POLIO GLOBAL ERADICATION INITIATIVE

Annual Consultation between the GPEI and polio vaccine manufacturers, National Authorities for Containment and National Regulatory Authorities

23 October 2024 | Geneva, Switzerland (and broadcast online)

EVERY LAST CHILD

Contents

Foreword

Polio vaccines have been central to global public health, preventing an estimated 20 million cases of paralysis since the inception of the Global Polio Eradication Initiative (GPEI) in 1988 and reducing polio cases by over 99%. As we near the culmination of this monumental effort, vaccine security remains critical—not only to ensure the complete eradication of polio but also to protect future generations from its return.

This 23rd Annual Consultation took place in the wake of a profound loss. Earlier this year, we lost Aidan O'Leary, the Director of Polio Eradication at the World Health Organization. Aidan was a tireless advocate for polio eradication—embodying dedication, vision and compassion in his work. His leadership was instrumental in sustaining our momentum and inspiring everyone engaged in this mission. We must now honor Aidan's legacy by reaffirming our commitment to the goal he held so passionately—a polio-free world.

During the consultation, we focused on critical programmatic updates, including the extension of the Global Polio Eradication Strategy to 2029, which reflects our determination to adapt our approach to the evolving epidemiological landscape. A key highlight of this year's discussion was the operationalization of the Polio Vaccine Security Framework—a blueprint that will guide our efforts in removing obstacles, securing vaccine supply, and ensuring resilience up to and beyond the point of eradication. Addressing the evolving timelines for OPV cessation, uncertainties in vaccine demand forecasting, and the regulatory and containment requirements were essential topics that garnered substantial discussion.

I also had the privilege of underscoring, during my remarks, the crucial role that collaboration plays in our efforts. Strengthening coordination with vaccine manufacturers, national containment and regulatory bodies is fundamental to achieving our shared goal. This year, industry partners had the opportunity to present their latest innovations and offer valuable feedback, which is important to refining our approaches to IPV demand forecasting, OPV cessation readiness, and broader vaccine policy alignment. These conversations are instrumental to maintaining a healthy vaccine market and ensuring an uninterrupted supply chain.

The success of the polio eradication programme hinges on the cohesion of stakeholders across vaccine supply, research, regulation, and containment. As we move forward, GPEI is steadfast in fostering these collaborations, implementing the Polio Vaccine Security Framework, and addressing industry concerns to ensure a sustainable supply of vaccines into the future.

As we conclude this year's consultation, we look ahead with resolve. The challenges are significant, but so too is our collective expertise, dedication, and passion. Together, we can take decisive steps forward, overcoming the barriers that remain and ultimately achieve the polio-free world we have all work so hard to create.

Dr Mike Ryan
Deputy Director-General, WHO; and Executive Director, WHO Health Emergencies Programme

List of abbreviations

bOPV	bivalent oral polio vaccine
CCS	Containment Certification Scheme
CP	certificate of participation
cVDPV	circulating vaccine-derived poliovirus
EUL	Emergency Use Listing
GAPIV	Global Action Plan for Poliovirus Containment, fourth edition
GCC	Global Commission for the Certification of Eradication of Poliomyelitis
GPEI	Global Polio Eradication Initiative
IPV	inactivated polio vaccine
mOPV	monovalent oral polio vaccine
NAC	national authority for containment
NRA	national regulatory authority
nOPV	novel oral polio vaccine
OPV	oral polio vaccine
PHEIC	public health emergency of international concern
PQ	WHO Prequalification of Medical Products
PV	poliovirus
RI	routine immunization
SAGE	Strategic Advisory Group of Experts on Immunization
SIA	supplementary immunization activity
sIPV	Sabin IPV
tOPV	trivalent oral polio vaccine
UNICEF	United Nations Children's Fund
VLP	virus-like particle
WHO	World Health Organization
WPV	wild poliovirus

Executive summary

Polio vaccines have saved millions from paralytic polio and banished poliovirus from almost all corners of the world. With eradication within reach, ensuring vaccine security is more critical than ever—not only to achieve this historic milestone but to sustain a polio-free world indefinitely.

On 23 October 2024, the Global Polio Eradication Initiative (GPEI) held its annual consultation with polio vaccine manufacturers, national regulatory authorities, and national authorities of containment. This gathering focused on strategies to secure the supply and optimal use of polio vaccines.

Nearly 300 participants, from 23 countries, attended the consultation, either in person or online. Together, they explored the opportunities and obstacles in polio vaccine development and production. They discussed the plans and processes that are being developed to secure the timely, sustained and uninterrupted supply of suitable affordable, quality assured polio vaccines to eradication and beyond.

After opening remarks from Dr Mike Ryan, Deputy Director-General of WHO, participants focused their deliberations on five key topics: progress in polio eradication, strategic frameworks for vaccine security, vaccine supply and demand, new products and innovations, and containment and certification. As part of this year's consultation, several vaccine manufacturers also presented their experiences on new tools and technologies for polio eradication.

This report presents a summary of the presentations and discussions held during the consultation. Key messages to emerge from these are highlighted on the next pages.

Key messages from GPEI's 2024 consultation with stakeholders

Topic of discussion	Key messages
Polio eradication	• Both endemic countries have seen a rise in reports of wild poliovirus type 1 (WPV1) cases and detections from environmental samples. • Outbreaks and overall cases of circulating vaccine derived polioviruses (cVDPVs) continue to show a downward trend. Interruption of cVDPVs largely depends on progress in four consequential geographies (east Democratic Republic of Congo, north Nigeria, south central Somalia, and north Yemen) with competing humanitarian emergencies and significant operational gaps. • In 2025, GPEI's focus will be on improving the speed, scope and quality of operational performance at country level.
Strategy developments	• The timelines for certifying poliovirus eradication have been extended to the end of 2027 for WPV1; and the end of 2029 for all VDPVs. The cessation of oral polio vaccines (OPVs) is now planned for 2030. • The new Polio Vaccine Security Framework is designed to secure viable markets for vaccines to eradication and beyond. It is built on three pillars: containment, vaccine manufacturing and supply, and R&D.
Vaccine supply and demand	• The market for bOPV is highly uncertain and the pool of suppliers is shrinking, which increases the risk of supply interruptions. • In total, 35 countries, including some high-risk ones remain on IPV1. • UNICEF is considering making compliance with global containment requirements mandatory in its next tender for standalone IPV. • Demand for hexavalent IPV has been slower than anticipated. • GPEI's model for forecasting long-term IPV and bOPV needs is expected to go live in 2025.
New products and innovations	• The 2016 switch from tOPV to bOPV was a failure. Drastic strategy changes are required to achieve successful bOPV cessation. • bOPV cessation will only proceed if all five non-negotiable triggers can be met. • Key products under development to eliminate the use of live viruses in vaccine production include nOPV1/3 Sabin IPV, S19 strains, virus-like particles, antivirals and monoclonal antibodies. • In July 2024, Biological E Ltd was prequalified for finished product nOPV2 that is filled using bulk from PT Bio Farma.
Containment and certification	• Timelines for containment by end of 2026 will remain in place, independent of the status of WPV eradication. • There are 78 facilities in 22 countries retaining polioviruses, of which 60 plan to continue to do so after eradication. To date, 16 facilities have achieved an interim certificate of containment (ICC). • The principles and procedures for certifying VDPV eradication will mirror the approach taken for WPVs, and only after OPV cessation.
Manufacturer insights	• CanSino Biologics' virus-like particle (VLP) polio vaccine has proved to be safe and highly immunogenic as a booster dose during Phase I clinical trials; their production is scalable and quality is consistent. • PT Bio Farma's manufacturing of nOPV2 has enabled the administration of more than 1.2 billion doses across 41 countries. A second manufacturer, Biological E, has now been prequalified for nOPV2. • Batavia Biosciences have used novel fixed-bed bioreactors to produce Sabin poliovirus strains, increasing average yields compared with conventional microcarrier processes. • The latest study of PharmaJet's needle-free injections in Nigeria has shown this technology is easy to use and can achieve high coverage.

1. Introduction

Speaker: Mike Ryan, Deputy Director General, WHO

Since launching in 1988 the GPEI has helped countries reduce the incidence of polio by 99.9%, saving more than 20 million people from paralysis and preventing more than 1.5 million childhood deaths. Today in 2024, five of the six WHO Regions are free from wild poliovirus and polio is only endemic in two countries.

Yet polio still poses a global threat and remains a public health emergency of international concern (PHEIC). From persistent violence to climate emergencies, the challenges to reaching all children with vaccines are serious. Over the past year, new transmission of polio in conflict-affected areas of Gaza, Sudan and Yemen reminds us that where conflict weakens health systems, polio can reappear unless all forms of the virus are eradicated. It also reminds us that the epidemiological realities of polio are underpinned by much more complex issues and obstacles to eradication.

Vaccines provide the cornerstone for polio eradication. Vaccine manufacturers, national authorities and global partners must work together to secure access to a steady and affordable supply of safe and effective polio vaccines that can be used for both routine immunization and outbreak response. There is no single intervention that can finally eradicate polio. Only a collective effort to improve implementation in each and every area will put a stop to this persistent virus.

This requires a strategic approach to polio vaccine production that can secure adequate and sustainable supply chains today and build viable markets not only through the final stages of eradication but well beyond. The recently developed Polio Vaccine Security Framework aims to support that effort by removing critical obstacles faced by the vaccine industry and country authorities.

This year's annual consultation meeting aims to share experience and expertise, and to strengthen collaboration with stakeholders. Accordingly, the consultation will aim to brief stakeholders on:

- the status of GPEI and the extension of the polio eradication strategy timelines;
- use of the Polio Vaccine Security Framework as the overarching context for all future vaccine supply;
- plans for stopping the use of OPVs after the global certification of eradication; and
- key operational areas, including containment, supply and research.

Around 295 participants from 23 countries – including representatives of 33 manufacturers, 14 NACs and 6 NRAs – attended the consultation, both in-person or online.

The consultation began with a tribute to Aidan O'Leary, whose dedication and leadership left an indelible mark on the GPEI and the wider polio community. Participants spoke movingly about Aidan's tireless efforts to end polio, including in some of the most difficult parts of the planet. Participants underscored their commitment to continuing his legacy and realising their collective vision of a polio-free world.

2. Polio today

Speaker: Arshad Quddus, WHO, GPEI

In 1988, wild poliovirus was endemic in 125 countries. Today, wild poliovirus types 2 and 3 (WPV2 and WPV3) have been eradicated (see section 6.2). But transmission of WPV1 continues, even if confined to just a few districts of two countries. Outbreaks of circulating vaccine-derived polioviruses (cVDPVs) also persist but are similarly localized in just a few sub-national geographies.

New emergences and ongoing transmission of polio provide a constant reminder that no place is safe until every place is safe.

In practice, tackling the final few pockets of polio means operating in areas affected by some of the most difficult humanitarian crises faced by the world today, including Afghanistan, Democratic Republic of Congo, Gaza, Yemen, South Sudan, and Sudan.

2024 overview

Goal 1: interrupt WPV1 transmission in endemic countries

In 2024, WPV1 transmission continues in both endemic countries, Afghanistan and Pakistan. Recent cases and the surge in detections of WPV1 from environmental samples indicate much wider geographic spread across both countries with risk of transmission re-establishing in Quetta-Kandahar and Peshawar-Nangarhar blocks. Insecurity and restrictions on house-to-house campaigns posed serious challenges to accessing all children in these areas with vaccines.

Diverse strategies are being used to overcome these obstacles, including continued political advocacy, cross-border collaboration, community engagement, high-quality supplementary immunization activities (SIAs), and targeted outbreak response in new districts.

Goal 2: stop cVDPV transmission and prevent outbreaks in non-endemic countries

Since the arrival of novel oral polio vaccines (nOPVs) for outbreak response in 2019, the number of new cVDPV2 emergences has trended downwards. In 2024, it continued this trend and decreased significantly compared with 2023.

More than 80% of cVDPV2 cases were reported from four consequential geographies: eastern Democratic Republic of Congo, northern Nigeria, south-central Somalia, and northern Yemen. Routine immunization (RI) in these geographies is low, insecurity is high and there are multiple competing humanitarian emergencies and significant operational gaps.

Outbreak response in 2024 was also challenged by a shortage of nOPVs in the first half of the year. Strategies to interrupt cVDPV transmission vary by region but include synchronized multi-country polio vaccination campaigns alongside enhanced RI, a global surveillance action plan and renewed commitment to deep community engagement.

2025 priorities

Looking ahead, the GPEI will focus its eradication efforts on core reservoirs and consequential geographies (see Box 2.1). Rather than revising its strategy, the programme focuses on improved speed, scope and quality of operational performance at country level.

These are the critical ingredients of successful outbreak responses – for example, nOPV2 rounds must be less than four weeks apart to minimize the risk of new emergences. Tactical planning is so important: mapping communities of high risk and targeting activities to areas with persistently low coverage will maximize chances of success.

Resourcing remains a challenge and GPEI will continue to use a risk-based approach to prioritize and allocate resources, focusing on zero-dose communities.

Box 2.1. Five priorities for 2024–2025.

1. Interrupt WPV1 transmission by end 2025, enhancing the focus on Quetta-Kandahar block, Peshawar-Khyber block and Karachi; and maintaining momentum in South KP, Pakistan and Eastern Afghanistan.

2. Stop cVDPV transmission in the most consequential geographies of eastern Democratic Republic of Congo, north-west Nigeria, south-central Somalia, and northern Yemen.

3. Respond to new outbreaks in emergency mode.

4. Prevent new outbreaks.

5. Mobilize and prioritize resources to meet the extended 2022–2029 budget.

3. Strategy developments

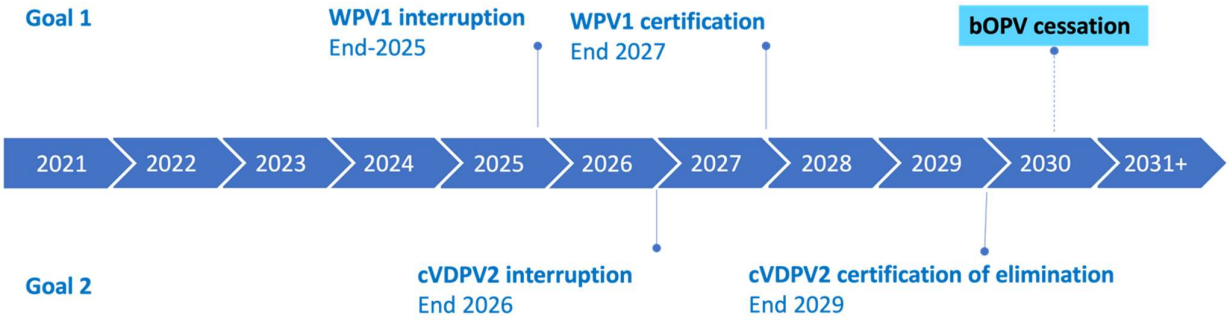
3.1. GPEI strategy extension

Speaker: Arshad Quddus, WHO, GPEI

Recognizing the serious challenges facing GPEI to deliver on its two strategic goals to stop WPV and cVDPV transmission, in July 2024 the GPEI's Polio Oversight Board made the difficult but necessary decision to extend the timelines needed to achieve polio eradication – to the end of 2027 for the certification of wild poliovirus interruption; and the end of 2029 for type 2 variant poliovirus (see Fig. 3.1). The use of bivalent OPVs (bOPVs) is now tentatively scheduled to end in 2030.

Importantly, the two strategic goals themselves will not change, only the timelines for achievement.

Fig. 3.1. Extended timelines for WPV1 and cVDPV2 interruption and certification.



3.2. The Polio Vaccine Security Framework

Speaker: Vachagan Harutyunyan, WHO

Long-term polio vaccine security—the timely, sustained, and uninterrupted supply of suitable types of affordable, quality-assured polio vaccines—is essential in the global effort to achieve and maintain a polio-free world. However, fragmented approaches and short-term planning have historically hindered the achievement of this goal.

In February 2023, the chairs of the advisory groups to GPEI, along with the Independent Monitoring Board (IMB) in its 22nd report, called for the development of a comprehensive polio vaccine strategy and a roadmap for the development and rollout of new vaccines, including the integration of safe, cost-effective technologies and stringent containment measures. In response, the Polio Vaccine Security Framework was developed by the GPEI Vaccine Supply Group steering team through an inclusive consultative process, engaging a wide array of stakeholders such as GPEI, global health organizations, vaccine manufacturers, and national authorities.

The framework was presented to the GPEI Strategy Committee in August 2024 and formally launched in September 2024. It serves as a critical tool to address the evolving challenges of polio vaccine supply, providing a structured approach to ensure the availability of vaccines throughout the eradication process and beyond.

The Polio Vaccine Security Framework is built around three operational pillars:

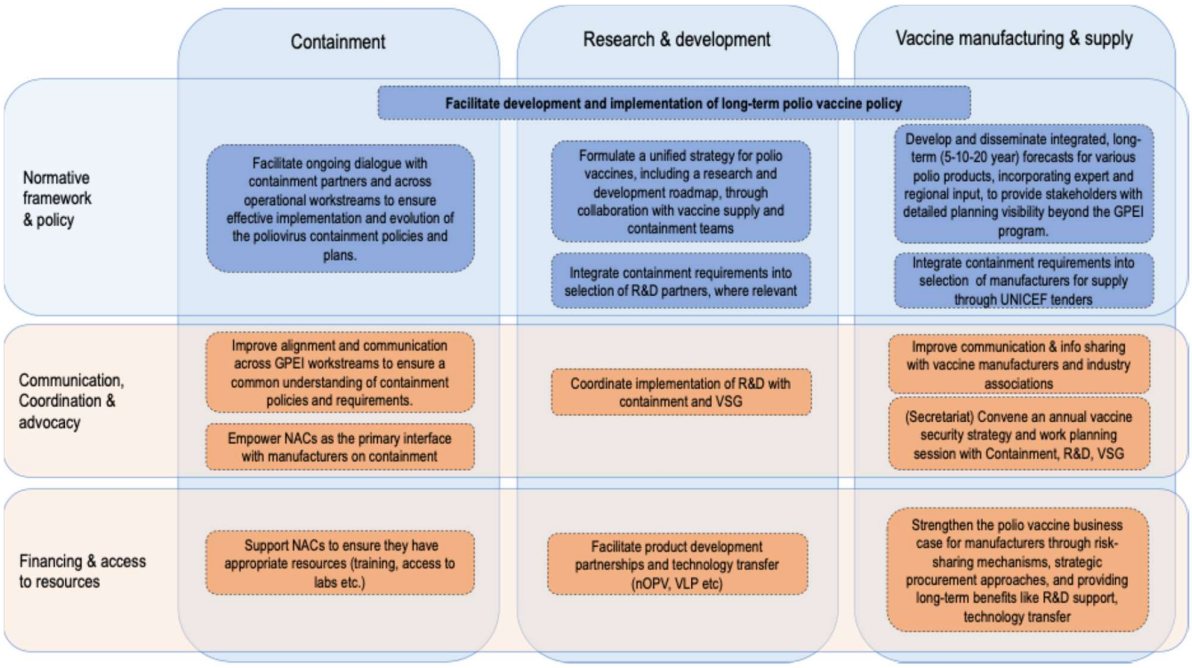
1. **Containment**: Ensuring all vaccine-related activities meet rigorous biosafety and biosecurity standards to minimize risks associated with poliovirus containment.
2. **Vaccine Manufacturing and Supply**: Fostering resilient production and supply chains to guarantee timely access to high-quality polio vaccines.
3. **Research and Development**: Promoting innovative approaches to polio vaccine production, including the exploration of new technologies and alternative vaccine types.

In addition to these pillars, the framework identifies three cross-cutting areas of activity:

- **Normative Framework and Policy**: Establishing guidelines and policies that provide consistent direction to vaccine-related efforts.
- **Communication, Coordination, and Advocacy**: Ensuring alignment among all stakeholders and facilitating timely dissemination of information and advocacy for vaccine security.

- **Financing and Access to Resources**: Securing adequate funding and resources to support sustainable vaccine production and equitable distribution.

Fig. 3.2. The Polio Vaccine Supply Framework.



These components collectively form the backbone of the Polio Vaccine Security Framework, guiding the efforts needed to create a resilient and adaptable vaccine supply system (see Fig. 3.2).

Before the end of 2024, GPEI will establish a technical group to oversee the implementation of this new framework, in collaboration with partners and stakeholders. The technical group will work alongside the Vaccine Supply Group (VSG) as well as Polio Research and Analytics Group (PRAG) and Containment Mamangeemnt Group (CMG) to develop a comprehensive work plan for 2025, including a monitoring and evaluation component to track progress and adapt strategies as necessary.

Importantly, the Polio Vaccine Security Framework is designed to be a living document, adaptable to shifts in epidemiology, context, and global polio priorities. Regular updates will ensure that the framework remains relevant and effective in addressing emerging challenges in polio vaccine security.

The Polio Vaccine Security Framework will be made available to all stakeholders on the GPEI website: https://polioeradication.org.

4. Vaccine supply and demand

4.1. OPV landscape

Speakers: Ann Ottosen, UNICEF

bOPVs

For much of 2024, the demand for bOPV increased beyond what was initially forecasted. The gap was fuelled by unplanned demand for outbreak response and the Big Catch-Up initiative. The shortages in supply meant the rotating buffer stock could not be maintained at the 100 million dose target.

Overall, the current global capacity to produce bOPV is capable of meeting current and projected demand for bOPV. Yet the pool of suppliers is shrinking, which increases the risk of supply interruptions.

In 2024, UNICEF extended its long-term agreements with manufacturers producing bulk in house. It made awards for 2025 to cover expected demand from Afghanistan, Pakistan and RI needs of other countries that procure through UNICEF. In 2025, UNICEF plans to issue a tender for bOPV supply from 2026 through to bOPV cessation. It is also considering making some additional awards for 2025 to fillers that rely on getting drug substances from third parties. In the meantime, UNICEF continues to work with GPEI, modellers and countries to secure the best possible longer-term demand forecasts.

The market for bOPV remains highly uncertain. bOPV cessation is currently planned for 2030 but timelines have been delayed before and the evolving epidemiology of polio means the 2030 deadline may have to shift again.

UNICEF is developing a procurement strategy with the aim of ensuring the sustainable and uninterrupted supply of bOPV through to cessation. This will be developed in consultation with GPEI partners and industry.

NRAs can also help secure bOPV supplies by relying on WHO prequalification and the licensure and continued oversight of vaccine-producing countries that are considered functional by WHO, rather than asking for their own national registration of bOPVs. These vaccines have been used in large quantities for decades. They have a very high safety profile. It is important to maintain a broad supplier base, and not to push manufacturers out of the market because they lack capacity to register their products in multiple countries. Polio is a PHEIC and as such there are special tools that regulators can use to secure access to supply.

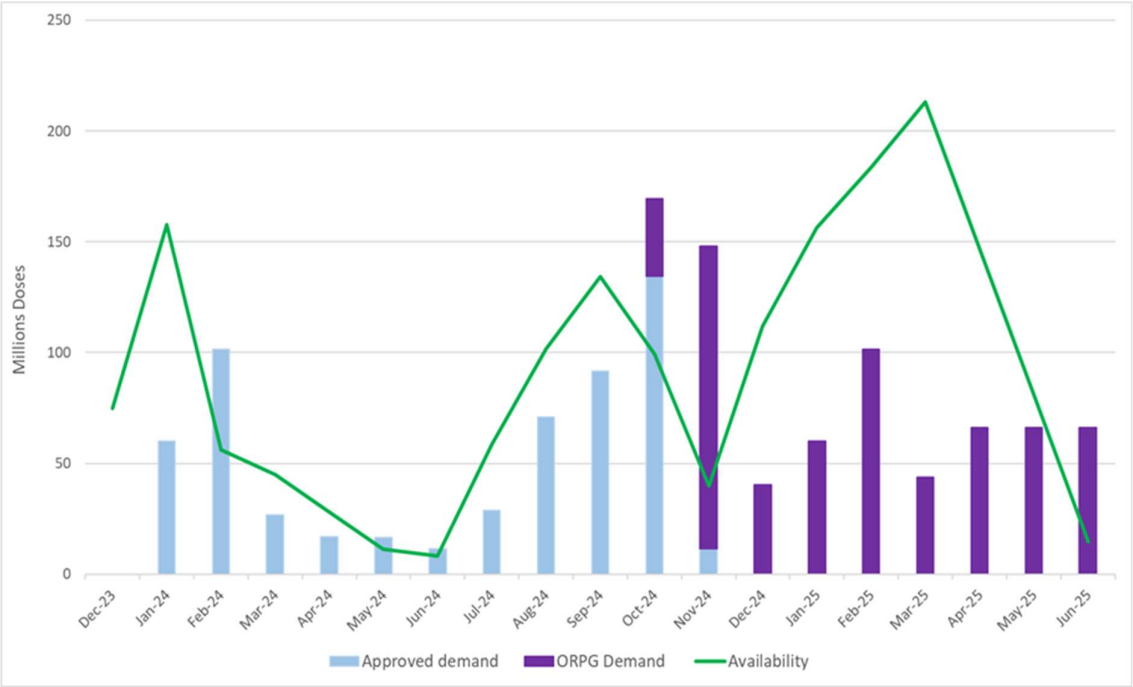
nOPVs

nOPVs have been the de-facto vaccine of choice for responding to cVDPV2 outbreaks for three years. Until the middle of 2024, there was just one manufacturer producing nOPV2 (see section 7.2) and there were supply shortages during the first half of 2024. Global outbreak response teams were forced to prioritize demand based on risk assessment.

Looking forward to 2025, UNICEF will aim for a 200 million dose minimum buffer and will continue to make awards to achieve that (see Fig. 4.1). Demand forecasts for nOPV2 are currently based on 50 dose vials. Efforts are ongoing to consider when would be an opportune moment to transition to 20 dose vials, ensuring that such a move is done in a coordinated way to minimize problems caused by having different products in the field.

Even after bOPV cessation, nOPVs will still be required for outbreak response and the world will need stockpiles that can be readily deployed.

Fig. 4.1. nOPV2 supply and demand for January 2024 to June 2025.



4.2. Polio routine immunization and vaccine supply

Speakers: Ian Lewis, UNICEF; Alejandro Ramirez Gonzalez, WHO; Elie Akki, Gavi

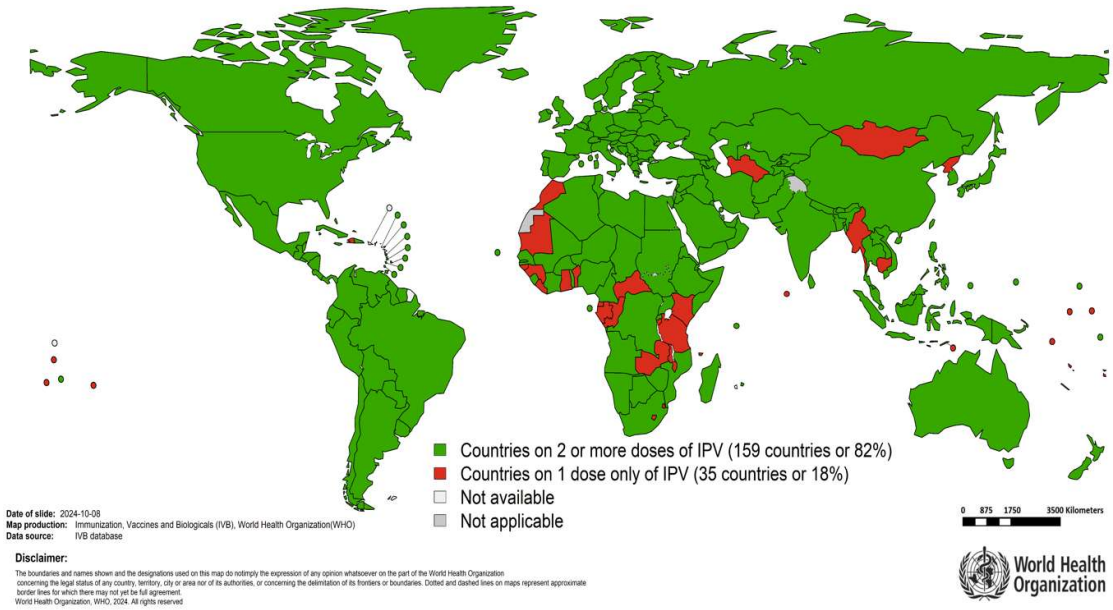
Rolling out IPV2

Since 2022, WHO has recommended that all countries using bOPV should have at least two doses of IPV in their RI schedules (IPV2),. Progress in implementing this recommendation continues, with 159 countries now having two or more doses of IPV in their RI schedules.

Yet IPV2 is being rolled out at a slower rate than IPV1 and overall RI coverage for OPV-using countries remains relatively low (42%). In total, 35 countries remain on IPV1.[1] These are mostly found in WHO's African and Western Pacific Regions, and include some high-risk countries (see Fig. 4.2).

Fig. 4.2. IPV schedules globally, October 2024.

[1] Ten IPV1 countries are expected to introduce a second dose shortly, after which two WHO Regions –Europe and Eastern Mediterranean – will have fully transitioned to IPV2.



More worryingly, RI coverage in IPV1 countries is sometimes lower, with seven countries having below 50% coverage. Equally worrying, among OPV-using countries, RI coverage with IPV1 is lower in countries with cVDPVs.

In 2023, the Big Catch-Up initiative was launched to address key immunization gaps caused by the COVID-19 pandemic. Funded by Gavi, the Vaccine Alliance, the Big Catch-Up aims to reach under-five-year-olds who missed vaccinations during 2019–2022 and restore coverage to at least pre-pandemic levels. In 2024, 35 countries, including several polio priority countries, received nearly 33 million doses for catch-up IPV activities.

Standalone IPV supply

The supply market for standalone IPV has improved in the past few years to the point where there is now sufficient supply for all countries to introduce the second dose of IPV into their routine schedules.

UNICEF's latest tender for IPV was extended to the end of 2026 and UNICEF has made additional awards to five manufacturers to cover projected demand for the extra year. The overall price has decreased since 2003. Further price reductions could have been achieved through consolidation but were not pursued to ensure multiple suppliers for each presentation.

Overall, the standalone IPV supply market can be considered healthy, with some overcapacity. With this change, and to support containment goals, UNICEF is considering how to strengthen containment requirements in the next IPV tender..

Hexavalent vaccine

Starting from 1 December 2023, countries eligible for Gavi support can apply to switch to a whole-cell pertussis hexavalent vaccine (hexavalent) – a six-in-one vaccine that combines antigens for six diseases, including polio (using IPV).

For those countries that do shift to the hexavalent vaccine, Gavi anticipates a range of benefits including comprehensive protection, fewer injections and health centre visits, improved vaccination compliance, programmatic cost efficiencies and potentially better coverage. Ongoing discussions with GPEI are focused on how the hexavalent vaccine can contribute to the programme's objectives.

Currently there is one WHO-prequalified hexavalent vaccine available, with two more vaccines expected to achieve prequalification in 2026; and a fourth vaccine in 2027. UNICEF has established two long-term agreements for 2024 and 2025: one for Gavi-eligible countries for hexavalent support and one for middle-income countries and Gavi countries not eligible for hexavalent support.

Five middle-income countries and one Gavi-eligible country are set to switch to the hexavalent vaccine during 2025. Four more Gavi-eligible countries have also applied for support and more applications are expected in the upcoming application windows.

4.3. Forecasting IPV and bOPV needs

Speaker: David Woods, WHO

In response to a request from the 2023 annual consultation with stakeholders, GPEI is developing a model to produce reliable long-term forecasts of IPV and bOPV needs.

The model prioritizes verified data, using Gavi and UNICEF planning numbers where these are available. Where such data are not available, the model forecasts needs for different scenarios based on various parameters, such as vaccination schedule, population, target coverage rates, with a wastage rate layered in also.

The working group behind the model want to ensure the model can reliably predict current demand before making longer-term multi-year forecasts, so it is focusing on modelling demand for the next 12 months using known variables.

The model is expected to go live before next year's stakeholder consultation and is intended to support the Polio Vaccine Security Framework. It will then be available for use by manufacturers, regions and countries to inform their planning. Its forecasts will be presented annually at the stakeholder consultation and will be made available all year round through an interactive dashboard.

During discussions on the new model, participants agreed that it would be a good tool for capturing routine demand but acknowledged it will need to also include the non-routine demand and demand from self-producing countries.

5. New developments and innovations

5.1. Evaluating the 2016 switch from tOPV to bOPV

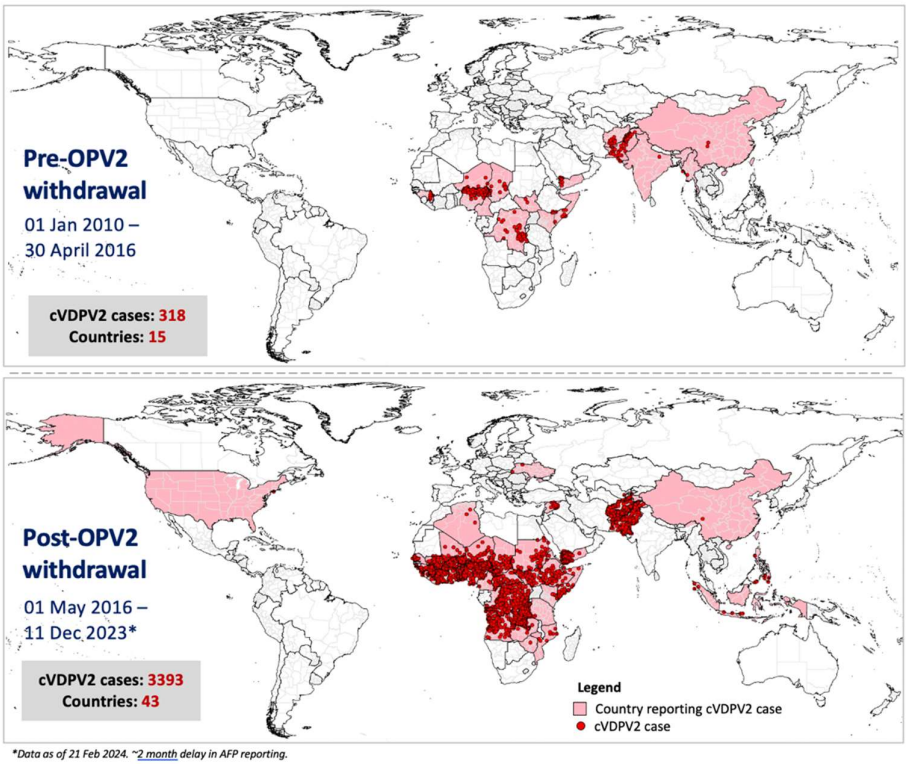
Speaker: Roland Sutter, Switch Evaluation Team

In April 2016, the global switch from tOPV to bOPV was implemented, ending the use of OPV2. It was a monumental undertaking of unprecedented scale, affecting all 155 OPV-using countries. In 2024, in anticipation of bOPV cessation, the GPEI Strategy Committee commissioned an evaluation of the 2016 switch to better understand why cVDPV2 is still circulating, and what lessons can be learnt to inform future OPV withdrawal efforts.

Evaluation findings

The overall conclusion of the evaluation was that the 2016 switch was a failure. The switch was intended to eliminate cVDPV2, yet there has been a ten-fold increase in global cVDPV2 cases since the switch (see Fig. 5.1). In total, 43 countries have since been re-infected with cVDPV2; more than 3 300 children have been paralyzed by cVDPV2; and more than US$ 1.8 billion has been spent on cVDPV2 outbreak response.

Fig. 5.1. Global cVDPV2 cases before and after the switch.



While new emergences have contributed to these numbers, the greatest challenge has been ongoing and long-term cVDPV2 transmission. The overriding reasons for the switch's failure was the GPEI's inability to close out outbreaks and the inability of leaders to recognize the seriousness of the problem and make corrections. Key contributing factors included:

- IPV supply constraints, affecting RI and outbreak control;
- left over tOPV vials in storage sites, resulting in at least one cVDPV2 outbreak;

- insufficient mOPV2 stockpiles, resulting in focused and insufficient outbreak response scope;
- delays in the introduction of nOPV2, resulting in delays in outbreak response;
- limited progress in RI coverage, resulting in a weak foundation of type-2 immunity;
- inadequate or late detections, resulting in delayed outbreak control;
- delays in processing and notifying cVDPV samples, exacerbating delayed responses; and
- revised outbreak control standard operating protocols that reduced the number of rounds and target populations for vaccination campaigns.

Yet the evaluation suggested that polio eradication remains doable. Eight years of OPV2 SIAs on the African continent have pushed up type 2 population immunity. New strategies, including the IPV2 schedule in RI, is now standard, allowing more infants to receive at least one IPV dose. And new products, especially nOPVs and the hexavalent vaccine, are available and can contribute to control polio and increase immunity in a safer way.

Lessons learnt for bOPV cessation

The evaluation recommended ten prerequisites for bOPV cessation, based on lessons learnt from the 2016 switch. These were grouped into four main categories.

Vaccine availability

1. Ensure sufficient stockpiles of all relevant vaccines for "worst-case" outbreak scenarios.
2. Continue to manufacture bulk production and maintain fill-finish capacity for at least five years post-switch.
3. Modify containment goals to be more flexible and realistic.

Population immunity

4. Do preventive SIAs in high-risk countries.
5. Design realistic outbreak response standard operating protocols and secure sufficient funds for "worst-case" scenarios.
6. Develop special pre- and post-switch strategies for consequential geographies (for example intensively increasing population immunity pre-switch and pre-approving outbreak activities post-switch).

Routine immunization, especially in high-risk countries

7. Improve RI coverage above herd immunity thresholds.
8. Include nOPV2 in pre-switch routine immunization schedules.
9. Accelerate the introduction of hexavalent IPV and promote high coverage with it.

Phased withdrawal

10. Improve surveillance sensitivity, including speed of detection, and shipping and processing of samples.

The evaluation also recommended strengthening planning, risk management and programme performance, for example by defining success and failure before the bOPV switch, evaluating the switch quarterly, and ensuring a "Plan B" and contingencies for unexpected eventualities. It further recommended developing new ways to rapidly measure population immunity; and streamlining decision-making to accelerate action in the field.

A second switch failure is not an option. Drastic strategy changes and much closer collaboration with RI partners are required to achieve successful bOPV cessation. Prioritizing

approaches for outbreak response that incorporate innovative ideas with a consistent back-to-basics strategy, will ensure sustained success.

5.2. Planning for the end of bOPV

Speaker: Concepcion Estivariz, US Centers for Disease Control and Prevention

The end of bOPV use is currently planned for 2030 and this process is being guided by the bOPV cessation Team (BoCET), which is made up of immunization stakeholders within and beyond GPEI. It will adopt a phased approach.

- Phase I (2023–2025) will develop the policy framework and pre-requisites for bOPV cessation, incorporating lessons learnt from the 2016 switch.
- Phase II (2025–2030) will focus on planning and implementation, agreeing vaccine supplies with manufacturers and supporting country readiness for bOPV cessation and post-OPV RI schedules.

As endorsed by SAGE, bOPV cessation will only proceed if five non-negotiable conditions, or "triggers", can be met:

1. certification of WPV1 eradication by the Global Commission for the Certification of Eradication of Poliomyelitis (GCC);
2. certification of cVDPV2 elimination by GCC (as proof that OPV cessation is possible);
3. 24 consecutive months with no persistent (circulation >6 months) cVDPV1/3 outbreaks;
4. sufficient and available stockpiles of type-specific OPV vaccines (novel or Sabin); and
5. at least two years with *all* countries using RI schedules with two or more doses of IPV.

If one or more of these conditions cannot be met by 2030, the current timeline for bOPV cessation will have to change. In all cases, planning and implementing bOPV cessation must follow a "do no harm" principle and avoid the failures seen after the 2016 switch. The chances of success will be maximized if countries can ensure:

- high population immunity (through RI and risk-based pre-cessation SIAs using bOPV, done as close as possible to the cessation deadline, starting in 2027);
- outbreak response capacity (including risk-based standard operating protocols for post-cessation outbreaks);
- sensitive surveillance (that meets GCC standards pre- and post-cessation); and
- sufficient vaccines (including clinical and regulatory approval of nOPV1/3, see Box 5.1).

Box 5.1. Anticipated vaccine needs for bOPV cessation

To plan and implement bOPV cessation, sufficient vaccines of different types will be required, including:

- bOPV for pre-cessation campaigns;
- bulk and finished products of m/nOPV1/3 for post-cessation outbreak response* (current demand is projected to be 1.3 billion doses of m/nOPV1 and 650 million doses of m/nOPV3);
- bOPV buffer stockpile to cover RI in case of a delay in cessation; and
- IPV stockpile for pre- and post-cessation outbreak response.

* If there is a global residual stock of bOPV left over at the time of bOPV cessation, it may be used for outbreak response during the first year after cessation.

5.3. Research and development priorities

Speaker: Martin Eisenhawer, WHO

Traditional polio vaccines (IPVs and OPVs) have many strengths: they are licensed, safe, effective and widely used. Yet they have their disadvantages: IPVs provide poor mucosal immunity and OPV use can give rise to VDPVs. OPVs, including nOPVs, require the use of live virus during manufacturing, which creates a containment issue. And while polio vaccines are well established, there are still no treatments fully available for immunocompromised individuals who shed poliovirus for extended periods of time (also known as chronic excretors). These people pose a risk especially after eradication. GPEI is actively developing antivirals and monoclonal antibodies and other products to address this issue.

nOPV2 has become the de facto tool for outbreak response and the likelihood of new emergences with this vaccine is 9–10 times lower than with Sabin OPV2. nOPV1/3 are under development and are expected to have similar safety and stability profiles to their type 2 counterpart.

The following are some examples for new product developments in line with GPEI priorities:

Sabin IPV (sIPV). This technology was promoted because of potential cost savings as well as perceived less stringent containment requirements. Thanks to a technology transfer project managed by WHO, three manufacturers have successfully achieved prequalification for at least one presentation of sIPV and are actively pursuing it for others. Together, they have established a major international supply, with significant cost savings compared with wild type IPV. Containment requirements did not give an advantage to sIPV over wildtype IPV.

S19 strains. S19 strains are highly attenuated and genetically stable versions of poliovirus that are currently exempt by a temporary waiver from containment requirements for specific uses.[2] They are already available (from UK MHRA) as vaccine seeds for IPV production; and as a challenge virus for various laboratory assays. One manufacturer is currently in clinical phase 3 for a standalone product and phase 2 for a hexavalent product.

Virus-like particles (VLPs). Polio VLPs do not contain polio RNA but mimic the polio virus and induce an immune response. They could potentially replace IPVs in both standalone and combination presentations. In 2011, a research consortium established by WHO and led by the University of Leeds (United Kingdom) started researching and developing recombinant VLPs, based on a yeast expression system as well as baculovirus. Yields are good in both systems and stability and immunogenicity are similar or superior to IPV. Efforts to commercialize VLPs are ongoing based on the consortium's collaborations. Polio VLPs manufactured by CanSino, China, are the most advanced (see section 7.1). WHO has started having internal discussions about regulatory pathways for this promising vaccine candidate.

Antivirals and monoclonal antibodies. Various antivirals and monoclonal antibodies are under development as potentially useful treatments for chronic excretors.

[2] For a full list of specific strains and uses of S19 that are exempt from containment requirements, see Table 1 in the report of the Sixth Meeting of the CAG, January 2023.

5.4. Polio vaccines and prequalification

Speaker: Mathias Janssen, WHO

WHO prequalification for a vaccine equates to a WHO recommendation that it is of high quality, safe and effective. It is distinct from WHO Emergency Use Listing (EUL), which is a risk-based procedure that provides a time-limited recommendation for use during a PHEIC and necessitates ongoing efforts toward both prequalification and full market approval by NRAs.

Several polio vaccines have been prequalified to date (see Table 5.1).

Table 5.1. Number and type of prequalified polio vaccines to date.

Vaccine	Current	Under evaluation
combinations	2 (3 presentations)	-
wIPV	6 (12 presentations)	-
sIPV	3 (5 presentations)	-
mOPV1	3 (4 presentations)	2
mOPV2	3 (4 presentations)	-
mOPV3	1 (2 presentations)	1
bOPV	8 (13 presentations)	1
tOPV	3 (4 presentations)	-
nOPV2	2 (3 presentations)	1

There have been several achievements in polio vaccine prequalification since the 2023 annual consultation.

- PT Biofarma transitioned from EUL to prequalification for nOPV2.
- In July 2024, Biological E Ltd became the second manufacturer prequalified for nOPV2 (for finished product filled with bulk from PT Bio Farma, see section 7.2).
- A new bulk manufacturer is under assessment for bOPV.
- mOPV1/3 vaccines have been submitted for prequalification (although these are not high-priority vaccines).

In addition, three inspections and two sets of initial testing have been carried out as part of ongoing prequalification activities. Discussions on vaccines in development (including nOPV1/3 and VLPs) are also ongoing.

Post-prequalification activities

All vaccines are subject to activities after prequalification to ensure their continued acceptability. For example, manufacturers must submit annual reports, retain sample lots for WHO-targeted testing, and notify WHO of any changes to products, labels, or inserts. They must also report any product complaints or adverse events that occur as a result of immunization.

Other post-prequalification activities undertaken by WHO include assessing OPV batches for inclusion in global stockpiles.

6. Containment and certification

6.1. Global containment update

Speaker: Arlene King, GCC

Following certification of polio eradication, facilities that retain polioviruses will pose the greatest threat to maintaining a polio-free world. This makes poliovirus containment certification one of the three criteria for WPV eradication[3].

At the 71st World Health Assembly in 2018, WHO Member States adopted Resolution WHA71.16, which urged acceleration of containment activities globally and committed countries to implementing GAPIII. All WPVs and VDPVs as well as Sabin 2 strains must be either destroyed or transferred to another facility (risk elimination) or safely and securely contained (biorisk management) in a designated Poliovirus Essential Facility. The handling of Sabin 1 and 3 currently do not require GAPIV containment until bOPV cessation; and novel poliovirus strains (e.g. nOPVs and S19 strains) have been granted a temporary waiver for GAPIV containment.

The global mechanism for confirming containment associated with global poliovirus is the Poliovirus Containment Certification Scheme (CCS), which certifies define the process to certify facilities retaining polioviruses against GAPIV requirements. The CCS has three certification phases: certificate of participation (CP) which initiates the CCS process; interim certificate of containment (ICC) which marks a transitional phase of compliance; and certificate of containment (CC) which indicates full compliance with GAPIV.

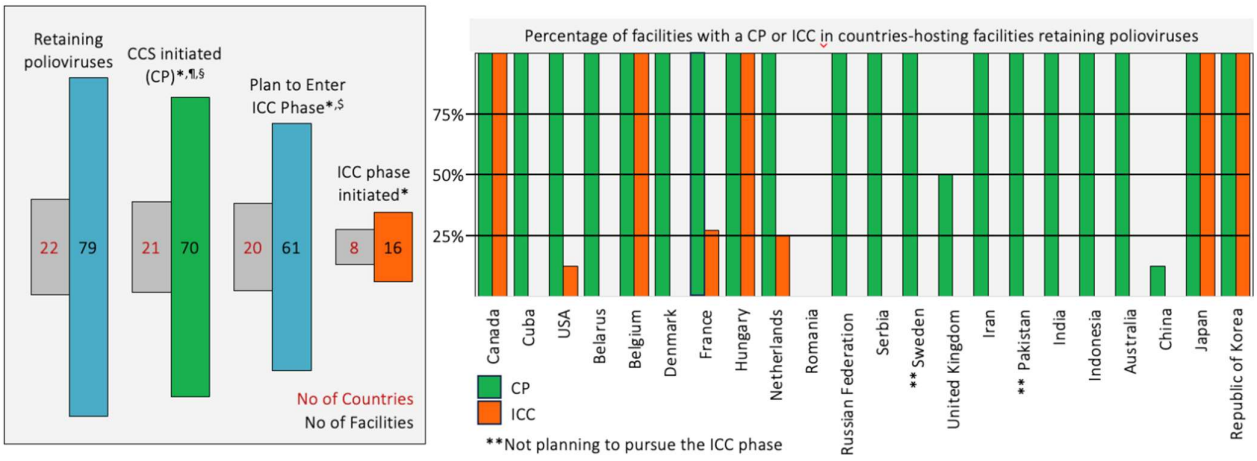
Progress in containment

In total, 78 facilities in 22 countries are retaining polioviruses. Most of these are laboratories, and most are located in the WHO European Region and the WHO Region of the Americas. In other regions, vaccine producers account for at least half of the facilities retaining polioviruses. Worldwide, 8% of facilities retaining polioviruses are storage-only facilities.

Overall, there is a decreasing trend in the number of facilities going through the CCS process to become poliovirus-essential facilities (PEFs) certified to store or handle eradicated polioviruses (see Fig. 6.1). While 70 out of 78 facilities were awarded an initial CP, only 60 have chosen to pursue an ICC. So far, 16 facilities in 8 countries have been awarded an ICC; with 9 ICC applications currently under review. Applications for CCs have yet to be submitted.

[3] 17th meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis, 26-27 February 2018, Geneva, SWITZERLAND. Available at: https://polioeradication.org/wp-content/uploads/2024/05/polio-eradication-certification-17th-meeting-global-commission-for-certification-of-poliomyelitis-eradication-20180412.pdf

Fig. 6.1. Global progress in containment certification of PEFs.



An analysis of ICC applications reviewed to date revealed that establishing and implementing a biorisk management system (Element 1 Biorisk Management System) was one of the biggest challenges for facilities of all types. Physical security (Sub-element 7.1, Element 7 Security) was also a major issue for vaccine production facilities, while many laboratories had problems with change management (Sub-element 1.10, Element 1 Biorisk Management System).

In November 2023, the GCC, which oversees the certification process for polio eradication, held its twenty-fourth meeting and reviewed the status of containment activities. It made three key recommendations to ensure continued progress in containment.

- Timelines to meet the containment requirements for certifying WPV eradication by the end of 2026 will remain in place independent of the status of WPV eradication.
- All facilities holding WPV3/VDPV3 must apply for an ICC immediately and are expected to achieve a full CC by the end of 2026.
- Facilities holding WPV1/VDPV1 in all but endemic countries must apply for an ICC immediately and are expected to achieve a full CC by the end of 2026.

Importantly, these recommendations remain unaffected by the GPEI strategy extension.

6.2. Global certification update

Speaker: Zubair Wadood, WHO

The Global Polio Eradication Strategy aims to certify the elimination of all WPVs by the end of 2027; and all cVDPVs by the end of 2029.

Certification of WPVs

The eradication of WPV2 and WPV3 were globally certified in 2015 and 2019 respectively. WPV1 has also been certified as eradicated in five out of six WHO Regions; only the Eastern Mediterranean Region remains uncertified because of endemic WPV1 transmission in Afghanistan and Pakistan. Since 2010 four outbreaks of WPV1 have also occurred in certified regions.

In February 2023, the GCC updated the criteria for global certification of WPV1 eradication, based on recommendations from an expert working group. The revised criteria include ensuring:

- no WPV transmission detected from any population source for at least two years;
- adequate global polio surveillance; and
- safe and secure containment of WPVs retained in facilities (see section 6.1).

Certification of VDPVs

The eradication of VDPVs is complicated by the fact that, while live OPV is used, new emergences of cVDPV outbreaks remain a real risk. In November 2023, the GCC agreed principles and procedures for certifying VDPV eradication that mirror the approach taken for WPVs.

The process will be globally uniform, coordinated by the GCC and Regional Certification Commissions using an agreed framework, with thorough engagement of National Certification Committees. Certification of VDPV eradication will:

- only be considered after all OPV use has ended;
- comprise two phases (elimination then eradication);
- consider each polio serotype sequentially, starting with cVDPV2;
- be conducted on a regional basis; and
- require the same standards of global surveillance and containment as those used for WPV.

The requirements for period of non-detection have yet to be determined. It will likely be a flexible period of not less than two years, considering factors such as surveillance quality, OPV and IPV coverage, and local geographical risk.

The period of time between global certification of VDPV elimination and certification of eradication is also yet to be determined. This is largely because the precise effect of ending OPV on VDPV prevalence is not yet fully known.

The GCC will continue providing guidance on this subject in view of the evolving epidemiological and programmatic situation.

7. Insights from manufacturers

7.1. Polio virus-like particles (VLPs)

Speaker: Xuefeng Yu, CanSino Biologics (CanSinoBIO)

After ten years of research and development, CanSinoBIO has created a VLP-polio vaccine using a recombinant structural protein assembled into VLPs of type I, type II and type III. The new vaccine is intended for use as a replacement (or supplement) for OPV/IPV in RI or outbreak response after eradication, in standalone or combination presentations.

Structural analysis of all three types of CanSinoBIO's VLPs show they are very similar to the actual virus. Purity is high and the VLPs remain stable over 12 months. Animal studies have shown that immunogenicity was at least comparable to sIPV; and can be significantly enhanced with the use of aluminium adjuvant..

In 2024, the first in-human trial of the VLP-polio vaccine was completed on adults in Australia. The vaccine was found to be safe (with no grade 3 adverse events) and highly immunogenic as a booster dose. CanSinoBIO has recently gained approval for Phase I/II clinical trials of its VLP-polio vaccine on infants and toddlers in Indonesia. And it is working with partners on including its VLPs into combination vaccines (both pentavalent and hexavalent).

VLPs do not rely on live viruses for their production and so are not infectious and reduce the biosafety risk associated with current polio vaccines. CanSinoBIO has shown that the production process for the VLP-polio vaccine is also scalable and cost–effective, with consistent quality. It is ready to scale up to commercial levels and already has capacity to produce around 200 million doses per year.

CanSinoBIO is aiming for regulatory approval in 2029 and will then apply for WHO prequalification. Following a request from participants, CanSinoBIO confirmed it was open to discussions on technology transfer.

7.2. nOPV2 supplies

Speaker: Iin Susanti, PT Bio Farma

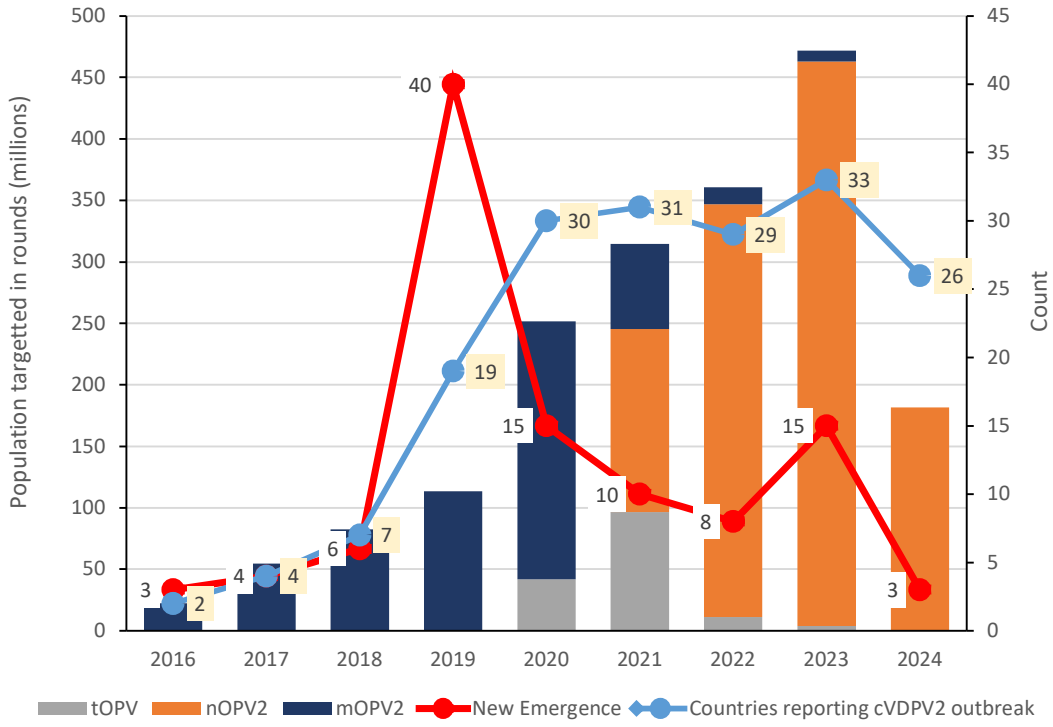
Developed by PT Bio Farma, nOPV2 is a next generation version of the Sabin OPV2 used in cVDPV2 outbreak response. It has similar immunogenicity and safety profiles to Sabin OPV2 and greater genetic stability.

In November 2020, nOPV2 became the first vaccine to be issued an EUL recommendation and rollout under the EUL procedure began in early 2021. In March 2023, SAGE recommended using nOPV2 as the preferred option for responding to cVDPV2 outbreaks and later that year it transitioned from EUL to WHO prequalification status.

To date, GPEI has administered more than 1.2 billion doses of nOPV2 to children in 41 countries. Nearly half of these (580 million doses) have been targeted at children in consequential geographies. In the past 12 months alone, 50 campaigns targeting 220.7 million children have been conducted globally. This includes the first of two rounds of polio vaccinations in Gaza, which reached 87% coverage of a target 640 000 children).

The global shift to nOPV2 has driven a dramatic decline in the number of new emergences (see Fig. 7.1).

Fig. 7.1. Increased nOPV use has driven a decline in new emergences and countries infected.



Until July 2024, PT Bio Farma was the only global supplier of nOPV2. Now, following a successful technology transfer project, Biological E has joined the pool of suppliers, prequalified to provide finished product nOPV2 filled with bulks from PT Bio Farma (see section 5.4).

Following the success of nOPV2, PT Bio Farma is now developing nOPV1 and nOPV3. It is working in collaboration with PATH with support from the Bill and Melinda Gates Foundation. It is aiming to achieve an EUL recommendation for nOPV1 in 2026 and another one for nOPV3 in 2027, followed by WHO prequalification two years after.

After certification of polio eradication, PT Bio Farma will remain a poliovirus-essential facility; it is in the process of applying for an ICC.

7.3. Novel bioreactor system for Sabin IPV

Speaker: Ahd Hamidi, Batavia Biosciences

A highly intensified process including the use of fixed-bed bioreactors, continuous processing and capture chromatography systems provide a novel platform for scaling up the production of viral vaccines and viral vectors. This platform is less labour intensive than traditional platforms, has a smaller footprint and can reach very high cell densities that improve product yield. At Batavia Biosciences, fixed-bed bioreactors have been successfully used to develop a manufacturing process for IPV based on Sabin strains.

Batavia Biosciences' high intensity process manufacturing platform (HIP-Vax) is designed to reduce the footprint and therefore cost of vaccine manufacturing, and so improve vaccine equity. It has been proven to work for various different vaccines, including live, inactivated and vector-based vaccines.

With funding from the Bill and Melinda Gates Foundation, Batavia Biosciences is applying its HIP-Vax technology to Sabin IPV production and transferring the technology to vaccine manufacturers in low- and middle-income countries. The technology transfer package is fully comprehensive, including:

- process know-how (e.g. analytical methods, assays, equipment assembly etc);
- biological materials (including virus seeds for Sabin types 1, 2 and 3),
- safety and containment documentation; and
- personnel training (e.g. in cell culture, virus infection and purification procedures).

Through the project, Batavia Biosciences has also been able to demonstrate the scalability of its process, with equal upstream performance at small, pilot and commercial scales.

7.4. Needle-free injections for polio RI

Speaker: Paul LaBarre, PharmaJet

PharmaJet's Tropis needle-free injection system for delivering intradermal fractional dose IPV (fIPV) has a strong evidence base for improved coverage, decreased immunization costs, and high acceptability from campaigns in Nigeria, Pakistan and Somalia. New, unpublished data from a randomized study in Nigeria shows similar results when Tropis is used in RI programming.

The Tropis device is the first and only needle-free technology to achieve WHO prequalification. Through a network of global development and commercial partners, it has also gained regulatory approval in many countries around the world.

The device itself is handheld, with no external power source. It has no sharps waste and the injection takes 0.1 seconds, which is more than 100 times faster than other intradermal techniques. It can be used with any multidose vial and each device is durable for 20 000 injections or more.

To date, more than ten million fIPV doses have been given to children using the Tropis device. Several studies in the field have shown that needle-free injections enable house-to-house administration and consistently have high acceptability among infants, caregivers and non-traditional health care workers. Tropis delivery has also been found to achieve higher coverage compared with needle and syringe implementation. Until now, evidence showing decreased total immunization costs and improved coverage was limited to campaign settings.

With funding from USAID, study partners (Jhpiego, Johns Hopkins University, Nigeria National Primary Healthcare Development Agency, PATH, PharmaJet and Sydani Group) conducted a cluster randomized trial in 52 facilities using the Tropis device to deliver fIPV in Nigeria's RI programme. The results are as follows:

Coverage: Tropis is an effective intervention for increasing coverage of IPV2.

- Among those vaccinated with Tropis, IPV2 coverage was 11.2% higher compared with the standard of care.
- The odds of receiving two doses of IPV are doubled when Tropis is used.

Costs: All intervention scenarios show cost savings compared with the standard of care.

- Incremental cost savings with Tropis ranged from US$ 0.07 to US$ 1.00 per dose administered across evaluated scenarios with up to 47% total immunization cost savings compared with the standard of care at full scale.
- Switching to needle-free delivered fIPV could save the Nigeria immunization programme around US$ 50 million over five years.

Feasibility: Needle-free was highly valued compared with the standard of care.

- Caregivers: 96% acceptability.
- Healthcare workers: 95% (preference), 89% (easier), 78% (safer).
- Tropis reduced administration time by five seconds on average compared with the standard of care.
- Zero device malfunctions (over six months).

Following a query from participants, PharmaJet confirmed that it has current production capacity of 50 million syringes per year and could easily quadruple that within six months if there were clear demand signals and forecasts.

Conclusion

The strategies for eradicating polio work when they are fully implemented, as evidenced by the incredible progress in eradication achieved over the past 30 years. Vaccines remain the critical ingredient for success. Overcoming the final hurdles to eradication requires a strong focus on those last few pockets of the world where polio still lingers and where health systems are fragile.

It cannot be done without collaboration and cooperation on a global scale and this is the GPEI's strongest asset. The value of working in partnership with vaccine manufacturers, regulators and containment authorities cannot be understated.

Before closing the meeting, Dr Vachagan Harutyunyan, Team Lead for the Detection and Interruption Unit of WHO's Department of Polio Eradication, thanked all participants for their active involvement in this year's consultation and for the useful, insightful and informative updates and deliberations. He encouraged participants to maintain their engagement with the GPEI and to continue being open, sharing ideas and working together to achieve the programme's ambitions for a polio-free world. Dr Harutyunyan also thanked all speakers and facilitators for their contributions, and the organizing team.

Annex

Annex 1. Agenda

Consultation between the GPEI and poliovirus vaccine manufacturers, national authorities for containment and national regulatory authorities

23 October 2024 | Geneva, Switzerland (and online)

Chairs: Mike Ryan (Deputy Director-General, WHO; Chair, GPEI Strategy Committee). Alternates: Dan Walter and Arshad Quddus (WHO).

09.00 –09.20	**Introduction**	
Welcome and opening remarks		Mike Ryan, WHO
Introduction and orientation		David Woods, WHO
09.20–10.15	**Session I. Update on the status of the programme and the strategy addendum**	
Global update on polio eradication and the addendum to the GPEI strategy		**Arshad Quddus, WHO**
10.15 –10.30	**Break**	
10.30–11.00	**Session II. The Polio Vaccine Security Framework**	
Briefing on the Polio Vaccine Security Framework and its implementation		**Vachagan Harutyunyan, WHO** **Ann Ottosen, UNICEF**
11.00–12.30	**Session III. Demand forecasts for OPV and IPV**	
Update on OPVs		Ann Ottosen & Ian Lewis, UNICEF
Update on IPV		Ian Lewis, UNICEF Alejandro Ramirez Gonzalez, WHO Katy Clark & Elie Akiki, Gavi
Forecasting of global IPV and bOPV requirements		David Woods and Vachagan Harutyunyan (WHO)
12.30 –13.30	**Lunch**	
13.30–15.15	**Session IV. New developments in polio vaccines and products**	
Evaluation of the 2016 switch from tOPV to bOPV		Roland Sutter, Consultant
Update on the process and status of planning for the cessation of OPV use		Conchi Estivariz, US CDC
R&D: Update on GPEI's priorities and new developments		Martin Eisenhawer, WHO
Update from the Vaccine Prequalification Team on polio-related activities		Mathias Janssen, WHO
15.15 –15.30	**Break**	
15.30–16.30	**Session V. Containment and certification**	
Global update on progress towards the certification of poliovirus containment		**Arlene King, GCC** **Derek Ehrhardt, WHO**
Update on the certification of polio eradication at the regional and global levels		**Zubair Wadood, WHO**
16.30–17.45	**Session VI. Presentations from manufacturers**	
Updates and insights from manufacturers on innovations in polio eradication		**CanSino** **Bio Farma** **Batavia** **PharmaJet**
17.45–18.00	**Wrap-up**	
Concluding remarks		**Arshad Quddus & Dan Walter, WHO**

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