EXECUTIVE SUMMARY

Value proposition for next-generation poliovirus vaccines

PATH

PATH received a grant from from the Gates Foundation to evaluate the value proposition (i.e., developability, use case, and market demand) of potential technologies for manufacturing next-generation poliovirus vaccines from noninfectious sources. As bivalent oral polio vaccine (bOPV) cessation and polio eradication approach, it becomes increasingly necessary to consider how to reduce the risk of containment breaches in manufacturing facilities to ensure that poliovirus is not released into the environment and communities. Next-generation poliovirus vaccines are expected to mitigate that risk.

Developability

PATH focused the next-generation poliovirus vaccine developability assessment on three potential vaccine platforms: S19-strain-based inactivated poliovirus vaccine (IPV), virus-like particle (VLP) vaccine, and mRNA vaccine. The analysis identified S19-strain-based IPVs and VLPs as having the best potential to develop next-generation poliovirus vaccines from noninfectious sources. mRNA based vaccines were deprioritized as it was deemed likely too complex to develop combination vaccines, and costs of production are likely to be higher than S19 and VLP based vaccines.

S19-based IPVs are likely to face fewer challenges to development because the platform has established clinical and regulatory pathways. Findings from the use-case analysis that PATH conducted as a part of this project indicated that injectable combination vaccines protecting against poliovirus are needed following bOPV cessation. As such, S19-based vaccines have the clearest pathway to use in combination vaccines (e.g., hexavalent whole-cell pertussis). Multiple manufacturers that already have hexavalent products using either conventional or Sabin-strain IPVs can readily develop S19-based IPVs. The main drawback to the S19-based vaccine platform is that it uses live poliovirus in the manufacturing process and may be subject to World Health Organization (WHO) Global Action Plan for Poliovirus (GAP) containment guidelines[1] after polio eradication is achieved. If a lack of human infectiousness in clinical evidence could be demonstrated, an exception to GAP containment requirements could possibly be granted. This question warrants additional conversations with relevant stakeholders in WHO and the Global Polio Eradication Initiative (GPEI).

VLP-based vaccines have a more complicated clinical and regulatory pathway since a licensed VLP poliovirus vaccine does not currently exist. Further, there are uncertainties around this platform being able to support the development of combination vaccines. The advantage to this platform, however, is that it will not be subject to containment policies since no live virus is used. This may lead to cost savings for VLP vaccines because manufacturers would not need to manufacture under GAP containment conditions. Details on the developability assessment can be found in the PATH presentation "Developability assessment for next-generation, 'non-infectious' poliovirus vaccines."[2]

Use case

PATH consulted with global and country stakeholders to develop a use case for next-generation poliovirus vaccines. The use case outlines stakeholders' views on how they would use these vaccines

after bOPV cessation occurs, with the assumption that only non-live poliovirus vaccines will be used for routine immunization. Therefore, understanding how these vaccines will be used is important since routine immunization will continue globally for at least ten years in countries without poliovirus-essential facilities (PEFs) and indefinitely in countries with PEFs.[3] Stakeholders confirmed that current IPV schedules will continue after bOPV cessation.

Switch decisions to next-generation vaccines consider vaccine efficacy, safety, vaccine presentation, and price, so all these factors should be the same, if not better, than current IPVs. To facilitate a switch, next-generation vaccines would need to be available in all of the same combination IPVs (hexavalent, pentavalent, and quadrivalent) and standalone vaccines being used in countries to facilitate adoption. Additionally, countries indicated that a WHO recommendation for the use of next-generation injectable poliovirus vaccines (NGI-PVs) would greatly influence policymakers to adopt such products. Finally, countries emphasized that a reliable global supply of vaccine would be needed before a full switch to using only NGI-PVs is undertaken. Detailed use-case information can be found in the PATH presentation "Use case for next-generation injectable poliovirus vaccines."[4]

Market demand

PATH engaged Linksbridge to conduct a market demand assessment to understand potential country demand for NGI-PVs from 2025 to 2045 and beyond. We modeled the following distinct periods with an assumption that bOPV cessation would occur in 2034 at the latest:

- Period A—2025 to 2034, representing potential use once the first products are available until bOPV cessation.
- Period B—2035 to 2044, starting after bOPV cessation to ten years after bOPV cessation takes place.
- Period C—2045 and beyond, which represents the ten-plus years after bOPV cessation takes place.

Currently, no projected timelines are universally agreed upon for bOPV cessation; therefore, we have assumed these time periods for modeling purposes. The latest bOPV timelines are available on the GPEI website.[5]

Demand for NGI-PVs will be dependent on vaccine availability and assumes that NGI-PVs would be interchangeable with current IPVs. We also assume that separate decision-making to introduce NGI-PVs in Gavi-eligible or Gavi-supported countries is not required. Therefore, NGI-PV use does not require bOPV cessation but does require vaccines to be licensed and WHO prequalified in order to be available for use interchangeably with current IPVs. The assumption is that containment policies will become increasingly stringent over time, which may decrease profitability and prompt manufacturers to switch to producing NGI-PVs over conventional or Sabin-strain IPV production.

Peak demand for next-generation vaccines could reach 350 million doses per annum in Period B in a scenario where all countries switch to NGI-PVs and SAGE extends vaccination timelines. Note that this is a scenario-based projection, not a forecast, and actual demand will depend on several factors, including policy decisions, regulatory pathways, and country-level decisions. In Period C, the assumption is that non-PEF countries will stop vaccinating children against poliovirus since the current WHO Strategic Advisory Group of Experts on Immunization (SAGE) recommendation indicates that a need to do so will not be likely.[6] In this scenario for Period C, demand could drop to approximately 125 million doses per annum, representing current PEF countries continuing to vaccinate indefinitely. Note that recommendations regarding the length of time for vaccination after bOPV cessation are likely to increase from ten years to a longer time period as that period becomes closer and policy decisions are refined. If

the SAGE recommendation increases the time for non-PEF countries to continue vaccinating post-cessation, this will result in longer Period B demand and the continued need for a substantial amount of poliovirus vaccines (≥ 350 million per annum) beyond 2045. Since considerable uncertainty remains regarding the timelines for bOPV cessation and post-cessation vaccination, demand estimates should be considered as broadly indicative and subject to change. Details on the market demand assessment can be found in the PATH presentation "NGI-PV market analysis: Methodology and demand forecast."[7]

Conclusion

Next-generation poliovirus vaccines are expected to mitigate the risk of manufacturer containment breaches during vaccine production by either using a form of the virus that does not infect humans (as is anticipated for S19) or by using VLPs that do not use live viruses in production. To reduce the risk of containment breaches and maintain profitability, it is anticipated that manufacturers of conventional or Sabin-strain IPVs would switch to noninfectious platforms or exit the market. Countries will expect NGI-PVs to be safe, have the same or better vaccine efficacy, and be priced at least comparably to current IPVs. Countries remain wary of switching to new vaccines until supply is sufficient to meet demand; therefore, multiple manufacturers must be present to ensure a consistent supply.

The investment in switching to these platforms is already occurring among vaccine manufacturers in the Developing Countries Vaccine Manufacturers Network (DCVMN), with support from the Gates Foundation.[8] Manufacturers in high-income countries, however, will also need to start investing in developing next-generation vaccines to supply their customers in high-income and upper-middle-income countries. This assumes that high-income and upper-middle-income countries will require combination vaccines not traditionally manufactured by DCVMN companies and used in low- and middle-income countries (i.e., DTaP-IPV, DTaP-IPV-Hib, DTaP-IPV-Hep B, and DTaP-IPV-Hib-Hep B).[a]

To meet the potential peak demand of 350 million per annum, all countries would need to switch to next-generation vaccines, which will only occur if manufacturing of such vaccines can reach this demand target. As such, investments needed by manufacturers and donors are significant. To generate and maintain momentum in next-generation vaccine investment, transparent communication of anticipated bOPV cessation timelines and the post-cessation vaccination strategy will be critical to decision-making. To facilitate switches to next-generation vaccines, WHO recommendations for their use will be essential (specifically, recommendations on interchangeability with existing IPVs). While we do not anticipate that a separate country-level decision will be needed to introduce NGI-PVs in Gavi-eligible or Gavi-supported countries, communication with countries is required to ensure they have the data and evidence needed to answer key questions regarding vaccine safety and efficacy.

[a] DTaP-IPV is an abbreviation for the diphtheria, tetanus toxoids, acellular pertussis, and inactivated poliovirus combined vaccine. DTaP-IPV-Hib adds the Haemophilus influenzae type B vaccine, DTaP-IPV-Hep B adds the hepatitis B vaccine, and DTaP-IPV-Hib-Hep B adds both the Hib and Heb B vaccines to DTaP-IPV.

References

1. Global Polio Eradication Initiative. Containment. June, 2025. https://polioeradication.org/who-we-are/containment/
2. PATH. Developability assessment for next-generation, “non-infectious” poliovirus vaccines. PowerPoint presentation. PATH; March 2024 (minor revisions July 2025). https://media.path.org/documents/NGPV_Developability.pdf?_gl=1*47wrk6*_gcl_au*MTE1MjM0Njk0MC4xNzczNjc5NTA2*_ga*ODEwMDUxMjU3LjE3NjMwNTc0NjU.*_ga_YBSE7ZKDQM*czE3NzM3NTYyNzMkbzE0JGcwJHQxNzczNzU2MjczJGo2MCRsMCRoMA
3. Global Polio Eradication Initiative. Containment. See image titled *20 Countries Hosting Facilities with Plans for the Retention of Polioviruses Post-Eradication*. May, 2026. https://polioeradication.org/who-we-are/containment/
4. PATH. Use case for next-generation injectable poliovirus vaccines. PowerPoint presentation. PATH; January 8, 2026. https://media.path.org/documents/NGI-PV_Use_case_slide_deck_EXT_Website.pdf?_gl=1*h8ce7a*_gcl_au*MTE1MjM0Njk0MC4xNzczNjc5NTA2*_ga*ODEwMDUxMjU3LjE3NjMwNTc0NjU.*_ga_YBSE7ZKDQM*czE3NzM3NTYyNzMkbzE0JGcxJHQxNzczNzU2NDg0JGo2MCRsMCRoMA
5. World Health Organization (WHO). *Polio Eradication Strategy 2022–2026: Delivering on a Promise*. WHO; 2021. https://www.who.int/publications/i/item/9789240031937
6. Strategic Advisory Group of Experts on Immunization, ed. Meeting of the strategic advisory group of experts on immunization, April 2017: conclusions and recommendations. *Weekly Epidemiological Record*. 2017;92(22):301-320. https://www.who.int/publications/i/item/WER9222
7. Windus P, Hajizada A. NGI-PV market analysis: Methodology and demand forecast. PowerPoint presentation. PATH and Linksbridge; July 21, 2025. https://media.path.org/documents/NGI-PV_Market_Demand_Slide_Deck_Final.pdf?_gl=1*h8ce7a*_gcl_au*MTE1MjM0Njk0MC4xNzczNjc5NTA2*_ga*ODEwMDUxMjU3LjE3NjMwNTc0NjU.*_ga_YBSE7ZKDQM*czE3NzM3NTYyNzMkbzE0JGcxJHQxNzczNzU2NDg0JGo2MCRsMCRoMA
8. ACN Newswire. CanSinoBIO receives another strong boost. Press release. ACN Newswire. October 9, 2024. https://www.acnnewswire.com/press-release/english/93212/cansino-receives-another-strong-boost