BRIEFING NOTE

for

DONOR MEETING ON IPV FINANCING

London | September 10, 2013

Updated 11 October for sharing with SAGE members

Note: a full set of the background materials that were shared with donors in early September can be found online at http://tinyurl.com/IPV-Donor-Meeting

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Since mid-April 2013, GAVI and GPEI have been working together through the Immunization Systems Management Group (IMG), utilizing their complementary strengths to ensure that the IPV introduction as well as existing vaccine introduction plans for other vaccines-- including those supported by GAVI-- can be achieved. The IMG's work has also focused on the broader objective 2 of the Endgame strategy and includes opportunities to strengthen routine immunisation services, through the use of polio human resources and through greater coordination between polio, GAVI and routine immunization programmes.

As the group responsible for the management and coordination of partners' activities to achieve Objective 2 of the Polio Eradication Endgame Strategic Plan 2013-2018, the IMG's work focuses on the following:

- Introducing IPV
- Withdrawing OPV2 from Routine and Supplementary Immunization Activities
- Ensuring the availability of appropriate IPV and bOPV products
- Increasing immunization coverage in 10 GAVI and WHO/UNICEF focus countries *(Afghanistan, Chad, the Democratic Republic of the Congo (DRC), Ethiopia, India, Nigeria, Pakistan, Somalia, South Sudan, Angola)*
- Ensuring clear recognition and understanding of the rationale for and urgency of the Endgame and the Objective 2 activities across their respective agencies

In preparation for the IPV donor meeting, a series of working meetings had been held to more clearly articulate points of alignment, and define how to best work together to deliver on shared mandates most efficiently and effectively. Central in these discussions was the definition of the appropriate coordination and accountability mechanisms to support IPV implementation. The partners also sought to understand the incremental investments and changes to current operating models that would need to be made in order to ensure currently planned activities and vaccine introductions aren't derailed.

The outcomes of these discussions include decisions on how to tackle each of the key priority issues for both GAVI and non-GAVI countries, through the coordinating mechanism of the IMG: **jointly** *(in which activities are implemented through a single process, with one partner serving as 'lead')*, in a **coordinated fashion** *(activities are implemented separately, but with regular discussion and collaboration)* or s**eparately** as indicated in the table below:

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

A series of background documents summarizing the current state of plans for IPV introduction have been made available for your review, along with some more general documents—such as the IMG workplan—which highlight the inter-linkages between IPV introduction and the other Endgame objective 2 workstreams.

These documents are works in progress, and will evolve as more information becomes available and further planning is completed. Nonetheless, they highlight the progress that has been made since the IMG was established , providing a venue for the expertise in GAVI and GPEI to collaborate on key areas such as planning for country introduction, revising policies, and issuing a strategic demand forecast.

These background documents are summarized in the next pages, and their full versions can be accessed online at: http://tinyurl.com/IPV-Donor-Meeting.

1. Background on the IMG and its workstreams

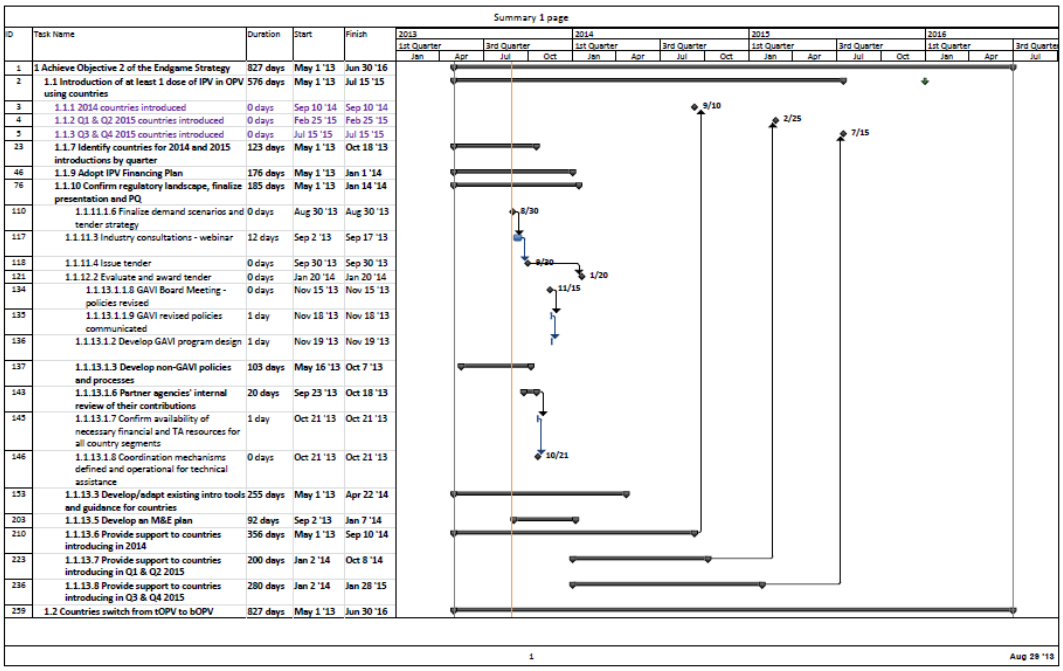
(Full document title: 1_IMG and its workstreams.pdf)

The IMG is comprised of representatives from both the polio program and routine immunization program from each of the GPEI core partners: WHO, UNICEF, BMGF, Rotary, and US-CDC, with the addition of the GAVI Secretariat. UNICEF and WHO regional offices are also invited to participate in IMG calls. The IMG is co-chaired by WHO and UNICEF on a rotating basis. While other key groups such as NGOs and implementing partners are not core members of the GPEI partners group and are not represented on the IMG, their input is critical. Discussions are on-going to determine what form and level of representation would be useful. The IMG has five sub-groups, each representing an IMG workstream. These include: Regulatory issues, Implementation (including country readiness, supply and demand), Financing, Communications and Routine Immunization Strengthening.

2. Current draft of the IMG Workplan

(Full document title: 2_Summary IMG Workplan.pdf. *Note that the workplan prints best in A3 or 11X17"*)

The IMG has through its sub-groups and workstreams developed a workplan to address objective 2 of the Endgame strategy. This is the guiding document for the IMG activities and serves as a key tool for coordination of all partner efforts. This workplan, which is still under refinement and development, outlines key activities that need to be completed and shows linkages between them. A five-page version of the workplan provided gives a highlights view, which shows the key tasks and deliverables, and their targeted start and completion dates. The complete workplan is available upon request from the IMG.



3. Preliminary IPV Financing Plan

(Full document title: 3_Preliminary IPV Financing Plan.pptx)

The IMG is working to develop financing plan for the Endgame's Objective2, and particularly the investments necessary to facilitate rapid uptake of IPV in line with Endgame timelines in a cost effective manner. The IMG is working to develop an estimate of total costs for IPV introduction, with appropriate financing plans for all 124 countries, which can be incorporated into the Endgame budget for 2014-2018. The technical support line includes the IMG's estimate of the costs associated with introducing IPV intro.

	GAVI Countries	India and China	PAHO (non-GAVI)	Other LMICs	UMICs/HICs
Vaccine	Full support for vaccines priced at a range encompassing $1/dose	Assumed to self-finance	Potential subsidy ranging from $0.00 to $0.75 per dose on average	Potential subsidy ranging from $0.00 to $1.00 per dose	Potential subsidy ranging from $0.00 to $0.50 per dose
Introduction needs	Introduction grants of $0.80 per child or $100K	Assumed to self-finance	N/A	N/A	N/A
Technical support	WHO, UNICEF, GAVI secretariat and/or IMG direct costs to support IPV introduction, as well as technical assistance to countries and regions based on prioritization according to tiers and need. Estimates range from $40M to $60M for 2014-2018.				
Funding flows	GAVI	N/A	UNICEF SD or PAHO revolving fund*	UNICEF SD*	UNICEF SD*

Based on the plans outlined on the previous slide, the estimated total costs for IPV during the period 2014-2018 ranges from **$328M to $449M,** which equates to roughly 6 to 8% of the total Endgame budget**.** The breakdown of costs is as follows:

- Vaccine costs (GAVI countries): $230M to $294M
- Subsidies (Non-GAVI): $22M to $54M
- Introduction grants (GAVI): $36M to $41M
- Tech. support & partner costs[1]: $40M to $60M

The initial cost projection for IPV introduction in the Financial Resource Requirements (FRRs) accompanying the Polio Eradication & Endgame Strategic Plan was $322 million (including vaccine costs, introduction grants and subsidies). This is consistent with the lower end of the cost range estimate

- [1]Approximately 78% ($31M-47M) is anticipated for support to GAVI countries (through the Business Plan) according to % of total IPV doses going to GAVI countries

above. The increase to arrive at the upper end of the cost range estimate is due to a combination of the higher number of doses / more rapid uptake (as per the "ideal" demand scenario), higher vaccine price assumptions, higher subsidy assumptions, and full application of the introduction grant to GAVI-eligible and GAVI-graduating countries. The estimated requirements for technical support and partner costs can be accommodated within the "ongoing quality improvement" budget line in the FRRs.

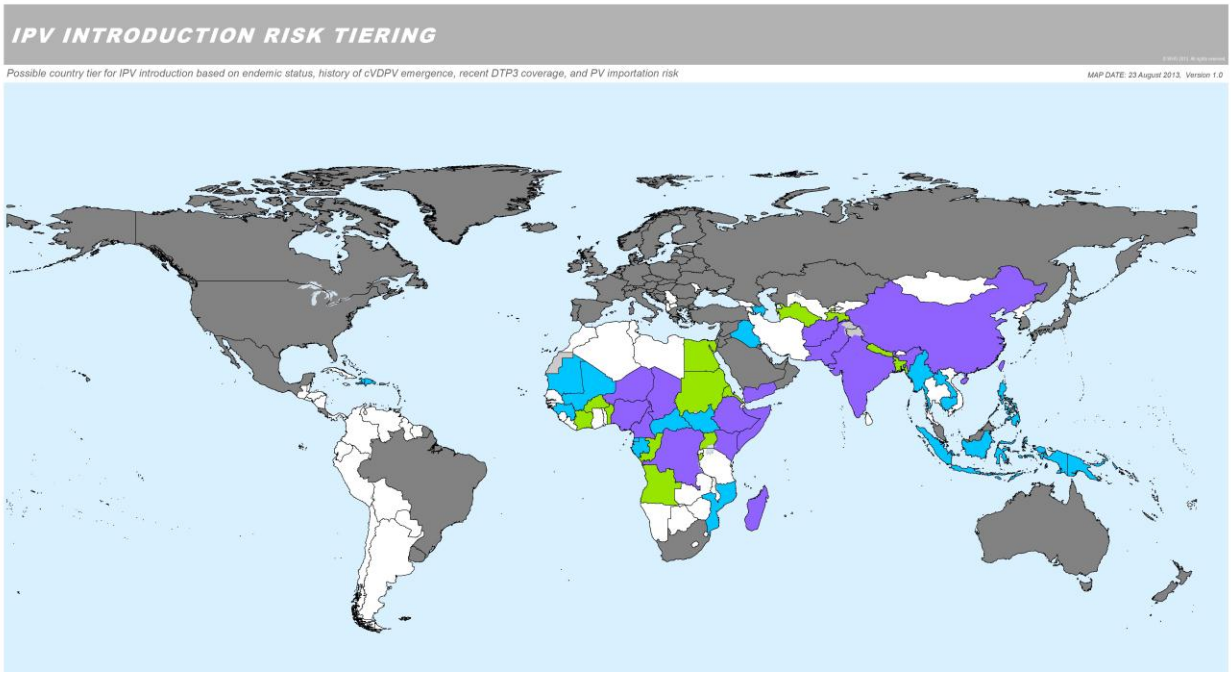
Update Note : At the London meeting, donors confirmed their agreement in principle to support this effort. They have requested more details on the budget- the IMG is in the process of providing these details

4. Country Tiering

(Full document titles: 4a_Risk Tiers for IPV Introduction.pdf and 4b_Map of Risk Tiers for IPV introduction.jpg)

In November 2012, the Strategic Advisory Group of Experts on Immunization (SAGE) recommended that all countries should introduce at least 1 dose of IPV in their routine immunization program to mitigate the risks following the withdrawal of OPV2. Because IPV introduction is a risk mitigation strategy, the IMG has established criteria to identify countries at the highest risk of a cVDPV2 outbreak and importations following OPV2 cessation. In order to highlight countries where the risk is greatest, and prioritize efforts and focus, the 124 OPV-only using countries have been grouped into four tiers, with Tier 1 countries being at the greatest risk, and Tier 4 countries at the lowest risk level. These are depicted on the map and defined below.

Update Note: The Tiering will be used by the IMG and the implementing partners to guide the level of technical assistance, communication and advocacy efforts required to support IPV introduction. However all four tiers countries are encouraged to introduce IPV by the end of 2015.

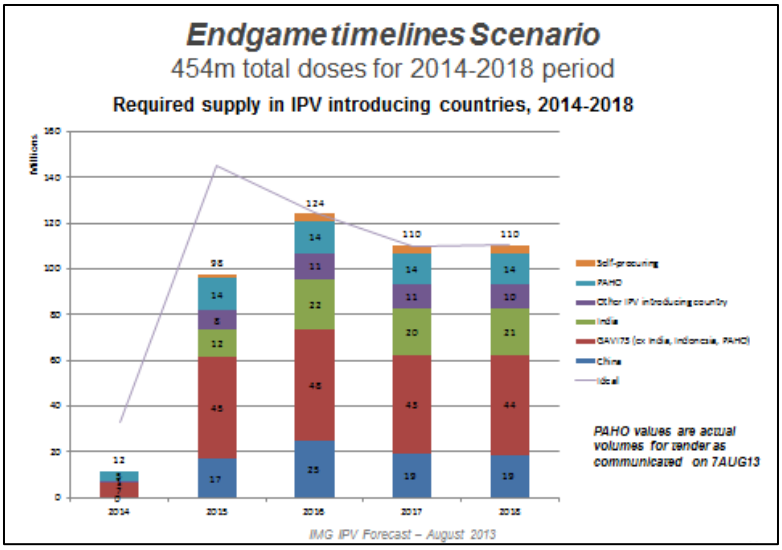


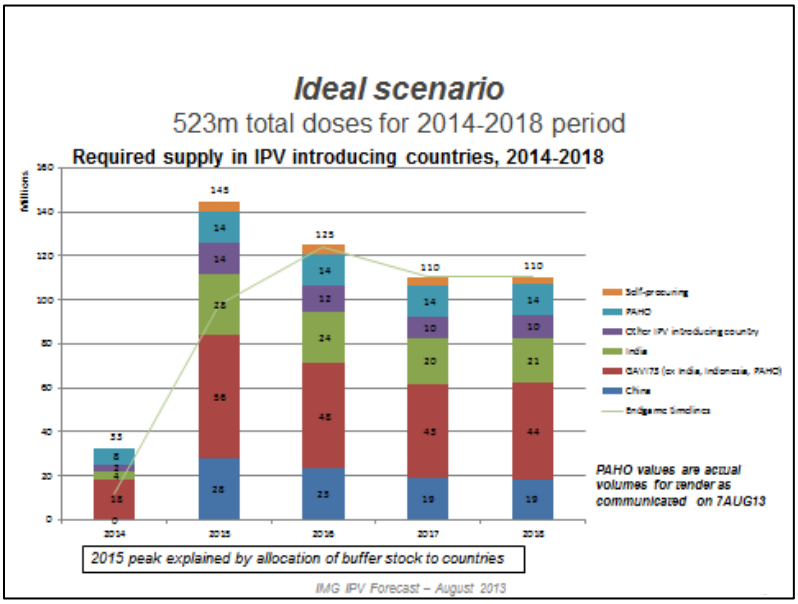
Tier Definitions:		
Tier 1		WPV endemic countries OR countries that have reported a cVDPV2 since 2000[1]
Tier 2		Countries who have reported a cVDPV1/cVDPV3 since 2000[1] OR large/medium[2] sized countries with DTP3 coverage <80% in 2009, 2010, 2011 as per WUNIC
Tier 3		Large/medium[2] countries adjacent to Tier 1 countries that reported WPV since 2003 OR countries that have experienced a WPV Importation since 2011
Tier 4		All other OPV only using countries

5. DRAFT Strategic Demand Forecast; IPV Supply and Procurement

(Full document title: 5_IPV DRAFT Strategic Demand Forecast.pdf)

The IMG IPV Strategic Demand Forecast scenarios- which covers all 124 OPV using countries - was developed jointly by GAVI and GPEI through the IMG. It represents an initial view into demand to inform financial resource requirements, supply and procurement Roadmap development and IPV tender strategy. Forecasts were generated only through global-level discussions with partners; future iterations will be refined with country input. Two scenarios are described—the Endgame timelines scenario, which requires 454 million doses of IPV by 2018, and the Ideal scenario, which requires 523 million doses of IPV by 2018. The difference between them is the rate of uptake/introduction by countries. Both scenarios, however, are highly ambitious, representing an unprecedented scaling-up requiring effective and clear communications with countries, streamlined financing, technical assistance and procurement processes. These scenarios are described below:





GAVI and GPEI are also working closely together to anticipate supply and procurement-related aspects of IPV introduction. Work is underway to ensure appropriate supply availability for the coming years, inform procurement activities in Q3/Q4 2013, obtain acceptable price conditions for IPV, and strengthen the development of a long-term sustainable market adaptable to Endgame requirements. Further materials are anticipated to be available on IPV supply and procurement in the coming weeks. **Update**

Update Notes:

- The forecast will continue to be refined as more clarity is received on the intent of countries, on the vaccine presentations available (and therefore the expected levels of wastage)
- On 4 October, UNICEF issued a tender for IPV on the basis of the above demand forecast. It will close on 15 November and awards will be made in early 2014.

6. DRAFT GAVI policy considerations for support to IPV

(6_GAVI policy considerations for support to IPV DRAFT.pdf)

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."[2]

This document provides an overview of GAVI's policy objectives and issues related to its support for the introduction of inactivated polio vaccine (IPV). It recommends where 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. The document is a working draft, which will be provided to the GAVI Executive Committee on 27 September 2013 for guidance, to GAVI's Programme and Policy Committee in October, and to the GAVI Board for decision in November.

An analysis is also underway by the GAVI Secretariat in consultation with partners, considering the design of processes such as country application and review mechanisms. The purpose is to plan for opening a window of support for GAVI-eligible countries, depending on the GAVI Board decision in November, in late Q4 2013.

7. DRAFT IPV Financing strategy for non-GAVI countries

(Full document title: 7_Draft IPV Financing Strategy for non-GAVI countries.pdf)

Work is in the early stages in order to address the following: (1) which countries would receive a subsidy and/or introductory grant for IPV adoption, (2) the appropriate subsidy and/or introductory grant amount by type of country, and (3) given those subsidy and introductory grant levels, the likelihood of non-GAVI country adoption of IPV.

[2] GAVI Alliance Board, "Review of Decisions", 11-12 June 2013.

The current thinking is that non-GAVI countries should be grouped by a combination of World Bank income level (e.g., LMIC, UMIC, etc., as determined by 2012 GNI per capita) and IPV pricing/procurement mechanism (i.e., PAHO countries).

Work is ongoing on a number of key assumptions to establish a range of potential costs for the introduction of IPV in non-GAVI countries. Current thinking is as follows:

8. Technical Rationale for IPV introduction

(Full document title: 8_Technical Rationale for IPV introduction.pdf)

This document highlights the technical and scientific rationale for introducing a dose of IPV in all OPV using countries. Key points include:

1. IPV by inducing immunity to type 2 will facilitate outbreak control with mOPV2 should type 2 viruses be reintroduced.
2. IPV in conjunction with withdrawal of type 2 virus from tOPV will boost immunity to types 1 & 3 which should hasten eradication of types 1 and 3 wild polioviruses and reduce polio disease caused by types 1 and 3 cVDPVs.
3. IPV induces immunity in a proportion of children which will protect them against polio caused by vaccine viruses and polio caused by wild poliovirus
4. IPV in conjunction with bOPV will decrease the number of cases of VAPP caused by types 1 & 3.
5. While the higher the IPV coverage the better, even low coverage will provide direct benefit to those vaccinated and greatly facilitate building population immunity in an emergency response.

9. DRAFT FAQs on IPV introduction

(Full document titles: 9a_General FAQ on IPV Introduction.docx; 9b_Technical FAQ for countries on IPV introduction.docx)

A set of two documents, the FAQ sheets provide answers to common questions around IPV introduction and the tOPV/bOPV switch. The first document is a more general FAQ, while the second answers country specific questions on introduction, such as the types of vaccine presentation available, anticipated schedule and avenues for financial and technical support. These FAQs are still under development and are presented as DRAFT documents.