



Report to the GAVI Alliance Board

21-22 November 2013

Subject:	Polio & routine immunisation
Report of:	Hind Khatib-Othman, Managing Director, Country Programmes Nina Schwalbe, Managing Director, Policy and Performance Barry Greene, Managing Director, Finance and Operations
Authored by:	Alan Brooks, Special Adviser for Immunisation, Country Programmes; Aurelia Nguyen, Director, Policy and Market Shaping; Stefano Malvolti, Director, Vaccine Implementation
Agenda item:	13
Category:	For Decision
Strategic goal:	Affects all strategic goals

Section A: Overview

1 Purpose of the report

- 1.1 The Programme and Policy Committee (PPC) considered the attached paper on polio and routine immunisation at its meeting of 9-10 October 2013.

2 Executive Summary – Update

- 2.1 This report provides an update on questions raised by the PPC and on financial estimates. It seeks a decision from the Board related to GAVI's complementary role in strengthening routine immunisation and supporting introduction of inactivated polio vaccine (IPV) as part of the polio eradication effort and in the implementation of the Global Polio Eradication Initiative's (GPEI's) Polio Eradication and Endgame Strategic Plan (2013-2018). The PPC has proposed recommendations, exempting IPV from a number of GAVI's established policies, due to the exceptional context of polio and the global public good nature of eradication.
- 2.2 Since the PPC meeting, the GAVI Alliance Secretariat and GPEI have continued to refine budget estimates (see section 4). Refinements have focused on 1) estimates of vaccine and introduction grant costs; 2) estimates of country readiness costs; and 3) business plan-related costs.

3 Recommendations

- 3.1 The PPC and, where appropriate, the AFC and the EC recommended to the GAVI Alliance Board that it:

- (a) **Endorse**, recognising the Global Polio Eradication Initiative's (GPEI) responsibility for eradicating polio, GAVI's overall objective related to polio eradication 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.
- (b) **Open** a funding window for IPV such that the GAVI Secretariat can invite GAVI eligible and graduating countries (the "GAVI IPV Eligible Countries"), in line with the GPEI Endgame Strategy 2013-2018, to submit country proposals for support in accordance with the following policy arrangements and exceptions:
 - i. Accept IPV applications until June 2015 with introduction targeted by the end of 2015. However, should the need arise, following review by GAVI's CEO and in consultation with GPEI, the funding window could remain open for a longer period;
 - ii. Subject to polio-specific additional funding being available beyond 2018, provide support for GAVI IPV Eligible Countries until the Endgame target for stopping vaccination of approximately 2024 or an appropriate exit strategy for GAVI has been identified prior to 2024;
 - iii. Approve an exception to the programme filter requirement set out in the GAVI Alliance Country Eligibility Policy so that countries with DTP3 coverage less than 70% are eligible to apply for the IPV vaccine;
 - iv. While encouraging countries to co-finance IPV, exempt IPV co-financing requirements for GAVI IPV Eligible Countries;
 - v. Approve an exception to the GAVI Alliance Co-Financing Policy so that GAVI IPV Eligible Countries can be approved for IPV vaccine even if they are in default on co-financing requirements of other vaccines;
 - vi. Decide that GAVI Graduating Countries approved for IPV routine introduction with GAVI support are eligible for a vaccine introduction grant per the terms stipulated in the GAVI Alliance Vaccine Introduction Grant and Operational Support for Campaigns Policy;

- vii. Exclude IPV vaccine from the existing prioritisation mechanism given that the funding for IPV will be additional and earmarked. However, in the event that the additional, earmarked funding for IPV is anticipated to be insufficient to cover all GAVI IPV Eligible Countries approved for IPV support, GAVI will use polio funding to: 1) continue support for routine use where already introduced, if relevant, and 2) rely on guidance from GPEI to prioritise countries which have not yet introduced IPV, as well as countries that have not yet applied;
 - viii. All policy exceptions mentioned above will be reviewed by the Board in 2018.
- (c) **Approve** using a funding envelope mechanism consistent with the principles of the GAVI Alliance Programme Funding Policy to fund approved IPV applications with the exception that any application from India related to IPV will be considered by the Board.
- (d) **Approve**, subject to polio-specific additional funds being made available from donors, an initial IPV Funding Envelope from which the Secretariat shall allot funding to IPV programmes until 31 December 2014, to:
- i. Endorse or adjust previously endorsed amounts of programme multi-year budgets for IPV programmes for an aggregate amount not exceeding US\$ 182 million. (These endorsements would constitute acknowledgement of such budget amounts at the time of allotment but would not constitute a funding approval, decision, obligation or commitment of the GAVI Alliance or its contributors.)
 - ii. Establish or adjust near-term liabilities of the GAVI Alliance in respect of endorsed IPV programme budgets for periods ending no later than 31 December 2015 for an aggregate amount not exceeding US\$ 98 million. (These amounts are a subcomponent of endorsed programme budgets.)
- (e) **Approve** an amount up to US\$ 12.1 million for polio-related Secretariat and partner costs to be added to the 2014 Business Plan, subject to polio-specific additional funds being made available from donors.
- 3.2 As explained in Section 4 of this report, the revised vaccine and introduction grant cost projections have led to a re-calculation of the amount needed for the 2014 IPV Programme Funding Envelope. The Secretariat consulted with the Chairs of the AFC and PPC. Given that the IPV Funding Envelope would be subject to sufficient IPV-specific funding being made available by donors, they indicated that the Board can approve the updated amounts for the 2014 IPV Programme Funding Envelope. Accordingly, it is recommended that the Board consider the wording below to replace section (d) of the PPC recommendation presented in paragraph 3.1:

- (d) **Approve**, subject to polio-specific additional funds being made available from donors, an initial IPV Funding Envelope from which the Secretariat shall allot funding to IPV programmes until 31 December 2014, to:
- i. Endorse or adjust previously endorsed amounts of programme multi-year budgets for IPV programmes for an aggregate amount not exceeding US\$ 231 million. (These endorsements would constitute acknowledgement of such budget amounts at the time of allotment but would not constitute a funding approval, decision, obligation or commitment of the GAVI Alliance or its contributors.)
 - ii. Establish or adjust near-term liabilities of the GAVI Alliance in respect of endorsed IPV programme budgets for periods ending no later than 31 December 2015 for an aggregate amount not exceeding US\$ 121 million. (These amounts are a subcomponent of endorsed programme budgets.)

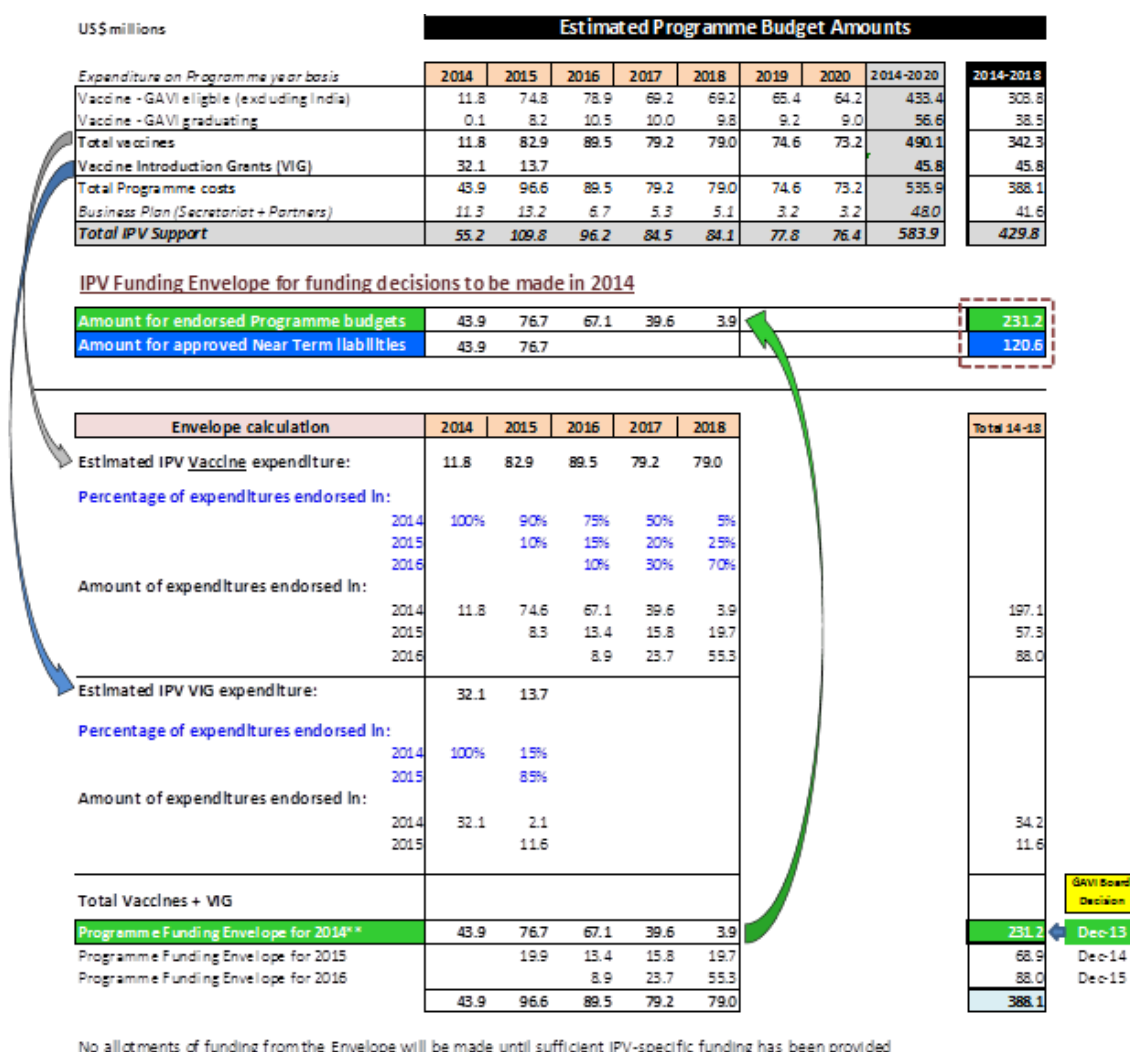
4 Risk and Financial Implications – Update

- 4.1 There have been 322 polio cases in 2013 through 30 October versus 177 through the same period in 2012. The number of cases, including recent outbreaks such as in the Horn of Africa, reflects a significant risk, noted by the PPC, of wild polio cases continuing longer than the Endgame premise of transmission being stopped by the end 2014.
- (a) On-going transmission would not alter planning in terms of the introduction of inactivated polio vaccine (IPV) into routine immunisation of all countries currently using oral polio vaccine (OPV).
 - (b) The introduction of IPV is part of the Endgame's strategy to mitigate the risk of future outbreaks and it will allow for the phasing out of type 2 virus from Oral Polio Vaccine (OPV). Wild type 2 virus was last identified in 1999 while the attenuated virus in OPV is the source of most circulating vaccine-derived poliovirus, causing 68 polio cases in 2012 and 43 to date in 2013.
- 4.2 The PPC also noted the risk of poor coordination with countries, and by partners within countries, in particular regarding the linkages between efforts to strengthen routine immunisation and eradicate polio and planning for IPV introduction. GAVI's dialogue with countries to date has mirrored guidance and decisions from GAVI's governance bodies.
- (a) WHO has started to communicate with different regions regarding the state of country plans for IPV introduction. A series of tailored documents and FAQs have been shared.
 - (b) A letter was sent in October by GAVI to countries providing information on pending decisions related to support for IPV, and asking about the status of and encouraging planning by national authorities and partners. The Secretariat intends to summarise the responses from countries in its presentation to the Board.

- (c) In November 2013, subject to the GAVI Board approving the PPC recommendations, GAVI, WHO and UNICEF are anticipating sending a joint letter to reinforce the linkages between routine immunisation and polio, and inform countries the window for IPV applications is open.
 - (d) Proposed policy exemptions and tailored GAVI processes are intended to allow country implementation of IPV according to the timelines of the Endgame. The Endgame calls for 124 countries, including all GAVI countries, to introduce IPV by the end of 2015, then remove type 2 OPV from the second quarter of 2016 onward. However there remains insufficient information from countries to predict if all GAVI countries will strive to meet the unprecedented timelines for IPV introduction.
- 4.3 GPEI has recently updated all of its cost estimates for GAVI and non-GAVI countries under Endgame Objective 2. Its budget range encompasses GAVI's budget estimate while considering wider ranges of price forecasts and scenarios with more rapid vaccine introduction. GPEI is evaluating how GAVI's costs could be covered from the original Endgame budget and flexible funds available within it. GAVI's financial commitment to polio, regardless of the range, is subject to donor confirmation of resources.
- 4.4 The total budget from 2014-2018 for GAVI's complementary role in polio, excluding vaccine support to India, has increased from the estimate provided to the PPC of \$343M to \$430M. The following paragraphs describe the changes.
- 4.5 Several assumptions impacting vaccine and introduction grant costs have been further analysed leading to changes from the PPC estimate of \$306M (2014-2018) to a revised estimate of \$389M. The estimate is a product of the forecasted number of doses demanded and price assumptions.
- 4.6 The increase in cost above was due to additional dose demand based primarily on the timing of availability of different vaccine presentations and assumed wastage rates for the presentations (e.g. an increase from 10% to 30% for the 5-dose vials). Other potential sources of variability to the dose forecast are the pace of country introduction (estimated reduction of doses demanded by up to 30%) and variability between country and standardised published data on populations and vaccine coverage (estimated increase of up to 25%). Each of these drivers of variance have been analysed independently.
- 4.7 GAVI's price per dose assumptions are unchanged from the PPC. The final vaccine price if impacted by PAHO's Lowest Price Clause could results in cost increases of up to approximately 30%.
- 4.8 It should be noted that all estimates in the preceding paragraphs are still preliminary and subject to change based on the outcomes of the

procurement process in early 2014, recommendations by the WHO Strategic Advisory Group of Experts (SAGE), and country demand.

- 4.9 The revised vaccine and introduction grant cost projections have led to a re-calculation of the amount requested for the 2014 IPV Programme Funding Envelope. The endorsed programme budgets would increase from \$182M presented to the AFC and PPC to \$231M. The near term liabilities would increase from \$98M to \$121M. The updated calculations are presented in Figure 1. These funds are contingent on additional polio resources being available from donors.



- 4.10 Country readiness is being evaluated on a country by country basis in order to further understand the introduction requirements and associated costs. The great majority of costs related to country readiness work will be covered under the business plan technical assistance activities as well as through GAVI's established policy for the vaccine introduction grant of \$0.80 per child in the birth cohort. Current analysis suggests that cold chain may be an obstacle to IPV introduction, given other new vaccine introductions planned, not specifically due to IPV given that its cold chain

implications *per se* are minimal. Should country needs not be addressed by GAVI's Health System Strengthening Support (HSS) in time for vaccine introduction by end 2015, additional means may need to be established by the Alliance. Alliance partners will continue to work closely to assess cold chain needs for the full range of forecasted vaccine introductions.

4.11 Costs of the Immunisation Systems Management Group (IMG) for coordinating and providing support to GAVI countries will be provided through the Business Plan.

(a) For the PPC, it was estimated that the 2014 Business Plan cost would be up to \$12.1M and 2015 cost would be up to \$15M. In 2015, the peak year, 31.7 staff positions were estimated as necessary to implement the incremental work related to the polio through WHO, UNICEF, the GAVI Secretariat and the US Centers for Disease Control and Prevention (CDC).

(b) Further analysis since the PPC has led to a refined estimate of Business Plan costs. The partner budget has now been projected for the entire period of 2014 – 2018. The total Business Plan budget for 2014 – 2018 is estimated to be \$41.6M, while the 2014 budget has decreased to \$11.3M, which remains consistent with the PPC and AFC decision recommending support of up to \$12.1M, and 2015 budget decreased to \$13.2M as summarised in Table 1 and detailed in Annex 1.

(a) Of the total IMG costs shared between GAVI and non-GAVI countries, the percentage allocated to GAVI decreased from 72% to an average of approximately 67% due to the changes in the total IMG budgets.

(b) Since the PPC, the total Business Plan supported staff required in the peak year of activities (2015) has decreased to 20.7 positions. The changes reflect 7.6 staff at CDC which have been removed entirely from GAVI's business plan budget, and removing 2.9 WHO and 0.5 UNICEF staff which are partially offset by additional consultant funds at WHO and UNICEF. The additional consultant funds may be used to engage other research and technical health institutes, and will, for example, leverage funds for retraining polio staff to work on RI strengthening. Elements of the budget were increased due to the inclusion of staff and consultant fees for WHO and UNICEF in 2016, such as to support completion of IPV scale up, and in 2017 – 2018, although at a lower level than previous years. GAVI Secretariat staff projections are unchanged. Updated staffing projections are presented in Table 2.

Table 1. Estimated costs for GAVI countries, Endgame scenario (2014 - 2024) (Updated)

US\$ millions (Rounded)	2014	2015	2016	2017	2018	Endgame 2014- 2018	GAVI Strategic Plan 2016- 2020	Project Total 2014- 2024
Vaccine Costs								
GAVI eligible (excluding India)	\$12	\$75	\$79	\$69	\$69	\$304	\$347	\$691
GAVI graduating	-	\$8	\$11	\$10	\$10	\$39	\$48	\$92
Introduction grant (excluding India)	\$32	\$14	-	-	-	\$46	-	\$46
SUBTOTAL	\$44	\$97	\$89	\$79	\$79	\$389	\$395	\$829
Partner and secretariat costs	\$11	\$13	\$7	\$5	\$5	\$42	\$24	\$62
TOTAL	\$55	\$110	\$97	\$85	\$84	\$431	\$419	\$891
India (Vaccine costs only)	\$0	\$19	\$35	\$34	\$34	\$122	\$165	\$305

Table 2. Staff FTEs by Strategic Goal (in peak year, 2015) (Updated)

	WHO	UNICEF	Secretariat	Total
Strategic Goal 1 (IPV)	3.7	5.4	3.15	12.25
Strategic Goal 2 (RI strengthening)	--	--	3.75	3.75
Strategic Goal 3 (Sustainability)	--	--	--	--
Strategic Goal 4 (Market shaping; Regulatory)	1.3	--	1	2.3
Cross Cutting: Advocacy, Communication and Public Policy	0.3	--	1	1.3
Cross Cutting: Monitoring and Evaluation	--	--	1	1
Total FTEs	5.4	5.4	9.9	20.7



Report to the Programme and Policy Committee

9-10 October 2013

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Agenda item:	11
Category:	For Decision
Strategic goal:	Affects all strategic goals

Section A: Overview

1 Purpose of the report

- 1.1 This report provides an update on GAVI's work to respond to the June 2013 Board decision on polio. It summarises activities to advance the partnership and complementarity between GAVI and the Global Polio Eradication Initiative (GPEI) in order to strengthen routine immunisation (RI) services and contribute to completing polio eradication.
- 1.2 This report provides the analyses requested by the Board in order to take a further decision regarding GAVI's lead role in the introduction of inactivated polio vaccine (IPV) into routine immunisation services of 73 GAVI countries as part of the Polio Eradication Endgame Strategy and Plan in collaboration with GPEI.
- 1.3 If the decision is to support GAVI's role in polio and IPV specifically, contingent on funding beyond that currently available to GAVI, the Secretariat seeks approval of a budget for 2014 to support polio-related activities by partners and the Secretariat. It also sets out consideration for the establishment of a Board-approved IPV-specific funding envelope (IPV Funding Envelope) to ensure rapid disbursement of IPV support following recommendation of a country application for an IPV programme by an Independent Review Committee (IRC), and asks the Board to approve an initial funding allocation to the envelope.

2 Recommendations

2.1 The PPC is requested to

Recommend to the GAVI Alliance Board that it

- (a) Endorse GAVI's overall objective related to polio eradication to improve immunisation services in accordance with GAVI's mission and goals while supporting polio eradication by harnessing the complementary strengths of GAVI and the Global Polio Eradication Initiative (**GPEI**) in support of countries.
- (b) Open a funding window for IPV such that the GAVI Secretariat can invite GAVI eligible and graduating countries (the "**GAVI IPV Eligible Countries**") to submit country proposals for support in accordance with the following policy arrangements and exceptions:
 - i. Accept IPV applications until June 2015 with introduction targeted within one year of date of application approval. However, should the need arise, following review by GAVI's CEO and in consultation with GPEI, the funding window could remain open for a longer period;
 - ii. **OPTION 1:** Provide full support for GAVI IPV Eligible Countries until the Endgame target for stopping vaccination of approximately 2024 or an appropriate exit strategy for GAVI has been identified prior to 2024 (e.g. product affordable to countries); **OR**
OPTION 2: Provide full support for GAVI eligible countries until the Endgame target for stopping vaccination of approximately 2024 or an appropriate exit strategy for GAVI has been identified prior to 2024, and provide full support for GAVI graduating countries through 2020. GAVI to revisit by 2018 whether to continue to support IPV in graduating countries past 2020;
 - iii. Approve an exception to the programme filter requirement set out in the GAVI Alliance Country Eligibility Policy so that countries with DTP3 coverage less than 70% are eligible to apply for the IPV vaccine;
 - iv. **OPTION 1:** Exempt IPV co-financing requirements for GAVI IPV Eligible Countries until 2024; **OR**
OPTION 2: Exempt IPV co-financing requirements for GAVI eligible countries until 2024 and for GAVI graduating countries until 2020 and reassess by 2018, with the option of requiring graduating countries to scale up to full financing over the subsequent four years;

- v. Approve an exception to the GAVI Alliance Co-financing Policy so that GAVI IPV Eligible Countries can be approved for IPV vaccine even if they are in default on co-financing requirements of other vaccines;
 - vi. Decide that GAVI Graduating Countries approved for IPV routine introduction with GAVI support are eligible for a vaccine introduction grant per the terms stipulated in the GAVI Alliance Vaccine Introduction Grant and Operational Support for Campaigns Policy;
 - vii. Exclude IPV vaccine from the existing prioritisation mechanism given that the funding for IPV will be additional and earmarked. However, in the event that the additional, earmarked funding for IPV is anticipated to be insufficient to cover all GAVI IPV Eligible Countries approved for IPV support, GAVI will use polio funding to: 1) continue support for routine use where already introduced, if relevant, and 2) rely on guidance from GPEI to prioritise countries which have not yet introduced IPV, as well as countries that have not yet applied;
- (c) Approve, subject to endorsement by the Audit and Finance Committee, using a funding envelope mechanism consistent with the principles of the GAVI Alliance Programme Funding Policy to fund approved IPV applications with the exception that any application from India related to IPV will be considered by the Board;
- (d) Approve, subject to endorsement by the Audit and Finance Committee and to polio-specific additional funds being made available from donors, an initial IPV Funding Envelope from which the Secretariat shall allot funding to IPV programmes until 31 December 2014, to:
- i. Endorse or adjust previously endorsed amounts of programme multi-year budgets for IPV programmes for an aggregate amount not exceeding US\$ 182 million. (These endorsements would constitute acknowledgement of such budget amounts at the time of allotment but would not constitute a funding approval, decision, obligation or commitment of the GAVI Alliance or its contributors.)
 - ii. Establish or adjust near-term liabilities of the GAVI Alliance in respect of endorsed IPV programme budgets for periods ending no later than 31 December 2015 for an aggregate amount not exceeding US\$ 57 million. (These amounts are a sub-component of endorsed programme budgets.)

2.2 The PPC is also requested to

Recommend, subject to endorsement by the Audit and Finance Committee, to the Executive Committee that it, in turn, recommend to the Board to approve an amount up to US\$ 12.1 million for polio-related Secretariat and partner costs to be added to the 2014 Business Plan, subject to polio-specific additional funds being made available from donors.

3 Executive summary

3.1 As part of the Polio Eradication Endgame Strategic Plan 2013-2018, GPEI has committed to strengthening immunisation programmes and introducing IPV into routine immunisation as part of efforts to eradicate polio.

3.2 In light of the potential for synergies, the GAVI Alliance Board in December 2012 and further in June 2013 recognised the importance of a strong partnership and complementarity between the GAVI Alliance and GPEI's efforts eradicating polio. The GAVI Alliance Board provided further guidance in June 2013, when it supported the Alliance playing a lead role in the introduction of inactivated polio vaccine (IPV) in routine immunisation (RI) services in 73 GAVI countries as part of the Endgame.

3.3 The Secretariat and partners have been working intensively with GPEI to define mechanisms of coordination, develop joint workplans where appropriate, and begin discussing IPV with countries. The GAVI Secretariat has updated the draft of GAVI's long term approach to polio provided to the Board in June 2013, including further details of how GAVI will support the introduction of IPV in eligible countries, pending Board decision (document available on myGAVI). GAVI's funding requirements for polio through 2018, including IPV procurement and excluding India, are estimated to be \$343M, all of which is part of the Endgame financial projections against which pledges were received at the April 2013 Global Vaccine Summit. Secretariat and partner costs are estimated to be US\$ 12.1 million in 2014.

3.4 Attached to this report and informing its recommendations are:

(a) Annex A - An analysis of the proposed policy exceptions including eligibility and graduation, co-financing and the prioritisation mechanism; and

(b) Annex B - Detailed cost projections (2014-2024).

3.5 Additional documents available on myGAVI which respond to June 2013 Board decisions related to polio are:

(a) GAVI's supply and procurement objectives ("roadmap") related to IPV; and

- (b) A draft analysis of the risks and opportunities for GAVI's other vaccine programmes from supporting IPV.

Funding envelope

- 3.6 In order for GAVI's processes to be able to accommodate the rapid decision-making on IPV support necessary for the Endgame, the Secretariat suggests the Board establish an "IPV Funding Envelope" from which funds would be allotted by the Secretariat in the upcoming year or other period as the Board or EC may specify for new IPV programmes. The Secretariat acting within that Board-approved funding envelope, would during this period allot funding to individual programmes based on the recommendations of the Independent Review Committee. This means that – unlike for other applications for new vaccine support – the Secretariat rather than the AFC and EC would be responsible for approving and allotting funding to individual applications for the introduction of IPV.
- 3.7 The Secretariat, under principles covered in GAVI's "Programme Funding Policy", would allot funding to programmes until 31 December 2014. The initial funding envelope would be for an amount sufficient to cover endorsed programme budgets for the duration of multi-year plans of individual countries for the period 2014-2018.
- 3.8 The IPV funding envelope would be managed independently of GAVI's existing Funding Envelope¹. Any allotment from the IPV Funding Envelope would be subject to sufficient IPV-specific funding being available in accordance with the principles of the Programme Funding Policy.
- 3.9 The IPV funding envelope would be managed independently of GAVI's traditional Programme Funding Envelope for New and Underused Vaccines Support (NVS) and Cash Programmes. No allotment from the IPV envelope would be made without the appropriate incremental funding being secured from donors to cover these new investments.

4 Risk implication and mitigation

- 4.1 The major risks to GAVI of its complementary role on polio and associated mitigation strategies are summarised below, in the respective annexes, and in the documents on myGAVI. Annex A summarises risks related to proposed policy exceptions. The document describing GAVI's approach to polio on myGAVI addresses broad risks and mitigation strategies (e.g. negative perceptions of polio, unclear country demand for IPV, and implications for GAVI's systems.) A second document on myGAVI addresses the risks and mitigation strategies for GAVI's other vaccine programmes.
- 4.2 Ongoing polio outbreaks, such as in the Horn of Africa, limit the ability of countries to focus on RI but are not thought to present a direct risk to or

¹ The Funding Envelope for the continuation and adjustment of funding for existing programmes, and for new cash programmes.

undermine the importance of supporting IPV introduction. IPV is critical to securing the eradication of type 2 polio virus (last case in 1999) and potentially type 3 (last case November 2012). IPV also allows countries to shift to bivalent or monovalent oral polio vaccine (bOPV or mOPV) which are more immunogenic and therefore may speed eradication of type 1 virus.

4.3 There are a number of financial risks.

- (a) As a tender has not been completed, vaccine prices and product characteristics (e.g. number of doses per vial which impacts prices and wastage) are not yet confirmed. Mitigating this risk are advance discussions by GAVI partners and the Secretariat with manufacturers to establish realistic price estimates and signal characteristics which will support efficient implementation of IPV through RI. Early discussions with the government of India suggest it will pay for its own IPV-related costs (e.g. through savings from fewer polio campaigns). Ongoing discussions with the government will mitigate this risk as well as clearly identifying the potential financial implications of IPV for India and the GAVI Board.
- (b) There is a risk of insufficient funds to support GAVI's complementary role on polio. Mitigating this is the June 2013 Board requirement that funds for polio must be incremental to GAVI's current resources and therefore available prior to expenditures, polio-related costs will be separately accounted, and cost estimates in this report are within the Endgame budget of US\$ 5.5 billion against which pledges were made at the 2013 Global Vaccine Summit.
- (c) There is a risk that IPV introduction will not be completed by end of 2015 but continue into at least 2016. Mitigating this is that if introduction is slower, some partner costs will be lower partially offsetting financial requirements in 2016. Secretariat costs are already budgeted to assume that activities could remain more intense through 2016.

5 Financial implications: Business plan and budgets

- 5.1 Resources for costs related to GAVI's work on polio (e.g. vaccines, introduction grants, and business plan) are additional to those currently available to GAVI. Cost estimates will be provided to the Audit and Finance Committee (AFC) and the Executive Committee, as appropriate, prior to presentation to the Board.
- 5.2 Funds for vaccine and introduction grants for GAVI countries will follow GAVI's usual mechanisms. All funds for GAVI will flow directly from donors to GAVI, and be reported on directly by GAVI to donors. The funds will be incremental to GAVI's current resources and will be counted as part of donor contributions to the Polio Endgame (i.e. counted as part of the US\$ 4 billion pledged at the April 2013 Global Vaccine Summit.)

- 5.3 GAVI and GPEI have agreed that support for technical assistance by partners, Secretariat costs and routine immunisation strengthening (aside from polio staff salaries) related to GAVI countries will flow through GAVI Business Plan (BP) systems. Costs have been structured in the same framework as the business plan. Existing BP resources will be leveraged but are insufficient to address the unique challenges and short timeframes associated with polio. For example BP investments supporting country decision-making on vaccines, vaccine introduction, and immunisation coverage improvement planning will be leveraged through GAVI's work on polio. There will be a similar performance framework as for other BP activities and polio-related activities are being integrated into existing management structures where appropriate.
- 5.4 The Immunisation Systems Management Group (IMG) was established by the GPEI and is accountable for coordinating polio-related activities in support of RI and global IPV introduction. It includes core GPEI partners (WHO, UNICEF, Bill and Melinda Gates Foundation (BMGF), the US Centers for Disease Control and Prevention (CDC), and Rotary International). The GAVI Secretariat was invited to join the IMG. The IMG with the GAVI Secretariat have estimated staffing requirements and costs for the Endgame activities related to IPV and support for strengthening routine immunisation activities by polio staff in focus countries (e.g. incremental costs for re-training; salaries of polio staff in the field are already reflected in the GPEI budget). Costs and staffing needs are highest in 2014 and 2015, then should drop substantially from 2016 or 2017 onwards when IPV is fully introduced.
- 5.5 Initial cost projections are presented in Table 1. The costs represent approximately a 4% increase in GAVI's projected budgets through 2018 for each of vaccines, introduction grants (cash support), and Business Plan expenses. Estimated costs from 2014 and 2015 are approximately US\$ 53 million and US\$ 90 million. For the period 2014-2018, costs are estimated at US\$ 343 million. Vaccine support for India would increase the cost by approximately US\$ 26 million/year. The partner costs from 2016 onwards, after IPV introduction, are thought to be substantially lower than in 2014-2015 but have not yet been fully estimated.

Table 1. Estimated costs for GAVI countries (2014 - 2024)

US\$ millions	2014	2015	2016	2017	2018	Project Total 2014-2024	Endgame 2014-2018	GAVI Strat Plan 2016-2020
Vaccine Costs								
GAVI eligible (excluding India)	\$9	\$56	\$59	\$54	\$54	\$535	\$230	\$270
GAVI graduating	-	\$6	\$8	\$8	\$8	\$72	\$29	\$38
Introduction grant (excluding India)	\$32	\$14	-	-	-	\$46	\$46	-
Partner and secretariat costs	\$ 12	\$ 15	\$ 4	\$ 3	\$ 3	\$56	\$37	\$17
TOTAL	\$53	\$90	\$70	\$65	\$65	\$708	\$343	\$325
India (Vaccine costs only)	\$0	\$16	\$28	\$27	\$26	\$240	\$96	\$131

- 5.6 Additional cost projections and ranges are provided in Annex B. Major financial risks are presented in section 4.3.
- 5.7 Table 2 summarises the full time equivalent (FTE) staff requirements for partners and the Secretariat in the peak year (2015). Partners propose hiring staff on temporary or limited contracts ending in 2015.
- 5.8 The Secretariat anticipates a more gradual scaling down of activities through 2016 in case all countries do not apply as rapidly as called for in the Endgame. Of the Secretariat staff, approximately half would work on Strategic Goal 1 (SG1) related to IPV introduction, SG4 related to IPV market shaping, or one of the cross-cutting functions central to IPV introduction (e.g. country application process.) Approximately half of the FTEs, those categorised under SG 2, would support grant management, facilitate engagement, and reinforce GAVI and GPEI efforts to strengthen RI in countries identified by both as needing greater focus². For example, instead of one Country Responsible Officer (CRO) being accountable for GAVI's support to Afghanistan, Pakistan, Somalia, Sudan, South Sudan, and Yemen, additional FTEs would allow such responsibilities to be split. The Secretariat could further strengthen its stewardship as individual CRO's would be accountable for GAVI's support in fewer countries, strengthening engagement in countries identified by GAVI and GPEI. Parts of two staff

² Afghanistan, Chad, DR Congo, Ethiopia, India, Nigeria, Pakistan, Somalia, South Sudan, and Angola, a graduating country

(0.9 FTE) would be allocated for overall management of the GAVI-GPEI relationship and financial tracking of the polio-related finances.

- 5.9 Partners currently anticipate that additional IPV staffing would be needed through 2015 due to lessening support for IPV-related decision-making and introduction, and because they are already engaged in polio with significant staffing dedicated to the effort. The Secretariat anticipates a continued need after 2016 for approximately eight staff relating to managing the GAVI-GPEI relationship, and maintaining higher levels of grant monitoring and stewardship in countries identified by both organisations as needing additional focus.

Table 2. Staff FTEs by Strategic Goal (in peak year, 2015)

	WHO	UNICEF	CDC	Secretariat	Total
Strategic Goal 1 (IPV)	4.3	5.9	3.2	3.15	16.55
Strategic Goal 2 (RI strengthening)	--	--	4	3.75	7.75
Strategic Goal 3 (Sustainability)	--	--	--	--	--
Strategic Goal 4 (Market shaping)	2.9	--	--	1	3.9
Cross Cutting: Advocacy, Communication and Public Policy	1.1	--	.4	1	2.5
Cross Cutting: Monitoring and Evaluation	--	--	--	1	1
Total FTEs	8.3	5.9	7.6	9.9	31.7

Section B: Content

6 Background

- 6.1 In May 2013, the World Health Assembly (WHA) and countries endorsed the Endgame Strategic Plan (Endgame), established in response to WHA Resolution 65.5 that requested the Director-General to develop a comprehensive strategy to complete polio eradication. The Endgame's second of four objectives is to strengthen routine immunisation services, introduce IPV, and begin a phased withdrawal of oral polio vaccines (OPV).
- 6.2 The GAVI Alliance Board in December 2012 and further in June 2013 recognised the importance of a strong partnership and complementarity between the GAVI Alliance and GPEI in eradicating polio based on

mutually agreed understanding of roles, responsibilities, and results in countries. The GAVI Alliance Board provided further guidance in June 2013, when it supported the Alliance playing a lead role in the introduction of inactivated polio vaccine (IPV) in routine immunisation (RI) services in 73 GAVI countries as part of the Polio Endgame Strategic Plan.

- 6.3 The Secretariat and partners have been working intensively with GPEI to define mechanisms of coordination, develop joint workplans where appropriate, and begin discussing IPV with countries. The GAVI Secretariat has updated the working draft of its long term approach to polio provided to the Board in June 2013, including further details of how GAVI will support the introduction of IPV in eligible and graduating countries, pending Board decision.
- 6.4 Per the Endgame, GPEI is dedicating greater than 50% of the time of polio funded field personnel to immunisation services strengthening tasks. This commitment from GPEI could be an opportunity for countries and GAVI. Polio staff are particularly concentrated in complex countries where GAVI shares a focus with GPEI³. GPEI is committed to supporting improvements in routine immunisation coverage in high risk districts of focus countries. It will require intensive engagement in countries between the government, GAVI and GPEI to maximise the impact and strengthen the integration of these commitments within routine services.
- 6.5 The Endgame Plan also includes introducing at least one dose of IPV into the routine schedules of 124 countries which currently use OPV by 2015 (including all but one GAVI eligible or graduating country⁴). Per the Endgame, the introduction of IPV is primarily to mitigate against risks of outbreaks as countries begin to withdraw OPV, switching from trivalent OPV (tOPV) to bOPV in order to remove the type 2 component of the vaccine. The switch to bOPV is anticipated to occur in Q2 2016. Worldwide bOPV cessation is envisaged for 2019.
- 6.6 GPEI has prioritised countries into four tiers for IPV introduction, with Tier 1 containing the highest priority countries, including the three endemic countries (See Annex A). All Tier 1 countries except China are GAVI eligible or graduating countries. Most Tier 2 countries are also GAVI eligible or graduating countries. Notably, there is only one non-GAVI lower middle income country in Tier 2 (the Philippines). GAVI countries are also found in Tiers 3 and 4. The concentration of GAVI eligible and graduating countries in Tiers 1 and 2 affirms the importance of GAVI support and policies which are consistent with rapid IPV introduction.

Collaboration, role definition, and accountability between GAVI and GPEI

- 6.7 GAVI and GPEI have developed a joint workplan for supporting countries; clarified anticipated roles, responsibilities, and accountabilities; assisted

³ Afghanistan, Chad, DR Congo, Ethiopia, India, Nigeria, Pakistan, Somalia, South Sudan, and Angola, a graduating country.

⁴ Ukraine has already introduced IPV.

donors to further define funding processes and flows; and begun to support countries to both strengthen polio eradication efforts and routine immunisation services. There remain a number of areas where work to fully define and align plans continues, including evolving assumptions about likely speed of introduction. The primary means of GAVI-GPEI coordination on operational areas is the Immunisation Systems Management Group. GAVI and GPEI have aligned our support for key issues in GAVI and non-GAVI countries. Activities are *joint* (both organisations work through a single process); *coordinated* (activities are implemented separately, but with regular discussion and close collaboration); or *separate* as indicated in Table 3.

Table 3. Proposed roles, responsibilities and accountabilities for IPV support

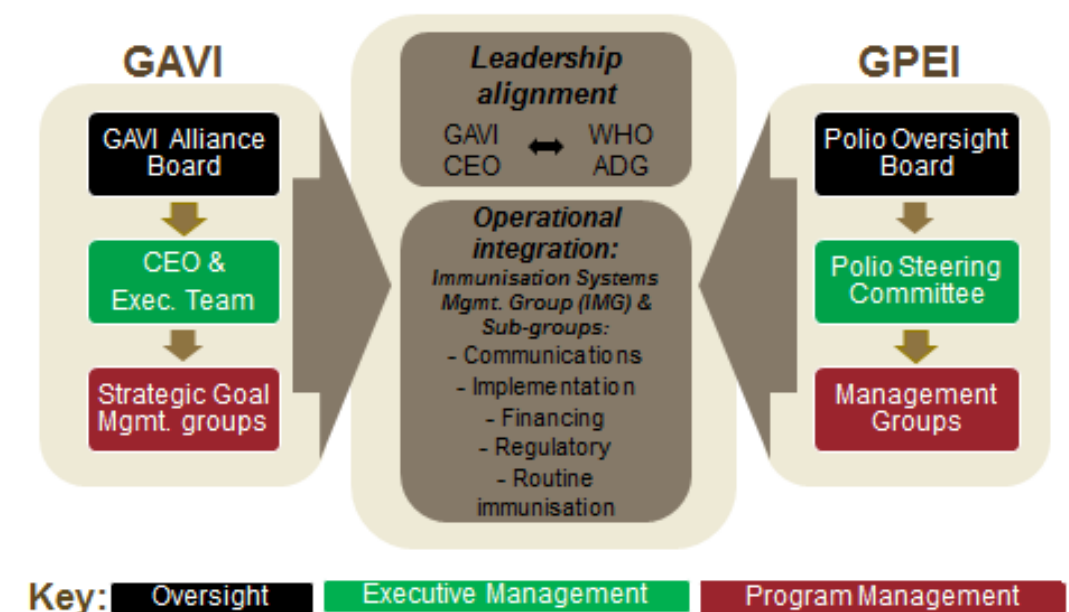
Topic	GAVI Countries	Non-GAVI Countries
Demand forecasts	Joint	Joint
Supply	Joint	Coordinated
Procurement	Joint	Coordinated
Regulatory	Joint	Separate
Implementation / Technical Assistance	Joint	Coordinated
Communications & programmatic reporting	Coordinated, often joint	Coordinated
Financial projections	Coordinated	Coordinated
Financial flow	Coordinated	Separate
Financial reporting	Separate	Separate

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

6.8 GAVI's overall objective related to 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 the Global Polio Eradication Initiative (GPEI) in support of countries." A working draft of GAVI's approach to accomplish this objective, revised from the June 2013 Board meeting, is available on myGAVI, and most sections are summarised below. The key elements of the approach are routine immunisation strengthening, IPV market shaping, communications and country dialogue, and IPV implementation.

- 6.9 In order to implement this approach, GAVI works closely with GPEI. Figure 1 illustrates the coordination and accountability mechanisms. These coordination mechanisms are further defined in a detailed, joint workplan.

Figure 1: Alignment of coordination and accountability mechanisms between GAVI and GPEI



Implications of IPV support for GAVI's principles and policies

- 6.10 The document in Annex A provides an overview of GAVI's policy objectives and issues related to its support for the introduction of IPV. It considers in detail whether exceptions to current policies may be required given the unique nature of the activities and challenges represented by the Endgame. Finally, it outlines policy-related risks to GAVI associated with its participation in IPV introduction as well as risks to the Endgame from GAVI's policy choices.

GAVI's operating principles

- 6.11 GAVI's third operating principle, supporting national priorities, integrated delivery, budget processes and decision-making, may have to be applied with some modification to IPV introduction. Unlike other GAVI-supported vaccines, IPV will not prevent significant mortality or morbidity in adopting countries. It is thus not clear that all countries would be prepared and willing to introduce IPV, particularly on the timeframe set out in the Endgame strategy (end 2015), without financial and technical support.

GAVI's Strategic Goals

- 6.12 Support to IPV would be consistent with GAVI's strategic goals of accelerating uptake and use of underused and new vaccines, strengthening health systems to deliver immunisation, and shaping vaccine markets. It is anticipated that GAVI's support would be time-limited, through approximately 2024, which suggests that GAVI's financing and sustainability goal is less relevant to IPV.

Implications of IPV support for specific policies

- 6.13 Analyses conclude that exceptions are likely to be needed to the following programmatic policies: eligibility and graduation (application and adoption window, duration of support, immunisation coverage filter), co-financing, and prioritisation policies. Annex A provides details on the rationale and proposed recommendations for the policy exceptions.
- 6.14 Analyses also conclude that exceptions are not anticipated to be needed for policies related to the country-by-country approach, gender, supply and procurement strategy, self-procurement, vaccine introduction grant, performance-based financing, donation, and transparency and accountability policies (Annex A).

Market Shaping: Demand, supply and procurement

- 6.15 The Secretariat, working closely with Alliance partners and GPEI, has developed an IPV Supply and Procurement Roadmap in response to the June 2013 Board decision. It includes market shaping activities for GAVI-supported countries within the context of the global IPV market. The public summary of the Roadmap is available on myGAVI.
- 6.16 The Secretariat has coordinated inputs to generate an initial forecast of demand using largely the same methodology as used for the strategic demand forecasting of other GAVI vaccines. However, the IPV forecasts are generated by global level partners and without extensive country input as yet, pending more definitive guidance on GAVI's commitment. The result is a highly ambitious forecast of what would be necessary to meet the Endgame timelines. The forecast reflects potential funding requirements and allows GAVI to confirm supply availability. The forecast, including that used for the financing projections, should not be considered an implementation forecast, which the Alliance would be held to delivering.
- 6.17 For the entire 2000-2012 period, 131 vaccine introductions took place in GAVI countries (an average of 10 per year.) If IPV demand from countries materialises as called for in the Endgame, it will contribute to an escalation from approximately 47 vaccine introductions supported by GAVI in 2013 to 79 in 2014 and 123 introductions in 2015, of which more than 40% in 2015 could be from IPV. Further analyses of forecasted vaccine introductions are available on myGAVI in *Risk and opportunities for GAVI's vaccine programmes related to IPV introduction in GAVI countries*.

- 6.18 Supply of vaccines in both the near and longer term is expected to meet demand overall, however the high degree of uncertainty on the timing of near term demand introduces some risk of short-term imbalances which will be monitored closely. The need for a low multi-dose vial presentation to increase programme efficiency and longer term diversification of the supplier base to increase supply security are both priority objectives for the partners.
- 6.19 An initial procurement strategy has been discussed with partners and initiated through the anticipated issuance of a multi-year tender by UNICEF Supply Division in late September/early October 2013. Achieving an initially low price will be critical to introduction of IPV in a time-frame that fits the broader Endgame Strategy. Partners are exploring market-shaping strategies that, for example, could achieve prices lower than publicly pledged by manufacturers (e.g. US\$ 1.14 - US\$ 1.59/dose).

Communications and country dialogue on IPV introduction

- 6.20 While the June 2013 Board decision has been instrumental in moving forward a dialogue and sensitising in-country partners, the absence of a definitive decision has delayed a more complete and comprehensive discussion of demand and how GAVI will specifically support countries to introduce IPV. Dialogue with countries is being supported through WHO regional committee and technical advisory group meetings, and at country level by Secretariat and partner staff. Activities and messaging have been closely coordinated and complemented with a joint GAVI and GPEI focus on reinforcing the importance of strengthening RI and eradicating polio, as well as the rationale for IPV introduction. FAQs and key message documents intended to support partner understanding and country dialogue have been circulated widely.
- 6.21 It is anticipated that GAVI's CEO will circulate a further letter to countries after GAVI's Executive Committee meeting of 27 September 2013. It is anticipated to include an 'Expression of Interest' (EOI) form and supporting materials. Responses from the EOI will feed into GAVI demand forecasts. A joint memo is anticipated to follow the GAVI Alliance Board meeting of 21-22 November 2013 from the leadership of GAVI, WHO and UNICEF. This letter, pending the Board's decision, would be accompanied by an IPV application form, guidelines and other supporting information inviting country applications from early 2014. Communication will be further scaled up once GAVI's role and mechanisms of support (e.g. application of the co-financing policy) are further defined by the Board.

IPV implementation

- 6.22 GAVI is leveraging its existing business plan investments, structures and experience to begin preparing for IPV implementation. Partner support to countries is being coordinated through a shared workplan, data is being analysed related to country readiness, and risks and opportunities related to GAVI's other vaccine introductions are being analysed to allow for planning of mitigating actions (see *Risk and opportunities for GAVI's*

vaccine programmes related to IPV introduction in GAVI countries on myGAVI.)

- 6.23 Of particular focus are analyses of each country to determine the potential number of introductions per year (Table 4.) These analyses assist the country and partners to anticipate and manage the implications, particularly for countries with lower coverage, considering introduction of multiple vaccines, and/or which are identified as priorities for IPV (see section 6.6).

Table 4. Number of introductions per country per year

Number of forecasted vaccine introductions in a year	Number of countries (2014)	Number of countries (2015)
1	25	30
2	16	25
3	6	13
4	1	1

- 6.24 An initial analysis of cold chain requirements for IPV has been conducted based on data from 34 GAVI countries. The data suggest cold chain capacity constraints exist that could potentially slow introduction of IPV and other vaccines in 2014 and 2015 if not addressed. Analyses are ongoing of wider supply chain constraints in countries. The IPV-specific cold chain impact will be relatively minimal since it is only one dose per infant. Initial estimates of the incremental cold chain cost requirements for IPV are on the order of US\$1.3M for all 34 countries. Health system strengthening funds may be leveraged in some places or partner support will be sought by countries.

IPV funding envelope

- 6.25 The Secretariat has begun to consider possible designs of processes such as for application, review and monitoring. In such considerations, the Secretariat is looking to ensure that processes are consistent with the timeframes called for by the Endgame, even if there is not yet additional evidence from countries that they are anticipating introducing by the end of 2015.
- 6.26 According to the Endgame timelines, more than 70 GAVI countries would need to apply in 2014 and early 2015 for IPV introduction through the end of 2015, all of which, in the absence of a funding envelope for IPV, would need to be decided upon through Executive Committee (EC) or Board meetings. As such, the concentration of applications, magnified by the need to batch applications for decisions according to the timings of EC and Board meetings, could potentially resulting in introduction delays of countries into 2016.

- 6.27 At the June 2012 Board meeting, the Board approved an amendment to the Programme Funding Policy to allow the Board each year to approve a funding envelope for new Health System Strengthening (HSS) proposals and for extension/renewal and adjustments of all existing programme budgets (vaccine and HSS). The Secretariat reports to the AFC and the Board on funding provided under the approved envelope. The current policy does not include new vaccine applications as would be required for IPV.
- 6.28 In order to help address the challenge presented by the number and potential concentration of applications, the Secretariat suggests the Board pre-approve an IPV Funding Envelope and delegate authority to the Secretariat to “allocate funding” under the Funding Envelope. The Secretariat would only allot funding to IPV programmes if funding to support those programmes has been secured and following recommendation by an IRC. The funding envelope will be for an amount sufficient to cover endorsed programme budgets for the duration of multi-year plans of individual countries for the period 2014-2018. The first envelope requested would be for US\$ 182 million, an amount projected to be sufficient to cover funding allotments to programmes until 31 December 2014. The Secretariat would report to the AFC and Board on the use of the funds.
- 6.29 An IPV Funding Envelope would allow GAVI to have greater flexibility, responsiveness to countries, and more quickly commit funds to applications following IRC review. Allowing IPV programme applications to be approved exceptionally through the envelope mechanism could help diminish the concentration of applications at certain time points and save an estimated 3-4 months between application review and approval, enhancing speed of introduction. The IPV Funding Envelope could allow additional countries to introduce prior to or early in 2015, smoothing out the resources required of the Secretariat and partners. A shorter time lag between application and approval also implies fewer changes at country level (e.g. changes in targets, less likely change in political situation) and thus facilitating implementation.

Section C: Implications

7 Impact on countries

- 7.1 Countries endorsed the Endgame through the World Health Assembly, nonetheless, the compressed timelines of the Endgame will be challenging. GAVI's complementary role to GPEI reinforces established mechanisms of support to countries for routine immunisation services and decreases potential confusion. Using purpose-built but familiar mechanisms to provide support increases opportunities to leverage ongoing activities and investments, such as training activities planned for other new vaccines. The proposed policy exceptions will allow countries to consider rapid introduction of IPV. The exceptions will allow countries to prioritise the use of national resources towards co-financing of vaccines

which are targeted for long-term use. Clear communication materials and stand-alone guidelines and applications forms for IPV will assist in managing the potential impact of GAVI's tailored approach for IPV with policy exceptions.

- 7.2 GAVI's support for IPV is instrumental to countries mitigating the risk of polio outbreaks and securing eradication of types 2 and 3 polio virus.

8 Impact on GAVI stakeholders

- 8.1 The Endgame and GAVI's role in polio eradication has a number of implications for stakeholders. Since current resources cannot be used, donors must rapidly consider committing funds for multiple years to GAVI, per pledges made at the Vaccine Summit. Until such resources are in place, GAVI will be unable to progress in its complementary role.
- 8.2 WHO, UNICEF, CDC, and BMGF are GAVI partners and core partners in GPEI. WHO, UNICEF and CDC are members of the IMG and are seeking funds through the Business Plan (taken from the polio eradication resources) to support their role in GAVI countries. Their roles are identified in the IMG workplan and are in addition to their ongoing GAVI-related activities. Additional funds are important to avoid existing staff accountable for the Business Plan activities being called to work primarily on polio.
- 8.3 Provision of a range of communication materials, including Powerpoints, FAQs and stand-alone guidelines and applications forms for IPV will assist partners in understanding and communicating to others GAVI's support for polio and policy exceptions.

9 Impact on Secretariat

- 9.1 The work on polio represents both an opportunity and an opportunity cost for the Secretariat. Additional resources are important to allow Secretariat staff to engage in activities, such as those related to market shaping, the increased number of applications needing review and monitoring, and others identified in the IMG workplan and GAVI's Approach document on myGAVI.
- 9.2 The workload will increase significantly for Country Responsible Officers (CROs) and staff engaged with application, review and monitoring processes due to more than 70 anticipated applications. As noted under the Business Plan implications above, realising the complementary roles of GAVI and GPEI, particularly in large countries with large investments from both, will require focused attention which is not feasible without additional staff and resources.
- 9.3 The policy exceptions will have a small and generally time-limited impact on the Secretariat. The most complex aspect will be developing the processes and communications to manage the engagement with countries around the policy exceptions. The Secretariat may need to increase its presence with partners at meetings with countries to support clear

communication. Part of the communication may need to be why exceptions were not created for some policies. After approximately 2016, when all countries should have applied, it is anticipated that the impact of managing IPV exceptions by the Secretariat will diminish.

10 Legal and governance implications

- 10.1 Agreements will need to be entered into with donors to secure funding for the polio programmes.

11 Consultation

- 11.1 This report results from extensive collaboration and consultation with Alliance partners from headquarters and regional levels who are also actively engaged with GPEI. Consultations with countries have happened through the WHA and regional committee meetings, focusing more generally on the Endgame than the specifics of GAVI's support. The Secretariat and partners are seeking to intensify consultation and dialogue with countries carefully paced with GAVI's Governance decisions, such as through discussions by Interagency Coordinating Committees (ICCs). Dialogue is particularly important in the countries identified by GPEI as priorities for IPV introduction.
- 11.2 GAVI and GPEI participated in a meeting with donors in September 2013 to discuss coordination between the organisations, estimates of funding requirements, and potential funding flows.
- 11.3 The policy considerations are the result of extensive consultations with GAVI and GPEI partners, including through the Immunisation Management Group which included regional participants, Vaccine Implementation Management Team, and Immunisation Financing and Sustainability Task Team. Countries have not been consulted due to the short timeframes since the June 2013 Board decision.

12 Gender implications

- 12.1 GAVI's current gender policies apply. No specific gender implications are foreseen.

Section D: Annexes

Annex A: GAVI policy considerations for support to IPV

Annex B: Cost projections (2014 – 2024)

Further documents available on myGAVI:

- GAVI's complementary role to the Global Polio Eradication Initiative (GPEI) in the polio eradication effort (i.e. Long Term Approach document)

- IPV Supply and Procurement Roadmap
- Risk and Opportunities for GAVI's Vaccine Programmes Related to IPV Introduction in GAVI Countries

GAVI policy considerations for support to IPV

September 2013

1. Issue

- 1.1 The Polio Eradication Endgame Strategy and Plan 2013-2018 (Endgame), endorsed by the WHO's Executive Board in January 2013, outlines steps both to eradicate wildtype polio virus and eliminate the threat of circulating vaccine-derived polioviruses (cVDPVs). To achieve the latter objective, the Endgame calls for the eventual withdrawal of all oral polio vaccines (OPVs) from routine immunisation programmes, beginning with the type 2 component responsible for most cVDPV cases. The withdrawal of OPV2 is in turn to be facilitated by the introduction of at least one dose of inactivated polio vaccine (IPV) in all countries by the end of 2015. IPV would mitigate risks associated with OPV withdrawal by protecting against cVDPV and priming children if an outbreak made vaccination necessary in the future.¹ GPEI has prioritised countries into four tiers for IPV introduction, with Tier 1 containing the highest priority countries, including the three endemic countries (Annex, Table 1). All Tier 1 countries except China are GAVI countries. Most Tier 2 countries are also GAVI countries. Notably, there is only one non-GAVI lower middle income country in Tier 2 (the Philippines). GAVI countries are also found in Tiers 3 and 4.
- 1.2 GAVI's overall objective related to polio eradication is to "to improve immunisation services in accordance with GAVI's mission and goals while supporting polio eradication by harnessing the complementary strengths of GAVI and the Global Polio Eradication Initiative (GPEI) in support of countries."²
- 1.3 The GAVI Board has indicated its support to "the GAVI Alliance playing a lead role in the introduction of IPV into routine immunisation services in 73 GAVI countries as part of the Polio Eradication Endgame Strategy and Plan in collaboration with GPEI. Consistent with previous Board decisions, the GAVI Alliance should work with countries using GAVI's structures, policies and processes where possible."³
- 1.4 This note provides an overview of GAVI's policy objectives and issues related to its support for the introduction of inactivated polio vaccine (IPV). The note considers in detail whether exceptions to current policies may be required given the unique nature of the activities and challenges represented by the Endgame. Finally, it outlines policy-related risks to GAVI associated with its participation in IPV introduction as well as risks to the Endgame from GAVI's policy choices.

2. Policy objective

- 2.1. GAVI will contribute to its overall objective related to polio, and in accordance with Board decisions, by supporting the introduction of IPV into routine immunisation

¹ World Health Organization, "Weekly Epidemiological Record", No. 1, 2013, 88. 4 Jan 2013, page 6, accessible via: <http://www.who.int/wer>

² GAVI's complementary role to the Global Polio Eradication Initiative (GPEI) in the polio eradication effort (May 2013)

³ GAVI Alliance Board, "Review of Decisions", 11-12 June 2013.

programmes whilst minimising potential risks to the implementation of other GAVI programmes. There may be in some cases a tension between the objective of very rapid uptake of IPV—the primary imperative from the perspective of polio eradication—and the integrity and objectives of GAVI's existing policy framework. The underlying justification for extraordinary measures in support of the Endgame is that polio eradication would undeniably be an important global public good. Withdrawal of OPV2 is itself a global public good, in that cVDPV can cross national borders. While IPV introduction itself benefits directly the introducing country, it also brings broader benefits by facilitating the withdrawal of OPV.

3. Scope of GAVI support for IPV

- 3.1. Programmes and Products: The Secretariat will recommend to the Board that GAVI support IPV procurement and introduction for use in routine immunisation services. Hence, both New Vaccines Support (NVS)⁴ and related cash support (e.g. Vaccine Introduction Grants) are in scope.
- 3.2. HSS is not in scope because this cash support, intended to strengthen immunization programs more broadly, would not replace IPV immunization operational funding at the country level.
- 3.3. GAVI support for IPV introduction into routine immunization is one component of the Endgame strategy.⁵ WHO reports that there is a technical consensus that no campaigns will be needed for this component. IPV might be called for in campaigns in the context of the objective of poliovirus detection and interruption⁶ in some high risk areas of endemic countries as a strategy to support the eradication of the wild virus, but this is currently outside of the scope of GAVI support. Support to procurement of Oral Polio Vaccine (OPV) is out of scope.
- 3.4. The Endgame suggests that countries could stop all polio vaccination (IPV and OPV) in approximately 2024, assuming the Endgame timeline is followed and eradication is successful. This review therefore focuses on support through 2024, but considers risks associated with continued need for IPV should the eradication timeline slip.
- 3.5. If hexavalent (DTwP-HepB-Hib-IPV) vaccines are eventually available, the Board will be consulted on possible implications for GAVI support and policies.
- 3.6. Countries: The GAVI Board decision covers both the 56 currently GAVI-eligible countries and the 17 graduating countries that have passed the eligibility threshold since 2011. The special cases of India and Indonesia are discussed below.
- 3.7. Lower Middle Income Countries (LMICs) that have never been GAVI-eligible and the four countries that were only eligible in GAVI's first phase (Albania, Bosnia-Herzegovina, China, and Turkmenistan) would not receive IPV support from GAVI. Of note, however, the GAVI Board recommended in April 2012 that GAVI explore its potential role in facilitating access to lower vaccine prices for all LMICs, including graduating countries.⁷ A paper will be brought forward to the GAVI Programme and Policy Committee's meeting in October 2013 where various mechanisms to support LMICs in accessing affordable prices will be considered as part of a wider effort for the broader GAVI vaccine portfolio. Such mechanisms would be considered for IPV

⁴ NVS support includes auto-disable syringes, disposal boxes and freight.

⁵ GAVI support falls under Endgame strategy Objective 2 (Strengthen immunization systems and OPV withdrawal).

⁶ Objective 1 of the Endgame strategy.

⁷ GAVI Alliance Board Retreat. Note of discussions, 16-17 April 2012.

procurement as well. Other Upper Middle Income Countries (UMICs) and all High Income Countries (HICs) are out of scope.

4. Consistency with GAVI's mission, operating principles and strategic goals

4.1. GAVI's mission

- 4.2. IPV introduction, as part of the Global Polio Eradication Endgame, is fully consistent with GAVI's mission to save children's lives and protect people's health by increasing access to immunization in poor countries. The poorest countries, which GAVI serves, have the least capacity to finance IPV from their own resources.

4.3. GAVI's operating principles

- 4.4. GAVI support to polio eradication would be fully consistent with its operating principles on advocating for immunisation in the context of a broader set of health interventions; focusing on innovation, efficiency, equity, performance and results; maximizing cooperation and accountability among partners; and ensuring gender equity.
- 4.5. GAVI's third operating principle, *supporting national priorities, integrated delivery, budget processes and decision-making*, may have to be applied with some modification to IPV introduction. GAVI is a country-led Alliance in which countries express the preferred timing for a new vaccine introduction through an application process. The polio Endgame has been endorsed by the World Health Assembly and thus all member states. However, unlike other GAVI-supported vaccines, IPV will not prevent significant mortality or morbidity in the adopting countries.⁸ It is thus not clear that all countries would be prepared and willing to introduce IPV, particularly on the timeframe set out in the Endgame strategy (end 2015). Countries may be strongly encouraged by GPEI and partners to introduce IPV following the World Health Assembly-endorsed Endgame timeline as a contribution to eradication when they would not otherwise have done so or would have done so at a later date.

4.6. GAVI's strategic goals

- 4.7. Support to IPV would be consistent with GAVI's strategic goals of accelerating uptake and use of underused and new vaccines, strengthening health systems to deliver immunisation, and shaping vaccine markets.
- 4.8. GAVI's Strategic Goal #3, "*increase the predictability of global financing and improve the sustainability of national financing for immunisation*", may not be directly relevant in this case because the need for IPV, and thus for GAVI support, is meant to be time-limited, with a target of approximately 2024 for the end of all polio vaccination. Moreover, the GAVI Board has called on donors to clarify that the costs to GAVI of implementing IPV will be fully and separately funded without drawing on GAVI resources for its other objectives. However, should separate polio funding prove inadequate, or should the need for IPV support continue beyond 2024, considerations of financing predictability and sustainability at the national and global levels could become important.
- 4.9. If countries decide to transition to a more expensive IPV-containing vaccine (e.g. hexavalent), or if SAGE recommends more than one dose or large campaigns, then sustainability may need to be reconsidered (see paragraph 5.24).

⁸ The introduction of IPV and removal of OPV2 will help prevent at least 80% of Vaccine Associated Polio Paralysis (VAPP).

5. Implications for specific policies

- 5.1. This section considers whether exemptions to particular policies may be required or desirable and makes recommendations, and, in some cases, presents an alternative. Although from a governance perspective, GAVI must decide how its policies may need to be modified for IPV, the risk to the credibility of existing policies may be minimised by emphasizing the special, time-limited nature of GAVI's IPV support.
- 5.2. **Eligibility and graduation:**
- 5.3. The Board decision to support IPV introduction in graduating as well as currently eligible countries clearly implies an exception to the eligibility policy, which states that countries can no longer apply for new vaccines once they cross the eligibility threshold for income.⁹ This exception would also apply to countries that cross the threshold in the next few years, before they have applied for IPV but while the IPV application window is still open.
- 5.4. The eligibility exception could apply indefinitely, or could be time-limited to encourage graduating countries to apply and introduce quickly, as called for in the Endgame strategy (see paragraph 5.8 below).
- 5.5. The Board decision on eligibility may also imply relaxation for IPV of another element of graduation policy: the phasing out of GAVI support for graduating countries over five years as country contributions are scaled up (see paragraph 5.9 below on duration of support and paragraph 5.13 on co-financing).
- 5.6. Special Cases of India and Indonesia: India (Tier 1) and Indonesia (Tier 2) are GAVI's two largest countries and also have domestic polio vaccine manufacturers. India has indicated it will self-finance IPV vaccines and introduction costs as a contribution to the Endgame strategy. This would be a key contribution given India's importance as a Tier 1 country and its sizeable vaccine needs, relative to the Endgame strategy's constrained budget. IPV costs for India are presented separately in the financial projections so the costs are apparent should GAVI need to fund them. The risk of India self-financing its IPV is that domestic financing issues could delay introduction in which case GAVI and GPEI have few incentives to accelerate implementation. However, India's contribution would allow GAVI to target resources to other countries and would reinforce India's domestic ownership of its successful polio program.
- 5.7. Indonesia has indicated some willingness to self-finance IPV vaccine, especially once domestically-produced IPV is available. It has also indicated it may need some external support to purchase IPV on the international market before domestic production is available (likely 2018 or later). As Indonesia's financing is still under discussion, the financial projections include the conservative view of the full cost of IPV vaccines for Indonesia. Once plans are confirmed, the projections will be adjusted as needed.
- 5.8. Application and adoption windows: GAVI may want to make the IPV window time-limited in order to encourage countries to apply quickly as required by the Endgame timeline. The following recommendation was developed to generally align with the adoption targets, bearing in mind implementation feasibility.

Recommendation (1): Open the window for IPV applications until June 2015, with introduction targeted within one year of date of application approval. However, should the need arise, following review by GAVI's CEO and in consultation with GPEI, the window could remain open for a longer period.

⁹ Graduated countries e.g. Albania, China etc. remain ineligible for GAVI support

The recommendation aligns with the Endgame timelines and signals a sense of urgency. It is also an ambitious target. It should be noted that GAVI has no leverage if high risk countries choose not to apply in the short time window. The risk of having a narrowly defined introduction window is that GAVI would not be supporting its primary policy objective of supporting polio eradication if it were to refuse support to key countries that had not been able/willing to apply within such a short timeframe. Another potential risk is that it may deter some countries from applying at all. These risks are mitigated to some extent by the fact that the recommendation leaves open the possibility that the window might need to be extended.

5.9. Duration of GAVI support:

Recommendation (2): Full support for all GAVI-eligible and GAVI-graduating countries until the Endgame target for stopping vaccination of approximately 2024, or an appropriate exit strategy for GAVI has been identified prior to 2024 (e.g. product affordable to countries).

Alternative recommendation (2a): Full support for GAVI-eligible countries as per recommendation above. Support for graduating countries to be guaranteed through 2020, provided there is sufficient polio eradication funding. GAVI support for IPV in graduating countries past 2020 would be revisited by 2018 based on progress with the eradication strategy, IPV prices, funding considerations, and other factors.

The recommendation has the advantage that it provides maximum assurance of continued support to all countries and therefore promotes rapid adoption, but it has risks to GAVI since currently pledged funding to the Endgame only goes to 2018. The alternative gives GAVI greater flexibility and mitigates some of the risks associated with funding and changes or challenges to the eradication plan. However, less predictable funding may lead fewer graduating countries to adopt IPV.

- 5.10. Immunisation coverage programme filter: The eligibility policy also states that countries with DTP3 coverage below 70% cannot apply for new vaccines, on the grounds that such a filter would (a) ensure minimum performance standards, (b) encourage high vaccine coverage, and (c) increase public health benefit per dollar invested.¹⁰ If the filter were applied, certain high priority countries such as Nigeria¹¹ may not be able to apply, as current levels of DTP3 coverage are below 70%. Given the urgency of the Endgame strategy and the need for all countries to participate, the programme filter would be an obstacle to that goal.

Recommendation (3): An exception to the immunisation coverage filter requirement will be made for IPV.

- 5.11. Sub-national support: As per current policy, eligibility would not be considered for poorer states/provinces within higher income GAVI countries (i.e. no sub-national support for countries).

5.12. **Co-financing:**

- 5.13. The overall objective of the co-financing policy is to put countries on a trajectory towards financial sustainability in order to prepare them for phasing out of GAVI support for new vaccines. The intermediate objective for countries with an extended time frame for achieving financial sustainability is to enhance country ownership of vaccine financing. The Endgame is intended to be time-limited, so sustainability considerations are less critical. Moreover, requiring co-financing,

¹⁰ GAVI Eligibility Policy, November 2009

¹¹ Of the twelve tier one countries, Ethiopia, Nigeria, and Somalia all have DTP3 coverage under 70%

especially from graduating countries, for whom the required amounts become more significant, may discourage countries from adopting IPV. A co-financing recommendation and alternative are presented in the interest of promoting rapid and universal adoption.

Recommendation (4): Exempt IPV from GAVI's co-financing requirements until 2024.

Alternative recommendation (4a): Consistent with the alternative recommendation on duration of support, waive IPV co-financing for eligible countries until 2024 and for graduating countries through 2020 and then reassess by 2018, with the option of requiring that graduating countries ramp up to full financing over the subsequent four years.

The recommendation has the advantages of simplicity and removing financial impediments of vaccine costs to rapid adoption. The alternative would give GAVI greater flexibility in case there are significant changes to the Endgame strategy or funding is highly constrained. Note that in the alternative, requiring co-financing for graduating countries may not make sense if polio eradication is on track, as countries would be scaling up financing just before use of the vaccine would be stopped. If eradication fails, co-financing could be used to set countries up for continued IPV financing if that were desirable.

- 5.14. Defaulting Countries: The desire to maximise adoption also argues for exempting IPV from the policy that countries in default of co-financing obligations for other vaccines cannot be approved for new vaccine support (although they can apply).

Recommendation (5): Countries can be approved for IPV vaccine even if they are in default on co-financing requirements of other vaccines.

- 5.15. **Vaccine introduction grants:**

- 5.16. GAVI currently provides a cash grant of US\$0.80 per child in the birth cohort or a lump sum amount of \$100,000, whichever is larger, ahead of new vaccine introduction for all GAVI-supported vaccines delivered to infants on a routine basis.¹² Countries apply for new vaccine introduction grants as part of their application for vaccine support to GAVI and receive one introduction grant per new vaccine introduction, including when introductions are done simultaneously.

- 5.17. Countries adopting IPV should receive introduction grants, especially given the urgency and programmatic challenges of rapid introduction. IPV vaccine introduction, even as a one dose course, will require information, education, and communication; social mobilisation; health worker training; printing of immunisation cards; and possibly some expansion of cold chain equipment and additional vehicles. Introduction grants are intended to support a large share of the cost of these pre-introduction activities, essentially none of which are dependent on the number of IPV doses administered per person. To facilitate introduction, it will be important that countries receive their vaccine introduction grants as quickly as possible following application approval. It should also be recognised that given the rapid timeline for introduction, most countries will not be able to allocate funds for pre-introduction activities in their own budget planning cycle.

Recommendation (6): All countries approved for IPV routine introduction with GAVI support are eligible for a vaccine introduction grant per current GAVI policy.

¹² This currently includes routine introductions of DTP-HepB-Hib containing vaccines, pneumococcal, rotavirus, yellow fever, measles (2nd dose and SIA), meningococcal A, and rubella (MR vaccine).

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- 5.18. As per the current policy, countries can apply for an additional “product switch” grant to facilitate transition to a new IPV product following introduction if they can meet the conditions specified in the policy. The grant could be needed for countries switching at a later date to dose-sparing formulations (e.g. fractional dose use, adjuvanted formulations).
- 5.19. Under current procedures, there are sometimes significant delays in disbursing vaccine introduction grants to countries. Given the urgency of timely introduction, GAVI is working to develop streamlined processes for IPV application, review, and release of the introduction grants.
- 5.20. **Country by country approach:** Under the policy on GAVI and fragile states – the country by country approach – eleven countries receive a tailored approach to GAVI support. This policy allows for flexibilities to existing GAVI policies, and where additional resources are required for activities that may set policy precedents, such matters are to be reviewed by the Executive Committee (EC) to the Board.¹³ Therefore, flexibilities considered for these countries would also be applied to polio activities, and the review mechanism would remain the same. All countries currently identified in the country by country approach are among the Tier 1 and Tier 2 priority countries of the GPEI strategy. No exemption is required for this policy.
- 5.21. **Supply and procurement strategy:**
- 5.22. GAVI’s supply and procurement strategy aims to contribute to GAVI’s market shaping goal by balancing supply and demand and ensuring security of supply, minimising the cost of vaccines to GAVI and countries, and fostering development of appropriate and innovative vaccines. The same objectives and tools (e.g. development of roadmaps, procurement tools) would be applied to support the efficient procurement of IPV vaccines.
- 5.23. Many product development, regulatory, and scientific guidance questions remain open at this stage, which will require careful monitoring and adaptation of the supply and procurement strategy over the course of the next 4-5 years, for example relating to dosing schedule required, availability of dose-sparing formulations and combination products (IPV-containing hexavalent vaccines). These will be regularly reflected in the strategy led and executed by the partners.
- 5.24. Hexavalent¹⁴ vaccine: The current Board decision assumes a single dose of stand-alone IPV. It is anticipated that a new GAVI Board decision would be needed prior to providing support for hexavalent vaccine in place of pentavalent vaccine, including reconsideration of the IPV exemption from some policies such as co-financing requirements.
- 5.25. **Prioritisation mechanism:**
- 5.26. Funding for IPV vaccines would be additional to GAVI funding and earmarked for IPV. Therefore, a shortfall in GAVI funding would not affect polio programmes and IPV applications would not need to be included in the existing prioritisation mechanism. It is possible, however, that GAVI could receive insufficient earmarked funding for IPV, in which case GAVI will need to consult with GPEI to use an efficient, evidence-driven means of determining which countries should be prioritised to receive this vaccine.

Recommendation (7): IPV vaccine will be excluded from the existing prioritisation mechanism. However, in the event that the additional, earmarked

¹³ GAVI Alliance Board, 4-5 December 2012, GAVI and fragile states: a country by country approach. Doc #12

¹⁴ Diphtheria, Tetanus, whole cell Pertussis, Hepatitis B, *Haemophilus influenzae* type B, IPV (DTwP-HepB-Hiv-IPV)

funding for IPV is anticipated to be insufficient to cover all countries approved for IPV support, GAVI will use polio funding to: 1) continue support for routine use where already introduced, if relevant, and 2) rely on guidance from GPEI to prioritise countries which have not yet introduced IPV, as well as countries that have not yet applied.

It is possible that additional, earmarked funding for IPV will be insufficient in the years beyond the Endgame pledges (2019-2024) requiring further prioritization. Duration of Support Alternative envisions an opportunity for the Board to reassess options by 2018 given what is known at that time about progress with eradication and funding considerations.

5.27. **Other policies:** The policies on gender, performance-based financing, self-procurement, product donation, and transparency and accountability would hold for IPV without exceptions.

5.28. A summary table for each policy recommendation including rationale, counterfactual, and key risks is included in Annex Table 2. The Grant Application, Monitoring and Review Mechanism (GAMR) is not a policy so has not been reviewed in this paper but requires modification to processes because of the necessity for streamlined processes for IPV. The GAVI Secretariat will bring forward a proposal in parallel to this paper as part of implementation plans.

6. Effective date

Recommendation (8): The policy exceptions proposed will be reviewed by the Policy and Programme Committee (PPC) in October and will be put forward for endorsement by the GAVI Board in November 2013 [with the effective date determined with that endorsement].

7. Risks

7.1 Risks to GAVI from its involvement in polio eradication fall into three main groups.

7.2 First, the exemptions to existing policies made to encourage rapid IPV adoption could confuse countries or weaken the credibility of these policies, including the eligibility, graduation, and co-financing policies. These risks are real, but they can be reduced by emphasising strongly the special character of GAVI support for IPV, especially its time-limited nature and its separate source of funding.

7.3 Second, there are risks associated with possible slippage of the Endgame timeline or even failure of the eradication enterprise. The main risk of slippage of the timeline is that GAVI may have to support IPV for longer than anticipated, and that this may require additional resources. This risk can be partially mitigated by making GAVI support beyond a certain period subject to reexamination, at least for graduating countries, rather than committing to fully support IPV in all 73 countries “as long as needed” (see Alternatives for Duration of Support and for Co-financing). Failure to interrupt wildtype PV transmission by the end of 2014 may also result in delays in succeeding steps in the Endgame plan, including IPV adoption.

7.4 The implications of outright failure of eradication are less obvious. Would countries that had adopted IPV continue its use if efforts to end transmission in endemic countries were abandoned or if wildtype transmission were reestablished in other countries, making withdrawal of OPV inadvisable?

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- 7.5 Third, the urgency of rapid introduction of IPV carries the risk that already planned introductions of other important GAVI vaccines will be delayed or compromised. It may be possible to mitigate this risk to some extent by encouraging and supporting simultaneous adoption. However, simultaneous introductions in countries with weaker infrastructures are unlikely. IPV introduction may delay rotavirus and pneumococcal introductions in some cases.
- 7.6 There is also some risk that GAVI support for IPV introduction in graduating countries will exacerbate tensions over vaccine affordability in GAVI-supported and non-GAVI countries, some of which are less well off than the better-off graduating countries. This tension can be mitigated to some degree by pushing for the lowest possible prices for non-GAVI LMICs and other support that GPEI may provide for non-GAVI LMICs. It should be noted that the differential approach to vaccine support for GAVI LMICs and non-GAVI LMICs has existed for some time. Furthermore, of the top priority countries for IPV introduction (Tiers 1 and 2), only one LMIC country is non-GAVI (the Philippines). All other countries are either GAVI countries or non-GAVI UMICs or High Income countries (Annex, Table 1).

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Annex Table 1. Endgame Strategy Country Tiers by GAVI Status and Income Category ¹⁷				
Tiers: Per WHO based on endemic status, history of cVDPV emergence, recent DTP3 coverage and polio virus importation risk				
Tier 1	WPV Endemic countries OR countries that have reported a cVDPV2 since 2000			
Tier 2	Countries who have reported a cVDPV1/cVDPV3 since 2000 OR large/Medium sized countries with DTP3 coverage <80% in 2009, 2010, 2011 as per WUNIC			
Tier 3	Large/medium countries adjacent to Tier 1 countries that reported WPV since 2003 OR countries that have experienced a WPV Importation since 2011			
(LIC=Low Income, LMIC=Lower Middle Income, UMIC=Upper Middle Income)				
GAVI eligible (LIC or LMIC)	GAVI Graduating (LMIC or UMIC) ^{2/}	Non-GAVI LMIC	Non-GAVI UMIC	High Income
TIER ONE (14 countries)				
Afghanistan (LIC) Chad (LIC) Cameroon (LMIC) DR Congo (LIC) Ethiopia (LIC) India (LMIC) Kenya (LIC) Madagascar (LIC) Niger (LIC) Nigeria (LMIC) Pakistan (LMIC) Somalia (LIC) Yemen (LMIC)			China	
TIER TWO (19 countries)				
Cambodia (LIC) CAR (LIC) Guinea (LIC) Haiti (LIC) Lao PDR (LMIC) Mali (LIC) Mauritania (LMIC) Mozambique (LIC) Myanmar (LIC) Papua New Guinea (LMIC) South Sudan (LIC)	Azerbaijan (UMIC) Indonesia (LMIC) Timor Leste (LMIC)	Philippines	Dominican Republic Gabon Iraq	Equatorial Guinea
TIER THREE (14 countries)				
Bangladesh (LIC) Benin (LIC) Burkina Faso (LIC) Burundi (LIC) Cote d'Ivoire (LMIC)	Angola (UMIC) Congo (LMIC)	Egypt	Turkmenistan	

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Eritrea (LIC)				
Nepal (LIC)				
Sudan (LMIC)				
Tajikistan (LIC)				
Uganda (LIC)				
TIER FOUR (77 countries) ^{3/}				
Comoros (LIC)	Armenia (LMIC)	Cape Verde	Albania	Antigua & Barbuda
DR Korea (LIC)	Bhutan (LMIC)	El Salvador	Algeria	Barbados
Djibouti (LMIC)	Bolivia (LMIC)	Guatemala	Argentina	Chile
Gambia (LIC)	Cuba (UMIC)	Morocco	Belize	St. Kitts and Nevis
Ghana (LMIC)	Georgia (LMIC)	Paraguay	Botswana	Trinidad and Tobago
Guinea Bissau (LIC)	Guyana (LMIC)	Samoa	Colombia	
Kyrgyzstan (LIC)	Honduras (LMIC)	Swaziland	Dominica	
Lesotho (LMIC)	Kiribati (LMIC)	Vanuatu	Ecuador	
Liberia (LIC)	Moldova (LMIC)		Fiji	
Malawi (LIC)	Mongolia (LMIC)		Grenada	
Nicaragua (LMIC)	Sri Lanka (LMIC)		Iran	
Rwanda (LIC)			Jamaica	
Sao Tome and Principe (LMIC)			Libya	
Senegal (LMIC)			Macedonia	
Sierra Leone (LIC)			Maldives	
Solomon Islands (LMIC)			Mauritius	
Tanzania (LIC)			Namibia	
Togo (LIC)			Panama	
Vietnam (LMIC)			Peru	
Zambia (LMIC)			St. Lucia	
Zimbabwe (LIC)			St. Vincent and the Grenadines	
Uzbekistan (LMIC)			Serbia	
			Seychelles	
			Suriname	
			Thailand	
			Tonga	
			Tunisia	
			Tuvalu	
			Venezuela	

^{1/} Income groups as of July 1, 2013 World Bank income classifications. Low Income: 2012 GNI p.c. \$1,035 or less; Lower Middle Income: 2012 GNI p.c. between \$1,036 and \$4,085; Upper Middle Income: 2012 GNI p.c. between \$4,086 and 12,615; High income: 2012 GNI p.c. above \$12,615.

^{2/} Ukraine is a GAVI-graduating country that is not classified in the table because it has already had some introduction of IPV. It may, however, be included at a later date.

^{3/} Cook Islands and Nauru are Tier 4 but not classified in an income group and are not in the table.

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Annex Table 2 - Summary table of proposed policy changes

Policy	Recommendations	Rationale	Counterfactual	Risks - <i>mitigation</i>
Eligibility	Create an exception for IPV so that graduating as well as currently eligible countries can apply for IPV for routine immunisation.	Support rapid uptake in graduating countries, as required to achieve Endgame objectives. Take advantage of GAVI's relationship with these countries.	Graduating countries are not eligible for GAVI IPV support. Would have to seek support for IPV introduction elsewhere (GPEI), less likely to adopt quickly.	Precedent setting for other global programmes to request exception for other vaccines. May be confusing to graduating countries. <i>To be communicated as one-off, time-limited measure to support Endgame timing.</i>
Application and adoption windows	Open the window for IPV applications until June 2015, with introduction targeted within one year of date of application approval. However, should the need arise, following review by GAVI's CEO and in consultation with GPEI, the window could remain open for a longer period.	Time-limited application window and requirement for quick introduction would encourage countries to introduce quickly.	Other GAVI vaccine windows have remained open, and a longer gap has been allowed between approval and introduction. IPV introduction on these terms would almost certainly be slower.	A narrow introduction window may not be credible. GAVI would not be supporting its primary policy objective of supporting polio eradication if it were to refuse support to key countries that had not been able/willing to apply within such a short timeframe. Strong pressure to introduce IPV quickly could delay or comprise other important vaccine introductions. A time-limited window could also make some countries less likely to apply for IPV support at all. <i>GAVI and partners should work with countries on simultaneous or concurrent introductions, taking advantage of joint health worker trainings and other possible synergies.</i>
Duration of support	Full support for all GAVI-eligible and GAVI-graduating countries until the Endgame target for stopping vaccination of approximately	Recommendation maximizes financial certainty for all GAVI countries, promoting uptake. Alternative provides an opportunity to fine-tune the	Graduating countries not eligible to apply; implied long-term support to approved eligible countries.	Funding shortfalls in later years may jeopardise GAVI support, and slippage of Endgame may leave GAVI with longer-term obligations than anticipated. <i>Under the alternative</i>

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	<p>2024 or an appropriate exit strategy for GAVI has been identified prior to 2024 (e.g. product affordable to countries).</p> <p>Alternative: Full support for GAVI-eligible countries as per recommendation above. Support for graduating countries to be guaranteed through 2020, provided there is sufficient polio eradication funding. GAVI support for IPV in graduating countries past 2020 would be revisited by 2018, based on progress with the eradication strategy, IPV prices, funding considerations, and other factors.</p>	<p>approach based on changing circumstances and some protection against funding and other risks.</p>		<p><i>option, GAVI would have more flexibility in these scenarios, mitigating this risk.</i> However, if support is not guaranteed until Endgame targets have been achieved, graduating countries may be less likely to apply.</p>
Immunisation Coverage Filter	<p>Do not apply the immunisation coverage filter for IPV.</p>	<p>Promotes rapid uptake in all GAVI countries, including those with low DTP3 levels, a category that includes some high-priority countries for IPV.</p>	<p>Some Tier 1 and 2 countries would not be eligible for GAVI support and might not adopt IPV.</p>	<p>Risk of weakening understanding and credibility of coverage filter. <i>Need to communicate rationale for exception clearly.</i></p>
Co-financing	<p>Make an exception for IPV from GAVI's co-financing requirements until 2024.</p> <p>Alternative: Consistent with duration of support alternative, make an exception for IPV co-financing for eligible countries until 2024, and for graduating countries through 2020 and then reassess by</p>	<p>Minimises any financial obstacles to vaccine uptake. Keeps it simple. Financial sustainability rationale for co-financing weak since need for vaccine theoretically time-limited.</p> <p>Alternative gives GAVI greater flexibility in the face of unforeseen events; mitigates some risks.</p>	<p>Standard co-financing requirements apply to both eligible and graduating countries. Some countries could perhaps be deterred from adopting by financing burden and hassle.</p>	<p>Confuses countries on co-financing, encourages requests for exceptions for other vaccines. <i>Can be mitigated partly by clear communication on exceptional nature of IPV support.</i> Also puts greater financial burden on GAVI.</p> <p>Alternative: May deter some countries from adopting, requiring more active follow-up.</p>

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	2018, with the option of requiring that graduating countries ramp up to full financing over the subsequent four years.			
Country-by-country approach	No change			
Gender	No change			
Supply and procurement strategy	No change			
Vaccine Introduction Grant	No change – review for new formulations and hexavalent	Rapid IPV introduction will involve substantial preintroduction activity costs. Providing for these costs will be important to getting introduction right.	If VIGs are not included, GPEI or countries would have to support all introduction costs directly.	No serious risks unless there are delays in Vaccine Introduction Grants to countries (see below on Vaccine Introduction Grant Disbursements).
Performance Based Financing	No change			
Prioritisation	IPV vaccine will be excluded from the existing prioritisation mechanism. However, in the event that the additional, earmarked funding for IPV is anticipated to be insufficient to cover all countries approved for IPV support, GAVI will use polio funding to: 1) continue support for routine use where already introduced, if relevant, and 2) rely on guidance from GPEI to prioritise countries which have not yet introduced IPV,	Polio funding is incremental to current GAVI funding and earmarked. Thus IPV does not compete with other vaccines for core funding. A separate mechanism should be in place to determine how IPV resources would be allocated if there were a shortfall in IPV funding.	If IPV were included in the existing prioritization mechanism, IPV would have to compete with other vaccines for limited funding. Current prioritization criteria would put IPV at the bottom of any ranking.	Polio funding becomes part of GAVI funding and creates a funding shortfall – <i>need to ensure donor pledges to polio remain fully ring-fenced and are adequate to the task.</i>

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	as well as countries that have not yet applied.			
Self-procurement	No change			
Donation	No change			
TAP	No change			



ANNEX 1: GAVI Alliance: Polio Cost Estimates

Draft as of 4 November, 2013

Projected costs are anticipated to be within GPEI Endgame Budget

all figures in USD millions

Polio Project Costs															
By Strategic Goal Staff	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Grand Total 2014 - 2024	Endgame 2014- 2018	GAVI Strat Plan 2016-2020	
Strategic Goal 1	\$ 1.8	\$ 3.0	\$ 2.5	\$ 1.5	\$ 1.5	\$ 0.5	\$ 0.5	\$ 0.5	\$ 0.5	\$ 0.5	\$ 0.5	\$ 13.1	\$ 10.2	\$ 6.3	
Strategic Goal 2	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 7.8	\$ 3.5	\$ 3.5	
Strategic Goal 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Strategic Goal 4	\$ 0.4	\$ 0.5	\$ 0.5	\$ 0.4	\$ 0.4	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 3.3	\$ 2.2	\$ 1.7	
Cross Cutting: Advocacy, Communication and Public Policy	\$ 0.2	\$ 0.3	\$ 0.3	\$ 0.1	\$ 0.1	-	-	-	-	-	-	\$ 0.9	\$ 0.9	\$ 0.5	
Cross Cutting: Monitoring and Evaluation	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 2.1	\$ 0.9	\$ 0.9	
Cross Cutting : Policy Development	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Mission Support	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Sub total - Polio Project Staff Costs	\$ 3.3	\$ 4.7	\$ 4.2	\$ 2.8	\$ 2.8	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 27.1	\$ 17.8	\$ 13.0	
Activities	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2014 - 2024	2014- 2018	2016-2020	
Strategic Goal 1	\$ 2.1	\$ 2.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 4.8	\$ 4.4	\$ 0.3	
Strategic Goal 2	\$ 3.5	\$ 3.5	\$ 0.4	\$ 0.4	\$ 0.4	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 8.4	\$ 8.1	\$ 1.3	
Strategic Goal 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Strategic Goal 4	\$ 0.8	\$ 1.7	\$ 1.7	\$ 1.7	\$ 1.7	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 16.7	\$ 7.6	\$ 8.1	
Cross Cutting: Advocacy, Communication and Public Policy	\$ 0.3	\$ 0.3	\$ 0.2	\$ 0.0	\$ 0.0	-	-	-	-	-	-	\$ 0.7	\$ 0.7	\$ 0.2	
Cross Cutting: Monitoring and Evaluation	\$ 0.4	\$ 0.4	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 1.0	\$ 0.9	\$ 0.1	
Cross Cutting : Policy Development	-	-	-	\$ 0.2	-	-	-	-	-	-	-	\$ 0.2	\$ 0.2	\$ 0.2	
Mission Support	\$ 0.4	-	-	-	-	-	-	-	-	-	-	\$ 0.4	\$ 0.4	-	
Sub total - Polio Project Activity Costs	\$ 7.5	\$ 7.9	\$ 2.3	\$ 2.4	\$ 2.2	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 32.2	\$ 22.3	\$ 10.2	
Overhead on partner costs @ 7%	\$ 0.5	\$ 0.6	\$ 0.2	\$ 0.1	\$ 0.1	-	-	-	-	-	-	\$ 1.5	\$ 1.5	\$ 0.4	
Sub-Total Polio Project Staff & Partner Costs	\$ 11.3	\$ 13.2	\$ 6.7	\$ 5.3	\$ 5.1	\$ 3.2	\$ 3.2	\$ 3.2	\$ 3.2	\$ 3.2	\$ 3.2	\$ 60.8	\$ 41.6	\$ 23.6	
Sub-Total Vaccine and Introduction Grant Costs (excluding India) *	\$ 43.9	\$ 96.6	\$ 89.5	\$ 79.2	\$ 79.0	\$ 74.6	\$ 73.2	\$ 74.3	\$ 72.1	\$ 73.1	\$ 74.0	\$ 829.3	\$ 388.1	\$ 395.3	
Grand Total Polio Project Costs (Excluding India)	\$ 55.2	\$ 109.8	\$ 96.2	\$ 84.5	\$ 84.1	\$ 77.8	\$ 76.4	\$ 77.5	\$ 75.3	\$ 76.3	\$ 77.2	\$ 890.1	\$ 429.8	\$ 418.9	

*2014 IPV Funding Envelope request of \$231M is an estimate of the 2014-2018 costs for applications approved in 2014.

GAVI Secretariat Costs																
By Strategic Goal Staff		2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Grand Total 2014 - 2024	Endgame 2014- 2018	GAVI Strat Plan 2016-2020	
Strategic Goal 1	\$ 0.6	\$ 0.6	\$ 0.6	\$ 0.5	\$ 0.5	\$ 0.5	\$ 0.5	\$ 0.5	\$ 0.5	\$ 0.5	\$ 0.5	\$ 0.5	\$ 5.6	\$ 2.8	\$ 2.5	
Strategic Goal 2	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 0.7	\$ 7.8	\$ 3.5	\$ 3.5	
Strategic Goal 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Strategic Goal 4	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 2.1	\$ 0.9	\$ 0.9	
Cross Cutting: Advocacy, Communication and Public Policy	\$ 0.2	\$ 0.2	\$ 0.2	-	-	-	-	-	-	-	-	-	\$ 0.6	\$ 0.6	\$ 0.2	
Cross Cutting: Monitoring and Evaluation	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 0.2	\$ 2.1	\$ 0.9	\$ 0.9	
Cross Cutting : Policy Development	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Mission Support	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Sub total - GAVI Secretariat Staff	\$ 1.9	\$ 1.9	\$ 1.9	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 1.6	\$ 18.1	\$ 8.8	\$ 8.1	
Activities		2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2014 - 2024	2014- 2018	2016-2020	
Strategic Goal 1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.8	\$ 0.4	\$ 0.3	
Strategic Goal 2	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.6	\$ 0.3	\$ 0.3	
Strategic Goal 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Strategic Goal 4	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.2	\$ 0.2	\$ 0.1	
Cross Cutting: Advocacy, Communication and Public Policy	\$ 0.2	\$ 0.2	\$ 0.2	-	-	-	-	-	-	-	-	-	\$ 0.5	\$ 0.5	\$ 0.2	
Cross Cutting: Monitoring and Evaluation	\$ 0.4	\$ 0.4	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 0.0	\$ 1.0	\$ 0.9	\$ 0.1	
Cross Cutting : Policy Development	-	-	-	\$ 0.2	-	-	-	-	-	-	-	-	\$ 0.2	\$ 0.2	\$ 0.2	
Mission Support	\$ 0.4	-	-	-	-	-	-	-	-	-	-	-	\$ 0.4	\$ 0.4	-	
Sub total - GAVI Secretariat Activities	\$ 1.2	\$ 0.7	\$ 0.3	\$ 0.4	\$ 0.2	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	\$ 3.7	\$ 2.8	\$ 1.2	
Grand Total GAVI Secretariat	\$ 3.1	\$ 2.6	\$ 2.2	\$ 1.9	\$ 1.7	\$ 1.7	\$ 1.7	\$ 1.7	\$ 1.7	\$ 1.7	\$ 1.7	\$ 1.7	\$ 21.8	\$ 11.6	\$ 9.3	

Partner Costs*														
By Strategic Goal Staff**	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Grand Total 2014 - 2024	Endgame 2014- 2018	GAVI Strat Plan 2016-2020
Strategic Goal 1	\$ 1.2	\$ 2.4	\$ 1.8	\$ 1.0	\$ 1.0	-	-	-	-	-	-	\$ 7.4	\$ 7.4	\$ 3.8
Strategic Goal 2	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Strategic Goal 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Strategic Goal 4	\$ 0.2	\$ 0.3	\$ 0.3	\$ 0.2	\$ 0.2	-	-	-	-	-	-	\$ 1.2	\$ 1.2	\$ 0.8
Cross Cutting: Advocacy, Communication and Public Policy	-	\$ 0.1	\$ 0.1	\$ 0.1	\$ 0.1	-	-	-	-	-	-	\$ 0.3	\$ 0.3	\$ 0.3
Cross Cutting: Monitoring and Evaluation	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cross Cutting : Policy Development	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Mission Support	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Sub total - Partner Staff	\$ 1.4	\$ 2.8	\$ 2.3	\$ 1.3	\$ 1.3	-	-	-	-	-	-	\$ 9.0	\$ 9.0	\$ 4.9
Activities	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2014 - 2024	2014- 2018	2016-2020
Strategic Goal 1	\$ 2.0	\$ 2.0	\$ 0.0	\$ 0.0	\$ 0.0	-	-	-	-	-	-	\$ 4.0	\$ 4.0	\$ 0.0
Strategic Goal 2	\$ 3.4	\$ 3.4	\$ 0.3	\$ 0.3	\$ 0.3	-	-	-	-	-	-	\$ 7.8	\$ 7.8	\$ 1.0
Strategic Goal 3	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Strategic Goal 4***	\$ 0.8	\$ 1.7	\$ 1.7	\$ 1.7	\$ 1.7	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 16.4	\$ 7.4	\$ 8.0
Cross Cutting: Advocacy, Communication and Public Policy	\$ 0.1	\$ 0.1	\$ 0.0	\$ 0.0	\$ 0.0	-	-	-	-	-	-	\$ 0.3	\$ 0.3	\$ 0.0
Cross Cutting: Monitoring and Evaluation	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cross Cutting : Policy Development	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Mission Support	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Sub total - Partner Activities	\$ 6.3	\$ 7.2	\$ 2.0	\$ 2.0	\$ 2.0	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 28.5	\$ 19.5	\$ 9.0
Overhead on partner costs @ 7%	\$ 0.5	\$ 0.6	\$ 0.2	\$ 0.1	\$ 0.1	-	-	-	-	-	-	\$ 1.5	\$ 1.5	\$ 0.4
Grand Total Partners	\$ 8.2	\$ 10.5	\$ 4.5	\$ 3.4	\$ 3.4	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 1.5	\$ 39.0	\$ 30.0	\$ 14.3

*Assumes approximately 67% of Immunisation Systems Management Group costs (WHO and UNICEF) for IPV are to support GAVI countries through Business Plan (67% = half of IMG costs related to IPV allocated on % of countries GAVI support and half allocated according to number of doses in GAVI countries). All IMG costs for RI strengthening flow through GAVI. Overhead of 7% included in all fees unless otherwise specified.

**Information on long term commitments to staff

WHO: All staff positions hired under IPV funding will be temporary appointments, renewable for 2 years.

UNICEF: All staff positions hired under IPV funding will be temporary appointments, renewable for 2 years: SG4 includes UNICEF SD Procurement Costs

***Overhead of 7% not added to estimated UNICEF Supply Division procurement fees.

Vaccine and Introduction Grants Costs														
Endgame Timeline Forecasts*	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Project Total 2014 - 2024	Endgame 2014- 2018	GAVI Strat Plan 2016-2020
Vaccine Costs (including syringe, safety box, and freight)**														
GAVI eligible (excluding India)	\$ 11.8	\$ 74.8	\$ 78.9	\$ 69.2	\$ 69.2	\$ 65.4	\$ 64.2	\$ 65.2	\$ 63.3	\$ 64.2	\$ 65.1	\$ 691.4	\$ 303.8	\$ 346.9
GAVI graduating	\$ 0.1	\$ 8.2	\$ 10.5	\$ 10.0	\$ 9.8	\$ 9.2	\$ 9.0	\$ 9.0	\$ 8.7	\$ 8.8	\$ 8.9	\$ 92.1	\$ 38.5	\$ 48.4
Introduction Grant***	\$ 32.1	\$ 13.7	\$ -	\$ -	\$ -							\$ 45.8	\$ 45.8	\$ -
TOTAL	\$ 43.9	\$ 96.6	\$ 89.5	\$ 79.2	\$ 79.0	\$ 74.6	\$ 73.2	\$ 74.3	\$ 72.1	\$ 73.1	\$ 74.0	\$ 829.3	\$ 388.1	\$ 395.3
India	\$ -	\$ 19.2	\$ 35.1	\$ 34.2	\$ 33.8	\$ 31.6	\$ 30.7	\$ 30.9	\$ 29.7	\$ 29.9	\$ 30.0	\$ 305.1	\$ 122.2	\$ 165.3

*Endgame Timeline forecast developed with partners relying primarily on global level input; Methodology largely consistent with GAVI's Strategic Demand Forecasts

**Given the unusually high level of uncertainty on, for example, both introduction timing and product presentation, the financial forecast for vaccines is likely to change as more information becomes available. Slower introductions and/or availability of a lower dose vial presentation could reduce the total volumes required and therefore the total vaccine costs. Faster introductions or estimates of a larger target population could increase total vaccine costs.

***Introduction grants assume all of 2014 and approximately 50% of 2015 paid out in 2014 as funds should arrive in country six months before introduction

Incremental Vaccine Cost if a Second Dose of IPV is Phased in from 2017 (Note this it not the current SAGE recommendation; Provided for illustrative purposes only)														
Endgame Timeline Forecasts	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Grand Total 2014 - 2024	Endgame 2014- 2018	GAVI Strat Plan 2016-2020
Vaccine Costs (including syringe, safety box, and freight)														
GAVI eligible (excluding India)	\$ -	\$ -	\$ -	\$ 69.2	\$ 69.2	\$ 65.4	\$ 64.2	\$ 65.2	\$ 63.3	\$ 64.2	\$ 65.1	\$ 525.9	\$ 138.4	\$ 268.0
GAVI graduating	\$ -	\$ -	\$ -	\$ 10.0	\$ 9.8	\$ 9	\$ 9.0	\$ 9	\$ 8.7	\$ 9	\$ 8.9	\$ 73.4	\$ 19.7	\$ 37.9
TOTAL	\$ -	\$ -	\$ -	\$ 79.2	\$ 79.0	\$ 74.6	\$ 73.2	\$ 74	\$ 72.1	\$ 73	\$ 74.0	\$ 599.3	\$ 158.1	\$ 305.9
India	\$ -	\$ -	\$ -	\$ 34.2	\$ 33.8	\$ 32	\$ 30.7	\$ 30.9	\$ 29.7	\$ 29.9	\$ 30.0	\$ 250.8	\$ 67.9	\$ 130.3