

SUBJECT: GAVI'S ENGAGEMENT IN POLIO ERADICATION

Agenda item: 08

Category: For Decision

Section A: Introduction

- This report requests a decision by the Board to support the incremental cost of inactivated poliovirus vaccine (IPV) for the period 2019-2020 using core Gavi resources, as recommended by the Programme and Policy Committee (PPC) in May 2018. This exceptional funding request by the Polio Oversight Board (POB) to Gavi is due primarily to the extension of polio eradication timelines and programme budget constraints. To date, Gavi's support for IPV through 2020 has been predicated on the assumption of additional funding being provided by the Global Polio Eradication Initiative (GPEI) to defray the incremental cost that is not covered by existing available funding and hence not in Gavi's Board-approved financial forecast.
- In addition, the Board's guidance is sought on two issues. First, potential Gavi investment in IPV beyond 2020, as considered through the Vaccine Investment Strategy (VIS). Second, on Gavi's engagement in broader polio eradication activities beyond IPV that include country-level polio transition and the Post-Certification Strategy.
- As the Board considers increasing resources in support of polio eradication, the appropriate role for the Secretariat in GPEI decision-making processes will need to be considered.

Section B: Facts and Data

1. IPV support 2019-2020

1.1 In November 2013 the Board approved support for the introduction of inactivated poliovirus vaccine (IPV) in all 73 Gavi eligible countries as part of the polio eradication 'Endgame' strategy. Of these, 70 countries are currently supported by Gavi¹. As part of this decision, the Board approved a series of policy exceptions to allow for the unprecedented introduction timelines and other aspects of IPV support that were different to Gavi's regular vaccine support. These included waivers to the policies on country co-financing and country eligibility. Support was contingent on the

¹ Ukraine was not supported as IPV was already introduced in 2006, Georgia opted for a combination vaccine not supported by the Alliance and India was provided one-time catalytic vaccine support from GPEI donors that ended in 2016.

introductions being financed by the GPEI programme not using any of Gavi's core funds.

- 1.2 In June 2017 with global IPV supply shortages leading to delayed national introductions, the Board approved an extension of Gavi's support for IPV under the originally approved policy and financial arrangements. Approval was again contingent on additional funding being provided by GPEI to fully cover the cost through 2020, the end of Gavi's current strategic period.
- 1.3 Continued poliovirus circulation in three endemic countries (Afghanistan, Nigeria and Pakistan) has delayed eradication timelines and forced GPEI to consider alternative financing measures and prompted the Polio Oversight Board (POB) to request Gavi to fund IPV with core Alliance resources for the period 2019-2020. The updated cost estimate for this period is approximately US\$ 300 million (indicative range US\$ 240 to US\$ 360 million)². This update was finalised in collaboration with GPEI and driven by the recently-completed UNICEF IPV supply tender that has resulted in a significant price increase (see Annex B for demand and pricing assumptions). The estimate includes cost of routine IPV vaccination and vaccination of missed cohorts as recommended by SAGE and WHO, as well as additional introduction support, and operational cost support. It is estimated that up to US\$ 100 million of original GPEI donor funding for 2013-2018 will be available for the 2019-2020 period to offset the above figure. This amount includes NOK 190 million secured by GPEI for 2019. As a result, the incremental cost is estimated at approximately US\$ 200 million.
- 1.4 Without additional funding being secured, the IPV programme will run out of dedicated resources in the course of 2019. As countries are currently in the process of submitting 2019 vaccine grant renewal requests, a decision to support IPV through 2020 must be taken in mid-2018 to enable the procurement process to continue and not jeopardise planned IPV supply shipments to countries.
- 1.5 This PPC recommendation reflects the exceptional nature of the situation with polio. Committee members noted that polio remains a public health emergency of international concern. Unprecedented progress to eradicate the virus is marked by the fewest number of cases ever reported (8 wild poliovirus cases in 2018 compared to 22 in 2017) but the epidemiologic situation and prevailing security situation in several geographies means that eradication is far from assured. The PPC therefore recommended that all efforts should be made to ensure continuity of support.
- 1.6 PPC members voiced concern that a decision to use core Gavi resources in support of IPV in the pre-2020 period will create country expectations of similar support for IPV post-2020 before a VIS decision is made at the end of this year. Given the significant level of funding and commitment that will be required for IPV in the post-2020 period, this decision will need to be carefully communicated to not pre-empt the VIS process.

² The estimates exclude India, Ukraine and Georgia.

2. Guidance on potential support for IPV post-2020

- 2.1 In November 2017, the Board advised that any investment in IPV beyond 2020 should be considered as part of the Vaccine Investment Strategy (VIS). However, VIS evaluation criteria such as lives saved and value for money do not adequately capture IPV’s unique role in mitigating the re-emergence of poliovirus. Therefore a tailored assessment approach and consultation process is being used to assess IPV. Board guidance is requested on the principles, scope and design of Gavi’s potential support of IPV in the period beyond 2020.
- 2.2 Three primary principles are proposed for Gavi’s engagement in IPV post-2020. These are:
- (a) Polio eradication is a global public good and IPV is both an essential tool by which this goal can be achieved and the insurance policy to maintain this achievement once attained.
 - (b) Gavi support will aim to align with SAGE recommendations, subject to examination of specific risks (fiscal, policy and programmatic) and caveats associated with shifting eradication timelines, IPV supply constraints and cost considerations.
 - (c) The level and duration of Gavi support needs to balance the risk of IPV programme discontinuation against the principles of country ownership as per Gavi’s eligibility and transition and co-financing policies.
- 2.3 In addition to the principles, a number of funding levers can be considered that will have important cost and risk implications for the Alliance, including: country eligibility and transition, funding level and funding duration (as summarised in Table 1). For example, continuing to provide support to all 70 countries with current policy exceptions (*status quo*) minimises the risk of IPV programme interruption and potential polio re-emergence, emphasising the notion of polio eradication as a global public good that supersedes core Gavi policies. Conversely, encouraging country financing of IPV and stopping Gavi funding over time (in-line with the current Gavi policies), places emphasis on fostering country ownership but could result in some countries not financing IPV after 2020 with domestic resources, allowing IPV vaccination to lapse and increasing the risk of polio re-emergence.

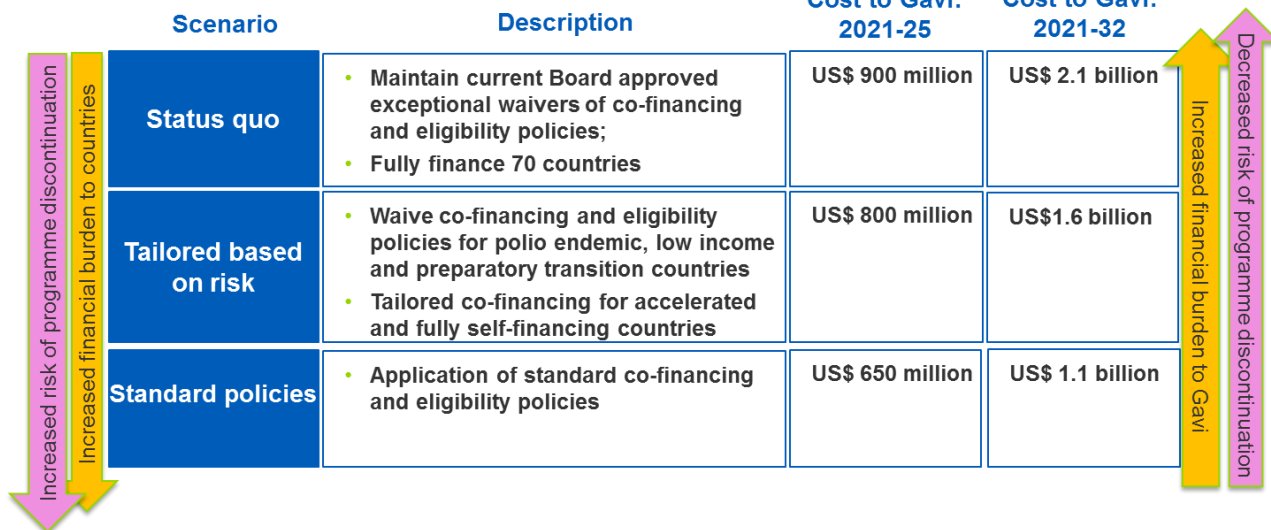
Table 1: Funding Levers

Country inclusion, eligibility	Country funding level	Funding duration
<ul style="list-style-type: none"> • 70 countries (<i>status quo</i>) • Tailored based on risk • Standard eligibility + transition policy 	<ul style="list-style-type: none"> • Fully funded (<i>status quo</i>); • Tailored based on risk • Standard co-financing policy 	<ul style="list-style-type: none"> • 10 yrs from bOPV removal • Tailored based on risk • Standard eligibility + transition policy • Until certification

- 2.4 Gavi’s support for IPV post 2020 can be based on different combinations of the funding levers. To provide a basis for Board guidance, three illustrative costed scenarios of IPV support for the period 2021-2032 are shown in Table 2. These scenarios range from continuing current policy exceptions (risk averse, most costly), to treating IPV the same as other routine vaccines supported by Gavi with standard application of eligibility, transition and co-financing policies (risk-tolerant, least costly), with a mid-point scenario that is tailored and balances cost implications with the risk of IPV programme discontinuation and polio re-emergence³. The estimated costs of IPV support to Gavi through the next strategic period, 2021-2025 ranged from US\$ 650 million – US\$ 900 million, none of which was included in the Berlin projections for support in the 2016-2020 period or in the next strategic period.
- 2.5 Illustrative scenarios in Table 2 do not include the potential support of whole-cell pertussis Hexavalent vaccine⁴. Gavi and partners are currently reviewing the landscape to develop an Alliance strategic position on hexavalent vaccines; findings from this assessment will be integrated into the overall VIS investment case presented to the Board in November 2018.

Table 2: Illustrative scenarios for 2021-2025 and 2021-2032

Scenario	Description	Cost to Gavi: 2021-25	Cost to Gavi: 2021-32
Status quo	<ul style="list-style-type: none"> Maintain current Board approved exceptional waivers of co-financing and eligibility policies; Fully finance 70 countries 	US\$ 900 million	US\$ 2.1 billion
Tailored based on risk	<ul style="list-style-type: none"> Waive co-financing and eligibility policies for polio endemic, low income and preparatory transition countries Tailored co-financing for accelerated and fully self-financing countries 	US\$ 800 million	US\$1.6 billion
Standard policies	<ul style="list-style-type: none"> Application of standard co-financing and eligibility policies 	US\$ 650 million	US\$ 1.1 billion



2.6 The PPC underlined the need to analyse the opportunity costs of IPV to better understand the trade-offs with potential future Gavi investments, given the significant level of funding and commitment required. Committee members highlighted the need to work with partners to review the implications to countries if IPV were required to be absorbed into domestic budgets. A few members found the tailored scenario based on risk the most attractive while others emphasised that any action that increases the risk of IPV discontinuation and therefore jeopardises polio eradication would be unacceptable.

³ Note, illustrative scenarios do not include Ukraine, Georgia or India.

⁴ Diphtheria, whole-cell pertussis, tetanus, Haemophilus influenzae b, hepatitis B and IPV.

3. Guidance on potential engagement in broader polio activities

- 3.1 The Board is requested to provide guidance on the future role of Gavi vis-à-vis the activities described in GPEI’s Post-Certification Strategy (PCS). GPEI has developed a PCS that identifies the set of activities critical to maintaining a polio-free world.
- 3.2 With GPEI planning to “sun-set” its activities soon after the certification of polio eradication, critical immunisation programme functions are potentially at risk of discontinuation in select fragile countries. Gavi is working with countries, through annual joint appraisals, in polio transition planning to better understand the risks and opportunities posed by decreasing polio budgets and to mitigate negative effects to immunisation programme performance. A handful of countries are currently leveraging Gavi resources (Health Systems Strengthening and Targeted Country Assistance under the Partners’ Engagement Framework) to support important immunisation programme functions that polio funding no longer finances.
- 3.3 The Secretariat considers that fragile countries are at greatest risk of negative programmatic impact of polio transition due to poor planning capacity and/or the inability to absorb critical immunisation functions that are currently funded by GPEI. During this crucial period, Gavi will redouble its efforts with select fragile countries to determine which immunisation functions may be affected and whether Gavi can provide time-limited bridging support to mitigate immediate risks.
- 3.4 PPC members agreed that Gavi should continue to play an important role in programmatic activities where the Alliance is already involved (i.e., immunisation system strengthening, improving coverage and equity and vaccine preventable disease surveillance) and could be engaged in other areas where it has a demonstrated comparative advantage (i.e., vaccine stockpiles). However, Committee members were clear that issues related to the containment of polioviruses, polio surveillance, detection and response to polio outbreaks are outside of Gavi’s mandate.

Table 3: Gavi’s role in essential polio functions post certification of polio eradication

Already part of current activities	Strong alignment with current role and activities for other vaccines	Areas not currently supported, lack of comparative advantage
<ul style="list-style-type: none"> • Strengthening of immunisation systems • Ensure the availability and affordability of IPV • Strengthening vaccine preventable disease (VPD) surveillance, including laboratory capacity 	<ul style="list-style-type: none"> • Maintaining and managing an adequate stockpile of polio vaccines (IPV and mOPV) • Ensuring the development of strategies for sustained IPV use and financing 	<ul style="list-style-type: none"> • Maintaining sensitive polio surveillance that includes acute flaccid paralysis (AFP) and environmental surveillance • Poliovirus containment activities in laboratories, vaccine manufacturers and other facilities • Polio outbreak preparedness, detection and response

- 3.5 The PPC encouraged the Secretariat to be engaged in future discussions with GPEI and other stakeholders to ensure that the scope and role that Gavi plays in helping to maintain a polio-free world fully aligns with the mandate and objective of Gavi's next strategic period (2021-2025). It is also important to note that the Gavi Secretariat currently is not part of GPEI's governance structures and therefore has limited ability to influence the programmatic approaches and strategies recommended for IPV. As Gavi's financial commitment to GPEI increases so too does its exposure to risks associated with polio eradication. As a result, the Board may like to consider the importance of Gavi participating in GPEI decision-making processes to better ensure coherence of eradication strategies and Gavi's objective of strengthening immunisation coverage and equity.

Section C: Actions requested of the Board

The Gavi Alliance Programme and Policy Committee recommends to the Gavi Alliance Board that it:

Approve the use of core resources for Gavi's support for inactivated poliovirus vaccine (IPV) for the period 2019-2020, noting that the financial implications associated with this approval are expected to be approximately US\$ 200 million.

Annexes

Annex A: Implications/Anticipated impact

Additional information available on BoardEffect

Appendix 1 (in May 2018 PPC meeting book): Annex A to Doc 11 *SAGE recommendations for IPV and Polio*

Appendix 2 (in May 2018 PPC meeting book): Annex B to Doc 11 *Assumptions used to refine IPV cost estimates for 2019-2020*

Appendix 3 (in May 2018 PPC meeting book): Annex C to Doc 11 *Assumptions for illustrative scenarios for the period 2021-2032*

Appendix 4 (in PPC Library – Additional materials for May 2018 meeting): Appendix 1 to Doc 11 *Post-Certification Strategic Plan*

Appendix 5 (in PPC Library – Additional materials for May 2018 meeting): Appendix 2 to Doc 11 *Polio Oversight Board meeting minutes, 29 Jan 2018*

Appendix 6 (in PPC Library – Additional materials for May 2018 meeting): Appendix 3 to Doc 11 *Country-level Gavi engagement with polio transition planning*

Appendix 7 (in PPC Library – Additional materials for May 2018 meeting): Appendix 4 to Doc 11 *Investment Framework*