



# Strategy for the Response to Type 2 Circulating Vaccine-Derived Poliovirus 2020–2021

**AN ADDENDUM TO THE POLIO ENDGAME STRATEGY  
2019–2023**

WHO/Polio/20.02

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This report reflects contributions from a process led by the GPEI agency partners: Rotary International, WHO, the US Centers for Disease Control and Prevention (CDC), the United Nations Children's Fund (UNICEF), the Bill & Melinda Gates Foundation and Gavi, the Vaccine Alliance.

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# Acronyms and abbreviations

AFP	Acute flaccid paralysis	OPRTT	Outbreak Preparedness and Response Task Team
AG	Advisory Group on the monovalent OPV2 Stockpile	OPV	Oral polio vaccine
BMGF	Bill & Melinda Gates Foundation	OPV1	Oral polio vaccine serotype 1
bOPV	Bivalent OPV (containing OPV1 and OPV3)	OPV2	Oral polio vaccine serotype 2
C4D	Communication for development	OPV3	Oral polio vaccine serotype 3
CDC	Centers for Disease Control and Prevention (United States of America)	PHEIC	Public Health Emergency of International Concern
CRTT	Cessation Risk Task Team	PID	Primary immunodeficiency disorder
CSO	Civil society organization	PIRI	Periodic intensification of routine immunization
cVDPV	Circulating vaccine-derived poliovirus	R0, R1	Vaccination round zero, round 1, etc.
cVDPV1	cVDPV serotype 1	RRT	Rapid Response Team
cVDPV2	cVDPV serotype 2	SAGE	Strategic Advisory Group of Experts on Immunization
cVDPV3	cVDPV serotype 3	SC	Strategy Committee
DD	Direct detection	SD	Supply Division (UNICEF)
EB	Executive Board of the World Health Assembly	SIA	Supplementary immunization activity
EOC	Emergency Operations Centre	SOPs	Standard operating procedures
EOMG	Eradication and Outbreak Management Group	STT	Surveillance Task Team
EPI	Expanded Programme on Immunization	TAG	Technical Advisory Group
ES	Environmental surveillance	tOPV	trivalent OPV (containing OPV1, OPV2 and OPV3)
EUL	Emergency Use Listing	UNICEF	United Nations Children's Fund
fIPV	Fractional dose of inactivated polio vaccine	VDPV	Vaccine-derived poliovirus
FMT	Finance Management Team	VDPV1	Vaccine-derived poliovirus serotype 1
FRR	Financial Resource Requirements	VDPV2	Vaccine-derived poliovirus serotype 2
Gavi	Gavi, the Vaccine Alliance (formerly Global Alliance for Vaccines and Immunization)	VDPV3	Vaccine-derived poliovirus serotype 3
GCC	Global Commission for the Certification of Poliomyelitis Eradication	VPD	Vaccine-preventable disease
GPEI	Global Polio Eradication Initiative	VSTT	Vaccine Supply Task Team
GPLN	Global Polio Laboratory Network	WHA	World Health Assembly
IHR	International Health Regulations	WHE	World Health Organization Health Emergencies
IMB	Independent Monitoring Board	WHO	World Health Organization
IPV	Inactivated polio vaccine	WPV	Wild poliovirus
ITD	Intratypic differentiation	WPV1	WPV serotype 1
mOPV	Monovalent oral polio vaccine	WPV2	WPV serotype 2
mOPV2	mOPV2 serotype 2	WPV3	WPV serotype 3
NGO	Nongovernmental organization		
Novel OPV	Novel oral polio vaccine		
Novel OPV2	Novel OPV serotype 2		
NRA	National Regulatory Authority		

# STRATEGY RATIONALE

## Background

In 2016, following the 2015 certification of the eradication of wild poliovirus type 2 (WPV2), the synchronized worldwide withdrawal of the trivalent oral polio vaccine (tOPV) was planned and implemented as a milestone toward eradication through the careful removal of the live attenuated type 2-containing vaccine. Termed “the Switch,” this global effort impacted both country immunization systems and supplementary immunization activities (SIAs) supported by the Global Polio Eradication Initiative (GPEI). For risk mitigation purposes, the Switch was preceded by the introduction of at least one dose of inactivated polio vaccine (IPV) into national immunization schedules in countries that did not already use IPV. The Switch also included intensified efforts to increase type 2 population immunity in many countries with elevated risk through the administration of tOPV in national and subnational SIAs prior to its cessation.

The removal of live attenuated polio vaccine is a critical step in the post-eradication workstream to ensure the complete interruption of all polio transmission, including wild poliovirus type 1 (WPV1) and the secondary circulation that occurs in rare cases when the virus contained in the Sabin oral polio vaccine (OPV) regains neurovirulence and contributes to the emergence of vaccine-derived poliovirus (VDPV).<sup>1</sup>

The GPEI anticipated that the post-Switch period would include the emergence of VDPVs and subsequent circulating type 2 VDPVs (or cVDPV2s), and that several outbreak responses using Sabin OPV2 would be required to stop such outbreaks. Pre-Switch modeling indicated that the majority of post-Switch VDPV2 emergence and cVDPV2 outbreaks would occur in the 12- to 24-month period after the Switch (i.e., 2017–2018), that appropriate campaigns with Sabin OPV2 would stop transmission, and that new VDPV2 detections would decline until they ceased altogether.

However, pre-Switch intensification efforts were not equally successful in all countries. Due to a global IPV shortage in 2016, 20 countries (including 13 in Africa) did not introduce IPV prior to the Switch, which contributed to critical gaps in immunity that were left unaddressed in countries with fragile immunization systems. These immunity gaps, combined with an uneven quality of outbreak response and more post-Switch use of Sabin OPV2 than anticipated (over 350 million doses have been administered since the Switch), have resulted in considerably more post-Switch VDPV2 emergences and cVDPV2 outbreaks than predicted by the programme. While the global IPV shortage was remedied by the end of 2018 and sufficient supply allowed for all countries to introduce at least one dose of IPV into their national immunization programmes by April 2019, the programme now contends with a rapidly unfolding epidemiology.

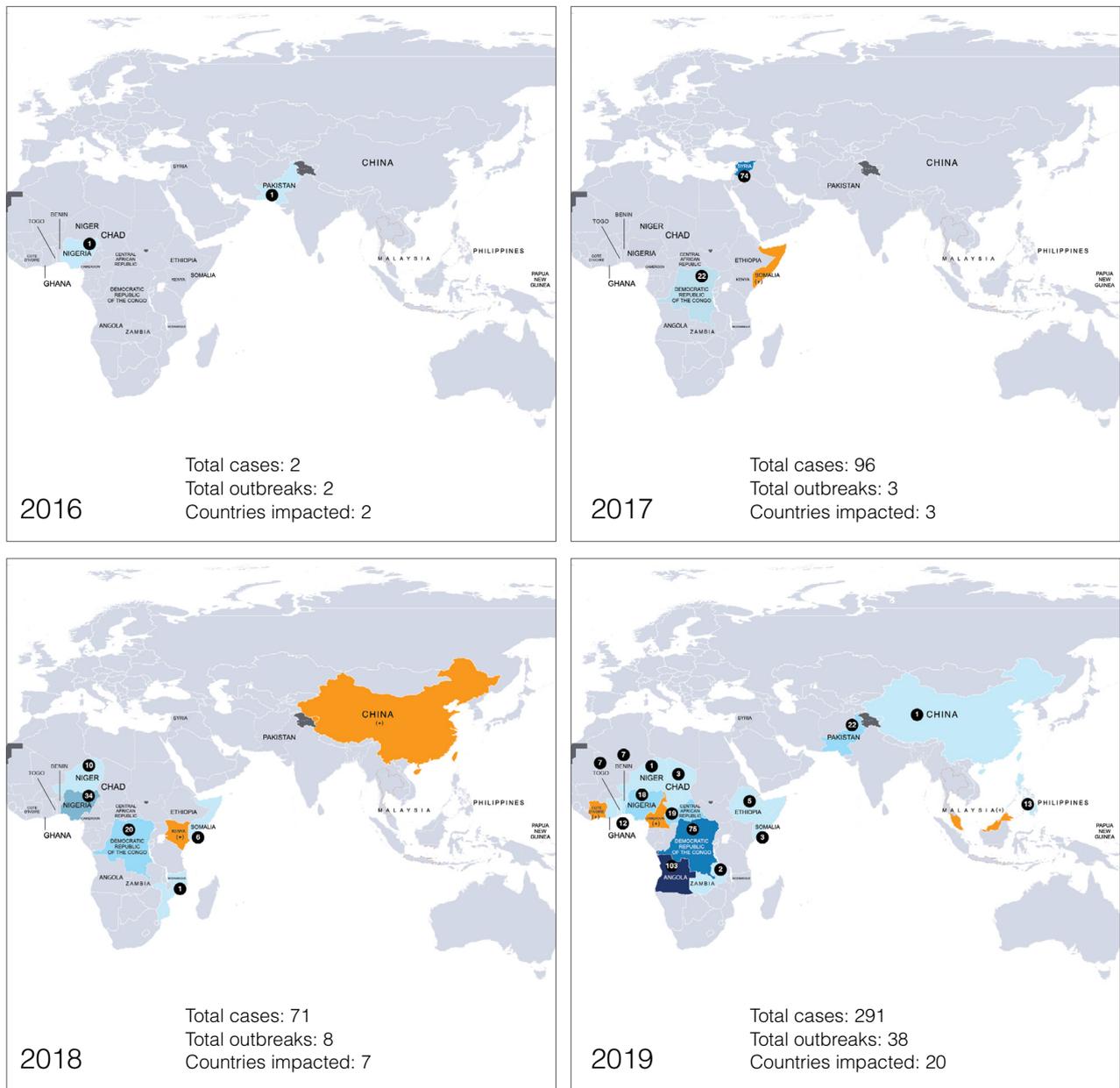
In 2019, three years after the Switch and against the backdrop of declining type 2 population immunity in many geographies as cohorts of children who never received Sabin OPV2 expand, the number of new VDPV2 emergences and cVDPV2 outbreaks quickly and substantially increased. Moreover, cVDPV2 outbreaks in areas that border outbreak zones but are outside of Sabin OPV2 response areas also increased. This trend demonstrates an increased risk of generating new cVDPV2 viruses when using Sabin OPV2, even though VDPV2 emergences are rare events in the context of the administration of hundreds of millions of doses of vaccine.

<sup>1</sup> Sabin OPV has been critical to the worldwide reduction of polio cases and the global eradication of WPV2 and WPV3, as declared by the Global Commission for the Certification of Poliomyelitis Eradication (GCC) in 2015 and 2019, respectively. In rare instances, however, the live attenuated virus in the vaccine can cause neurological symptoms of poliomyelitis and become vaccine-derived poliovirus (VDPV). Where population immunity is low, this VDPV can begin to circulate, causing an outbreak of circulating vaccine derived poliovirus (cVDPV). While this can occur with all three serotypes, historically cVDPV2 has emerged the most, followed by cVDPV1 with cVDPV3 appearing least frequently.

### Context

At the end of 2019, the number of VDPV2-affected countries stood at 20 countries from three WHO regions (the African, Eastern Mediterranean, and Western Pacific regions), a notable increase when compared with seven countries in 2018 and only three in 2017 from two WHO regions (the African and Eastern Mediterranean regions). Moreover, several affected countries have more than one cVDPV2 outbreak occurring. **Figure 1** presents the spread of cVDPV2s. Possible sources underlying the spread of cVDPV2 outbreaks are highlighted in **Table 1**.

**Figure 1. Global cVDPV2 cases, May 2016–December 2020**



Data as of 28 Jan 2020

Number of cases



Outbreak classified by environmental detection

**Table 1. Possible sources of cVDPV2 outbreaks**

Possible source	Affected countries (n=19)
<b>Local emergence</b>	
From tOPV use (either pre- or post-switch)	China, Democratic Republic of the Congo, Nigeria, Philippines, Somalia, Syria
From Sabin OPV2 use in-country	Democratic Republic of the Congo, Mozambique, Nigeria
Following Sabin OPV2 use in neighbouring country	Angola, Central African Republic, Zambia
<b>Importation of cVDPV2 from another country</b>	
From Nigeria (directly or via other country)	Benin, Cameroon, Chad, Côte d'Ivoire, Ghana, Niger, Togo
From Somalia	Ethiopia
From the Philippines	Malaysia
<b>Other</b>	
Unknown	Pakistan

cVDPV2= circulating vaccine-derived poliovirus serotype 2; OPV2= oral polio vaccine (serotype 2); tOPV= trivalent oral polio vaccine (containing OPV1, OPV2 and OPV3)

## Purpose

The *Polio Endgame Strategy 2019–2023* positioned the GPEI's current five-year strategic period in relation to the dual emergency facing the polio eradication effort: that the programme must interrupt WPV1 and stop cVDPV transmission. In consideration of the potential long-term implications for cVDPV outbreaks, the Endgame Strategy signaled the importance of a contingency plan to mitigate the risk of cVDPVs through near-term interventions, emergency protocols and policy changes.<sup>2</sup>

The *Strategy for the Response to Type 2 Circulating Vaccine-Derived Poliovirus 2020–2021* is offered as an addendum that fulfills this need for a contingency plan. It has been developed by a working group and in consultation with experts across the GPEI partnership: the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), Rotary International, the U.S. Centers for Disease Control and Prevention (CDC), the Bill & Melinda Gates Foundation (BMGF) and Gavi, the Vaccine Alliance. **Annex A** provides an overview on the oversight and management of this addendum to respond to cVDPV2 outbreaks. The strategy will be regularly reviewed and updated as needed to meet ongoing needs.

This 18-month strategy (January 2020–June 2021) presents a series of risk mitigation measures to stop cVDPV2 spread. It prioritizes the use of programme assets and utilizes a new vaccine to improve outbreak response outcomes. This new vaccine, called novel OPV2, is anticipated to provide similar intestinal immunity to Sabin OPV2 while being substantially more genetically stable and thus resistant to reversion, lowering the risks associated with cVDPV2 response. With two candidates in the research and development pipeline, novel OPV2 is expected to be available in mid-2020 via WHO Emergency Use Listing (EUL).<sup>3</sup> Information regarding the licensure and production of novel OPV2 is provided in **Annex B**.

This strategy offers contingency measures across four mutually supportive areas of work:

1. enhanced outbreak response;
2. vaccine supply and usage;
3. early detection of new outbreaks; and
4. communication and promotion of the strategy.

While each area of work outlines specific protocols and procedures to strengthen outbreak response and free up or fast-track resources where needed (see **Table 2: Key interventions**), they work together to support the following objectives.

<sup>2</sup> Global Polio Eradication Initiative. *Polio Endgame Strategy 2019–2023: Eradication, integration and containment*. Geneva: World Health Organization; 2019. (<http://polioeradication.org/wp-content/uploads/2019/06/english-polio-endgame-strategy.pdf>).

<sup>3</sup> World Health Organization. *Emergency Use Listing Procedure, version 8 January 2020*. Geneva: World Health Organization; 2020. ([https://www.who.int/diagnostics\\_laboratory/eual/procedure/en/](https://www.who.int/diagnostics_laboratory/eual/procedure/en/)).

## OBJECTIVES

- Rapidly detect and control cVDPV2 outbreaks using Sabin OPV2 while minimizing the risk of further spread.
- Ensure an adequate supply of Sabin OPV2 is available until it is no longer required.
- Utilize IPV to boost immunity, mitigate paralytic risk and improve population immunity.
- Continue to accelerate IPV catch-up campaigns in countries with delayed introduction.
- Synergize efforts with the Expanded Programme on Immunization (EPI) and Gavi to strengthen immunization systems and primary healthcare delivery in high-risk areas and in populations with low type 2 immunity.
- Support novel OPV2 licensure, production and distribution processes through the GPEI novel OPV2 working group.
- Articulate a contingency plan in the event that cVDPV2 epidemiology outstrips the current supply of vaccine and human and financial resources.
- Ensure Member States, GPEI stakeholders and the general public understand how the programme proposes to mitigate and manage cVDPV2 risks.

## Stages

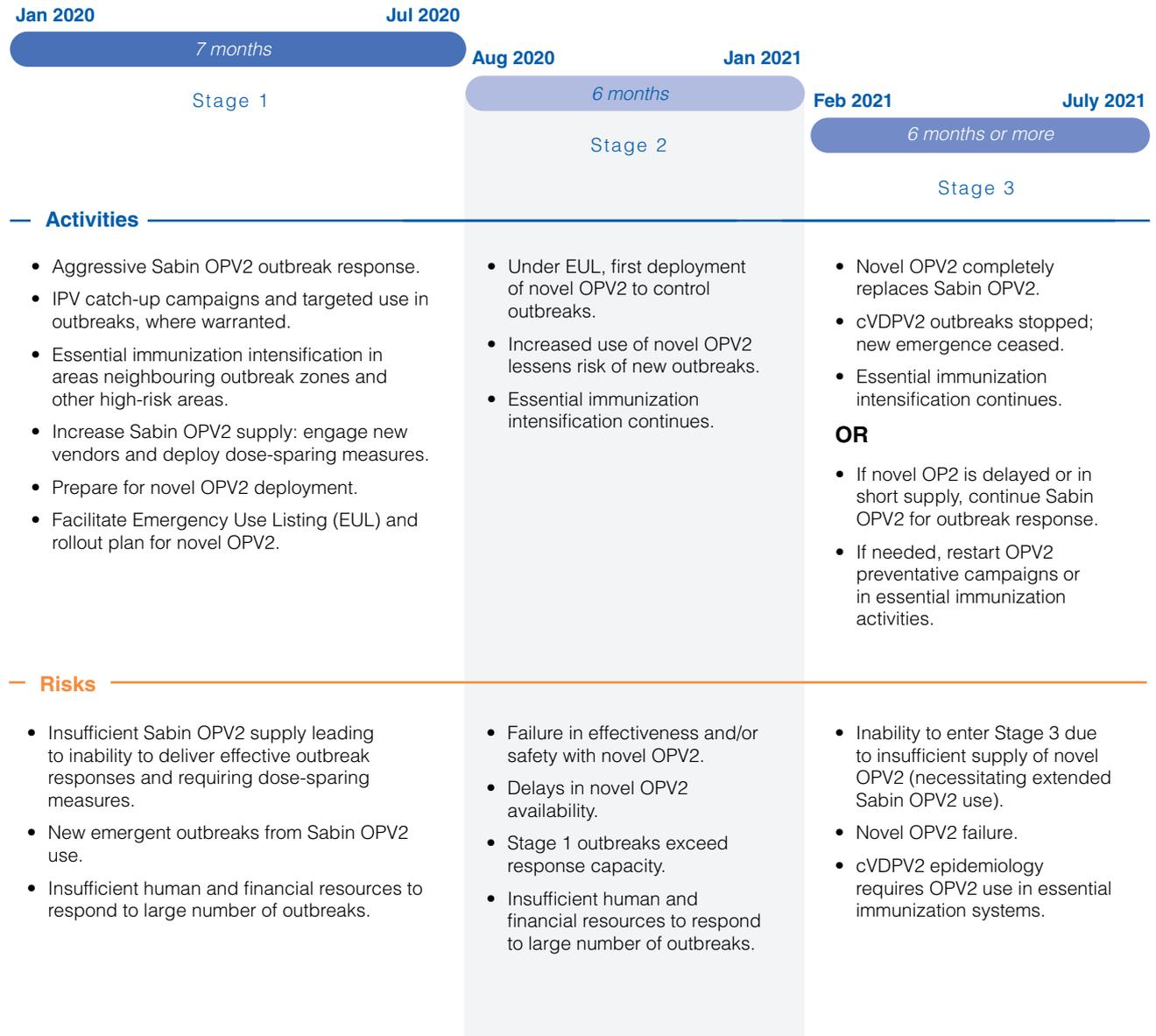
The strategy is structured into three stages that are defined by vaccine availability, as the risks and challenges vary with each vaccine strategy employed. Furthermore, contingency measures are built into each stage to ensure that resources are available to address risks that will need to be managed in subsequent stages. **Figure 2** (below) presents a timeline of the stages, their associated risks and key interventions or risk mitigation activities.

- **Stage 1:** Stage 1 is characterized by prompt, aggressive and quality response within 14 days of notification and with >90% coverage using Sabin OPV2 and strategic IPV use,<sup>4</sup> with the goal of controlling new and ongoing cVDPV2 outbreaks and mitigating paralytic risk while concurrently preparing for deployment of novel OPV2.<sup>5</sup> At defined Sabin OPV2 supply thresholds, dose-sparing measures will be introduced to minimize the likelihood of global stockout. Trivalent Sabin OPV stocks will also be produced, and efforts to prepare for its use in-country will be completed. In addition, immunization strengthening activities with IPV will be prioritized for the highest-risk geographies to reduce long-term polio risk. In a best-case scenario, Stage 1 is expected to end in July 2020, as novel OPV2 is expected to become available for use. The main risks in Stage 1 are: (1) insufficient Sabin OPV2 supply leading to an inability to deliver effective outbreak responses and requiring dose-sparing measures; (2) new emergent outbreaks seeded by Sabin OPV2 use; (3) insufficient qualified human and financial resources to respond to the large number of outbreaks; and (4) continued poor-quality SIAs.
- **Stage 2:** Stage 2 begins with first deployment of novel OPV2 to control outbreaks and ends when the supply of novel OPV2 is sufficient to wholly replace Sabin OPV2. Sabin OPV2 (either as monovalent OPV2 or in a trivalent formulation, where epidemiologically warranted) will continue to be used for outbreak response throughout this period, modulated by novel OPV2 availability. Stage 1 essential immunization intensification activities will continue. In a best-case scenario, Stage 2 will extend from August 2020 to January 2021 and be defined by effective cVDPV2 response with progressively less risk of seeding new outbreaks. The main risks in Stage 2 are: (1) failure in efficacy or unexpected adverse events with novel OPV2; (2) delays in novel OPV2 availability and/or insufficient supply; (3) outbreaks exceeding response capacity, triggering a process that will prepare for a Sabin OPV2 restart in essential immunization systems in Stage 3, if required to contain cVDPV2; and (4) insufficient human and financial resources to respond to the large number of outbreaks.
- **Stage 3:** Stage 3 begins when novel OPV2 completely replaces Sabin OPV2, with the risk of seeding new emergencies significantly reduced. Continuous monitoring commensurate with EUL requirements will continue until full licensure. During this stage, essential immunization intensification activities will continue. In a best-case scenario, Stage 3 begins in February 2021 and continues as needed until cVDPV2 outbreaks are stopped. The main risks to Stage 3 are: (1) indications that novel OPV2 is insufficiently efficacious, or significant adverse events are reported following immunization; and (2) cVDPV2 epidemiology requires OPV2 use in broad preventive SIAs or Sabin OPV2 restart (in a monovalent or trivalent formulation) in essential immunization systems (i.e., Switch failure).

<sup>4</sup> The utilization of IPV as a preventative measure in high-risk areas may require increasing IPV allocations for this purpose. Six million IPV doses have been allocated to Goal 1 in 2020. IPV will be used in several strategic ways as defined in the strategy, but essential immunization supplies will be prioritized and limitations in supply for other use may limit the extent of IPV use for some of these interventions.

<sup>5</sup> Information regarding licensure and production of novel OPV2 is provided in Annex B.

**Figure 2. GPEI cVDPV2 strategy stages**



**Key interventions**

- **Securing vaccine supply and optimizing usage** →
- **Enhancing outbreak response** →
- **Ensuring early detection of outbreaks** →
- **Implementing dynamic communication / community engagement activities** →
- **Employing strategic use of IPV to protect populations** →
- **Strengthening essential immunization systems in priority geographies** →
- **Monitoring novel OPV2 safety and effectiveness** →

*An initial use framework proposing the nature of first three months of novel OPV2 use following interim EUL being granted is under discussion with the Strategic Advisory Group of Experts (SAGE)*

cVDPV2= circulating vaccine-derived poliovirus type 2; EUL= Emergency Use Listing; IPV= inactivated polio vaccine; OPV2= oral polio vaccine type 2

The timeframes articulated above are dependent on novel OPV2 availability and EUL timeline, the availability of sufficient financial and human resources, the willingness of countries to accept novel OPV2 under EUL, and the rapidly evolving cVDPV2 epidemiology.

During implementation of the strategy, IPV catch-up activities will continue to be implemented. In addition, the GPEI is working towards introducing a second dose of IPV beginning in 2021. These activities will be coordinated with the implementation of this strategy to optimize the use of IPV in mitigating cVDPV2 paralytic risk.

Vaccine supply and management will be a major challenge during the strategy timeframe. The GPEI will be required to mobilize additional doses of Sabin OPV2 (either in a monovalent or trivalent formulation) to account for the potential expansion of cVDPV2 outbreaks while not compromising production of novel OPV2 or bivalent OPV. Furthermore, as novel OPV1 and OPV3 progress in the research and development pipeline, future assessments will determine if OPV1/3 should be made available with novel OPV2 in a trivalent formulation. Balancing current and future needs will require prioritizing risk-based Sabin OPV2 use and dose-sparing measures, maximizing filling with existing partners, establishing new fill-finish partners, and producing new bulk Sabin OPV2.

## Key interventions

**Table 2** outlines key activities planned for the 18-month cVDPV2 response strategy which begins in Q1 2020, though many of the workstreams prescribed in this strategy have already begun.

**Table 2. Summary of key interventions**

Enhanced outbreak response
<ul style="list-style-type: none"> <li>• Strengthen outbreak response procedures to improve response time and quality and make the most effective use of resources and vaccine.</li> <li>• Ensure that cVDPV2 outbreaks are immediately declared a Grade 2 emergency, according to the WHO Health Emergencies (WHE) Emergency Response Framework.<sup>6</sup></li> <li>• Ensure that all Grade 2 emergency functions are implemented by each partner agency; consistently use fast-track procedures to enable rapid deployment of human and financial resources.</li> <li>• Streamline processes of the monovalent OPV2 Advisory Group (AG).</li> <li>• In select situations, use IPV to augment monovalent OPV2 response.</li> <li>• Increase the size of the Africa Rapid Response Team (RRT) and form a global RRT to respond to outbreaks outside of Africa.</li> <li>• Strengthen the Surge Support Team (formerly “Team B”) by expanding technical staff capacity.</li> <li>• Increase GPEI field-deployed technical assistance in high-risk areas neighbouring outbreaks to support surveillance, outbreak preparedness and response efforts.</li> </ul>
Vaccine supply and usage
<ul style="list-style-type: none"> <li>• Resource the 2020–2023 Sabin OPV2 fill/finish supply and identify and contractually engage an additional bulk supplier and a fill/finisher.</li> <li>• Optimize use of limited Sabin OPV2 supply and, if necessary, employ dose-sparing measures.</li> <li>• Fast-track the development and availability of novel OPV2 under EUL.</li> <li>• Secure a trivalent Sabin OPV supply to use in place of monovalent OPV2 and engage countries and relevant regulatory bodies to prepare for tOPV use in Stage 2.</li> <li>• Develop a novel OPV2 prioritization scheme.</li> <li>• As a contingency measure, in case of novel OPV failure, procure sufficient Sabin OPV2 supplies to restart preventive OPV2 SIAs and/or restart OPV2 in essential immunization schedules.</li> <li>• Ensure sufficient IPV supply for catch-up campaigns, essential immunization intensification, targeted use in outbreaks in conjunction with Sabin OPV2, and expanded use in the event of a monovalent OPV2 stockout.</li> </ul>

<sup>6</sup> WHO Health Emergencies. Emergency Response Framework – 2nd edition. Geneva: World Health Organization; 2017. (<https://www.who.int/hac/about/erf/en/>)

**Early detection of new outbreaks**

- Strengthen AFP surveillance and expand environmental surveillance in areas at highest risk of cVDPV2 circulation, particularly areas that border a cVDPV2 outbreak zone or Sabin OPV2 use.
- Revise and fully implement the Global Polio Surveillance Action Plan.<sup>7</sup>
- Fast-track laboratory rollout of direct poliovirus detection from stool specimens.

**Communication**

- Form a Strategic Communication Working Group that integrates various communication workstreams related to outbreak readiness and response.
- Proactively garner support for the cVDPV2 response strategy by engaging global health bodies, national regulatory authorities, donors, journalists and the scientific community.
- Develop core communication products and advocacy tools that target specific audiences and equip countries, regions and partners to communicate effectively across social sectors.
- Deploy communication for development (C4D) tactics to track social barriers to vaccine acceptance and pilot communication approaches that effectively build trust in the programme and vaccines.
- Support coherence and clarity about the cVDPV2 response strategy among GPEI stakeholders and programme staff through internal communication tools.

**Targeted use of IPV to protect populations**

- Accelerate catch-up campaigns in countries with delayed introduction.
- Ensure targeted IPV use through Periodic Intensification of Routine Immunization activities (PIRIs).
- Limited IPV use in outbreak response targeting the most vulnerable populations. Priority will be given to newly accessible populations who haven't received essential immunization services.
- If monovalent OPV2 supply is exhausted, expand IPV use in cVDPV2 responses to mitigate paralytic risk.

AFP= acute flaccid paralysis; cVDPV2= circulating vaccine-derived poliovirus type 2; EUL= Emergency Use Listing; IPV= inactivated polio vaccine; OPV2= oral polio vaccine (serotype 2); RRT= Rapid Response Team; SIAs= supplementary immunization activities<sup>1</sup>. Enhanced outbreak response

<sup>7</sup> Global Polio Eradication Initiative. Global Polio Surveillance Action Plan, 2018–2020. Geneva: World Health Organization; 2018. (<http://polioeradication.org/wp-content/uploads/2016/07/GPEI-global-polio-surveillance-action-plan-2018-2020-EN-1.pdf>).

# 1. ENHANCED OUTBREAK RESPONSE

The response to a cVDPV2 outbreak is typically coordinated by the national EPI manager, with support from WHO and UNICEF EPI and polio managers, under the direction of the Minister of Health.

Early in the response, the GPEI deploys a coordinator and technical surge team to support the government in all major programmatic areas: surveillance, vaccination, operations, communication and vaccine management. Where possible, these activities are housed in an Emergency Operations Centre (EOC). To varying degrees, some of these structures are also established at the subnational level within provinces or districts, depending on the size of the country. The development and implementation of response activities are the responsibility of regional, provincial and district-based teams comprised of government officials, with GPEI surge support. Government capacity is strengthened throughout the response period, especially by the introduction and use of tools and processes to improve planning, budgeting, monitoring and evaluation of response activities.

Communities are fully engaged to improve response quality. This includes local leaders who advise during microplanning, civil society and religious organizations that are engaged to increase awareness and participation, and local vaccinators and community mobilizers who deliver vaccines on the frontlines.

This outbreak structure will be maintained with important enhancements to the response system described below – some of which have already commenced and will continue throughout the three stages of the strategy.

## A. IMPROVING THE QUALITY AND RAPIDITY OF VACCINATION ROUNDS

Stopping a cVDPV outbreak requires high-quality case response rounds that fully incorporate lessons learned by the polio eradication programme to make effective and efficient use of vaccine supplies and other resources.

The following enhancements will be included as revisions to the GPEI's standard operating procedures (SOPs) for responding to a polio event or outbreak:<sup>8</sup>

- Conduct a quick, high-quality case response round (R0) as prescribed in the outbreak SOPs (for example, conducting a vaccination campaign within 14 days and achieving >90% coverage), which should typically be focused on the immediate area of the detection where transmission is most likely to be occurring.
- Conduct at least two high-quality rounds (>90% coverage) to reach all areas where transmission may be possibly occurring.
- If breakthrough cases occur in an area which has received Sabin OPV2, target smaller areas where ongoing transmission is demonstrated or highly likely, rather than another wider round.
- Incorporate local factors, such as the presence of high-risk groups and known population movements, into all response plans.
- Strengthen surveillance in high-risk areas, especially those bordering the outbreak response zone.
- Support essential immunization and primary healthcare system strengthening in high-risk areas that border an outbreak response zone and utilize outbreak response zone and utilize outbreak response microplanning, communication and monitoring to address broader immunization system weaknesses in areas where cVDPV2s have been detected.<sup>9</sup>

## B. IMPROVING RESPONSE DELIVERY BY ADDRESSING OPERATIONAL AND PROGRAMMATIC RISKS

Insufficiently qualified or misaligned human resources present operational and programmatic risks to the quick and effective delivery of outbreak response activities. To mitigate these risks, the cVDPV2 strategy builds capacity in response teams, streamlines coordination and activates emergency protocols to fast-track processes and provide flexibility.

### 1. Enhance global outbreak preparedness and response capacity

The Outbreak Preparedness & Response Task Team (OPRTT) housed within the Eradication and Outbreak Management Group (EOMG) coordinates GPEI global outbreak preparedness and response. It operates virtually with members drawn from across the partnership.

<sup>8</sup> Global Polio Eradication Initiative. Standard operating procedures; Responding to a poliovirus event or outbreak, version 3. Geneva: World Health Organization; 2019. (<http://polioeradication.org/wp-content/uploads/2016/07/sop-polio-outbreak-response-version-20193101.pdf>). Currently under revision.

<sup>9</sup> The GPEI will incorporate successful GPEI-EPI-GAVI collaborative activities into future outbreak responses, as illustrated in the 2018. Papua New Guinea outbreak. See <http://polioeradication.org/news-post/going-the-distance-to-end-polio/>.

To enhance its ability to manage and respond to the increasing number of outbreaks, in the first half of 2020, the OPRTT will expand the capacity of the multi-agency team that is working face-to-face from WHO headquarters and expand the size of the virtual team. The team will be further empowered to coordinate outbreak response activities, including advising headquarters and regional offices on the scale and scope of response, response staffing, and the release and use of contingency outbreak funds. The OPRTT secretariat will be restructured to enhance its ability to manage these responsibilities and the increased work volume.

## 2. **Scale up rapid response teams**

WHO and UNICEF, together with other partners of the GPEI, have established a multidisciplinary Rapid Response Team (RRT) in Africa to initiate an effective response within 72 hours of a declared outbreak. The 22-member RRT is comprised of technical experts in epidemiology, surveillance, immunization, communication and social mobilization, vaccine management and programme operations. The purpose of the team is to streamline and strengthen coordinated partner support to national polio eradication initiatives (PEIs) to mount an effective response within the first six to eight weeks of an outbreak, in alignment with the outbreak SOPs.

Given the number of outbreaks occurring within the WHO African Region, the Africa RRT human resource capacity will be increased in Q1 2020.

Additionally, recognizing the increased risk of outbreaks outside of Africa, the GPEI will establish a global Rapid Response Team to support WHO and UNICEF country offices in all other regions. The global RRT will be comprised of technical officers with core capacities in outbreak planning and management, surveillance, vaccine management and communication, and will be deployed in response to outbreak requirements. The global RRT lead will report to the co-chairs of the OPRTT. The global RRT will be housed at WHO headquarters in Geneva but will include agency staff physically present in Geneva and contributing to the team remotely. Deployment will be managed in coordination with regional and country office consultation.

## 3. **Improve field coordination through a roster of outbreak coordinators**

To meet the needs of an expanding number of outbreaks and to enhance response coordination capacity, a roster of GPEI outbreak coordinators is being identified and trained to lead response efforts in the outbreak countries to which they are deployed. Coordinators will represent the GPEI in-country and liaise with partners at the country and regional levels, facilitate the implementation of the incident management system for responding to the public health emergency and provide reports to the GPEI about progress, challenges and potential solutions.

## 4. **Increase long-term outbreak field support**

The Surge Support Team is an interagency on-call roster for longer-term deployment that uses a central platform managed by WHO headquarters for ease of visibility and reporting. Within six weeks of outbreak confirmation, the Surge Support Team (previously designated as 'Team B' in GPEI outbreak response documents) should be in place to take over from the RRT staff who were deployed immediately after notification of the outbreak to develop the response plan and implement early response activities. The Surge Support Team should be deployed for a minimum of six months or until the outbreak closure. The composition of the team will be aligned with country needs and will include a GPEI outbreak coordinator to lead the effort, as well as experts as needed in surveillance, SIAs, communication for development (C4D), vaccine management, data management, operations and essential immunization systems. The Surge Support Team will be briefed in-country, including a refresher on the local poliovirus epidemiology, the status of polio eradication and the GPEI partnership, and will be provided with an overview of the core response strategy. They will support the national, district and local response teams. As with the outbreak coordinator roster, the Surge Support Team roster will be updated, expanded and maintained by the GPEI. Longer-term efforts to address essential immunization system recovery will be supported by immunization partners, such as Gavi and WHO.

## 5. **Increase GPEI agency technical presence on the ground in high-risk areas**

In addition to the Surge Support team, the CDC has implemented a staffing deployment surge initiative to address ongoing outbreak and readiness needs. Dozens of staff are in various stages of deployment across Africa to support national, provincial and district-level outbreak planning, implementation and management. The geographies and work priorities for these staff have been developed as an extension of ongoing GPEI efforts in the region and are fully integrated with GPEI response structures. Deployments include national- and district-level placements in several countries either with current outbreaks or areas that are at risk of cVDPV2 due to the widening outbreak in the African region. In-country, they support surveillance improvement, outbreak preparedness and essential immunization strengthening to improve EPI and IPV coverage by leveraging Gavi investments.

During the first half of 2020, other GPEI partners will endeavor to deploy an additional 100 technical experts, following the same terms of reference, training regime, reporting structure and coordination with the regional offices of WHO and UNICEF. Immunization system strengthening and intensification activities to reduce the longer-term risk of polio and other vaccine-preventable diseases (VPDs) are being planned for several countries with the highest risk for cVDPV2s through the efforts of several GPEI agencies. These will be further prioritized through this strategy.

#### 6. **Activate emergency response**

Outbreaks of cVDPV2 will be declared as a national public health emergency and submitted as a Grade 2 emergency, according to the WHE Emergency Response Framework.<sup>10</sup> This grading will provide additional flexibility for fast-tracking work processes and for speedy service delivery. Procedures for any kind of procurement services will be flagged as 'Emergency' and processed on a priority basis within 24 to 48 hours. RRT members and GPEI outbreak coordinators will be briefed on the use of emergency protocols. Various monitoring tools will be used to measure programme performance in activating its emergency response, such as the 'Preparedness Dashboard.' Where needed, the global team will deploy management and business service experts versed in emergency procedures to ensure that country offices are able to rapidly execute emergency capacities in the field.

#### 7. **Streamline processes of the advisory group on monovalent OPV2 provision**

The monovalent OPV2 Advisory Group (AG) was established by the GPEI after the 2016 Switch to advise the WHO Director-General on the release of all monovalent OPV2 globally. Within the GPEI, the primary responsibility for the operational management of outbreaks, including estimating the initial scope of the response and ensuring optimal use of available vaccines, rests with the WHO and UNICEF regional and country offices, supported by the OPRTT.

Rapid, early response is critical, particularly with fast-evolving type 2 epidemiology. Early outbreak planning at the country level can become misaligned (and has been in several instances) with the information needs of the monovalent OPV2 AG, or an outbreak scope can be presented beyond what the global supply or current Sabin OPV2 use patterns support. As such, in advance of a monovalent OPV2 AG call, the OPRTT will work closely with the regional offices and countries to ensure that locally planned responses reflect global priorities, align with current outbreak SOPs and include all elements required by monovalent OPV2 AG to complete a timely review. These changes will improve the quality of information available and make better use of the AG in the face of an increasing number of cVDPV2 outbreaks and limited vaccine supply. The AG terms of reference will be reviewed and revised with this new strategy, with the goal of simplifying procedures and defining mechanisms to improve the speed of the review process.

<sup>10</sup> WHO Health Emergencies. Emergency response framework – 2nd ed. Geneva: World Health Organization; 2017. (<https://www.who.int/hac/about/erf/en/>)

## 2. VACCINE SUPPLY AND USAGE

As the deployment of novel OPV2 is the primary dependency for this strategy, and as contingency planning prioritizes particular vaccine formulations to account for and mitigate potential future risks, vaccine supply is a critical area of work. It includes forecasting supply needs, securing manufacturers, monitoring global stockpiles and releasing vaccines to countries experiencing outbreaks.

The vaccine to respond to cVDPV2 outbreaks is provided through the global monovalent OPV2 stockpile established at the Sixty-eighth World Health Assembly in 2015, ahead of the 2016 Switch from the trivalent oral polio vaccine (tOPV) to the bivalent oral polio vaccine (bOPV). To ensure uninterrupted supply of Sabin OPV2, the GPEI also developed a five-year global monovalent OPV2 stockpile plan based on the analysis of the current trends and past patterns of poliovirus outbreaks. Supply information provided in this strategy is drawn from that plan.

Possible risks to supply during this response strategy's 18-month period include: a shortage of Sabin OPV2 either because of the amount needed for outbreak response or because of delays in novel OPV2 rollout; and delayed introduction and transition to novel OPV2, insufficient production or candidate failure.

Several risk mitigation measures are planned to ensure consistent vaccine supply, including: (1) concurrent production of Sabin OPV2 and novel OPV2; (2) when necessary, employing dose-sparing measures; (3) a Sabin OPV2 to novel OPV2 transition plan; (4) targeted use of IPV to increase population immunity, mitigate paralytic risk, and (where warranted) boost intestinal immunity following Sabin OPV2 administration; (5) coordination with EPI and Gavi, the Vaccine Alliance, to provide essential immunization intensification campaigns in high-risk areas that border outbreak areas as an efficiency measure; (6) tOPV use in type 2 outbreak response, depending on tOPV availability; and (7) a contingency plan that utilizes Sabin OPV2 in preventive SIAs and essential immunization in the event of novel OPV2 failure.

This cVDPV2 response strategy provides contingencies in each stage to prepare for that worst-case scenario, while focusing on efforts to avert it. **Figure 3** provides an overview of both the conditions under which the GPEI advances into each stage of the strategy and risk mitigation steps that will be introduced in the event that novel OPV2 is delayed or vaccine supplies reach critically low levels.

### A. VACCINES IN STAGE 1

#### 1) SABIN OPV2

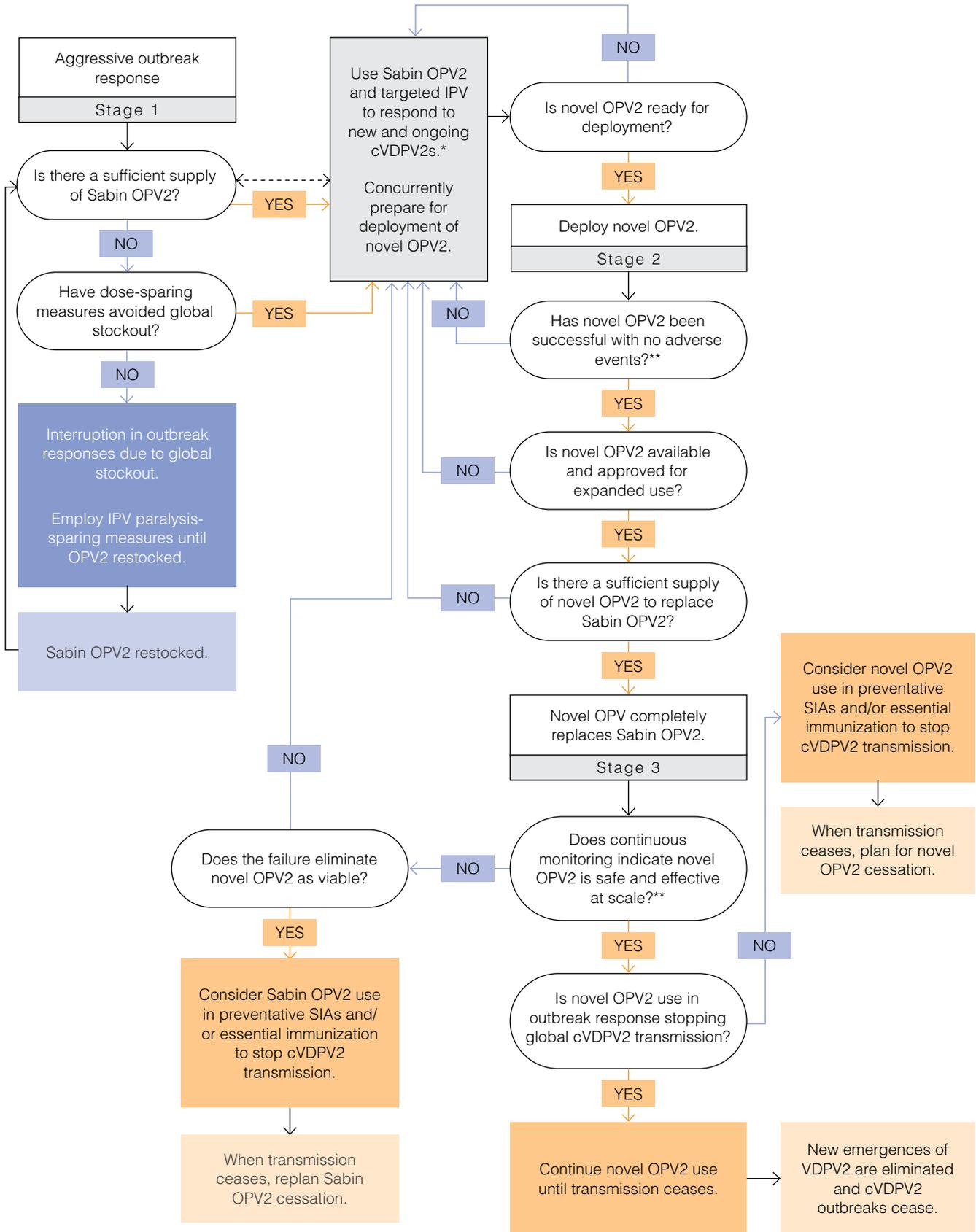
To ensure an adequate supply of Sabin OPV2 in the face of unpredictable cVDPV2 epidemiology, the GPEI recently approved planning for a substantial expansion of the global stockpile that requires replenishment of over 5 billion doses of monovalent OPV2. In order to secure this supply, the GPEI must, in Q1 2020, make investments for the 2020 fill/finish supply and identify and contractually engage an additional Sabin OPV2 bulk supplier and a fill/finisher.

#### *Managing a limited Sabin OPV2 supply*

In Stage 1, the primary risk is a shortage of Sabin OPV2 that could impede continued vaccination in ongoing or new outbreak responses.

To address this risk, the programme has developed a prioritization scheme for managing the limited supply (see **Table 3**). The programme has also proposed dose-sparing measures that include, as a final contingency measure if supply is critically low, a temporary 'one drop' Sabin OPV2 vaccination response strategy.

**Figure 3. GPEI cVDPV2 response strategy**



\* Sabin OPV2 will be administered either as a monovalent or trivalent formulation, depending upon epidemiologic/local factors and vaccine availability.

\*\*In the event of novel OPV2 candidate 1 failure, novel OPV2 candidate 2 production and use will be assessed. If candidate 2 production and use is deemed appropriate, this cycle reverts to Stage 1 Sabin OPV use and preparation for candidate 2 rollout.

**Table 3. Sabin OPV2 prioritization scheme\***

<b>1. cVDPV2 in areas where OPV2 has not been used recently (&gt; 1 year)</b>
<ul style="list-style-type: none"> <li>a. Expansion of a well-established outbreak to a new population.</li> <li>b. A new outbreak (e.g. Kasai-Angola, Mozambique, Bauchi).</li> <li>c. If vaccine supply is critically low, consider revising the age group down in age.</li> </ul>
<b>2. High-risk areas near an ongoing outbreak</b>
(e.g. parts of the Democratic Republic of the Congo, Nigeria, Ethiopia, Benin).
<b>3. cVDPV2 in areas where Sabin OPV2 has been used recently (&lt; 1 year)</b>
<ul style="list-style-type: none"> <li>a. Continuation of an ongoing outbreak (e.g. Yobe, Niger, Borno).</li> <li>b. If vaccine supply is critically low, consider adjusting the age group down in age.</li> </ul>
<b>4. VDPV2</b>
New emergence with unconfirmed circulation (e.g. Somalia 2017, China, Rawalpindi, etc). Rapid risk assessment mandatory.

\* The monovalent OPV2 AG should not allow supply to go below 5m doses by responding to (2), (3), or (4), and the monovalent OPV2 AG shall actively scrutinize requested scope to assure best use of limited vaccine.

Another critical contingency plan for a potentially limited Sabin OPV2 supply is employing dose-sparing measures that account for the global stockpile by regulating the scope of a vaccination campaign.

- a. Restricted age group campaigns  
Age-restricted rounds may be considered, particularly in instances where primary response rounds (Rounds 1 and 2) have already been conducted and included children <5 years old. The age range to be included should be defined based on local context, ensuring the most vulnerable groups are prioritized for vaccination.
- b. Restricted campaign scope  
If necessary, in conjunction with a restricted age group, the scope of the target population and area can be prioritized based on risk assessments and the local context, including the number of Sabin OPV2 rounds in last six to 12 months, breakthrough transmission or new emergence (or other high-risk areas based on large population movements).
- c. In the event that other options are not adequate to maintain Sabin OPV2 supply, a one-drop vaccination strategy has been developed and will be presented to regions, countries and other technical bodies for consideration for adoption as a last resort dose-sparing measure.<sup>11</sup> The rationale for one-drop vaccination is provided in **Annex C**.

The mechanism by which dose-sparing measures should be implemented require setting a minimum threshold that will trigger an alert regarding the global stockpile, defining the process by which advisory bodies decide on dose-sparing measures, and outlining the conditions under which they will be applied.

1. The GPEI will institute ongoing intensive monitoring of Sabin OPV2 supply, tracking projected supply versus projected demand.
2. These data will be made available to the OPRTT, EOMG and AG on a weekly basis.
3. When projected demand at any time in the future is projected to exceed projected supply minimum threshold (20M doses), the EOMG and AG will be alerted.
4. The EOMG will review the data and consider age restrictions and further reductions in campaign scope.
5. At 10 million doses, the EOMG will review the data and assess the need to enact one-drop vaccination. If deemed necessary, the EOMG will recommend to the GPEI Strategy Committee that a supply emergency alert will be made
6. If the SC endorses the recommendation, the EOMG will set a date from which all new outbreaks will be subject to one-drop vaccination.
7. The WHO Director-General and regional directors in WHO and UNICEF regions in which campaigns are being conducted will be informed of the initial alert and the planned start date for a shift to one-drop dose.
8. Existing campaigns (i.e., vaccine supply released from the stockpile before the alert) will continue as before.
9. To avoid equity issues and minimize confusion, the dose-sparing measure would commence and terminate universally at the same time. In other words, whether a new outbreak was large or small, or in whichever region, it would apply equally.

<sup>11</sup> A one-drop dose sparing strategy is only an option to conserve Sabin OPV2 supply; the one-drop strategy is not being considered to conserve novel OPV2 supply.

These dose-sparing measures would not impact production planning, as maximizing Sabin OPV2 and novel OPV2 production will remain the strategy's core goal.

## 2) INACTIVATED POLIO VACCINE

Although IPV use cannot stop cVDPV2 transmission, it can provide individuals with a high level of immunity and mitigate paralytic risk. There are complementary approaches for providing IPV to high-risk populations, which include catch-up campaigns, periodic intensifications of routine immunization (PIRIs), and fractional dose IPV (fIPV) vaccination in outbreak zones and as a contingency measure if OPV2 supplies are exhausted.

### Accelerated catch-up campaigns

At the time of the 2016 Switch, some countries assessed at lower polio risk delayed IPV introduction into their EPI schedules due to a limitation on the global IPV supply. IPV catch-up vaccination was planned to ensure these countries received the IPV vaccination coverage prescribed by the 2013–2018 Polio Eradication & Endgame Strategy (PEESP).<sup>12</sup>

These campaigns have not always been implemented on schedule, due to competing country priorities or continued limitations on global IPV supply. Catch-up vaccination has been prioritized according to cVDPV2 risk and will be carried out at the earliest dates, with an emphasis on achieving high coverage in areas bordering a cVDPV2 outbreak. Gavi, the Vaccine Alliance, has provided resources for catch-up campaigns, including the operational costs to support implementation of IPV SIAs in countries with a designated need. See **Annex D** for more information on IPV catch-up campaigns. Additionally, in their recommendations for the post-eradication workflow, the Strategic Advisory Group of Experts on Immunization (SAGE) has advised that all countries should introduce at least one dose of IPV in their immunization programmes to mitigate the risks and consequences associated with the eventual post-certification withdrawal of OPV2.<sup>13</sup>

### Periodic Intensification of Routine Immunization activities

The programme also works with national immunization programmes that leverage Gavi support to deliver high-quality targeted IPV campaigns through Periodic Intensifications of Routine Immunization (PIRIs). This uses country immunization stocks to boost IPV coverage in populations with elevated risk. Importantly, if expanded ages are considered for these activities, assessments will be completed in advance to ensure the activity does not inadvertently negatively impact the supply or that additional vaccine supply is provided. Collaboration across organizations with common immunization goals will help to deliver IPV and other essential antigens to high-risk populations, thus potentially having an added effect of mitigating risk for other vaccine-preventable diseases (VPDs). In order to ensure impact, PIRIs will need to be of high quality and reach a high proportion of at-risk children. As such, careful assessment of need and local capacity will factor heavily into the decision to use this targeted strategy.

### Fractional dose IPV

IPV can prevent paralytic risk and, additionally, may boost mucosal immunity in persons previously vaccinated with OPV2. However, due to its limited utility in stopping cVDPV2 transmission, its high cost and supply concerns, IPV use for outbreak response will be restricted to very specific settings.<sup>14</sup> It will be prioritized as follows:

- In areas with cVDPV2 transmission, IPV may be used as a part of immediate response actions, with scope and age group to be determined based on local circumstances and availability.
- In areas not infected but at high risk of VDPV2 transmission, IPV may be used to build population immunity against type 2 poliovirus.

### Expanded use in cVDPV2 response

As a contingency measure in the event OPV2 supplies are exhausted, expanded use of IPV in cVDPV2 responses can mitigate paralytic risk. In outbreak response, IPV use will be limited and targeted to the most vulnerable populations, such as newly accessible populations who have not had access to essential immunization services.

It is important to note that the highest-priority use of IPV will be through essential immunization systems. It is also anticipated that currently planned 2020 IPV stock will have approximately 6 million residual doses after fully providing for country immunization system needs. Therefore, the scope of interventions described here, when not already provided for through the essential immunization programmes, may be limited by the available stock.

<sup>12</sup> Global Polio Eradication Initiative. Polio Eradication & Endgame Strategic Plan 2013–2018. Geneva: WHO; 2013 ([http://polioeradication.org/wp-content/uploads/2016/07/PEESP\\_EN\\_A4.pdf](http://polioeradication.org/wp-content/uploads/2016/07/PEESP_EN_A4.pdf)).

<sup>13</sup> [http://www10.who.int/immunization/sage/meetings/2017/october/presentations\\_background\\_docs/en/](http://www10.who.int/immunization/sage/meetings/2017/october/presentations_background_docs/en/)

<sup>14</sup> Full-dose IPV will only be considered if country regulation does not allow use of intradermal IPV.

### 3) NOVEL OPV2

Due to the increasing risk of seeding more emergences of VDPV2 from the use of Sabin OPV2, as well as supply shortages of Sabin OPV2 affecting outbreak response, the GPEI has accelerated the development and emergency availability of novel OPV2.

The Novel OPV2 Working Group was recently created to manage and coordinate GPEI activities to enable a rapid and effective novel OPV2 rollout. The Working Group's responsibilities include developing overarching workplans and budgetary requirements for the following areas of work:

- **Research:** Support new clinical trials and pilot field projects through provision of technical guidance, ensuring field operational needs are met; coordinate operations monitoring/studies of initial field use of novel OPV2; and disseminate results and reports across stakeholders.
- **Regulatory:** Support fast-track submission under WHO's Emergency Use Listing Procedure (EUL) and eventual full licensure, along with WHO prequalification.
- **Supply:** Ensure the availability of novel OPV2 in sufficient quantities and establish risk mitigation strategies.
- **Implementation readiness:** Plan for the deployment of novel OPV2, including providing technical guidance for decision making and training, regulatory approvals, and continued surveillance and monitoring following use; coordinate laboratory and diagnostics work to enable strain identification.
- **Communication:** Ensure stakeholders and countries have timely and accurate information about novel OPV2 to support its use, including assessing feasibility of conducting behavioural and anthropological research, developing crisis communications strategies, and promoting proactive information dissemination.
- **Policy:** Work with the Strategic Advisory Group of Experts (SAGE) and its polio working group to develop prioritization guidance for the initial use of novel OPV2, including priority countries and strategies, as well as provide guidance on candidate selection and manufacturing decisions for novel OPV2 as needed.

In addition to the Novel OPV2 Working Group's efforts, regional offices will work with their respective Member States or National Regulatory Authorities (NRAs) to facilitate acceptance of novel OPV2.

### 4) tOPV USE

While the use of bivalent OPV (bOPV, which protects against types 1 and 3) in essential immunization systems and SIAs have made the relative risk of cVDPV1 and cVDPV3 emergence less than cVDPV2, populations experiencing cVDPV2 outbreaks are at an elevated risk for cVDPV1, cVDPV3 or WPV1. In some countries the length and large scale of Sabin OPV2 responses have displaced planned bOPV SIAs (Nigeria, the Democratic Republic of the Congo [DRC]) or have had concurrent ongoing WPV1 circulation (Pakistan) or concurrent cVDPV1 or 3 (DRC, Somalia) that complicate response planning due to alternating bOPV and Sabin OPV2 delivery. Furthermore, the cost of delivery of the cVDPV2 responses is considerable (over \$110M in 2019) and reaches some populations with very elevated polio risk.

For these reasons, trivalent OPV (tOPV, which protects against all three types) should be manufactured and used in place of Sabin OPV2 for cVDPV2 response at the earliest availability (anticipated in Q2/Q3 2020). Because the type 2 component of tOPV has high efficacy, the use of tOPV will not negatively impact type 2 outbreak responses and instead will have the added value of providing critical type 1 and 3 protection to the most vulnerable populations, with only a modest price difference for the vaccine. The opportunity to provide a boost in type 1 and 3 immunity by using tOPV in place of Sabin OPV2 is an investment in the future, as it will reduce cVDPV1 and cVDPV3 risk in very vulnerable populations and potentially avert future outbreaks.<sup>15</sup> tOPV will be subject to the same usage controls that are currently followed for monovalent Sabin OPV2 use.

Because the GPEI, at the time of the Switch, indicated that tOPV would not be used after that time, there are necessary actions required prior to its 2020 use. These include: (1) working with vaccine manufacturers to renew licenses and replace Sabin OPV2 production with tOPV production; (2) consulting Member States on tOPV use; and (3) engaging countries, relevant regulatory bodies and the Executive Board of the World Health Assembly to prepare for tOPV use. tOPV could be available as early as mid-2020 and will be used as a substitute for monovalent OPV2 for cVDPV2 response.

<sup>15</sup> Countries that do not use bOPV in essential immunization systems or through SIAs may prefer using Sabin OPV2 to respond to cVDPV2 outbreaks to negate possible seeding of VDPV1/3.

## VACCINE STOCKPILE RISKS DURING STAGE 1

**Risk:** Insufficient budget available for the stockpile.

### Mitigation activities

- Identify funding for the stockpile.
- Ensure mainstreaming of the stockpile budget into the GPEI Financial Resource Requirements (FRR) without further constraining programmatic budgets.
- Carry out regular six-month reviews of the stockpile plan and budget to identify efficiencies that can be realized.

**Risk:** Sabin OPV2 use will need to be extended if novel OPV2 availability is delayed.

### Mitigation activities

- Support timely novel OPV2 deployment through strong planning and a clear legal framework.
- Facilitate the development of a roadmap for Emergency Use Listing of novel OPV2 by the WHO pre-qualification team.
- Prepare for mainstreaming novel OPV2 through the development of guidelines and training, for example, and through the integration of monitoring for pharmacovigilance and other EUL requirements into outbreak response operations.
- Prepare communications for both external and internal audiences involved in novel OPV2 rollout.
- Prepare for tOPV use in place of Sabin OPV2 in outbreak response (see above).

## B. VACCINES IN STAGE 2: NOVEL OPV2 ROLLOUT

The accelerated development and rollout of novel OPV2 in Stage 2 will lead to replacing Sabin OPV2 in the stockpile with novel OPV2, if it appears to be effective in controlling outbreaks during large-scale deployment. As shown in **Figure 2** (in Strategy rationale), novel OPV2 and Sabin OPV2 production are scheduled to be manufactured concurrently to assure that if novel OPV2 fails, Sabin OPV2 will be available. Because novel OPV2 production is not subject to containment, there is the potential to diversify the supplier base.

Until supplies are adequate to wholly replace Sabin OPV2, novel OPV2 use will need to be prioritized. The Novel OPV2 Working Group will develop prioritization strategies, in consultation with EUL regulators.

There are currently two candidates for novel OPV2, with candidate 1 selected as the first to be manufactured at risk. To account for the potential delay or failure of one or both of the novel OPV2 candidates, the GPEI has factored in scale-up of Sabin OPV2 production as a contingency measure. Operating within a delay scenario, Sabin OPV2 would likely need to be used in large geographies for a prolonged period of time. In a worst-case scenario of failure, Sabin OPV2 (in a monovalent or trivalent formulation) would be needed indefinitely while the GPEI determines a path to cessation.

## VACCINE STOCKPILE RISKS DURING STAGE 2

During the intermediate period of the strategy, vaccine risks shift toward those concerning use of novel OPV2.

**Risk:** Failure of novel OPV2 candidate 1. Failure may include lack of efficacy, unexpected adverse events including tendency to transmission and reversion to neurovirulence, or production failures.

### Mitigation activities

Review data on whether candidate 2 would likely suffer from the same risk of failure. A partial failure of candidate 1, such as post-use recombination risk in a specific setting, may suggest candidate 2 is still viable. If so, put in motion plans for accelerating candidate 2 deployment.

- Prepare for Emergency Use Listing alongside other activities (manufacturer agreements, production, pilot studies and data generation).
- Adjust the global stockpile plan and budget to account for a potential 18-month delay of the novel OPV2 (candidate 2) rollout.
- Outbreak response operations (and SOPs/guidance and training) will need to be adjusted to account for withdrawal of candidate 1 and reliance on Sabin OPV2/tOPV for a period until candidate 2 is ready.

**Risk:** BioFarma halts production to meet other demands

#### Mitigation activities

- Shift filling or production of novel OPV2 bulk to alternative supplier.
- Carry out EUL of the novel OPV2 filled (this will need to be initiated immediately).

**Risk:** Stockpile budget shortage

#### Mitigation activities

- Identify additional funding for the stockpile.

**Risk:** Sabin OPV2 Stockpile Shortage

#### Mitigation activities

- Increase filling capacity and consider expanded IPV use where it will mitigate paralytic risk while Sabin OPV2 stockpile is resupplied.

### C. VACCINES IN STAGE 3: 2021 AND BEYOND

During the final stage of the strategy, novel OPV2 will replace Sabin OPV2 within the stockpile. Large-scale novel OPV2 use will become the primary tool to stop cVDPV2s.

#### VACCINE STOCKPILE RISKS DURING STAGE 3

**Risk:** Failure of novel OPV2. The main risk in the final stage is that the strategy has a delayed start or cannot commence because novel OPV2 fails either through lack of immunogenicity or production failures.

#### Mitigation activities

If novel OPV2 fails to control outbreaks or is found to transmit more readily and revert to neurovirulence, then the underlying aim of this strategy will not be achieved and implementation of widespread preventive SIAs or restart of OPV2 will need to be considered. If Stage 3 risks actualize, a protracted use of Sabin OPV2 is likely and strategies to define that use and refocus cVDPV2 response will be developed as a contingency measure in 2020.

If enacted, this contingency measure will require close programme review of cVDPV2 epidemiology to determine whether all existing evidence indicates widespread transmission that cannot be controlled through outbreak response rounds. With no viable novel OPV2, this would trigger consideration of Sabin OPV2 use in large-scale preventive campaigns and potentially Sabin OPV2 restart in essential immunization programmes (see **Figure 3**, cVDPV2 response strategy flow chart). This last-resort measure is reserved for a worst-case scenario. It represents a reversal of the 2016 Switch that replaced tOPV with bOPV – and it will thus require careful assessment of all associated risks, as well as comprehensive planning with Member States and vaccine manufacturers.

Additional risks include:

**Risk:** Failure to secure adequate novel OPV2 supply. This failure would create a delay or lack of entry into Stage 3 of the strategy.

#### Mitigation activities

- Adjust outbreak response operations to account for a reliance on Sabin OPV2 or tOPV.
- Implement other contingencies that likely include broad, longer term Sabin OPV2 use.

**Risk:** BioFarma halts production to meet other national vaccine demands

#### Mitigation activities

- Shift filling and / or production of novel OPV2 bulk to alternative supplier.
- Carry out EUL of the novel OPV2 filled (this will need to be initiated immediately).

**Risk:** Stockpile budget shortage

#### Mitigation activities

- Identify funding for the stockpile and ensure mainstreaming of the stockpile budget into GPEI FRR.

**Risk:** Sabin OPV2 stockpile shortage

#### Mitigation activities

- Employ IPV strategically to mitigate paralytic risk while rebuilding the Sabin OPV2 stockpile.

# 3. EARLY DETECTION OF NEW OUTBREAKS

High-quality poliovirus surveillance is not only critical to achieving early detection of events and outbreaks; it is also essential to assessing the geographic scope of circulation and determining the scope or scale of response. Surveillance activities to help control cVDPV2 outbreaks are informed by an understanding of VDPV2s, starting with their case-to-infection ratio. Compared to WPV1 which has a paralytic rate of one case for every 200 infections (1:200), VDPV2 has an infection rate of one case for 2,000 infections (1:2000). This 90% lower infection rate requires a highly sensitive surveillance system to both detect ongoing cVDPV2 transmission in a timely manner and enable a rapid, appropriately sized response.

## A. DETERMINING PRIORITY AREAS

Surveillance resources should be prioritized to those areas that border (1) areas of known circulation and Sabin OPV2 use, (2) areas with chronically underperforming immunization systems, or (3) areas at high risk due to large population movements. Early detection in these bordering areas provides an opportunity for more rapid response and can therefore limit spread.

In the first few years following the Switch in 2016, the risk of emergence of a type 2 event was associated with low essential immunization coverage in areas that were also not well covered by tOPV supplementary immunization prior to the Switch. In 2019, however, the risk of emergence of a type 2 event has been associated with variable quality outbreak response SIAs in response zones – and also geographic spread to areas without ongoing responses but in proximity to response zones. Given population movements, the geographic spread of cVDPV2s is now a broad risk because birth cohorts of children >3 years old have no intestinal immunity to type 2 poliovirus, and therefore countries bordering outbreak zones are at high risk for new emergence or spread of the outbreak.

Other priority areas for potential type 2 outbreaks include:

- areas which have historically detected a high incidence of primary immunodeficiency disorders (PID) and have used tOPV;
- conflict-affected areas and areas with other destabilizing challenges; and
- countries and regions that have been polio-free with declining surveillance quality.

## B. INCREASING SURVEILLANCE SENSITIVITY

The GPEI has already started to expand investments in surveillance strengthening through the implementation of the Global Polio Surveillance Action Plan, 2018–2020.<sup>16</sup> In addition, specific surveillance actions and activities over the next 12 months for areas at high risk for cVDPV2 outbreaks are described in **Annex E**. It is important to note that regions and countries at risk for cVDPV2s which are currently developing integrated VPD surveillance systems, in alignment with the goals of the 2019–2023 Polio Endgame Strategy, must also ensure that the sensitivity of poliovirus detection is sustained.<sup>17</sup>

### 1) IMPROVE ACUTE FLACCID PARALYSIS SURVEILLANCE QUALITY

The GPEI will aim to improve acute flaccid paralysis (AFP) surveillance quality for cVDPV2s in the highest-risk countries through targeted investments in training and capacity building, improvements in active and passive surveillance, and the ongoing introduction of innovative approaches such as community informant networks and the engagement of nongovernmental organizations (NGOs) and civil society organizations (CSOs).

AFP surveillance support will include:

- desk reviews in all high-risk countries by February 2020;
- field surveillance reviews in the highest-risk countries by June 2020; and
- field support and capacity building in the highest-risk countries.

<sup>16</sup> Global Polio Eradication Initiative. Global Polio Surveillance Action Plan, 2018–2020. Geneva: World Health Organization; 2019. (<http://polioeradication.org/wp-content/uploads/2016/07/GPEI-global-polio-surveillance-action-plan-2018-2020-EN-1.pdf>)

<sup>17</sup> Global Polio Eradication Initiative. Polio Endgame Strategy 2019–2023: Eradication, integration, certification and containment. Geneva: World Health Organization; 2019. (<http://polioeradication.org/wp-content/uploads/2019/06/english-polio-endgame-strategy.pdf>).

## 2) EXPAND ENVIRONMENTAL SURVEILLANCE

Building on the Polio Environmental Surveillance Expansion Plan, the GPEI will enhance the quality of the existing environmental surveillance (ES) network and strategically expand the network to new geographies, where quality ES is feasible.<sup>18</sup>

ES support will include:

- desk quality review of all highest-risk countries by April 2020;
- field reviews in many high-risk countries;
- prioritized expansion in at least six high-risk countries by April 2020, focusing on major population centres, trade routes and other key risk indicators;
- documentation of laboratory capacity and contingency plans for workload increases; and
- the identification of resource needs for the ES expansion plan.

## 3) IMPROVE SUPPORT, COORDINATION AND OVERSIGHT IN HIGH-RISK COUNTRIES

Additional support to high-risk countries and regions will be provided by aligning policy and strategic objectives to enhance coordination and improve management, oversight and accountability.

## C. EXPANDING LABORATORY DIAGNOSTIC CAPACITIES

Rapid and accurate diagnosis of specimens is a critical parameter for outbreak response and control. The Global Polio Laboratory Network (GPLN) was established in 1990 to equip specialized laboratories with new tools and approaches in this area of work. A critical first step was to increase the molecular diagnostic capacity in GPLN laboratories, with a focus on those serving high-risk and priority countries. The number of laboratories trained and equipped to provide intratypic differentiation (ITD) of poliovirus has increased from 44 in 2009 to 131 in 2019. This expansion of the GPLN reduced the maximum laboratory turnaround time from 56 days to 28 days.

Of the 16 countries that have detected cVDPV2 since the Switch, 12 have a viral isolation and ITD polio laboratory within the country, and the remaining four have direct access within their region to a laboratory with well-established stool specimen referral systems.

Activities to expand the diagnostic capacities of the GPLN for the next 12 to 18 months of the current strategy are outlined in **Table 4**. Key among diagnostic innovations will be direct detection (DD) methods for testing stool samples, which may reduce laboratory turnaround time from 28 days to four to seven days.

**Table 4. Laboratory surveillance priorities**

Priority	Activities
<b>Detection</b>	Fast-track pilot testing and parallel testing of direct detection (DD) of poliovirus from stool specimens, to be used instead of current cell culture-based poliovirus detection, by Q3 2020. Its implementation may reduce laboratory turnaround time from 28 days to four to seven days.
	Begin introduction of DD by end of 2020, with priority given to laboratories serving cVDPV2 outbreak and high-risk countries.
	Identify resources to implement DD testing, as this will not be possible with the current laboratory resources
<b>Outbreak control using novel OPV2</b>	Standard ITD testing will detect novel OPV2 candidate strains, and specific assays developed by the CDC can differentiate the two novel OPV2 candidates. A new nomenclature and reporting scheme will be established to further distinguish poliovirus type 2.
	Standard GPLN sequencing protocol can be used for definitive identification of novel OPV2 candidate strains, in addition to current poliovirus type 2 strains.

CDC= U.S. Centers for Disease Control and Prevention; cVDPV2= circulating vaccine-derived poliovirus type 2; DD= direct detection; GPLN= Global Polio Laboratory Network; ITD= intratypic differentiation; OPV2= oral polio vaccine type 2

<sup>18</sup> Global Polio Eradication Initiative. Polio Environmental Surveillance Expansion Plan: Global expansion plan under the Endgame Strategy, 2013-2018. Geneva: World Health Organization; 2015. ([http://polioeradication.org/wp-content/uploads/2016/07/9\\_6\\_131MB.pdf](http://polioeradication.org/wp-content/uploads/2016/07/9_6_131MB.pdf)).

# 4. COMMUNICATION AND PROMOTION OF THE STRATEGY

Successful strategy implementation requires targeted communication to implementers, partners and the public at the global, regional, country and subnational levels.

A detailed communication workplanning process has begun and is expected to be finalized in early February 2020. The process is focused on: (1) clearly identifying target audiences across all levels (e.g. influencers, policy makers, political leaders, donors, Rotarians, civil administrative leaders at the district level, community leaders, media, partners, regulatory authorities, and vaccine manufacturers); and (2) developing key messages and core communication products aimed at individually identified audiences.

Communication implementation will proactively garner support for the new cVDPV2 response strategy by focusing on external relations, internal relations, advocacy and all stakeholder and community engagement, alongside developing the necessary communication and advocacy tools to minimize any potential risks that may adversely impact the programme's ability to fully implement the strategy (for example, community concerns as to the safety of a new vaccine).

To coordinate among GPEI communication teams – including the recent official addition of Gavi, the Vaccine Alliance, as a core GPEI partner – a time-limited working group has been formed to design and implement the various communication components of this strategy. The Strategic Communication Working Group consists of experts in external communication, advocacy and donor relations, communication for development (C4D), technical fields, internal communication and training. In developing the workplan, the group is actively engaging with regions, countries and external experts, such as public health communication specialists who were engaged in rolling out the Ebola and malaria vaccines and who coordinated the global rollout of IPV in 2015.

The overall aim is to ensure that all resources at the global level are available to both strengthen stakeholder confidence in the GPEI's ability to address the cVDPV2 emergency and equip regions, countries and key partners (including governments) with tools to engage all sectors of civil society, local communities and the general public in this process.

## A. KEY COMMUNICATION RISKS

- Continued circulation and spread of VDPV2s and lack of a well-articulated global narrative explaining the current situation may result in waning confidence in the GPEI.
- The introduction of dose-sparing measures may affect programme decision-making and adversely impact field-level delivery of vaccines, as well as alter public perceptions of dose efficacy or vaccine safety.
- The introduction of a new vaccine under Emergency Use Listing (EUL) may trigger doubts about vaccine safety, bioethical considerations of use and, in the event of adverse effects, cause fallout in vaccine confidence.
- The success of novel OPV2 may negatively impact demand for Sabin OPV2 before novel OPV2 can fully meet outbreak dose requirements.
- Internally driven skepticism, lack of stakeholder buy-in and ambiguity may lead to consistency challenges in strategy rollout, affecting public perception and credibility of the GPEI.

## B. EXTERNAL COMMUNICATION AND ADVOCACY

Building support for the strategy will require strategic engagement with key audiences.

### *Key stakeholders and target groups*

- WHO governing bodies: The proposed strategy links with resolution WHA 71.16 and WHA 68.3 and should be presented and discussed at Regional Committee Meetings, Executive Board Meetings and the World Health Assembly.<sup>19,20</sup>
- Outbreak affected and high-risk countries: National Regulatory Authorities (NRAs), Ministries of Health and EPI programme managers and polio teams.
- GPEI oversight mechanism and advisory groups: Independent Monitoring Board, Monovalent OPV2 Advisory Group, Containment Advisory Group, Polio Research Committee.

<sup>19</sup> World Health Assembly. Poliomyelitis – containment of polioviruses. WHA71.16. 26 May 2018. ([http://apps.who.int/gb/ebwha/pdf\\_files/WHA71/A71\\_R16-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf)).

<sup>20</sup> World Health Assembly. Poliomyelitis. WHA68.3. 26 May 2015. ([http://apps.who.int/gb/ebwha/pdf\\_files/WHA68/A68\\_R3-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R3-en.pdf)).

- Vaccine producing countries: Manufacturers (public and private), NRAs, National Authorities on Containment.
- GPEI partners.
- GPEI donors.
- NGO and CSO advocacy partners and broader immunization community partners.
- WHO advisory bodies: including the Polio IHR Committee, SAGE, Global and Regional Certification Commissions and Technical Advisory Groups.

#### *External communication engagement tactics*

- Engage global public health governing bodies by presenting to the 2020 Executive Board and World Health Assembly, including direct engagement with Member States (planned for January 2020).
- Directly communicate with government public health authorities and provide countries guidance on messaging and creative approaches to help rollout novel OPV2 and/or dose-sparing measures.
- Communicate regularly with donors to bring them along in the process, convey potential funding implications and request their advocacy with countries.
- Design an updated global narrative on cVDPV.
- Build support amongst the scientific community by engaging public health experts through SAGE, GPEI, Gavi, WHO and CDC platforms.
- Conduct briefings with public health and science journalists and gatekeepers in mainstream international media.
- Develop reactive crisis communication response protocols to manage communication issues associated with real or perceived vaccine-related events for either Sabin or novel OPV2.
- Create a core set of communication materials on the strategy, cVDPV2 and novel OPV2, including fact sheets and Q&A documents.

## **C. COMMUNICATION FOR DEVELOPMENT**

The Strategic Communication Working Group and its partners will continue the communication for development (C4D) goal to (1) create an enabling environment for sustained polio vaccines uptake and broader immunization as a social norm; (2) resolve vaccine doubts; (3) address social barriers and misperceptions and; (4) equip frontline workers and health teams with critical information, knowledge and skills for a successful implementation of the strategy.

C4D target groups for engagement include:

- national health authorities, scientists, experts and laboratory personnel;
- health practitioners and community health physicians;
- private health practitioners and clinics;
- frontline workers and vaccinators;
- health reporters and journalists;
- online influencers, bloggers/vloggers and opinion leaders on health;
- parent groups in digital spaces and social media; and
- parents and caregivers.

#### *Engagement tactics*

- Synthesize the existing concerns and social barriers with regard to Sabin OPV2 use in countries; for novel OPV2, draw from experience of IPV and Ebola vaccine introductions.
- Conduct rapid communication research among target audiences about their perceptions concerning novel OPV2 and dose-sparing strategies.
- Prototype and pilot communication approaches and products on the ground.
- Sensitize national health authorities and expert health community and roll out orientation to community-level health practitioners.
- Develop training modules and materials; train frontline workers and vaccinators to administer new vaccine or new delivery protocols (e.g. co-administration); build capacity to respond to parental inquiries.
- Perform one-on-one and small group engagement in digital spaces with health influencers.
- Engage in preparedness and response to the vaccine-related events at community level through early warning, listening and pre-engagement of health influencers and practitioners.

- Closely track public acceptance of novel OPV2; evaluate and document experience for replication in other contexts.

#### **D. INTERNAL COMMUNICATION TACTICS**

Internal communication efforts aim to ensure strategic coherence, synergy and clarity among GPEI stakeholders and programme implementers, to support a successful strategy rollout.

##### *Internal communications tactics*

- Ensure all programme participants can easily access the strategy and relevant communications resources.
- Develop and roll out GPEI webinar on the essentials of the new strategy.
- Provide country- and regional-level technical assistance and support prior to rollout, including technical orientations.
- Develop and provide regional and country offices with strategy-relevant communication resources.
- Develop and roll out strategy implementation feedback/resolution mechanisms.

# ANNEX A: OVERSIGHT AND MONITORING OF THE cVDPV2 STRATEGY

This strategy will be considered an addendum to the GPEI Polio Endgame Strategy 2019–2023, which lays out the roadmap to achieving and sustaining a world free of all polioviruses.<sup>21</sup> The Endgame Strategy focuses on three key pillars: eradication, integration, and containment and certification, as well as critical enabling factors such as gender, polio research and development, and preparing for Post-Certification Strategy (PCS) implementation.<sup>22</sup>

Implementation of this addendum will be integrated and financed as part of the Polio Endgame Strategy 2019–2023. Additionally, implementation of this cVDPV2 response strategy will be in the context of the GPEI Gender Equality Strategy, 2019–2023, which was endorsed on 11 May 2019 by the GPEI Polio Oversight Board to promote the integration of a gender perspective into different aspects of the GPEI's programming, to support countries in addressing gender-related barriers to polio vaccination to increase coverage and to increase women's meaningful participation in the polio eradication programme.<sup>23</sup>

The GPEI Strategy Committee has ultimate responsibility to monitor the effectiveness of the strategy and ensure it is appropriately funded, with the technical and management advisement of the Eradication and Outbreak Management Group (EOMG). The Strategy Committee, EOMG, and UNICEF and WHO regional offices will routinely review the cVDPV2 response strategy to account for changing factors, such as the latest epidemiological evidence, vaccine supply forecasts and resource mobilization developments.

The EOMG will oversee the implementation of the strategy, coordinate field and headquarter personnel and monitor the work of task teams involved in outbreak management and preparedness, surveillance, vaccine forecasting and stockpile management, and communication and advocacy.

GPEI task teams and working groups responsible to implement the various components of the Strategy, include:

- **WHO and UNICEF Regional and Country Offices and Rapid Response Teams (RRTs):** Support governments in implementing their outbreak responses and other polio activities in regions/countries.
- **Outbreak Preparedness and Response Task Team (OPRTT):** Outbreak response, including surveillance strengthening during outbreaks, and secretariat responsibility to the monovalent OPV2 Advisory Group.
- **Surveillance Task Team (STT):** Early detection, risk assessment, outbreak preparedness, and enhancing surveillance activities in high risk countries, and sustaining surveillance after outbreak response.
- **Vaccine Supply Task Team (VSTT):** Vaccine forecasting and stockpile management for Sabin OPV2 and novel OPV2.
- **Monovalent OPV2 Advisory Group (AG):** Determine need and scope for monovalent OPV2 use in individual outbreaks and provide Director-General WHO recommendation for monovalent OPV2 release.
- **Novel OPV2 Working Group:** Lead novel OPV2 introduction scheduling, country-use approvals.
- **cVDPV2 Strategy Comms Team:** Communication strategy design and execution.
- **Cessation Risk Task Team (CRTT):** Technical assessment of global risk and technical guidance on response.
- **Financial Management Team (FMT):** Financial management.
- **Expanded Programme on Immunization (EPI) and Gavi, the Vaccine Alliance:** IPV catch-up campaigns, essential immunization and immunization intensification activities in targeted geographies.

<sup>21</sup> Global Polio Eradication Initiative. Polio Endgame Strategy 2019–2023: Eradication, integration, certification and containment. Geneva: World Health Organization; 2019. (<http://polioeradication.org/wp-content/uploads/2019/06/english-polio-endgame-strategy.pdf>).

<sup>22</sup> Global Polio Eradication Initiative. Polio Post-Certification Strategy. Geneva: WHO; 2018 (<http://polioeradication.org/wp-content/uploads/2018/04/polio-post-certification-strategy-20180424-2.pdf>).

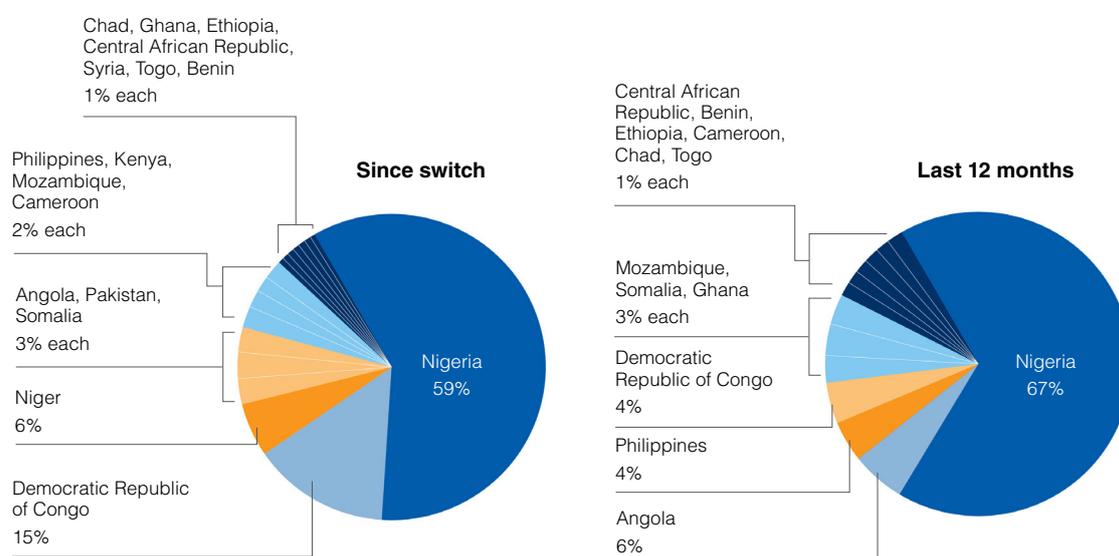
<sup>23</sup> Global Polio Eradication Initiative. Gender Equality Strategy 2019–2023. Geneva: World Health Organization; 2019. ([http://polioeradication.org/wp-content/uploads/2019/11/GPEI\\_Gender\\_Strategy\\_EN\\_web.pdf](http://polioeradication.org/wp-content/uploads/2019/11/GPEI_Gender_Strategy_EN_web.pdf)).

# ANNEX B: BACKGROUND ON THE GLOBAL STOCKPILE

The global stockpile of monovalent OPV2 is an essential component of the cVDPV2 outbreak response strategy. The establishment of this stockpile was one of the prerequisites for the Switch from tOPV to bOPV as laid out by the Strategic Advisory Group of Experts on Immunization (SAGE), and the stockpile was operationalized in 2015. Since the Switch in 2016, 347 million doses of Sabin OPV2 were released to eighteen countries affected by cVDPV2 outbreaks and events,<sup>24</sup> of which 262 million doses were released in 2018 and 2019.

The acceleration of the clinical development and subsequent production and rollout of novel OPV2 is a key priority, which has been approved by the Strategy Committee (SC) as a core component of the global Sabin OPV2 stockpile plan and budget. Considering the benefits of using novel OPV2 compared to Sabin OPV2, it is now considered that the use of Sabin OPV2 be phased out during novel OPV2 rollout.

**Figure B1. Releases from the global monovalent OPV2 stockpile**



Within the GPEI structure, the Vaccine Supply Task Team (VSTT), co-led by WHO and UNICEF, is responsible for the management of the monovalent OPV stockpile. Amongst others, its functions include: (1) quarterly reviews of the stockpile status; (2) forecasting and planning of the monovalent OPV supply; and (3) identification and assessment of risks to monovalent OPV supply for responses to polio outbreaks. The VSTT reports directly to the Eradication and Outbreak Management Group (EOMG) while decisions regarding the replenishment of the stockpile are escalated from the VSTT to the SC via the EOMG.

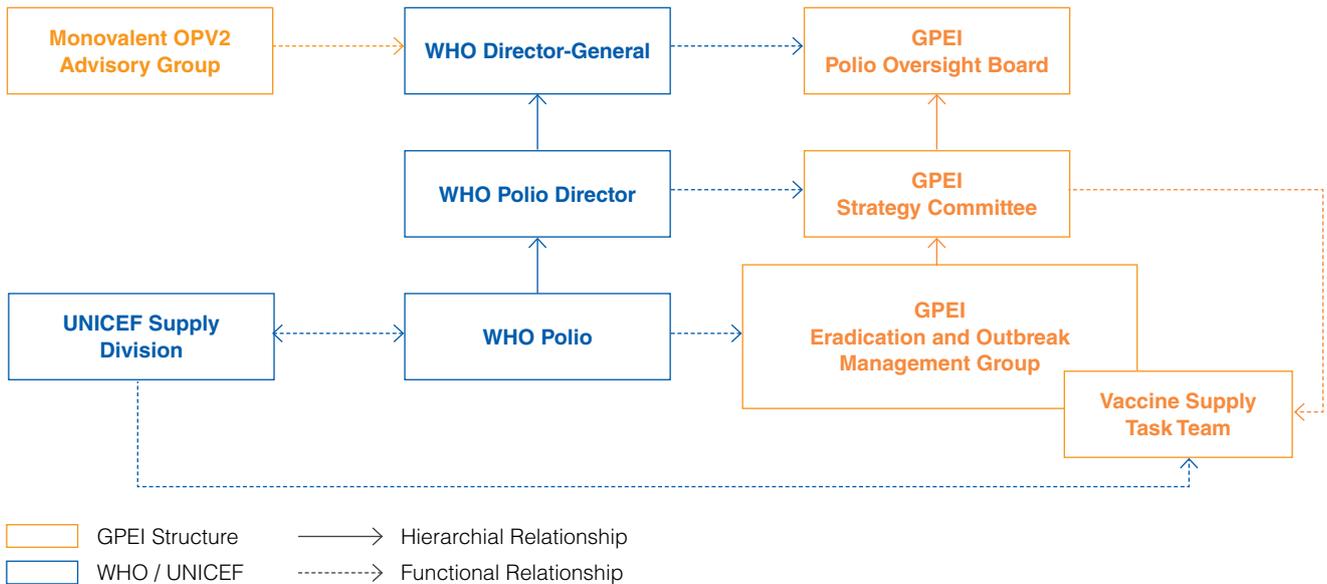
The 'Advisory Group (AG) on Monovalent OPV2 Vaccine Provision in Response to type 2 Poliovirus Event or Outbreak' assesses country Sabin OPV2 requests and advises the WHO Director-General about releases from the global stockpile (see **Figure B2**). It consists of both members of the GPEI and independent agencies.

## DEVELOPMENT AND MANAGEMENT OF THE GLOBAL MONOVALENT STOCKPILE PLAN

- WHA Resolution A68/21 puts the governance of the global monovalent OPV2 stockpiles under the authority of the WHO Director-General. WHO headquarters maintains governance of the stockpile, including oversight, planning and vaccine movements in and out of the stockpile. WHO and UNICEF Supply Division (SD) jointly manage the stockpiles based on legal agreements and an SOP regulating roles and responsibilities between the two agencies. This framework enables UNICEF SD to engage with the vaccine manufacturers to negotiate supply agreements on behalf of WHO, secure replenishment of the stockpile, and manage vaccine shipments to affected countries – activities which rely on the GPEI for management and financing.

<sup>24</sup> Angola, Benin, Nigeria, Niger, Chad, Central African Republic, Ghana, Cameroon, Pakistan, Philippines, Mozambique, Democratic Republic of the Congo, Syria, Somalia, Ethiopia, Kenya, Togo, Zambia

**Figure B2. Governance and management of the stockpile**



- Vaccine needs are estimated based on a set of empirical scenarios that consider current trends and past patterns of poliovirus outbreaks and assumed further expansion of the outbreaks. Scenario D, a worst-case scenario with four WHO regions affected, estimates the total target population for monovalent OPV2 vaccination at 471 million children under 5 years of age.

**PRINCIPLES AND ASSUMPTIONS OF THE GLOBAL MONOVALENT OPV2 STOCKPILE PLAN**

The development of the stockpile plan and budget was driven by a set of principles and assumptions that are listed below:

*Principles*

- Supply of monovalent OPV2 (both Sabin and novel) to enable full-scale responses necessary to stop cVDPV2 outbreaks.
- Acceleration of novel OPV2 is prioritized over Sabin OPV2 to the extent this does not lead to premature depletion of Sabin OPV2 stocks.
- The switch to novel OPV2 will be utilized in outbreak response as soon as supply allows.

*Planning assumptions*

- Vaccine shelf life is not a significant factor in 2020–2023 due to fast-moving stocks.
- Emergency Use Listing (EUL) will be secured by July 2020 and will not delay rollout of novel OPV2.<sup>25</sup>
- The GPEI will operationalize dose-sparing measures (e.g. Sabin OPV2 prioritization schemes and one-drop Sabin OPV2) without delay when supply falls short of meeting projected demand particularly in 2020.
- Full financing will be available to implement proposed monovalent OPV2 supply options.
- Implementation of the plan will require restarting Sabin OPV2 bulk production in 2020.
- Bulk production of Sabin OPV2 is maintained.
- Biofarma produces novel OPV2 in 50-dose vials.

*Critical enablers*

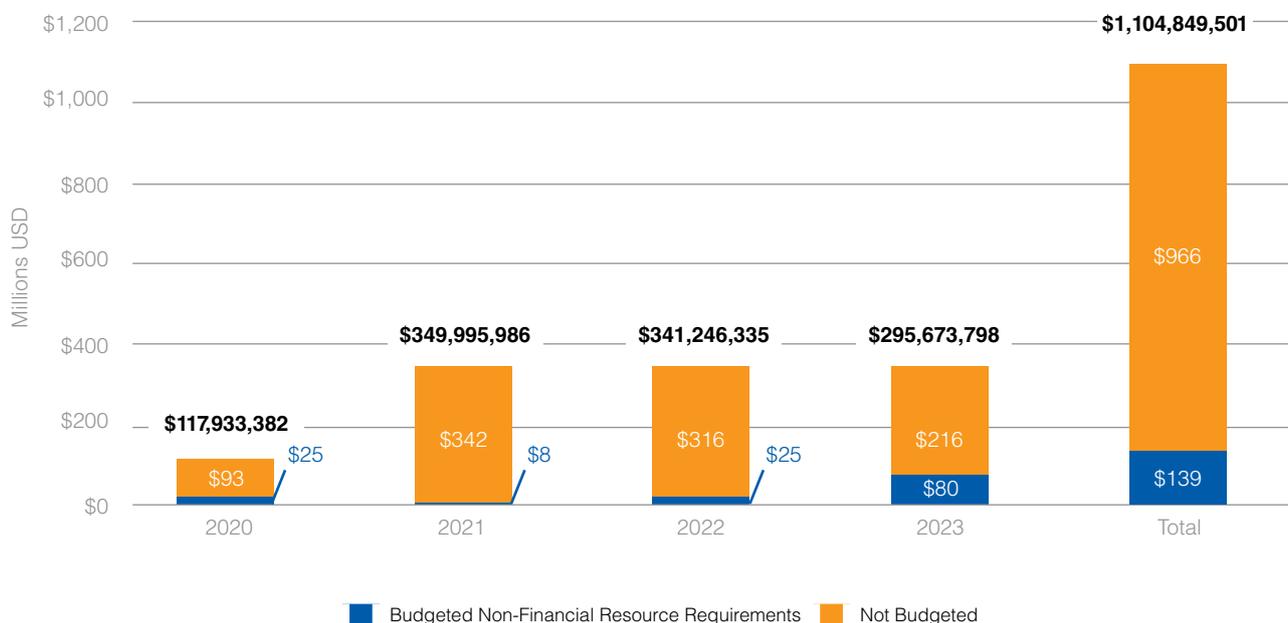
- The GPEI negotiates additional Sabin and novel OPV2 bulk production and filling capacities immediately.
- Dose-sparing measures and their triggers are agreed to in advance and operationalized if the GPEI does not source additional filling capacity.
- EUL of novel OPV2 candidate 1 is secured by July 2020.
- Updated Outbreak Response SOPs include clear parameters for Sabin OPV2 and novel OPV2 SIAs.

<sup>25</sup> 4-8 million doses of novel OPV2 will likely become available in early Q2 2020. Depending on the timing of first/interim EUL recommendation (expected in June–July), the first use of novel OPV2 is anticipated in early Q3, before more doses become available by the end of August 2020.

- Novel OPV2 acceleration and distribution plan is developed and aligned with the updated Outbreak Response SOPs before June 2020.

Agreement on the size of the monovalent OPV2 stockpile buffer is calibrated to the expected outbreak response.

**Figure B3: Global monovalent OPV2 stockpile budget**



### FAST-TRACKING NOVEL OPV2 PRODUCTION AND LICENSURE

Because of the serious risk of seeding more emergences of VDPV2 and the risk of shortages of Sabin OPV2 severely affecting outbreak response, the GPEI will facilitate fast-tracking of the development and emergency availability of novel OPV2 as a top priority.

Emergency Use Listing (EUL) is a special procedure for medicines in the case of a public health emergency, when the community may be willing to tolerate less certainty about the efficacy and safety of products, given the morbidity and/or mortality of the disease and the shortfall of treatment and/or prevention options. In such instances, it is paramount to determine the minimal level of information needed prior to making a product available under a time-limited EUL, while further data are being gathered and evaluated. WHO recognizes the prime importance of conducting and completing clinical trials of any novel product, including when used in a public health emergency. The inclusion of a product in the EUL list should not compromise such trials. WHO has developed the EUL procedure to expedite the availability of medicines needed in public health emergencies. The EUL procedure is intended to assist interested UN procurement agencies and Member States on the acceptability for use of a specific medicine in the context of a public health emergency, based on a minimum set of available quality, safety and efficacy data. It is the sole prerogative of WHO Member States whether or not to allow the emergency use of a candidate medicine in their country.

### ELIGIBILITY

In order to qualify for an EUL, the use of the medicine must meet the following conditions:

- The disease for which the medicine is intended has been declared by the WHO Director-General to be a Public Health Emergency of International Concern (PHEIC).<sup>26</sup> This is the case for cVDPV since 2015.<sup>27</sup>
- The disease for which the product is intended is serious or immediately life-threatening, causing an outbreak, epidemic or pandemic, and there is no licensed product for this disease.
- Based on the contingencies of the specific public health emergency, it is reasonable to consider a medicine for EUL assessment (i.e., there are no licensed therapies for the indication or for a critical subpopulation, such as children).

<sup>26</sup> The IHR 2005 defined the declaration of a PHEIC. World Health Organization. International Health Regulations (2005) 3rd edition. Geneva: World Health Organization; 2016. (<https://www.who.int/ihr/publications/9789241580496/en/>).

<sup>27</sup> See Statement on the Seventh IHR Emergency Committee meeting regarding the international spread of poliovirus. 26 Nov 2015. (<https://www.who.int/news-room/detail/26-11-2015-statement-on-the-seventh-ihc-emergency-committee-meeting-regarding-the-international-spread-of-poliovirus>).

- The medicine is manufactured in compliance with current Good Manufacturing Practices (GMP) in the case of medicines and vaccines and under a functional Quality Management System (QMS) in the case of immunization and vaccine development (IVD).
- The applicant attests that it intends to complete the development of the product (validation and verification of the product in the case of IVDs) and apply for WHO prequalification. In the ideal situation, the remaining clinical trials and other requisite testing will already be underway at the time of the application for an EUL. The future application should incorporate all information submitted for the EUL, plus any other information needed to complete a prequalification application.

Establishment of the evaluation committee with members from a roster of experts

- The role of the evaluation committee is to prepare a refined list of the essential data requirements for the EUL submission and to establish the set of guidelines and scientific literature that will be used for the assessment and recommendation.
- Preparations for the assessment upon reception of the application (Q1-Q2/2020).
- Assessment of preliminary chemistry, manufacturing, and control (CMC) and clinical data (Q2/2020) and interim EUL recommendation.
- Assessment of complete data and Emergency Use Listing (during Q3 or Q4/2020).

## ■ ANNEX C: ONE-DROP VACCINATION

If the global Sabin OPV2 supply reaches a critically low threshold, the strategic deployment of dose-sparing measures may effectively mitigate against a situation in which an outbreak can't be responded to because of a possible stockout.

While one-drop vaccination is not the first dose-sparing measure to consider, using one drop of vaccine in the context of multiple administrations (as occurs during an outbreak response) does provide important benefits:

- It potentially increases the number of children who can be vaccinated;
- It saves on cost; and
- It also avoids a situation where a campaign is restricted simply to preserve the stockpile.

To assess whether the available Sabin OPV2 could have expanded reach through the use of one drop of vaccine, a small field trial conducted in Mozambique compared the immunogenicity of one drop of vaccine to the standard two-drop dose. Based on the results, as well as the assumption that one drop of vaccine was a better option than giving no vaccine, the Strategic Advisory Group of Experts on Immunization (SAGE) endorsed using one drop of Sabin OPV2 in cases where a critically low supply would not be sufficient for cVDPV outbreak control.<sup>28</sup> What constitutes a critically low level has not yet been defined.

The decision to use one-drop vaccination should also address potential challenges, such as confusion or non-compliance in the field, uncertainty about triggers to implement the measure, possible equity issues and potential reputational risk to the GPEI. Communication will be essential to ensure the programme remains invested with public trust.

<sup>28</sup> For notes on the 19 October 2019 meeting of the Strategic Advisory Group of Experts on Immunization, see: World Health Organization. Weekly Epidem Rec, 22 November 2019; 94 (47) 541–60. (<https://www.who.int/wer/2019/wer9447/en/>).

## ANNEX D: IPV CATCH-UP CAMPAIGNS

From a public health point of view, inactivated polio vaccine (IPV) is one of the safest vaccines – and consequently can be used indefinitely after polio eradication. Because of this sustained long-term need, the global supply of IPV is closely monitored by WHO and the UNICEF Supply Division (SD), which engages with vaccine manufacturers to negotiate supply agreements and manage vaccine shipments to countries.

Beginning in 2016, a global IPV shortage delayed the introduction of IPV into essential immunization schedules. During this shortage, 38 countries were unable to access IPV supply. Of these, 20 countries did not have access to IPV for introduction in essential immunization systems, and 18 countries had their supply interrupted post-introduction (see **Table D1**).

The IPV shortage was resolved by the end of 2018, and the successful increase in global supply resulted in all 85 UNICEF-procuring countries being able to receive one dose for essential immunization schedules by April 2019.

**Table D1. IPV supply-affected countries**

Type of delay	Affected countries
<b>Delayed introduction</b> (n=20)	Angola, Burkina Faso, Egypt, Eritrea, Ghana, Kyrgyzstan, Liberia, Malawi, Moldova, Mongolia, Rwanda, Sierra Leone, Tajikistan, Tanzania, Togo, Turkmenistan, Uzbekistan, Vietnam, Zambia, Zimbabwe
<b>Delayed resupply, stock out and re-introduced</b> (n=16)	Bangladesh, Bhutan, Burundi, Comoros, Côte d'Ivoire, Djibouti, Gambia, Guinea Bissau, Iran, Democratic People's Republic of Korea, Lesotho, Morocco, Nepal, São Tomé and Príncipe, Senegal, Sudan
<b>Delayed resupply, no stock-out</b> (n=2)	Cabo Verde, Swaziland

With the introduction and re-introduction of IPV into all countries now complete, the GPEI has begun prioritizing IPV catch-up campaigns to immunize children who missed IPV in country immunization schedules from 2016 to 2019 – an estimated 42 million children.

The programme has defined the following parameters for prioritizing IPV catch-up campaigns:

- Estimated number of children under 5 years who are susceptible to type 2 poliovirus.
- Child mortality rates (as a proxy for poliovirus transmission efficiency).
- Migration from countries with cVDPV2 reported after OPV2 withdrawal.
- Estimated number of patients with primary immunodeficiency disorders (PIDs) that may be shedding iVDPV2.
- Location of poliovirus-essential facilities (as a risk of containment failure).

**Table D2. IPV catch-up campaign planning (as of February 2020)**

IPV catch-up campaign	Country
<b>Completed</b> (n=9)	Bangladesh, Bhutan, Comoros, Liberia, Moldova, Morocco, Tanzania, São Tomé and Príncipe, Tanzania and Turkmenistan
<b>Ongoing</b> (n=1)	Iran
<b>Approved with doses in country</b> (n=4)	Angola, Ghana, Sudan (planned for 14-19 March) and Zambia (planned for June 2020)
<b>Currently planning 2020</b> (n=10)	<ul style="list-style-type: none"> <li>• Egypt (March 2020)</li> <li>• Zimbabwe (June 2020)</li> <li>• Malawi (July 2020)</li> <li>• Vietnam (July 2020)</li> <li>• Sierra Leone (November 2020)</li> <li>• Côte d'Ivoire (TBC)</li> <li>• Burundi (TBC)</li> <li>• Burkina Faso (TBC)</li> <li>• Djibouti (TBC)</li> <li>• Tajikistan (TBC)</li> </ul>
<b>Pending</b> (n=12)	Eritrea, Gambia, Guinea Bissau, Democratic People's Republic of Korea, Kyrgyzstan, Lesotho, Mongolia, Nepal, Rwanda, Senegal, Togo and Uzbekistan

# ANNEX E: SURVEILLANCE ACTIVITIES

**Table E1. Surveillance activities and expected deliverables for 2020–2021**

<b>Objective 1. Strengthen AFP surveillance in priority countries</b>	
<b>Specific action</b>	<b>Expected deliverables in next 18 months</b>
<p><b>Surveillance data review</b></p> <p>Detailed desk review of AFP surveillance quality for all outbreak and other high-risk countries.</p> <p>Assessment of surveillance quality at the subnational level in all outbreak and other high-risk countries; review will include subnational AFP surveillance data analysis.</p>	<p>Complete desk review of AFP surveillance performance for priority countries. (West and Central Africa due December 2019; all other priority countries, January 2020).</p> <p>Publish a detailed subnational surveillance performance map for AFR, EMR, SEAR, and WPR regions and flag potential 'blind spots' (January 2020).</p>
<p><b>Field surveillance review</b></p> <p>Thorough assessments and audits of AFP surveillance quality in selected priority countries. This will include assessment of both active and passive surveillance quality through the review of active surveillance visits and weekly 'zero' reporting. It will also include review of the reverse cold chain for stool samples.</p> <p>In priority countries with additional surveillance data (e.g. ISS, eSURV and other ODK-based active surveillance data), review the available data with the aim of developing a plan for enhanced utilization of tools.</p> <p>Evaluate needs in all areas affected by conflict, insecurity, inaccessibility and/or other challenges; review ongoing surveillance activities (e.g. community-based surveillance).</p>	<p>AFP surveillance quality audit carried out in at least eight countries (due June 2020).</p> <p>Reviewed surveillance needs in at least four conflict-affected countries, including Yemen and South Sudan.</p> <p>Implemented country-specific polio surveillance enhancements plans based on results and recommendations from desk and field surveillance reviews (due October 2020).</p> <p>Establish mechanism for enhanced country-level data analysis to guide surveillance activities.</p>
<p><b>Field support and capacity building</b></p> <p>In coordination with the regional office, carry out cascade AFP surveillance training for priority countries.</p> <p>Deploy external field surveillance technical support to priority countries at high risk of cVDPV2 importation and/or emergence of type 2 outbreaks.</p> <p>Map and expand active and passive surveillance network and encourage the adoption of technology to monitor active surveillance visits.</p>	<p>Complete cascade training for at least eight priority countries (due April 2020).</p> <p>From the global and regional resource pool, provide field support through the extended deployment of technical officers to at least six countries at imminent risk of cVDPV2 outbreaks and subnationally for countries with outbreaks.</p> <p>Expand the use of ISS, eSurv and other ODK-based active surveillance monitoring tools.</p> <p>Use new technologies and innovations to provide evidence for impact of field support and capacity-building.</p>
<b>Objective 2. Enhance environmental surveillance</b>	
<b>Specific action</b>	<b>Expected deliverables</b>
<p><b>ES quality in existing sites</b></p> <p>Review the performance of all operational ES sites in 2019, flag underperforming sites to regional office and respective countries.</p> <p>Develop specific quality improvement plans by country.</p> <p>Expand the skills of all field surveillance officers in priority countries with environmental surveillance by including ES in planned trainings.</p>	<p>Desk review of ES quality carried out in all priority countries (due April 2020).</p> <p>With the support of the global and regional teams, field and laboratory surveillance assessment and full implementation of recommendations completed in at least six priority countries.</p> <p>All surveillance desk reviews, field reviews, field and laboratory support missions, and trainings include ES (due March 2020).</p>

<p><b>Strategic expansion of ES network</b></p> <p>Review the status of ES in subregions with ongoing cVDPV2 outbreaks and explore for potential new sites.</p> <p>To ensure lab capacity is optimally utilized, rationalize existing by, where possible, ensuring a more diffuse distribution of sites across key population centres.</p> <p>To support an expanded network, where appropriate, decrease frequency of collection of samples to once per month and propose a plan for increasing laboratory ES capacity in key regions (AFR, EMR, WPR).</p>	<p>Field and laboratory assessment for potential ES expansion assessed in at least six new countries (due April 2020).</p> <p>In key hotspots of cVDPV2 transmission (e.g. West Africa), field and laboratory assessment for potential ES expansion assessed in major population centres and trade routes (due April 2020).</p> <p>Default sample collection is shifted to monthly from biweekly across all priority countries, and biweekly sample collection is only instituted on a short-term basis when epidemiologically needed and not for more than six months at a time (due June 2020).</p> <p>A budgeted and time-bound global plan to create ES hubs in AFR, EMR and WPR is proposed (due March 2020).</p>
<p><b>Objective 3. Shorten duration between sample collection and availability of final lab results</b></p>	
<p><b>Specific action</b></p>	<p><b>Expected deliverables</b></p>
<p><b>Decrease time-to-results</b></p> <p>Ensure all samples in priority countries are received at the first testing lab within seven days of collection.</p> <p>Decrease the time taken from samples reaching lab to receipt of final results.</p>	<p>Review contributors to delay in final results across all stages – from date of onset to results – in Afghanistan and Pakistan, Horn of Africa (Yemen, Ethiopia, Kenya, Somalia), West and Central Africa (due March 2020).</p> <p>Depending on findings, develop and implement a specific action plan to address challenges associated with key contributors to delay.</p> <p>Depending on final validation of direct detection of poliovirus from stool samples and resources availability:</p> <ol style="list-style-type: none"> <li>1. Explore the potential for the accelerated implementation of molecular detection in selected laboratories serving high-risk countries and develop an implementation plan for up to 10 laboratories (due December 2020).</li> <li>2. Deploy this methodology in at least three labs serving high-priority countries (due June 2021).</li> </ol> <p>Continue evaluation, resourcing and training to expand local sequencing capacity in regional labs serving selected priority countries in West and Central Africa (due December 2020).</p>
<p><b>Objective 4. Provide coordinated support and improve management and oversight</b></p>	
<p><b>Specific action</b></p>	<p><b>Expected deliverables in next 12 months</b></p>
<p><b>Strategic alignment</b></p> <p>In coordination with the regional office, review and revise global country prioritization.</p> <p>Depending on the evolving epidemiology, review on a quarterly basis and, where necessary, update priority countries for surveillance strengthening.</p> <p>Ensure new Global Surveillance Action Plan for 2021–2023 fully takes into account and builds on the new cVDPV2 strategy.</p>	<p>Revised priority countries map published (due December 2019).</p> <p>Priority countries map reviewed and, where necessary, updated every quarter (due February, June, October and December 2020).</p> <p>New Global Polio Surveillance Action Plan for 2021–2023 (due December 2020).</p>
<p><b>Outbreak country support</b></p> <p>Facilitate the deployment of at least one surveillance coordinator to all outbreak countries.</p> <p>For all outbreak countries in Phase 2 of their outbreak response, in close coordination with OPRTT, support countries to develop extended surveillance enhancement plans.</p> <p>Support the transitioning of countries from enhanced polio surveillance during outbreaks to maintaining high-quality surveillance post-outbreak.</p>	<p>All countries with ongoing outbreaks have dedicated surveillance focal person (due March 2020).</p> <p>Review and complete 12-month surveillance action plan for all outbreak countries in Phase 2 (due March 2020).</p> <p>Integrate post-outbreak surveillance support for countries with no ongoing circulation for at least 12 months (due January 2020).</p>

AFP= acute flaccid paralysis; AFR= African Region; cVDPV2= circulating vaccine-derived poliovirus (serotype 2); EMR= Eastern Mediterranean Region; ES= environmental surveillance; eSURV= electronic surveillance; ISS= integrated supportive supervision; ODK= open data kit; OPRTT= Outbreak Preparedness and Response Task Team; SEAR= South-East Asia Region; WPR= Western Pacific Region

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