



Bivalent Oral Polio Vaccines: Supply and Demand Update

UNICEF Supply Division
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Bivalent Oral Polio Vaccine: Supply and Demand Update – April 2024

This note provides a historic overview as well as key vaccine demand and supply projections for the bivalent Oral Polio Vaccine (bOPV) for 2024 to 2027 and key considerations for the polio eradication endgame including milestones and timelines of importance for the bOPV market.

1. Summary

- There is a critical need to continue surveillance of polioviruses. As evidenced by the notification of Wild Polio Virus type 1 (WPV1) cases in Malawi and Mozambique in 2021 and 2022, likely to have circulated silently for a couple of years, connected to a Pakistan virus; the occurrence of poliomyelitis cases in 2022 and 2023 in the United States of America (cVDPV2) and Israel (cVDPV2 and 3); and of environmental samples of cVDPV2 collected in the United Kingdom and Canada; these cases are a strong reminder that as long as the poliovirus is anywhere in the world it is a threat everywhere. High immunisation coverage rates are prerequisites for achieving polio eradication, and the availability of sufficient vaccines of the right type at the right time of assured quality at affordable prices are a key accountability of UNICEF Supply Division (UNICEF SD).
- The Global Polio Eradication Initiative (GPEI) partners, including UNICEF and the World Health Organization (WHO), vaccine manufacturers and countries are preparing for the final phase of bOPV cessation in line with the Polio Eradication Strategy 2022-2026: *Delivering on a Promise*.
- In 2023, GPEI and its partners, through front line health workers, vaccinated more than 400 million children preventing an estimated 650,000 cases of paralyses from polio and saving the lives of up to 60,000 children¹.
- Following a reassessment in October 2023, the GPEI considers that despite missing the 2023 deadline to interrupt transmission of WPV1, certification of eradication may still be achievable in 2026 – a minimum of two years after the last WPV1 – with a subsequent phase out of bOPV earliest in 2027. Timelines will be revisited mid 2024.
- The current global supply capacity of bOPV vaccine meets the current global demand from 143 countries and territories that continue to use bOPV. Although there is a strong reliance on one manufacturer for supply of drug substance to the global market, domestic manufacturers continue to provide critical contributions to overall supplies by meeting local demand. There is a need for advance planning in case of any increase in demand, e.g., as part of pre-cessation activities.
- In 2022 and 2023, UNICEF made awards to seven OPV manufacturers having vaccines prequalified by WHO for global supply based on the GPEI forecast. Awards were made in line with tender award criteria, including product presentations and licensure in multiple countries.

¹ [GPEI – a brief review of 2023 and full focus on 2024 – GPEI \(polioeradication.org\)](https://polioeradication.org)

- UNICEF continues its efforts with the GPEI and modellers to enhance the accuracy of demand forecasts. In recent years, UNICEF's demand forecasts for bOPV have not been fully achieved because of the cancellation of preventive campaigns due to financial constraints caused by the need to prioritise outbreaks; and because in 2020 more than 60 campaigns were cancelled due to the Covid-19 pandemic.
- While demand has not fully materialised, manufacturer risks have been mitigated by carrying forward stocks produced against forecast across years, and provided residual shelf life has been acceptable to countries, bOPV has been consumed although with some delays. It is critical that vaccine manufacturers do not make unilateral decisions to exit the bOPV market at this critical stage. Strategies to continue to mitigate risks to vaccine manufacturers and the GPEI will continue to be explored to secure required supplies.
- UNICEF will require between 3.7 to 3.9 billion doses of bOPV over the next 4 years should bOPV withdrawal take place in 2027. This demand will represent a value of around \$500 million based on the weighted average price of 2023. Should the bOPV withdrawal be delayed further, demand will extend beyond 2027 and increase with an estimated 800 million doses annually, all things being equal.
- UNICEF is revisiting its procurement strategy and assessing options for the extension of supply agreements to ensure supply post 2024.
- UNICEF will continue to work with vaccine manufacturers to secure sufficient bOPV to achieve the goal of global eradication of poliomyelitis, including to fully meet the potential increased needs for pre-cessation immunity boosting activities in advance of cessation, and establishing appropriate OPV stockpiles as required.
- In this final phase towards global eradication of wild polio viruses, a continued close collaboration across all stakeholders along the vaccine supply chain will determine if the goal is achieved. Without sufficient vaccine – as well as resources to administer the vaccines to achieve a sufficient level of immunity in the most difficult areas – there is a risk that poliomyelitis may not be eradicated and makes a return to countries and continents earlier declared free from poliomyelitis.

2. Background

Poliomyelitis² is a highly contagious acute disease caused by one of three poliovirus serotypes (poliovirus types 1, 2 and 3). Transmission occurs through faecal-oral and oral-oral routes, with faecal-oral transmission being more common in areas with poor access to water and sanitation. Polio mainly affects children below 5 years of age. Infected individuals excrete poliovirus through faecal and pharyngeal shedding, typically for 4 and 2 weeks respectively. In 72% of cases the infection will be asymptomatic; 24% of infections cause minor illness such as fever, malaise, drowsiness, headache, nausea, vomiting, constipation, or sore throats. Rare outcomes are nonparalytic poliomyelitis - aseptic meningitis – which occurs in 4% of cases; and with paralytic poliomyelitis presenting in less than 1% of cases. The probability of severe paralysis and fatality increases with age of infection. 25 to 40% of children recovering from paralytic poliomyelitis develop post-polio syndrome – acute or increased muscle weakness, pain and fatigue within 15-40 years from initial recovery. There is no cure for paralytic poliomyelitis.

² This section is based on WHO's Weekly Epidemiologic Report [WER9725-eng-fre.pdf \(who.int\)](https://www.who.int/publications/m/item/wer9725-eng-fre)

In 1985, Rotary International launched a global effort to immunize the **world's children against polio**³, and in 1988 at a time when an estimated 350,000 cases were seen annually in more than 125 countries, the World Health Assembly launched the Global Polio Eradication Initiative⁴, initially convening Rotary, WHO, UNICEF, US Center for Disease Control and Prevention (USCDC) and national governments, later joined by the Bill & Melinda Gates Foundation and Gavi, and the Vaccine Alliance. In September 2015, the Global Commission for the Certification of Poliomyelitis Eradication (GCC) declared that wild polioviruses type 2 had been eradicated, paving the way for the global synchronised withdrawal of type 2 containing oral poliovirus vaccines in April 2016 (the Switch). In October 2019, the GCC declared wild poliovirus type 3 as eradicated globally. It is estimated that since the inception of the GPEI, 20 million people are walking today who would otherwise have been paralysed.⁵ As of week 52, 2023, 12 cases of WPV1 were confirmed across two countries: Pakistan and Afghanistan, which are the only two countries where polio remains endemic today. The number of cases in 2023 is a 60% reduction from the number of cases in 2022 (30 cases).

While transmission of WPV1 is now highly concentrated and focused in subgeographies in the two remaining endemic countries, there has been an increase in the number of cases caused by circulating vaccine-derived polioviruses of types 2 and 1 (cVDPV2 and cVDPV1). In communities with low immunization rates, as the attenuated virus of the vaccine spread from one unimmunized child to another over a long period of time (typically 12-18 months), the weakened virus can mutate and take the form that can cause paralysis like the wild virus. The mutated poliovirus can then spread in communities.⁶ In the last four years, the cVDPVs have outnumbered the WPV cases, with a predominance of cases of cVDPV2 confirmed across 40 countries over the period, peaking with 1,009 cases in 2020; and cases of cVDPV1 in 7 countries peaking in 2022 at 193 cases.

3. Programme Update

The current *Polio Eradication Strategy 2022-2026: Delivering on a Promise*⁷ has two goals: first, to interrupt all remaining transmission of WPV1 in endemic countries, and second, to stop cVDPV2 transmission and prevent outbreaks in non-endemic countries. Both goals were initially set to be achieved by the end of 2023. While the first target is off track, the GPEI remains confident that WPV1 certification of eradication can still be achieved by 2026 which is the prerequisite for global cessation of bOPV use after 2027.⁸ With regards to goal two, the GPEI confirms that the target has been missed, but the Programme is scaling up outbreak responses to ensure interruption can be achieved in 2025, provided there is sufficient funding and vaccine supply. The GPEI is operating in the most challenging contexts of the world where insecurity, inaccessibility, and political challenges present roadblocks for reaching all children with life saving vaccines. The highest priority now is reaching high population immunity in i) the endemic countries; and ii) in subgeographies in DRC, Nigeria, Somalia and Yemen which are considered at highest risk for reintroduction of polioviruses.

³ [History of Polio – GPEI \(polioeradication.org\)](https://polioeradication.org/history-of-polio/)

⁴ [GPEI – a brief review of 2023 and full focus on 2024 – GPEI \(polioeradication.org\)](https://polioeradication.org/gpe-i-a-brief-review-of-2023-and-full-focus-on-2024/)

⁵ [GPEI-response-to-midterm-review-20231127.pdf \(polioeradication.org\)](https://polioeradication.org/gpe-i-response-to-midterm-review-20231127.pdf)

⁶ [Variant Poliovirus \(cVDPV\) – GPEI \(polioeradication.org\)](https://polioeradication.org/variant-poliovirus-cvdpv/)

⁷ [GPEI Strategy 2022-2026 – GPEI \(polioeradication.org\)](https://polioeradication.org/gpe-i-strategy-2022-2026/)

⁸ [GPEI-response-to-midterm-review-20231127.pdf \(polioeradication.org\)](https://polioeradication.org/gpe-i-response-to-midterm-review-20231127.pdf)

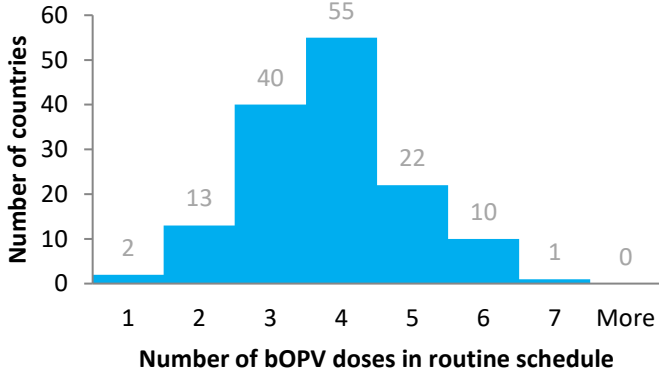
While there have been setbacks, the GPEI is moving forward setting the stage for a future polio free world, in parallel with intensifying efforts to increase immunization reach and coverage. Following April 2022 recommendations by the Strategic Advisory Group of Experts on Immunisation to WHO (SAGE), the GPEI has established a working group to enable efficient planning and implementation of the withdrawal of OPV from routine immunization programs one year after certification of wild poliovirus eradication.⁹ Also, efforts are also picking up to update the Polio Post Certification Strategy,¹⁰ which defines the global technical standards or core sets of activities that will be needed in order to sustain a polio-free world after global certification of wild poliovirus eradication; with the goals to i) contain polioviruses; ii) protect populations; and iii) detect and respond. A Global OPV Stockpile Strategy was published in 2023 to secure vaccine supply to support these efforts.¹¹ The next step is for the GPEI to finalise a revised certification timeline, plan, and budget to be submitted to the Polio Oversight Board in the first quarter of 2024. The current budget to cover the 2022-2026 Strategic Plan is \$4.8 billion, out of which with \$3.3 billion have been pledged.

4. Current Market and Trends

4.1. Global demand

In 2013, at the time of the decision to proceed with the global withdrawal of the trivalent OPV (tOPV), 155 countries and territories used trivalent OPV (tOPV) as part of their Expanded Program on Immunization (EPI); some countries had a mixed schedule using OPV and Inactivated Poliovirus Vaccines (IPV) together; however, 126 countries did not have IPV in their immunization schedule. As of 2023, 143 countries and territories are still using bOPV as the backbone of their routine immunization schedule; in 40 countries this is supplemented with only one dose of IPV, and with at least two IPV doses in the rest of the countries, which is in compliance with current SAGE recommendations.

Figure 1: Number of bOPV doses in EPI schedule, by number of countries



Source: UNICEF based on WHO Immunization data, Vaccination schedule for Poliomyelitis.¹²

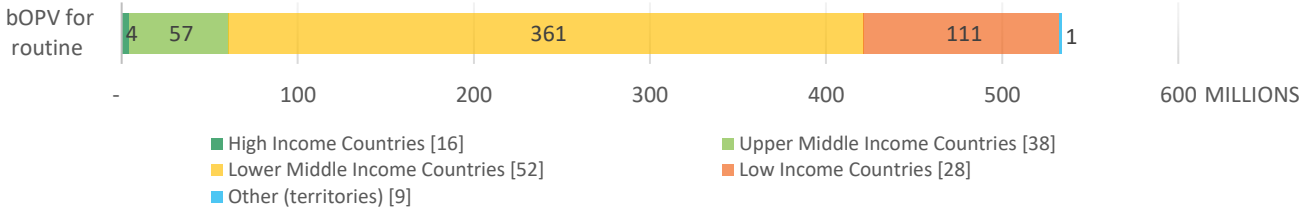
⁹ [sage_april2022meetinghighlights_11apr2022_final.pdf \(who.int\)](#)
¹⁰ [Polio Post-Certification Strategy – GPEI \(polioeradication.org\)](#)
¹¹ [Global OPV Stockpile Strategy 2022-2026 \(polioeradication.org\)](#)
¹² [Vaccination schedule for Poliomyelitis \(who.int\)](#), accessed 29 February 2024

Most countries – 95 countries and territories out of 143 - are offering three or four doses of bOPV in their EPI schedule, while some countries are offering five or six doses. Most doses are usually administered in the first year of life, and the last dose is given up to 10 years of age as per the EPI schedule. One country that had discontinued use of OPV and relied on an IPV only schedule, reintroduced two doses of bOPV due to circulation of viruses in order to build mucosal immunity and prevent outbreaks.

In 2016, at the time of the global switch from tOPV to bOPV, 155 countries and territories were using OPV. Since then, 12 countries and territories have switched to an all IPV schedule using either a pentavalent combined vaccine protecting against diphtheria, tetanus, pertussis, hepatitis B and haemophilus influenzae type b, plus an IPV stand alone vaccine administered as a fractional or full dose, or a hexavalent vaccine.

UNICEF estimates that global demand for bOPV to meet routine requirements was around 534¹³ million doses in 2023.

Figure 2: bOPV Global Demand for Routine Immunization for 2023



Source: UNICEF estimate.

Approximately 52 per cent of the global demand for bOPV for routine immunization is self-procured by countries directly from vaccine manufacturers, with India purchasing over 50 per cent of the self-procured volumes. UNICEF SD procures approximately 45 per cent of the global routine demand annually and the remaining 3 per cent is procured through PAHO Revolving Fund on behalf of 27 countries and territories across Latin America and the Caribbean.

In addition to the demand for bOPV to meet routine requirements of countries, the supply of bOPV is required to respond to outbreaks of WPV1, cVDPV1 and cVDPV3 as well as for supplementary preventative immunisation activities. UNICEF estimates that the global annual demand for bOPV is around 1.3 billion doses.

The bOPV vaccine market value is estimated at a range between \$172 million to \$533 million in 2024 with the low range based on UNICEF’s weighted average price per dose in 2023, and the high range based on the average price per dose of \$0.41 as reported by countries to WHO in 2022.¹⁴

¹³ Methodology: Estimated based on data provided by countries through UNICEF’s annual forecast exercise for 2023; historical procurement data by country up to 2022; WUENIC DTP1; Polio3 coverage estimates; UN’s population data and administrative immunization targets; wastage data from countries and model assumptions to estimate missing data.

¹⁴ [Immunization, Vaccines and Biologicals \(who.int\)](https://www.who.int/immunization/vaccines-and-biologicals), accessed 29 February 2024

While the updated GPEI planning as of February 2024 targets eradication of WPV1 in 2024, and certification of eradication in 2026 leading to bOPV withdrawal in 2027, historically, the set targets have been missed repeatedly since the initial target of year 2000. Delays in eradication are due to challenges in stopping transmission of wild polio viruses through campaign activities in some of the most difficult geographies and low routine coverage. Based on this background UNICEF considers that it is highly likely that there will continue to be demand for bOPV at a high level even beyond 2027.

4.2. Global Supply

Since 1961, when the live attenuated OPV was first licensed following development by Dr. Albert Sabin, a global supply market has materialised which today provides sufficient production capacity to meet global requirements. As of today, eight vaccine manufacturers have bOPV prequalified by WHO, with a minimum of 24 months of shelf life, and in 10 and 20 dose vial presentations.

Table 1: Overview of WHO Prequalified bOPV Product Presentations by Manufacturer

Manufacturer	WHO Preq	Presentation	Shelf life
Beijing Institute of Biological Products Co., Ltd.	2017	20 dose vial	24 months
	2015	20 dose vial	24 months
Bharat Biotech International Limited	2017	10 dose vial	24 months
	2009	20 dose vial	24 months
GlaxoSmithKline Biologicals SA	2009	10 dose vial	24 months
	2010	20 dose vial	24 months
Haffkine Bio Pharmaceutical Corporation Ltd	2018	20 dose vial	24 months
	2021	10 dose vial	24 months
Panacea Biotec Ltd	2010	20 dose vial	24 months
	2015	10 dose vial	24 months
PT Bio Farma (Persero)	2011	20 dose vial	36 months
	2013	20 dose vial	24 months
Serum Institute of India Pvt. Ltd	2014	10 dose vial	24 months

Source: World Health Organization¹⁵
 * Production discontinued.

In addition to the vaccine manufacturers which have pursued WHO prequalification with the purpose to supply to the global market, a number of vaccine manufacturers are producing and supplying bOPV for domestic use in Brazil, China, India, Iran, and Russia.

Over the last decade, three European manufacturers have decided to exit the OPV market. The strategic decisions to discontinue production have been triggered by the eventual cessation of OPV use, low profit margins, investments required to upgrade outdated production sites, and

¹⁵ [List of Prequalified Vaccines | WHO - Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)](#) – accessed 31st January 2024

opportunity costs. Two of the manufacturers – Novartis and Sanofi Pasteur - are no longer producing bOPV, whereas the third manufacturer GlaxoSmithKline Biologicals SA is expected to deliver the last doses to UNICEF in 2024 and 2025. This production is based on drug substance initially produced on order from UNICEF in 2015 with the purpose and intent to convert the drug substance to monovalent vaccines for a Global OPV Stockpile in advance of OPV cessation, at the time expected to take place in 2018. Given the delay in bOPV withdrawal and therefore the requirements for stockpiling of monovalent vaccines at this point in time, the GPEI has authorised the release of the drug substance for bOPV production.

Based on supply offers received by UNICEF in 2023 for 2024 supplies of 1.8 billion doses, global filling capacity of bOPV is sufficient to meet the global demand of 1.3 billion doses as estimated above. However, UNICEF considers the global bOPV supply market to be highly vulnerable and at considerable risk of supply interruption as currently only two global manufacturers are producing drug substance, and only one of these is supplying to global fillers. Four manufacturers of prequalified bOPV are sourcing the Sabin OPV1 and OPV3 drug substance from the same production source and filling in India. When reassessing the offered capacity based on availability of drug substance, UNICEF estimates that the supply capacity from global suppliers in 2024 is around 1.2 billion doses. Therefore, the production from domestic suppliers remains critical to ensure sufficient supply to meet the estimated global demand.

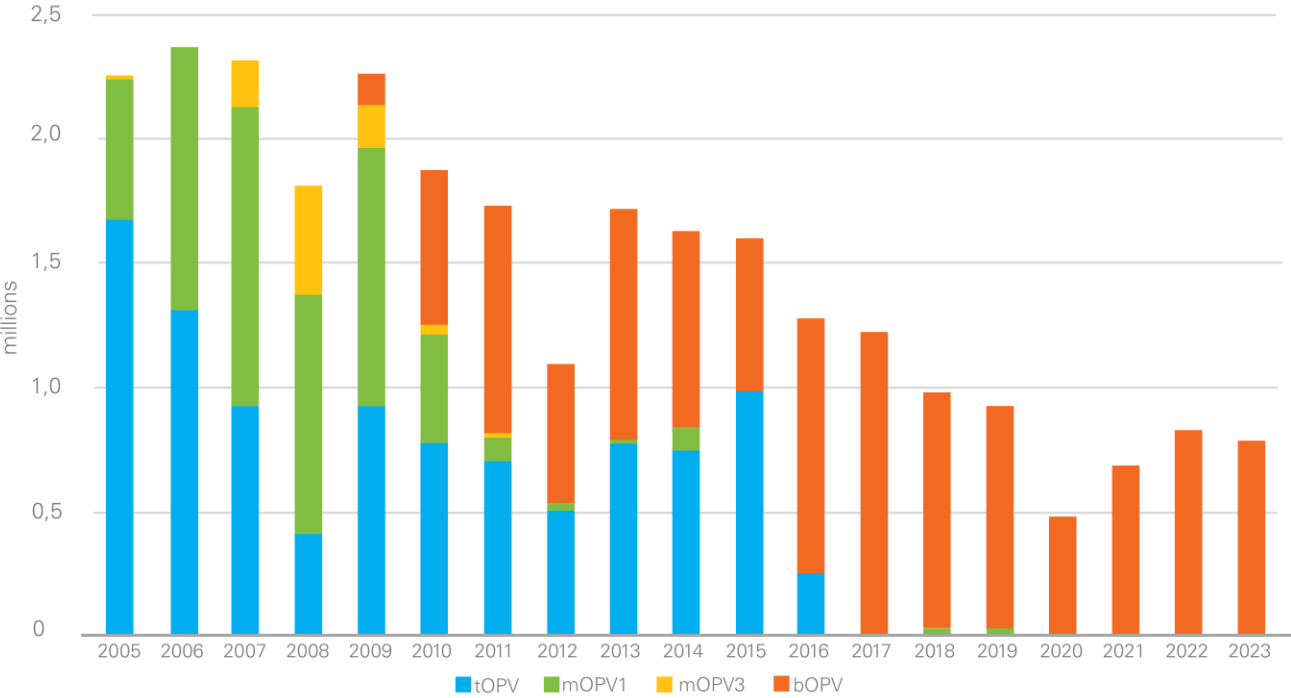
Given the expectation that bOPV will eventually be withdrawn from use and the low price per dose, despite a considerable annual demand at this point in time, there are limited commercial incentives for new manufacturers to enter this market. However, to mitigate potential supply risks UNICEF continues to explore options to expand the supplier base for drug substance production, as well as other risk mitigating measures such as stockpiling of drug substance and finished product. The need to share risks related to demand uncertainty between the program and manufacturers continue to require exploration in the critical last phase of the eradication program.

5. Procurement through UNICEF

5.1. Historic Procurement and Weighted Average Prices

UNICEF has been procuring OPV for decades on behalf of countries to meet the requirements for routine immunization and supplementary activities, as well as operating as a procurement agency for the GPEI securing supplies for outbreak response and Supplementary Immunisation Activities (SIAs). The demand profile has been very dynamic and new vaccines have been developed with financial and technical support from the GPEI to be implemented without delays to respond to the evolving epidemiology.

Figure 3: All types of OPV doses procurement through UNICEF 2005-2023 (excluding OPV doses for stockpiles)



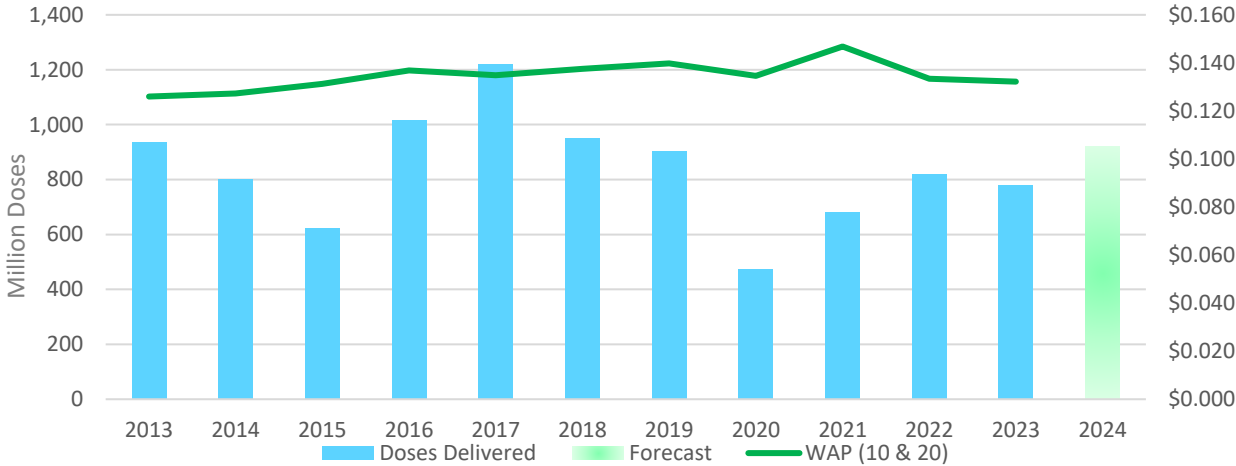
Source: UNICEF Procurement Data.

The demand through UNICEF peaked in 2005-2009 at around 2.3 billion doses annually, at a time when India sourced OPV through UNICEF. Since 2009, the demand for OPV has been gradually but slowly declining as polio has been eradicated in large parts of the world, however, due to the risks of viruses spreading from endemic countries, routine coverage and outbreak responses still require OPV.

The preferred mix of products between 2005 to 2009 were tOPV and monovalent OPV1 (mOPV1). In 2009 bOPV was initially launched in the market and demand for mOPV1 rapidly discontinued with demand predominantly being split between tOPV and bOPV until the global withdrawal of tOPV in April 2016. There has been sporadic but low demand for mOPV1 in 2018 and 2019, but this vaccine is no longer routinely in production and therefore only produced to order in case of funded demand.

In addition to bOPV, as mentioned above, UNICEF supplied between 500 to 980 million doses of tOPV for use in 2012 to 2015 for routine and supplementary requirements, including to boost type 2 immunity in advance of the tOPV withdrawal in April 2016. Demand across the two vaccines was stable around 1.5 billion doses of vaccines in the years 2013 to 2015.

Figure 4: Annual Procurement and Weighted Average Price of bOPV through UNICEF (2012-2023), and UNICEF demand forecast for 2024



Source: UNICEF Procurement Data, GPEI Forecasts.

Between 2013 and 2023, UNICEF procured around 9.2 billion doses of WHO prequalified bOPV across 10 and 20 dose presentations, delivering to around 80 countries annually.

The bOPV demand peaked in 2017, the first full year of bOPV use after tOPV withdrawal, at around 1.2 billion doses. In 2020, demand dipped due to the Covid pandemic, with more than 60 OPV campaigns being cancelled or postponed. Demand through UNICEF appears to have plateaued around 800 million doses annual disregarding pandemic years 2020 and 2021.

The weighted average price per dose procured through UNICEF across the two presentations (10 and 20 dose vials) has fluctuated between \$0.126 and \$0.147 across 2013-2023. Drivers of change in weighted average prices are the mix of product presentations in demand, different prices offered by different manufacturers, volume discounts, prepaid drug substance, country requirements for licensed vaccines and availability across manufacturers at time of requirement. **UNICEF’s procurement prices** are available at [OPV-vaccine-prices-15082023-1.pdf \(unicef.org\)](#). While it is critical to continue to maintain a low price per dose to ensure continued cost efficiency of the Programme and make donor contributions go further, the ability to pursue volume discounts need to be carefully balanced against the potential risks to secure uninterrupted supplies through an increased dependency on a limited number of suppliers and national regulatory authorities for release of vaccines.

5.2. Procurement and tender approach

UNICEF issued a tender for the supply of bOPV in 2016, with the purpose to secure supply starting from 2018 through to bOPV cessation, which at the time was anticipated to take place in 2021 or 2022. The overall objectives of the tender were to i) sustain sufficient supply of OPV to meet demand through polio eradication and OPV cessation; and ii) guide the cessation of the OPV market in a responsible manner while maintaining affordability. These objectives continue

to drive **UNICEF's procurement approach for bOPV**. UNICEF has so far aimed to maintain the broadest possible supplier base by awarding all manufacturers of WHO prequalified vaccines through 2023, maximising awards to manufacturers which are producing finished product based on their own drug substance to reduce risks of further market exits of drug substance producers.

As such, in 2022 and 2023, UNICEF made awards to four OPV manufacturers of bOPV having vaccines prequalified by WHO for supply in 2023 and 2024. This was done based on demand forecasts provided by countries to UNICEF as part of the annual forecasting exercise for routine requirements and from GPEI with regards to planned SIAs in the endemic countries and preventative activities, as well as securing a buffer to draw on in case of outbreaks. Awards were made in line with tender award criteria, including with regards to product presentations and licensure in multiple countries for the respective years. In 2021, 2022 and 2023 GPEI had forecasted preventative bOPV campaigns in a number of high-risk countries. However, these activities were cancelled due to a need for the Program to prioritise available funding for outbreak response of cVDPV2 over preventive bOPV campaigns. Therefore, UNICEF did not fully procure forecasted doses which at end of 2023 led to excess supply being available with UNICEF contracted suppliers of around 150 million doses, despite some manufacturers having stopped production in consultation with UNICEF as demand signals firmed up during the year. As of April 2024, carried over stocks in 20 dose vial presentations have been fully procured.

To avoid any financial losses with suppliers and to ensure continued incentives to produce against UNICEF awards and forecasts, doses which were produced but not procured under good faith agreements in year of award have been accepted for delivery in the following year. UNICEF appreciates the challenges from a financial perspective to carry large stocks of bulk and finished products as well as constraints on cold chain capacity. UNICEF will continue to support suppliers to ensure bOPV vaccines that are produced against forecasts under good faith agreements are delivered to countries even if shelf life is shorter than the standard 18 months requirements; recognizing however, that country acceptance is required in each case and that for 10 dose vials, which are used for routine, may be less acceptable with short shelf life.

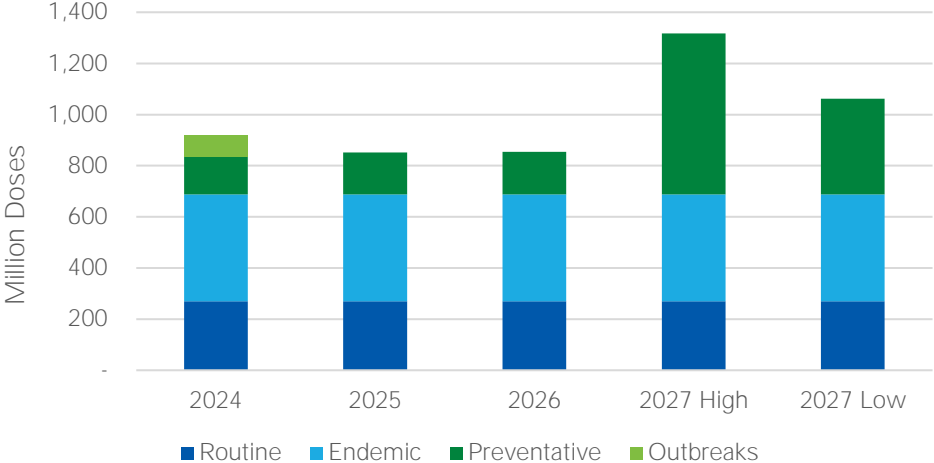
5.3. UNICEF's Preliminary Demand Forecast for 2024 and Beyond

Based on the currently available GPEI calendar of programmatic activities planned for 2024 as well as forecasted requirements from countries for routine needs, UNICEF is planning to secure supply to meet a demand of around 800 million doses across bOPV product presentations. The below forecast assumes that around 80 countries which have so far sourced their routine requirements through UNICEF will continue to do so. Additionally, for now the forecast assumes bOPV pre-cessation campaigns in 2027 in advance of bOPV cessation in Q3 of 2027, appreciating that triggers and timelines for these activities are under review.

With regards to supplementary activities, the below forecast for 2024 is based on a Programme forecast and includes some preventive activities. For 2025-2026, the activities for endemic countries are based on historic requirements and for preventive activities in Africa and Eastern Mediterranean region. The projected activities are to address risk due to suboptimal immunization coverage from routine activities leading to immunity gaps; and for 2027, anticipated scaling up of activities to provide immunity boosting SIAs prior to bOPV withdrawal. It should be noted that the quantification and confirmation of 2027 activities will be determined

as part of the bOPV cessation activities to take place during 2024, to be firmed up based on further assessment of the epidemiologic situation, risk/benefit profiles including routine coverage and potential interruption of transmission in endemic countries.

Figure 5: UNICEF bOPV Demand Forecast (2024-2027)



Source: UNICEF Supply Division.

The demand forecast for 2024 will be updated on an ongoing basis as the year progresses as per standard practice, and as the GPEI continues to monitor, reassess, and adjust the activity calendar based on epidemiology, risk assessment and funding in the pursuit of interrupting WPV1 in the low transmission season of early 2024 to allow for certification of eradication in 2026.

Based on the above forecast, UNICEF will require between 3.7 to 3.9 billion doses of bOPV over the next 4 years which will represent a value of around \$500 million based on the weighted average price of 2023.

With regard to the above forecast for supply through UNICEF for 2025-2027, a number of activities related to cessation planning, including detailed planning of roadmaps defining triggers, prerequisites and readiness criteria to be achieved to progress to bOPV withdrawal are scheduled to be defined in 2024 and presented to the Strategic Advisory Group of Experts on Immunization to WHO for endorsement. Efforts to refine further demand forecasts with modelers and supply requirements, development of policy guidance on cessation and bOPV withdrawal as well as epidemiology will determine the actual supply requirements as well as the timing of cessation.

Possible increase in demand could materialise if former self procuring countries would request bOPV supplies through UNICEF, in case of additional outbreaks caused by wild or cVDPV1 or cVDPV3 viruses, or in case the GPEI decides to increase its buffer capacity to secure outbreak responses. Given the expected short residual life cycle of bOPV and the fact that manufacturers with the broadest portfolio of national licensures have exited the market, there is a risk that some countries that are usually self-procuring may not be able to access bOPV supplies from their usual sources. If such transitions are not planned well in advance, countries may

experience supply interruptions. This has already been the case for two countries in 2023, which requested UNICEF to facilitate access to avoid interruption of their programmes. Should more countries source through UNICEF the demand forecast will be adjusted accordingly. Some countries currently sourcing bOPV through UNICEF may also decide to discontinue use of bOPV and transition to an all-IPV schedule in advance of the global withdrawal, which would reduce demand through UNICEF. SAGE reiterated in March 2024¹⁶ that only low-polio-risk countries with high coverage of at least two doses of IPV in the routine immunization schedule should consider transitioning to IPV-only vaccination schedules ahead of a planned synchronized bOPV cessation.

UNICEF continues to aim to maintain a rolling buffer across manufacturers of around 100 million doses in 20 dose vials to ensure supply capacity to meet any unplanned outbreak response requirements. Stockpiling of finished product and drug substance has been discussed as a risk mitigation strategy with the GPEI, and modelling work was done in 2023 to reassess requirements. The recommended levels of stockpiling based on certain assumptions, indicated requirements between 112 to 190 million doses of finished product, combined with 94 to 160 million doses of bulk vaccine. These considerations continue to be discussed within GPEI as options and may impact the demand in 2024 and beyond.

6. Sustainability

UNICEF is committed to fulfilling its mandate of ensuring a sustainable world for present and future generations of children as outlined in [UNICEF's Sustainability and Climate Action Plan \(SCAP\)](#). Sustainability is a core value for UNICEF and the organization continues to advocate for and work towards the fulfilment of ambitious international climate change and sustainability agreements.

Through the SCAP, UNICEF will fulfil its mandate by increasing resilience of critical social services to the impacts of a changing climate, equipping children with the skills and knowledge to be champions for the environment, reducing its carbon emissions and encouraging its global network of partners to do the same.

UNICEF is one of the largest procurers of products and services in the United Nations system, with the overall vision to demonstrate measurable contributions to the achievement of SDGs by 2030. With its network of over 10,000 global suppliers, UNICEF Supply Division and the Supply Community across more than 160 countries, will progressively reduce the footprint of products and services it purchases through end to end focus from production to disposal, while ensuring timely access to high quality supplies is maintained, especially in emergencies. Data and evidence will drive decision making and action, for which our supply base and end user feedback are essential inputs.

6.1. Sustainable Procurement

Sustainable procurement is an approach to procurement that incorporates the three sustainability pillars of social, economic, and environmental impact considerations. It goes

¹⁶ [sage-meeting-highlights_v3-march2024.pdf \(who.int\)](#)

beyond the more familiar “green” public procurement, to ensure that all products and services procured support local economic and social development, with the least environmental impact, and the best value for money.

UNICEF originally launched its Procedure on Sustainable Procurement in 2018, and more recently in 2023, has issued a revised version making the implementation of sustainable procurement mandatory across the organization. UNICEF's vision is that:

- By 2025, UNICEF is a major contributor to and practitioner of UN sustainable procurement, and that sustainable procurement is a fundamental approach to UNICEF's supply and logistics operations.
- By 2030, UNICEF's supply function demonstrates measurable contributions to the [Strategy for Sustainability Management in the United Nations System 2020-2030](#) (Phase I and II) and in achieving the Sustainable Development Goals through sustainable procurement.

UNICEF's Guidance Note on sustainable procurement was launched in 2021, and an updated version will be issued in 2024.

As of May 2023, UNICEF has included environmental and social sustainability aspects in all tenders for vaccine procurement. Further updates should be expected in the future, including performance monitoring of manufacturers with regards to sustainability criteria.

7. Issues and Challenges

- **Market prospects:** After certification of eradication of WPV1, bOPV will be withdrawn from global use due to the risk of emergence of cVDPV1, cVDPV3, and Vaccine-associated Paralytic Polio. While the current target is for certification of eradication to take place in 2026 and subsequent bOPV withdrawal 12 months later in 2027, the timing of cessation is uncertain due to the evolving epidemiology. Based on past experiences, it is highly likely that the timelines will be delayed, and therefore supplies will be required beyond 2027 and further into the future.
- **Demand forecasting:** Accurate forecasting of both short- and longer-term demand as a basis for supply planning continues to be a challenge. Actual demand materialisation has been considerably below forecasts for the period 2019 to 2023 due to Covid-19 as well as GPEI funding constraints and the need to prioritise activities in response to cVDPV2 outbreaks over preventive bOPV activities.
- **Concentration:** Due to market exits of drug substance manufacturers, bOPV supplies are increasingly dependent on two manufacturers. One of these manufacturers is the sole source of drug substance to global fillers, with the risk that any disruption to the production, testing or product release would directly impact global access to bOPV. Due to products already in production and under release, such a disruption may hit the market with a delay of 3 to 6 months.

8. Steps Forward

- **Market prospects:** UNICEF and partners will continue efforts to develop a detailed roadmap towards bOPV cessation, building on experiences from the tOPV to bOPV switch, and with clear milestones factoring in vaccine production lead times as planning parameters. Close consultation with vaccine manufacturers will continue as part of the process to provide visibility, transparency and joint accountability towards securing access to sufficient supply of bOPV to reach the goal of global eradication. Any risk mitigations required to secure bOPV supply through to cessation will be explored. Based on past experience and on recent epidemiology, there is a risk of delay in the interruption of virus transmission that would require supply beyond 2027 and towards the end of the decade.
- **Demand forecasting:** UNICEF and partners continue to work with modelers and countries to provide best possible demand forecasts, with the commitment that forecasts will continue to be updated towards cessation. UNICEF will continue to work closely with bOPV suppliers on supply planning, including sharing demand updates without delays. UNICEF requests that manufacturers do not take steps to discontinue bOPV production and encourages a discussion with UNICEF and GPEI in advance of any strategic decisions to exit the market.
- **Vaccine management:** UNICEF and WHO require countries to improve in-country vaccine management, to reduce costs and increase efficiencies. Countries are required to report on all available polio SIA vaccine stock balances in their central and sub-national level stores when requesting polio SIA vaccine supplies from UNICEF. As was done for the tOPV to bOPV switch, in the final run up to the bOPV cessation, countries will also be asked to report on routine stocks to reduce residual in-country stocks at time of withdrawal.
- **Concentration:** UNICEF with partners will continue to support and encourage vaccine manufacturers to initiate production of drug substance, and to explore stockpile options of drug substance and finished product to mitigate supply risks. UNICEF will continue to monitor the global supply and demand market for bOPV, to explore options and facilitate solutions with all partners, including self-procuring countries.
- **Registration:** UNICEF encourages national regulatory authorities to rely on WHO prequalification as well as the licensure and continued oversight of the the regulatory authority in the country of production and consider waiving local licensure requirements in order to ensure uninterrupted access to bOPV. Because of market exits by manufacturers with a high portfolio of licensures, it is highly likely that the remaining pool of global manufacturers may not have capacity or be willing to invest resources in lengthy and costly processes to meet local licensure requirements in addition to WHO prequalification and domestic licensure, as processes might not conclude prior to withdrawal and resource investments - money and staff time - may not be recouped, and may be prioritised for other products with more sustainable market outlooks.

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Other UNICEF market notes can be found at: <https://www.unicef.org/supply/market-notes-and-updates>

UNICEF issues market and information notes on products and supplies that are essential for the needs of children, and by extension their families. While some products are easily available and affordable, the availability of others can be limited, or in some instances, non-existent in the quality and price required. UNICEF places a strategic focus on these supplies to shape healthy markets. Ensuring a sustainable planet for children continues to be a priority for UNICEF, including through its operations and supply management. UNICEF seeks to influence the market to achieve greater coverage, affordable prices, diversified supplier bases, environmental sustainability, and **product quality that is ‘fit for purpose’** and in the right form for children.