Draft for Comment:

Strategy for Control of cVDPV2, 2020 – 2021

An addendum to the Polio Endgame Strategy 2019 – 2023
TABLE OF CONTENTS

PREFACE – A note to stakeholders on this draft ................................................................. 3
1. STRATEGY RATIONALE ................................................................................................. 4
   1.1. The three stages of the strategy ........................................................................... 5
   1.2. Specific objectives of the strategy ....................................................................... 6
2. KEY INTERVENTIONS .................................................................................................... 7
3. ENHANCING OUTBREAK RESPONSE ........................................................................ 8
   3.1. Improving quality and rapidity of vaccination rounds ....................................... 8
   3.2. Addressing operational and programmatic risks to improve response delivery .... 9
4. VACCINE SUPPLY ....................................................................................................... 11
   4.1. Vaccines in Stage 1: Sabin OPV2 and Inactivated Polio Vaccine (IPV) ................... 11
   4.2. Vaccines in the Intermediate/Period 2: novel OPV2 roll-out ............................. 15
   4.3. Vaccines in the Final/Third Period (2021 and beyond) ...................................... 17
5. EARLY DETECTION OF NEW OUTBREAKS ............................................................. 18
   5.1. Determining priority areas ............................................................................... 18
   5.2. Priority surveillance activities to enable early detection of cVDPV2 ................. 18
   5.3. Laboratory Surveillance for early detection and response to cVDPV2 outbreaks .... 19
6. COMMUNICATION AND PROMOTION OF THE STRATEGY ...................................... 20
   6.1. Key Communication Risks during Strategy Implementation ............................ 20
   6.2. External Communication and Public Relations Tactics ..................................... 20
   6.3. Communication 4 Development ....................................................................... 21
   6.4. Internal Communication Tactics ...................................................................... 21
Annex A ......................................................................................................................... 23
OVERSIGHT AND MONITORING OF THE STRATEGY .................................................. 23
   Annex B: BACKGROUND ON THE GLOBAL STOCKPILE ........................................ 24
   Governance and management of the stockpile ....................................................... 24
   Development and Management of the Global Monovalent Stockpile Plan .............. 25
Annex D: CALENDAR OF KEY COMMITTEES AND ADVISORY GROUP MEETINGS .... 29
PREFACE – A note to stakeholders on this draft

This draft Strategy for Control of cVDPV2, 2020 –2021 has been developed by GPEI technical and operational staff to address the rapidly changing cVDPV2 epidemiology and is published here for stakeholder input.

Recognising that immunization tactics implemented to date have been unsuccessful at preventing an increase in cVDPV2 case numbers, the Strategy lays out a series of new measures to stop the further spread of cVDPV2s and protect populations from paralysis, while building contingency measures in the event that the situation deteriorates. The Strategy focuses predominantly on cVDPV2 outbreak response and continues to emphasize the importance of building stronger immunization systems capable of achieving a polio-free world. In light of the significant risk that cVDPV2s pose to vulnerable, under-immunized populations, the GPEI aims to operationalize this response strategy in Q1 of 2020.

As evolving cVDPV2 outbreaks continue to have an impact on program resources – including vaccine stockpiles - this Strategy includes contingency measures such as the potential use of fractional doses of mOPV2 and IPV, and the potential reintroduction of tOPV for outbreak response. Discussion around these areas is critical and certain elements proposed in the draft Strategy may not be contained in the finalised version, once stakeholder and expert feedback is taken into account.

To facilitate stakeholder feedback, GPEI has scheduled a range of discussions with external stakeholders between December 2019 and January 2020.

Stakeholders who wish to provide written comments on the draft Strategy can send them to Graham Tallis (tallisg@who.int) and Patrick Brown (nnk5@cdc.gov).

Comments should be shared no later than 7 January 2020. If you wish to comment and are unable to meet this deadline, please inform us as soon as possible when you will be able to.

We welcome input from all polio stakeholders to enable the finalisation of a cohesive Strategy that will help GPEI urgently stop cVDPV2 outbreaks moving forward.
1. STRATEGY RATIONALE

In 2016, following the 2015 global certification of the eradication of wild poliovirus type 2, there was a synchronized global removal of type 2 containing live attenuated polio vaccine from routine immunization systems and supplemental immunization activities. This global effort, termed “the Switch” was preceded, for risk mitigation purposes, 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, as well as efforts to increase population immunity in many countries with elevated polio risk through the administration of trivalent oral polio vaccine in supplemental immunization activities at national and subnational levels.

The removal of live attenuated polio vaccine is a critical step in the post-eradication polio workstream to ensure that all polio transmission ceases, including wild poliovirus and the secondary circulation of polio vaccine virus that occurs with administration of OPV. It was anticipated that the post-Switch period would include the emergence and circulation of type 2 vaccine derived poliovirus and that several outbreak responses using monovalent OPV2 would be required to stop the outbreaks.

Pre-Switch modeling predicted that the majority of post-Switch VDPV2 emergence and cVDPV2 outbreaks would occur in the 12 - 24 month period after the Switch (i.e., 2017-2018), and that appropriate campaigns with mOPV2 would stop transmission and new VDPV2 detections would decline until they ceased altogether. However, pre-Switch intensification efforts were not equally successful and critical gaps in immunity were left in countries with fragile immunization systems. These immunity gaps, combined with uneven quality of outbreak response and more post-Switch use of Sabin OPV2 than anticipated (over 300M doses since the Switch), has resulted in considerably more post-Switch VDPV2 emergences and cVDPV2 outbreaks than predicted by the program.

In 2019, three years after the Switch, against the backdrop of declining type 2 population immunity in many geographies, the number of new emergences and circulation of VDPV2 substantially and rapidly increased. Moreover, there have been increasing cVDPV2 outbreaks in areas bordering, but outside of Sabin OPV2 response zones. This trend demonstrates an increase in the risk of generating new cVDPV2 viruses when using Sabin OPV2, even though cVDPV2 emergences are extremely rare events in the

---

1 Due to a global IPV shortage in 2016, 10 African countries (which included several countries that are currently combatting cVDPV2 outbreaks) did not receive introduce IPV prior to the Switch period.

2 Sabin Oral Polio Vaccine has been critical to the global reduction of poliovirus and facilitated the eradication of type 2 and 3 wild poliovirus globally. In extremely rare instances the live Sabin vaccine can regain its ability to cause the neurological symptoms associated with wild poliovirus and emerge as vaccine derived poliovirus (VDPV). In situations where polio vaccine coverage and the correlating population immunity is low in the community, this VDPV can begin to circulate causing an outbreak of circulating vaccine derived poliovirus (cVDPV). While this can occur with all three types of poliovirus, historically cVDPV2 has emerged most, followed by cVDPV1, and least frequently cVDPV3.

3 In this document, the term mOPV2 is not used; instead the more specific nomenclature of Sabin OPV2 vaccine and the newly developed novel OPV2 vaccine is used preferentially, while the term monovalent OPV2 refers generically to any monovalent type 2 oral polio vaccine and is used only in limited contexts.
context of the administration of hundreds of millions of doses of vaccine. The situation is rapidly evolving and the future trajectory is uncertain.

Stopping current outbreaks while preventing new emergences requires a new strategy that improves on current response methods, prioritizes use of assets, and utilizes innovations, notably accelerating deployment of novel OPV2. Novel OPV2 is expected to be available in 2020 and is anticipated to provide similar intestinal immunity to Sabin OPV2 while being substantially more genetically stable and thus resistant to reversion. Below GPEI outlines a 18 month cVDPV2 response strategy, which will begin in Q1 2020.

1.1. The three stages of the strategy

The proposed Strategy to control cVDPV2s is structured into three stages according to vaccine availability, as the risks and challenges vary with each vaccine strategy employed:

- **Stage 1**: Stage 1 is characterized by aggressive outbreak response using Sabin OPV2 and strategic IPV use, with the goal of controlling new and ongoing cVDPV2 and mitigating paralytic risk while concurrently preparing for deployment of novel OPV2. In addition, RI intensification activities with IPV will be carried out in highest-risk geographies to curtail transmission and reduce long term polio risk. In a best-case scenario, Stage 1 will end in July 2020 when novel OPV2 is expected to become available for use. The main risks in Stage 1 are: 1) insufficient Sabin OPV2 supply leading to inability to deliver effective outbreak responses and requiring dose sparing measures; 2) new emergent outbreaks seeded by Sabin OPV2 use; and 3) insufficient human and financial resources to respond to the large number of outbreaks.

- **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 will continue to be used for outbreak response throughout this period, modulated by novel OPV2 availability. Also, Stage 1 RI intensification activities will continue. In a best-case scenario, Stage 2 will extend from July 2020 to December 31, 2020 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 nOPV2; 2) delays in nOPV2 availability; 3) Stage 1 outbreaks exceed response capacity triggering a process that will prepare for an OPV2 restart in routine 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. Risk of seeding new emergences effectively eliminated. RI intensification activities will continue. In a best-case scenario, Stage 3 begins in January 2021 and continues as needed until cVDPV2 outbreaks are stopped. The main risks to Stage 3 are: 1) inability to enter Stage 3 due to insufficient supply of novel OPV2 requires extended Sabin OPV2 use; 2) novel OPV2 failure; 3) cVDPV2 epidemiology requires OPV2 use in broad preventive SIAs and OPV2 restart in routine immunization (i.e., Switch failure).

---

4 The utilization of IPV in outbreak response and as a preventative measure in high risk areas may require increasing IPV allocations to Objective 1. 6 million IPV doses have been allocated to Objective 1 in 2020. IPV will be used in several strategic ways as defined in the strategy, but routine immunization supplies will be prioritized and limitations in supply for non-RI use may limit the extent of IPV use for some of these interventions.

5 Information regarding licensure and production of nOPV2 are provided in Annex A
The timeframes articulated in the three stages of the strategy above are dependent on nOPV2 availability, the availability of sufficient financial and human resources, and rapidly evolving cVDPV2 epidemiology.

The strategy will be regularly reviewed and updated as needed to meet ongoing needs. Furthermore, contingency measures are built into each Stage to ensure that resources are available to address risks that will need to be managed in the subsequent Stages. For example, vaccine stockpiles are being created in Stage 1 to accommodate a Stage 3 restart of OPV2 in RI, if needed.

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

Vaccine supply and management will be a major challenge during the Strategy time frame. GPEI will be required to mobilize additional doses of Sabin OPV2 to account for the potential expansion of cVDPV2 outbreaks while not compromising production of novel OPV2 or bOPV. Balancing current and future needs will require prioritized risk-based Sabin OPV2 use and dose sparing strategies, maximizing filling with existing partners, establishing new fill-finish partners, and production of new bulk Sabin OPV2.

*The extent and modalities of IPV use continue to be considered and may be impacted by IPV supply.

**The extent and timing of tOPV use continues to be considered.

### 1.2. Specific objectives of the strategy

- To ensure cVDPV2 outbreaks are rapidly detected and controlled using Sabin OPV2 while minimizing the risk of further spread
- To ensure an adequate supply of monovalent Sabin OPV2 is available until it is no longer required
Strategy to Control cVDPV2s, 2020–2021
Draft for Comments, 16 December 2019

To utilize IPV to boost immunity, mitigate paralytic risk, and improve population immunity.
To accelerate catchup campaigns in countries with delayed introduction
To synergize efforts with EPI and GAVI to strengthen RI in high risk areas, with low-Type 2 immunity
Accelerate novel OPV2 availability through GPEI’s nOPV2 working group
To ensure member states, GPEI stakeholders, and the general public understand the risk and benefit of cVDPV2 and how GPEI proposes to mitigate and manage risks
To articulate a contingency plan in the event that cVDPV2 epidemiology outstrips the current supply of vaccine and human and financial resources.

2. KEY INTERVENTIONS

Table 1. Summary of Key Interventions

<table>
<thead>
<tr>
<th>Enhancing Outbreak Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Strengthen outbreak response procedures to improve response time and quality and make the most effective use of resources and vaccine</td>
</tr>
<tr>
<td>– Ensure that cVDPV2 outbreaks are immediately declared as an emergency and graded level 2 according to the WHE Emergency Framework</td>
</tr>
<tr>
<td>– Each partner agency ensures that all level 2 emergency functions are implemented; consistently use fast-track procedures to enable rapid deployment of human and financial resources</td>
</tr>
<tr>
<td>– Streamline processes of the monovalent OPV2 Advisory Group</td>
</tr>
<tr>
<td>– In select situations, use IPV to boost mucosal immunity after priming with Sabin OPV2</td>
</tr>
<tr>
<td>– Double the size of the Africa Rapid Response Team (RRT) and form a global RRT to respond to outbreaks outside of Africa</td>
</tr>
<tr>
<td>– Strengthen the Surge Support Team (formerly “Team B”) by expanding technical staff capacity</td>
</tr>
<tr>
<td>– Increase GPEI’s field deployed technical assistance in high risk areas to support surveillance, outbreak preparedness, and outbreak response efforts</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccine Supply and Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>– In Q4 2019, GPEI to resource the 2020 Sabin OPV2 fill/finish supply and identify and contractually engage an additional bulk supplier and a fill/finisher</td>
</tr>
<tr>
<td>– Optimize use of limited Sabin OPV2 supply by employing dose sparing measures</td>
</tr>
<tr>
<td>– Fast track the development and emergency availability of novel OPV2</td>
</tr>
<tr>
<td>– Support the development of a novel OPV2 prioritization scheme</td>
</tr>
<tr>
<td>– Secure a tOPV supply to use in place of mOPV2</td>
</tr>
<tr>
<td>– As a contingency, in case of Switch failure, procure sufficient OPV2 supplies to restart preventive OPV2 SIAs and/or restart of OPV2 in routine immunization schedules</td>
</tr>
<tr>
<td>– Ensure sufficient IPV supply for catchup, RI intensification, targeted use in outbreaks, and for expanded use in event of an mOPV2 stockout</td>
</tr>
</tbody>
</table>
Early Detection of New Outbreaks

- Strengthen AFP and expand environmental surveillance in areas at highest risk of cVPDV2 circulation, particularly highest risk areas bordering an area of cVPDV2 or Sabin OPV2 use
- Fully implement the Global Polio Surveillance Action Plan
- Fast-track laboratory rollout of direct poliovirus detection from stool specimens

Communications

- Form a strategic communication working group that integrates various communication workstreams related to outbreak readiness and response

Targeted use of IPV to protect populations

- Accelerate catchup campaigns in countries with delayed introduction
- Targeted use in Periodic Intensive Routine Immunization activities
- In select outbreak situations, boost mucosal immunity after priming with Sabin OPV2
- If mOPV2 supply is exhausted, expanded use in cVPDV2 responses to mitigate paralytic risk

3. ENHANCING OUTBREAK RESPONSE

Outbreak response enhancements will start immediately in Stage 1 and continue as necessary.

3.1. Improving quality and rapidity of vaccination rounds

The outbreak SOPs ⁶ are being revised to make the most effective use of vaccine and other resources and incorporate lessons learnt; revisions to include, broadly:

- Conduct a quick, high quality case response round (R0) of vaccination, which should typically be focused on the immediate area of the detection where transmission is most likely to be occurring; if it cannot be conducted quickly (within three weeks) R0 should not be done
- Conduct at least two high quality rounds (>90% coverage) to cover all areas where transmission may be possibly occurring
- If breakthrough cases occur in an area which has received mOPV2, target smaller areas where ongoing transmission is demonstrated or highly likely, rather than another wider round
- Standardized practice of targeted response to meet local context, such as the presence of high-risk groups and known population movements
- Strengthen surveillance in high risk areas bordering the outbreak response zone
- Support the strengthening essential immunization in high risk areas that border an outbreak response zone and utilize outbreak response microplanning, communication and monitoring to address broader immunization system weaknesses ⁷.

---

⁶ “Standard Operating Procedures: Responding to a poliovirus event or outbreak”, v3 published December 2018
⁷ GPEI will incorporate successful GPEI-EPI-GAVI collaborative activities (e.g. PNG) into future outbreak responses
3.2. Addressing operational and programmatic risks to improve response delivery

3.2.1 Enhanced Global Outbreak Preparedness and Response Capacity

The EOMG’s Outbreak Preparedness & Response Task Team (OPRTT) coordinates GPEI’s global outbreak preparedness and response. It operates virtually, with members drawn from across the partnership. 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 HQ and expand the size of the virtual team. The team will be further empowered to coordinate outbreak response activities, including advising HQs and Regions on scale and scope of response, response staffing, and release and use of contingency outbreak funds. The OPRTT secretariat will be restructured to enhance its ability to manage these responsibilities and increased work volume.

3.2.2 Scale up Rapid Response Teams

WHO and UNICEF regional offices together with other partners of the GPEI have established a multi-disciplinary Rapid Response Team (RRT) in Africa to initiate an effective response within 72 hours of a declared outbreak. The 19 member RRT is comprised of technical experts in epidemiology, surveillance, immunization, communication and social mobilization, vaccine management and program operations. The purpose of the team is to streamline and strengthen coordinated partner support to national programs to mount an effective response within the first 6-8 weeks of an outbreak, in line with the outbreak SOPs. Given the number of outbreaks occurring within the WHO African Region, the Africa RRT HR capacity will be doubled (to 38) in Q1 2020.

Recognizing the increased risk of outbreak outside of Africa, GPEI will establish an additional global Rapid Response Team to support the regional offices of WHO and UNICEF 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 and will be housed at WHO HQ 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.

3.2.3 Improving field coordination through maintaining a roster of outbreak coordinators

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

3.2.3 Increase Surge Support

The Surge Support Team is an interagency on-call roster for longer-term deployment using a central platform for ease of visibility and reporting (previously designated as Team B in GPEI outbreak response documents), which is managed by WHO HQ. The Surge Support Team should be in place within six weeks of outbreak confirmation and should take over from the RRT and be deployed for a minimum of six months or until the outbreak closure. The composition of the Surge team needs to be aligned with country needs and include a GPEI outbreak coordinator to lead the effort, and experts in surveillance, SIA, C4D, vaccine management, data management and operations, and RI systems. The surge team will be briefed in country, including refreshing participants on the basics of the poliovirus, the status of polio
eradication, the GPEI partnership and provide an overview of the core response strategy. Analogous to the GPEI coordinator roster, the surge support roster will be updated, expanded, and maintained.

3.2.5 Increasing GPEI Agency Technical Presence on the Ground in High Risk Areas

In addition to the Surge Support team, CDC has implemented a staffing deployment surge initiative to address ongoing outbreak and readiness needs. Approximately 100 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 that are at risk of cVDPV2 due to the widening outbreak in the Africa region. In country they support surveillance improvement, outbreak preparedness, and essential immunization strengthening to improve EPI and IPV coverage, leveraging Gavi investments in the countries. During the first half of 2020, other GPEI partners 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. RI intensification to reduce polio and other vaccine preventable disease risk longer term is being planned for several countries with the highest polio risk for vaccine derive poliovirus through the efforts of several GPEI agencies, and will be further prioritized through this effort.

3.2.6 Activating Emergency Response

cVDPV2 outbreaks will be declared as a national public health emergency and submitted for grading at level 2 according to the WHO Emergency Response Framework. This grading will provide additional flexibilities for fast-tracking work processes and for speedy service delivery. Processes 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 procedures. Various monitoring tools will be used to measure the program’s 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 agency country offices are able to rapidly execute emergency capacities in the field.

3.2.7 Streamline Processes of the Advisory Group on monovalent OPV2 Provision

The monovalent OPV2 Advisory Group was established by GPEI after the Switch to advise the Director General of WHO on the release of all mOPV2 globally. Operationally, within 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 in the context of this rapidly evolving type 2 epidemiology. There have been several instances where early outbreak planning at the country level has been misaligned with information needs of the mOPV2 AG or that has presented outbreak scope that is 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 locally planned responses align global priorities, align with current outbreak SOPs, and include all typical elements required by mOPV2 AG to complete a timely review. These changes will improve the quality of information available and make better use of the Advisory Group in the face of an increasing number of cVDPV2 outbreaks and limited vaccine supply. The AG Terms of Reference will be reviewed and aligned with this new Strategy with the goal of simplifying procedures and defining mechanisms to improve the speed of the review process.
4. VACCINE SUPPLY

The vaccine to respond to cVDPV2 outbreaks is provided through the Global Monovalent OPV Stockpile that was established by the World Health assembly in 2015, ahead of the global tOPV to bOPV switch.

To ensure uninterrupted supply of Sabin OPV2, GPEI developed a five-year Global mOPV stockpile plan based on the analysis of the current trends and past patterns of poliovirus outbreaks. Vaccine supply information in the current Strategy is drawn from that plan.

Several contingency risk mitigation measures are planned to assure consistent vaccine supply, including: 1) concurrent production of Sabin OPV2 and novel OPV2; 2) when necessary, employ dose sparing strategies, such as limiting campaign scope; 3) a Sabin OPV2 to novel OPV2 transition plan; 4) targeted use of IPV to increase population immunity to poliovirus, mitigate paralytic risk, and where warranted boosting gut immunity following OPV2 administration; 5) coordination with EPI and GAVI to provide RI intensification campaigns in high risk areas that border outbreak areas as an efficiency measure; 6) use tOPV in type 2 outbreak response; and 7) a contingency strategy that utilizes Sabin OPV2 in preventive SIAs and routine immunization in the event of Switch failure.

4.1 Vaccines in Stage 1: Sabin OPV2 and Inactivated Polio Vaccine (IPV)

4.1.1. Sabin OPV2 supply

To ensure an adequate supply of Sabin OPV2, in the face of the unpredictable cVDPV2 epidemiology, 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, GPEI must, in Q4 2019, invest $XX for the 2020 fill/finish supply and identify and contractually engage an additional Sabin OPV2 bulk supplier and a fill/finisher.

4.1.2. Managing a Limited Sabin OPV2 Supply

In Stage 1 of the Strategy, January 2020 – June 2020, 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 program has developed a prioritization scheme for managing the limited supply and proposes dose sparing measures, such reducing campaign scope (e.g. reducing population and/or age group) and, as a final contingency if supply is critically low, to temporarily employ a ‘one drop’ Sabin OPV2 vaccination response strategy.

4.1.2.1 Sabin OPV2 Prioritization scheme

Limited Sabin OPV2 supply will be prioritized in the following order:

1. cVDPV2 in areas where OPV2 has not been used recently (> 1 year)
   a. Expansion of a well-established outbreak to a new population
   b. A new outbreak (e.g. Kasai-Angola, Mozambique, Bauchi)
   c. If vaccine supply is critically low, consider revising the age group down in age

2. High risk areas near an ongoing outbreak (e.g., parts of DRC, Nigeria, Ethiopia, Benin)

3. cVDPV2 in areas where Sabin OPV2 has been used recently (< 1 year)
   a. Continuation of an ongoing outbreak (e.g. Yobe, Niger, Borno)
   b. If vaccine supply is critically low, consider adjusting the age group down in age

4. VDPV2
a. New emergence with unconfirmed circulation (e.g. Somalia 2017, China, Rawalpindi, etc).
Rapid risk assessment mandatory

Additionally:
- The monovalent OPV2 AG should not allow supply to go below 5m doses by responding to (2), (3), or (4)
- The monovalent OPV2 AG to scrutinize requested scope to assure best of use of limited vaccine.

4.1.2.2 Dose sparing strategies

1) Regulating campaign scope
   a. Restricted age group campaigns
      If Sabin OPV2 supply remains very tight then age restricted rounds may be considered for the response, particularly in instances where primary response rounds (Rounds 1 & 2) have already been conducted and included <5 years. The age range to be included should be defined based on local context and ensuring the most vulnerable groups are prioritized for vaccination.
   b. Restricting campaign scope
      If necessary, in conjunction with a restricted age group, areas will be prioritized based on risk assessment and local context including number of mOPV2 rounds in last 6-12 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. The rationale for one-drop strategy is provided in Annex C.

4.1.2.3 Proposed mechanism to implement dose sparing strategy
   i) GPEI will institute ongoing intensive monitoring of supply of monovalent OPV2, tracking projected supply versus projected demand.
   ii) These data will be made available to the OPRTT, EOMG and AG on a weekly basis.
   iii) When projected demand at any time in the future is projected to exceed projected supply minimum threshold (TBD but possibly 5-10M doses), the EOMG and AG will be alerted.
   iv) The EOMG will review the data and, if needed, recommend to the Strategy Committee that a supply emergency alert will be made.
   v) If the SC endorses the recommendation, the EOMG will set a date from which all new outbreaks will move to a one drop dosing for campaigns.
   vi) 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 1 drop dose.
   vii) Existing campaigns (i.e., vaccine supply was released from the stockpile before the alert) will continue with two drop dosing of OPV2.
   viii) To avoid equity issues and minimize confusion, the strategy would commence and terminate universally at the same time. In other words, whether a new outbreak was large or small, or in which ever region, it would apply equally.
This dose sparing strategy would not impact production planning as maximizing Sabin and novel OPV2 production will remain the strategy’s core goal.

4.1.3 Inactivated polio vaccine (IPV) use in outbreaks response and risk mitigation

Although, IPV use cannot stop cVDPV2 transmission, IPV can provide individuals a high-level of immunity and mitigate cVDPV2 paralytic risk. There are several, complementary, approaches to provide IPV to high risk populations, which include catch-up campaigns, PIRI, fIPV vaccination in outbreak zones and as a contingency vaccine if OPV2 supplies are exhausted. It is important to note that the highest priority use of IPV will be through routine immunization systems. It is anticipated that currently planned 2020 IPV stock will have approximately 6 million residual doses after fully providing for RI need, and therefore the scope of interventions described here, when not already provided for through the RI program, may be limited by stock available.

4.1.3.1 Accelerated catchup campaigns in countries with delayed introduction

At the time of the Switch, some countries with lower polio risk had delayed IPV introduction due to a limitation on the global IPV supply. IPV “catchup vaccination” was planned by GPEI to assure these countries received the IPV vaccination coverage prescribed by the GPEI end-game strategy. These campaigns have not always implemented on schedule, due to competing country priorities. For any country at high-risk of cVDPV2 exposure, catch-up vaccination should be prioritized and carried out at the earliest dates, with an emphasis on achieving high coverage in areas bordering a cVDPV2 outbreak. Gavi has resourced this activity, including the operational costs to support implementation of IPV SIAs in countries with a designated need.

4.1.3.2 Targeted use in Periodic Intensive Routine Immunization (PIRI) activities

By sharing resources and local information, strengthen collaboration with national immunization programs that leverage in-country Gavi support to deliver high quality targeted IPV campaigns through Periodic Intensive Routine Immunization activities. This will use routine stocks at the country level provide an opportunity 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.

4.1.3.3 In select outbreak situations, boost mucosal immunity after priming with Sabin OPV2

IPV can prevent paralytic risk and, additionally, may boost mucosal immunity in persons previously vaccinated with OPV2. Due to the high cost of IPV use compared with OPV use, and due to limited doses available for use in cVDPV2 risk mitigation, fractional dose IPV® (fIPV) will be utilized in response settings, and prioritized accordingly:

- 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

---

8 Full dose IPV will only be considered if country regulation does not allow use of intradermal IPV
Areas not infected, but at high risk of VDPV2 transmission, IPV may be used to build population immunity against type-2 poliovirus.

4.1.3.4 If mOPV2 supply is exhausted, expanded use in cVDPV2 responses

As a contingency measure in the event OPV2 supplies are exhausted, expanded use in cVDPV2 responses to mitigate paralytic risk.

4.1.3 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, GPEI has accelerated the development and emergency availability (in a process known as EUL) of novel OPV2.

The nOPV2 Working Group was recently created to manage and coordinate GPEI’s activities to enable a rapid and effective nOPV2 rollout. The Working Group’s responsibilities include developing overarching workplans and budgetary requirements for the following areas of work:

1. Research: Support clinical trials through provision of technical guidance and ensuring field operational needs.
2. Regulatory: Support fast-track submission under WHO’s Emergency Use Listing Procedure (EUL), and full licensorse, along with WHO prequalification.
3. Supply: Ensure the availability of nOPV2, in sufficient quantities, and establish risk mitigation strategies to ensure uninterrupted supply.
4. Implementation: Plan for the deployment, including prioritization of where to deploy; and provide technical guidance to countries for decision making and training, regulatory approvals and continued monitoring following use.
5. Communications: Ensure stakeholders and countries have timely and accurate information about nOPV2.

In addition to the nOPV2 Working Groups efforts, Regional Offices will work with their respective member states or national regulatory agencies to facilitate acceptance of novel OPV2.

4.1.4 tOPV Use in Outbreak Response

cVDPV typically occurs in populations with considerable gaps in polio immunity. While current cVDPV outbreaks are predominantly type 2, there are ongoing or recent cVDPV1 and cVDPV3 outbreaks. While the continued use of bOPV, which protects against polio type 1 and 3, in routine and supplemental immunization activities makes the relative risk of cVDPV1,3 emergence less than cVDPV2 currently, the populations experiencing cVDPV2 outbreaks typically are also at elevated risk for cVDPV1, cVDPV3, or WPV1. In some countries the length and large scale of Sabin OPV2 responses have displaced planned bOPV SIAs (e.g., Nigeria, DRC) or have had concurrent ongoing WPV1 circulation (Pakistan) or concurrent cVDPV1 or 3 (e.g., DRC; Somalia) complicating response planning due to alternating bOPV and Sabin OPV2 delivery. Further, 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, tOPV, which protects against all three types of polio, should be manufactured and at earliest availability (anticipated in Q2/Q3 2020) should be used in place of Sabin OPV2 for cVDPV2 response. Because the type 2 component of tOPV has high efficacy, the use of tOPV will not negatively impact type 2 outbreak responses and will have the added value of providing critical type 1 and 3 protection to these most vulnerable populations, with the only additional cost being 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 essential investment in the future, as it will reduce cVDPV1,3 risk in very vulnerable populations and potentially avert future outbreaks.

Because the program, at the time of the OPV2 withdrawal, 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 monovalent Sabin OPV2 production with tOPV production; 2) consult member states on tOPV use; and 3) initiate a 2020 WHA resolution to gain endorsement for its use. Assuming a Q4 2019 actions to procure it, tOPV could be available as early as mid 2020.

4.1.5 Vaccine Stockpile Risks during Period 1
There is a risk that there may be insufficient budget available for the stockpile. Mitigation activities include the following:

- Identify funding for the stockpile;
- Ensure mainstreaming of the stockpile budget into the GPEI FRR without further constraining programmatic budgets;
- Carry out 6-monthly reviews of the stockpile plan and budget to identify efficiencies that can be made.

There is a risk that use of Sabin OPV2 will need to be extended if novel OPV2 availability is delayed. Mitigation activities include:

- Support timely deployment of novel OPV2 by ensuring it is well planned and that a clear legal framework is in place.
- Facilitate the development of a roadmap for listing of novel OPV2 by the WHO pre-qualification team.
- Mainstreaming preparations for the deployment of novel OPV2 such as development of guidelines, training, integration of monitoring for pharmacovigilance and other EUL requirements into OBR operations

Prepare communications for both external and internal audiences involved in rolling out novel Sabin OPV2. Prepare for tOPV use in Outbreak Response in place of Sabin OPV2 (see above)

4.2 Vaccines in the Intermediate/ Period 2: novel OPV2 roll-out
During this period, the accelerated development and rollout of novel OPV2 in 2020/21 will lead to it replacing Sabin OPV2 in the stockpile, if effectiveness of novel OPV2 is confirmed during large scale deployment. As shown in Figure 2, novel OPV2 and Sabin OPV2 production is scheduled to be manufactured concurrently to assure that if nOPV2 fails, Sabin OPV2 will be available. Because novel OPV2 production is not subject to containment, there is the potential to diversify the supplier base.

Vaccine production schedules outlined in Figure 2 will be periodically reviewed and adjusted as needed.

9 Countries that do not use bOPV in routine immunization or through annual supplemental immunization activities may prefer using monovalent OPV2 to respond to cVDPV2 outbreaks to negate possible seeding of VDPV1/3
Until supplies are adequate to wholly replace Sabin OPV2, use of novel OPV2 will need to be prioritized. The nOPV2 Working Group will develop prioritization strategies that may include considerations, such as:

- Priority use in outbreak response in areas that had not been exposed to live type 2 vaccine in the past two years, to minimize the areas at highest risk of emergence of new VDPV2.
- Secondly, in outbreak response in areas surrounding cVDPV2 outbreaks that had not been exposed to live type 2 vaccine in the past 2 years.
- Thirdly, other outbreak response areas

There are currently two candidate viruses developed for novel OPV2, with candidate 1 selected as the first to manufactured at risk. To account for the potential delay or failure of one or both of the novel OPV2 candidates, the plan factors in scale up of Sabin OPV2 production as a contingency measure. Operating within a delay or failure scenario, Sabin OPV2 would likely need to be used in large geographies for an indefinite period of time.

4.2.1 Period 2: Vaccine Stockpile Risks and Mitigation Measures

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

Risk: Novel OPV2 candidate 1 failure

Mitigation activities:
- Put in place plans for acceleration of candidate 2 deployment;
- Adjust the Global Stockpile plan and budget to account for potential 18 months delay of the novel OPV2 (candidate 2) rollout;
- OBR operations (and SOPs/Guidance, training) will need to be adjusted to account for withdrawal of the Novel OPV2 (candidate 1) and reliance on Sabin OPV2/tOPV solely for the period until candidate 2 is ready.
Risk: BioFarma halts production to meet other national demands
Mitigation activities:
- Shift filling of novel OPV2 bulk to alternative supplier (India);
- Carry out EUAL of the novel OPV2 filled in India (need to be initiated ASAP).

Risk: Stockpile budget shortage
Mitigation – as above in Period 1

Risk: Sabin OPV2 Stockpile Shortage
Mitigation: Increase filling capacity and consider expanded IPV where it will mitigate paralytic risk while Sabin OPV2 stockpile is resupplied

4.3 Vaccines in the Final / Third Period (2021 and beyond)
During the final period of the Strategy Novel mOPV2 will replace Sabin mOPV2 with in the stockpile. Large scale Novel mOPV2 use will the primary tool to stop cVPDV2.

4.3.1 Third Period Risks: Failure of novel OPV2
The main risk in the final period of the strategy is it has an very delayed start or cannot commence because the introduction of novel OPV2 fails either through lack of immunogenicity or, production failures. Risks in the intermediate period and final period are mostly the same. If novel OPV2 fails to control outbreaks or transmits and becomes neurovirulent, 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 will be developed as a contingency in 2020. The current document provides contingencies in each Stage to prepare for that scenario, while focusing on efforts to avert it.

Other third period risks include:
- **Failure to secure adequate novel OPV2 supply and therefore a delay or lack of entry into Stage 3**
  Mitigation – as above and also implementing contingencies that likely include broad, longer term sabin OPV2 use
- **BioFarma halts production to meet other national vaccine demands**
  Mitigation – as above
- **Stockpile Budget Shortage**
  Mitigation – as above
- **Sabin OPV2 Stockpile Shortage**
  Mitigation – Employ IPV strategically to mitigate paralytic risk while rebuilding the sabin OPV2 stockpile
5. EARLY DETECTION OF NEW OUTBREAKS

High-quality poliovirus surveillance is critical not only to achieving early detection of events and outbreaks, it is necessary to understand the geographic scope of circulation and essential to the determination of the scope of response. Compared to WPV1, the case to infection ratio in a susceptible population is approximately 90% lower with cVDPV2 (paralytic rate is 1:2,000 for type 2). A robust surveillance system is critical to enable timely detection of ongoing circulation, which enables a rapid and appropriately sized response.

5.1 Determining priority areas

Surveillance resources should be prioritized to areas bordering an area of known circulation and Sabin OPV2 use, or other high-risk areas based on large population movements. Early detection in these bordering areas provide an opportunity for more rapid response and therefore limiting spread.

The risk of emergence of a type 2 event in the first years following the Switch in 2016 was associated with low routine immunization coverage in areas also not well covered by tOPV supplementary immunizations prior to the switch. In 2019, the risk of emergence of a type 2 event has been associated with variable quality outbreak response SIAs in response zones or areas without ongoing responses with geographic proximity to ongoing response zones. Given population movements, geographic spread of cVDPV2 outbreaks are now a broad risk because >3 birth cohorts have no intestinal immunity to type 2 poliovirus, so countries bordering outbreaks are at high risk for new emergence or extension of the outbreak.

Other priority areas include:
- Areas with primary immunodeficiency incidences that have historically used tOPV remain a potential source of new type 2 outbreaks
- Conflict-affected areas and areas with other destabilizing challenges
- Countries and regions that have been polio-free with declining surveillance quality

5.2 Priority surveillance activities to enable early detection of cVDPV2

With the aim of ensuring early detection, the program will expand investment in surveillance strengthening in areas at high-risk for cVDPV2, which has already begun with implementation of GPEI’s Global Surveillance Action Plan for 2018/2020. Specific surveillance actions and activities that are described in Annex C will be implemented in the next 12 months.

5.2.1 Improve AFP surveillance quality

GPEI will aim to improve AFP surveillance quality in the highest risk countries for cVDPV2 through targeted investment in training, capacity building, and improvement in active and passive surveillance. Surveillance support will include:
- Desk reviews in the highest risk countries by December 2019, and in remaining high-risk countries by January 2020
- Field surveillance reviews in highest risk countries by June 2020
- Field support and capacity building in the highest risk countries
5.2.2 Expand environmental surveillance

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. ES support will include:

- Desk quality review of all highest risk countries by April 2020
- Field reviews in many risk countries
- Expansion plan prioritizing at least six high risk countries by April 2020, focusing on major population centers and trade routes etc.
- Laboratory capacity for ES documented and contingency planning for increases in work load
- Identify resource needs for the expansion plan

5.2.3 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 enhancing coordination, improving management, oversight and accountability.

5.3 Laboratory Surveillance for early detection and response to cVDPV2 outbreaks

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

Of 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 to such a laboratory within the Region where they reside, with well-established stool specimen referral systems.

5.3.1 Laboratory Surveillance Priorities for the next 12-18 months

Detection

- Fast-track pilot-testing and parallel testing of direct detection (DD) of PV from stool specimens, to be used instead of current cell-culture-based poliovirus detection, by Q3 2020. Its implementation may reduce laboratory turn-around time from 28 days to 4-7 days.
- Begin introduction of DD by end of 2020, with priority given to laboratories serving cVDPV2 outbreak/high-risk countries
- Identify resources to implement the DD testing, which is not possible to accomplish with the current laboratory resources

Outbreak Control using novel OPV2

- Standard ITD testing will detect novel OPV2 candidate strains and specific assays developed by US CDC can differentiate the two novel OPV2 candidates. However, a new nomenclature and reporting scheme will be established to further distinguish PV2s
- Standard GPLN sequencing protocol can be used for definitive identification of novel OPV2 candidate strains, in addition to current PV2 strains
6. COMMUNICATION AND PROMOTION OF THE STRATEGY

Successful Strategy implementation will require targeted communication to implementers, partners and the public. To coordinate the efforts of GPEI’s communication teams, a time-limited working group has been formed to design and implement the various communication components of this strategy. The working group consists of experts in external communication, advocacy and donor relations, Communication 4 Development, training, internal communication and technical fields.

6.1 Key Communication Risks during Strategy Implementation

- Continued circulation and spread of VDPV2s and lack of a well-articulated global narrative explaining the current situation may result in waning confidence in GPEI
- Introduction of dose sparing strategies may impact program decision making and adversely impact field level delivery of vaccine, as well as alter public perceptions of vaccine dose efficacy and/or safety
- Introduction of new vaccine under emergency use listing may trigger doubts of vaccine safety, bioethical considerations of use, and in case of adverse effects, cause fallout in vaccine confidence;
- Success of novel OPV may negatively impact demand for Sabin OPV2 before nOPV2 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 GPEI.

6.2 External Communication and Public Relations Tactics

Building support for the Strategy will require strategic engagement with key audiences. Key stakeholders and target groups include:

- WHO governing bodies: the proposed Strategy links with resolution WHA 71.16 and WHA68.3 and should be presented and discussed at Regional Committee Meetings, Executive Board Meetings and the World Health Assembly
- Outbreak affected and at-risk countries: NRAS, Ministries of Health and EPI program managers and polio teams
- GPEI oversight mechanism and advisory groups: Independent Monitoring Board, monovalent OPV2 Advisory Group, Containment Advisory Group, Polio Research Committee
- Vaccine producing countries: manufacturers (public and private), National Regulatory Authorities, National Authorities on Containment
- GPEI Partners
- WHO advisory bodies: including, Polio IHR committee, SAGE, Global and Regional Certification commissions, Technical Advisory Groups.

External communication engagement tactics will include:

- Engage world 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 roll-out a vaccine switch (e.g. Sabin to Novel OPV2) and dose sparing strategies
- Sensitize donors individually and request their advocacy with countries
- Design an updated global narrative on cVDPV to dispel myths/rumours
- To build support amongst the scientific community, engage public health experts through SAGE, GPEI, Gavi, WHO, CDC platforms
Sensitize public health and science journalists and gatekeepers in mainstream international media through one-on-one engagement

Develop reactive crisis communication response protocols to manage communication issues associated with real or perceived Adverse Events from Immunization (AEFI) for either Sabin or novel OPV2.

6.3 Communication Development

The Strategic Communications WG and its partners will continue the C4D goal to create an enabling environment for sustained polio vaccine uptake and broader immunization as a social norm, resolve vaccine doubts, address social barriers and misperceptions, 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
- Health practitioners and community health physicians
- Private health practitioners and clinics
- Frontline workers and vaccinators
- Health reporters and journalists
- Online influencers, b/vloggers and opinion leaders on health
- Parent groups in digital spaces and social media
- Parents and caregivers

Engagement tactics will include (in the order of priority)
- Desk reviews and synthesis of the existing concerns and social barriers in regard to Sabin OPV2 use in countries; for novel OPV2 draw from experience of IPV introduction
- Rapid communication research among target audiences about their perceptions and questions concerning nOPV2 and dose sparing strategies
- Prototyping and piloting communication approaches and products on the ground
- Sensitization of national health authorities, expert health community and roll-out of orientation to community level health practitioners
- Development of training modules; training of frontline workers and vaccinators to administer new vaccine or new delivery protocols (e.g. co-administration); build capacity to respond to parental inquiries
- One-on-one and small group engagement in digital space with health influencers
- Preparedness and response to the alleged AEFI at community level – early warning and listening, pre-engagement of health influencers and practitioners
- Closely track public acceptance of nOPV2; evaluation, documenting experience for replication in other contexts

6.4 Internal Communication Tactics

Internal communication efforts aim to ensure strategic coherence, synergy and clarity among GPEI stakeholders and program implementers, to support a successful Strategy roll-out.

Internal Comms Tactics
- Assure all program participants can easily access the Strategy
- Develop and roll-out GPEI webinar on the essentials of the new strategy
- Country and regional level technical assistance and support prior to roll-out, including technical orientations
- Develop and provide ROs and COs Strategy relevant communication resources
- Development and roll-out of feedback/resolution mechanism
OVERSIGHT AND MONITORING OF THE STRATEGY

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 Strategy to account for changing factors, such as epidemiological, vaccine supply and resource mobilization developments.¹¹

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**: Support Governments in implementing their outbreak responses and other polio activities in regions/countries.
- **OPR TT**: Outbreak response, including surveillance strengthening during outbreaks, and secretariat responsibility to the monovalent OPV2 Advisory Group
- **STT**: Early detection, risk assessment, outbreak preparedness, and enhancing surveillance activities in high risk countries, and sustaining surveillance after outbreak response
- **VSTT**: Vaccine forecasting and stockpile management for Sabin OPV2 and novel OPV2
- **mOPV2 AG**: Determine need and scope for mOPV2 use in individual outbreaks and provide Director General WHO recommendation for mOPV2 release.
- **nOPV2 WG**: lead novel OPV2 introduction scheduling, country use approvals
- **cVDPV2 Strategy Comms Team**: Communication strategy design and execution
- **CRTT**: Technical assessment of global risk and technical guidance on response
- **FMT**: Financial management
- **EPI and GAVI**: IPV catchup campaigns, routine immunization (RI), and RI intensification activities in targeted geographies

¹¹ A calendar of global meetings that may be relevant to the Strategy’s acceptance are listed in Annex B
Annex B: BACKGROUND ON THE GLOBAL STOCKPILE

The global stockpile of monovalent OPV2 is an essential component of the strategy. The establishment of this stockpile was one of the prerequisites for the switch from tOPV to bOPV laid out by the Strategic Advisory Group of Experts on Immunization (SAGE), and the stockpile was operationalized in 2015. Since the tOPV to bOPV switch in 2016 347 million doses of Sabin OPV2 were released to eighteen countries affected by VDPV2 outbreaks and events of which 262mds were 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 GPEI strategy committee as a core component of the Global Sabin OPV2 stockpile plan and budget. Considering the benefits of using nOPV2 compared to Sabin OPV2, it is now considered that its use be phased out during novel OPV2 rollout.

12 Angola, Benin, Nigeria, Niger, Chad, CAR, Ghana, Cameroon, Pakistan, Philippines, Mozambique, DRC, Syria, Somalia, Ethiopia, Kenya, Togo, Zambia
Within the GPEI structure, the Vaccine Supply Task Team (VSTT), co-led by WHO and UNICEF is responsible for the management of the mOPV stockpiles. Amongst others, its functions include quarterly reviews of the stockpile status, forecasting and planning of the mOPV supply, and identification and addressing of risks to mOPV supply for responses to polio outbreaks. The VSTT reports directly to the GPEI’s Eradication and Outbreak Management Group (EOMG) while decisions regarding the replenishment of the stockpile are escalated from the VSTT to the GPEI Strategy Committee (SC) via 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. 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 manage the stockpiles jointly, based on legal agreements and an SOP regulating roles and responsibilities between the two agencies. This framework enables UNICEF Supply Division 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. This relies on GPEI’s management and financing.

- Vaccine needs were estimated based on a set of empirical scenarios that considered 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 to be utilized in outbreak mitigation responses 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 Assessment and Listing (EUAL) will be secured by July 2020 and will not delay rollout of novel OPV2
- GPEI will operationalize dose sparing strategies (one drop Sabin OPV2, Sabin OPV2 prioritization schemes etc). 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
Strategy to Control cVDPV2s, 2020 –2021
Draft for Comments, 16 December 2019

− Implementation of the plan will require restarting Sabin OPV2 bulk production in 2020
− Bulk production of Sabin OPV2 is not affected by competing priorities at Biofarma for measles bulk production
− Biofarma produces novel OPV2 in 50 dose vials.

Critical Enablers
− GPEI negotiates additional Sabin and novel OPV2 bulk production and filing capacities asap
− dose sparing strategies and their triggers are agreed in advance and operationalized if GPEI does not source additional filling capacity
− EUAL of novel OPV2 is candidate 1 is secured by June 2020
− Updated OBR SOPs include clear parameters for Sabin OPV2 and Novel OPV2 SIAs
− Novel OPV2 acceleration and distribution plan is developed aligned with the updated OBR SOPs before June 2020
− Agreement on the size of the monovalent OPV2 stockpile buffer calibrated to the expected outbreak response

Fast tracking novel OPV2 production and licensure using EUAL

Because of the serious risk of seeding more emergences of VDPV2 and the risk of shortages of Sabin OPV2 severely affecting outbreak response, GPEI as a top priority will facilitate fast tracking of the development and emergency availability (in a process known as EUAL) of novel OPV2

Emergency Use Assessment and Listing (EUAL) 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 EUAL, 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 EUAL list should not compromise such trials. WHO has developed the EUAL procedure to expedite the availability of medicines needed in public health emergency situations. The EUAL 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 EUAL, 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). This is the case for cVDPV since 2015.
− Based on the contingencies of the specific public health emergency, it is reasonable to consider a medicine for EUAL assessment e.g., there are no medicines that have undergone comprehensive premarket regulatory assessment for the indication or for a critical subpopulation, or there is a specific shortage of such medicine.
− The medicine is manufactured in compliance with current Good Manufacturing Practices (GMP). If a manufacturer has a documented acceptable history of quality manufacturing of medicines, WHO may waive the requirement for conducting an on-site inspection
The applicant attests that it intends to complete the development of the product 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 EUAL.

**Expected timeline for completion of this process for novel OPV2**

- Receipt of additional product information required (Q4 2019)
- Establishment of the evaluation committee with members from a roster of experts. (Q4/2019)
- 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 quality and clinical data (Q2/2020)
- Assessment of complete data (Q3-Q4/2020)

![Global Monovalent OPV2 Stockpile Budget](image)

**FIGURE 1: GLOBAL MONOVALENT OPV2 STOCKPILE BUDGET**

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$1,173,382</td>
<td>$349,995,986</td>
<td>$341,246,335</td>
<td>$295,673,798</td>
<td>$1,104,849,501</td>
</tr>
</tbody>
</table>
Annex C: ONE-DROP VACCINATION CONTINGENCY MEASURE TO PRESERVE mOPV SUPPLY

To assess whether the available Sabin OPV2 could have expanded reach through use of one drop of vaccine instead of two, a small field trial was performed in Mozambique to compare the immunogenicity of one drop of vaccine to the standard two drop dose. Based on the results of this study and the assumption that one drop of vaccine was a better option than giving no vaccine, SAGE, during its meeting in October 2019, endorsed using one-drop Sabin OPV2 strategy when the vaccine supply reaches critically low levels and is not sufficient for cVDPV2 outbreak control. What constitutes “critically low level” was not defined.

Using one drop of vaccine, assuming it is almost as effective as the classic two drop dosage in the context of multiple administrations provided during outbreaks, is critical to consider when demand is likely to outstrip supply. There are a number of advantages as follows. It avoids the disastrous situation where an outbreak cannot be responded to at all do to a global Sabin OPV2 vaccine stockout. It also saves costs and avoids restricting vaccine campaigns simply to preserve the stockpile, and potentially increases the number of children who can be vaccinated by a substantial margin, depending on acceptability and compliance among vaccinators, parents, EPI programs, and governments. Disadvantages include reputational risk to the GPEI, confusion and non-compliance in the field, uncertainty about triggers to implement it, equity issues and possible effects of all these factors on campaign quality, and local outages if planning figures are based on one-drop but field teams continue to administer two-drop doses. Communication activities will be essential to managing these perceptions (see section 6).
### Annex D: CALENDAR OF KEY COMMITTEES AND ADVISORY GROUP MEETINGS

The calendar below shows scheduled meetings that may have relevance to the Strategy.

<table>
<thead>
<tr>
<th>Month</th>
<th>Committee</th>
<th>Agenda</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2019</td>
<td>PPG meeting</td>
<td>Awareness raising/building consensus in WHO governing bodies and partnership. Possible first presentation of strategy</td>
</tr>
<tr>
<td>December 2019</td>
<td>IHR</td>
<td>Decision on continuation of PHEIC, possible further recommendations on outbreak response</td>
</tr>
<tr>
<td>January 2020</td>
<td>Pre EB-briefing</td>
<td>Awareness raising/building consensus in WHO governing bodies (tb assessed)</td>
</tr>
<tr>
<td>February 2020</td>
<td>Stakeholder consultation</td>
<td>Better understanding of how countries can prevent and stop type 2 outbreaks</td>
</tr>
<tr>
<td>3-8 February 2020</td>
<td>Executive Board</td>
<td>Report on Polio eradication, consensus on direction of strategy, possible presentation of strategy First potential moment for resolution/decision related to stopping outbreaks</td>
</tr>
<tr>
<td>February 2020</td>
<td>IHR committee</td>
<td>Decision on continuation of PHEIC, possible further recommendations on outbreak response</td>
</tr>
<tr>
<td>March 2020</td>
<td>African RCCPE</td>
<td>Recommendations on countries with outbreaks in WHO African Region</td>
</tr>
<tr>
<td>March 2020</td>
<td>Gavi Board retreat</td>
<td>May not have polio on agenda,</td>
</tr>
<tr>
<td>Q1 2020</td>
<td>SAGE WG on polio</td>
<td>Key topics for consideration at SAGE, could include update, discussion on increased use of IPV</td>
</tr>
<tr>
<td>31 March to 2 April 2020</td>
<td>SAGE meeting</td>
<td>Further recommendations on mOPV use and IPV for outbreak response and novel OPV2</td>
</tr>
<tr>
<td>20 – 28 May 2020</td>
<td>WHA</td>
<td>Recommitment to polio eradication Discussions with affected/outbreak countries, either bilaterally or through joint meetings/side events</td>
</tr>
<tr>
<td>May 2020</td>
<td>IHR committee</td>
<td>Decision on continuation of PHEIC, possible further recommendations on outbreak response</td>
</tr>
<tr>
<td>June 2020</td>
<td>Gavi Board</td>
<td>May not have polio on agenda,</td>
</tr>
</tbody>
</table>
Annex E

SURVEILLANCE ACTIVITIES

Table 2. Specific activities for 2020/2021:

<table>
<thead>
<tr>
<th>Objective 1. Strengthen AFP surveillance in priority countries</th>
<th>Expected deliverables in next 18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specific action</strong></td>
<td><strong>Expected deliverables in next 18 months</strong></td>
</tr>
<tr>
<td>Surveillance data review</td>
<td>Complete desk review of AFP surveillance performance for priority countries (Due, West and Central Africa December 2019; all other priority countries, January 2020). Publish a detailed sub-national surveillance performance map for AFR, EMR, SEAR, and WPR regions and flag potential ‘blind spots’ (January 2020)</td>
</tr>
<tr>
<td>Detailed desk review of AFP surveillance quality for all outbreak and other high-risk countries</td>
<td></td>
</tr>
<tr>
<td>Assessment of surveillance quality at the sub-national level in all outbreak and other high-risk countries; review will include sub-national AFP surveillance data analysis</td>
<td></td>
</tr>
<tr>
<td><strong>Field surveillance review</strong></td>
<td></td>
</tr>
<tr>
<td>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</td>
<td>AFP surveillance quality audit carried out in at least 8 countries (Due June 2020)</td>
</tr>
<tr>
<td>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</td>
<td>Reviewed surveillance needs in at least 4 conflict-affected countries including Yemen, and South Sudan</td>
</tr>
<tr>
<td>Evaluate needs in all areas affected by conflict, insecurity, inaccessibility and/or other challenges; review ongoing surveillance activities e.g. community-based surveillance</td>
<td>Implemented country-specific polio surveillance enhancements plans based on results and recommendations from desk and field surveillance reviews (Due October 2020). Establish mechanism for enhanced country-level data analysis to guide surveillance activities</td>
</tr>
<tr>
<td><strong>Field support and capacity building</strong></td>
<td>Complete cascade training for at least 8 priority countries (Due, April 2020)</td>
</tr>
<tr>
<td>In coordination with the Regional Office, carry out cascade AFP surveillance training for priority countries</td>
<td>From the global and regional resource pool, provide field support through the extended deployment of technical officers to at least 6 countries at imminent risk of cVDPV2 outbreaks and sub-nationally for countries with outbreaks</td>
</tr>
<tr>
<td>Deploy external field surveillance technical support to priority countries at high-risk of cVDPV2 importation and/or emergence of type 2 outbreaks</td>
<td>Expand the use of ISS, eSurv, and other ODK-based active surveillance monitoring tools</td>
</tr>
<tr>
<td>Map and expand active and passive surveillance network and encourage the adoption of technology to monitor active surveillance visits</td>
<td></td>
</tr>
<tr>
<td>Objective 2. Enhance environmental surveillance</td>
<td>Use new technologies and innovations to provide evidence for impact of field support and capacity-building</td>
</tr>
<tr>
<td>Specific action</td>
<td>Expected deliverables</td>
</tr>
<tr>
<td>ES quality in existing sites</td>
<td>Review the performance of all operational ES sites in 2019, flag underperforming sites to regional office and respective countries and Develop specific quality improvement plans by country Expand the skills of all field surveillance officers in priority countries with Environmental Surveillance by including ES in planned trainings</td>
</tr>
<tr>
<td>Desk ES quality reviewed carried out in all priority countries (Due, April 2020) With the support of the global and regional teams, field and laboratory surveillance assessment followed by full implementation of recommendations completed in at least 6 priority countries All surveillance desk reviews, field reviews, field and laboratory support missions, and trainings include ES (January 2020)</td>
<td></td>
</tr>
<tr>
<td>Strategic expansion of ES network</td>
<td>Review the status of ES in sub-regions with ongoing cVDPV2 outbreaks and explore for potential new sites To ensure lab capacity is optimally utilized, rationalize existing by, where possible, ensuring a more diffuse distribution of sites across key population centres 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)</td>
</tr>
<tr>
<td>Field and laboratory assessment for potential ES expansion assessed in at least 6 new countries (Due, April 2020) 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) 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 6 months at a time (Due, June 2020) A budgeted and time-bound global plan to create ES hubs in AFR, EMR and WPR is proposed (Due March 2020)</td>
<td></td>
</tr>
<tr>
<td>Objective 3. Shorten duration between sample collection and availability of final lab results</td>
<td>Decrease time-to-results Ensure all samples in priority countries are received at the 1st testing lab within 7 days of collection Decrease the time taken between samples reaching lab to receipt of final results</td>
</tr>
<tr>
<td>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 January 2020) Depending on findings, develop and implement a specific action plan to address challenges associated with key contributors to delay. Depending on final validation of direct detection of PV from stool samples and resources availability: (i) Explore the potential for the accelerated implementation of molecular detection in selected regions</td>
<td></td>
</tr>
</tbody>
</table>

---

**Strategy to Control cVDPV2s, 2020 – 2021**

**Draft for Comments, 16 December 2019**
<table>
<thead>
<tr>
<th>Specific action</th>
<th>Expected deliverables in next 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strategic alignment</strong></td>
<td>- Revised priority countries map published (Due December 1\textsuperscript{st} 2019) \n- Priority countries map reviewed and where necessary updated every quarter (Due February, June, October and December 2020) \n- New Global Polio Surveillance Action Plan for 2021/2023 (Due December 2020)</td>
</tr>
<tr>
<td>In coordination with the regional office review and revise global country prioritization</td>
<td></td>
</tr>
<tr>
<td>Depending on the evolving epidemiology, on a quarterly basis, review and where necessary update priority countries for surveillance strengthening</td>
<td></td>
</tr>
<tr>
<td>Ensure new Global Surveillance Action Plan for 2021/2023 fully takes into account and builds on the new VDPV2 strategy</td>
<td></td>
</tr>
<tr>
<td><strong>Outbreak country support</strong></td>
<td>- All countries with ongoing outbreaks have dedicated surveillance focal person (Due January 2020) \n- Review and complete 12-month surveillance action plan for all outbreak countries in Phase 2 (Due March 2020) \n- Integrate post-outbreak surveillance support for countries with no ongoing circulation for at least 12 months (Due January 2020)</td>
</tr>
<tr>
<td>Facilitate the deployment of at least one surveillance coordinator to all outbreak countries</td>
<td></td>
</tr>
<tr>
<td>For all outbreak countries in Phase 2 of their outbreak response, in close coordination with the outbreak preparedness and response task team, support countries to develop extended surveillance enhancement plans</td>
<td></td>
</tr>
<tr>
<td>Support the transitioning of countries from enhanced polio surveillance during outbreaks to maintaining high quality surveillance post-outbreak</td>
<td></td>
</tr>
</tbody>
</table>