



## Report to the GAVI Alliance Board

11-12 June 2013

|                        |   |
|------------------------|---|
| <b>Subject:</b>        | <b>Polio and routine immunisation</b>                     |
| <b>Report of:</b>      | Hind Khatib-Othman, Managing Director, Country Programmes |
| <b>Authored by:</b>    | Alan Brooks, Special Adviser for Immunisation             |
| <b>Agenda item:</b>    | 07  |
| <b>Category:</b>       | For Decision  |
| <b>Strategic goal:</b> | Affects all strategic goals                               |

### Section A Overview

#### 1 Purpose of the report

- 1.1 This report updates the Board on progress made since its decision in December 2012 approving *GAVI playing a complementary role to the GPEI in the polio eradication effort, specifically through routine immunisation within GAVI's strategy and mission using existing structures, processes, and procedures.*
- 1.2 Inactivated polio vaccine (IPV) has been evaluated for potential GAVI support as part of phase I of the Vaccine Investment Strategy (VIS) process. While a final decision on the VIS is scheduled for discussion at the Board meeting in November, the PPC recommended the Board consider GAVI's involvement in IPV at its meeting in June.

#### 2 Recommendations

- 2.1 At its meeting on 29 and 30 April, the PPC recommended that the Board:

**Request** the Secretariat – recognising the urgency of timing in the polio eradication effort and that considerations for Inactivated Polio Vaccine (IPV) are not consistent with the VIS criteria or timing – to prepare for procurement and implementation of GAVI support for the introduction of IPV in the routine immunisation programmes of GAVI countries as recommended by WHO as a contribution to polio eradication. These preparations and implementation shall take into account forthcoming recommendations from SAGE and be in consultation with Alliance partners. Approval will be subject to sufficient additional funding being available and Board endorsement of moving this forward outside the timing of the VIS process and the Board will note that there may need to

be changes to GAVI policies which would need to be approved by the Board or the Executive Committee.

- 2.2 At the Vaccine Summit in April 2013, over US\$4 billion was pledged for the polio eradication effort through 2018. The budget for this effort included approximately US\$300 million for IPV use in routine immunisation programmes, most of which was intended to support GAVI eligible countries. For the period 2014 through 2024 (the earliest date after eradication that IPV vaccinations could be stopped globally), the Secretariat's initial estimate of the costs for IPV procurement is US\$400 million to US\$500 million, plus approximately US\$40 million in introduction grants (Table 1).
- 2.3 Having reviewed the PPC decision and taking into account events at the Vaccine Summit and discussions with bilateral donors who are engaged with both GAVI and GPEI, the Secretariat proposes for Board consideration the recommendation below that remains consistent with the PPC recommendation and provides further guidance on its implementation:

**Requests** the Secretariat, having recognised the urgency of a decision on GAVI's support for implementing IPV as part of the Polio Endgame Strategy and Plan (2013-18), to prepare for the implementation of IPV introduction into the routine immunisation programmes in GAVI countries. Approval will be subject to:

- (a) Confirmation that additional funding is available for the implementation of IPV. This funding should be in addition to current GAVI resources and future pledges for support GAVI currently provides and may add as part of the Vaccine Investment Strategy process;
- (b) GAVI support for the implementation of IPV in eligible countries being:
  - (i) based on country-driven decisions to introduce IPV, that are part of national planning processes;
  - (ii) carried out using GAVI's structures, policies and processes in so far as this is possible, recognizing that some exceptions may need to be made; and
- (c) GAVI partners committing to implement steps to mitigate potential negative impacts on achieving GAVI's business plan targets.

### **3 Executive Summary – Update**

- 3.1 Attached as Annex 1 is a report on GAVI's proposed complementary role to the Global Polio Eradication Initiative (GPEI) in the polio eradication effort that the Secretariat provided to the Programme and Policy Committee (PPC) at its meeting on 29 and 30 April 2013. The Report includes a working draft of a document describing GAVI's proposed approach. This Board paper provides updates on the attached report to the PPC (Annex 1) to reflect the PPC discussion and events since April

2013 including the outcomes of the Vaccine Summit in Abu Dhabi at which approximately US\$4 billion was pledged to polio eradication efforts through 2018 (See Section 5).

- 3.2 Attached as Annex 2 is the updated working draft of the approach document, taking into account the PPC comments and other events.
- 3.3 The PPC expressed their support for GAVI's proposed approach to seeking complementarities with GPEI outlined in the document annexed to the PPC report. GAVI's approach is intended to achieve the following objective: *to improve immunisation services in accordance with GAVI's mission and goals while supporting polio eradication by harnessing the complementary strengths of GAVI and GPEI in support of countries.* Among its complementary roles, the Alliance brings technical and financial investments in routine immunisation strengthening, experience with and infrastructure supporting new vaccine introduction, advocacy and communications, and innovative financing approaches that can contribute to strengthen routine immunisation services. These roles can complement polio eradication efforts, reinforce country processes within eradication efforts, and increase the potential sustainability of polio investments. Routine immunisation staff in a number of GAVI partners (e.g. WHO, UNICEF, US Centers for Disease Control and Prevention) are leading relevant aspects of the Polio Endgame activities, and have also invited the Secretariat to participate in relevant management and coordination structures.

### **Background on IPV**

- 3.4 The weakened virus in oral polio vaccine (OPV) is excreted by vaccinated children and can spread to others in the community before dying out. Typically this limited spreading helps increase the immunity in a community. The longer the vaccine virus survives the more genetic changes it undergoes. If there is low immunisation coverage and immunity in a population, in very rare circumstances the weakened virus used in OPV can genetically change into a form that can paralyse, referred to as circulating vaccine-derived poliovirus. As the number of wild polio cases has decreased, the proportion of cases caused by vaccine-derived poliovirus has increased. There were 650 polio cases caused by wild virus in 2011 and 223 in 2012. There were 67 vaccine-derived polio cases in 2011, and 68 in 2012, of which 66 were caused by Type 2 polio virus and two by Type 3 virus.
- 3.5 IPV is a killed-virus, injectable vaccine that protects against all three types of polio virus (both wild and vaccine-derived) but is more expensive and difficult to implement than OPV and provides protection only to an individual. The GPEI Endgame targets IPV implementation globally by the end of 2015 in order to allow countries to continue immunising children against all types of virus while changing from trivalent Oral Polio Vaccine (tOPV) to a safer and more immunogenic bivalent OPV, without Type 2 virus, in 2016. The Endgame strategy assumes that all countries will need to implement at least one dose of IPV as part of routine immunization.

Using IPV will allow OPV to be phased out and stop vaccine-derived polio. Current projections are that IPV would be used until approximately 2024 when all polio vaccination potentially could be stopped.

### **VIS discussion on IPV in the PPC**

- 3.6 Inactivated polio vaccine (IPV) was analysed in phase I of the Vaccine Investment Strategy (VIS), which evaluates vaccine candidates based on direct health impact, amongst other criteria identified through consultations. The PPC recognized that the basis for decision on support for IPV and implementation timing as part of the eradication effort are different from the prioritised VIS criteria and is not aligned with VIS decision timelines. The PPC therefore recommended to consider IPV outside the evaluation framework developed for the VIS and to initiate preparations for implementation in light of the Endgame timelines. The PPC recommended a definitive funding commitment should be made once final resource requirements are confirmed (see section 2.1). The following considerations further informed the recommendation of the PPC related to IPV:
- (a) It is now apparent that the Endgame will be implemented based upon financial pledges from the April 2013 Vaccine Summit to the 2013-18 Polio Endgame Strategy. Financial support will be needed for GAVI-eligible countries to introduce IPV.
  - (b) The PPC noted that GAVI has the most extensive expertise, systems and investments through the Business Plan in partners to effectively support introducing a new vaccine into routine immunisation systems, and integration with GAVI's ongoing support to countries. GAVI can also ensure that national decisions on use of IPV reinforce country processes such as integration with national immunisation work plans, oversight by Interagency Coordinating Committees, and operational planning such as for cold chain expansion for GAVI-supported routine immunisations.
  - (c) PPC members noted that there was a risk of GAVI not preparing sufficiently early for the procurement and implementation of GAVI support for the introduction of IPV in the routine immunisation programmes of GAVI countries if no decision was taken until the November Board meeting. The risk arises if GPEI partners establish duplicate, parallel mechanisms to support countries with introducing IPV into routine immunisation services. Such a duplicate system could substantially confuse ongoing partnerships and support for routine immunisation services with countries. It could also lead to significant inefficiencies if another parallel system, such as that created by polio efforts in a number of countries, is established.

### Further analyses to be conducted

- 3.7 There are a number of outstanding analyses from GPEI and GAVI partners and/or pieces of information that will affect and inform GAVI's commitment to IPV. A non-exhaustive list of likely analyses includes:
- (a) *Detailed IPV activity timeline throughout the Endgame period:* A detailed plan will be critical to more fully understand risks and confirm performance metrics for GAVI's investments. GPEI partners, working with the GAVI Secretariat, aim to develop a timeline over the coming months.
  - (b) *Contingency plan around Endgame timeline:* The extremely ambitious nature of the Endgame calling for over 140 countries to introduce IPV by 2015 (as compared, for example, to the approximately 130 total vaccine introductions implemented with GAVI's support since 2001), suggests it will be important to complement the activity timeline noted above with contingencies if introduction targets are not met. For example, the analyses in Table 1 include a scenario where priority is placed on countries at higher risk of vaccine-derived polio outbreaks implementing IPV first.
  - (c) *Required coverage levels for the strategy of using IPV for risk mitigation to be effective:* IPV is intended to help contain spread should there be an outbreak; however it is not clear what minimum coverage level is necessary to help ensure transmission would be stopped, and therefore to evaluate the impact of GAVI's support. The GAVI Secretariat could seek further guidance on this from partners and from SAGE.
  - (d) *WHO Strategy Advisory Group of Experts (SAGE) guidance on schedule (and associated financial implications):* The SAGE has so far recommended countries introduce at least one dose of IPV into routine immunisation programmes. The likely schedule is at the same time as the third dose of pentavalent vaccine however definitive guidance on the IPV schedule is not anticipated until the November 2013 SAGE. The current recommendation does not preclude the SAGE from eventually recommending additional doses such that GAVI's financial analyses include a scenario where a two-dose schedule is implemented from 2019 (Table 1).
  - (e) *WHO guidance on product profile:* Characteristics that will impact vaccine supply and implementation strategies, including the number of doses per vial and potentially administering 1/5 the normal vaccine volume in order to save costs, are to be developed in the coming months and years.
  - (f) *Regulatory and pre-qualification strategy:* The strategy to ensure appropriate products are available will need to be developed and may be impacted by pending SAGE and WHO guidance, for example on schedule and product profiles.

- (g) *Supply and market shaping strategy and implications, including for pentavalent vaccines reformulated to add IPV (i.e. hexavalent DTwP-Hib-Hepatitis B-IPV):* The strategy to ensure appropriate products are available will need to be developed and may be impacted by pending SAGE and WHO guidance, for example on schedule and product profiles.

### **Potential policy and process implications**

- 3.8 In its recommendation to the Board, the PPC recognised that support for IPV procurement may require changes to GAVI policies which would need to be approved by the Board or the Executive Committee. IPV may also impact processes or business-plan supported activities. These are likely to need further consideration and consultation prior to November 2013. A non-exhaustive list includes:

#### Policies

- (a) *Country eligibility:* GAVI only supports countries below or equal to a gross national income (GNI) per capita threshold currently set at US\$ 1550. GAVI could consider if the same threshold would apply for eligibility of support to IPV vaccines, with particular consideration for graduating countries.
- (b) *Eligibility to apply for new vaccine support:* Countries with DTP3 coverage levels greater than or equal to 70%, based on the latest available WHO/UNICEF estimates, are eligible to apply for support to introduce new vaccines. They can apply for Meningitis A, Yellow fever and Measles-Rubella vaccines irrespective of DTP3 coverage levels. GAVI will need to consider if a coverage threshold would apply to IPV support.
- (c) *Vaccine introduction grant policy:* GAVI provides countries with \$0.80 per child targeted to help with costs of launching a new vaccine. GAVI would need to determine if the same amounts apply to IPV support.
- (d) *Application review, approval, and monitoring:* The appropriateness of application requirements for IPV introduction will need to be reviewed. Timely review and Board approval will be important to ensure efficient IPV implementation. Rapid partner assistance will be critical to support countries when unsuccessful applications indicate countries are not ready for implementation. The appropriate means of monitoring IPV implementation will need to be considered.
- (e) *Co-financing (and default):* GAVI requires countries to pay a portion of the cost for all routine vaccines (but not for campaign vaccines), and countries are not allowed to introduce new vaccines when they are in default. GAVI would need to determine if these policies would apply to IPV support and if so, how.

- (f) *Prioritisation mechanism:* If GAVI has insufficient funds to cover vaccine commitments it uses a transparent means of prioritising support between countries. GAVI would need to consider how IPV would relate to other vaccines within such a prioritisation mechanism if there was a funding shortfall.

### Processes and targets

- (g) *Application requirements:* The Secretariat will need to develop appropriate guidelines and forms to allow country-driven requests for IPV support which acknowledge the ambitious implementation timelines.
- (h) *Timing, coordination and prioritisation of IPV implementation:* Secretariat and Alliance partners will need to consider the potential impact of IPV on other (GAVI-supported) vaccines and therefore potential implications for achieving GAVI's business plan targets.

## 4 Risk and Financial Implications – Update

- 4.1 The attached report to the PPC presents an overview of the risks and financial implications in addition to those noted here.
- 4.2 The PPC noted that an issue of concern for some of the countries is the top-down approach of eradication plans driven by international organisations and developed-world donors, as compared to GAVI's country-led, application-based processes. It was noted that GAVI should reflect on potential implications for its core business model and partnership with countries if it is to be involved in wide scale IPV introduction.
- 4.3 The Polio Endgame, which was the basis for pledges at the Vaccine Summit, includes support for IPV in routine immunisation programmes through 2018 costing approximately US\$300 million. The costs are largely for GAVI-eligible countries. The amounts do not include India which is anticipated to fund IPV from domestic resources.
- 4.4 There are considerable uncertainties around the financial estimates of IPV procurement and associated costs, as estimated in the VIS process (See Doc 06). GAVI's estimates have been reconciled with GPEI estimates. Remaining differences with GPEI estimates relate to uncertainties on the speed of introduction and price.
- (a) Costs for vaccine procurement (not including vaccine introduction grants) range from US\$400 to 500 million through 2024 (see Table 1) depending on speed of introduction. It is estimated that 2024 is the earliest that IPV use could stop after eradication.
- (b) If a second dose were added from 2019 following a WHO SAGE recommendation, the cost through 2024 would increase by approximately US\$200 million (over 40%) to US\$700 million.

- (c) There remains considerable uncertainty on the price projections used, mostly suggesting per dose vaccine costs should decrease.
  - (d) If countries were to switch to hexavalent vaccine from 2019, it may increase costs by approximately \$1 billion, over and above the cost of pentavalent vaccine which it would replace in routine programs.
- 4.5 There is a risk that countries will delay planning for IPV implementation until the provision of funding for it is clear. If the Board defers making a decision on IPV, it may consider mitigating this risk. To do so, the Board could request GAVI to collaborate with GPEI and other partners to communicate formally to countries that they will be supported by international partners, based upon commitments at the Vaccine Summit, to implement IPV and encouraged to begin planning while the precise mechanism for providing support is finalized by international organisations.
- 4.6 The financial implications of the intense period to prepare for procurement and implementation of GAVI support, including working on the considerations above and beginning to coordinate with countries and partners, will require additional staff in the Secretariat. The activities of WHO and UNICEF, which are core GPEI partners, are budgeted for in the Endgame financial requirements. The Secretariat will need to recruit a number of short-term staff initially, and assess the need for additional regular staff eventually, to support GAVI's complementary role on polio. Other GAVI partners may request support for IPV-related activities in future business planning processes.

## **5 Summary of guidance from the PPC (April 2013) on the Report Polio and routine immunisation**

- 5.1 The approach document annexed to the PPC report has been updated (see Annex 2) to reflect events since April 2013, and guidance from the PPC including:
- (a) The PPC discussed the fact that there has been a large degree of 'territorialism' in immunisation and that it is now time to bring together all those engaged with immunisation, whether engaged in routine immunisation, polio eradication, and/or preventive campaigns.
  - (b) It was noted that identifying concrete, complementary roles between GAVI and GPEI at country-level that build upon the relative strengths of each must occur through consultation and planning between governments and partners, and should be done in the context of ongoing programmatic considerations and priorities of the countries. It was noted that incentives need to be aligned and organisational cultures reconciled.

- (c) The PPC noted that the views of countries are critical when considering the sustainability of human and financial resources currently committed to polio when determining if or how to build upon them to strengthen routine immunisation services as part of polio's "legacy".
- (d) The PPC agreed that it would be useful to have clarity on where GAVI might add value in terms of oversight and/or management within the GPEI collaboration. The PPC report was updated to emphasise the leadership of WHO and UNICEF routine immunisation staff for GPEI's Immunisation Systems Management Group, accountable for the routine immunisation-related objective, and that the GAVI Secretariat has also been invited to join the Group.
- (e) The PPC emphasised that polio efforts have strengthened and been integrated into routine immunisation services in many countries. Such countries may have little GPEI-supported infrastructure today. However many of the countries receiving extensive financial and technical support through GAVI (e.g. Afghanistan, DR Congo, Nigeria, Pakistan, Somalia) also have concentrated support for polio eradication separate from the staff and management of the routine immunisation programme (e.g. almost 5,000 full or part-time WHO and UNICEF staff in Nigeria and almost 20,000 in DR Congo).
- (f) The PPC noted that GAVI Alliance partners can help reinforce and monitor the contribution of GPEI staff to routine immunisation strengthening, as committed by GPEI in the Polio Endgame. Such monitoring could be done, for example, by Interagency-Coordinating Committees (ICCs).

Table 1: Preliminary cost estimates of IPV introduction in GAVI-eligible countries

**Preliminary cost estimates (USD millions), 1 dose of IPV**

All GAVI-eligible countries, excluding India\*

| Introduction timing                                      | 2015-2019 | 2015-2024 | 2014-15 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 |
|--|-----------|-----------|---------|------|------|------|------|------|------|------|------|------|
| A) 10 priority countries in 2015, remainder (42) in 2016 | 250       | 440       | 35      | 72   | 54   | 43   | 44   | 37   | 38   | 38   | 39   | 39   |
| B) Instant introduction in all 52 countries in 2015      | 300       | 490       | 89      | 65   | 54   | 43   | 44   | 37   | 38   | 38   | 39   | 39   |

\*Three countries are forecasted to graduate before introduction and would not be eligible for support per the current GAVI eligibility policy

Additional Scenarios

- If a second dose were added from 2019, the cost through 2024 would increase by approximately US\$200 million (over 40%) to US\$700 million.
- If countries were to switch to hexavalent vaccine from 2019, it may increase costs by approximately \$1 billion, over and above the cost of pentavalent vaccine, which it would replace in routine programs.
- The cost of IPV in India, assuming a one dose schedule, is estimated to be approximately US\$240 million (2015-2024) and is not included in the totals above.

All costs reflect only vaccine procurement, syringes, safety boxes and freight. Vaccine introduction grants would require an additional approximately \$40million, not including India.



## Report to the Programme and Policy Committee

29-30 April 2013

|                        |  |
|------------------------|--|
| <b>Subject:</b>        | <b>Polio and routine immunisation</b>  |
| <b>Report of:</b>      | Hind Khatib-Othman, Managing Director, Country Programmes  |
| <b>Authored by:</b>    | Alan Brooks <sup>1</sup> , Special Advisor for Immunisation; Lori Sloate, Deputy Director Advocacy and Public Policy; Stephen Sosler, Head of Country Team |
| <b>Agenda item:</b>    | 05   |
| <b>Category:</b>       | For Guidance   |
| <b>Strategic goal:</b> | Affects all strategic goals  |

### Section A Overview

#### **1 Purpose of the report**

- 1.1 The Secretariat seeks guidance on GAVI's proposed role in the polio eradication effort to implement the December 2012 Board decision stating:

*Approved GAVI playing a complementary role to the GPEI in the polio eradication effort, specifically through routine immunisation within GAVI's strategy and mission using existing structures, processes, and procedures. Any change to GAVI's vaccine portfolio should be decided within the framework of the new vaccine investment strategy.*

*Approved GAVI exploring the suitability and possible use of IFFIm as one potential financing mechanism to support this activity within GAVI's strategy and mission using existing structures, processes, and procedures.*

- 1.2 The Secretariat also seeks guidance on the process for revising the document attached as Annex 1 reflecting GAVI's proposed role.

#### **2 Recommendations**

- 2.1 The agenda item is for guidance.

#### **3 Executive Summary**

- 3.1 Elements of the goals of the GAVI Alliance (GAVI) and the GPEI are converging. GPEI commits itself to strengthening immunisation services in

---

<sup>1</sup> The annexed document was developed by a cross-disciplinary team in the Secretariat chaired by Alan Brooks.

order to successfully eradicate polio as part of its Endgame Strategy. The GAVI Board has asked the Alliance to seek ways to play a complementary role to eradication using existing processes. Lessons from polio and its infrastructure, which tends to be concentrated in focus countries for GAVI such as those with the most unimmunised children, could be targeted to help strengthen immunisation services and improve vaccine coverage. It would be important to consider their roles in light of sustainability and programmatic challenges specific to delivering routine immunisation services.

- 3.2 How potential complementarities come to be realised remains a critical and not easily answered question. GAVI and GPEI have been investing in many of the same developing countries for over 12 years, but frequently with different approaches to, for example, supporting human resources and immunisation programmes. Today there is an opportunity for not only a shared commitment to seek complementarities but explore where synergies may reside in addressing bottlenecks to improving coverage. GPEI's approach is reflected in the Polio Endgame Strategy to which GAVI has contributed extensively.
- 3.3 In 2006, GAVI committed \$191M to global polio eradication efforts. The funds have been used to help catalyse the development of monovalent OPV (mOPV), to evaluate the impact of mOPV on virus transmission, and from 2007 to support intensified eradication activities. mOPV has played an important role in eliminating polio from a number of countries (e.g. India, Indonesia, Sudan and Yemen).
- 3.4 Annex 1 is a draft of GAVI's approach to seeking complementarities and synergies with GPEI. It draws upon interactions and discussions by the Secretariat with GPEI and GAVI stakeholders following the December 2012 Board decision. The approach is not fixed, but reflects current, concrete priorities which will continue to evolve with the changing contexts in countries through the Endgame period (2013-18), and during GAVI's current strategy (2011–15) and next strategy (2016-20).
- 3.5 GAVI's approach is intended to achieve the following objective: to improve immunisation services in accordance with GAVI's mission and goals while supporting polio eradication by harnessing the complementary strengths of GAVI and GPEI in support of countries. The approach encompasses programmatic aspects at global/regional and country levels, as well as those related to procurement and implementation of inactivated polio vaccine (IPV) from 2015 to 2024 pending a GAVI Board decision, anticipated by December 2013, media and communications, and financing. GAVI, such as through activities identified in its 2013-14 Business Plan, and GPEI have a shared geographic focus in a number of countries, particularly Afghanistan, Chad, DR Congo, Ethiopia, India, Nigeria, Pakistan, Somalia, and South Sudan.
- 3.6 There are a number of risks identified by the Secretariat for GAVI with this approach. Mitigation strategies are also presented. Risks include GAVI's focus being diverted leading to coverage for routine vaccines not

increasing; GPEI's resources or strategies are not sustainably deployed in support of immunisation services; finances targeted to polio limit funds available from domestic sources for routine immunisation and/or at the international level available for GAVI; and that negative perceptions of polio vaccines impact demand for other immunisation services. The risks can be mitigated to some extent and/or are likely to remain or be amplified if GAVI does not consider a complementary role to GPEI. A results framework is presented.

#### **4 Risk implication and mitigation**

4.1 See Annex 1.

#### **5 Financial implications: Business plan and budgets**

5.1 The Board decided that GAVI activities in the polio eradication effort occur within GAVI's *strategy and mission using existing structures, processes, and procedures*. The approach in Annex 1 has been developed with an initial focus on complementary roles which are not anticipated to require new financial allocations for countries, partners or the Secretariat. In case of financial implications arising in the short-term beyond those already approved, the Secretariat will revert to the Board.

5.2 In the longer-term, GAVI's complementary role is likely to require funding, especially if IPV is prioritised in the VIS process for future funding. The Secretariat anticipates including such a provision in the next replenishment process. The provision will be developed as GAVI's approach evolves in the coming twelve months, and presented in 2014 to the Board and donors.

### **Section B Content**

**1 See document in Annex 1.**

#### **2 Revisions to the document in Annex 1**

2.1 The document in Annex 1 is intended to be a living document, which will be updated through an iterative process. Changes will arise from the guidance received at the PPC, further consultations with partners and ongoing experiences in countries.

2.2 The Secretariat anticipates updating the document in Annex 1 following guidance from the PPC and in consultation with Alliance members during May - June 2013. The document would then be updated in the future as lessons are learned about GAVI's complementary roles. It is anticipated that reports will be provided to the Board as the approach evolves.

### **Section C Implications**

#### **1 Impact on countries**

- 1.1 This approach should decrease the burden on countries, particularly those which are a shared focus for GAVI, such as through its Business Plan, and GPEI: Afghanistan, Chad, DR Congo, Ethiopia, India, Nigeria, Pakistan, Somalia, and South Sudan. It should help to bring greater coherence to partner supported activities, strategies, staffing and other investments. The GAVI and GPEI partners should align behind national strategies.
- 1.2 The initial stages may be managerially challenging for countries as lessons are developed around how to bring together what have often been divergent approaches. It may be most challenging for staff traditionally focused on routine immunisation services as they have the opportunity for greater leadership in defining the role of partner supported staff traditionally focused on polio.
- 1.3 The GPEI Endgame Strategy is anticipated to be launched around the World Health Assembly in May 2013. Under the draft Endgame strategy, GAVI-eligible countries will be faced with the implications of introducing IPV regardless of the outcomes from the GAVI Board anticipated by November 2013 on support for purchasing the vaccine, as part of the new Vaccine Investment Strategy.

#### **2 Impact on GAVI stakeholders**

- 2.1 WHO, UNICEF, CDC, and the BMGF are among the most deeply engaged partners in GPEI and the GAVI Alliance. Implementing complementary approaches will likely reinforce internal coordination within these and other GAVI stakeholders. In addition, developed and developing country manufacturers are important partners in both GPEI and GAVI. Clarity regarding GAVI's role, following the Board decision on whether or not to financially support IPV, should assist these stakeholders to better understand the supply and demand from low and lower-middle income countries.

#### **3 Impact on Secretariat**

- 3.1 The approach document has been developed by a cross-disciplinary team of the Secretariat chaired by the Special Advisor for Immunisation, and reporting to the Managing Director, Country Programmes (CP). Priorities for major functional areas are articulated in the document, including programmatic implications for CP and Policy and Performance; Media and Communications; Advocacy and Public Policy; and Resource Mobilisation and Innovative Financing. It is anticipated that the cross-disciplinary team will continue to serve as the coordination point in the Secretariat.

### **4 Legal and governance implications**

- 4.1 In the coming months, the role of the GAVI Alliance in the oversight and management structures of the Global Polio Eradication Initiative will need to be considered. Any governance implications for GAVI will be taken into account in those considerations and addressed through appropriate channels.

### **5 Consultation**

- 5.1 The proposed Approach (Annex 1) for GAVI is a product of numerous discussions with Alliance stakeholders, GPEI, and countries. Alliance members include WHO, UNICEF, CDC, BMGF, USAID, vaccine manufacturers, and others. These were done at the GAVI Partners' Forum and subsequent discussions. The Approach has been informed by participation in ongoing processes and/or consultations in Nigeria and India, with immunisation staff from Tanzania, and through discussions with a number of GAVI country responsible officers including those responsible for Nigeria, Pakistan, and Afghanistan. The Secretariat has also participated in partnership and technical meetings organised by the Global Polio Partners Group between December 2012 and April 2013.

### **6 Gender implications**

- 6.1 There are no gender implications.

### **Section D Annex**



## ANNEX 1

**WORKING DRAFT – NOT FOR QUOTATION**

**April 2013**

# **GAVI's role in the polio eradication effort**

## **Preface**

The mission of the GAVI Alliance (GAVI) is to save children's lives and protect people's health by increasing access to immunisation in poor countries. This document articulates the Alliance's approach for working more closely with the Global Polio Eradication Initiative (GPEI). It is intended for GAVI and GPEI partners, including countries, and will evolve over time. The approach arose from a December 2012 GAVI Board decision which:

*Approved GAVI playing a complementary role to the GPEI in the polio eradication effort, specifically through routine immunisation within GAVI's strategy and mission using existing structures, processes, and procedures. Any change to GAVI's vaccine portfolio should be decided within the framework of the new vaccine investment strategy.*

*Approved GAVI exploring the suitability and possible use of IFFIm as one potential financing mechanism to support this activity within GAVI's strategy and mission using existing structures, processes, and procedures.*

Section 1 describes the context and objective of GAVI's approach. Section 2 describes specific areas of complementarity related to programmatic, IPV supply and implementation, advocacy and communications, and financing approaches. These are considered in terms of the current context and priorities for the remainder of 2013 and 2014-2018. Section 3 describes the result framework, timeline, risks and risk mitigation strategies for GAVI. This approach document has drawn on the advice and input from a wide cross-section of GAVI and GPEI partners and GAVI Secretariat staff.

## **Executive Summary**

Elements of the goals of the GAVI Alliance and the GPEI are converging. GPEI commits itself to strengthening immunisation services in order to successfully eradicate polio as part of its Endgame Strategy. The GAVI Board has asked the Alliance to seek ways to play a complementary role to eradication using existing processes. Lessons from polio and its infrastructure, which tends to be concentrated in focus countries for GAVI such as those with the most unimmunised children, could be targeted to help strengthen immunisation services and improve vaccine coverage. It would be important to consider their roles in light of sustainability and programmatic challenges specific to delivering routine immunisation services.

*How* potential complementarities come to be realised remains a critical and not easily answered question. GAVI and GPEI have been investing in often the same developing countries for over 12 years, but frequently with different approaches to, for example, supporting human resources and immunisation programmes. Today there is an opportunity for not only a shared commitment to seek complementarities but explore where synergies may reside in addressing bottlenecks to improving coverage. GPEI's approach is reflected in the Polio Endgame Strategy to which GAVI has contributed extensively.

This document reflects GAVI's approach to seeking complementarities and synergies with GPEI. It draws upon extensive interactions and discussions with GPEI and GAVI partners following the December 2012 Board decision. The approach is not fixed, but reflects current, concrete priorities which will continue to evolve with the changing contexts in countries through the Endgame period (2013-18), and during GAVI's current Strategy (2011–15) and next strategy (2016-20).

GAVI's approach is intended to achieve the following objective: *to improve immunisation services in accordance with GAVI's mission and goals while supporting polio eradication by harnessing the complementary strengths of GAVI and GPEI in support of countries.* The approach encompasses programmatic aspects at global/regional and country levels, as well as those related to procurement and implementation of inactivated polio vaccine (IPV) from 2015 to 2024 pending a GAVI Board decision by November 2013, media and communications, and financing. GAVI and GPEI have a shared geographic focus in a number of countries, reflected in policies and investments, particularly Afghanistan, Chad, DR Congo, Ethiopia, India, Nigeria, Pakistan, Somalia, and South Sudan.

There are a number of risks identified for GAVI with this approach. Mitigation strategies are also presented. Risks include GAVI's focus being diverted leading to coverage for routine vaccines not increasing; GPEI's resources or strategies are not sustainably deployed in support of immunisation services; finances targeted to polio limit funds available from domestic sources for routine immunisation and/or at the international level available for GAVI; and that negative perceptions of polio vaccines impact demand for other immunisation services. The risks can be mitigated to some extent and/or are likely to remain or be amplified if GAVI does not consider a complementary role to GPEI.

## **1. Context & Objective**

### **1.1. Context**

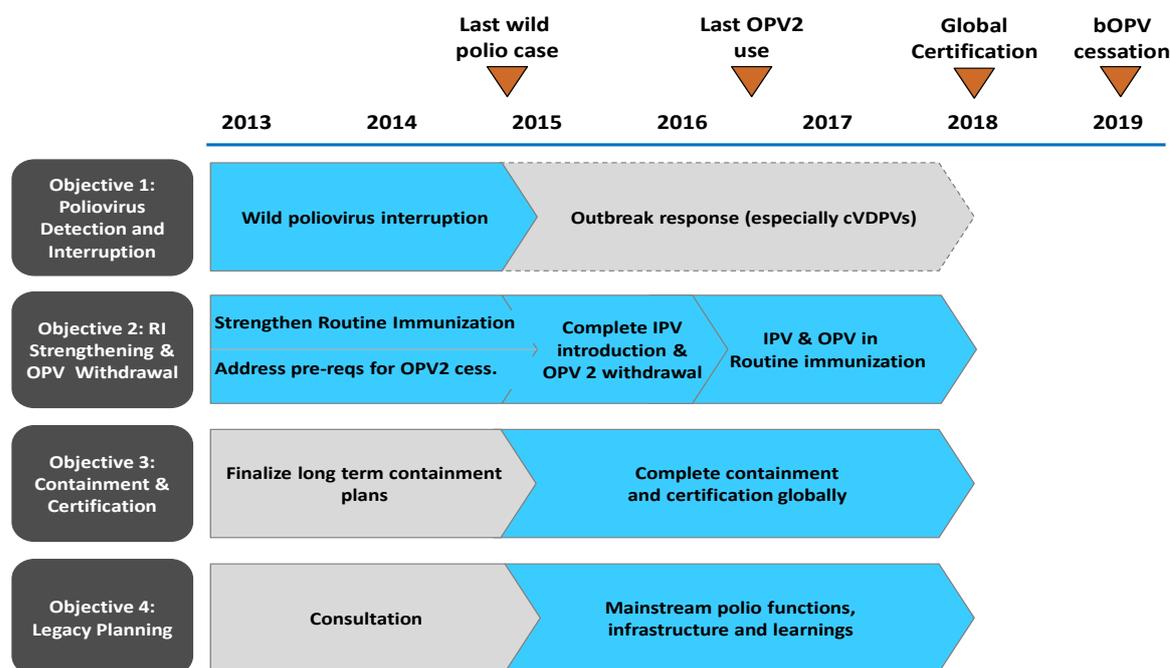
Polio typically infects young children through oral-faecal transmission, and in some cases causes paralysis, life-long disability, and death. An estimated 350,000 cases occurred in 1988, decreasing to 223 in 2012. Three countries continue to have wild polio virus (WPV) transmission, all of which are GAVI eligible, totalling 217 cases from 2012: Nigeria had 122 cases; Pakistan 58; and Afghanistan 37. A further five cases were reported from Chad and one from Niger in 2012, related to importations from Nigeria. India was the last endemic country to stop wild polio transmission in January 2011. Current targets are to stop all wild transmission by the end of 2014. Polio vaccinators have been killed by militants in Pakistan and Nigeria recently, leading to additional security and outreach efforts.

In rare circumstances when a population is very under-immunised and susceptible individuals accumulate, the live, attenuated virus used in oral polio vaccine (OPV) can revert and acquire the ability to circulate for extended periods and cause paralysis. The longer it is allowed to replicate, the more genetic changes it undergoes. This genetically reverted virus that establishes circulation and is able to cause paralysis is referred to as circulating vaccine-derived poliovirus (cVDPV). As the number of wild polio cases decreases, the number of vaccine-derived polio cases has increased. A total of 68 vaccine-derived polio cases were reported in 2012. Switching from OPV to inactivated polio vaccine (IPV) is a critical strategy for preventing vaccine-derived polio cases.

The Global Polio Eradication Initiative (WHO, UNICEF, US Centers for Disease Control and Prevention (CDC), and Rotary International with the Bill & Melinda Gates Foundation), with extensive input from GAVI, key stakeholders, and donor partners, is developing a “Polio Eradication & Endgame Strategic Plan 2013-18.” (Figure 1) The plan will be formally launched around the World Health Assembly in May 2013. The strategy covers 2013-2018 and is anticipated to cost approximately \$5.5 billion (plus approximately \$1.2 billion that India is anticipated to self-fund). One of the four strategic objectives is “Routine Immunisation Strengthening and OPV Withdrawal.”

In a number of countries, polio eradication has progressed using a strategy relying on supplementary immunisation activities (in addition to routine immunisation services) and management systems parallel to the national health and routine immunisation systems in which GAVI invests. The Endgame is broadly consistent with the wording of the original WHA resolution calling for polio eradication, a view shared by GAVI, that strong routine immunisation services and high coverage are essential to achieve eradication and maintain countries polio free during a multi-year certification period. The Endgame presents an opportunity to seek sustainable, complementary approaches between polio and wider immunisation services. Such approaches will also be central to implementing IPV.

**Figure 1. Overview of eradication and endgame strategic plan**



Nine countries are foci for GAVI (e.g. with DTP3 coverage less than 70%) and polio endemic or identified by GPEI as at high risk of WPV outbreaks and recurrent VDPV emergence: Afghanistan, Chad, DR Congo, Ethiopia, India, Nigeria, Pakistan, Somalia, and South Sudan. The monitoring and evaluation framework for the Endgame is not finalized, but will include commitment of GPEI to supporting improvement in coverage in focus countries, most likely with the goal of achieving 80% DPT3 (and OPV3) coverage in high risk districts of nationally by 2018. It is anticipated that at least 50% of the time of polio-funded field personnel will be devoted to specific activities to strengthen routine immunisation systems by end-2014, while addressing the sustainability of staffing and strategies.

## 1.2. Objective

The objective of GAVI's engagement with polio eradication is:

*To improve immunisation services in accordance with GAVI's mission and goals while supporting polio eradication by harnessing the complementary strengths of GAVI and GPEI in support of countries*

Immunisation services are part of the wider health system. Immunisation services deliver a package of vaccines routinely to infants and children according to a national schedule. They also include supplementary immunisation activities (SIAs or campaigns) which are implemented for specific epidemiological reasons (e.g. to more rapidly increase population immunity to specific diseases or respond to an outbreak). SIAs should be designed to strengthen underlying routine immunisation services and the wider health system.

## **2. Complementary approaches**

The following section describes specific areas of complementarity and synergy related to programmatic, IPV implementation, advocacy and communication, and financing approaches. These are considered in terms of the current context for each and priorities for 2013 and 2014-2018. These are not fixed but will continue to evolve, shape and be shaped by progress on immunisation targets and polio eradication.

### **2.1. Programmatic – Global & Regional**

#### **2.1.1. Current context**

There is a mixed history among GAVI Alliance partners of coordination between those focused on eradicating polio and those focused on other immunisation services. In some situations staff funded by GPEI partners (i.e. polio funded)-have worked partially or largely on routine immunisation. However, staff have been or continue to be physically and managerially separated in some organizations.

Polio eradication has remained largely separated from GAVI's programmatic scope. GAVI has invested broadly in strengthening immunisation and health systems over the past decade, particularly to improve routine immunisation coverage. According to WHO-UNICEF estimates, coverage in GAVI-eligible countries has largely plateaued from 2009-2011 (the most recent data available). DTP3, OPV3, and first dose of measles containing vaccines have remained at approximately 76%, reinforcing the potential value of GAVI seeking new partnerships and innovative approaches to raise coverage. GPEI is also seeking new partnerships and innovative programmatic approaches to respond to the World Health Assembly (2012) declaration of polio as a "programmatic public health emergency."

In the Endgame Strategy and this document, GPEI and GAVI seek a new collaboration and focus on sustainably strengthening routine immunisation services and eradicating polio.

#### **2.1.2. 2013 priorities**

During 2013, global/regional programmatic priorities will include:

**Discussing and determining an appropriate role for GAVI** within the oversight and management structures supporting polio eradication. In this context, GAVI will need to consider any potential governance implications. Clarity on GAVI's role will help strengthen coordination in support of the Endgame and immunisation services across GAVI and GPEI's investments.

**Seeking a convergence of strategies** for Alliance partners to support countries, consistent with complementary approaches between GAVI and GPEI. GAVI has contributed extensively to the Endgame Strategy, and GPEI input has heavily influenced the development of this approach document. GAVI will be taking a decision on financing IPV by November 2013.

**Participate in the consultation process related to the polio legacy planning.**

GAVI anticipates participating in the legacy discussions which will be coordinated by the main GPEI partners. Long-term planning is essential if lessons learnt during polio eradication, trained personnel, infrastructure, surveillance, and other investments are to be transitioned to other development goals and global health priorities. By participating in the legacy consultation process, it will, for example, seek to understand the perspectives of developing countries relative to polio's legacy and GAVI's role, if any. Decisions on GAVI's role in relation to the polio legacy will be determined by the Board.

**2.1.3. 2014-2018 priorities**

The coming years will see:

**Consolidation and reinforcement of the coordination and communication channels** between GAVI and GPEI at global level.

**Harmonisation of GAVI and GPEI programmatic commitments** from global and regional levels in support of countries, and sharing lessons across countries on complementarities between polio and other immunisation services.

**Decision by the GAVI Board on the type and level of contribution GAVI may make in support of the polio legacy**, and based upon that decision, determining appropriate implementation steps if relevant. GAVI anticipates that its decision will build upon the views of developing countries, and a diverse range of GAVI stakeholders. GAVI will begin in 2014 to develop its new strategy for 2016-2020, which could be informed by and inform discussions around polio's legacy.

**2.2. Programmatic – Country**

**2.2.1. Current context**

Improving immunisation services, including in polio-endemic and high-risk countries, is a shared priority for GPEI and GAVI. Strengthened immunisation services complement and will help sustain polio eradication by decreasing the need for supplementary activities which can be costly and interrupt primary health care services. Strengthened routine immunisation can help to facilitate and sustain the interruption of wild poliovirus transmission, reduce the risk of cVDPV emergence as well as virus importation and spread. Robust, quality immunisation services capable of obtaining high equitable coverage levels of all antigens will also be required for effective IPV introduction, tOPV to bOPV switch, and eventually complete OPV removal.

The level of GPEI resources and support varies by country. Endemic countries (Afghanistan, Nigeria and Pakistan) and recently endemic countries (India) maintain significant polio infrastructures with hundreds and in the case of India and Nigeria, thousands of dedicated polio staff (e.g. technical, surveillance, and communication specialists and community mobilisers) supported by WHO, UNICEF, and others. Countries at high risk of importation, outbreaks and VDPV emergence (Chad, DRC,

Ethiopia, Somalia and South Sudan) have relatively less yet still significant polio infrastructures.

There are a number of management and programmatic strategies supported by such staff at the country level related to polio eradication that have the potential to strengthen immunisation services. These include: strong management and accountability structures; detailed microplanning and systematic updating of plans; social mapping, mobilisation and advocacy with influential community and religious leaders; programme monitoring; and vaccine preventable disease surveillance (epidemiology and laboratory). Lessons and priorities can be drawn from India and elsewhere about how to utilise polio strategies to strengthen immunisation, particularly approaches like the Social Mobilization Network and special strategies for high risk areas and provision of routine immunisation services, including OPV, to underserved populations.

To best identify points of complementarity and ensure positive and realistic synergies, the differences between routine immunisation and polio approaches as well as commonalities must be recognized and addressed. The differences form the basis of understanding how complementary roles can be realised. For example, the polio Endgame Strategy proposes that at least 50% of the time of polio-funded field personnel in the identified priority areas be devoted to specific activities to strengthen routine immunisation systems by end-2014. These terms of reference should be clearly defined as part of routine immunisation national and micro-plans, not only through polio-related plans.

Beyond the countries with extensive staff, GPEI has invested heavily over the years to strengthen human resources and infrastructure for acute flaccid paralysis (AFP) surveillance in many GAVI eligible countries. These investments hold the potential to strengthen aspects of other vaccine-preventable disease surveillance activities.

All GAVI-eligible countries can apply for cash support, such as for health system strengthening to improve immunisation services. GAVI's Board has indicated that 15-25% of overall programmatic expenditures should be in the form of cash support. Countries can access extensive technical support to plan how to use such resources to strengthen immunisation services, including increasing coverage, vaccine implementation, and improving equity. The technical support is available through approximately 130 staff, particularly in WHO and UNICEF, funded under the GAVI Business Plan. These are in addition to the many staff in GAVI partners funded from other sources. In the same countries where polio resources are concentrated, GAVI provides additional flexibility to meet country needs and/or financial resources to overcome health and immunisation system bottlenecks. GAVI's policy on fragility and immunisation (i.e. Country Tailored Approach) support for countries with less than 70% DTP3 coverage, and targeted support to countries struggling to overcome equity issues (i.e., geographic, socio-economic and gender) provide three additional avenues for working together with countries to build their capacities to ensure complementarity between GAVI support and GPEI resources. (Annex 1)

### **2.2.2. 2013 priorities & activities**

In order to realize complementarity between GAVI and GPEI, governments must lead and be effective stewards of better collaboration, with support from polio and Alliance partners. It will require:

- **Annual, harmonised, operational work plans** elaborated and aligned with overarching planning documents (e.g. cMYP) and local microplans for immunisation services, with routine, polio and other SIAs falling under the workplans. Plans should identify programme objectives and detail the activities, timelines, budget and technical support required. GAVI and GPEI support should follow and be reflected in national work plans, endorsed by inter-agency coordinating committees (ICCs). Some countries are developing such harmonized workplans (e.g. Nigeria) while others would develop the plans late in the year for 2014.
- **Terms of reference (ToRs)** of individuals funded to work on polio eradication must be revised in coordination with national immunisation priorities and government immunisation staff responsible for routine immunisation services. Revised ToRs will include elements related to immunisation strengthening, as appropriate for the country plan and aligned with GPEI's strengths, such as management, microplanning, mobilization and monitoring. The numbers and locations of these staff are summarized in Annex 1.
- **Measuring contributions** of polio-staff to improve immunisation services using indicators reflected in the ToRs.
- **Re-tooling and re-training of polio staff** to impart the knowledge and skills required to better engage on broader immunisation issues, such as those related to routine immunisation services and schedules, cold chain and logistics management, injection safety, waste disposal, community partnerships, local monitoring by local staff at each level, AEFI management and vaccine preventable disease surveillance.
- **Encouraging SIAs (or periodic intensification of routine immunisation (PIRI)) for other vaccines** to contribute to polio eradication, where appropriate, and to explicitly strengthen immunisation services and/or wider primary health services, regardless of the vaccine(s) being delivered and funding source. GAVI supported vaccines being delivered by SIAs (e.g. Meningitis A) may be in high demand by communities helping increase the coverage of OPV administered during the same campaign.

### **2.2.3. 2014-2018 priorities**

To realize the benefits of greater GAVI – GPEI complementarity, the near term priorities noted above need to be implemented and followed-up on in focus countries over a number of years. Assisting and monitoring progress on each, such as the training and involvement of polio-funded staff in strengthening immunisation services and coverage

improvements with all vaccines in the lowest performing districts, is essential to determine where mid-course corrections and adjustments need to be made. Existing and future country applications for GAVI support and resources, whether for new vaccine introduction, SIAs and/or health system strengthening (HSS) will be instrumental to assist focus countries to strengthen immunisation services. GAVI's support continues to evolve, such as efforts underway to modernize supply chains and work on equity between and within countries. Secretariat staff will work closely with focus countries and partners to support harmonisation of resources and approaches.

Measurement of progress at the country level will be monitored through existing and improved partner and GAVI systems and indicators, such as through the WHO-UNICEF Joint Report Form and reporting on GAVI's Performance-Based Funding.

## **2.3. IPV Supply and Implementation**

### **2.3.1. Current context**

The Endgame calls for all countries to introduce at least one dose of IPV six months before phasing out the use of tOPV. IPV will prime individuals or maintain population immunity against all three types of polio virus, while transitioning from trivalent OPV to bivalent OPV (types 1 and 3 virus) in 2016. Phasing out the use of bOPV in 2019 will prevent new vaccine-derived polio viruses. Approximately 23% (68 of 291) of total polio cases in 2012 were caused by VDPVs, a proportion that will increase as wild cases decrease.

A single dose of IPV is anticipated to prime the immune system of individuals, if not fully protect them. Primed individuals who were re-vaccinated would be rapidly protected with high levels of immunity. This rapid protection would be critical to stop transmission if an outbreak occurred. Current assumptions anticipate the single priming dose of IPV will be delivered with the third dose of DTP-containing vaccine.

### **2.3.2. 2013 priorities**

Countries, manufacturers, and other partners will need a number of years to prepare for the switch to IPV. Therefore, the focus for 2013 will include:

- **Decision on GAVI support for IPV** to be taken through GAVI's Vaccine Investment Strategy (VIS) by November 2013. A base case scenario of GAVI support for a single dose of IPV given at the same time as the third dose of DTP-containing vaccine is considered in phase I of the VIS through June 2013. Alternative scenarios for potential consideration prior to November include additional support for a second dose of IPV, or three doses of IPV as part of combination hexavalent (DTwP-HepB-Hib-IPV) vaccine. If the GAVI Board decides to support IPV, the final decision on vaccination strategy will be based on WHO recommendations. GAVI's support would only be for GAVI-eligible countries and delivered when infants are brought for their routinely administered vaccines. In all scenarios, GAVI's support for IPV

would end in 2024, per the Endgame. Support for catch-up or outbreak response scenarios would need to be provided through GPEI as would IPV for GAVI-eligible countries if the Board decides not to support it.

- **Monitor policy developments and additional R&D data informing IPV assumptions** that may arise from research and/or ongoing product development efforts related to dose-sparing, adjuvanting, and other potentially cost-saving strategies, as well as hexavalent vaccines.
- **Share lessons on vaccine introduction and vaccination** from GAVI's experience. The scale and timelines anticipated for IPV implementation are unprecedented. They are likely to be extremely challenging for countries and partners, and to have implications for GAVI's vaccine-related support to countries. Regardless of GAVI's support for IPV procurement, its experience supporting dozens of countries through hundreds of vaccine introductions for HepB, Hib, pneumococcal, rotavirus and other vaccines will be used to inform planning for IPV implementation.

### 2.3.3. 2014-2018 priorities

Decisions on future priorities will follow from the GAVI Board decision in late 2013. If the Board decides to support IPV for GAVI-eligible countries, the Secretariat will work with partners to:

- Engage with GPEI, and particularly UNICEF, on **supply planning and market shaping** activities for programmatically suitable and financially feasible products. This would include developing a strategy (roadmap) for IPV. The strategy would include working with manufacturers to determine the potential role of hexavalent vaccine given the timelines reflected in the Endgame, and relative to the pentavalent supply relied upon by GAVI-eligible countries.
- Encourage pursuit of **cost-saving strategies** by manufacturers, product-development partnerships and others.
- Coordinate with GPEI, WHO and UNICEF SD on **regulatory strategy and procurement planning** to ensure supply to countries from 2015.
- Rapidly accelerate **implementation planning** including establishing an appropriate country application mechanism.
- Invite **country applications** in time for vaccine implementation in countries from early 2015, and intended to support scaling up to all GAVI-eligible countries in accordance with targets in the Endgame and according to recommendations from WHO.

## 2.4. Advocacy and communications

### 2.4.1. Current context

GAVI recognizes the importance of strong coordination and alignment between partners in support of the Decade of Vaccines/Global Vaccine Action Plan (DoV/GVAP) goals and strategic objectives as well as with the four major objectives of the Endgame Strategic Plan.

As such GAVI and GPEI are increasing coordination around communication and advocacy efforts in support of completing polio eradication and strengthening immunisation services.

Ensuring connection between polio eradication efforts and immunisation services will require a strong advocacy and communication effort. At country level, it will include an emphasis on coordinating across polio, SIAs, new vaccine implementation, and other approaches within a harmonised national immunisation service and including linkages with communities, civil society, and the private sector.

### 2.4.2. 2013 priorities

Given the current context, 2013 priorities will focus on:

- **Global advocacy and consensus building to support greater integration** between polio eradication and wider immunisation services; and
- **Expanding messaging** around polio-led initiatives to focus on strengthening immunisation services. This will have benefits for GPEI, for rolling out new vaccines supported by GAVI, and for strengthening coverage of routine vaccines. Messaging will also include the need for direct investment in routine immunisation services including recurrent operational costs.

Additional activities will include:

- Current donors to the GPEI have built-in strong incentives for country-level staff to reach specific goals by defined time points. This has led staff to prioritise polio campaigns over strengthening routine immunisation services in many instances. Therefore, a meeting with the leadership of key global partners in polio eradication and immunisation (e.g. WHO, UNICEF, BMGF, CDC, GAVI, and bilateral development agencies) is required to align agency priorities, develop shared objectives and consider what new incentives are needed to integrate polio with national immunisation services. This meeting could be held as part of the discussions on polio's legacy.
- Work closely with GPEI partners on joint messaging and joint media activities where possible (Vaccine Summit, World Immunisation Week, World Health Assembly, UN General Assembly, World Polio Day).

- Work closely with GPEI partners to generate online and social media activity in support of the polio endgame and in support of strengthened routine immunisation.
- Develop a special polio page for the GAVI website, highlighting key events (Vaccine Summit, World Polio Day) and a special routine immunisation page for the GPEI web site.
- Share with the GPEI advocacy network groups updates on GAVI vaccine launches and other highlights
- Communicate clearly GAVI Vaccine Investment Strategy (VIS) and Board decision (due by November 2013) on supporting IPV

### **2.4.3. 2014-2018 priorities**

GPEI is developing a Legacy Options strategy (transition of key staff, infrastructure and systems according to national, global development priorities) – through consultations in 2013. Current estimates envision an agreement on a proposed legacy programme by Q3 2014. This will be a critical component for advocacy efforts in the lead-up to the endgame. Under this context, priorities and activities for 2014-2018 will focus on:

- Clear messaging for a coordinated approach on legacy implementation and GAVI's role.
- Work with GPEI on communications activities to build the narrative around the polio legacy.
- Consensus of implementing and donor governments, international agencies, and immunisation groups to advocate for synergies and investing in one national immunisation service to improve the timely coverage of fully-immunised children and reach DoV/GVAP targets.
- Outreach to GPEI and other partners (eg Global Poverty Partners) to advocate for immunisation services to fully immunise children.
- Work closely with GPEI partners to maximize media coverage (online, print and broadcast) of the polio endgame strategy - focus on integration of polio eradication and routine immunisation programmes.
- Place blogs and op-eds by GAVI CEO and GPEI partners in select media outlets.

## **2.5. Financing – Resource mobilization**

### **2.5.1. Current context**

GAVI's Long Term Funding Strategy (LTFS) was approved by the Board in December 2012. The resource mobilization efforts are driven by the vaccines and activities that have been approved by the Board. The current approach has been developed with an initial focus on complementary roles which are not anticipated to require new financial allocations for countries, partners or the Secretariat. In case of financial implications arising in the short-term beyond those already approved, the Secretariat will revert to the Board.

In the longer-term, GAVI's complementary role is likely to require funding. The Secretariat anticipates including such a provision in the next replenishment process. The provision will be developed as GAVI's approach evolves in the coming twelve months, and presented in 2014 to the Board and donors. This will be informed further by the Vaccine Investment Strategy where a decision on IPV support will be considered by November 2013.

### **2.5.2. 2013 priorities**

Pending further guidance from the Board, for example in relation to the VIS, the near term priorities in relation to complementarity with polio include:

- Working closely with the GPEI initiative, GAVI is a co-organiser of the Vaccine Summit in Abu Dhabi on 25 April 2013, in support of the BMGF. We will also host a side event which will touch on routine immunisation. This will reinforce the importance of investments in routine immunisation for polio and for strengthening of wider immunisation services.
- The **Mid-Term Review** (MTR) in October 2013 is a step in GAVI's replenishment process towards sustainable long-term funding of GAVI programmes. It will showcase the performance to date and the challenges ahead in supporting immunisation services.

### **2.5.3. 2014-2018 priorities**

It is assumed that most of the initial areas of potential complementarity will not require additional funding beyond the levels in the LTFS. If complementary activities requiring additional funding from GAVI are to be considered by the Board, the scope and duration of these activities will need to be clearly defined. For example costs, other necessary resources, other potential funders, and opportunity costs to GAVI would be among the considerations. These costs would then be considered alongside GAVI's portfolio of responsibilities

## **2.6. Financing – Innovative Finance Facility for Immunisation (IFFIm)**

### **2.6.1. Current context**

IFFIm could be well-placed as a funding mechanism to assist the polio eradication Endgame. An intensification of activities for eradication, and the increase in routine immunisation coverage that is required, are a classic case of the public health value of frontloading that IFFIm can provide. This would facilitate eventual cost savings once countries are able to decrease investments in polio-specific immunisation and surveillance.

IFFIm provides potential polio donors with the flexibility to provide additional resources today while spreading their contribution over a longer period. This benefit may be advantageous to some donors, particularly emerging countries or countries that are currently facing fiscal constraints. The Bill & Melinda Gates Foundation has indicated that it would consider channeling part of its contribution to polio eradication through IFFIm if it is catalytic and encourages new donors to join.

In 2006, GAVI committed \$191M of IFFIm funds to global polio eradication efforts. The funds have been used to help catalyse the development of monovalent OPV (mOPV), to evaluate the impact of mOPV on virus transmission, and from 2007 to support intensified eradication activities. mOPV has played an important role in eliminating polio from a number of countries (e.g. India, Indonesia, Sudan, Yemen).

### **2.6.2. 2013 priorities**

**Priorities will be determined by donor interest and demand.** The April 2013 Vaccine Summit will provide a clearer indication of resource needs and donor demand to utilise IFFIm.

**IFFIm, GAVI, the United Kingdom's Department for International Development, the World Bank and GPEI** have formed a working group to jointly evaluate structural considerations of using IFFIm for polio. The purpose of the working group is to discuss and solve structuring issues that may arise at a technical level.

### **2.6.3. 2014-2018 priorities**

Priorities will be based upon donor interest and demand to utilise IFFIm as part of their support towards polio eradication.

## **3. Result framework, timeline and risks**

### **3.1. Results framework**

GAVI's results framework is presented in Annex 2.

### 3.2. Timeline (Shaded items reflect indicative timeline, for example if GAVI Board approves support for IPV by November 2013)

| Date             | Activity  |
|------------------|---|
| April 2013       | Vaccine Summit  |
| May 2013         | World Health Assembly considers Endgame Strategy            |
| Through 2013     | GAVI Vaccine Investment Strategy considers IPV              |
| Mid 2013-2014    | Polio legacy planning                                       |
| By November 2013 | GAVI Board decision on IPV                                  |
| Early 2014       | Tender for IPV including GAVI-eligible countries            |
| Early 2014       | Issue GAVI guidelines for country applications              |
| Mid 2014         | Decision on IPV applications for initial round of countries |
| Mid-Late 2014    | Vaccine implementation planning & delivery                  |
| Mid-Late 2014    | GAVI initiates planning for 2016-20 Strategy                |
| End 2014         | Last wild poliovirus case                                   |
| Early 2015       | Initial IPV vaccination with GAVI support                   |
| From 2015        | Withdrawal of OPV2 vaccine (after a country has begun IPV)  |
| End-2018         | Global wild polio virus certification                       |
| During 2019      | bivalent OPV cessation                                      |
| 2024             | Stop IPV  |

### 3.3. Risk & mitigation strategies

Seeking complementarities between polio and other immunisation services is not without risks. The Endgame Strategy includes a section on input risks (e.g. insufficient funding, appropriate staff, and or vaccine supply) and implementation risks (e.g. operating in insecure areas, decreased political or social will, or lack of accountability for quality services) from the perspective of GPEI. The following relate to a GAVI view of risks associated with seeking complementarities with GPEI:

#### 3.3.1. GAVI not seeking complementary approaches with GPEI (High Risk; 0-2 year timeline)

**Context:** GAVI and GPEI could continue to engage relatively little, as per previous practice. However, an important conclusion in this section is that most of the risks below would remain or be significantly magnified if past approaches with relatively little coordination between GPEI and GAVI continue.

**Mitigation:** GAVI should seek complementarities per the December 2012 Board decision.

#### 3.3.2. GAVI implements complementary approaches with GPEI but immunisation coverage does not increase (Moderate Risk; 2-4 year timeline)

**Context:** Immunisation coverage has plateaued since 2008. GPEI has experience which may help improve coverage when fully aligned behind immunisation services. For example, polio resources have contributed to efforts in parts of North India where polio has been eliminated while approaching international coverage

targets for routine vaccines. Application of this experience would need to be done relative to the sustainability and programmatic context of routine programs.

**Mitigation:** GAVI will work with countries through existing systems when aligning with GPEI behind nationally-prioritised strategies for improving coverage; GAVI and GPEI will to a large extent focus on the same countries, those eligible for GAVI's country-tailored approach and/or additional assistance through the Business Plan.

### **3.3.3. GPEI's polio resources are not sustainably deployed for immunisation services (Moderate Risk; 0-2 year timeline)**

**Context:** GPEI has indicated that at least 50% of the time of polio-funded field personnel will be devoted to specific activities to strengthen routine immunisation systems by end-2014, while the potential sustainability of these personnel and their contributions will be unclear until there is international agreement on GPEI's legacy plans.

**Mitigation:** Engage with countries and GPEI global and country staff to monitor this indicator; Monitor that the terms of reference of polio staff are informed by national routine immunisation staff and aligned behind routine immunisation needs; Ensure that legacy discussions consider sustainability of polio resources.

### **3.3.4. IPV implementation (speed, supply, messaging) (High Risk; 2-4 year timeline)**

**Context:** Regardless of GAVI's support for procuring IPV, the implementation of IPV in GAVI-eligible countries will impact implementation of other GAVI-supported activities and vaccines.

**Mitigation:** GAVI partners collaborate with GPEI in the early planning and development of policy guidelines, normative documents, training and communication materials, and other resources; Begin implementation planning and market shaping for programmatically suitable and financially feasible products immediately, if the Board decides to support IPV.

### **3.3.5. Resources targeted to polio limit funds available from domestic sources for routine immunisation and/or at the international level available for GAVI (High Risk; 0-2 year timeline)**

**Context:** GAVI and GPEI are both seeking funding during 2013-15 to support their missions through 2018 and beyond; Countries are being challenged to increase their investments in immunisation and other health care services.

**Mitigation:** GAVI and GPEI can coordinate messages and timing of outreach; GAVI can emphasise that routine immunisation services are essential to completing polio and yet full focus on immunisation and primary health care services will not be possible for several countries until polio is finished. GAVI can continue to reinforce the message that growing amounts of direct investment in routine immunisation services will be needed in the years to come.

**3.3.6. Negative perception of polio SIAs and/or violence towards polio vaccinators in some countries impacts perception of immunisation services and GAVI (High Risk; 0-2 year timeline)**

**Context:** Intensive campaigns, up to 6-8 times per year, have created hostility to polio activities in some areas; Polio vaccinators have been killed in Nigeria and Pakistan.

**Mitigation:** Communicating to parents and delivery of OPV integrated with other primary health care services can decrease parent hesitancy, targeting of health workers, and dilute immunisation-specific concerns.

**3.3.7. Polio resources are not sustainably transitioned to legacy period (Moderate Risk; 4-6 year timeline)**

**Context:** Some polio resources are playing, and are anticipated to increase, their roles in strengthening immunisation services such as in India; Good and bad lessons from over 20 years of eradication should not be lost

**Mitigation:** GAVI will engage in the process to seek a global consensus on transitioning polio's legacy; GAVI partners can support the development of case studies prior to the legacy decision and/or prior to 2018 to demonstrate how and where polio could positively contribute most to RI and other primary health care services.

**Annex 1. Examples of Support to GAVI and GPEI Focus Countries (March 2013) (Reviewed by GPEI; Additional input from GPEI and UNICEF pending)**

| <b>GAVI-GPEI Overlapping Focus Countries</b> | <b>GAVI Health System Strengthening Amount Timeframe</b> | <b>Focused GAVI Support per 2013-14 Business Plan</b>         | <b>Number of field personnel (WHO)<sup>1</sup></b> | <b>Number of field personnel (UNICEF)</b> | <b>Number of field personnel (Other GPEI)<sup>2</sup><br/>To be added</b> | <b>Number of highest-risk districts<br/>To be added</b> | <b>Distribution of districts (e.g. North of country; Nationwide, etc)<br/>To be added</b> |
|--|--|---|--|---|---|---|---|
| <b>Afghanistan</b>                           | \$18.2M<br>2013-14                                       | Country tailored approach; Under 70% coverage                 | 155  | 20  |   |   |   |
| <b>Chad</b>                                  | \$5M<br>2008-14  | Country tailored approach; Under 70% coverage; Improve equity | 36   | 37  |   |   |   |
| <b>DRC</b>                                   | \$56.8M<br>2007-13                                       | Country tailored approach; Under 70% coverage                 | 95   | 28  |   |   |   |
| <b>Ethiopia</b>                              | \$75.2M<br>2012-15                                       | Under 70% coverage  | 73   | 1   |   |   |   |
| <b>India</b>                                 | \$106.9M<br>2013-15                                      | Board guides customised relationship; Improve equity          | 1158   | 25  |   |   |   |
| <b>Nigeria</b>                               | \$44.7M<br>2008-13                                       | Country tailored approach; Under 70% coverage                 | 298  | 32  |   |   |   |
| <b>Pakistan</b>                              | \$23.5M<br>2008-14                                       | Country tailored approach; Improve equity                     | 265  | 65  |   |   |   |
| <b>Somalia</b>                               | \$11.5M<br>2010-15                                       | Country tailored approach; Under 70% coverage                 | 186  | 1   |   |   |   |
| <b>South Sudan</b>                           | \$5.3M<br>2009-11  | Country tailored approach; Under 70% coverage                 | 363  | 13  |   |   |   |

<sup>1</sup> Figures represent core international and national staff, excluding surge capacity, at central and sub-national levels

<sup>2</sup> To be added: Columns for field implementers on non-staff contracts (WHO) or workers contracted through other agencies (UNICEF). These workers will be key for field activities in support of RI.

## **Annex 2: Results Framework**

### **GAVI's role in the polio eradication effort**

#### **Purpose of this framework**

This framework articulates the theory of change and intended outcomes and impact from the GAVI Alliance (GAVI) working more closely with the Global Polio Eradication Initiative (GPEI). This framework is intended to be iterative and will be amended, added to and refined as this approach is rolled out and appropriately tailored to different countries.

The approach arose from a December 2012 GAVI Board decision which:

*Approved GAVI playing a complementary role to the GPEI in the polio eradication effort, specifically through routine immunisation within GAVI's strategy and mission using existing structures, processes, and procedures. Any change to GAVI's vaccine portfolio should be decided within the framework of the new vaccine investment strategy.*

*Approved GAVI exploring the suitability and possible use of IFFIm as one potential financing mechanism to support this activity within GAVI's strategy and mission using existing structures, processes, and procedures.*

For a more comprehensive explanation of the scope and approach overall, please refer to the main approach document *GAVI's approach to complementarity with the Global Polio Eradication Initiative*.

#### **Background**

The Global Polio Eradication Initiative (WHO, UNICEF, Bill and Melinda Gates Foundation, US Centers for Disease Control and Prevention (CDC), Rotary International), with extensive input from GAVI and other partners, is developing a polio "Endgame Strategy." It will be formally launched around the World Health Assembly in May 2013. The strategy covers 2013-2018 and is anticipated to cost approximately \$5.5 billion (plus approximately \$1.2 billion that India is anticipated to self-fund). One of the four strategic objectives is "Routine Immunisation Strengthening and OPV Withdrawal. The GAVI Board has approved playing a complementary role to GPEI. This role is articulated in a document detailing GAVI's approach.

#### **Objective related to polio:**

*Improve immunisation services in accordance with GAVI's mission and goals while supporting polio eradication by harnessing the complementary strengths of GAVI and GPEI in support of countries*

#### **Theory of Change**

- There has been significant progress to date, and challenges, in completing polio eradication

- It is agreed across the immunisation community that strengthening immunisation services is critical to polio eradication, and completing polio eradication is critical to immunisation services. There are implications of polio eradication that will affect either positively or negatively routine immunisation services. If we do not have an established and agreed upon approach between GAVI and GPEI, there is a risk that opportunities may not be maximized and negative consequences and effects may not be minimised.
  - Routine immunisation services can limit the number and spread of outbreaks and prevent vaccine-derived polio cases.
  - Completing polio eradication will free up resources to focus on primary health care.
- Through collaboration between GAVI and GPEI we can jointly and sustainably support countries by harnessing the strengths of polio eradication and routine immunisation to more efficiently improve immunisation services. Complementary roles are anticipated to include:
  - Programmatic
    - There are a number of opportunities to maximise programmatic synergies. For example, at the global level GAVI will define its role as a partner within the governance, oversight and management structures of the GPEI; seek a convergence of strategies for Alliance partners to support countries; and determine its role in the consultation process related to the polio legacy.
    - At country level, GAVI and GPEI will support annual, harmonised, operational work plans of countries, the terms of reference of polio-supported staff will be modified to reflect support for routine immunisation, and such staff will be retrained accordingly. Immunisation services could benefit from the significant investments and systems that have already been set up for surveillance of polio and use these to strengthen surveillance and broader monitoring of other diseases.
  - IPV Supply and Implementation: GAVI will take a decision on support for IPV through the Vaccine Investment Strategy by November 2013; monitor policy developments and additional R&D data informing IPV assumptions; and share lessons on vaccine implementation from GAVI's experience.
  - Advocacy/Communication: Ensuring connection between polio eradication efforts and immunisation services will require a strong advocacy effort. At country level, it will include an emphasis on coordinating across polio, SIAs, new vaccine implementation, and other approaches within a harmonised national immunisation service.

- Financing:
  - Resource mobilization efforts will be informed further by the Vaccine Investment Strategy where a decision on IPV support will be considered by November 2013.
  - IFFIm could be well-placed as a funding mechanism to assist the polio eradication Endgame. An intensification of activities for eradication, and the increase in routine immunisation coverage that is required, are a classic case of the public health value of frontloading that IFFIm can provide.
- Sustainability and efficiency of immunisation services can be better ensured. Polio eradication has utilised approaches in some countries that have been supported and nurtured by intensive staff and financial support for management, planning, monitoring, demand, and surveillance and other activities. Where such approaches and staff resources are appropriate for and sustainably embedded in national systems, they could be applied to support long-term improvements in immunisation services as a whole.
- Through this mutual support to countries we can increase the number of fully-immunized children.
- Fully immunizing children prevents morbidity and mortality.

#### **Key assumptions underpinning the results framework**

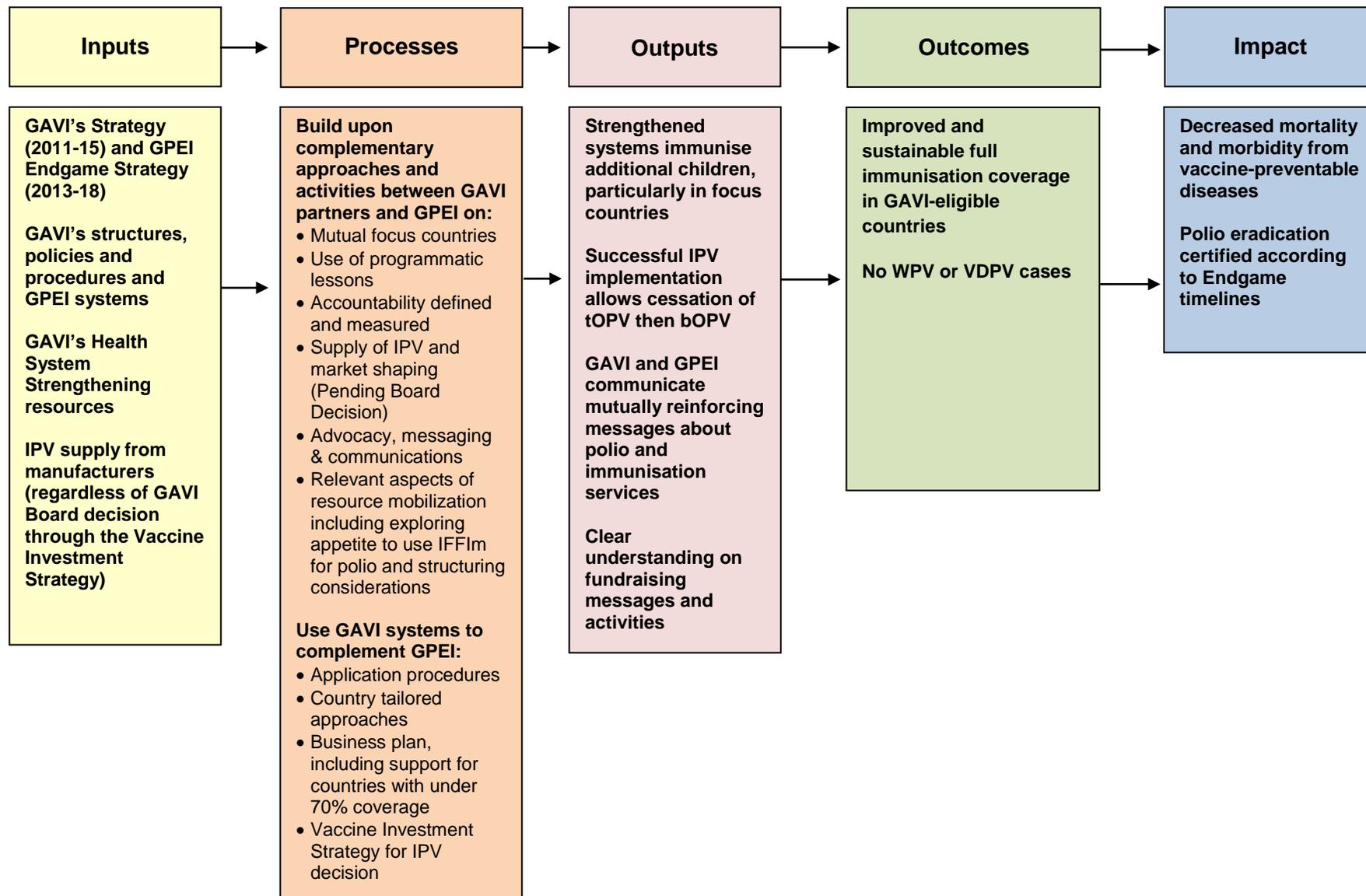
- Complementarity approaches between routine immunisation services and polio are more efficient and/or effective for completing eradication than only relying on supplementary immunisation activities (SIAs; campaigns) alone.
- That there are strong synergies between GAVI and GPEI and that negative unintended consequences can be minimised through careful planning, explicit accountability with agreed indicators, and a concerted effort by the two entities
- Assuming programmatic and timeline assumptions in the Endgame Strategy are correct, the international community is at a crucial juncture, requiring polio eradication and other immunisation services to come together.
- Countries share the understanding that strengthening routine within immunisation services will be crucial to eradicating polio and to ensuring sustainable improvements in immunisation and primary health care services.
- GAVI's investments will lead to increases in coverage with routine vaccines in eligible countries, and particularly with oral polio vaccine and IPV (regardless of if GAVI supports procurement of IPV – Decision to be taken by Board by November 2013).
- GPEI and other partners will support non GAVI-eligible countries where necessary.
- Vaccine manufacturers supply sufficient IPV.

- GAVI and GPEI are successful in upcoming pledging rounds with financial donors.

### **Monitoring and evaluation**

GAVI's approach will be monitored through existing partner and GAVI systems and indicators, such as through the WHO-UNICEF Joint Report Form and reporting on GAVI's Performance-Based Funding. Opportunities to build upon existing systems in country and at the global level will be fully explored.

## Results Framework for GAVI's Complementary Role in Polio Eradication





## ANNEX 2

WORKING DRAFT

May 2013

# **GAVI's complementary role to the Global Polio Eradication Initiative (GPEI) in the polio eradication effort**

## **Preface**

The mission of the GAVI Alliance (GAVI) is to save children's lives and protect people's health by increasing access to immunisation in poor countries. This document articulates the Alliance's approach for working more closely with the Global Polio Eradication Initiative (GPEI). It is intended for GAVI and GPEI partners, including countries, and will evolve over time. The approach arose from a December 2012 GAVI Board decision which:

*Approved GAVI playing a complementary role to the GPEI in the polio eradication effort, specifically through routine immunisation within GAVI's strategy and mission using existing structures, processes, and procedures. Any change to GAVI's vaccine portfolio should be decided within the framework of the new vaccine investment strategy.*

*Approved GAVI exploring the suitability and possible use of IFFIm as one potential financing mechanism to support this activity within GAVI's strategy and mission using existing structures, processes, and procedures.*

Section 1 describes the context and objective of GAVI's approach. Section 2 describes specific areas of complementarity related to programmatic, IPV supply and implementation, advocacy and communications, and financing approaches. These are considered in terms of the current context and priorities for the remainder of 2013 and 2014-2018. Section 3 describes the result framework, timeline, risks and risk mitigation strategies for GAVI. This approach document has drawn on the advice and input from a wide cross-section of GAVI and GPEI partners and GAVI Secretariat staff.

## **Executive Summary**

Elements of the goals of the GAVI Alliance and the GPEI are converging. GPEI commits itself to strengthening immunisation services in order to successfully eradicate polio as part of its Endgame Strategy. The GAVI Board has asked the Alliance to seek ways to play a complementary role to eradication using existing processes. Lessons from polio and its infrastructure, which tends to be concentrated in focus countries for GAVI such as those with the most unimmunised children, could be targeted to help strengthen immunisation services and improve vaccine coverage. It would be important to consider their roles in light of sustainability and programmatic challenges specific to delivering routine immunisation services.

*How* potential complementarities come to be realised remains a critical and not easily answered question. GAVI and GPEI have been investing in often the same developing countries for over 12 years, but frequently with different approaches to, for example, supporting human resources and immunisation programmes. Today there is an opportunity for not only a shared commitment to seek complementarities but explore where synergies may reside in addressing bottlenecks to improving coverage. GPEI's approach is reflected in the Polio Endgame Strategy to which GAVI has contributed extensively.

This document reflects GAVI's approach to seeking complementarities and synergies with GPEI. It draws upon extensive interactions and discussions with GPEI and GAVI partners following the December 2012 Board decision. The approach is not fixed, but reflects current, concrete priorities which will continue to evolve with the changing contexts in countries through the Endgame period (2013-18), and during GAVI's current Strategy (2011–15) and next strategy (2016-20).

GAVI's approach is intended to achieve the following objective: *to improve immunisation services in accordance with GAVI's mission and goals while supporting polio eradication by harnessing the complementary strengths of GAVI and GPEI in support of countries.* The approach encompasses programmatic aspects at global/regional and country levels, as well as those related to procurement and implementation of inactivated polio vaccine (IPV) from 2015 to 2024 pending a GAVI Board decision by November 2013, media and communications, and financing. GAVI and GPEI have a shared geographic focus in a number of countries, reflected in policies and investments, particularly Afghanistan, Chad, DR Congo, Ethiopia, India, Nigeria, Pakistan, Somalia, and South Sudan.

There are a number of risks identified for GAVI with this approach. Mitigation strategies are also presented. Risks include GAVI's focus being diverted leading to coverage for routine vaccines not increasing; GPEI's human resources or strategies are not sustainably deployed in support of immunisation services; finances targeted to polio limit funds available from domestic sources for routine immunisation and/or at the international level available for GAVI; and that negative perceptions of polio vaccines impact demand for other immunisation services. The risks can be mitigated to some extent and/or are likely to remain or be amplified if GAVI does not consider a complementary role to GPEI.

## 1. Context & Objective

### 1.1. Context

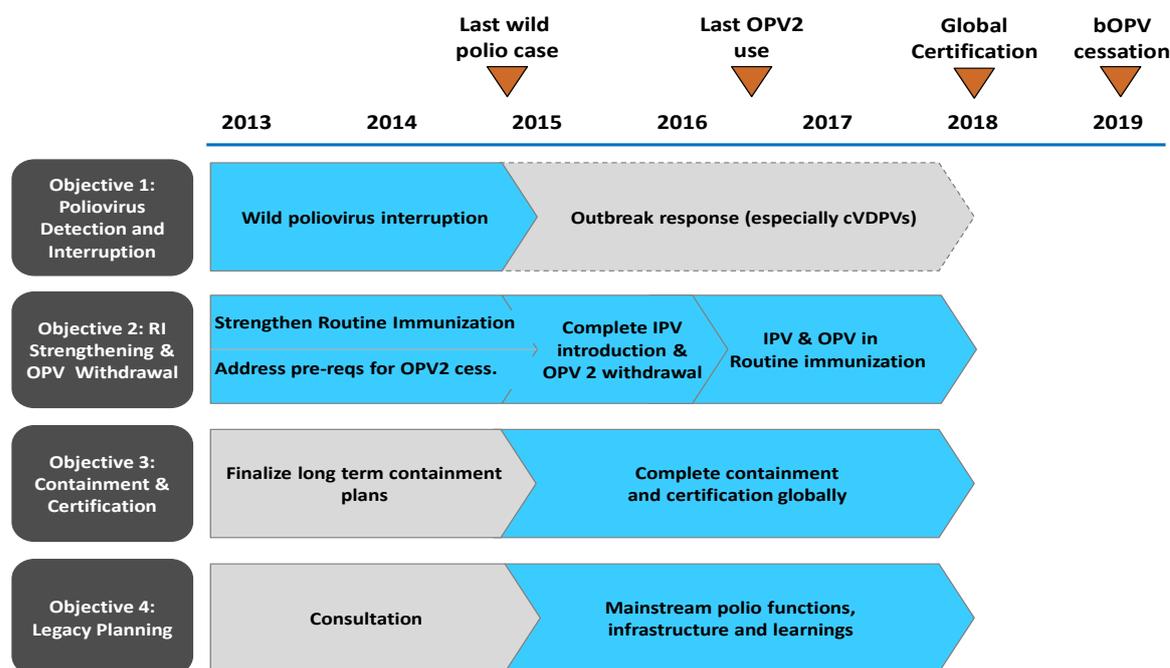
Polio typically infects young children through oral-faecal transmission, and in some cases causes paralysis, life-long disability, and death. An estimated 350,000 cases occurred in 1988, decreasing to 223 in 2012. Three countries continue to have wild polio virus (WPV) transmission, all of which are GAVI eligible, totalling 217 cases from 2012: Nigeria had 122 cases; Pakistan 58; and Afghanistan 37. A further five cases were reported from Chad and one from Niger in 2012, related to importations from Nigeria. India was the last endemic country to stop wild polio transmission in January 2011. Current targets are to stop all wild transmission by the end of 2014. Polio vaccinators have been killed by militants in Pakistan and Nigeria recently, leading to additional security and outreach efforts.

In rare circumstances when a population is very under-immunised and susceptible individuals accumulate, the live, attenuated virus used in oral polio vaccine (OPV) can revert and acquire the ability to circulate for extended periods and cause paralysis. The longer it is allowed to replicate, the more genetic changes it undergoes. This genetically reverted virus that establishes circulation and is able to cause paralysis is referred to as circulating vaccine-derived poliovirus (cVDPV). As the number of wild polio cases decreases, the number of vaccine-derived polio cases has increased. A total of 68 vaccine-derived polio cases were reported in 2012. Switching from OPV to inactivated polio vaccine (IPV) is a critical strategy for preventing vaccine-derived polio cases. IPV protects individuals against cVDPVs, and since it is made from a killed virus, it cannot lead to new cVDPVs.

The Global Polio Eradication Initiative (WHO, UNICEF, US Centers for Disease Control and Prevention (CDC), and Rotary International with the Bill & Melinda Gates Foundation), with extensive input from GAVI, key stakeholders, and donor partners, is developing a “Polio Eradication & Endgame Strategic Plan 2013-18.” (Figure 1) The plan will be formally launched around the World Health Assembly in May 2013. The strategy covers 2013-2018 and is anticipated to cost approximately \$5.5 billion (plus approximately \$1.2 billion that India is anticipated to self-fund). One of the four strategic objectives is “Routine Immunisation Strengthening and OPV Withdrawal.”

In some countries, polio eradication has progressed largely relying on high routine coverage, while in others, particularly after 1998, it has relied on a strategy of supplementary immunisation activities (in addition to routine immunisation services.) In a number of countries, polio has supported management systems parallel to the national health and routine immunisation systems in which GAVI invests. The Endgame is broadly consistent with the wording of the original WHA resolution calling for polio eradication, a view shared by GAVI, that strong routine immunisation services and high coverage are essential to achieve eradication and maintain countries polio free during a multi-year certification period. The Endgame presents an opportunity to seek sustainable, complementary approaches between polio and wider immunisation services. Such approaches will also be central to successfully implementing IPV.

**Figure 1. Overview of eradication and endgame strategic plan**



Nine countries are foci for GAVI (e.g. with DTP3 coverage less than 70%) and polio endemic or identified by GPEI as at high risk of WPV outbreaks and recurrent VDPV emergence: Afghanistan, Chad, DR Congo, Ethiopia, India, Nigeria, Pakistan, Somalia, and South Sudan. The monitoring and evaluation framework for the Endgame is not finalized, but will include the commitment of GPEI to supporting improvement in coverage (e.g. at least 10% annual increase in DTP3 coverage achieved in 80% of high risk districts of all focus countries from 2014 to 2018 [e.g. 50% to 55% in year one; 55% to 60.5% in year two, etc.] It is anticipated that at least 50% of the time of polio-funded field personnel will be devoted to specific activities to strengthen routine immunisation systems by end-2014, while consideration is given to the sustainability of staffing and strategies.

## 1.2. Objective

The objective of GAVI’s engagement with polio eradication is:

*To improve immunisation services in accordance with GAVI’s mission and goals while supporting polio eradication by harnessing the complementary strengths of GAVI and GPEI in support of countries*

Immunisation services are part of the wider health system. Immunisation services deliver a package of vaccines routinely to infants and children according to a national schedule. They also include supplementary immunisation activities (SIAs or campaigns) which are implemented for specific epidemiological reasons (e.g. to more rapidly increase population immunity to specific diseases or respond to an outbreak). SIAs should be

designed to strengthen underlying routine immunisation services and the wider health system.

## **2. Complementary approaches**

The following section describes specific areas of complementarity and synergy related to programmatic, potential GAVI support for IPV procurement and implementation, advocacy and communication, and financing approaches. These are considered in terms of the current context for each and priorities for 2013 and 2014-2018. These are not fixed but will continue to evolve, shape and be shaped by progress on immunisation targets and polio eradication.

### **2.1. Programmatic – Global & Regional**

#### **2.1.1. Current context**

There is a mixed history among GAVI Alliance partners of coordination between those focused on eradicating polio and those focused on other immunisation services. In some situations staff funded by GPEI partners (i.e. polio funded) have worked partially or largely on routine immunisation. However, staff have been or continue to be physically and managerially separated in some organizations.

Polio eradication has remained largely separated from GAVI's programmatic scope. GAVI has invested broadly in strengthening immunisation and health systems over the past decade, particularly to improve routine immunisation coverage. According to WHO-UNICEF estimates, coverage in GAVI-eligible countries has largely plateaued from 2009-2011 (the most recent data available). DTP3, OPV3, and first dose of measles containing vaccines have remained at approximately 76%, reinforcing the potential value of GAVI seeking new partnerships and innovative approaches to raise coverage. GPEI is also seeking new partnerships and innovative programmatic approaches to respond to the World Health Assembly (2012) declaration of polio as a "programmatic public health emergency."

In the Endgame Strategy and this document, GPEI and GAVI seek a new collaboration and focus on sustainably strengthening routine immunisation services and eradicating polio.

#### **2.1.2. 2013 priorities**

During 2013, global/regional programmatic priorities will include:

**Discussing and determining an appropriate role for GAVI** within the oversight and management structures supporting polio eradication. In this context, GAVI will need to consider any potential governance implications. Clarity on GAVI's role will help strengthen coordination in support of the Endgame and immunisation services across GAVI and GPEI's investments. The newly established GPEI Immunisation Management Group responsible for objective two of the Endgame on routine

immunisation strengthening, OPV withdrawal and IPV implementation, is led by staff responsible for routine immunisation in WHO and UNICEF; staff which collaborate daily with other GAVI partners. The GAVI Secretariat has also been invited to join the Group.

**Seeking a convergence of strategies** for Alliance partners to support countries, consistent with complementary approaches between GAVI and GPEI. GAVI has contributed extensively to the Endgame Strategy, and GPEI input has heavily influenced the development of this approach document. GAVI will be taking a decision on whether it will finance IPV procurement by November 2013.

**Participate in the consultation process related to the polio legacy planning.**

GAVI anticipates participating in the legacy discussions which will be coordinated by the main GPEI partners. Long-term planning is essential if lessons learnt during polio eradication, trained personnel, infrastructure, surveillance, and other investments are to be transitioned to other development goals and global health priorities. By participating in the legacy consultation process, GAVI will, for example, seek to understand the perspectives of developing countries relative to polio's legacy and GAVI's role, if any. Decisions on GAVI's role in relation to the polio legacy will be determined by the Board.

**2.1.3. 2014-2018 priorities**

The coming years will see:

**Consolidation and reinforcement of the coordination and communication channels** between GAVI and GPEI at global level.

**Harmonisation of GAVI and GPEI programmatic commitments** from global and regional levels in support of countries, and sharing lessons across countries on complementarities between polio and other immunisation services. During 2014, GAVI will develop a new 2015-16 Business Plan which could reflect human and financial resources of WHO, UNICEF, the Secretariat, and other partners related to GAVI's complementary role in support of polio eradication.

**Decision by the GAVI Board on the type and level of contribution GAVI may make in support of the polio legacy**, and based upon that decision, determining appropriate implementation steps if relevant. GAVI anticipates that its decision will build upon the views of developing countries, and a diverse range of GAVI stakeholders. GAVI will begin in 2014 to develop its new strategy for 2016-2020, which could be informed by and inform discussions around polio's legacy.

**2.2. Programmatic – Country**

**2.2.1. Current context**

Improving immunisation services, including in polio-endemic and high-risk countries, is a shared priority for GPEI and GAVI. Strengthened immunisation services complement

and will help sustain polio eradication by decreasing the need for supplementary activities which can be costly and interrupt primary health care services. Strengthened routine immunisation can help to facilitate and sustain the interruption of wild poliovirus transmission, reduce the risk of cVDPV emergence as well as virus importation and spread. Robust, quality immunisation services capable of obtaining high equitable coverage levels of all antigens will also be required for effective IPV introduction, tOPV to bOPV switch, and eventually complete OPV removal.

The level of GPEI human and financial resources and support varies by country. Many countries at low risk of polio, such as Tanzania, may have few dedicated staff funded by GPEI and staff present largely focus on surveillance. In recent years such countries may have largely relied on routine immunisation services to maintain high population immunity and prevent outbreaks. Endemic countries (Afghanistan, Nigeria and Pakistan) and recently endemic countries (India) maintain significant polio infrastructures with hundreds and in the case of India and Nigeria, thousands of dedicated polio staff (e.g. technical, surveillance, and communication specialists and community mobilisers) supported by WHO, UNICEF, and others. Countries at high risk of importation, outbreaks and VDPV emergence (Chad, DRC, Ethiopia, Somalia and South Sudan) have relatively less yet still significant polio infrastructures.

There are a number of management and programmatic strategies supported by staff in countries with significant polio personnel that have the potential to strengthen immunisation services. These include: strong management and accountability structures; detailed microplanning and systematic updating of plans; social mapping, mobilisation and advocacy with influential community and religious leaders; programme monitoring; and vaccine preventable disease surveillance (epidemiology and laboratory). Lessons and priorities can be drawn from India and elsewhere about how to utilise polio strategies to strengthen immunisation, particularly approaches like the Social Mobilization Network and special strategies for high risk areas and provision of routine immunisation services, including OPV, to underserved populations.

To best identify points of complementarity and ensure positive and realistic synergies, the differences between routine immunisation and polio approaches as well as commonalities must be recognized and addressed. The differences form the basis of understanding how complementary roles can be realised. For example, the polio Endgame Strategy proposes that at least 50% of the time of polio-funded field personnel in the identified priority areas be devoted to specific activities to strengthen routine immunisation systems by end-2014. These terms of reference should be clearly defined as part of routine immunisation national and micro-plans, not only through polio-related plans.

Beyond the countries with extensive staff, GPEI has invested heavily over the years to strengthen human resources and infrastructure for acute flaccid paralysis (AFP) surveillance in many GAVI eligible countries. These investments hold the potential to strengthen aspects of other vaccine-preventable disease surveillance activities.

All GAVI-eligible countries can apply for cash support to improve immunisation services through investments in health system strengthening, GAVI's Board has indicated that

15-25% of overall programmatic expenditures should be in the form of cash support. Countries can choose to use such financial resources to build upon or extended strategies utilised by GPEI, integrating such approaches into their annual, operational plans. Countries can access extensive technical support to plan how to use such financial resources to strengthen immunisation services, including increasing coverage, new vaccine implementation, and improving equity. The technical support is available through approximately 130 staff, particularly in WHO and UNICEF, funded under the GAVI Business Plan. These are in addition to the many staff in GAVI partners funded from other sources, including GPEI. In the same countries where polio financial and human resources are concentrated, GAVI provides additional flexibility to meet country needs and/or financial resources to overcome health and immunisation system bottlenecks (“focus countries”). GAVI’s policy on fragility and immunisation (i.e. Country Tailored Approach) support for countries with less than 70% DTP3 coverage, and targeted support to countries struggling to overcome equity issues (i.e., geographic, socio-economic and gender) provide three additional avenues for working together with countries to build their capacities to ensure complementarity between GAVI support and GPEI resources. (Annex 1)

### **2.2.2. 2013 priorities & activities**

In order to realize complementarity between GAVI and GPEI, governments must lead and be effective stewards of better collaboration, with support from polio and Alliance partners. It will require:

- **Annual, harmonised, operational work plans** elaborated and aligned with overarching planning documents (e.g. cMYPs) and local microplans for immunisation services, with routine, polio and other SIAs falling under the workplans. Some countries are developing such harmonized workplans (e.g. Nigeria) while others would develop the plans late in the year for 2014. Plans should identify programme objectives and detail the activities, timelines, budget and technical support required using government, GAVI, GPEI, and other partner resources. The workplans should identify how and where GPEI’s strengths, such as related to microplanning, session monitoring, and improving data (e.g. coverage, surveillance) will be used for routine services. Annual operational work plans should be endorsed by inter-agency coordinating committees (ICCs).
- **Terms of reference (ToRs)** of individuals funded to work on polio eradication are being revised. Revisions should be done in coordination with national immunisation priorities and government immunisation staff responsible for routine immunisation services. Government input into such revisions could be important to increasing the sustainability of human resources as GPEI eventually concludes its work through the Legacy period. Revised ToRs will include elements related to immunisation strengthening, as appropriate for the country plan and aligned with GPEI’s strengths, such as management, microplanning, mobilization and monitoring. The numbers and locations of these staff are summarized in Annex 1.

- **Measuring contributions** of polio-staff to improve immunisation services using indicators reflected in the ToRs, and monitoring such contributions. Structures and systems for strengthening the accountability for results for polio eradication and routine immunisation should be harmonized, such as through partner reporting mechanisms, Inter-Agency Coordinating Committees (ICCs) and/or the polio-supported Expert Review Committees.
- **Re-tooling and re-training of polio staff** to impart the knowledge and skills required to better engage on broader immunisation issues, such as those related to routine immunisation services and schedules, cold chain and logistics management, injection safety, waste disposal, community partnerships, local monitoring by local staff at each level, AEFI management and vaccine preventable disease surveillance. Polio staff are participating in trainings provided in countries on routine immunisation by governments and partners.
- **Providing vaccines in high-demand by communities, including through planned campaigns or periodic intensification of routine immunisation (PIRI).** GAVI can strengthen demand for immunisation services and wider primary health services. GAVI supported vaccines such as Meningitis A may be in high demand by communities such that OPV delivered at the same time also achieves high coverage.

### **2.2.3. 2014-2018 priorities**

To realize the benefits of greater GAVI – GPEI complementarity, the near term priorities noted above need to be implemented and followed-up on in focus countries (Annex 1) over a number of years. Assisting and monitoring progress on each, such as the training and involvement of polio-funded staff in strengthening immunisation services and coverage improvements with all vaccines in the lowest performing districts, is essential to determine where mid-course corrections and adjustments need to be made. Existing and future country applications for GAVI support and financial resources, whether for new vaccine introduction, SIAs and/or health system strengthening (HSS) will be instrumental to assist focus countries to strengthen immunisation services and potentially implement strategies used by polio eradication. GAVI's support continues to evolve, such as efforts underway to modernize supply chains and work on equity between and within countries. Secretariat staff will work closely with focus countries and partners to support harmonisation of financial and human resources and approaches.

Measurement of progress at the country level will be monitored through existing and improved partner and GAVI systems and indicators, such as through the WHO-UNICEF Joint Report Form and reporting on GAVI's Performance-Based Funding.

## 2.3. IPV Supply and Implementation

### 2.3.1. Current context

The Endgame calls for all countries to introduce at least one dose of IPV six months before phasing out the use of tOPV. IPV will prime individuals or maintain population immunity against all three types of polio virus, while transitioning from trivalent OPV to bivalent OPV (types 1 and 3 virus) in 2016. Phasing out the use of bOPV in 2019 will prevent new vaccine-derived polio viruses. Approximately 23% (68 of 291) of total polio cases in 2012 were caused by VDPVs, a proportion that will increase as wild cases decrease.

A single dose of IPV is anticipated to prime the immune system of individuals, if not fully protect them. Primed individuals who were re-vaccinated with OPV would be rapidly protected with high levels of immunity. This rapid protection would be critical to stop transmission if an outbreak occurred. Current assumptions anticipate the single priming dose of IPV will be delivered with the third dose of DTP-containing vaccine.

### 2.3.2. 2013 priorities

Countries, manufacturers, and other partners will need a number of years to prepare for the switch to IPV. Therefore, the focus for 2013 will include:

- **Decision on whether GAVI will support IPV** to be taken through GAVI's Vaccine Investment Strategy (VIS) by November 2013. A base case scenario of GAVI support for a single dose of IPV given at the same time as the third dose of DTP-containing vaccine is considered in phase I of the VIS through June 2013. Alternative scenarios for potential consideration prior to November include additional support for a second dose of IPV, or three doses of IPV as part of combination hexavalent (DTwP-HepB-Hib-IPV) vaccine. If the GAVI Board decides to support IPV, the final decision on vaccination strategy will be based on WHO recommendations. GAVI's support would only be for GAVI-eligible countries and delivered when infants are brought for their routinely administered vaccines. In all scenarios, GAVI's support for IPV would end in 2024, per the Endgame. After 2024, countries would be able to decide to stop using IPV or continue with domestic or other financial resources. Support for catch-up or outbreak response scenarios would need to be provided through GPEI as would IPV for GAVI-eligible countries if the Board decides not to support it.
- **Monitor policy developments and additional R&D data informing IPV assumptions** that may arise from research and/or ongoing product development efforts related to dose-sparing, adjuvanting, and other potentially cost-saving strategies, as well as hexavalent vaccines.
- **Share lessons on vaccine implementation** from GAVI's experience. The scale and timelines anticipated for IPV implementation are unprecedented. They are likely to be extremely challenging for countries and partners, and to

have implications for GAVI's vaccine-related support to countries. Regardless of GAVI's support for IPV procurement, its experience supporting more than 150 countries through introductions for HepB, Hib, pneumococcal, rotavirus and other vaccines will be used to inform planning for IPV implementation.

### 2.3.3. 2014-2018 priorities

Decisions on future priorities will follow from the GAVI Board decision in late 2013. If the Board decides to support IPV for GAVI-eligible countries, the Secretariat will work with partners to:

- Engage with GPEI, and particularly UNICEF, on **supply planning and market shaping** activities for programmatically suitable and financially feasible products. This would include developing a strategy (roadmap) for IPV. The strategy would include working with manufacturers to determine the potential role of hexavalent vaccine given the timelines reflected in the Endgame, and relative to the pentavalent supply relied upon by GAVI-eligible countries.
- Encourage pursuit of **cost-saving strategies** by manufacturers, product-development partnerships and others.
- Coordinate with GPEI, WHO and UNICEF SD on **regulatory strategy and procurement planning** to ensure supply to countries from 2015.
- Rapidly accelerate **implementation planning** including establishing an appropriate country application mechanism and addressing implications for GAVI's policies and processes.
- Invite **country applications** in time for vaccine implementation in countries from early 2015, and intended to support scaling up to all GAVI-eligible countries in accordance with timelines in the Endgame where feasible and according to recommendations from WHO.

## 2.4. Advocacy and communications

### 2.4.1. Current context

GAVI recognizes the importance of strong coordination and alignment between partners in support of the Decade of Vaccines/Global Vaccine Action Plan (DoV/GVAP) goals and strategic objectives as well as with the four major objectives of the Endgame Strategic Plan.

As such GAVI and GPEI are increasing coordination around communication and advocacy efforts in support of completing polio eradication and strengthening immunisation services.

Ensuring connection between polio eradication efforts and immunisation services will require a strong advocacy and communication effort. At country level, it will include an

emphasis on coordinating across polio, SIAs, new vaccine implementation, and other approaches within a harmonised national immunisation service and including linkages with communities, civil society, and the private sector.

#### 2.4.2. 2013 priorities

Given the current context, 2013 priorities will focus on:

- **Global advocacy and consensus building to support greater integration** between polio eradication and wider immunisation services; and
- **Expanding messaging** around polio-led initiatives to focus on strengthening immunisation services. This will have benefits for GPEI, for rolling out new vaccines supported by GAVI, and for strengthening coverage of routine vaccines. Messaging will also include the need for direct investment in routine immunisation services including recurrent operational costs.

Additional activities will include:

- Current donors to the GPEI have built-in strong incentives for country-level staff to reach specific goals by defined time points. This has led staff to prioritise polio campaigns over strengthening routine immunisation services in many instances. Therefore, a meeting with the leadership of key global partners in polio eradication and immunisation (e.g. WHO, UNICEF, BMGF, CDC, GAVI, and bilateral development agencies) is required to align agency priorities, develop shared objectives and consider what new incentives are needed to integrate polio with national immunisation services. This meeting could be held as part of the discussions on polio's legacy.
- Work closely with GPEI partners on joint messaging and joint media activities where possible (Vaccine Summit, World Immunisation Week, World Health Assembly, UN General Assembly, World Polio Day).
- Work closely with GPEI partners to generate online and social media activity in support of the polio endgame and in support of strengthened routine immunisation.
- Develop a special polio page for the GAVI website, highlighting key events (Vaccine Summit, World Polio Day) and a special routine immunisation page for the GPEI web site.
- Share with the GPEI advocacy network groups updates on GAVI vaccine launches and other highlights
- Communicate clearly GAVI Vaccine Investment Strategy (VIS) and Board decision (due by November 2013) on supporting IPV

### **2.4.3. 2014-2018 priorities**

GPEI is developing a Legacy Options strategy (transition of key staff, infrastructure and systems according to national, global development priorities) – through consultations in 2013. Current estimates envision an agreement on a proposed legacy programme by Q3 2014. This will be a critical component for advocacy efforts in the lead-up to the endgame. Under this context, priorities and activities for 2014-2018 will focus on:

- Clear messaging for a coordinated approach on legacy implementation and GAVI's role.
- Work with GPEI on communications activities to build the narrative around the polio legacy.
- Consensus of implementing and donor governments, international agencies, and immunisation groups to advocate for synergies and investing in one national immunisation service to improve the timely coverage of fully-immunised children and reach DoV/GVAP targets.
- Outreach to GPEI and other partners (e.g. Global Poverty Partners) to advocate for immunisation services to fully immunise children.
- Work closely with GPEI partners to maximize media coverage (online, print and broadcast) of the polio endgame strategy - focus on integration of polio eradication and routine immunisation programmes.
- Place blogs and op-eds by GAVI CEO and GPEI partners in select media outlets.

## 2.5. Financing – Resource mobilization

### 2.5.1. Current context

GAVI's Long Term Funding Strategy (LTFS) was approved by the Board in December 2012. The resource mobilization efforts are driven by the vaccines and activities that have been approved by the Board. Aside from a decision on whether GAVI will support IPV procurement, the current approach has been developed with an initial focus on complementary roles which are not anticipated to require new financial allocations for countries, partners or the Secretariat. In case of financial implications arising in the short-term beyond those already approved, the Secretariat will revert to the Board.

In the longer-term, GAVI's complementary role is likely to require funding. The Secretariat anticipates including such a provision in the next replenishment process. The provision will be developed as GAVI's approach evolves in the coming twelve months, and presented in 2014 to the Board and donors. This will be informed further by the Vaccine Investment Strategy where a decision to IPV, or not, will be considered by November 2013.

### 2.5.2. 2013 priorities

Pending further guidance from the Board, for example in relation to the VIS, the near term priorities in relation to complementarity with polio include:

- Working closely with GPEI and in support of the BMGF, GAVI served as a co-organiser of the Vaccine Summit in Abu Dhabi on 25 April 2013. The Summit resulted in contributions of approximately \$4 billion through 2018 towards the \$5.5 billion in resources required for the Endgame. GAVI also hosted a side event which touched on routine immunisation. This reinforced the importance of investments in routine immunisation for polio and for strengthening of wider immunisation services.
- The **Mid-Term Review** (MTR) in October 2013 is a step in GAVI's replenishment process towards sustainable long-term funding of GAVI programmes. It will showcase the performance to date and the challenges ahead in supporting immunisation services.

### 2.5.3. 2014-2018 priorities

It is assumed that most of the initial areas of potential complementarity, aside from IPV, will not require additional funding beyond the levels in the LTFS. If complementary activities requiring additional funding from GAVI are to be considered by the Board, the scope and duration of these activities will need to be clearly defined. For example costs, other necessary resources, other potential funders, and opportunity costs to GAVI would be among the considerations. These costs would then be considered alongside GAVI's portfolio of responsibilities.

## 2.6. Financing – Innovative Finance Facility for Immunisation (IFFIm)

### 2.6.1. Current context

IFFIm could be well-placed as a funding mechanism to assist the polio eradication Endgame. An intensification of activities for eradication, and the increase in routine immunisation coverage that is required, are a classic case of the public health value of frontloading that IFFIm can provide. This would facilitate eventual cost savings once countries are able to decrease investments in polio-specific immunisation and surveillance.

IFFIm provides potential polio donors with the flexibility to provide additional financial resources today while spreading their contribution over a longer period. This benefit may be advantageous to some donors, particularly emerging countries or countries that are currently facing fiscal constraints. The Bill & Melinda Gates Foundation has indicated that it would consider channeling part of its contribution to polio eradication through IFFIm if it is catalytic and encourages new donors to join.

In 2006, GAVI committed \$191M of IFFIm funds to global polio eradication efforts. The funds have been used to help catalyse the development of monovalent OPV (mOPV), to evaluate the impact of mOPV on virus transmission, and from 2007 to support intensified eradication activities. mOPV has played an important role in eliminating polio from a number of countries (e.g. India, Indonesia, Sudan, Yemen).

### 2.6.2. 2013 priorities

**Priorities will be determined by donor interest and demand.** The April 2013 Vaccine Summit provided a clearer indication of financial resources available to GPEI, and may further inform donor demand to utilise IFFIm.

**IFFIm, GAVI, the United Kingdom's Department for International Development, the World Bank and GPEI** have formed a working group to jointly evaluate structural considerations of using IFFIm for polio. The purpose of the working group is to discuss and solve structuring issues that may arise at a technical level.

### 2.6.3. 2014-2018 priorities

Priorities will be based upon donor interest and demand to utilise IFFIm as part of their support towards polio eradication.

## 3. Result framework, timeline and risks

### 3.1. Results framework

GAVI's results framework is presented in Annex 2.

### 3.2. Timeline (Shaded items reflect indicative timeline, for example if GAVI Board decides to support for IPV by November 2013)

| Date             | Activity  |
|------------------|---|
| April 2013       | Vaccine Summit  |
| May 2013         | World Health Assembly considers Endgame Strategy            |
| Through 2013     | GAVI Vaccine Investment Strategy considers IPV              |
| Mid 2013-2014    | Polio legacy planning                                       |
| By November 2013 | GAVI Board decision on IPV                                  |
| Early 2014       | Tender for IPV including GAVI-eligible countries            |
| Early 2014       | Issue GAVI guidelines for country applications              |
| Mid 2014         | Decision on IPV applications for initial round of countries |
| Mid-Late 2014    | Vaccine implementation planning & delivery                  |
| Mid-Late 2014    | GAVI initiates planning for 2016-20 Strategy                |
| End 2014         | Last wild poliovirus case                                   |
| Early 2015       | Initial IPV vaccination with GAVI support                   |
| From 2015        | Withdrawal of OPV2 vaccine (after a country has begun IPV)  |
| End-2018         | Global wild polio virus certification                       |
| During 2019      | bivalent OPV cessation                                      |
| 2024             | Stop IPV  |

### 3.3. Risk & mitigation strategies

Seeking complementarities between polio and other immunisation services is not without risks. The Endgame Strategy includes a section on input risks (e.g. insufficient funding, appropriate staff, and or vaccine supply) and implementation risks (e.g. operating in insecure areas, decreased political or social will, or lack of accountability for quality services) from the perspective of GPEI. The following relate to a GAVI view of risks associated with seeking complementarities with GPEI:

#### 3.3.1. GAVI not seeking complementary approaches with GPEI (High Risk; 0-2 year timeline)

**Context:** GAVI and GPEI could continue to engage relatively little, as per previous practice. However, an important conclusion in this section is that most of the risks below would remain or be significantly magnified if past approaches with relatively little coordination between GPEI and GAVI continue.

**Mitigation:** GAVI should seek complementarities per the December 2012 Board decision.

#### 3.3.2. GAVI implements complementary approaches with GPEI but immunisation coverage does not increase (Moderate Risk; 2-4 year timeline)

**Context:** Immunisation coverage has plateaued since 2008. GPEI has experience which may help improve coverage when fully aligned behind immunisation services. For example, polio resources have contributed to efforts in parts of North India where polio has been eliminated while approaching international coverage

targets for routine vaccines. Application of this experience would need to be done relative to the sustainability and programmatic context of routine programs.

**Mitigation:** GAVI will work with countries through existing systems when aligning with GPEI behind nationally-prioritised strategies for improving coverage; GAVI and GPEI will to a large extent focus on the same countries, those eligible for GAVI's country-tailored approach and/or additional assistance through the Business Plan.

### **3.3.3. GPEI's polio resources are not sustainably deployed for immunisation services (Moderate Risk; 0-2 year timeline)**

**Context:** GPEI has indicated that at least 50% of the time of polio-funded field personnel will be devoted to specific activities to strengthen routine immunisation systems by end-2014, while the potential sustainability of these personnel and their contributions will be unclear until there is international agreement on GPEI's legacy plans.

**Mitigation:** Engage with countries and GPEI global and country staff to monitor this indicator; Monitor that the terms of reference of polio staff are informed by national routine immunisation staff and aligned behind routine immunisation needs; Ensure that legacy discussions consider sustainability of polio resources.

### **3.3.4. IPV implementation (speed, supply, messaging) (High Risk; 2-4 year timeline)**

**Context:** Regardless of GAVI's support for procuring IPV, the implementation of IPV in GAVI-eligible countries will impact implementation of other GAVI-supported activities and vaccines.

**Mitigation:** GAVI partners collaborate with GPEI in the early planning and development of policy guidelines, normative documents, training and communication materials, and other resources; Begin implementation planning and market shaping for programmatically suitable and financially feasible products immediately, if the Board decides to support IPV.

### **3.3.5. Resources targeted to polio limit funds available from domestic sources for routine immunisation and/or at the international level available for GAVI (High Risk; 0-2 year timeline)**

**Context:** GAVI and GPEI are both seeking funding during 2013-15 to support their missions through 2018 and beyond; Countries are being challenged to increase their investments in immunisation and other health care services.

**Mitigation:** GAVI and GPEI can coordinate messages and timing of outreach; GAVI can emphasise that routine immunisation services are essential to completing polio and yet full focus on immunisation and primary health care services will not be possible for several countries until polio is finished. GAVI can continue to reinforce the message that growing amounts of direct investment in routine immunisation services will be needed in the years to come.

**3.3.6. Negative perception of polio SIAs and/or violence towards polio vaccinators in some countries impacts perception of immunisation services and GAVI (High Risk; 0-2 year timeline)**

**Context:** Intensive campaigns, up to 6-8 times per year, have created hostility to polio activities in some areas; Polio vaccinators have been killed in Nigeria and Pakistan.

**Mitigation:** Communicating to parents and delivery of OPV integrated with other primary health care services can decrease parent hesitancy, targeting of health workers, and dilute immunisation-specific concerns.

**3.3.7. Polio resources are not sustainably transitioned to legacy period (Moderate Risk; 4-6 year timeline)**

**Context:** Some polio resources are playing, and are anticipated to increase, their roles in strengthening immunisation services such as in India; Good and bad lessons from over 20 years of eradication should not be lost

**Mitigation:** GAVI will engage in the process to seek a global consensus on transitioning polio's legacy; GAVI partners can support the development of case studies prior to the legacy decision and/or prior to 2018 to demonstrate how and where polio could positively contribute most to RI and other primary health care services.

## Annex 1. Examples of Support to GAVI and GPEI Focus Countries (May 2013)

| GAVI-GPEI overlapping focus countries <sup>1</sup> | GAVI Health System Strengthening amount (End of current; may start new grant) | Supplemental GAVI support (e.g. per 2013-14 Business Plan)    | Number of WHO GPEI field personnel <sup>2</sup> (Surge <sup>3</sup> ) | Number of UNICEF GPEI field personnel (Social Mobilisers) |
|--|---|---|---|---|
| <b>Afghanistan</b>                                 | \$18.2M (2014)  | Country tailored approach; Under 70% coverage                 | 155 (22)  | 18 (3,436)  |
| <b>Chad</b>  | \$5M (2014)   | Country tailored approach; Under 70% coverage; Improve equity | 36 (35)   | 27  |
| <b>DRC</b>   | \$56.8M (2013)  | Country tailored approach; Under 70% coverage                 | 95 (35)   | 18 (18,688)   |
| <b>Ethiopia</b>                                    | \$75.2M (2015)  | Under 70% coverage  | 73  | 1   |
| <b>India</b>                                       | \$106.9M (2015)   | Board guides customised relationship; Improve equity          | 1158  | 24 (8,177)  |
| <b>Nigeria</b>                                     | \$44.7M (2013)  | Country tailored approach; Under 70% coverage                 | 298 (2,207)   | 25 (2,127)  |
| <b>Pakistan</b>                                    | \$23.5M (2014)  | Country tailored approach; Improve equity                     | 265 (680)   | 49 (1,059)  |
| <b>Somalia</b>                                     | \$11.5M (2015)  | Country tailored approach; Under 70% coverage                 | 186   | 1   |
| <b>South Sudan</b>                                 | \$5.3M (2011)   | Country tailored approach; Under 70% coverage                 | 363   | 12  |

<sup>1</sup>For example countries where GAVI has supplemental support through the Business Plan and identified by GPEI as priorities due to polio risk

<sup>2</sup>'Regular' WHO staff working on polio

<sup>3</sup>Additional full-time polio field staff as part of "surge" begun end 2011

## **Annex 2: Results Framework**

### **GAVI's Complementary Role to GPEI in the Polio Eradication Effort**

#### **Purpose of this framework**

This framework articulates the theory of change and intended outcomes and impact from the GAVI Alliance (GAVI) working more closely with the Global Polio Eradication Initiative (GPEI). This framework is intended to be iterative and will be amended, added to and refined as this approach is rolled out and appropriately tailored to different countries.

The approach arose from a December 2012 GAVI Board decision which:

*Approved GAVI playing a complementary role to the GPEI in the polio eradication effort, specifically through routine immunisation within GAVI's strategy and mission using existing structures, processes, and procedures. Any change to GAVI's vaccine portfolio should be decided within the framework of the new vaccine investment strategy.*

*Approved GAVI exploring the suitability and possible use of IFFIm as one potential financing mechanism to support this activity within GAVI's strategy and mission using existing structures, processes, and procedures.*

For a more comprehensive explanation of the scope and approach overall, please refer to the main approach document *GAVI's approach to complementarity with the Global Polio Eradication Initiative*.

#### **Background**

The Global Polio Eradication Initiative (WHO, UNICEF, Bill and Melinda Gates Foundation, US Centers for Disease Control and Prevention (CDC), Rotary International), with extensive input from GAVI and other partners, is developing a polio "Endgame Strategy." It will be formally launched around the World Health Assembly in May 2013. The strategy covers 2013-2018 and is anticipated to cost approximately \$5.5 billion (plus approximately \$1.2 billion that India is anticipated to self-fund). One of the four strategic objectives is "Routine Immunisation Strengthening and OPV Withdrawal. The GAVI Board has approved playing a complementary role to GPEI. This role is articulated in a document detailing GAVI's approach.

#### **Objective related to polio:**

*Improve immunisation services in accordance with GAVI's mission and goals while supporting polio eradication by harnessing the complementary strengths of GAVI and GPEI in support of countries*

#### **Theory of Change**

- There has been significant progress to date, and challenges, in completing polio eradication
- It is agreed across the immunisation community that strengthening immunisation services is critical to polio eradication, and completing polio eradication is critical to immunisation services. There are implications of polio eradication that will affect

either positively or negatively routine immunisation services. If we do not have an established and agreed upon approach between GAVI and GPEI, there is a risk that opportunities may not be maximized and negative consequences and effects may not be minimised.

- Routine immunisation services can limit the number and spread of outbreaks and prevent vaccine-derived polio cases.
- Completing polio eradication will free up resources to focus on primary health care.
- Through collaboration between GAVI and GPEI we can jointly and sustainably support countries by harnessing the strengths of polio eradication and routine immunisation to more efficiently improve immunisation services. Complementary roles are anticipated to include:
  - Programmatic
    - There are a number of opportunities to maximise programmatic synergies. For example, at the global level GAVI will define its role as a partner within the governance, oversight and management structures of the GPEI; seek a convergence of strategies for Alliance partners to support countries; and determine its role in the consultation process related to the polio legacy.
    - At country level, GAVI and GPEI will support annual, harmonised, operational work plans of countries, the terms of reference of polio-supported staff will be modified to reflect support for routine immunisation, and such staff will be retrained accordingly. Immunisation services could benefit from the significant investments and systems that have already been set up for surveillance of polio and use these to strengthen surveillance and broader monitoring of other diseases.
  - IPV Supply and Implementation: GAVI will take a decision on support for IPV through the Vaccine Investment Strategy by November 2013; monitor policy developments and additional R&D data informing IPV assumptions; and share lessons on vaccine implementation from GAVI's experience.
  - Advocacy/Communication: Ensuring connection between polio eradication efforts and immunisation services will require a strong advocacy effort. At country level, it will include an emphasis on coordinating across polio, SIAs, new vaccine implementation, and other approaches within a harmonised national immunisation service.
  - Financing:
    - Resource mobilization efforts will be informed further by the Vaccine Investment Strategy where a decision on IPV support will be considered by November 2013.

- IFFIm could be well-placed as a funding mechanism to assist the polio eradication Endgame. An intensification of activities for eradication, and the increase in routine immunisation coverage that is required, are a classic case of the public health value of frontloading that IFFIm can provide.
- Sustainability and efficiency of immunisation services can be better ensured. Polio eradication has utilised approaches in some countries that have been supported and nurtured by intensive staff and financial support for management, planning, monitoring, demand, and surveillance and other activities. Where such approaches and staff resources are appropriate for and sustainably embedded in national systems, they could be applied to support long-term improvements in immunisation services as a whole.
- Through this mutual support to countries we can increase the number of fully-immunized children.
- Fully immunizing children prevents morbidity and mortality.

#### **Key assumptions underpinning the results framework**

- Complementarity approaches between routine immunisation services and polio are more efficient and/or effective for completing eradication than only relying on supplementary immunisation activities (SIAs; campaigns) alone.
- That there are strong synergies between GAVI and GPEI and that negative unintended consequences can be minimised through careful planning, explicit accountability with agreed indicators, and a concerted effort by the two entities
- Assuming programmatic and timeline assumptions in the Endgame Strategy are correct, the international community is at a crucial juncture, requiring polio eradication and other immunisation services to come together.
- Countries share the understanding that strengthening routine within immunisation services will be crucial to eradicating polio and to ensuring sustainable improvements in immunisation and primary health care services.
- GAVI's investments will lead to increases in coverage with routine vaccines in eligible countries, and particularly with oral polio vaccine and IPV (regardless of if GAVI supports procurement of IPV – Decision to be taken by Board by November 2013).
- GPEI and other partners will support non GAVI-eligible countries where necessary.
- Vaccine manufacturers supply sufficient IPV.
- GAVI and GPEI are successful in upcoming pledging rounds with financial donors.

#### **Monitoring and evaluation**

GAVI's approach will be monitored through existing partner and GAVI systems and indicators, such as through the WHO-UNICEF Joint Report Form and reporting on GAVI's

WORKING DRAFT

Performance-Based Funding. Opportunities to build upon existing systems in country and at the global level will be fully explored.

## Results Framework for GAVI's Complementary Role to GPEI in the Polio Eradication Effort

