Circulating vaccine-derived polioviruses

Global update

A new approach to control cVDPV2
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acronyms and abbreviations</td>
<td>v</td>
</tr>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Circulating vaccine-derived polioviruses explained</td>
<td>3</td>
</tr>
<tr>
<td>Responding to circulating vaccine-derived polioviruses in the context of COVID-19</td>
<td>7</td>
</tr>
<tr>
<td>Vaccine solutions for protection against poliovirus type 2</td>
<td>13</td>
</tr>
<tr>
<td>Novel oral polio vaccine type 2 roll-out explained</td>
<td>17</td>
</tr>
<tr>
<td>The role of Member States</td>
<td>20</td>
</tr>
<tr>
<td>Annex</td>
<td>22</td>
</tr>
<tr>
<td>Acronyms</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>AFP</td>
<td>Acute flaccid paralysis</td>
</tr>
<tr>
<td>bOPV</td>
<td>Bivalent oral polio vaccine</td>
</tr>
<tr>
<td>CDC</td>
<td>US Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>cVDPV</td>
<td>Circulating vaccine-derived poliovirus</td>
</tr>
<tr>
<td>cVDPV2</td>
<td>Circulating vaccine-derived poliovirus type 2</td>
</tr>
<tr>
<td>eIPV</td>
<td>Enhanced potency IPV</td>
</tr>
<tr>
<td>EUL</td>
<td>Emergency Use Listing</td>
</tr>
<tr>
<td>GPEI</td>
<td>Global Polio Eradication Initiative</td>
</tr>
<tr>
<td>IHR</td>
<td>International Health Regulations</td>
</tr>
<tr>
<td>IPV</td>
<td>Inactivated polio vaccine</td>
</tr>
<tr>
<td>mOPV2</td>
<td>Monovalent oral polio vaccine type 2</td>
</tr>
<tr>
<td>nOPV2</td>
<td>Novel oral polio vaccine type 2</td>
</tr>
<tr>
<td>OPV</td>
<td>Oral polio vaccine</td>
</tr>
<tr>
<td>OPV2</td>
<td>Oral polio vaccine type 2</td>
</tr>
<tr>
<td>SAGE</td>
<td>Strategic Advisory Group of Experts on Immunization</td>
</tr>
<tr>
<td>tOPV</td>
<td>Trivalent oral polio vaccine</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
</tr>
<tr>
<td>VLP</td>
<td>Virus-like particles</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WPV</td>
<td>Wild poliovirus</td>
</tr>
<tr>
<td>WPV1, 2, 3</td>
<td>Wild poliovirus types 1, 2, 3</td>
</tr>
</tbody>
</table>
Introduction

The global effort to eradicate polio has seen tremendous successes as a result of the Global Polio Eradication Initiative (GPEI), spearheaded by national governments, WHO, Rotary International, the US Centers for Disease Control and Prevention (CDC), UNICEF, the Bill & Melinda Gates Foundation and Gavi, the Vaccine Alliance. Wild poliovirus (WPV) has been reduced by 99%, from more than 350,000 cases every year in 1988 when the effort was launched in more than 125 endemic countries worldwide, to just two endemic countries (Pakistan and Afghanistan) in 2020. Two of three WPV serotypes have been certified as globally eradicated, and five of six WHO regions have been certified as free of all WPV.

However, the goal of the GPEI is to ensure that no child is ever paralysed again by any poliovirus – be it wild or vaccine-derived and, in 2019, a new challenge to this goal emerged: an increasing public health emergency due to circulating vaccine-derived poliovirus type 2 (cVDPV2). By August 2020, 323 cases of cVDPV2 and 84 cVDPV2-positive environmental samples were reported from 20 countries globally, primarily from Africa, but also from Pakistan and Afghanistan and the Philippines.

In all instances, the continued spread of existing outbreaks as well as the emergence of new cVDPV2 point to gaps in routine immunization coverage in addition to the insufficient quality of outbreak response with monovalent oral polio vaccine type 2 (mOPV2). The risk of further spread of such strains, or the emergence of new strains, is magnified by an ever-increasing global mucosal-immunity gap to type 2 poliovirus and dropping immunization rates related to COVID-19.

In 2019 and early 2020, the GPEI developed the Strategy for the Response to Type 2 Circulating Vaccine-Derived Poliovirus 2020-2021 to more effectively address the evolving cVDPV2 epidemiology. In decision EB146(11), the WHO Executive Board at its 146th session endorsed the main elements of this strategy. This decision emphasizes the importance of accelerating the assessment and roll-out of a novel oral polio vaccine type 2 (nOPV2), including through the WHO.
Emergency Use Listing (EUL) procedure, and calls on Member States to expedite national processes to enable the importation and use of this vaccine. It also calls on Member States to mobilize domestic financial resources to contribute to outbreak response efforts. The broader mix of new vaccine solutions will enable the programme to respond to a given situation in the most effective manner.

Ongoing circulating vaccine-derived poliovirus (cVDPV) outbreaks highlight the urgent need to continue the work of polio eradication. It is important to remember that cVDPV outbreaks occur in areas with under-immunized populations and that cVDPVs are not related to, nor indicative of, a re-emergence of WPV. The detection of cVDPV2 underscores the importance of maintaining high routine vaccination coverage everywhere to minimize the risk and consequences of any poliovirus circulation. These events also underscore the risk posed by any low-level transmission of the virus. A robust outbreak response is needed to rapidly stop circulation and ensure sufficient vaccination coverage in the affected areas to prevent similar outbreaks in the future. WHO will continue to evaluate the epidemiological situation and outbreak response measures being implemented.

This briefing document provides key definitions to complex terminology related to the topic of polio eradication. The document covers the current situation with vaccine-derived poliovirus outbreaks in the context of COVID-19 and explains the immediate steps the GPEI is taking right now to better address the evolving threat of cVDPVs.
What is polio?

Poliomyelitis (polio) is a highly infectious viral disease that mainly affects young children. The virus is transmitted through person-to-person contact and spreads mainly through the faecal-oral route or, less frequently, by a common vehicle (e.g. contaminated water or food). It multiplies in the intestine, from where it can invade the nervous system and can cause paralysis and death.

Initial symptoms of polio include fever, fatigue, headache, vomiting, stiffness in the neck and pain in the limbs. In a small proportion of cases, the disease causes paralysis, which is often permanent. There is no cure for polio; it can only be prevented by immunization.

Polio is caused by a human enterovirus called the “poliovirus”. Polio can interact in its host in two ways:

- infection not including the central nervous system, which causes a minor illness with mild symptoms; and
- infection including the central nervous system, which may cause paralysis.

Less than 1% of poliovirus infections result in paralysis. Poliovirus enters through the mouth and multiplies in the intestine. Infected individuals shed poliovirus into the environment for several weeks, where it can spread rapidly through a community, especially in areas of poor sanitation. The three serotypes of WPV, type 1 (WPV1), type 2 (WPV2) and type 3 (WPV3), each have a slightly different capsid protein. Immunity to one serotype does not confer immunity to the other two.

WPV2 was declared eradicated in September 2015, with the last virus detected in India in 1999. WPV3 was declared eradicated in October 2019. It was last detected in November 2012. Only WPV1 remains.
cVDPVs are well-documented strains of poliovirus sometimes found in populations that are poorly vaccinated. They are called “vaccine-derived” because they are a changed form of a strain originally contained in oral polio vaccine (OPV). OPV contains a live, weakened form of poliovirus. On rare occasions, when replicating in the human gut, OPV strains genetically change and may spread in communities that are not fully vaccinated against polio, especially in areas where there is poor hygiene, poor sanitation or overcrowding. Further changes occur as these viruses spread from person to person and, if one is allowed to continue to spread in an under-immunized population, over time it may genetically change to the point where it regains the ability to cause paralysis, giving rise to a cVDPV. Experience shows that low polio immunization coverage is the key risk factor for the emergence and spread of a cVDPV. If OPV is administered to only a few in a large susceptible population, the vaccine virus can continue to multiply, genetically change and spread in those not vaccinated. A population that is fully immunized will be protected against the change and spread of this virus.
The cVPDV2 AFP cases in 2019

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data source: WHO
Map production: 21 September 2020

World Health Organization
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In 2019 and early 2020, the GPEI put in place the **Strategy for the Response to Type 2 Circulating Vaccine-Derived Poliovirus 2020–2021** for the short, medium and long term to more effectively address the evolving cVDPV2 epidemiology. It was developed by a working group and in consultation with experts across the GPEI partnership.

This 18-month strategy (January 2020 to 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, novel OPV2 (nOPV2), is anticipated to provide similar intestinal immunity to Sabin oral polio vaccine type 2 (OPV2) while being substantially more genetically stable and thus resistant to reversion, lowering the risks associated with cVDPV2 response. It is expected to be available in late 2020 through the WHO EUL procedure.

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.

It aims to:

- optimize outbreak response using mOPV2, currently the best available tool for combatting type 2 vaccine-derived poliovirus;
- accelerate the development of the new vaccine – nOPV2 – as a potential alternative for outbreak response and ultimately as a replacement for mOPV2;
- strengthen routine immunization by increasing coverage with inactivated polio vaccine (IPV) in high-risk areas to protect children from paralysis; and
- ensure a sufficient supply of OPV2 is available to reach every at-risk child, utilizing innovative strategies as needed.

The 146th session of the WHO Executive Board endorsed the main elements of this strategy, in Decision EB146/21 Add.1. This decision emphasizes the importance of accelerating the assessment and rollout of a nOPV2, including through the WHO EUL procedure, and calls on Member States to expedite national processes to enable the importation and use of this vaccine. It also calls on Member States to mobilize domestic financial resources to contribute to outbreak response efforts. The Executive Board decision was further supported by the Strategic Advisory Group of Experts (SAGE) on Immunization.
The unprecedented COVID-19 pandemic is likely to continue to substantially negatively impact the polio eradication programme and outbreak control efforts. The need to take extra precautions to prevent COVID-19 transmission will probably affect vaccination coverage and also hamper polio surveillance activities, leading to an increased risk of missed transmission.

In many polio infected countries, the COVID-19 pandemic has disrupted polio surveillance to a varying extent, sometimes significantly, resulting in an unusual degree of uncertainty regarding the current true polio epidemiology. All of the countries reported postponements of immunization responses to cases, further increasing risk. In addition, routine immunization in many countries has also been adversely affected by the pandemic.

Evidence suggests that the pandemic has yet to hit its peak in some polio infected countries. As international travel begins to return, the risk of exportation of polioviruses is unknown. Many other challenges lie ahead, such as the effect of COVID-19 on community trust and support for immunization, the possibility of other epidemics such as measles, the risks to front-line workers and how these can be managed, and the risk of immunization activities being associated with COVID-19 outbreaks, either truly or spuriously.

Many countries have weak immunization systems that can be further impacted by various humanitarian emergencies including COVID-19, and the number of countries in which immunization systems have been weakened or disrupted by conflict and complex emergencies poses a growing risk, leaving populations in these fragile states vulnerable to outbreaks of polio. Inaccessibility continues to be a major risk, particularly in several countries currently infected with cVDPV, i.e. Afghanistan, Myanmar, the Niger, Nigeria and Somalia, which all have sizable populations that have been unreached with polio vaccine for prolonged periods. While border closures may have mitigated the short-term risk, conversely the risk once borders begin to be reopened is likely to be higher.

On a positive note, the contribution of polio infrastructure, such as the National Emergency Operation Centre in Pakistan, to pandemic control efforts was significant. An opportunity presents itself going forward to link polio eradication and pandemic response in positive ways.
Outbreak response

Once a cVDPV emerges, outbreak response is conducted, as would be the case for a WPV outbreak, through large-scale administration with OPV to rapidly boost population immunity and give this strain nowhere to hide. A fully immunized population is protected against both cVDPV and WPV.

In early 2020, because of the COVID-19 global pandemic, large-scale vaccination and outbreak response campaigns against polio and other vaccine-preventable diseases had to be temporarily postponed, due to risks associated with these campaigns contributing to the increased spread of COVID-19 transmission. By the start of the third quarter of 2020, it was anticipated that the large-scale outbreak response to polio would be able to resume. At the same time, the GPEI infrastructure continues to support COVID-response activities.

During this period, the GPEI focused its efforts on working to slow the spread of any poliovirus transmission by strengthening essential immunization services in areas most at risk of polio transmission and ensuring readiness to enable a rapid relaunch of large-scale vaccination campaigns as soon as the situation safely allowed. Given the risk of international spread, countries need to ensure that they are ready to use appropriate polio vaccines, as recommended by SAGE, in response to new outbreaks.

The polio International Health Regulations (IHR) Emergency Committee urges all countries, but particularly those at high risk of polio, to maintain a high level of polio surveillance throughout the ongoing pandemic, noting that the postponement of polio immunization campaigns, whether preventive or in response to outbreaks, may lead to an increase in polio transmission, including international spread. There may be opportunities, however, to strengthen polio and COVID-19 surveillance synergistically.

In addition, outbreak affected countries should resume immunization response campaigns as soon as feasible. The planning and implementation of the response should employ a flexible approach, whereby some activities are put on hold as the transmission of COVID-19 intensifies and then resumed as the COVID-19 transmission reverses back from community transmission to the interruption of COVID-19 transmission.

Critically, campaigns should be planned and implemented in such a
way that they protect front-line polio workers as well as the communities they serve so that COVID-19 transmission is not increased. This includes ensuring teams have access to appropriate personal protective equipment, teams are selected without putting the high-risk workers on the front line, and the risks related to the pandemic are factored into the selection and planning of areas targeted by polio campaigns.

The IHR Emergency Committee urges countries to maximize the use of polio assets to synergistically address the COVID-19 pandemic, noting that polio affected countries may be vulnerable to poorer outcomes in the pandemic due to health care system fragility and the poorer health status of the population generally. Furthermore, the pandemic should serve as a reminder to high-risk countries with poor immunization coverage that infectious disease outbreaks can lead to social and economic disruption as well as strains on the health care system, and that countries can increase their population resilience and recovery by prioritizing robust immunization programmes. This is relevant not only to polio, but to all other vaccine-preventable diseases, especially measles. In particular, whether eligible for Gavi support or not, countries should plan to implement a second dose of IPV now being introduced to protect children from paralytic polio.
In Africa, an emergency response network called the “Rapid Response Team” was established in 2019, in reaction to the increasing outbreaks affecting the continent.

The Rapid Response Team consists of highly experienced experts from a variety of related backgrounds, based in Brazzaville. These are the first responders to any new cVDPV2 confirmation, dispatched to the affected area within 72 hours. They will typically stay in-country for 6 to 8 weeks, at which time a Team B will take over. During those 6 to 8 weeks, they will put in place the building blocks of a six-month outbreak response, such as establishing a risk assessment and coordination mechanisms, setting up an Emergency Operations Centre, putting in place a six-month plan/budget and preparing for the initial outbreak response campaign.

The Rapid Response Team is a cross-partnership team comprised not just of WHO staff but also of UNICEF, CDC and other personnel, with a range of experience that includes epidemiology, logistics, vaccine-supply management, virology, community engagement, etc., to be able to offer the best and most relevant immediate support. A similar system is now being set up in the WHO Regional Office for the Eastern Mediterranean to address that region’s respective cVDPV2 emergence.
During a challenging year for polio eradication in the WHO Eastern Mediterranean Region, with rising cases of WPV in Afghanistan and Pakistan, as well as outbreaks of vaccine-derived poliovirus in Pakistan and Somalia, the GPEI began the process of overhauling operations to address programme vulnerabilities and increase vaccine coverage.

To support efforts in the two remaining endemic countries, the GPEI established a hub in the third quarter of 2019. The GPEI hub, located in Amman, Jordan, is staffed by a dedicated team of experts from across the partnership with decades of experience fighting the poliovirus. Dr Hamid Jafari, Director for Polio Eradication at the WHO Regional Office for the Eastern Mediterranean, provides overall leadership and guidance. GPEI staff in the hub have been brought together specifically to support the Pakistan and Afghanistan programmes as the countries focus on overhauling their management and operations. The hub will provide better coordination across the GPEI partnership, enable more rapid deployment of surge support and technical expertise to Pakistan and Afghanistan, and ensure quick, effective decision-making closer to the ground.

Support is organized into thematic areas, focusing on high-level advocacy, data analytics and risk assessment, country operational assistance and the strengthening of services beyond polio. It is anticipated that the Amman hub will offer critical support in the coming months as the programme resumes vaccination activities paused during the early stages of the COVID-19 pandemic and rapidly increases operations to protect vulnerable communities and fight outbreaks.
Vaccine solutions for protection against poliovirus type 2

Different combinations of vaccines will be used in different settings, based on the epidemiological reality and country readiness for a new vaccine in a given area. The polio programme has a number of vaccines containing protection against poliovirus type 2 - IPV, mOPV2, and trivalent OPV (tOPV) in areas of circulation of more than one serotype, and nOPV2.

A new outbreak response strategy for cVDPV2s includes the use of tOPV for outbreak response and a focused use of IPV. The GPEI has made the strategic decision to have tOPV manufactured, with approximately 148 million doses to be secured for June to December 2020. To respond to cVDPV2 outbreaks, the programme will start implementing the new strategy focusing on scope, speed, the strategic use of IPV, and tOPV.

SAGE reviewed the global supply of polio vaccine (mOPV2, bivalent oral polio vaccine (bOPV) and IPV) during its meeting from 31 March to 2 April 2020. SAGE agreed to maintain its recommendations to prioritize the available IPV supply for 2020: (1) the introduction of one dose into routine immunization; (2) catch-up activities to reach missed children due to delayed introduction; (3) supplemental immunization activities for endemic countries and high-risk areas, based on risk assessments; and (4) the introduction of a second dose of IPV into routine immunizations. In 2021, priority (4) will become priority (3) for the IPV supply in general. This does not change previous SAGE recommendations on fractional IPV administration.

SAGE also reviewed and agreed with the new GPEI strategy for responding to cVDPV2 outbreaks, and focused on aspects of policy decisions, such as the use of tOPV in the programme and of IPV in combination with an OPV for outbreak response. It recommended that tOPV be made available to countries for cVDPV2 outbreak response in subnational areas where there is co-circulation or high risk of co-circulation of cVDPV2 with circulating vaccine-derived poliovirus types 1 and 3 or WPV1, to avoid the need to conduct dual mOPV2 and bOPV campaigns. The use of tOPV will require the same authorizations and restrictions as for the use of mOPV2. SAGE requested that the GPEI further elaborate scenarios for using IPV in outbreak responses and present them to the SAGE Polio Working Group at its next meeting.

In the current epidemiological context and as a general principle, SAGE expressed the need for regions or countries to be cautious about moving from a bOPV-plus-IPV schedule to an IPV-only schedule in their routine immunization programmes, and recommended that they instead take a gradual approach, by first introducing a second dose of IPV into their routine immunization schedules.
Type of polioviruses

- Type 1 (endemic in Afghanistan and Pakistan)
- Type 2 (eradicated worldwide, last case in 1999)
- Type 3 (eradicated worldwide, last case in 2012)

Wild (WPV)

- VDPVs are mutated Sabin (OPV) polioviruses
- There are type 1, 2 and 3 VDPVs
- Epidemiology, transmissibility, neurovirulence and control measures for VDPVs are similar to WPVs

Vaccine-derived from OPV (VDPV)
Polio Vaccines

Inactivated Polio Vaccine (Salk)
Killed virus administered by injection
1955

IPV

• Injectable
• Expensive
• Does not provide gut immunity per se, but boosts it in OPV primed populations
• Highly immunogenic, prevents individual paralysis
• Very safe

Oral Polio Vaccine (Sabin)
Live weakened virus
1961

OPV

• Easy to administer
• Cheaper
• Provides gut immunity, required to stop transmission
• Problem of lower immunity in developing countries
• Major drawbacks are risk of vaccine-associated paralytic polio and VDPV

OPV AND IPV WORK VERY WELL TOGETHER, SUPPLEMENTING EACH OTHER’S STRENGTHS.
Following the certification in 2015 of WPV2 eradication globally, the type 2 component contained in tOPV was removed, by switching to bOPV, which contains only types 1 and 3 serotypes. As the type 2 component of tOPV accounted for 90% of cVDPV outbreaks and the wild form of the virus no longer circulated, this move was considered necessary from a public health point of view.

The risk of cVDPV2 outbreaks following the switch from tOPV to bOPV had been anticipated and was carefully considered in the planning phase. However, the number and scope of outbreaks currently faced is greater than anticipated. The key is to ensure high-quality outbreak responses. A population fully immunized against polio will be protected against both WPV and cVDPV.

The current tool used as part of cVDPV2 outbreak responses is mOPV2. The goal of any immunization response using mOPV2 is to achieve high levels of vaccination coverage to stop an outbreak. As cVDPVs tend to emerge in under-immunized populations, achieving vaccination coverage that stops an outbreak should also be sufficient to prevent new cVDPV from emerging.

The decision to use mOPV2 in any outbreak response is strictly guided by an advisory committee, which carefully evaluates the risks and benefits of using it. In addition, mOPV2 can only be released for use under the authority of the WHO Director-General, operating on the recommendation of the advisory committee.

Risks accompany the use of mOPV2, but the risks posed by any confirmed cVDPV2 outbreak far outweigh the risk of potentially seeding cVDPV in the future. If the outbreak response is of sufficient quality to stop the cVDPV2 outbreak by boosting population immunity levels high enough, those same high levels of population immunity will prevent a future cVDPV2 from being seeded as a result of the outbreak response.

By optimizing the outbreak response with mOPV2, it is feasible to stop the current cVDPV2 emergency. However, it is equally clear that, given the realities of waning mucosal immunity and inadequate outbreak response quality, mOPV2 is not an optimal tool.

The spread of poliovirus is a serious public health event that is considered under the IHR to be a public health emergency of international concern. nOPV2 will be used under a WHO EUL recommendation for use and specific monitoring requirements will apply to countries wishing to use it for cVDPV2 outbreak response (while under the
EUL mechanism). As the vaccine is yet to be used for large scale outbreak response, additional criteria during its initial use period - approximately three months from the date of first use under the EUL procedure - will apply. This is particularly important as it will allow the adequate and focused monitoring of the vaccine’s performance in the field and enable the programme to swiftly respond to unanticipated events, if any.

To support countries in their preparations for nOPV2 use, an nOPV2 readiness checklist and technical guidance document have been developed and can be accessed here. Countries are encouraged to start their nOPV2 preparations early.

A full framework of SAGE-endorsed criteria and considerations for the initial use of nOPV2 under the EUL procedure can be found on the GPEI nOPV2 webpage. Some key criteria include:

- country capacity to acquire and distribute the vaccine in a timely manner (e.g. approval and import processes, logistics);
- country capacity to conduct post-deployment monitoring surveillance (in addition to other post-monitoring requirements), including acute flaccid paralysis and environmental surveillance, and adverse event following immunization surveillance;
- country capacity to respond to an unanticipated finding; and
- a period of at least 12 weeks from mOPV2 use in the area to enable a dedicated analysis of nOPV2’s effectiveness.

Countries must also ensure that nOPV2 is the only vaccine used for the outbreak response and that sufficient vaccine is available for the full required number of campaign rounds.

It is key to note that it is the prerogative of WHO Member States to decide if they wish to use nOPV2 under the EUL procedure. If they do wish to do so, they will need to secure national approval to use and import the vaccine, which must be done through their National Regulatory Authority.

SAGE has agreed with the framework of the strategy. It recommended that the strategy be more cautious about setting timelines for the introduction of nOPV2 in terms of expectations about supply availability and regulatory approval.

The IHR Emergency Committee repeated its strong support for the development and proposed EUL of nOPV2, which should become available in late 2020 and which, it is anticipated, will result in no or very little seeding of further outbreaks.
The introduction of nOPV2 will mean that the GPEI vaccine arsenal is boosted by a further vaccine, alongside various other formulations of OPV and IPV. In response to cVDPV2 outbreaks, a combination of different vaccines should be used, depending on the prevailing epidemiology and the given situation. All vaccines, whether mOPV2, nOPV2, IPV, or tOPV in areas of co-circulation of multiple virus strains, are effective at stopping outbreaks, but only if they reach the children they are intended to. The different mix of vaccines available means Member States can apply the most appropriate and efficient strategy, using the most effective tools in a targeted manner, to boost immunity among their populations in the most rapid and safest manner. But key to success is coverage!
The role of Member States

Ultimately, Member States are the primary stakeholders and beneficiaries of the strategic approaches to eradicate polio, including in fully implementing all aspects of the cVDPV2 emergency response strategy, inclusive of the roll-out of nOPV2 as appropriate. To this effect, the GPEI partners stand ready to support Member States in this effort.

**All Member States**

Ensure strong routine immunization with IPV, and strong disease surveillance, to minimize the risk and consequences of any poliovirus introduction or emergence, including to type 2 poliovirus.

**Member States at high risk of type 2 poliovirus introduction or emergence**

Ensure strong outbreak response readiness plans are in place, and implement preventive supplementary immunization activities with an appropriate type-2-containing OPV (potentially in combination with IPV), in order to boost immunity levels to type 2 poliovirus. Countries at risk should also take steps to prepare for nOPV2 use, should they wish to use it for cVDPV2 outbreak response.

**Member States affected by cVDPV2 outbreaks**

Fully implement cVDPV2 outbreak response plans, using appropriate type-2-containing vaccine (or vaccines); if appropriate, fully roll out nOPV2 under the EUL procedure; and ensure head-of-state oversight to monitor outbreak response implementation.
WHO Executive Board
146th session Executive Board statement on polio eradication
7 February 2020

nOPV2 resource page
http://polioeradication.org/nopv2/

cVDPV resource page
http://polioeradication.org/年末today/polio-now/this-week/circulating-vaccine-derived-poliovirus/

Explaining vaccine-derived polioviruses animation
http://polioeradication.org/news-post/vaccine-derived-polioviruses/