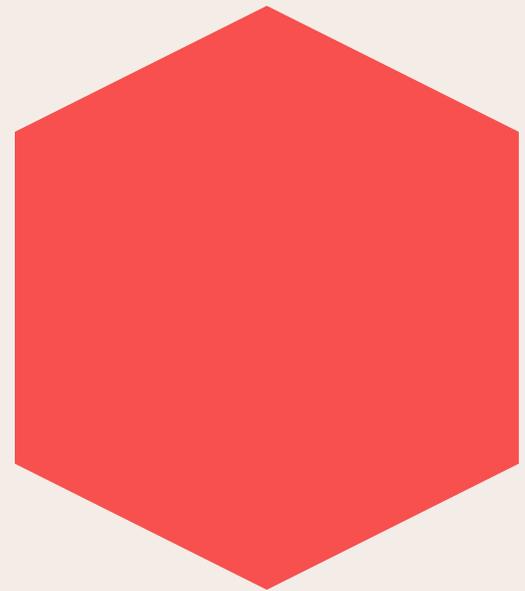


Next Gen Polio Virus Vaccine Value Proposition
Project (Gates Foundation INV-065369)

January 8th, 2026

Use case for next-generation injectable poliovirus vaccines



Abbreviations

| | | | |
|-------------------|--|--------|---|
| bOPV | bivalent oral polio vaccine | MIC | middle-income country |
| CEA | cost-effectiveness analysis | mRNA | messenger ribonucleic acid |
| cVDPV2 | circulating vaccine-derived poliovirus type 2 | MOH | ministry of health |
| DTaP-Hib-IPV | diphtheria and tetanus toxoids and acellular pertussis adsorbed, <i>Haemophilus influenzae</i> type b conjugate, and inactivated poliovirus vaccine | NGI-PV | next-generation injectable poliovirus vaccine |
| DTaP-Hib-HepB-IPV | diphtheria and tetanus toxoids and acellular pertussis adsorbed, <i>Haemophilus influenzae</i> type b conjugate, hepatitis B, and inactivated poliovirus vaccine | NITAG | National Immunization Technical Advisory Group |
| DTaP-IPV | diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine | OPV | oral polio vaccine |
| EPI | Essential Programme on Immunization (previously Expanded Programme on Immunization) | PEF | poliovirus-essential facility |
| GAPIV | WHO Global Action Plan for Poliovirus Containment, 4 th edition | RI | routine immunization |
| GAPV | WHO Global Action Plan for Poliovirus Containment, 5 th edition | SAGE | Strategic Advisory Group of Experts on Immunization |
| GPEI | Global Polio Eradication Initiative | TBD | to be determined |
| HIC | high-income country | Td-IPV | tetanus, diphtheria, and inactivated poliovirus vaccine |
| IPV | inactivated poliovirus vaccine | tOPV | trivalent oral polio vaccine |
| lower-MIC | lower-middle-income country | VLP | virus-like particle |
| | | WHO | World Health Organization |
| | | wP/aP | whole-cell pertussis vaccine/acellular pertussis |
| | | WPV1 | wild poliovirus type 1 |

Report scope

- Describe results from country stakeholder interviews around decision-making drivers for vaccine switch and/or introduction in relation to NGI-PVs.
- Present conclusions on how results from country stakeholder interviews confirm and/or change use case assumptions originally gleaned from prior global stakeholder interviews.
- Overall, contribute key additional information to support a larger evaluation conducted by PATH to assess use cases for NGI-PVs.

Background

Project purpose, activities, and prior use case assumptions from global stakeholders



A PATH project to clarify the use case for NGI-PVs

PROJECT: PATH is evaluating which vaccine platforms might be most appropriate for developing an NGI-PV.

GOAL: To understand the most likely use case of an NGI-PV.

PURPOSE: To accelerate the uptake of NGI-PVs, it is essential to understand the potential use cases for these vaccines and when they need to be available for introduction. Use cases provide essential information on target populations for the vaccines, preferred presentations, and the role, if any, that normative policy bodies may play in the in- country decision-making. It is important to understand how countries will use NGI-PVs so that vaccines are designed to meet country needs.

This work was supported by an unrestricted grant from the Gates Foundation.

Why develop NGI-PVs and what more needs to be known?

- Current manufacturing of IPVs employs virus seed materials that have the potential to transmit or cause disease in manufacturing staff and the wider community if there is a containment breach.
- NGI-PVs currently under development are designed to provide similar or better levels of safety and clinical protection as current IPVs.
- NGI-PVs are intended to eliminate the risk of containment breaches by employing virus seed materials that **do not** have the **potential** to transmit or cause disease in vaccine manufacturing staff and/or the wider community at any point.
- Three vaccine technology platforms are under consideration to produce these NGI-PVs:
 - S19 hyper-attenuated Sabin virus
 - Virus-like particles
 - mRNA

Understanding how the vaccines would be used and what characteristics and properties NGI-PVs should have is important to determining the relative advantages and disadvantages of these technologies.

Use case activities

Initial use case from global feedback

- In 2024, PATH interviewed 12 global polio and immunization experts and developed use cases of NGI-PV in different scenarios pre- and post-bOPV cessation.
- In September 2024, we convened 9 of these experts to share the use cases and further refine them with their inputs. *(See slides 9 and 10 for an overview of those use case results.)*

Revised use case with country feedback

- In 2025, PATH interviewed 11 stakeholders from 7 countries to understand the data and factors that they routinely consider when deciding to switch a vaccine presentation or to include a new vaccine in their schedule.

Additional scope

- Other project activities are using use case information to inform the technical analyses of specific candidate polio vaccine platforms.

Use case **pre-bOPV cessation** generated by global stakeholder meeting

| | Agreed-upon assumptions from discussion |
|-------------------------------|---|
| Time period | Pre-bOPV cessation. |
| Target age group | Same as current age in RI. |
| Schedule | Same as current age in RI. |
| Presentations required | Hexavalent (wP/aP), pentavalent (DTaP-Hib-IPV), quadrivalent (DTaP-IPV), trivalent (Td-IPV), standalone IPV. |
| WHO recommendation | Recommend as an alternative. |
| Uptake drivers | <p>Demand side</p> <ul style="list-style-type: none"> • Comparative advantage (program and cost/price implications). <p>Supply side</p> <ul style="list-style-type: none"> • Regulatory changes become stricter at global/national level. • Global/national containment policies become increasingly stringent (GAPV?) or current practices (including adoption of GAPIV) remain the same. • Donor preference for NGI-PV. |
| Use beyond RI | Very limited use as a stockpile vaccine as it competes with IPV and all OPVs. |

Recap: Use case **post-bOPV cessation** generated by global stakeholder meeting

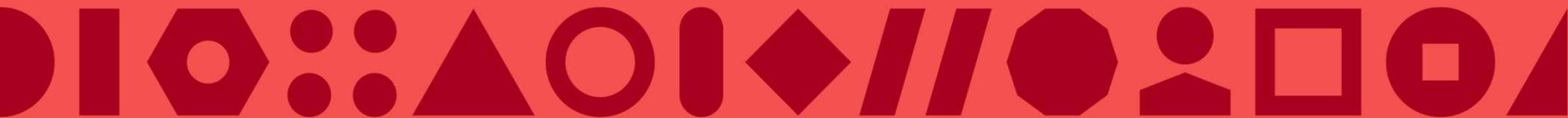
| | Agreed-upon assumptions from discussion |
|--|---|
| Time period | Post-bOPV cessation. |
| Target age group | Same as current age in RI (< 24 months) and boosters in older individuals. |
| Schedule | Same as current age in RI (< 24 months) and boosters in older individuals. |
| Presentations required | Hexavalent (wP/aP), pentavalent (DTaP-Hib-IPV), quadrivalent (DTaP-IPV), trivalent (Td-IPV), standalone IPV. |
| WHO recommendation and timeline for use | <ul style="list-style-type: none"> • Non-PEF country use post-bOPV cessation → at least 10 years.* • PEF country use post-bOPV cessation → indefinitely. |
| Switch policy | Recommend as an alternative vaccine (WHO/SAGE) or World Health Assembly endorsement of switch due to epidemiological reasons. |
| Uptake drivers | <p>Demand side</p> <ul style="list-style-type: none"> • Comparative advantage (e.g., substantially lower price**). <p>Supply side</p> <ul style="list-style-type: none"> • Regulatory changes become stricter at global/national level. • Global/national containment policies become increasingly stringent (GAPV?) or current practices (including adoption of GAPIV) remain the same. • Donor preference for NGI-PV. |
| Use beyond RI | Potential alternative to IPV, if any inactivated vaccine will be included as a stockpile vaccine. |

* If vaccination would stop in the post-eradication period or if the recommended timeline would be completed is uncertain.

** Mucosal immunity is not considered here as a comparative advantage because NGI-PV characteristics are assumed to be similar to IPV. If mucosal immunity is conferred with NGI-PV, the use case is substantially different, with likely immediate switches of all polio vaccines to a vaccine with mucosal immunity.

Methods

Country stakeholder interviews



Qualitative methodology

- **Primary goal:** To understand the decision-making process of countries when they switch to a new vaccine presentation, in the context of NGI-PV and polio scenarios.
- **Data collection approach:** Qualitative video/phone interviews held January through May 2025.
- **Purposive sampling:** To get a variety of decision-making processes and experiences, we targeted high-, middle-, and low-income countries with and without PEF facilities.
 - We identified multiple countries per category. Unfortunately, no responses were received for some of these categories despite multiple attempts made.
 - We aimed to include both low- and MICs in our sample, but we only received responses from **lower-MICs**, per World Bank 2025 classification.

| World Bank country classification | Non-PEF | PEF |
|-----------------------------------|-------------------------|---------------------------------------|
| Lower-MIC | Jordan, Nigeria, Zambia | None |
| HIC | New Zealand | Netherlands,* Australia, Canada |

*The only IPV vaccine manufacturer in our sample.

Study design

N = 11 stakeholders with different roles

- EPI manager (1)
- NITAG member (5)
- Other roles: prior EPI managers or supporting NITAG member (5)

One-hour interview sessions

- Given restricted time available, open-ended questions allowed for stakeholders to comment on the most salient factors, and probing was not all-encompassing.

Interview content covered

- The country's polio immunization schedule and general vaccine decision-making process.
- Broad decision-making factors in the country, such as immunization schedule, procurement, cold chain capacity, etc.
- Introduction to NGI-PV and future polio scenarios and asked for the type of information they would need to make decisions in those scenarios.

Analysis

- We used a thematic approach to analyzing qualitative data from all interviews by manually cleaning, sorting, categorizing, and summarizing data using table matrices to answer questions framed by the key areas of inquiry.
 - Note: The results section of this report mentions [in brackets] the type of country that brought up a certain topic during the interview, which helps discern differences between lower-MICs and HICs. Our qualitative methodology aim was to reach saturation and hear as many different perspectives as possible. Some countries did not raise a particular decision-making factor during the interview, but that does not imply that those factors are not routinely considered by those countries. Given limited stakeholder time availability, topics that were expressed by them can be inferred to be the most salient to them.

Vaccine characteristics presented to country stakeholders

| Characteristic | IPV | NGI-PV |
|---|--|---|
| Potential to cause disease and be transmitted | Employs virus seed materials that have the potential to transmit or cause disease in manufacturing staff and the wider community if there is a containment breach. | Does not employ virus seed materials that have the potential to transmit or cause disease in manufacturing staff and the wider community if there is a containment breach. |
| Need for GAPIV containment at manufacture | Yes (once bOPV cessation takes place). | Likely not needed, but uncertain at this point for some platforms. (S19 temporary waiver in place until post-eradication. Unlikely that a permanent waiver will be granted.) |
| Immunogenicity | No difference. | |
| Thermostability and cold chain requirements | | |
| Administration | | |
| Schedule | | |
| Trivalent | | |
| Cost | | |
| Combined or standalone | Multiple presentations | TBD |
| Mucosal immunity | Limited | TBD |

Clinical development status: Phase 1 studies

Results

Key data summary, post-bOPV cessation scenario, and post-eradication scenario specifics



Lower-MIC polio schedules and presentations

| Country | Polio vaccine presentations and schedule |
|---------|--|
| Jordan | Hexavalent (DTaP-Hib-HepB-IPV): at 3, 4, 5 months of age OPV: at 4, 5, 9, 18 months, 6 years of age |
| Nigeria | IPV: at 6, 14 weeks of age OPV: at birth, 6, 10, 14 weeks of age |
| Zambia | IPV: at 14 weeks, 9 months of age OPV: at birth, 6, 10, 14 weeks of age |

Note: Since 2023, Gavi, the Vaccine Alliance has supported introduction of whole-cell hexavalent vaccines in Gavi-eligible countries.

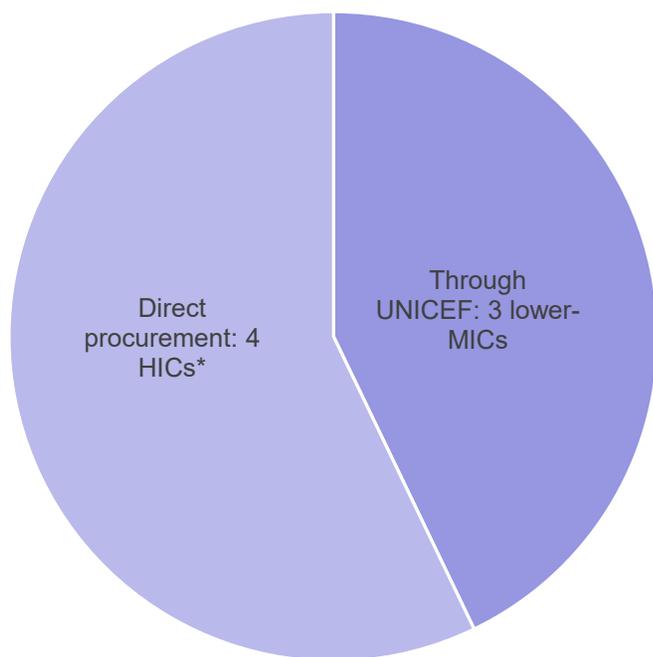
HIC polio schedules and presentations

| Country | Polio vaccine presentations and schedule |
|------------------|---|
| Australia | Hexavalent (DTaP-Hib-HepB-IPV): 2, 4, 6 months of age Quadrivalent (DTaP-IPV): 4 years of age |
| Canada | Hexavalent (DTaP-Hib-HepB-IPV): 2, 4, 6 months of age Pentavalent (DTaP-Hib-IPV): 2, 4, 6–12, 18 months of age Quadrivalent (DTaP-IPV): 4–6 years of age Dosing schedule depends on province/territory. A majority of provinces use pentavalent, not hexavalent. |

| Country | Polio vaccine presentations and schedule |
|--------------------|--|
| Netherlands | Current schedule: Hexavalent (DTaP-Hib-HepB-IPV): 3, 5, 11 months of age Quadrivalent (DTaP-IPV): 4 years of age Trivalent (Td-IPV): 9 years of age Changes planned for 2025: Hexavalent at 3, 5, 12 months Quadrivalent at 5 years Trivalent at 14 years |
| New Zealand | Hexavalent (DTaP-Hib-HepB-IPV): 6 weeks, 3, 5 months of age Quadrivalent (DTaP-IPV): 4 years of age IPV for non-immune adults and for revaccination of immunocompromised children. |

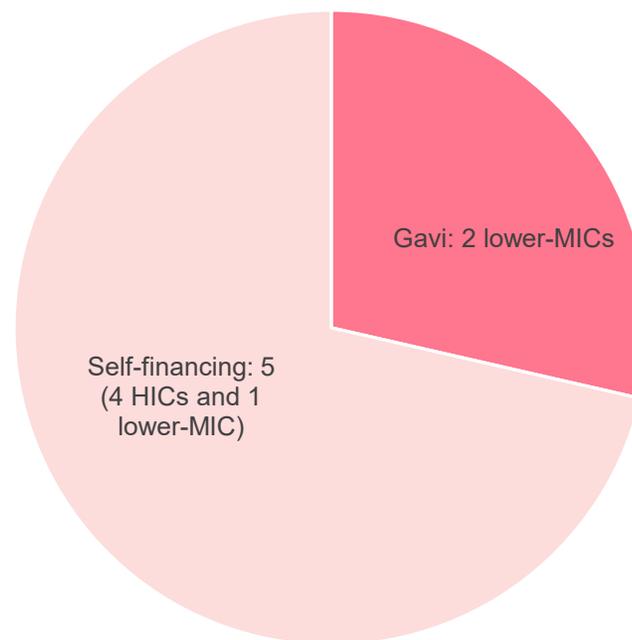
Country procurement and financing of IPV vaccines

Procurement mechanism



N = 7 countries

Financing mechanism



*In the case of one HIC, procurement is sometimes done independently at the subnational level.

tOPV cessation policy process (2016)

In 2016, WHO/GPEI coordinated a globally synchronized cessation of tOPV, switching use from trivalent OPV to bivalent OPV and IPV in RI programs. We asked stakeholders about the policy process their country went through to implement this switch. The countries in our sample reported two different situations:

- The HICs stopped using tOPV in RI (or never used it in RI in the case of the Netherlands) and started using IPV between 1957 and 2005. These were independent decisions made decades before WHO recommended the switch from tOPV to bOPV/IPV globally.
- The lower-MICs follow WHO/GPEI recommendations closely, so after the WHO/GPEI position was issued, their NITAGs met to review the data and agreed to move forward with tOPV cessation. In the case of Zambia, no NITAG existed at the time, and the recommendation prompted its creation.

Note: Other MICs not included in our sample might have stopped using tOPV and switched to IPV before the 2016 recommendation.

Lower-MIC process to evaluate switch potential or vaccine introduction

- 1) In the countries in our sample, the trigger for considering a switch is frequently a global or regional guideline recommendation.
- 2) The NITAG reviews the burden of disease, vaccine data, and, in some cases, cost-effectiveness.
- 3) The NITAG makes a recommendation to the MOH.
- 4) The senior MOH management discusses with other branches, such as an epidemic committee, interagency committee, or ministry of finance.
- 5) The MOH issues a formal position.
- 6) Depending on the country, licensure by the country's regulatory body may either be required to precede or follow the MOH recommendation.

HIC process to evaluate switch potential or vaccine introduction

- 1) In two HICs, the trigger for considering a switch is the NITAG itself. In the two other HICs, the most frequent trigger is the manufacturer presenting the vaccine to the first government body where the process for licensing starts.
- 2) The NITAG will always review all the information and provide a recommendation.
- 3) The processes in most of these HICs are somewhat complex, involving multiple government agencies.

Impacts of past vaccine presentation switch

- **Immunization schedule:** In the HICs and lower-MICs in our sample, a switch or new vaccine introduction led to a change in the schedule, typically simplifying it.
- **Training:** In HICs and lower-MICs in our sample, vaccinator training was needed for the vaccine switch. In HICs and one lower-MIC, this was not an issue because budget is always available for regular training.
- **Procurement:** A lower-MIC decided to move from local procurement to UNICEF to avoid stockouts. HICs had negotiation strategies for procurement.
- **Cold chain:** HICs and one lower-MIC tended not to struggle with cold chain capacity when incorporating a new vaccine, except when a surge occurred like for COVID-19. Another lower-MIC had to stagger delivery to deal with insufficient cold chain capacity.
- **Delivery strategy:** To increase coverage during COVID-19, an HIC started new delivery strategies such as using pharmacies and mobile units.
- **Community mobilization:** Only two lower-MICs mentioned the need for community sensitization as part of the switch, though in one case, they decided against it because the number of doses were not changing.
- **Home-based records:** One lower-MIC had to update the child health card.

Post-eradication scenario results

Stakeholders were introduced to NGI-PV and this future polio scenario and asked for the type of information they would need to make decisions in such scenario

Post-eradication scenario presented to stakeholders

- No poliovirus cases in the community and no poliovirus of any type in the environment.
- No OPVs of any type in the supply chain.
- WHO recommends an optional switch to NGI-PV.
- SAGE/GPEI recommendation:
 - Non-PEF country: Vaccination should continue for at least 10 years.
 - PEF country: Vaccination should continue indefinitely.
- The NGI-PV has similar efficacy, side effects, and costs and comes in a presentation like the one you are currently using.

Post-eradication decision factors: Epidemiology, global guidance, harmonization

| Category of factor | Data/factors the NITAG would discuss to consider continued vaccination of children in a world that manufactures only NGI-PV |
|-------------------------------------|--|
| Epidemiology | <ul style="list-style-type: none"> • NITAG would need to review local and international epidemiology of 7 to 10 years post-eradication to make decision. • Confidence in global surveillance and certainty of eradication status given no risk associated with manufacturing in such an era might mean reduced need to maintain immunity in the long term. |
| Global guidance | <ul style="list-style-type: none"> • NITAG would follow whatever WHO/SAGE recommended. Conservative NITAGs make them very unlikely to issue a recommendation that would go against WHO/SAGE. • The decision would probably start with whatever SAGE or WHO recommended, but a process of considering whether aspects in the country's situation could warrant a variation of the SAGE recommendation would be needed. • Solid evidence on what might happen in a scenario where NGI-PV (or any polio vaccines) are completely discontinued would need to be clearly communicated to the NITAG and supported by international entities (e.g., WHO recommendation, US Centers for Disease Control, or other respected public health organization). The strength of the WHO recommendation between "Optional" and "Optional but strongly recommended" would be considered in final decision. |
| Global harmonization in containment | <ul style="list-style-type: none"> • As with the bOPV cessation scenario, global containment issues on consistency will need to be closely considered by NITAGs. |

Post-eradication decision factors: Surveillance, geopolitics, acceptability

| Category of factor | Data/factors the NITAG would discuss to consider continued vaccination of children in a world that manufactures only NGI-PV |
|-----------------------------|---|
| Surveillance | With good surveillance after cessation of bOPV, indefinite vaccination might not be needed (like with smallpox). |
| Geopolitics | <ul style="list-style-type: none">• Vaccination has always been assumed to be discontinued in the post-eradication era; however, some countries already refuse to eliminate their stock of poliovirus. A global event (e.g., bioterrorism) would still be a possibility in this era, which would require preparation and impact containment and stockpile elimination agreements that are ultimately political decisions.• The country would not like to be seen as a bad local partner. In an eradication situation, the country would want to be a strong global partner at the forefront to ensure ultimate safety (i.e., global responsibility). |
| Acceptability by population | If vaccine platform did not have good acceptability, the government might be more inclined to discontinue sooner , but this is very hypothetical. |

Post-eradication decision factors: Vaccine cost, immunogenicity, safety, and schedule

| Category of factor | Data/factors the NITAG would discuss to consider continued vaccination of children in a world that manufactures only NGI-PV |
|------------------------|---|
| Vaccine cost | Cost would definitely be a factor in deciding how long to continue. |
| Vaccine immunogenicity | Any new positive information supporting polio's continuation in multivalent vaccines would bolster decision to continue. <ul style="list-style-type: none">• For example, a stakeholder referenced a publication from the Radboud University Medical Center that claims that the polio component in hexavalent vaccines is potentially an adjuvant that enhances immunity of others included. If this were confirmed and determined to be true, this would help. |
| Vaccine safety | As long as NGI-PV is in a combination vaccine and it is safe , the country would likely be on board to continue vaccination, even after eradication. |
| Immunization schedule | In this scenario, might consider dropping number of doses in the schedule . |

Conclusions

Putting country stakeholder interview and scenario results in context



Post-bOPV cessation era switch considerations

Global guidance

- WHO's guidance was generally the reason the lower-MICs in our sample began considering a vaccine switch, whereas the resources in HICs allowed for independent analysis and decision-making on vaccine switches ahead of WHO's recommendations.
- If WHO decided to recommend a mandatory switch to NGI-PV in future years, the lower-MICs and some HICs in our sample would likely align and follow it. Some HICs, however, might not do so if their leadership analyzes and determines a strong country reason not to.
- Any global recommendation for a switch would need to come with enough time and certainty of supply availability to do a smooth global transition. This is particularly relevant in HICs where the decision-making and regulatory processes can be complex and lengthy.

Epidemiology, surveillance, and containment

To consider a switch, HICs in our sample would want to understand the risk associated with vaccine-derived polio in a world with limited production facilities and if containment requirements are being met consistently across the globe.

Most countries will switch to NGI-PV if WHO recommends a mandatory switch, however HICs may do their own analysis before switching.

Additionally, supply certainty is needed for smooth global transition to NGI-PVs.

Post-bOPV cessation era switch considerations

NGI-PV characteristics

- NGI-PV should be available in all presentations to make adoption more likely (standalone, tri-, quadri-, penta-, hexavalent) given current schedules and countries' decision-making processes for vaccine switches whereby they consider either retaining or simplifying schedules.
- As expected, HICs and lower-MICs in our sample indicated that NGI-PV cost would need to be similar or lower to current IPV presentations to make adoption more likely, especially in lower-MICs graduating from Gavi support. Interestingly, some HICs have regulations and contract negotiations that allow them to retain similar prices for new presentations of vaccines already in their schedule.
- Not only does NGI-PV need to have a similar effectiveness profile as current IPV presentations, but it should also have a similar safety profile given the rarity of IPV adverse events contributing to IPV acceptability. Moreover, it should have the same cold chain requirements, and there should be certainty that it is completely non-infectious.
- One HIC was skeptical about VLPs and S19 because the former might not be combinable with other vaccines and the latter might still require containment. On the other hand, other HICs raised concern about mRNAs not inducing as long a duration of protection as other platforms.

NGI-PVs need to be available in all presentations, cost should be similar or lower than current IPV, and assurances of NI-PV effectiveness and safety to be the same as IPV are needed.

Post-eradication era considerations

Global guidance

- Just like in past switch decision-making processes, the lower-MICs and some HICs of our sample would very likely follow WHO's recommendation on immunization duration after eradication (indefinite vaccination or to stop vaccination after 10 years, as applicable).
- Some HICs, however, would do their own analysis and consider if a variation to the recommendation was needed for their country. One HIC thought that, with good surveillance, indefinite vaccination in a PEF country might not be necessary, as with smallpox.

Epidemiology, surveillance, and containment

- The HICs and lower-MICs in our sample would want to review local and global epidemiology and surveillance to decide on WHO's recommendation for either indefinite vaccination or to stop vaccination after 10 years, as applicable.
- An HIC raised that geopolitics and risk of bioterrorism at the time would also need to be considered for the decision. Another HIC PEF country would consider reducing the number of polio doses in its schedule in such a post-eradication era.

NGI-PV characteristics

- HIC PEF countries, which would be required to continue vaccination indefinitely in post-eradication, would be more likely to do so if the NGI-PV combination offered the same safety as current IPV combinations.
- Evidence of IPV playing an adjuvant role in hexavalent could promote continuing vaccination (if also proven for NGI-PV).

While global guidance is likely to be followed, some HICs will do their own analysis to determine if the recommendation applied to their own country.

However, all countries would want to understand local and global epidemiology and surveillance before making a decision on whether to stop or continue vaccination according to WHO guidance.

Updated NGI-PV use case in the post-bOPV cessation era

Incorporating input from country stakeholders



Final use case post-bOPV cessation

| | Final use case incorporating global and country input |
|---|--|
| Target age group | Same age group in RI according to national schedules and same age group of older individuals (≥ 2 years of age) according to current national schedule. |
| Schedule | Current RI schedule* to be preserved (country specific) and boosters in older individual (≥ 2 years of age) according to national schedule. |
| Presentations required | All presentations currently used in national immunizations schedules will be needed. (Hexavalent (wP/aP), pentavalent (DTaP-Hib-IPV), quadrivalent (DTaP-IPV), trivalent (Td-IPV), standalone IPV). *Exclusively having NGI-PV standalone would lead to additional visits and injections, which are unacceptable to countries.* |
| WHO recommendation on timeline for use | <ul style="list-style-type: none"> • Non-PEF low- and middle-income countries will likely vaccinate for at least 10 years or whatever timeline set by WHO. • Non-PEF HICs will make their own determination on timeline and might decide not to stop vaccinating (e.g., if threat of bioterrorism). |
| Switch policy | <ul style="list-style-type: none"> • WHO/SAGE recommendation will influence most low- and middle-income countries to switch to NGI-PV. Some HICs will likely also follow WHO's recommendation. • Some HICs will self-assess to make a determination regarding a switch • Similar cost and schedule to current IPV containing vaccines. |
| Uptake drivers | <p>Demand side drivers</p> <ul style="list-style-type: none"> • Comparative advantage (e.g. higher efficacy, lower cost, better safety profile etc.) • Donor preference for NGI-PV in Gavi-supported countries. • Similar clinical safety profile, effectiveness and duration of protection as current IPV. • Power of local politics and/or geopolitical context at the time (e.g., political promises, emulation, and/or prioritizing scientific recommendation over antivaccine politics). • Enough global supply of NGI-PV ensured before switch. <p>Supply side drivers</p> <ul style="list-style-type: none"> • Regulatory changes become stricter at global/national level. • Global/national containment policies become increasingly stringent (GAPV?) or current practices (including adoption of GAPIV) remain the same. • Geopolitics at the time (preference or aversion to manufacturing country). • Countries may have a preference for one platform (concerns that VLPs may not be combinable, S19 are still live virus) |

* Country specific RI schedules vary, assume that countries who decide to adopt a 6-10-14 week IPV schedule do not deliver a booster dose in the 2nd year of life as per updated WHO recommendation.

Conclusions

Putting country stakeholder interview and scenario results in context



Summary: NGI-PV use case in the post-bOPV cessation era

- Use case remains **largely unchanged** after country input analysis.
- Country stakeholders emphasized the following aspects of interchangeability for NGI-PVs and current IPVs:
 - NGI-PVs should have similar clinical safety, effectiveness, and duration of protection as current IPVs.
 - Vaccine presentations (combinations) should match currently available presentations.
 - For NGI-PVs, the cost and schedule should be as close as possible or the same as current IPVs. Lower cost would incentivize switching.
 - Broader and faster adoption could be possible if NGI-PVs can be used interchangeably with current IPVs and other NGI-PVs.
- Reliable supply, confirmed non-infectiousness of NGI-PVs, and strict global monitoring of containment were mentioned as demand drivers for NGI-PVs.
 - Supply shortages of critical vaccines lead to under- or unimmunized children. Therefore, ensuring a reliable supply of NGI-PVs will be critical.
- Geopolitics may influence adoption of vaccine, therefore manufacturers from multiple countries and regions are needed.
- HICs may have different preferences for vaccine platforms, which could impact NGI-PV uptake.

Drivers for decision-making

Post-bOPV cessation (Switching to NGI-PV)

- Understand the risk from containment breaches and why a switch is needed.
- WHO/SAGE recommendation especially if mandatory switch.
- Geopolitics (neighboring countries switching, or country where vaccine is manufactured may/not be preferred).
- Vaccine presentations used in country must be available before a switch happens.
- Vaccine cost and schedule must be similar to currently available IPV vaccines.
- Reliable supply of NGI-PV in place before a switch, though if it can be used interchangeably with current IPV presentations, this may facilitate a complete switch later.

Post-eradication of all PVs (continuing to vaccinate)

- NITAGs would consider local epidemiology and WHO/SAGE guidance before making a decision to continue or discontinue vaccination.
- Confidence in global surveillance and eradication would factor into countries decision to continue vaccinating (PEF and non-PEF).
- For non-PEF countries geopolitics and risk of bioterrorism at the time would also need to be considered for the decision to stop vaccinating.
- PEF country may consider reducing the number of polio doses in its schedule (boosters in older ages).
- PEF countries, which would be required to continue vaccination indefinitely in post-eradication, would be more likely to do so if the NGI-PV is offered in combination vaccines presentations and is confirmed to have a similar safety profile as IPV.

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