, 4-8 October 2021 (https://terrance.who.int/mediacentre/data/sage/SAGE_eYB_Oct2021.pdf, accessed on 15 Nov. 2021)

15. Kalkowska DA, Duintjer Tebbens RJ, Grotto I, Shulman L, Anis E, Wassilak SGF, Pallansch MA, Cochi SL, Thompson KM. Modeling options to manage population immunity and the impact of asymptomatic wild poliovirus transmission in Israel. *Journal of Infectious Diseases* 2015; 211(11):1800-1812

effective humoral immunity protection against individual paralysis, the mucosal immunity it provides is insufficient to stop transmission of polioviruses.

In a single environmental detection of WPV1, with no evidence of transmission, a vaccination response may still be warranted, if the routine immunization coverage is generally low (<90%) and/or in the presence of sizeable pockets of low routine immunization coverage. Alternatively, intensified surveillance, enhanced routine immunization activities (outreach, PIRI etc.) should be considered with special focus on mobile and other high-risk population groups.

For aVDPV1 and aVDPV3, a wide community level immunization response is not recommended; however, after detection in a human source a limited vaccination response may be considered involving the household and other close contacts such as neighbouring households, playmates etc. Surveillance strengthening measures should be taken to detect community transmission, if any.

Polio facility associated events (e.g. laboratory or vaccine production facility);

Apart from limited use of polio vaccine for exposed person/case, household/family and other close contacts, immunization response is not recommended. However, if any breach in containment results in demonstrated community transmission, broader type-specific response options described in these SOPs may be considered, based on epidemiological investigation and risk assessment. Guidance on how to respond is available¹⁶. A suspected or documented WPV2 outbreak should be managed as for cVDPV2, while such a WPV3 outbreak should be managed as for WPV1.

iVDPV; Isolation of an iVDPV requires careful assessment to ensure that all household members and close community contacts are immunized with IPV. Larger-scale SIAs are not required unless circulation in the community is established. An iVDPV carrier should receive appropriate therapy for their underlying immune deficiency syndrome and be offered optimal anti-poliovirus treatment where available

TIMING AND SCALE OF IMMUNIZATION ACTIVITIES

A four-step vaccination strategy is recommended by GPEI for outbreaks and high-risk events for all poliovirus types (types 1, 2 and 3) (see Figure 2). The four steps consist of a rapid response (RR) round, followed by two large scale rounds (SIA1, SIA2), and a mandatory targeted mop-up round. Further SIAs are justified if there is evidence of ongoing transmission such as by breakthrough isolates/cases.

The aim of this strategy is to ensure that:

- the response is as timely and rapid, as possible;
- at least two high quality large scale rounds are implemented; and
- re-vaccination of all areas where quality was insufficient.

For type 2 response, removal of all Sabin OPV2 (mOPV2/tOPV) or novel OPV2 from the field should be done as soon as possible (further details/timelines are available in the relevant vaccine management guidance documents).

16. See: Public Health Management of Facility Related Exposure to Live Polioviruses (<https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>), accessed on 15 Nov. 2021)

A rapid response (RR) vaccination campaign

For an outbreak or high-risk event, a RR vaccination campaign is the first vaccination response. It should commence by day 14 and target the immediate area of the virus isolation, to stop further transmission rapidly even if the source remains unknown.

If the rapid response cannot be commenced within two weeks, there should be consideration for proceeding directly to SIA1 with appropriate scope and target population. This decision should be made in consultation with Regional polio response teams.

If the available genetic information and detailed field investigation indicate the possibility that poliovirus transmission has been ongoing for a long duration and/or has likely spread beyond the place of detection by the time of notification, a small scale rapid response is not warranted. In such situations, focus should be on preparing and implementing an appropriately scoped and good quality SIA1 as soon as feasible.

SIA 1 and SIA 2

Two high-quality large-scale vaccination campaigns (>90% of children vaccinated) should be completed, preferably by day 42 and latest by day 56 from the outbreak notification. The response will be tailored to the virus type and local context. The duration of the campaign for SIA1 and SIA2 should be four days but can be extended up to seven days based on pressing needs in the local context or make additional efforts such as deployment of additional personnel and supervisors, to complete the campaign and reach missed children in areas of poor performance, as identified by intra-campaign monitoring or supervisors' observations.

Mop-up round

A mop-up round is required as an additional step wherever monitoring suggests, children have been missed in certain health districts or areas, to ensure interruption of transmission (even in the absence of new poliovirus detections). Information to guide the selection of districts for full mop-up can include: intra-campaign monitoring, independent monitoring, eyewitness accounts and spot checks, LQAS, post-campaign surveys, or new events such as population movements, and breakthrough cases. A mop-up round should be included in the initial outbreak response plan, appropriately scaled and implemented after SIA2, and only cancelled if ALL health areas demonstrated high-quality implementation and vaccination coverage. Preferably, the mop-up should be implemented within three weeks after the end of SIA2, to achieve maximum benefit and to boost population immunity within the shortest possible time.

Breakthrough Transmission and Need for Additional SIAs

Any WPV or cVDPV detected in an AFP case, healthy child or environmental sample with the date of onset of paralysis (for AFP cases) or the date of sample collection (for healthy child or environmental sample) more than 21 days after the first day of the last SIA in an area where at least two SIAs have been implemented is evidence of breakthrough transmission. Where there is a high-risk of continued circulation, a shorter threshold of 14 days rather than 21 may be used for triggering an additional SIA. High risk situations include for example, where there is inaccessibility, or evidence of poor SIA quality during outbreak response, or gaps in surveillance performance. The decision to perform any

additional SIAs will be jointly taken by the WHO regional office, other GPEI partners and local public health authorities.

Breakthrough transmission indicates inadequate quality of SIAs and a failure to stop transmission of poliovirus, necessitating additional vaccination rounds. The country polio programme should carry out a thorough field investigation and risk assessment for any breakthrough transmission including any evolution in the epidemiology, the quality of the SIAs, the sensitivity and quality of polio surveillance and any other notable local factors. The outcomes of the investigation and risk assessment should be utilized to decide upon the further course of outbreak response, including the scope of

additional SIAs. Evidence of breakthrough requires a mandatory vaccination response; however, absence of breakthrough does not necessarily negate the need for further vaccination.

Where quality is clearly inadequate in a large geographic area (based on the campaign monitoring modalities e.g. surveys, LQAS, spot checks etc.) break-through isolates are identified or the outbreak continues to spread to unvaccinated areas, additional SIAs should be considered and planned. Two campaigns must be completed after the last detected virus. A high-quality mop-up round may be considered as one of these campaigns, if the area of the detected virus was covered twice.

Figure 2: Visual representation of timing and scale of immunization activities required



Target population

Rapid Response rounds should generally target a minimum of 100 000 and a maximum of 400 000 children (final decision to be made based on the target population in the outbreak zone and country's capacity). SIA1 and SIA2 should typically target 1 - 2 million children for cVDPV/WPV type 1 and type 3, but because of the greater risk of type 2 spread, type 2 events or outbreaks should typically target 2–4 million children.

It is possible to consider increasing the scope further, in densely populated areas, or if there is evidence or risk of extensive circulation (e.g. outbreak population well connected to a major urban area). The geographic scope for response is assessed case-by-case through a detailed risk assessment, informed by discussion with technical experts (i.e. epidemiologists, virologists and country experts), to ensure that all high-risk zones are reached including any such zones in the neighbouring countries, if necessary.

The available data and modelling indicate that for VDPV2 there is a likelihood of 12% weekly increase in the outbreak size and 5% weekly increase in probability of spread if an immediate vaccination response is not implemented¹⁷. On average, delay of one month in implementing the vaccination response may require a 35% increase in the scope/target population¹⁸. Hence, there should be consideration for likelihood of spread of infection if there are delays in implementing vaccination response, while deciding upon the scope and target population. Significant delays in notification of outbreaks and implementing vaccination response call for larger scoped vaccination rounds to stop the transmission. This is particularly true for type-2 poliovirus outbreaks and high-risk events, given the continuously waning population mucosal immunity. In countries with good water and sanitation, the decision for the scope, target population and vaccine choice should consider the local context and findings of the epidemiological investigation.

The target population should be within the capacity of the programme to attain high coverage. Depending on the local context and capacity, phasing of campaigns may be considered to ensure quality in each geographic and demographic region covered.

Target age-group

Target for SIAs are children less than five years of age. An expanded age group (up to 10 or 15 years, or the whole population depending on local context) should be considered if there is significant evidence of virus circulation among older age groups. For type-2 poliovirus outbreaks and high-risk events, the time lapse since the tOPV-bOPV switch may be considered while deciding upon the target age group.

Short-interval campaigns

The interval between SIA rounds using Sabin OPV can be as short as one week; this applies regardless of the type of Sabin OPV used. For example, a Sabin OPV2 campaign could be followed one week later with an additional round of Sabin OPV2 or bOPV, where needed. A short interval additional dose (SIAD) strategy may be used in special circumstances when there are multiple circulating polioviruses and/or when short windows of access or opportunity to vaccinate arise (e.g. mobile or hard-to-access children). Novel OPV2 can be used for vaccination campaigns at 4-week interval from other OPV campaigns (for both pre and post campaign time); there is no limitation for the use of any OPV and other non-polio vaccines in routine immunization.¹⁹

Response strategies recommended for OPV using countries for each type of poliovirus are summarized in Table 4 and Table 5.

17. Alexander G Shaw, Laura V Cooper, Nicky Gumede, Ananda S Bandyopadhyay, Nicholas C Grassly, Isobel M Blake, Time Taken to Detect and Respond to Polio Outbreaks in Africa and the Potential Impact of Direct Molecular Detection and Nanopore Sequencing, *The Journal of Infectious Diseases*, 2021; jiaab518, <https://doi.org/10.1093/infdis/jiaab518>

18. Presentation (analyses to inform OBR SOP updates): GPEI Cessation Risk Task Team (CRTT) modelling groups (2021, April 16), quarterly meeting of the GPEI CRTT (virtual by MS Teams)

19. See: WHO department of IVB, Strategic Advisory Group of Experts on Immunization (SAGE) meeting, 4-8 October 2021 (https://terrance.who.int/mediacentre/data/sage/SAGE_eYB_Oct2021.pdf, accessed on 15 Nov. 2021)

Table 4: Response to Detection of Type 2 Poliovirus outbreak or high-risk event

Situation		Vaccination response			Vaccine preference
		Rounds	Timing	Scope/target	
cVDV2 Outbreak / cVDPV2 high risk event	Areas that previously used nOPV2	RR	≤14 days	100 000 - 400 000	1. novel OPV2* 2. Sabin OPV2, if novel OPV2 cannot be used/ not available
		SIA1	≤28 days	Min. 2-4 million	
		SIA2	≤42 days (latest ≤56 days)	Min. 2-4 million	
		Mop up	≤21 days of SIA2	Based on SIA1/2 quality	
	Areas with no previous use of nOPV2 & last Sabin OPV2 use >2 years ago	RR	≤14 days	100 000 - 400 000	1. novel OPV2* 2. Sabin OPV2, if novel OPV2 cannot be used/ not available
		SIA1	≤28 days	Min. 2-4 million (bigger if warranted)	
		SIA2	≤42 days (latest ≤56 days)		
		Mop up	≤21 days of SIA2	Based on SIA1/2 quality	
	Areas with no previous use of nOPV2 and last Sabin OPV2 use <2 years ago	RR	≤14 days	100 000 - 400 000	Sabin OPV2
		SIA1	≤28 days	Min. 2-4 million (bigger if warranted)	
		SIA2	≤42 days (latest ≤56 days)		
		Mop up	≤21 days of SIA2	Based on SIA1/2 quality	
Areas with co-circulation of cVDPV2 & type1/type3 PVs	Areas with no previous use of nOPV2	RR	≤14 days	As per the epidemiology	1. tOPV 2. Decision to be made on case to case basis if tOPV not available
		SIA1	≤28 days		
		SIA2	≤42 days (latest ≤56 days)		
		Mop up	≤21 days of SIA2		
	Areas with previous use of nOPV2	RR	≤14 days		Decision to be made on case to case basis
		SIA1	≤28 days		
		SIA2	≤42 days (latest ≤56 days)		
		Mop up	≤21 days of SIA2		

* after meeting the nOPV2 readiness criteria

Note: This table (4) is based on the currently available guidance from ORPG & Strategy Committee, in a time-limited nOPV2 stock constrained situation. The guidance will be updated as per need, with the evolving situation and an updated/revised guidance from ORPG/Strategy Committee will take preference.

Table 5: Response to Detection of type1 and type3 polioviruses outbreak

Situation	Vaccination response			Vaccine preference
	Rounds	Timing	Scope/target	
WPV1 Outbreak	RR	≤14 days	100 000 - 400 000	bOPV
	SIA1	≤28 days	Min. 1-2 million	
	SIA2	≤42 days (latest ≤56 days)		
	Mop up	≤21 days of SIA2	Based on SIA1/2 quality	
cVDPV1 /cVDPV3 outbreak	RR	≤14 days	100 000	
	SIA1	≤28 days	Up to 2 million	
	SIA2	≤42 days (latest ≤56 days)		
	Mop up	≤21 days of SIA2	Based on SIA1/2 quality	
Co-circulation of type 1 and type 3 polioviruses	RR	≤14 days	As per the epidemiology	
	SIA1	≤28 days		
	SIA2	≤42 days (latest ≤56 days)		
	Mop up	≤21 days of SIA2		

Routine immunization

Strengthening routine immunization (RI) remains a central pillar of polio eradication. Vaccination with bOPV/IPV and other antigens must continue as usual and be further strengthened, even if immunization sessions are conducted on same day as, or within days of, an outbreak response. Strategies to mitigate any negative impact of outbreak response on the conduct of RI should be planned in advance (e.g. if staff are diverted for the SIA efforts, immediate rescheduling of RI sessions). Outbreak response mechanisms should be appropriately utilized for routine immunization coverage improvement, with particular focus on high-risk areas/ populations.

CONCURRENT CIRCULATION OF DIFFERENT POLIOVIRUS TYPES

If polioviruses of different types circulate concurrently, the decision on response should be based on the epidemiology and vaccine availability. The trivalent OPV is the vaccine of choice for concurrent outbreaks of different poliovirus types. If tOPV is not available, rounds of monovalent Sabin OPV2 and bOPV might be staggered based on operational feasibility. Response strategy decisions will be made by the GPEI technical experts based on careful review of the epidemiology, the geographical areas affected, the capacity for robust response, and vaccine availability on a case-by-case basis. while waiting for the country to get verified.

Box 3

- During concurrent outbreaks of cVDPV2 and cVDPV1 or cVDPV3, immediate cVDPV2 response also takes precedence, in case tOPV is not available
- Co-administration of mOPV2 and bOPV is not recommended during campaigns for operational reasons
- A polio event or outbreak in a country that has been using only IPV in the RI programme requires immediate consultation with WHO, as for any polio event or outbreak anywhere

VACCINE CHOICE

Below are some guiding principles for decision-making on vaccine choice for responding to type-2 poliovirus outbreaks:

- Countries facing cVDPV2 outbreaks should avoid delay and prioritize rapid, high-quality cVDPV2 outbreak response with whichever oral polio vaccine is available to them²⁰.
- Countries will not be considered for novel OPV2 release unless verified ready for novel OPV2 use by the GPEI Readiness Verification Team. No novel OPV2 will be allocated for use in a specific country while waiting for the country to get verified.
- Where there is co-circulation with types 1 or 3 viruses, and no previous use of novel OPV2, tOPV is the vaccine of choice. In countries with previous use of novel OPV2, the decision will be made on a case-by-case basis.

HIGH-QUALITY CAMPAIGNS

In implementing the four-step vaccination strategy for outbreak response, a tension exists between achieving a timely response and achieving the desired vaccination coverage (>90%, as assessed by the post campaign assessment). In settings where poliovirus is detected, the RR (Round 0) may not meet all quality expectations (e.g. situations with security or access challenges, operational difficulties, hard-to-reach subpopulations and/or vaccine hesitancy, or simply lack of adequate time to plan). This is acceptable as long as the RR is timely. However, it is critical to ensure that the first and second large-scale vaccination rounds (SIA1 and SIA2) reach every child, to be able to stop the poliovirus transmission. Quality microplanning, preparedness monitoring, and intra- and post-campaign monitoring are essential strategies to prepare and achieve high-quality campaigns. Low quality campaigns (<90%, assessed by PCM) are not likely to

20. See "weekly epidemiological record/Relevé épidémiologique hebdomadaire, 4 June 2021, 96th YEAR, No 22, 2021, 96, 197–216, <http://www.who.int/wer>]

stop the outbreaks. If the post campaign assessment of a given outbreak response campaign indicates low quality, all necessary quality assurance measures must be taken before the subsequent campaign, with special focus on the identified weaknesses. Planning for mop up should highly focus on improving the SIA quality in the areas that did not perform well during SIA1 and/or SIA2. Sub-optimal quality across the entire four-step response vaccination (RR, SIA1, SIA2, mop up) may require carefully planned additional rounds to address the immunity gap. Decision for such additional rounds should be taken in close coordination with Regional polio response teams and ORPG.

Quality microplanning. Preparation of macro-level plans and budgets based on the target population, local conditions and operational costs allows stakeholders to discuss strategies and secure resources. Such top-down planning must rapidly be accompanied with effective bottom-up microplanning (i.e. developing and validating plans at the community level). House to house campaigns are the preferred modality. Experience has shown that house to house implementation results in higher coverage in most settings. Special strategies such as fixed posts supplemented by outreach teams and special vaccination teams in market places/ transport hubs, should be considered to effectively reach high-risk population

groups (e.g. nomads and refugees) based on the local context. Training and supportive supervision help ensure that micro plans are of high quality. Innovations such as GIS imagery are useful to validate plans in challenging or hard-to-reach contexts (e.g. densely populated urban areas, remote settlements with weak documentation or no prior SIAs, inaccessible or mobile populations). Spot checks carried out by independent sources may be considered as an additional measure to ensure quality of microplanning. See Microplanning Guidelines²¹ and Best Practices in Microplanning for Polio Eradication²².

Preparedness monitoring. A preparedness dashboard and/or a checklist and timeline are required to track country readiness to launch SIAs and support quality implementation. Detailed pre-campaign readiness and intra-campaign quality monitoring are expected for all vaccination responses. The GPEI has defined a set of minimum standards to guide decision making on the state of preparedness towards a high quality campaign. These should be jointly reviewed with Regional polio response teams and ORPG one week prior to the start of a campaign. Countries using novel OPV2 must ensure that the commitments and activities outlined in the documentation submitted to obtain their readiness verification are implemented²³.

21. See "Microplanning Guidelines". GPEI guidance. Geneva: Global Polio Eradication Initiative; 2011 (see document within GPEI library <http://polioeradication.org/tools-and-library/resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/>, accessed 15 Nov. 2021)

22. See "Best practices in microplanning for polio eradication". GPEI guidelines. Geneva: Global Polio Eradication Initiative; 2018 (<https://polioeradication.org/wp-content/uploads/2018/12/Best-practices-in-mircoplanning-for-polio-eradication.pdf>, accessed 15 November 2021)

23. See "Preparing for nOPV2 use: An overview on requirement for countries" (<https://polioeradication.org/wp-content/uploads/2021/10/nOPV2-Overview-Guidance.pdf>, accessed 15 Dec. 2021)

Campaign monitoring. A high-quality campaign must aim for coverage of >90% for SIA1 and SIA2 by independent monitoring with no persistently missed children. Intra- and post-campaign monitoring is essential to ensure quality of SIAs in all phases. All sources of intra- and post-campaign data must be reviewed and triangulated to assess the quality of the campaign, including but not limited to:

- administrative coverage
- rapid intra-campaign monitoring, convenience surveys and spot checks
- Independent monitoring: house-to-house and out-of-house (market surveys) monitoring
- clustered LQAS
- overall consistency of data sources
- ongoing and new population movements
- vaccine management, monitoring and reporting of vaccine wastage, doses remaining, number of vials unaccounted for (especially for OPV2)
- observations of campaign personnel, supervisors, monitors, and observers in the field.

For any areas or populations where suboptimal campaign planning and implementation are identified (e.g. coverage <90%, persistently missed children, vaccine hesitancy/refusal), mop-up vaccination must be rapidly carried out.

The Regional polio response teams and the ORPG will track pre, intra and post

campaign dashboards throughout the outbreak response, working collaboratively with the country team. Further details of monitoring approaches are provided in Best Practices for Monitoring the Quality of Polio Eradication Campaign Performance²⁴ and below in chapter 10.

Planning for mobile, hard-to-reach and special populations

Special populations are groups that are underserved or not served by the regular health system for reasons such as insecurity, inadequate infrastructure, and/or access barriers. Population groups may be mobile (e.g. economic migrants, internally displaced persons, refugees, nomadic populations) or stationary (e.g. remote, hard-to-reach communities, such as fisherman or islanders, or urban hard-to-reach populations, such as those who live in informal settlements, religious communities, or who are members of marginalized groups). All aspects of outbreak response, including surveillance, immunization and communication strategies, must be tailored to reach special populations.

Strategies for special populations should be developed in conjunction with community leaders, communication and social mobilization experts, and personnel knowledgeable of the context, as well as service providers with special expertise (e.g. non-governmental organizations (NGOs), public services, women's groups, faith-based organizations). Appropriate

24. See "Best Practices for Monitoring the Quality of Polio Eradication Campaign Performance", GPEI guidelines. Geneva: Global Polio Eradication Initiative; 2018 (<https://polioeradication.org/wp-content/uploads/2018/12/Best-practice-for-monitoring-the-quality-of-polio-eradication-campaign-performance.pdf>, accessed 15 Nov. 2021).

strategies to vaccinate every child may require creative thinking, and could include tactics such as transit posts, hit-and-run teams, market vaccinations, and/or combined outreach with veterinary or animal vaccinations or other special strategies.

Revisit Strategy to reach missed children

Appropriate revisit strategy should be developed during the planning phase and monitored during the implementation. The strategy should focus on efficient recording of the children missed due to any reason (e.g. absent, refusal etc.) during the visit of vaccination team to the households, and appropriately planned revisit to vaccinate those missed children. The revisit strategy should be tailored considering the local context, with necessary flexibility.

All strategies and tactics must be well documented to ensure that data on the number of children vaccinated, appropriate vaccine management, and other relevant information is collected.

INTEGRATION WITH OTHER HEALTH INTERVENTIONS

Through its strategy for 2022-2026, the GPEI envisions to expand its partnerships to achieve broader impact in polio-priority geographies alongside the key strategies and innovations that improve detection and response.

During outbreak response planning, consideration can be given to integrating

with other health interventions (e.g. measles campaign already planned, vitamin A, etc.) in the following circumstances:

- Full discussion with all partners has taken place at country and other relevant levels.
- Following types 1 and/or 3 outbreak response: RR, SIA1 and SIA2 rounds were successfully implemented, subsequent risk mitigation rounds could consider integration as a cost-saving measure.
- Plans are in place to secure high quality intervention for all antigens considered and monitoring mechanisms are agreed upon in advance.

Planned preventive bOPV rounds may be implemented after the type 2 outbreak response SIAs have been completed, to avoid generating type 1 and 3 immunity gaps.

CONTINUED ADAPTATION TO THE COVID-19 PANDEMIC

As the COVID-19 pandemic evolves through various phases and roll out of COVID-19 vaccines progresses in the polio affected countries, it will be important to continue close coordination with national and local COVID-19 response management mechanisms while planning and implementing the polio SIAs. The country polio programmes should also continue to ensure high quality pre-campaign briefings on IPC measures with health workers at the forefront and community leaders

and use local residents for pre-campaign community mobilization and for vaccination both to reduce risk of COVID-19 exposure and to improve community acceptance. It will also be important to continue close supportive supervision and in-process monitoring to ensure timely identification and correction of any existing gaps. The established tracking systems should be maintained and tweaked as per need, to rapidly detect and respond to rumours or misinformation, especially within the COVID-19 context.

INACTIVATED POLIO VACCINE (IPV)

IPV provides a high-level of individual immunity and protection against paralysis. IPV does not induce the necessary intestinal mucosal immunity in persons without prior OPV immunization for the corresponding serotype. In children without previous OPV vaccination, IPV does not stop transmission of the virus. The Strategic Advisory Group of Experts (SAGE) on Immunization recommends that IPV should not be used for outbreak response because evidence demonstrates that IPV campaigns are unlikely to reach children not reached with OPV campaigns, have limited impact on stopping transmission and have a high programmatic cost. The priority of

outbreak response is to stop transmission; therefore, activities should focus on rapidly achieving high coverage with OPV. SAGE also recommended that vigorous efforts be made to improve routine IPV coverage in locations at risk of cVDPV2 outbreaks to reduce the number of susceptible children before transmission or outbreaks can occur, especially in the context of reduced coverage caused by the COVID-19 pandemic²⁵.

REQUESTING VACCINE

For any outbreak or high-risk event that requires a vaccination response, the country team should submit a detailed risk assessment and vaccine request with the support of the regional teams by day 3 from the outbreak notification.

Sabin2 containing OPV (monovalent OPV2 and trivalent OPV) requests

In line with the World Health Assembly resolution²⁶, specific procedures are in place to access or use Sabin OPV2. The risk assessment and vaccine request are submitted to the Sabin OPV2 Advisory Group. Upon the recommendation of the Advisory Group, the WHO Director-General authorizes release of monovalent Sabin OPV2 or trivalent OPV from the global OPV stockpile or use of in-country remaining

25. See "Meeting of the Strategic Advisory Group of Experts on Immunization, 22-24 March 2021: conclusions and recommendations (<https://www.who.int/publications/i/item/meeting-of-the-strategic-advisory-group-of-experts-on-immunization-22-24-march-2021-conclusions-and-recommendations>), accessed on 15 November 2021]

26. See "Resolution WHA68. Poliomyelitis. In: Sixty-eighth World Health Assembly", pg. 10. Geneva: World Health Organization, 26 May 2015. (https://apps.who.int/gb/ebwha/pdf_files/WHA68-REC1/A68_R1_REC1-en.pdf, accessed on 15 November 2021).

Sabin OPV2 stocks. Upon approval, the Sabin OPV2 vaccine stock with the shortest shelf life will be released by UNICEF from the global OPV stockpile for immediate use. (See vaccine request form and template for approval of import, on the GPEI website²⁷).

novel OPV2 requests

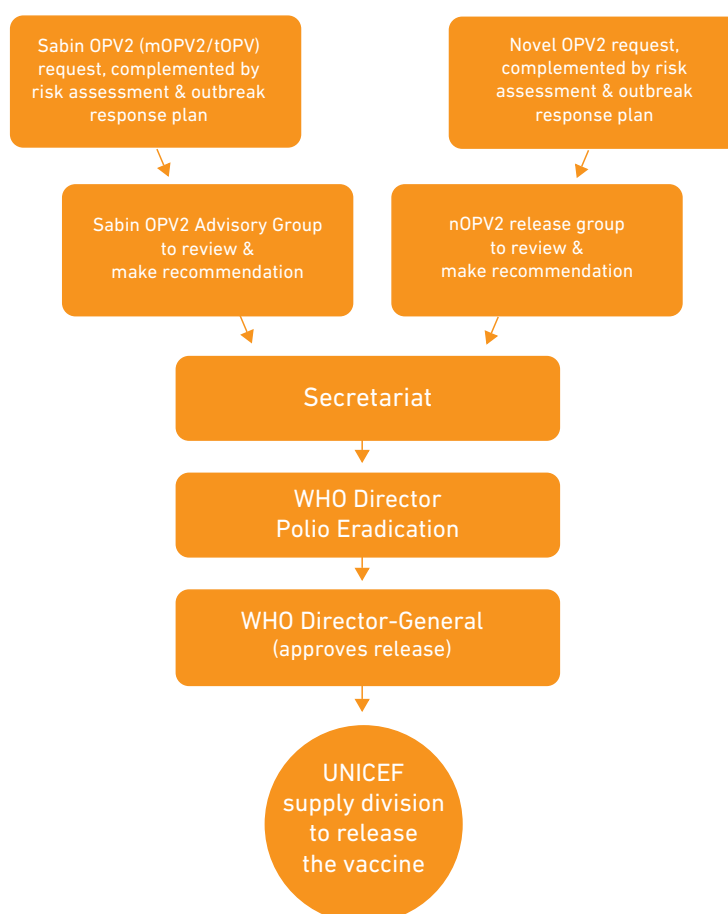
In line with the WHO Executive Board decision²⁸ and the GPEI strategy (2022-2026) noted by the WHA in May 2021, the requests for novel OPV2 should be prepared in coordination with the Regional

polio response teams and submitted to the ORPG nOPV2 release group. The nOPV2 release group will then advise the WHO Director General on the request and their recommendation through the Director of WHO Polio Department. A secretariat will process all necessary communication throughout this process.

bOPV requests

Vaccine requests for bOPV follow usual procurement procedures through the United Nations Children's Fund (UNICEF).

Figure 3: OPV2 vaccine release process



27. See "monovalent Sabin OPV2 Vaccine Request Form". (Document within GPEI library (<http://polioeradication.org/tools-and-library/resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/>) accessed 15 November 2021)

28. Please see: Executive Board 146th session agenda item 16.1, EB(11) 7 February 2020 ([https://apps.who.int/gb/ebwha/pdf_files/EB146/B146\(11\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB146/B146(11)-en.pdf), last accessed on 15 Dec. 2021)

VACCINE MANAGEMENT AND REPORTING

Vaccine management is integral to ensuring a high quality vaccination campaign and should be prioritized at all levels and at all stages of the response. The movement of any vaccine used in outbreak response must be monitored. All vaccine received, distributed, and administered must be recorded through stock management tools and/or vaccine utilization records. All vials and doses used, partially used or unused, must be fully recorded (whether due to partial use, contamination, or vaccine vial monitor changes) and vials returned must be fully accounted for each SIA.

A reverse logistics and vial disposal plan must be integrated with the outbreak response plan outlining:

- Health facilities and district vaccine stores will be left with a one-month supply of bOPV, following the end of type 1/type 3 outbreak response campaigns
- how excess unused vaccine will be returned to central or regional storage in a reverse cold chain
- all OPV2 containing vaccines to be immediately withdrawn following the conclusion of type 2 outbreak response campaigns
- (for OPV2 containing vaccines only), how all unusable vials will be returned to safe disposal sites (used, partially used, expired, damaged and vials with VVM reached the discard point).

For all OPV2 campaigns and mop-up rounds, it is of critical importance that every vial and dose of unused vaccine be accounted for and withdrawn to central storage in a safe and secure manner. Reporting on the status of vaccine used, retrieved and in storage is required after each SIA, including the immediate rapid response. All lost and missing vials must be reported²⁹.

For tracking of OPV2, the ORPG will engage with the WHO Global OPV Stockpile focal point and UNICEF supply division to track the decisions of the ORPG/Sabin OPV2 advisory group (as relevant), the WHO DG and the distribution of the vaccines to each country. The National Emergency Operations Center/country polio eradication team will report back to the secretariat on OPV2 containing vaccine stocks in the country two weeks after the end of each SIA. Use of novel OPV2 and Sabin-based OPV2 (mOPV2/tOPV) in country will be guided by the relevant technical guidance documents (*novel OPV2 Management, Monitoring, Removal and Disposal (in 50 dose vials with VVM type 2)*³⁰ and *mOPV2 vaccine management, monitoring, removal and validation*²⁶, respectively). Any future modifications in the novel OPV2 management and reporting will be documented and annexed to these SOPs and will be made available to the regional and country polio teams.

29. See: Technical Guidance for monovalent Sabin OPV2 vaccine management, monitoring, removal and validation. Geneva: Global Polio Eradication Initiative; 2016 (https://polioeradication.org/wp-content/uploads/2016/11/Technical-guidance-mOPV2-management-monitoring-removal-and-validation_Oct2016_EN.pdf, accessed on 15 November 2021).

30. See: nOPV2 management, monitoring, removal and disposal (in 50 dose vials with VVM type 2) (<https://polioeradication.org/wp-content/uploads/2021/02/nOPV2-Vaccine-Handling-Technical-Guidance-2021103-ENG.pdf>, accessed on 15 Nov 2021)

ROUTINE IMMUNIZATION COVERAGE IMPROVEMENT PLANNING, TO BE INTEGRAL PART OF POLIO OUTBREAK RESPONSE

The backbone of polio eradication and outbreak response remains routine immunization (RI) against polio in line with the national childhood immunization schedule. Most of the cVDPV outbreaks so far occurred in areas with sub-optimal routine immunization coverage. The new GPEI strategy (2022-2026) offers a more holistic approach in alignment with the Immunization Agenda 2030 (IA2030)³¹ and Gavi, the Vaccine Alliance's strategic plan ("Gavi 5.0").

While planning for specific polio outbreak response focusing on achieving high-quality polio vaccination, routine immunization coverage improvement must be an essential component of the overall planning process. The Emergency Operations Centres (EOC) established/ tasked to manage the outbreak response, should have dedicated section on routine immunization coverage improvement planning, led by the National EPI team and should effectively maximize the benefit of time-limited support to RI, through a thorough analysis of the reasons for low immunization coverage (including zero dose children and communities) in the outbreak areas. The National EPI should prioritize the high-risk areas/populations for enhanced routine immunization

through initiatives like PIRI and intensified outreach vaccination supported by locally appropriate social mobilization. Utilizing the time-limited support for RI followed, selected short and medium-term immunization systems strengthening actions may be feasibly taken in line with the operational components of the Reaching Every District (RED)³² approach, namely: effective planning and management of immunization resources, optimization of immunization services to reach all eligible populations (expansion/re-establishment), supportive supervision for immunization quality assurance, linking immunization services with communities and monitoring and use of data for action.

Outbreak response plans should contain the component on routine immunization coverage improvement, from the beginning and throughout the response until outbreak closure. GPEI partners should effectively engage with the routine immunization counterparts to ensure that routine immunization coverage improvement initiatives are effectively supported during the outbreak response. Polio surge resources can be appropriately utilized for this purpose. Key areas to be focused include strengthening of programme management, microplanning with special focus on identifying and mapping the Zero-Dose communities, community mobilization and performance monitoring. GPEI and Essential Immunization partners should coordinate on identifying possible opportunities for joint resource mobilization to support polio outbreak response and EPI coverage improvement. It is also beneficial to build on the political attention resulting from the cVDPV outbreak to ensure accountability for routine immunization service delivery.

31. See: IA2030, A global strategy to leave no one behind (<https://www.immunizationagenda2030.org/>, accessed on 15 Nov 2021)

32. See: Reaching Every District, a guide to increasing coverage and equity in all communities; (https://www.afro.who.int/sites/default/files/2018-02/Feb%202018_Reaching%20Every%20District%20%28RED%29%20English%20F%20web%20v3.pdf, accessed on 15 November 2021)

7. SURVEILLANCE FOLLOWING INVESTIGATION

Guidelines for routine poliovirus surveillance, including AFP and environmental surveillance, are outlined in other GPEI documents, including: Best Practices in Active Surveillance for Polio Eradication³³, the Global Polio Surveillance Action Plan³⁴ and Interim Quick Reference on Strengthening Polio Surveillance during a Poliovirus Outbreak³⁵. While Chapter 4 (above) outlines the initial surveillance steps required as part of a thorough investigation, the current chapter focuses on surveillance enhancement following initial investigation.

SURVEILLANCE ENHANCEMENT

Following the initial investigation of any polio event or outbreak, it is critical to assess and enhance poliovirus surveillance. Vigorous efforts are required to put the surveillance system on high alert and improve sensitivity to identify promptly any new virus or ongoing transmission, even outside the immediate outbreak zone. The outbreak response plan must include surveillance initiatives from Day 0 of the event/outbreak, continue surveillance in parallel with other aspects of the response, and maintain selected

supplemental strategies for six months or more after the last detected poliovirus. Further, plans should be made to increase data management capacity to ensure all databases and analysis are up to date, with weekly or twice a week data harmonisation with the laboratory.

A key objective of AFP surveillance, following identification of an event in a high-risk area or any outbreak, is to achieve an annualized rate of greater than three non-polio AFP cases per 100 000 children, younger than 15 years of age, in outbreak-affected and high-risk areas³⁵, for at least 12 months after the last case or isolate. At the national level, a rate of two non-polio AFP cases per 100 000 children is desirable in outbreak countries. While districts with fewer than 50 000 children under 15 years of age may not detect AFP every year, the quality of AFP surveillance should be checked for all districts that did not report any AFP case/silent districts, regardless of population size. Other surveillance indicators should also be thoroughly assessed to validate if they are meeting the standards at the national and sub-national level.

33. See: Best practices in Active Surveillance for Polio Eradication, 2018. GPEI guidelines. Geneva: Global Polio Eradication Initiative; 2018 (<https://www.who.int/polio-transition/documents-resources/best-practices-active-surveillance.pdf?ua=1>, accessed 15 November 2021)

34. See: The Global Polio Surveillance Action Plan [2022–2023] (<https://polioeradication.org/wp-content/uploads/2022/02/Global-Polio-Surveillance-Action-Plan-2022-2024.pdf>, accessed on 01 March 2022)

35. See: Interim quick reference on strengthening polio surveillance during an outbreak (https://polioeradication.org/wp-content/uploads/2021/12/Quick-Reference-Strengthening-Surveillance-during-Poliovirus-Outbreaks_24-March-2021.pdf, accessed on 15 Nov 2021)

Countries are to undertake the following activities to enhance AFP surveillance:

- Immediately notify all national and subnational surveillance units about the poliovirus event/outbreak.
- Rigorously sensitize all health care workers to AFP surveillance and notification requirements, including zero-reporting. Conduct sensitization activities among community members (e.g., polio volunteers, informants, community health workers), government and non-governmental organizations to increase awareness of AFP and polio.
- Review and re-prioritize reporting sites (if required) in the AFP active surveillance network in all districts and provinces and ensure that secondary and tertiary health facilities in public and private sectors are fully involved in AFP surveillance. The network should reflect the current health services providers including public and private facilities, NGOs, and refugee camps. Expand to include traditional healers, pharmacists and key community informants based on high-risk populations. Important relevant bodies like paediatric, neurologists' associations should also be engaged.
- Ensure prospective active surveillance visits are conducted regularly and passive surveillance is performing optimally. Conduct facility- and community-based, ad hoc active case search to identify unreported AFP cases.
- Ensure that supplemental AFP case-finding strategies are in place in the outbreak zone and high-risk areas, including ad hoc active search during campaigns by vaccination teams, independent monitors, and LQAS survey teams.

- Monitor and document that at least 90% of all planned active surveillance visits are conducted.
- Consider supplemental strategies, such as enhancing environmental surveillance, in consultation with national and GPEI surveillance experts.
- Ensure the national laboratory is involved in outbreak planning and that capacity is strengthened to handle additional workload and maintain rapid specimen handling.

While efforts are initially focused on enhancing surveillance in the outbreak zone and high-risk areas, it is important to enhance surveillance across the infected country and demographically linked areas in neighbouring countries to ensure detection of any geographical spread of poliovirus.

ENVIRONMENTAL SURVEILLANCE

Environmental surveillance (ES) serves as a complement to AFP surveillance, but never as a substitute. It is the monitoring of wastewater or sewage from designated locations to detect the presence of poliovirus. In the context of events and outbreaks, ES can provide information on the geographic extent, community transmission and duration of poliovirus circulation, as well as the excretion of polio vaccine virus following vaccination. Any adjustment in the environmental surveillance should be done with coordination among the epidemiologists, polio laboratories, and where needed, the environmental health departments in a country to ensure appropriate ES sites.

At the outset of a new event or outbreak, the following actions should be put in place:

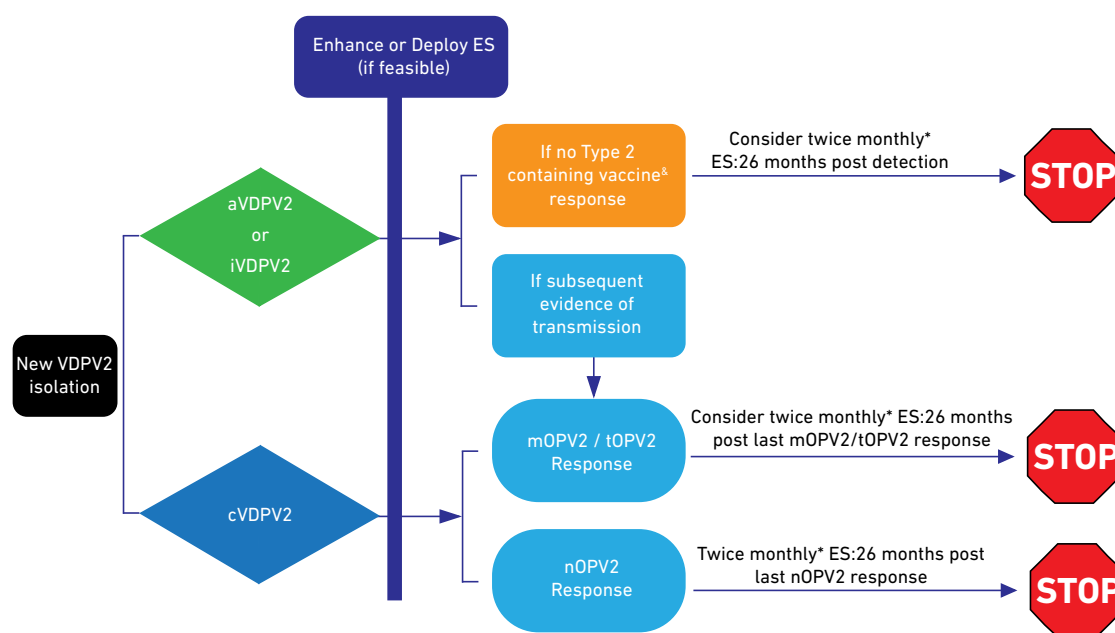
At the outset of a new event or outbreak, the following actions should be put in place:

- Assess the performance of all existing poliovirus ES sites in the area. Sites that have had no virus isolation (including non-polio enteroviruses and sabin-like viruses) for over 6 months should be thoroughly assessed, in particular.
- Increase the frequency of specimen collection to every two weeks, where feasible, for a minimum of six months following the most recent isolate detected or the most recent use of type2 containing OPV (in case of type2 poliovirus outbreaks/high-risk events), whichever is later³⁶.

- Consider new collection sites within and outside the outbreak or event area, where technically appropriate and laboratory capacity allows.
- Assess nearby urban areas with a population of 100 000 or more as candidates for new or enhanced environmental sampling.

Any proposal to scale up ES must consider laboratory capacity to support the effort, and not jeopardize AFP surveillance. Detailed guidelines on polio environmental surveillance enhancement following detection of vaccine-related type 2 poliovirus are available, from which Figure 4 is drawn³⁶.

Figure 4³⁶: Overview of timeline of enhanced environmental surveillance depending on the type of initial VDPV2 isolated



*Minimum sampling frequency is monthly; all changes must follow discussion or assessment by the Regional Office and partners;
^{*}Type 2 containing vaccine: mOPV2, nOPV2, tOPV

36. See: Standard operating procedures for polio environmental surveillance enhancement following investigation of a poliovirus event or outbreak (<https://polioeradication.org/wp-content/uploads/2021/02/SOPs-for-Polio-ES-enhancement-following-outbreak-20210208.pdf>, accessed on 15 Nov. 2021)

STRATEGIES FOR SPECIAL POPULATIONS AND SECURITY-COMPROMISED AREAS

Supplemental surveillance strategies³⁷ may be required in circumstances involving highly vulnerable populations (e.g. nomads, refugees, or other populations who do not routinely access health services) and/or inaccessible areas beyond the routine reach of even enhanced health or surveillance services. Activities will need to be tailored to the specific situation, but consider the following approaches:

1. If not already in place, identify community leaders or healers, with focus on equally and meaningfully engaging women, as focal points and provide the training and tools to facilitate access to and reporting of suspect AFP cases.
2. Increase community sensitization to polio and AFP surveillance, using culturally appropriate tools and gender analysis in the design and implementation of all community sensitization and outreach interventions to ensure they address specific gender-related needs, barriers and challenges
3. Leverage innovative partnership with other groups or services with access to special populations (e.g. other government ministries or departments, other United Nations organizations, NGOs, civil society groups and women's

groups and community/grassroots networks, veterinarians, etc.).

4. Selectively use other supplemental strategies that are usually only part of an initial field investigation. Given the relatively low yield and high resource needs of these strategies when used in the long term, they should only be considered in consultation with GPEI partners and laboratory counterparts.
 - a. Contact sampling in high-risk, security-compromised or hard-to-reach populations may exceptionally be advised for every AFP case for a limited time only, such as in recently accessed areas. As an ongoing surveillance strategy, systematic contact sampling can be maintained for no longer than six months.
 - b. In exceptional situations, a stool survey may be a screening tool for groups moving from an event/outbreak area to a new area (e.g. internally displaced populations, refugees). Once transmission has been demonstrated in an area, healthy children stool surveys are no longer necessary and not recommended.
5. If poliovirus is found in a high-risk mobile population (e.g. internally displaced populations, refugees, or nomads), or in an area frequented by populations on the move, then immediately assess surveillance network/sites (active and routine/zero reporting) along known migration routes to seek evidence of transmission.

37. See: Guidelines for implementing polio surveillance in hard-to-reach areas and populations (<https://polioeradication.org/wp-content/uploads/2020/10/Guidelines-polio-surveillance-H2R-areas.pdf>, accessed on 15 Nov. 2021)

8. COMMUNICATION AND SOCIAL MOBILIZATION

Communication for Development (C4D) is a systematic, planned and evidence-informed strategy to promote positive and measurable behaviour and social change. Effective social mobilization, with emphasis on high-risk populations, is a key component of polio outbreak response. The polio C4D outbreak response approach is designed to redress perceptions and social norms that deter caregivers from vaccinating their children, and rebuild commitment to vaccination, including routine immunization.

A strong communication strategy can strengthen performance of all response activities, increase uptake of vaccination in all population groups, and support robust surveillance with early notification of AFP.

Critical C4D steps include:

- raising awareness of campaign dates;
- strengthening community confidence in vaccination through building health worker capacity and trust in vaccine safety and efficacy;
- elevating perception of polio risk to children, families and communities;
- addressing bottlenecks in and barriers to the decision to vaccinate; and
- incorporating infodemic management as well as anticipatory and real-time strategies to counter dis- and misinformation.

In the context of vaccine-derived poliovirus, and against the backdrop of the COVID-19 pandemic, perceived risk of polio may be low, especially when the virus is detected only in the environment. While the C4D outbreak response for VDPVs follows the same principles as for WPV, it is important to reinforce vaccine safety messaging, including as necessary the type-specific messaging (e.g. nOPV2, mOPV2 etc.) and address any context-specific fears or misconceptions around vaccines. For VDPV detection only from environmental sources, it is important to explain that low immunity is the root cause.

STRATEGIC C4D FRAMEWORK FOR POLIO OUTBREAK RESPONSE

Outbreak response communication, including C4D and emergency risk communication, is initiated as soon as an outbreak is declared and should be integrated in all aspects of planning and responding to an outbreak or high-risk event. The outcome of the joint epidemiological and social investigation of the polio case/infected area is critical to understanding the social environment for areas or groups affected by the virus. Interventions should be based on understanding of all relevant social and environmental barriers to strengthen

vaccine acceptance and uptake (See Strategic Framework within the Communication for Development Guidelines for Responding to Polio Events and Outbreaks for detailed guidance³⁸).

At this phase, the focus is on building (or rebuilding) caregivers' critical awareness about polio, OPV and the fact that there is an outbreak in the community that puts children at risk. The primary goal is to raise awareness of the outbreak to at least 90%. Communication approaches should be straightforward, clear and elicit an urgent response from parents and the community at large.

Plans for campaigns, including SIA1, SIA2 and a mop-up round, should include C4D interventions to reach missed children and reduce refusals. Activities should continue to elevate public risk perception of the outbreak and its impact and empower decision making, especially for non-compliant groups or communities. For campaigns using the SIAD approach, locally appropriate messaging is important, so that caregivers and decision makers understand the process and why children may be vaccinated more than one time in short intervals.

Protracted outbreak response. Where an outbreak is ongoing for more than four months (120 days), there may be one or more underlying barriers. As the target audience may include acceptors, vulnerable acceptors, transient groups or even rejecters, conducting a root cause

analysis can help identify such barriers, whether social (including gender related barriers), or related to access or quality of the service. Reasons for missed children should be well investigated and analysed to adjust strategies for issues such as fatigue of repeated campaigns, gender related barriers or mistrust in vaccine or workers at the forefront.

In a protracted outbreak, the barriers to access and acceptance are specific to each community, culture and region, and may be complex. It is important to monitor systematically and understand patterns of reported reasons for missed children before designing communication solutions. The objective is to maintain or increase the percentage of awareness to 90% or more and keep total refusals below 2%.

Maintaining gains and strengthening routine immunization. Regardless of how the outbreak evolves, the focus of C4D strategies should shift towards supporting routine immunization as soon as possible, and also as the outbreak draws to a close. Outbreak response plans should be based on the analyses of existing routine immunization gaps that led to polio outbreak and should indicate how routine immunization services will be promoted, especially for low coverage areas. The outbreak coordination should also develop preparedness plans to mitigate the risk of future outbreaks. The final outbreak response assessment (OBRA) reviews country improvement plans

38. See "Communication for development guidelines for responding to polio events and outbreaks, post switch". 2016. Geneva: Global Polio Eradication Initiative (http://polioeradication.org/wp-content/uploads/2016/12/C4DGuidelines_OutbreakPostSwitch_Nov2016_EN.pdf, accessed on 15 November 2021)

for routine immunization and longer-term preparedness. Achievements and lessons learned from social mobilization, advocacy and media and partnership activities at the national, provincial, and district levels should be documented.

DATA GATHERING TO GUIDE C4D ACTIVITIES

At the beginning of an outbreak, it is important to review existing data sources for knowledge, attitudes, practices and behaviour, or if not available, to conduct a rapid social assessment of norms that may affect vaccination. The collection and analysis of data disaggregated by sex and other relevant variables is critical in all C4D assessments and plans to identify and address gender-related barriers and challenges. Gender analysis should be carried out to ensure that gender roles and norms are considered, and communications interventions address the different needs, challenges, preferences and perceptions of everyone in the community. This review should be done before initiating the response and to guide the development of C4D interventions.

After each campaign, IM/LQAS data and or other sources should be analyzed in a timely way, especially regarding the core indicators for C4D, in order to amend communication strategies as required. Core indicators include: overall percentage of missed children; percentage of missed children for different reasons (grouped into social, operational and absences); percentage of refusals; percentage of

refusals by reason; percentage of absence by reason; percentage of parents aware of the campaign prior to vaccinator's visit; and percentage reached through different communication channels. This data must be sex-disaggregated and analyzed accordingly.

At the end of the outbreak, it is important to assess community acceptance of, and commitment to, vaccination, for example, through small-scale surveys or secondary data analysis, and to document the outcome of C4D activities as well as the lessons learnt and good practices.

COMMUNICATION STRATEGIES

Strategic and coordinated communication strategies help ensure that communities and decision-makers at local, national, and regional levels are engaged in promoting vaccination. Risk communication plans and C4D interventions should precede vaccination activities to create awareness and minimize vaccine hesitancy and refusals. Immediately creating or reinvigorating a national communication or social mobilization committee is critical. The role of the committee is to plan, coordinate and ensure the successful implementation of risk communication plans and C4D interventions.

Risk communication plans should be developed and employed to provide credible, timely and accurate information to the community or affected population during the outbreak response. Effective risk mitigation strategies will help bring an

outbreak under control quickly by ensuring a community understands ongoing risk and actions they can take, including vaccination, to reduce harm within the community and further spread outside of the outbreak zone. Risk communication considerations during outbreak response include:

- **political advocacy** to garner the attention and resources needed to support response efforts and strengthen public trust in vaccination.
- **News media engagement** to ensure that information is clear, timely and reaching affected populations and key stakeholders when and where that access health information. Radio, for example, is an important channel in conflict or inaccessible areas. The Ministry of Health and WHO, generally the first to announce an outbreak, should take the lead in this area. As part of the C4D/communication strategy, it is recommended to establish immediately which agency is leading the media management. This leadership role will depend on capacity in each country, noting that UNICEF usually leads C4D and supports the media strategy development, spokesperson training and outreach to influencers.
- **Digital and social media** for targeted outreach to a large audience, especially where interpersonal communication networks are weaker and to counter rumours and misinformation quickly. Gender-related barriers should be analyzed and addressed in the

selection of appropriate communication channels, messages and tools to address the different needs, preferences and challenges of diverse women and men in the communities (e.g. acknowledging the lower literacy rates of women in many settings).

- **Stakeholder and Influencer engagement** to empower religious and community leaders, healthcare providers, parliamentarians, women's and youth groups and other groups to positively influence decision making toward a desired behaviour, including vaccination. Third party influencers and trusted sources on social network can play an important role in building strong public consensus about the urgency of the outbreak and the need to take collectively the decision to vaccinate. Efforts should be made to ensure the equal and meaningful participation of women in all community engagement efforts (engagement of women within communities and in terms of participation in social mobilization teams).
- **Workers at the forefront and community mobilizers** trained to ensure credible and accurate information is reaching the affected population to support a high-quality response, especially when the C4D strategy relies on interpersonal communication. Global training standards are available for training of vaccinators and other volunteers.³⁹

39. See Polio training manual for health worker supervisors. Geneva: Global Polio Eradication Initiative (https://polioeradication.org/wp-content/uploads/2022/03/GPEI-Health_Supervisors_Training_Manual.pdf, accessed 15 November 2021).

REACHING SPECIAL POPULATIONS AND CONFLICT-AFFECTED AREAS

Special populations that are hard-to-reach or in conflict areas can be particularly vulnerable to polio outbreaks. The design of strategic C4D interventions and messages for these populations should always be based on social profiling of polio-confirmed and zero-dose non-polio AFP cases or contact cases, as well as any other available social research for those groups.

Community mobilizers should be selected from target communities and efforts should be made to ensure the equal and meaningful participation of women in all social mobilization and outreach activities.

Community influencers/groups should be consulted and engaged in the planning phase of the campaign with continuation through to the end of the outbreak. These influencers can be a clan leader, mayor, grandmother, school teacher, or a community elder. It would be important to sensitize communities to AFP and encourage reporting, including through community networks if applicable.

Geographic, security or demographic challenges could limit access. The use of non-traditional means such as mobile texting, awareness around water points, days when a population moves from one place to the other, printing messages about polio on food bags, or inserting messages in bread packages and other innovations, may augment standard communication strategies.

9. GPEI SUPPORT

National authorities have the ultimate ownership and accountability for a robust and comprehensive response to poliovirus outbreaks and the maintenance of leadership throughout. The GPEI partners support key functions for an outbreak response including:

- outbreak preparedness;
- risk assessment and event/outbreak response planning;
- advocacy and coordination;
- technical and human resources, including:
 - information management;
 - communication, social mobilization and behaviour change;
 - vaccination activities;

- surveillance enhancement; and
- security and access.

- finance and logistics, including coordinated resource mobilization and leveraging resources from donors; and
- outbreak response assessment.

Table 6 offers a summary of the nature of support that GPEI is expected to provide, according to the grade of the outbreak as assigned by WHO or amended for GPEI surge support. Each outbreak is unique, and so are the support needs. Those responsible for outbreak coordination nationally, regionally and globally, will need to reassess support needs on a continuing basis to ensure effective and timely response.

Table 6: Outbreak response scale-up and support according to grade

Type of support	Grade 1	Grade 2	Grade 3
Response leadership	National coordinator	GPEI-nominated coordinator	GPEI-nominated coordinator and high-level advocacy as needed
Technical liaison	Polio expert mission from the GPEI partners to support outbreak response plan development	Deployment of a multidisciplinary rapid response team	Deployment of a multidisciplinary rapid response team
Surge	Stop Transmission of Polio (STOP) programme support if needed	<ul style="list-style-type: none"> • Deployment of surge support team:¹ multidisciplinary consultant team for minimum six-month deployment • STOP support 	<ul style="list-style-type: none"> • Deployment of surge support team:¹ multidisciplinary consultant team for minimum six-month deployment • STOP support
Financial	Standard financing for outbreak response immunization activities (an advance of up to US\$1 000 000) ²	"Pre-financing/No-regrets" funding policy (an advance of up to \$1 000 000) prior to completion of response budget	"Pre-financing/No-regrets" funding policy (an advance of up to \$1 000 000) prior to completion of response budget – to support the response preparedness and security measures, if required
Security and access	Coordination with United Nations and humanitarian agencies in the field	Coordination with United Nations and humanitarian agencies in the field	Deployment of field security officer(s) where necessary Coordination with United Nations and humanitarian agencies in the field

¹ Composition of team and number of experts deployed for rapid response and surge support teams will be scaled up to meet the needs of the country.

² Standard financing is subject to re-payment conditions, as determined on a case-by-case basis.

COORDINATION

Coordination mechanisms for polio are triggered by a laboratory notification (Day 0) of a new outbreak or high-risk event. The country, region and global levels will coordinate to support the investigation, rapid risk assessment and determination of next steps.

The ORPG will lead outbreak response coordination with national authorities, RRT in the African Region, IMST in the Eastern Mediterranean Region, WHO and UNICEF regional offices, and all GPEI partners. The ORPG will conduct a coordination call within 48 to 72 hours with partners to address the needs of the country, monitor the immediate provision of pre-financing (also referred to as no-regret funding), and plan the required resources and initial response support interventions. The ORPG will include all the necessary skill sets to coordinate outbreak response. Regular updates will be provided from ORPG to the GPEI Strategy Committee.

For grade 2 and 3 outbreaks (and high-risk events), WHO and UNICEF regional offices, in consultation with ORPG, will nominate an outbreak coordinator for deployment to the country level within 14 days of Day 0. The GPEI outbreak coordinator will be deployed as additional support for in-country authorities, supplementary to existing senior GPEI staff, to ensure comprehensive and timely coordination and outbreak management at national and subnational levels.

BUDGETS AND FINANCING

Coordinated approach

The goal of outbreak response financing is to ensure that cash flow challenges do not interfere with the roll-out of response activities, based on a “budget– mobilize– finance–replenish” model. National authorities should rapidly prepare a comprehensive budget, in collaboration with WHO, UNICEF and other partners. The budget should include a comprehensive estimate of costs for all activities (i.e. coordination, vaccination, surveillance, communication and social mobilization) and enabling functions (i.e. laboratory operations, training and transport). A joint comprehensive work plan and budget shared with all levels involved will aid in mobilizing funds from donors to secure financing for response activities. ORPG and WHO headquarters will provide specific guidance and timelines on outbreak budgeting.

“Pre-financing/No-regret funding” policy

The pre-financing/no-regret funding policy (an advance of up to USD 1 million) helps ensure a timely, barrier-free release of funds to countries to support outbreak response. This policy affirms that it is better to over-resource critical functions than to risk failure by delays in resources. The pre-financing limit can be enhanced above USD 1 million, upon provision of adequate justification by the country programme and respective regional offices/ RRT/IMST. The release of funds by GPEI partners may pre-date outbreak grading by

WHO, based on the initial risk assessment and discussion between national, regional and global levels. Whereas funds will usually be released by WHO and UNICEF, another GPEI partner may on occasion provide the funding. The pre-financed funds have to be included and accounted for in the outbreak response budget prepared by the country programme.

HUMAN RESOURCE SURGE

The objectives of GPEI surge support are to: i) **rapid activate deployment** of skilled professionals, especially for grade 2 and grade 3 outbreaks, to support the national response team for key outbreak response functions; and ii) **ensure smooth transition** to longer-term staffing. It is important to ensure the balanced recruitment of women and men into technical and operational roles at all levels.

Deployment should occur by Day 3 through a partner-wide mechanism for deploying staff and qualified consultants from the regional level and supported from the global level through the ORPG.

The ORPG coordinates surge support and technical assistance in the following areas:

- Identifying key roles, according to outbreak grade and assessed needs of the country. Expertise offered includes both technical (communication, immunization, surveillance, data management), and operational (coordination, finance, human resources) skill sets.

- Team composition scaled according to need, for example, outbreak response coordinator, operations manager, communications officer, and technical experts for immunization, surveillance and social mobilization.
- Personnel with specialized expertise may also be available to provide support to innovative strategies to improve the quality of response, such as for GIS mapping of the outbreak zone.
- The **Rapid Response Team** involves deployment from respective GPEI agencies, including regional offices. Recruitment for active support may extend beyond outbreak teams within each agency. The period of deployment is from outbreak notification until the rapid response SIA or the first large scale SIA (SIA1), where indicated.
- The **Surge Support Team** is an interagency on-call roster for longer-term deployment using a central platform for ease of visibility and reporting. The Surge Support Team should be in place within 21 days of outbreak notification. The expected period of deployment is from the rapid response SIA until the end of the outbreak. Response teams will aim for at least one week of overlap between the work of the Rapid Response Team and that of the Surge Support Team to ensure complete and detailed handover.
- Identifying needs and advocating for specialized support and innovation when warranted by context (e.g. GIS-informed microplanning, detailed enumeration, administration, and finance).

GPEI PERFORMANCE STANDARDS

The GPEI partners will undertake a range of activities to support a country-led response. Outbreak response performance standards describe the expected outputs from each level of GPEI partners in key outbreak response functions. The actions and deliverables expected of countries and GPEI partners by specific timeline (within hours, days and weeks of virus sequencing report) are outlined in Annex 2). These performance standards apply to polio outbreaks of all grades. These standards are not exhaustive and may be modified as required to fit the context specific to the country and the outbreak. The ORPG will

provide support to coordinate and monitor the outbreak response.

While there are specific outbreak response related in-depth designed indicators, the GPEI has devised in its strategy for 2022-2026, a high level monitoring and evaluation framework with specific desired outcomes and key performance indicators. Progress on these key performance indicators⁴⁰ will be assessed and presented to the Strategy Committee on quarterly basis. The Strategy Committee after reviewing the progress will brief the Polio Oversight Board and raise any key concerns. A thorough programme review against the strategy milestones, including the ones on outbreak response, will be carried out in the last quarter of 2023.

40. See "Polio Eradication Strategy 2022-2026: Delivering on a Promise". (<https://polioeradication.org/gpei-strategy-2022-2026/>, accessed on 15 Nov. 2021)

10. MONITORING AND EVALUATION OF RESPONSE

Quality assurance for outbreak response is critical and should include both quantitative and qualitative methods for all core aspects of response. Countries are encouraged to develop tools and indicators tailored to best monitor all stages and components of outbreak investigation and response. See GPEI library for tools and guidance documents (<https://polioeradication.org/tools-and-library/resources-for-polio-eradicators/gpei-%20tools-protocols-and-guidelines/>).

Table 7 outlines suggested, but not comprehensive, approaches and indicators for monitoring. Electronic data capture using mobile-enabled devices and real-time secure data upload is recommended wherever feasible to support timely and comprehensive reporting for all response activities (surveillance, vaccination, social indicators). The use of electronic data capture methods requires effective training, data cleaning and analysis, and continual quality checks. An effort should be made to build upon the existing national electronic data systems, if feasible. The national governments should make arrangements for possibly sustaining the electronic data system after the polio outbreak response for utilization across broader health and immunization programmes.

MONITORING QUALITY OF SIAS

The primary indicator for the **rapid response SIA** is the time in days from outbreak notification (Day 0) to the first day of vaccination (Target <14 days). Campaign monitoring may be carried out if capacity allows but should not detract resources from high-quality microplanning for large scale SIA1 and SIA2.

SIA 1 and SIA 2 must be fully monitored, and results communicated to GPEI partners within 14 days of each campaign. The purpose of monitoring is to identify all areas or sub-populations with <90% coverage or persistently missed children so that corrective action may be taken. Underperforming areas must be comprehensively discussed to determine special strategies, additional effort (e.g. extending the campaign, additional communications and/or vaccination teams, or a mop-up round with an adjusted communications strategy), and resources needed.

Strategies required to monitor campaigns for all SIAs (SIA1, SIA2), all mop-up activities, and additional large-scale SIAs – include, at a minimum, IM and clustered-LQAS.

Table 7: Assessing quality of response: factors to consider before, during and after implementation

Surveillance	Vaccination	Communication & social mobilization
Planning & preparation		
<ul style="list-style-type: none"> • Rapid review of available surveillance data • Increase ES sampling frequency to every two weeks • Initiate new ES if appropriate • Validate AFP cases and ES sewage sample collection 	<ul style="list-style-type: none"> • Preparedness dashboard indicators >90% • Evidence of training for all personnel • Accurate bottom-up microplans with detailed mapping, complemented by innovations such as GIS imagery and cross-validation where feasible 	<ul style="list-style-type: none"> • Evidence of engagement with community, women's groups and religious leaders • Engagement of national government with active support for response • Targeted strategies detailed and updated for special populations • In-depth social investigation of case(s) and/or community to identify special populations or under-vaccinated children
Implementation		
<ul style="list-style-type: none"> • AFP annualized rate >3 cases/100 000 children under 15 years of age in outbreak zone and immediate risk area • Impact of surveillance enhancement (e.g. source and number of AFP cases reported, active search) • ES process and performance indicators¹ 	<ul style="list-style-type: none"> • Intra-campaign independent monitoring >90% coverage • Spot checks and surveys >90% coverage (e.g. at markets, transit hubs) • Use of strategies to ensure that borders are covered (e.g. "handshake" hand-off between teams) 	<ul style="list-style-type: none"> • Targeted strategies used to optimize response activities in special populations • Evidence of overall increased community sensitization to AFP and importance of vaccination • Active support from community including women's groups and religious leaders active during vaccination campaigns • No block vaccination refusals
Post campaign follow-up		
<ul style="list-style-type: none"> • AFP surveillance >3/100 000 for at least 12 months after last poliovirus detection • Specific analysis of AFP rate for all high-risk populations • Evidence of impact of surveillance in hard-to-reach, inaccessible, and high-risk populations 	<ul style="list-style-type: none"> • Post-campaign independent monitoring >90% coverage; and >80% LQAS lots passed at 90% threshold • No evidence of persistently missed children or missed geographic areas • Robust and timely reporting, using innovations such as mobile-data collection and/or global positioning system (GPS) coordinates for coverage where feasible 	<ul style="list-style-type: none"> • Evidence that campaign awareness was >90% of all households (IM and/or LQAS) • Special populations >90% coverage • Analysis of disaggregated data for high-risk populations and gender for missed children or refusals, to guide interventions

Intra- and post-campaign monitoring. Intra and post-campaign monitoring employ survey methods with purposeful sampling in areas where coverage is expected to be insufficient and should be implemented according to protocol. The goal of intra-campaign monitoring is to ensure corrective action in a timely manner (e.g. the same day or the next day, including re-visit strategies) to improve implementation performance. Post-campaign monitoring allows in-depth and rigorous analysis for areas missed or not meeting coverage targets, and an examination of the reasons for missed or unvaccinated children.

Clustered LQAS surveys undertaken with sampling proportional to population size are recommended for all areas covered by outbreak response. For results to be valid, care must be taken to plan and implement according to protocol. Specific guidance is available⁴¹.

Spot checks, convenience surveys and verbal reports by monitors, supervisors, and independent campaign observers (e.g. international GPEI personnel or third-party agency personnel) are a very useful adjunct for SIA monitoring, and should be welcomed and used liberally to confirm or question coverage reporting.

Selection and training of monitors is important. Clear terms of reference outlining independence of the monitors from immunization activities are helpful for all monitors. Ideally, monitors should be recruited and trained for each SIA

round. Deploying the same personnel in the same areas for successive campaigns is discouraged, to maintain the independence. Sources for recruitment of monitors include universities and colleges (e.g. nursing or medical students), community NGOs or service agencies (e.g. health workers not directly involved in the response) and should be selected to fit the local context ensuring balanced participation of women and men.

Timeliness of reporting monitoring results is important to ensure accountability, rapid issue identification, and course correction where warranted. Monitoring results must be communicated to GPEI partners at national, regional and global levels within 14 days of campaign completion.

MONITORING SURVEILLANCE ENHANCEMENT

Countries should monitor weekly surveillance indicators and reporting from all subnational reporting units with emphasis on high-risk sub-populations and the outcome and impact of all enhancements.

In addition to routine AFP surveillance indicators with detail to subnational reporting level, regular updates on process indicators should be provided, including timeliness of investigation, sample collection, and receipt at laboratory.

41. See: Assessing vaccination coverage levels using clustered lot quality assurance sampling: field manual". 2012. Geneva, Global Polio Eradication Manual (http://polioeradication.org/wp-content/uploads/2016/09/Assessing-Vaccination-Coverage-Levels-Using-Clustered-LQAS_Apr2012_EN.pdf, accessed on 15 November 2021)

Reporting should be adequate to allow authorities to identify issues early, generate appropriate solutions to improve performance, and bolster confidence that the performance is good enough to detect ongoing virus transmission. For example, findings from retrospective and ad hoc active case searches in community and health facilities should be comprehensively summarized and reported in a timely manner.

The laboratory should also routinely summarize any capacity challenges they face and proposed solutions. Trends in laboratory workload as well as timeliness and accuracy of poliovirus testing should also be closely followed up and a reporting mechanism be defined at the laboratory and regional levels.

NOVEL OPV2 POST DEPLOYMENT MONITORING

For countries using novel OPV2 while under EUL, post-deployment monitoring (PDM) is an essential requirement, as countries must be able to contribute to documentation on the genetic stability, safety and effectiveness of the novel OPV2 by tracking its performance in the field. All countries using novel OPV2 will need to fulfill commitments agreed upon in the readiness verification process. Monitoring the fulfillment of these commitments following nOPV2 use is an essential step to ensuring countries meet the WHO EUL requirements. Such information will be

primarily based on existing polio and vaccine safety surveillance mechanisms in polio outbreak-affected countries. Post-deployment monitoring (PDM) begins once novel OPV2 has been used for the first time, and some PDM activities will last for up to 12 months after the last nOPV2 SIA⁴².

OUTBREAK RESPONSE ASSESSMENTS (OBRAS)

The purpose of OBRAs is to assess whether vaccination and surveillance response is robust enough to detect and stop poliovirus transmission and to determine the steps required to address gaps. Polio OBRAs should be carried out in a timely and effective manner, by independent experts not engaged directly with the outbreak response being assessed.

The first OBRA should be conducted 3 – 4 months after the outbreak notification. During the course of the outbreak response, GPEI/ORPG will deploy quarterly missions, joint or individual by the partner agencies (as needed and feasible), to support the country programme and to assess the progress. Extended outbreaks may warrant intermediate OBRAs or independent/external desk-reviews. An OBRA should be considered after six months interval from the last isolation of the outbreak poliovirus

For high-risk events, that had response vaccination carried out, an event response assessment or external desk review may also be undertaken. In situations when in-person assessment is not possible (including the COVID-19 pandemic

42. Please see: nOPV2 post campaign checklist; Activities to complete after an nOPV2 response (<https://bit.ly/nOPV2-post-campaign-checklist>), accessed on 15 Dec. 2021)

related limitations), virtual OBRAs and desk reviews may be considered. Focus, scope and emphasis of the OBRAs will be adjusted as per the interval since the last poliovirus isolate and local context and will be reflected in specific terms of reference of the assessment.

The ORPG, RRT, IMST and respective WHO regional office will jointly facilitate organization of the OBRAs and follow up programme desk reviews in coordination with the country teams. The OBRA team leader will debrief the country team before departing, and later submit a report to the country team, ORPG chair, Regional polio response teams and the Director of the WHO polio programme. The WHO regional office will confirm the end of the outbreak, if applicable, based on the assessment report and recommendations.

The country must develop an action plan based on the recommendations of the OBRA, aiming to strengthen the outbreak response. If the OBRA recommends closing an outbreak, the country should develop a post-OBRA plan within one month of the outbreak closure, focusing on sustaining the mechanisms for EPI coverage improvement and sensitive surveillance for polioviruses put in place during the outbreak response. OBRAs in special situations like multiple countries affected by the same outbreak (same strain/emergence of poliovirus), multiple cVDPV outbreaks in the same country etc., should be dealt with on case to case basis. Detailed guidance, tools and materials

for outbreak response assessments and vaccine management are available⁴³.

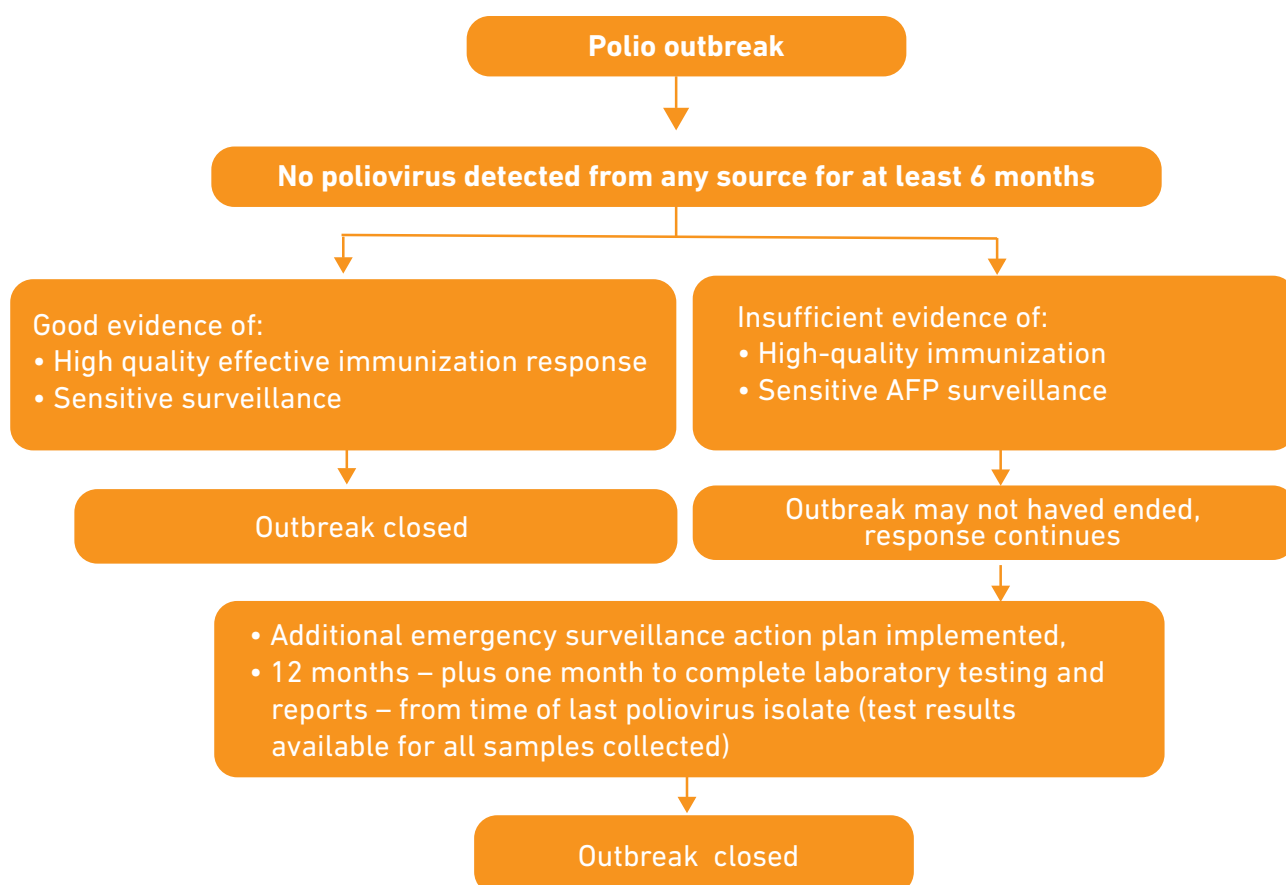
Is the outbreak over?

An outbreak can be considered over, and response can be terminated when no poliovirus has been detected for six months; provided surveillance is adequate in the outbreak zone and other high-risk areas and there is convincing evidence that sufficient measures are in place to halt the poliovirus transmission in the conflict affected areas as well as among the displaced and hard to reach populations. If these conditions are not met, the OBRA team will make recommendations for remedial actions (surveillance strengthening, vaccination quality improvement etc.). After a further six-month period (i.e. after 12 months from the last detection) without detection of a poliovirus from any source, the outbreak can be considered over and response may be closed, based on the OBRA's review and recommendation.

When 'end of outbreak' criteria are met and/or the OBRA team is satisfied that the outbreak response has been sufficient, in following the decision tree below (Figure 4), the WHO regional office may consider the OBRA findings in consultation with the ORPG, share the report with the national certification committee and the regional certification commission, and may confirm that the outbreak is over and can be 'closed'. The country is informed accordingly.

43. See: Polio Outbreak Response Assessment (OBRA): Aide Mémoire 2018 (<http://polioeradication.org/tools-and-library/resources-for-polio-eradication/gpei-tools-protocols-and-guidelines/>), accessed on 15 Nov. 2021)

Figure 4: Outbreak response assessment decision tree



Box 4

Polio was declared a public health emergency of international concern on the 5th of May 2014, and according to the Temporary Recommendations issued by the WHO Director General, the criteria to assess countries as no longer infected by WPV1 or cVDPV are as below:

- Poliovirus Case: 12 months after the onset date of the most recent case PLUS one month to account for case detection, investigation, laboratory testing and reporting period OR when all reported AFP cases with onset within 12 months of last case have been tested for polio and excluded for WPV1 or cVDPV, and environmental samples collected within 12 months of the last case have also tested negative, whichever is the longer.
- Environmental isolation of WPV1 or cVDPV (no poliovirus case): 12 months after collection of the most recent positive environmental sample PLUS one month to account for the laboratory testing and reporting period.
- Every three months, the committee meets to review the emergency status and to determine to which countries the Temporary Recommendations should apply. However, if a country is considered no-longer infected according to the Temporary Recommendations this does not always mean the outbreak is closed, as the response may need to continue.

DOCUMENTING LESSONS LEARNED

There is great value for countries to review the performance of the outbreak or event response and document lessons learned. The outbreak documentation should, among other things, include:

- a detailed outbreak investigation and risk assessment
- descriptive epidemiology (including index case investigation)
- surveillance response to monitor the evolution up to the end
- immunization response outlining the key milestones for quality assurance and innovations (micro-planning, training, preparedness monitoring, logistics management, community engagement

and monitoring/supervision)

- coordination of the outbreak response, including timing and effectiveness of surge of efforts.

Typically, best practice in emergency response includes a formal after-action review. The lessons learned are useful in improving emergency preparedness planning and can inform response to future events and outbreaks.

Outbreak documentation should also outline lessons learned and best practices highlighted by the OBRAs and external desk reviews, as strategies to successful interruption of polio outbreaks. Several relevant documents on best practice have already been published⁴⁴. Support is available for countries to document lessons learned from polio eradication.

44. See Capturing and sharing lessons learned [website] Geneva: Global Polio Eradication Initiative (<http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/transition-planning/lessons-learned-from-polio-eradication/>), accessed on 15 November 2021)

11. GENDER MAINSTREAMING

The new [Polio Eradication Strategy 2022-2026](#) emphasizes the importance of the use of rapid gender analysis for a more effective outbreak response. By collecting and analyzing sex-disaggregated data and gender-sensitive information, teams at the forefront of outbreak response develop a more robust understanding of the population that improves community engagement and increases vaccine acceptance.

Gender mainstreaming in outbreak response will concern the following areas:

Gender analysis

Rapid gender analysis provides essential information about gender roles and responsibilities, capacities and vulnerabilities to guide programming. It is used in situations where time is of the essence and resources are very scarce. As outlined in the new [Polio Eradication Strategy 2022-2026](#), rapid gender analysis in outbreak response will be guided by the [IASC Multi-Sector Initial Rapid Assessment \(MIRA\)](#)⁴⁵ and [CARE International's Rapid Gender Analysis](#)^{46,47}. Rapid gender analysis should be context specific and requires an approach tailored to the needs and interests of affected and at-risk communities. This may require engaging with local expertise in-country.

Communication

Community engagement, social and behavior change (SBC) are critical components of polio outbreak response. The polio outbreak response approach is designed to redress perceptions and social norms and beliefs that deter caregivers from vaccinating their children, particularly gendered norms that inhibit access and uptake of vaccinations, and rebuild commitment to vaccination through behavior development and social change efforts, including routine immunization. At the beginning of an outbreak, it is important to conduct rapid behavioral assessments and review existing and all available data sources to understand knowledge, attitudes, practices and behaviors. Understanding how gender issues interact with other factors to inhibit or promote access to information and services and impact uptake of services in communities is a critical component of SBC interventions. Gender issues should be integrated into data collection analysis to ensure that gender roles and norms are considered while designing strategies and interventions for and with communities. Evidence shows that women (often the main caregivers of children) are often disadvantaged when

45. See: Tool, Multi-Sector Initial Rapid Assessment (MIRA), July 2015 IASC Needs Assessment Task Force (https://interagencystandingcommittee.org/system/files/mira_manual_2015.pdf, accessed on 15 Nov. 2021)

46. See: In practice rapid gender analysis (<https://insights.careinternational.org.uk/in-practice/rapid-gender-analysis>, accessed on 15 Nov. 2021)

47. See: OXFAM minimum standards for gender in emergencies (https://oi-files-d8-prod.s3.eu-west-2.amazonaws.com/s3fs-public/file_attachments/ml-oxfam-gender-emergencies-minimum-standards-291113-en_o_o.pdf, accessed on 15 Nov. 2021)

it comes to accessibility to immunization and health information and services and comprehension of key behavioral interventions along with tailored messages, key modalities of providing information and risk communication, efforts should be aligned and carefully tailored to the needs of various communities and more importantly, be informed by the women and communities members for the best resonance and uptake.

Health workforce

Health workers have a crucial role in polio outbreak response. Attention must be given to guarantee a greater gender balance in recruitment procedures, with special attention to gender balance in all roles and at each level of the programme. Women health workers at the forefront of outbreak response should be actively supported in identifying and addressing the barriers and challenges they face (including ensuring a safe, inclusive and supportive work environment, prevention of sexual exploitation and abuse and safeguarding measures). Furthermore,

it is very important that the latest WHO guidelines^{48,49} on community health workers are taken into account during the recruitment, training and management process of health workers.

Sex disaggregated data

In line with the new Polio Eradication Strategy (2022-2026) and the Gender Equality Strategy (2019 – 2023), sex and age disaggregated data should be collected and analyzed in post-campaign monitoring. Sex and age disaggregated data should also be included in reporting, including on programmatic delivery.

To support the mainstreaming of gender activities in outbreak contexts, the checklist annexed (annex 3) outlines activities from the recruitment of gender-balanced teams (including surge staff), to the collection and analysis of sex-disaggregated data for AFP surveillance and campaign monitoring, and to the incorporation of gender-specific social data into social mobilization, communication and community engagement activities.

48. See: WHO guideline on health policy and system support to optimize community health worker programmes, (<https://apps.who.int/iris/bitstream/handle/10665/275501/WHO-HIS-HWF-CHW-2018.1-eng.pdf?ua=1>, last accessed on 15 Nov. 2021)

49. See: COVID-19: Occupational health and safety for health workers: interim guidance, 2 February 2021 (https://www.who.int/publications/i/item/WHO-2019-nCoV-HCW_advice-2021.1, last accessed 15 Nov. 2021)

12. PREVENTION OF SEXUAL EXPLOITATION, ABUSE AND HARASSMENT

In line with the Global Polio Eradication Initiative's zero tolerance for sexual misconduct⁵⁰ in all their operations, polio outbreak operations should include measures to ensure protection of the beneficiary population and of the personnel responding to the polio outbreak from sexual exploitation, abuse and harassment. This should include training, screening of personnel and consultants, accessible mechanisms for reporting of potential allegations, a victim centered approach to response to SEA allegation, working in close collaboration with Interagency Standing Committee and UN mechanisms.

- Outbreak managers should ensure that all team members, including national recruitments are aware of the need to abide by the Organization's policies on prevention and response to sexual exploitation abuse and harassment. This should be extended to implementing

partners and contractors with specific reference in contractual agreements as per individual partner standards.

- All consultants deployed will be subject to background checks and required to complete online trainings on preventing and responding to sexual exploitation and abuse before deployment.
- Incident managers/outbreak response coordinators should coordinate with the WHO/UNICEF/IASC PRSEAH focal point and coordinators if available, for a briefing on the risk assessment of SEA, mitigation activities at country level, reporting mechanisms at country level, what support for victims and survivors is available and how to provide safe and ethical referrals to assistance in accordance with existing referral pathways on a service mapping. Available resources^{51,52,53,54,55} on PRSEAH may be used in this regard.

50. See <https://polioeradication.org/wp-content/uploads/2018/04/polio-oversight-board-statement-on-sexual-misconduct-20180426.pdf>, accessed on 15 Nov. 2021]

51. See: WHO sexual exploitation and abuse prevention and response (<https://www.who.int/publications/m/item/who-sexual-exploitation-and-abuse-prevention-and-response>, accessed on 15 Nov. 2021)

52. See: The Integrity Hotline provides a safe and independent mechanism to report any concerns about issues involving WHO (<https://www.who.int/about/ethics/integrity-hotline>, accessed on 15 Nov. 2021)

53. See: UNICEF Strategy to Prevent and Respond to Sexual Exploitation and Abuse and Sexual Harassment (<https://www.unicef.org/sites/default/files/2019-05/UNICEF-Strategy-Prevent-Respond-Sexual-Exploitation-Abuse-Sexual-Harassment-January-2019.pdf>, accessed on 15 Nov 2021)

54. See: Report Wrongdoing, How to report suspected misconduct, fraud, abuse or other types of wrongdoing (<https://www.unicef.org/auditandinvestigation/report-wrongdoing>, accessed on 15 Nov 2021)

55. See: Protecting children from sexual exploitation and abuse (<https://www.unicef.org/protection/protecting-children-from-sexual-exploitation-and-abuse>, accessed on 15 Nov 2021)

- The outbreak response communications plan should ensure efforts to sensitize beneficiary populations on SEA risks, their rights, and channels for reporting possible allegations, using existing UN channels wherever possible.
- Any allegations of SEA or SH must be immediately reported through the appropriate organizational channels.
- Survivors/victims of SEA should be provided with immediate assistance and/or referrals to assistance upon receipt of an allegation, as per their wishes, in line with the UN Victim Assistance Protocol⁵⁶.
- Outbreak managers and team should not discuss or attempt to investigate any allegations.

56. See: UN protocol on the provision of assistance to victims of sexual exploitation and abuse (https://www.un.org/en/pdfs/UN%20Victim%20Assistance%20Protocol_English_Final.pdf, accessed on 15 Nov 2021)

ANNEXES

ANNEX 1: RISK ASSESSMENT OVERVIEW

Summary of elements for systematic risk assessment of a new VDPV, WPV or SL2 isolation

VIROLOGY			
cVDPV	Automatically defined as high-risk situation		
Virologic factors			
Genetic deviation from parent Sabin (nucleotide changes)	Substantial	Not substantial	Seek expert virologist assessment
Relatedness, if any, to past isolations	Related	Not related	
Virologist characterization / interpretation	Yes	No	
Co-circulation with WPV	Yes	No	
Detection of other (un-related) VDPVs in region	Yes	No	
Human Source			
Co-isolation with other Sabin or enterovirus	Yes	No	
Evidence of primary immunodeficiency	No	Yes	
Environmental source			
Number of virus in samples	High	Medium/low	
Genetic diversity (number of genetic clusters)			
CONTEXT			
Case Characteristics			
Member of known “high risk”/underserved population (slum, minority, refugee, mobile, internally displaced, etc.)	Yes	No	Review and discussion by technical experts, between country, region and global levels
0 dose or “under”-vaccinated	Yes	No	
Aged above 5 years	Yes	No	
Coverage data			
RI coverage (IPV if available-otherwise diphtheria-tetanus-pertussis (DPT3) in infected Admin 1 level	Poor	Good/high	Population Immunity” for type 2 polioviruses, should factor time since switch and use of IPV to estimate type 2 naïve population
Quality of prior SIAs (>5% missed children by IM data, >80% LQAS lots passed)	Poor	Fair/good	
Surveillance quality			

Risk category	High risk	Low risk	Remarks
Surveillance quality (e.g. sub-standard AFP indicators, infrequent or absent ES, orphan virus) in infected Admin 1 level	Evident	Fair/good	
Other recent poliovirus detection	Yes	No	
Admin level 1 context			
Large, densely populated area	Yes	No	
Known high risk populations (e.g. mobile, refugee, trade, pilgrimage, displacement)	Yes	No	
Insecure and/or inaccessible area affecting surveillance and/or immunization	Yes	No	
Any type of sentinel events suggesting higher risk of rapid spread	Yes	No	
Evidence of containment breach	Yes	No	
Finding tOPV/mOPV2 in a sweep of the vaccine distribution chain	Yes	No	
Environmental conditions associated with high levels of fecal-oral transmission	Poor water and sanitation	Fair/good water and sanitation	
INTERNATIONAL SPREAD			
Linkages with International Border			
Contiguous or direct transport link to int'l border (especially if other area is known high risk)	Yes	No	Local case investigation / based on available data
Links between site or person with poliovirus to other countries (e.g. markets, transport routes)	Yes	No	
Travel history of poliovirus case or household (e.g. refugee, nomadic, pilgrimage, stateless persons) to the neighbouring (or any other) country	Yes	No	Review and discussion by GPEI technical experts, in consultation with country, regional levels
Prior history of polio transmission patterns and outbreaks between countries	Yes	No	
Population mobility/migration			
Common service points between infected area and neighbouring areas like markets, pilgrim sites, common trading sites etc.	Yes	No	
Evidence of high levels of migration (from sequencing data, available cell phone data, prior migration patterns, etc.)	Yes	No	
Context of neighbouring areas			
Evidence of surveillance gaps or other high-risk factors in neighbouring areas susceptible to importation from affected area	Yes	No	
Population immunity in neighbouring countries/areas	Low	Good/hight	
Conflict	Present	None	

ANNEX 2: TIMELINE AND RESPONSIBILITY

Annex 2A: Timeline and responsibility for actions in the first month following poliovirus detection

Actions	Days post sequencing results																		
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15-30	30+		
Notification																			
GPLN informs health authorities of the affected country and WHO at country office, regional office and headquarters levels																			
Country informs health authorities, WHO headquarters informs relevant Global Polio Eradication Initiative (GPEI) partners																			
IHR focal point notifies WHO Regional contact point																			
National Government declares the outbreak as National Public Health Emergency																			
Investigation																			
Country team initiates epidemiological/social investigation																			
Coordination																			
Strategy Committee and Regional Directors of the concerned WHO and UNICEF regions coordinate on providing necessary enabling support and advocacy for a timely and effective outbreak response																			
Establish event/outbreak response mechanisms at regional offices and headquarters, including the ORPG for GPEI partner coordination																			
Activate rapid response surge and deploy as soon as available																			
Activate surge support and deploy as soon as available																			
Risk assessment and response plan																			
Country team presents risk assessment and response proposal to GPEI partners / ORPG and Advisory Group for Sabin OPV2																			
Country team submits vaccine request for Sabin OPV2 (if applicable)																			
Advisory Group for Sabin OPV2/GPEI partners meet and provide recommendations to country team																			
Outbreak to be graded by WHO Health Emergencies (WHE) Headquarters, as per the ERF Framework																			
Country team to finalize and submit outbreak response plan and budget																			
Vaccine management																			
WHO Director-General authorizes release of mOPV2 from stockpile (if applicable)																			
mOPV2 vaccine and syringes shipped to country (if applicable)																			
mOPV2 vaccine sent to field (if applicable)																			
Response activities																			
Pre-financing/no-regrets funding (up to USD 1,000,000) released to regional/country office (if required) to fund initial response activities																			
Develop and implement a national advocacy and communication plan																			
Initiate surveillance enhancement activities																			
Implement Rapid Response SIA (Round 0)																			
Outbreak response budget endorsed and funds release to the country																			
Implement SIA 1, SIA 2 and mop-up rounds																			

Annex 2B: Timeline and responsibility for outbreak response activities from Day 0 to close of outbreak

Timeline	Function	Activities	Responsibility	
			Country	Regional / Global
Notification of virus from laboratory - Day 0	Outbreak coordination	Establish an outbreak management team with representation from all relevant agencies.	National Government/health authorities, with support from WHO and UNICEF country offices	
	Resources	Find national polio outbreak preparedness and response plan (can be found in Annex in National Certification Committee (NCC) report).	National Government/health authorities, with support from WHO and UNICEF country offices	
	Resources	Identify trained or experienced polio outbreak response persons in country/region.	National Government/health authorities, with support from WHO and UNICEF country offices	WHO and UNICEF regional offices/ headquarters to rapidly provide required documents
	Resources	Read any reports or documents of previous outbreak response activities.	National Government/health authorities, with support from WHO and UNICEF country offices	
Within 24 hours of notification	Resources	Ensure country team has technical guidance documents to support investigation and response (outbreak SOPs, investigation template, risk assessment template, etc.).		WHO and UNICEF regional offices and headquarters
	Investigation	Initiate joint epidemiological and social investigation (see Chapter 3)	National Government/health authorities, with support from WHO and UNICEF country offices	With support from WHO and UNICEF regional office and headquarters
	Communication	Inform national authorities and other relevant partners	National Government/health authorities	WHO headquarters to inform GPEI partners (ORPG, Strategy Committee)
	Outbreak coordination and advocacy	<p>Brief Minister of Health, Head of Government/State and other relevant officials on the specific steps required for an urgent response to stop the outbreak:</p> <ol style="list-style-type: none"> 1. Establish a national emergency operation centre (EOC) if an existing emergency coordination structure is not already in place, led by a senior government official as the designated outbreak focal point and supported by staff for administration, strategic communication, operations, logistics, supply management and finance. 2. Implement the required response operations to stop the virus transmission as per the outbreak response SOPs, virus type and classification. 3. Ensure systematic monitoring mechanism at all levels (national, regional and district) to monitor progress of planning, implementation and follow up actions throughout response activities. 4. Timely and regular reporting of the progress of outbreak response activities to the head of government/ state and GPEI partners 	National health authorities, with support from WHO and UNICEF country offices	With support from GPEI partners to ensure the national health authorities have the necessary information to communicate effectively with country stakeholders.

Timeline	Function	Activities	Responsibility	
			Country	Regional / Global
Within 24 hours of notification	IHR notification	Submit IHR notifications to WHO Regional Contact Point.	National IHR focal point	WHO Headquarters to support
	Communication	Alert UNICEF supply division if type 2 poliovirus		WHO and UNICEF headquarters
	Outbreak coordination	Initiate event/outbreak response mechanisms at regional office and headquarters levels. Share any available information with country team (draft risk assessment, surveillance assessments, historical coverage, security assessments, high-risk groups, etc.).		GPEI partners
	Outbreak coordination	Outbreak Response and Preparedness Group (ORPG) to establish weekly conference calls between WHO, UNICEF and GPEI partners.	WHO and UNICEF to participate	ORPG to initiative and chair calls
	HR surge support	Assess the on-the-ground HR capacity of the national health system, WHO, UNICEF and other in-country partners to implement response operations.	National health authorities, WHO and UNICEF country offices	
		Request expedited procedures for visas at the port of entry for any international outbreak responders.	National health authorities	WHO and UNICEF regional offices/ headquarters to provide required documents rapidly
		Activate surge support processes; deploy as soon as available. (Target 72 hours - Rapid Response; Target 21 days - Surge Support).	WHO and UNICEF country offices to make in-country arrangements	ORPG and Regional polio response teams to coordinate
	Risk assessment and response	Initiate risk assessment template with proposal for immunization response strategy	National health authorities with support from WHO and UNICEF country offices	With support from WHO/UNICEF regional office and headquarters
	Communication	Identify a media focal person and spokesperson for the outbreak.	National health authorities, WHO and UNICEF country offices to agree and nominate	
Within 24 hours of notification	Communication	Work with partners and government counterparts to:	National health authorities with support from WHO and UNICEF country offices	With support from Regional polio response teams/regional offices and headquarters
		Conduct a media landscape analysis		
		Conduct a press briefing/media release		
		Initiate media monitoring.		
	Complex emergency settings (if applicable)	Inform the United Nations Resident Coordinator and the Humanitarian Country Team.	WHO country office	
		Coordinate with the United Nations Department of Safety and Security (UNDSS) on field missions.	WHO and UNICEF representatives	
		Assess the security and access in the area of the virus isolate and surrounding areas. Request security advisor to conduct a field level assessment.	UNDSS, in collaboration with national authorities	WHO regional office and headquarters security advisors support as required

Timeline	Function	Activities	Responsibility	
			Country	Regional / Global
Within 72 hours (3 days) of notification	Risk assessment and response planning	1) Finalize risk assessment and response proposal, with all available information, including from neighbouring countries 2) Present risk assessment and proposal to ORPG (Type 1 or Type 3 poliovirus) or Sabibn OPV2 Advisory Group (Type 2 poliovirus) for feedback and recommendations.	National Health Authorities with support from WHO and UNICEF country offices	Regional polio response teams / WHO/ UNICEF regional offices and Headquarters with ORPG support
	Logistics planning	Complete a logistics plan including: vaccine forecasts, cold storage, warehousing, distribution, utilization monitoring, vaccine accountability, and disposal (see vaccine management guidance).	National Health Authorities with support from WHO and UNICEF country offices	UNICEF Headquarters to support
	Vaccine request	Submit Sabin OPV2 or Novel OPV2 request for authorization of vaccine released by WHO Director-General	National Health Authorities with support from WHO and UNICEF country offices	Sabin OPV2 Advisory Group secretariat and ORPG-nOPV2 release group to review and send to UNICEF Supply Division
	Provision of information by WHO	a summary may be reported through the Event Information Site (EIS) for national IHR focal points or publicly on the WHO website as a Disease Outbreak News (DON).	National IHR focal point	WHO Regional office and Headquarters to support
	Grading	Prepare and participate in WHO 3-level call for grading by WHE, WHO Polio headquarters, regional office and country office, as per the Emergency Response Framework	WHO and UNICEF country offices with national health authorities	WHO Regional Office (Polio and WHE) to coordinate, WHE Headquarters to grade in consultation with WHO POL headquarters and regional office
	Finance	Release "pre-financing/no regret funding" (up to USD 1,000,000) to regional/country office to fund initial response activities		ORPG and WHO headquarters to coordinate and release
	Logistics	Initiate shipment of bundled response vaccine as per response proposal	UNICEF country office	UNICEF Supply Division
	Outbreak response	Communicate preliminary plan to all provinces and districts involved in response activities. Initiate development of the outbreak response plan <ul style="list-style-type: none"> • Background and risk for further transmission • Proposed strategy of SIAs (scope, timing, etc. • Surveillance enhancement activities • Advocacy, communication and social mobilization activities • Human resources assessment • Monitoring, evaluation and outbreak response assessments (OBRA) • Budget • Seek feedback and input from subnational teams 	National health authorities with support from WHO and UNICEF country offices National health authorities, with support from WHO and UNICEF country offices	ORPG to facilitate review and recommendations from GPEI partners

Timeline	Function	Activities	Responsibility	
			Country	Regional / Global
Within 72 hours (3 days) of notification	Outbreak response	Activate the national emergency operating center (EOC) or existing emergency coordination structure to roll out activities required for the first immunization response and subsequent activities in the outbreak response plan.	National health authorities with support from WHO and UNICEF country offices	Regional polio response teams to support
	Routine Immunization, coverage improvement	Include a unit on routine immunization coverage improvement in the EOC, led by the National EPI and supported by the immunization partners	National health authorities / National EPI supported by WHO and UNICEF country offices (EPI teams)	
	Advocacy and communication	Initiate development of a national advocacy and communication plan focusing on community engagement, social mobilization and general information dissemination strategies across the outbreak response period. (See Chapter 9 for detailed guidance.) Include: <ul style="list-style-type: none"> Pre-campaign awareness sessions targeting high-risk and hard-to-reach populations Proactive communication ensuring communities and health workers are sensitized to the dangers of the disease and benefits of the vaccine 	National health authorities with support from WHO and UNICEF country offices	Regional polio response teams to support
		<ul style="list-style-type: none"> Engagement of key influencers and key stakeholders (including political, religious, community leaders, celebrities) to provide access to hard-to-reach communities Development of a special crisis communication plan to address rumours in case of resistance to vaccination and rapid respond actions to adverse events following vaccination. 	National health authorities with support from WHO and UNICEF country offices	RRT/IMST and WHO/UNICEF regional offices to support
		Provide a briefing to the highest government authorities (e.g. cabinet memo or presidential brief) and other key strategic partners needed for a successful response (relevant ministries, parliamentarians, political/religious/civic leaders, health and NGO partners in the epicenter).	National health authorities, with support from WHO and UNICEF country offices	
	Communication	Conduct a follow up media briefing on plans and proposals for responding to the outbreak.	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams and UNICEF regional office and headquarters to support
	C4D, social mobilization and communication	Share the C4D polio toolkit and list of long-term agreements that the country office can immediately use to accelerate response activities.		Regional polio response teams and UNICEF regional office and headquarters to support
		Complete the social profiling of the case and context using special country investigation tools to guide the design of C4D interventions.	National health authorities and UNICEF country office	Regional polio response teams and UNICEF regional office and headquarters to support

Timeline	Function	Activities	Responsibility	
			Country	Regional / Global
Within 7 days of notification	Outbreak Coordination and Advocacy	Declare polio outbreak/high risk event as a National Public Health Emergency	National Government/ authorities	With necessary support from GPEI partners
	Human resources surge support	Determine human resources surge requirements with ORPG based on grading and country needs	National health authorities, with support from WHO and UNICEF country offices	ORPG to facilitate GPEI partner support
	Outbreak response	Develop a preparedness dashboard to assess readiness for "Round 0". Initiate tracking of activities (for example, dashboards available for guidance).	National health authorities. WHO and UNICEF country offices to support.	
	Surveillance enhancement	Initiate surveillance enhancement activities (See Chapter 7 for detailed guidance): Notify and sensitize health care workers at national and subnational surveillance units about notification requirements Implement supplemental AFP case-finding activities Review and reclassify reporting sites in the AFP active surveillance network Ensure the national laboratory is involved in outbreak planning to ensure capacity is strengthened Increase frequency of environmental sampling from already existing sites, where feasible and appropriate.	National health authorities, with WHO country office	GPEI partners to support
	Advocacy and communication	Develop an external advocacy plan to secure high-level political commitment from the affected country and complement in-country advocacy efforts	National health authorities, with support from WHO and UNICEF country offices	ORPG, WHO/UNICEF regional offices and Headquarters
		WHO and UNICEF regional directors to write to the Minister of Health highlighting the emergency and the full support of the country representatives and organizations for guidance and support.	WHO and UNICEF country offices to facilitate	WHO/UNICEF regional directors, in coordination with the GPEI Strategy Committee
	Communication	Initiate the development of a joint WHO/UNICEF situation report (SITREP) to update GPEI partners weekly on the progress of investigation, planning and response activities (template available for guidance).	WHO and UNICEF country offices	Regional polio response teams and UNICEF regional office and headquarters to support
		Inform broader donor community of poliovirus notification and status of polio response activities, including immunization and surveillance.	WHO and UNICEF country offices with in-country donors and media	
		Finalize media protocol kit with key messages, produce media briefs and other communication products relevant to the outbreak for local and regional/global use.	National health authorities with UNICEF country office	UNICEF regional office and headquarters to support

Timeline	Function	Activities	Responsibility	
			Country	Regional / Global
Within 7 days of notification	Communication	Initiate weekly media briefing on the response plan and status of immunization and surveillance activities.	National health authorities with UNICEF country office	
	Complex emergency settings (if applicable)	<ul style="list-style-type: none"> Initiate development of an access plan, including: Mapping community leaders, key players, stakeholders and identify influencers Planning for permanent/transit vaccination point strategies surrounding inaccessible areas Planning for opportunistic vaccination strategies to reach populations in inaccessible areas. 	National health authorities with support from UNDSS	Regional polio response teams, WHO regional office
	Partner coordination	Initiate partner coordination with other United Nations and humanitarian agencies on the ground.	WHO country office	Regional polio response team
Within 14 days of notification	Outbreak response plan and budget	Finalize outbreak response plan and six-month budget (see template and budget SOPs developed by the ORPG for guidance and timing); country team to finalize within one week	National health authorities with support from WHO and UNICEF country offices	ORPG to coordinate GPEI partners review and feedback
		Initiate outbreak response plan activity monitoring to track implementation (e.g. tracker, dashboard).	National health authorities with support from WHO and UNICEF country offices	
	Partner coordination	Establish a weekly meeting with key stakeholders in the country to coordinate and monitor implementation of the outbreak response plan.	National health authorities with support from WHO and UNICEF country offices	
	Outbreak response operations plan	<ul style="list-style-type: none"> Initiate development of the national operations macro plan for "Round 0" detailing strategy, coordination structure, vaccine, logistics, human resources, supervision, social mobilization, communication and training needs, etc. Revise macro plan for subsequent SIA 1/SIA 2 and additional mop-up round 	National health authorities with support from WHO and UNICEF country offices	Regional polio response teams
	Micro plan development	<ul style="list-style-type: none"> Develop tools and training for development of micro plans for "Round 0", detailing strategies, coordination structure, vaccine, logistics, human resources, supervision, social mobilization, communication and training needs, etc. (Best practice for microplanning available for guidance.) Revise micro plans for subsequent SIA 1/SIA 2 and additional mop-up round. 	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams
	C4D, social mobilization and communication	Implement the advocacy and communication plan to engage all relevant stakeholders at the national and subnational levels in outbreak response activities.	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams and ORPG to facilitate support from partners

Timeline	Function	Activities	Responsibility	
			Country	Regional / Global
Within 14 days of notification	Communication	Ensure that joint WHO/UNICEF situation report (SITREP) is generated and circulated among partners.	WHO and UNICEF country offices	Regional polio response teams to provide support
	Complex emergency settings (If applicable)	Initiate process to fill vacant positions in infected and high-risk areas.	National health authorities, with support from WHO and UNICEF country offices	WHO/UNICEF regional office to provide support
		Deploy a field security officer.	National health authorities	WHO regional office and headquarters to provide technical support
		<ul style="list-style-type: none"> Implement access plan (examples of strategies listed below): Engage the community leaders and identified influencers Negotiate access through key players, influencers and stakeholders Implement a permanent/transit vaccination point strategies surrounding inaccessible areas Implement opportunistic vaccination strategies to reach populations in inaccessible areas. 	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams and WHO regional office
	Immunization	Within 14 days, implement “Round 0” immunization response.	National health authorities, with support from WHO and UNICEF country offices	
	Vaccine management	For Sabin OPV2 response ensure comprehensive management of all vials. Detailed monitoring and reporting of vials deployed, retrieved, remaining and unaccounted for at the end of each immunization activity is required. (See vaccine management guidance)	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams and UNICEF regional office and headquarters to support
14 days until completion of immunization activities (75–90 days)	Finances	ORPG to provide endorsement of outbreak response plan and budget (within 20 days) and initiate mechanisms to release funds. Within 28 days funds should be available in country.	WHO and UNICEF country teams to prepare and submit budget	Regional polio response teams and ORPG to facilitate reviews and approval processes
	Monitoring preparedness	Develop SIAs preparedness monitoring dashboards to be used to assess SIAs readiness at national and subnational levels.	National health authorities with support from WHO and UNICEF country offices	
		Conduct readiness assessments two weeks, one week and three days prior to SIA implementation to inform targeted technical support for SIAs quality assurance.	National health authorities with support from WHO and UNICEF country offices	
	Monitoring advocacy	Track the implementation of the internal and external advocacy plans. Taking note of successful interventions and communicating further needs to RRT/IMST and ORPG.	National health authorities with support from WHO and UNICEF country offices	Regional polio response teams and ORPG to facilitate support from GPEI partners

Timeline	Function	Activities	Responsibility	
			Country	Regional / Global
14 days until completion of immunization activities (75–90 days)	Monitoring immunization	Establish campaign monitoring for SIAs: <ul style="list-style-type: none"> • Supervision • Independent monitoring (intra- and post-campaign) • Daily review meetings (team performance, daily reporting) • Lot quality assurance sampling (LQAS) • SIA reviews, including vaccine refusals, issues related to mistrust, etc. 	National health authorities with support from WHO and UNICEF country offices	Regional polio response teams and WHO/UNICEF regional offices and headquarters to provide support
	Monitoring communication	Establish monitoring of communication interventions.	National health authorities with WHO and UNICEF country office	Regional polio response teams and UNICEF regional office/ headquarters to provide support
	Micro plan development	Develop tools and training for development of micro plans detailing strategies, coordination structure, vaccine, logistics, human resources, supervision, social mobilization, communication and training needs etc. (Best practice for microplanning is available for guidance.)	National health authorities with support from WHO and UNICEF country offices	Regional polio response teams to provide any regional/global guidance documents
	Training	Conduct trainings of front-line workers (vaccinators, supervisors and social mobilizers) on technical skills, communication and interpersonal skills for SIA 1 and SIA 2 targeted areas.	National health authorities with support from WHO and UNICEF country offices	
	Information management	Liaise with in-country data managers to identify and resolve data format and completeness issues	National health authorities with support from WHO and UNICEF country offices	RRT/IMST/WHO regional office
	Vaccine management	Assess cold-chain capacity and vaccine management capabilities and take urgent steps to fill gaps prior to SIA1	National health authorities with support from WHO and UNICEF country offices	UNICEF regional office and headquarters to provide support
	Partner coordination	<ul style="list-style-type: none"> • Conduct regular donor meetings and advocacy activities • Ensure in-depth discussion and alignment with other health partners to consider additional interventions alongside OPV, such as providing vitamin A and deworming tablets, where feasible, particularly for type 1 and 3 outbreaks. (Integration for type 2 outbreaks should only be considered exceptionally.) 	National health authorities with support from WHO and UNICEF country offices	Regional polio response teams and ORPG to provide support
	Immunization	Implement subsequent immunization activities (SIA 1, SIA 2, mop-up round) as per outbreak response plan	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams and ORPG to facilitate support from GPEI partners

Timeline	Function	Activities	Responsibility	
			Country	Regional / Global
14 days until completion of immunization activities (75–90 days)	Immunization	<p>Conduct activities to improve the quality of SIAs with each subsequent round:</p> <ul style="list-style-type: none"> • Triangulation of data including: low performing areas, social data on refusals/missed children or other observed social barriers, surveillance data etc. • Conduct additional vaccinator and supervisor training for interpersonal skills • Strengthen supervision, monitoring and regular review meetings during campaign • Initiate special strategies to reach missed, high-risk or mobile populations • Conduct activities to improve the quality of SIAs, including detailed microplanning supported by GIS mapping where appropriate and feasible. 	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams, ORPG and WHO/UNICEF regional offices and headquarters to provide support
	Outbreak response plan	Review and adapt the outbreak response plan, including immunization, surveillance and communication activities for subsequent phases. Track progress made and/or support needed to close any remaining gaps.	National health authorities with support from WHO and UNICEF country offices	Regional polio response teams to support and ORPG to review and provide recommendation
	Information management	Ensure surveillance, SIA and monitoring data are completed and sent to WHO and UNICEF regional offices and headquarters, according to agreed timelines (within 14 days for all SIAs, and weekly for AFP data).	National health authorities with support from WHO and UNICEF country offices	
	Vaccine reporting and accountability	Complete vaccine utilization and accountability reports after each round, including round 0 (see vaccine management guidance).	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams and UNICEF regional office/ headquarters to provide support
	Vaccine disposal	Disposal of used, and partially used vaccine vials for type 2 immunization response. Unopened vials should be securely stored in strategic stores with access control facilities until the outbreak is considered closed (see vaccine management guidance).	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams and UNICEF regional office/ headquarters to provide support
Until close of outbreak	Data analysis	Analyse and triangulate all data to assess population immunity, sensitivity of surveillance and progress towards interrupting transmission.	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams and ORPG to facilitate support from GPEI partners

Timeline	Function	Activities	Responsibility	
			Country	Regional / Global
Until close of outbreak	Routine immunization, coverage improvement, recovery and strengthening	Ensure a well-functioning unit 'routine immunization coverage improvement' as part of the EOC that extends support to immunization during the outbreak response period, maximizing use of surge capacity to strengthen programme management, microplanning, community mobilization and performance monitoring. The EOC should effectively maximize the benefit of time-limited support to RI, through selected actions in line with the operational components of the Reaching Every District (RED)*approach. (See end of Chapter 7, and RED strategy for detailed guidance.)	National health authorities, with support from WHO and UNICEF country offices and polio surge resources in country	
	Surveillance enhancement	Continue surveillance enhancement activities (see chapter 8 for detailed guidance): <ul style="list-style-type: none"> • Notify and sensitize health care workers at national and subnational surveillance units about notification requirements • Review and reclassify reporting sites in the AFP active surveillance network. 	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams, ORPG and Surveillance group (SG)
	OBRA; 3-4 months	Conduct an independent outbreak response assessment (OBRA) (detailed guidance available in OBRA Aide-Mémoire)	National health authorities to facilitate, with support from WHO and UNICEF country offices	ORPG, in coordination with IMST/ RRT
	Follow up OBRA and desk reviews	follow up programme desk review will be conducted 6 – 9 months from last detected isolate, or as appropriate to the circumstances. Extended outbreaks may warrant intermediate OBRA or desk-reviews. In situations when in-person assessment is not possible (including the COVID-19 pandemic related limitations), virtual OBRA and desk reviews may be considered	National health authorities to facilitate, with support from WHO and UNICEF country offices	ORPG, in coordination with IMST/ RRT
	Grading review - 3 months	A review of the grading is conducted every three months; if the grade changes, the response will be adapted accordingly		WHO Regional Office (Polio and WHE) to coordinate, WHE Headquarters to grade in consultation with WHO POL headquarters and regional office
	Lessons learnt	Document the response and share lessons learned.	National health authorities, with support from WHO and UNICEF country offices	Regional polio response teams and ORPG to provide input

ANNEX 3: GENDER CHECKLIST FOR POLIO OUTBREAK RESPONSE

Human resources and operations

Balanced recruitment of women and men in all aspects of outbreak response at all levels and roles, both technical and operational (including in leadership roles), is ensured through specific measures (such as quotas and HR policies)

Women's meaningful participation in outbreak activities at all levels and in different roles is actively encouraged

Adequate budget is allocated to support gender mainstreaming activities and gender expertise

All staff working in outbreak response at all levels and in different roles have completed a mandatory training on the Prevention of Sexual Exploitation and Abuse (PSEA)

A zero tolerance policy on discrimination, sexual abuse and harassment or any misconduct, is upheld, and a functional reporting and support mechanism is in place

Stakeholders and participation

Women's groups, local women's organizations/grassroots networks/associations/CSOs and leaders are consulted in different stages of outbreak response planning, implementation, monitoring and evaluation

Data collection and analysis

Sex-disaggregated data is collected, analysed and used to guide interventions during outbreak response (including IM/LQAS post-campaign monitoring)

Sex-disaggregated data is used in all outbreak response sit-reps, briefings, reports and presentations

Gender-sensitive indicators are in place for monitoring and evaluation

Capacity building

Mechanism is in place to ensure that women and men benefit equally from training and other capacity-building activities conducted during outbreak response planning and implementation, identifying addressing specific barriers and challenges faced by women

Ensure that all staff received training on the organization's zero tolerance approach to all forms of sexual harassment, abuse and exploitation, and are informed about available support mechanisms and systems for reporting harassment and misconduct

Communications/C4D

Collect, analyse and use data disaggregated by sex and age, and also by other factors such as ethnicity, disability, socio-economic background, urban/rural/place of residence, in community engagement and social mobilization situation analyses, assessments and all communication intervention plans to identify and address gender-related barriers.

Equally consult with and ensure the meaningful participation of diverse women and men in the design, testing and delivery of outreach tools and materials (such as posters, flyers, radio messages, SMS, TV spots)

Ensure all communication materials take into account the different literacy levels of women and men in communities, ensuring that the content of materials/messages and distribution channels are tailored to their needs and preferences

Identify and work with key influencers within communities, including women's groups, grassroots networks and community organizations as well as other opinion influencers (based on context analysis)

Ensure that the content, design and visuals of polio materials, messages and interventions challenge harmful gender norms, roles and stereotypes

Address identified barriers for women and men to access or participate in planned polio outreach activities (e.g. by arranging transportation so women can attend a community meeting on polio information)

Ensure gender-balanced social mobilization and community engagement teams, as well as other communication-related polio groups and events

Ensure that all social mobilizers are trained on the organization's zero tolerance approach to all forms of sexual harassment, abuse and exploitation, and are informed about available support mechanisms and systems for reporting harassment and misconduct

Target both men and women as caregivers in all polio-related outreach, encouraging men's increased participation in children's care

