GAVI ALLIANCE

LESSONS LEARNT FROM THE ACCELERATED VACCINE INTRODUCTION (AVI) PROJECT

05 July 2012

FINAL REPORT - ANNEXES

Prepared by:

CEPA LLP

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ANNEX 1: BIBLIOGRAPHY AND DATA SOURCES

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ANNEX 2: LIST OF CONSULTATIONS

In Table A2.1 below, we set out the list of individuals that we have consulted with for this review.[1] CEPA also participated (as an observer) in the AVI Management Team (AMT) weekly call on 25th April 2012.

In addition, we circulated by email to all the AMT members a short questionnaire exploring the contribution/ value add of AVI in terms of the results achieved to date. We received responses from Carsten Mantel at WHO and David Lorenzo at AVI TAC.

Table A2.1: List of consultees

Stakeholder category	Name	Organisation/ Position
GAVI Secretariat	Helen Evans	Deputy CEO
	Nina Schwalbe	MD, Policy and Performance
	Mercy Ahun	Programme Delivery
	Marthe Sylvie Essenque Elouma	CRO for Central/ West Africa (Francophone)
	Paul Kelly	Director, Country Programmes
	Peter Hansen	Director, Monitoring and Evaluation
	Adrien de Chaisemertin	Head of Performance Management
	Susie Lee	Senior Programme Officer, Monitoring and Evaluation
	Jeffrey Rowland	Director, Media and Communications
	Jon Pearman	Director, AVI
	Tania Cernuschi	Senior Manager, AVI
	Johanna Fihman	Senior Programme Assistant, AVI
	Richard Poe	Senior Programme Assistant, AVI
	Santiago Cornejo	Director of co-financing, Programme Delivery
AVI Technical Assistance Consortium (TAC) members	John Wecker	Director, AVI TAC (PATH)
	Lauren Franzel	Lead, Strategic Vaccine Supply (SVS), AVI (PATH)
	Orin Levine	Area Director, Special Studies (John Hopkins Bloomberg School of Public Health (JHU))
	Rana Hajjeh	Center for Disease Control (CDC) co-lead
World Health Organisation (WHO)	Carsten Mantel	New Vaccines Coordinator
United Nations Children's Fund (UNICEF)	Ann Ottossen	Contracts Manager, Vaccine Centre, UNICEF Supply Division
	Osman Mansoor	Senior Advisor, Expanded Programme for Immunisation (EPI) (New Vaccines)

[1] We contacted 48 stakeholders seeking consultations as part of this work. In the end, we were able to speak to a total of 30 stakeholders, as listed in Table A2.1

Stakeholder category	Name	Organisation/ Position
Bill & Melinda Gates Foundation (BMGF)	Tasleem Kachra	Senior Programme Officer, Global Health Vaccine Delivery
	Greg Widmyer	Senior Programme Officer
Board members	Suresh Jadhav	Serum Institute of India
Vaccine manufacturers	Lynn Bodarky	Pfizer
	Silvija Staprans	Merck
WHO Regional Working Group	Alexis Satoulou	Financial Sustainability Officer, AFRO region, WHO
Country representatives	Dr Salah Haithami	WHO, Sudan
Individuals previously associated with design and implementation of AVI	Stefano Malvolti	Former Director, SVS sub-team, currently working at Novartis
	Alfred da Silva	Executive Director, AMP

ANNEX 3: ADIPS AND HI - KEY RECOMMENDATIONS FROM THE HLSP EVALUATION

This section outlines the key characteristics of the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative (HI), which were introduced by GAVI in 2002.

A3.1 Objectives

In 2002, GAVI created the ADIPs as a response to noted delays in the uptake of new vaccines in developing countries.[2] The vaccines to be included in these plans were proposed by GAVI's Research and Development (R&D) Task Force after an extensive process including country inputs. As noted in the 2007 evaluation of the ADIPs, the work of the Task Force led to the recommendation that the ADIPs should focus on the high burden diseases in developing countries and for which vaccines were being developed. Thus, rotavirus and pneumococcal conjugate vaccines were chosen as the focus of the first ADIPs.

The Rota and Pneumo ADIPs were approved by the GAVI Board in February 2003 and funded with US$ 30m each for a four year period. In 2006, approval for an additional year of operations and an additional budget of US$ 200m for the ADIPs was given by the GAVI Board. The overall aim of the two ADIPs was to shorten the time lag between a vaccine becoming available and its introduction into developing countries.

Following the slow uptake of Hib vaccine in developing countries, despite the availability of GAVI funds[3], the HI was approved by the GAVI Board in June 2005 for a period of four years with a financing of US$ 28m, plus US$ 9m for the India Hib Vaccine Probe Study. The objective of the HI was to expedite and sustain evidence-informed decisions regarding the use of Hib vaccination, in order to prevent childhood meningitis and pneumonia.[4] Supply-related issues were not part of the HI's mandate and were taken over by a GAVI Supply Strategy Group working with UNICEF's Supply Division.

A3.2 Management structure/ design

The management of the ADIPs was tendered through an open Request for Proposals (RFP). In terms of their original aims and management structures, the ADIP RFP issued by GAVI specified that the "ADIP teams would execute a product development and early introduction programme in coordination with a broad range of public and private GAVI partners". Oversight was to be provided by a "small managerial steering group that will include – but not be limited to – several GAVI Board members, with decision making authority delegated to them by the Board

[2] In 2002, only about 70 million doses of hepatitis B vaccine and fewer than 10 million doses of Hib vaccine were used by developing countries.

[3] This was due to (i) unclear disease burden; (ii) unclear demand forecasts; (iii) uncertain supply; and (iv) high vaccine prices and monopoly in the market.

[4] HLSP (2007): "An evaluation of GAVI Alliance efforts to introduce new vaccines via the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative (HI)".

to approve the plan and budget and to evaluate the team's use of resources and progress towards pre-specified milestones".[5]

The ADIPs and the HI were overseen by a Management Committee (MC) composed of scientific experts, donor organisations, an individual with private sector industry expertise, and a country health ministry official. The MC was the interface between the ADIPs and HI and the GAVI Board. The Pneumo ADIP was located at the JHU. The Rota ADIP, also known as the PATH Rotavirus Vaccine Program (RVP), was a PATH affiliate in partnership with the WHO and the US CDC. The HI consortium was composed of four members, including JHU, CDC, WHO, and the London School of Hygiene and Tropical Medicine.

A3.3 ADIPs and HI outcomes, as identified by the HLSP 2007 evaluation

A crucial outcome of the ADIPs was that a clear signal was sent to the vaccine industry that the public sector was interested in investing in specific vaccines.

Key outcomes of the Pneumo ADIP include:

- *Demand.* The Pneumo ADIP developed sound disease burden data (by supporting small grants in 16 countries on surveillance efforts) for which there is international consensus; clearly communicated key messages to core stakeholders about the disease, vaccine, and response to the vaccine based on technical information agreed by leading scientists in the field. Other advocacy efforts included conducting surveys of decision makers to identify different perceptions to craft appropriate communications strategies, as well as setting up a website with regular newsletters.
- *Capacity building.* The Pneumo ADIP developed a demand forecasting tool for dynamic construction of demand forecasts; worked with industry to assure appropriate formulations and presentation of vaccine; developed potential alternative regulatory strategies; inventoried both emerging suppliers and multinationals on their pipelines; and participated in GAVI's Supply Strategy Group.
- *Pricing.* The Pneumo ADIP drafted business cases to model affordable supply from various manufacturers; produced a costing analysis of goods for pneumococcal conjugate and protein vaccines; projected the total global market for infant pneumococcal conjugate vaccine; constructed a net present value model of an 11-valent vaccine; and contributed to the work on Advanced Market Commitments (AMCs). The Pneumo ADIP also developed an investment case to convince the GAVI Board to co-finance pneumococcal vaccine introduction in countries.

Key outcomes of the Rota ADIP include:

- *Demand.* The ADIP made a strong case for the cost-effectiveness of rotavirus vaccines as well as for impact on known disease burden, supporting potential early-adopter countries to introduce the vaccine. The Rota ADIP developed and published surveillance

[5] HLSP (2007): "An evaluation of GAVI Alliance efforts to introduce new vaccines via the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative (HI)".

protocols for both rotavirus disease and intussusceptions[6] with WHO; conducted five Phase 2, 3 and 4 clinical trials and four post-marketing studies in low resource countries which were key drivers of the policy decision by WHO to recommend rotavirus vaccines for all infants; established surveillance networks in several regions, with at least 40 countries participating; promoted laboratory diagnosis with the establishment of regional laboratories, training, a manual and diagnostic kits; funded a Regional Advisor in PAHO; produced global, regional and country cost-effectiveness analyses; and worked successfully with PAHO and the Sabin Vaccine Institute to accelerate rotavirus vaccine introduction in Latin America. Apart from the major clinical trial publications, RotaADIP published four journal supplements, featuring global, Asian and African disease surveillance, and clinical trial findings. Advocacy messages of expanded clinical safety trial results virtually dispelled safety concerns. [7] In addition, as part of the advocacy efforts, the Rota ADIP developed a website and an electronic newsletter, and developed an information packet on rotavirus.

- *Capacity building.* The Rota ADIP developed a demand forecast based on a similar methodology as used by the Pneumo ADIP; and a Delphi-methodology demand forecast. It also partnered with two multinational developers of rotavirus vaccine to assure regulatory pathways in clinical trials; partially supported two positions in WHO on regulatory pathways; and developed a manufacturer's resource guide to help emerging market manufacturers develop the rotavirus production technology.
- *Pricing.* The Rota ADIP identified early-adopting countries and worked with them on uptake decisions, specifically with a Latin American strategy. It developed an investment case to convince the GAVI Board to support county co-financing of rotavirus vaccine.

Key outcomes of the HI include:

- *Demand.* The HI supported, with the Pneumo ADIP, WHO estimation of burden of disease as well as development of a surveillance protocol; funding surveillance and impact studies in Europe and Africa; liaised with the India Probe study on impact of Hib in the country with unclear disease burden; summarising cost-effectiveness data on use of Hib; supporting three large country proposals on decision making in Pakistan, Bangladesh, and Mozambique; and contributed to the publishing of a new WHO Position Paper in November 2006 that advocated clearly the desirability of Hib use in all countries. The HI developed key consistent messages on Hib disease and Hib vaccine; developed a website and an electronic bulletin; contributed to a BBC documentary on immunisation; and worked at the country level through Regional Offices to support decision making and to disseminate the new WHO position.
- *Capacity.* While not in the workplan, the HI kept a running list of countries that were approved for funding to introduce Hib vaccine. While it did not have a mandate to work

[6] Intussusceptions is a medical condition in which a part of the intestine has invaginated into another section of the intestine.

[7] Some of the outcomes under 'demand' reflects feedback from a RotaADIP member and was not mentioned in the HLSP report.

on supply issues, it liaised with UNICEF and was an active member of a vaccine reference group and the Bridge Financing Team.

- *Price.* The HI's work in countries to promote use of Hib was expected to expand the market in middle income countries, increasing the size of the market. The HI worked with the GAVI Bridge Financing Team to support continued co-financing for Hib vaccine.

A3.4 Issues identified in ADIP Evaluation

This section summarises various issues related to design and organisation management of the ADIP and the results framework in the ADIP Evaluation conducted by HLSP in 2007.

Design and organisational management

- The Pneumo ADIP reported a general fuzziness in the goals stated in the RFP, with the result that their mandate and that of the Rota ADIP was clarified by the MC in 2003.
- The ADIPs felt that the GAVI Country Support Team are not always passing on complete information to countries about their work.
- Handling the differing visions with joint leadership was pointed out to be a challenge in Rota ADIP.
- Both the Pneumo and Rota ADIPs reported a lack of contact with the GAVI Secretariat in the early stages, as well as a perception that the GAVI Board was not interested in their work.
- There were some complaints from industry that the ADIP mandate was too broad and 'there is much liberty to do as they see fit'. Another complaint was related to a lack of understanding of the mandate and specifically what contacts were made with emerging suppliers when products produced by multinational companies were already available. In addition, there was significant criticism from industry on the oversight by the MC.
- Of the three client groups on the ADIPs – industry, donors and countries – the latter two are not well represented. More knowledge about vaccine logistics and administration, as well as increased decision making at the country level were suggestions for improvement.
- Lack of administrative support for the MC.
- Interaction between the ADIP and the GAVI Secretariat has not been optimal with no Secretariat person focused only on the ADIP.
- Frequent change of responsibilities amongst the Secretariat staff to manage the ADIP.
- The HI, on account of its limited mandate, could not address issues related to supply and the pricing of the Hib vaccine, which is essential country introductions.

- HI was suggested to have faced governance, managerial and coordination constraints on account of a less than optimal structure with an Executive Committee, rather than a strong manager and geographic dispersion of members.

Results

- Direct agreements with manufacturers were not used as originally envisioned. Delays in clinical trials impacted the ability to make recommendations in some regions.
- The actual impact at the country level was considered to be difficult to document and it was not clear to the evaluation team whether countries were aware that the information provided comes from the ADIPs, especially since the strategy of these initiatives is to hand off the actual introduction activities to WHO.

Response of interviewees on the impact of the ADIPs at regional and country levels has been contradictory and most often countries have displayed a poor understanding of the ADIPs.

A3.5 Evaluation recommendations

The HLSP evaluation team recommended that the GAVI Board consider approaches for further managing the new vaccine introduction process in three areas:

- scanning the pipeline (the pre-ADIP process) and keeping informed on projects in earlier stages of development;
- addressing the issues of the ADIP process in relation to capacity, demand, and pricing strategies that are needed to render a vaccine programme ready; and
- addressing the implementation issues for a range of programme ready vaccines.

Other recommendations include:

- GAVI should review its mission and working procedures to determine how best to manage these approaches and structures – either within the GAVI Secretariat, housed at a GAVI partner organisation, or at an outside organisation selected through an RFP process.
- For the ADIP implementation processes, oversight needs to involve the GAVI Board through a Management Committee, selected with appropriate skills, and with liaison through specifically charged GAVI Secretariat teams.
- The ADIPs should be focused in a single organisation, with a strong manager, and be target-oriented, time-limited and milestone-driven.
- The ADIPs should justify on a regular basis to the GAVI Board the continuing relevance of their product.
- The ADIPs should carefully define their interactions with GAVI Partners at the country level.
- The RFPs, mandate, and the governance structures must be clear and appropriate.

- The GAVI Board should ensure that there is collaboration and coordination among all groups performing an ADIP-like function by convening open fora where they can report latest results and resolve potential issues.

ANNEX 4: SUMMARY OF AMT SUB-TEAMS

We briefly describe here our understanding of the activities undertaken by each of the sub-teams:

- **Logistics and Cold Chain.** WHO is the lead for this sub-team, responsible for providing in-depth country level analysis of Cold Chain and Logistics Systems (CCL) status, identifying CCL expansion needs and logistics constraints within countries, documenting CCL best practices and mobilising technical and financial support to overcome in-country constraints. In 2010, WHO developed an updated evaluation and management tool for vaccines called Effective Vaccine Management (EVM), which is now a requirement for countries in order to be considered to receive funding from GAVI..[8]

- **Advocacy and Communication (A&C).** Led by PATH, this sub-team is responsible for disseminating information to countries, building coalitions/ alliances to generate local advocacy and supporting GAVI Secretariat in A&C efforts at global level.[9] Some of the work undertaken in this regard includes: (i) providing multi-media reportage and stories from GAVI-eligible countries, providing evidence-based data and messaging on pneumococcal and rotavirus diseases and vaccines, amongst other-related activities as part of GAVI's External Relations strategy; and (ii) country-based advocacy and communication in Burkina Faso, Georgia, Kenya etc. to support in-country decision making.[10]

- **Strategic Vaccine Supply (SVS).** Also led by PATH, SVS's role is to provide supply and demand forecasts and identify gaps, run scenarios to identify opportunities and risks, provide inputs into critical activities to achieve forecast and to link forecast with operational plan. Amongst other outcomes of this sub-team, v4.0 of the strategic demand forecast (SDF) was shared in August 2011.[11] The SVS had agreed terms of references but these have been recently revised and are awaiting approval from the AMT.

- **Special Studies.** This sub-team is led by JHU and is responsible for conducting scientific and economic studies to support decision making and assessing impact. These include studies on effectiveness in GAVI-eligible country settings; optimising dose/ delivery for Expanded Programme on Immunisation (EPI) compatible schedules; safety studies (both general and addressing vaccine-specific issues such as possible intussusception association); impact studies including herd immunity; and projects to measure economic variables, including cost effectiveness. As of November 2011, all the studies were expected to be completed by late 2011 and 2012.[12] This sub-team also has a draft terms of reference but these have not been finalised and approved by the AMT.

- **Pneumo and Rota Working Group.** The two working groups – pneumo and rota – were merged in August 2011 to ensure close coordination and improved information

[8] GAVI (2011), "Report to the GAVI Alliance Board, November 2011", presented by PPC
[9] Ibid
[10] AVI TAC (2012), "AVI TAC Annual Report 2011"
[11] GAVI (2011), "Report to the GAVI Alliance Board, November 2011", presented by PPC
[12] Ibid

flow around pre-launch activities, and day-to-day operational issues and actions. This sub-team aims to improve coordination among partners and provide increased support to countries approved (both pre- and post-launch) for both vaccines.[13] It considers wide-range of issues including country readiness, providing regular updates on implementation and information related to supply of the vaccine. The group provided improved information flow around pre-launch activities, addressed day-to-day operational issues and actions required for introduction of rotavirus vaccine in Sudan.

- **Rubella.** Set up in May 2011, the Rubella sub-team is led by WHO to prepare implementation guidelines and strategies for new vaccine introduction.[14]

- **Typhoid.** Set up in May 2011, the Typhoid sub-team is led by WHO to prepare implementation guidelines and strategies for new vaccine introduction. [15]

- **HPV.** Following approval of HPV vaccine by the GAVI Board in November 2011, HPV sub-team was proposed to be formed in March 2012 with a lead identified from the GAVI Secretariat.[16,17] Specific deliverables include providing technical advice and input to the GAVI Secretariat for development of application guidelines text and forms, discussing the use of roll-over funds from 2011 from GAVI Business plan-funded HPV related activities and discuss overall progress, counsel the GAVI Secretariat on design of GAVI-supported demonstration projects programme including goals, objectives, scope of GAVI support, budget implications and engagement of other partners and funds and provide guidance for development of global and country communication and social mobilisation strategies.[18]

- **Japanese Encephalitis (JE).** Set up in May 2011, the JE sub-team is led by WHO to prepare implementation guidelines and strategies for new vaccine introduction. [19]

- **Yellow Fever (YF).** Led by WHO, the YF sub-team was linked to AVI in 2011.[20] As part of this, WHO is refining strategies to assess the risk of the disease in new areas and ascertain the immediate needs for ongoing country support for yellow fever prevention.[21]

- **Meningococcal A vaccine (MenA)**. In 2011, the WHO-led MenA team was linked to AVI to facilitate the introduction of MenA in affected countries. The MenA working group supported the introduction of vaccine in Mali, Niger, Cameroon, Chad and Nigeria. Prior to its association with AVI, MenA working group also provided support in launching the vaccine in Burkina Faso.

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[13] Ibid

[14] GAVI (2011), "Report to the PPC, September 2011"

[15] Ibid

[16] GAVI (2012), "AVI HPV sub-team – Terms of Reference"

[17] AVI Progress Report, presented to the PPC in September 2011 suggests that WHO is the leading entity for HPV sub-team.

[18] GAVI (2012), "AVI HPV sub-team – Terms of Reference"

[19] GAVI (2011), "Report to the PPC, September 2011"

[20]GAVI (2011), "Accelerated Vaccine Introduction update" by Jon Pearman, GAVI Alliance Board Meeting, November 2011

[21] GAVI (2011), "Report to the GAVI Alliance Board, November 2011", presented by PPC

ANNEX 5: EXPECTED COSTS OF THE AVI INITIATIVE

This annex sets out the 2008 estimate of costs of AVI activities by different entities. The information has been sourced from the "Report on the mapping and costing of activities", 2008.

We note the following caveats with regard to these graphs:

(i) these may not necessarily depict the actual expenditures incurred since certain activities were not undertaken on account of change of plans, and external factors such as GAVI's constrained financial situation;

(ii) AVI TAC has a specific budget allocation of US$ 51.3m[22] through the GAVI Business Plan 2011-15, and has spent US$ 36.74[23] until 2011; and

(iii) budget allocation for various activities conducted by WHO and UNICEF is through the GAVI Business Plan and this does not differentiate between budget-allocation for AVI-specific activities and other Alliance activities.

Figure A5.1 details the estimated costs of the AVI initiative by entity, with the majority of the costs (48%) expected to be incurred by countries, followed by WHO (30%). Other than for AVI TAC, we have not identified any information on the actual spend by entity or activity to date.

Figure A5.1: Estimated costs related to accelerated vaccine introduction by entity (2008)

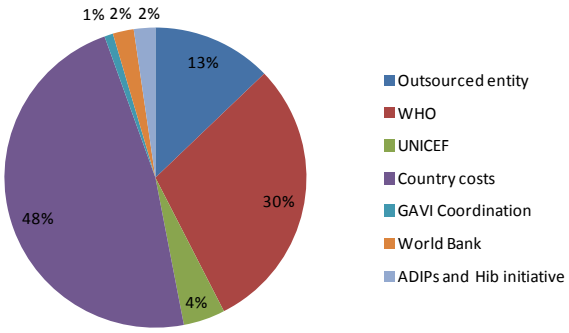
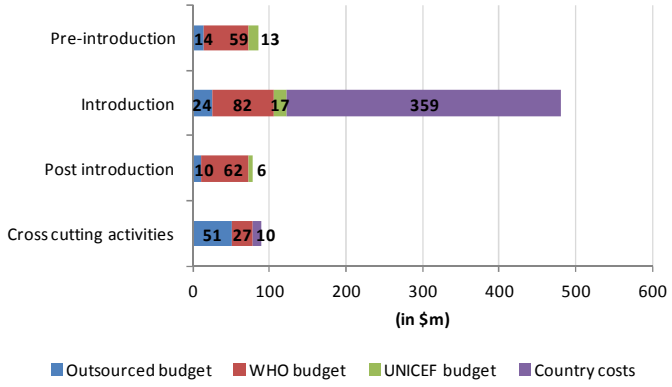


Figure A5.2 below presents the distribution of these expected costs across four categories of activities. About 65% of the costs were expected to be on introduction-related activities with majority of it (75%) to be incurred by countries.

[22] The October 2008 Board minutes state that the Board approved "US$ 51.3m for 2009-15 for PATH/JHU/CDC to conduct work as the AVI outsourced entity".

[23] This has been calculated from the actual expenses incurred, as mentioned in the AVI TAC annual report 2009, 2010 and 2011. These expenditures also include some in-kind contributions from CDC as well as grants to build the evidence base for decision -making related to pneumococcal vaccine introduction in developing countries, assigned via a framework grant provided to JHU.

Figure A5.2: Estimated costs related to accelerated vaccine introduction by activity and by entity (2008)



ANNEX 6: MATRIX MANAGEMENT

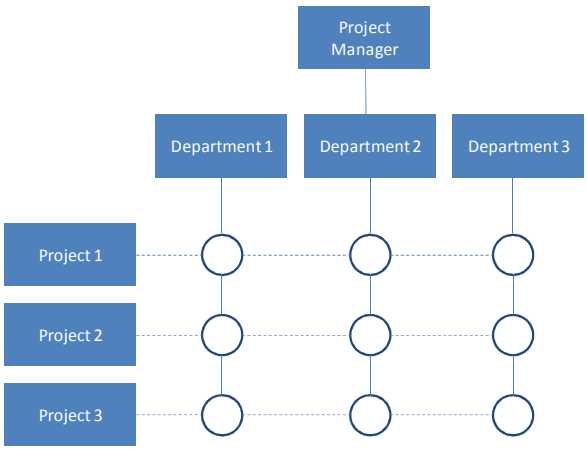
This annex describes the matrix management approach to organising the delivery of cross-functional tasks. It also explores the challenges faced and best practices to overcome these.

Matrix management is a commonly adopted approach to managing multiple priorities and combining capabilities efficiently within an organisation. It is a structure that is often adopted in circumstances when the organisations and/ or individual projects are characterised by a diversity of products, markets and stakeholders, thus requiring specialised inputs from various partners.[24] The matrix model came from the recognition that organisations not only have vertical chains of command but that people also work horizontally, across their functional specialisation.[25] In theory, the matrix allows project managers to leverage talent of various staff members to work collaboratively on projects that require cross-specialisation, while staying small and task-oriented. Matrix organisations tend to be adopted for four primary reasons: (i) allows organisations to focus on multiple goals; (ii) facilitates the management of information; (iii) enables organisations to establish economies of scale; and (iv) speeds up response to environmental demands.[26]

The matrix organisational form emerged in the aerospace industry during the 1960s as government contracts required a project-based system linked directly to top management. The matrix organisation became popular and organisations such as Xerox, Digital Equipment Corporation and Citibank all employed two boss matrix management structures as they sought to maximise productivity and harness resources. Although people applauded the intent to keep organisations agile, by the 1980s, it was clear that it was not such an easy task and corporate enthusiasm began to wane.[27]

While in theory, adding a 'dotted reporting line' on the organisation chart, as set out in Figure A6.1, might seem easy, it has often been considered to be difficult to implement in practice.

Figure A6.1: Simple matrix management model



[24] http://www.economist.com/node/14299841

[25] Matrix Management, The Management Lab (link: www.managementlab.org/files/u2/pdf/classic%20innovations/Matrix_Management.pdf)

[26] Adapted from Sy, T. (year), "Challenges and Strategies of Matrix Organisations: Top-level and Mid-level Managers' Perspectives", Human Resource Planning

[27] Matrix Management, The Management Lab (link: http://www.managementlab.org/files/u2/pdf/classic%20innovations/Matrix_Management.pdf)

On the one hand, the matrix encourages innovation and fast action, and speeds up information flows to those who know how to use it, but at the same time it can also be complex and unpredictable since it violates the traditional principles of authority tending to sometimes result in ambiguity and conflict. [28]

In an article in Harvard Business Review in 1990, Christopher Bartlett and Sumantra Ghoshal suggested that the problem with regard to matrix management was that:

> *"Dual reporting led to conflict and confusion; the proliferation of channels created informational log-jams as a proliferation of committees and reports bogged down the organisation; and overlapping responsibilities produced turf battles and a loss of accountability. Separated by barriers of distance, language, time and culture, managers found it virtually impossible to clarify the confusion and resolve the conflicts."*

Thomas Sy from California State University through an extensive survey, identified the following challenges facing the matrix management, in addition to pointing to some of the best practices:[29]

(i) *Misaligned goals* due to competing objectives between matrix dimensions, insufficient communication between matrix management, lack of synchronisation of work plans and objectives in addition to inadequate processes to align goals and detect misalignments. Certain organisations have tried to overcome this by developing 'cascading spreadsheet planning' charts that sets goals by years and cascades them vertically and horizontally. Communicating constantly across members on the vision and objectives of the project is also a useful tool to minimise discord and clarify any ambiguity.

(ii) *Unclear roles and responsibilities* due to unclear job descriptions and guidelines that can often create tension among employees and not knowing whom to contact for information. In order to overcome this, the study points out that the project teams must have clear guidelines and descriptions on roles/ areas of responsibility, assignment of accountability for business objectives, a single point of contact for information or approval for areas of responsibility and a set plan for communication and information sharing. In addition, project managers are also suggested to adopt 'RASIC' tool which is essentially a matrix whereby each project member's roles are defined across work streams as Responsible/ Approval/ Supports/ Informed/ Consulted.

(iii) *Ambiguous authority* due to lack of clarity on areas of accountability, confusion over who has the final authority and leaders unaccustomed to sharing decision rights, all leading to delay in decision making process. The survey found out that team members/ project managers with the most accurate information made the best decisions.

(iv) *Lack of a matrix guardian* who is responsible to identify best practices that can be disseminated throughout the company and is in a position to influence within the organisation. This leads to problems in establishing a monitoring process to detect and identify matrix performance related problems.

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[28] Sy, T. (year), "Challenges and Strategies of Matrix Organisations: Top-level and Mid-level Managers' Perspectives", Human Resource Planning

[29] Ibid

(v) *Silo-faced employees* as they view their membership, and loyalty as belonging to a certain (part of) organisation leading to personal conflicts, withholding resources from others and lack of trust between employees. Best practices in this regard include defining expectations from the team members through organising workshops and emphasising on the desired behaviours and attitudes that facilitate matrix performance, providing training to reinforce desired behaviour and also ensuring that the team members buy-in the concept of the project as well as the management structure.

ANNEX 7: KEY DECISIONS AND REFERENCES TO AVI BY THE GAVI BOARD AND PPC

This annex provides a summary of the key issues discussed and the decisions made by the GAVI Board and the PPC with regards to the AVI initiative. Tables A7.1 and A7.2 identify the relevant points from the GAVI Board and PPC minutes respectively (full references are included in the bibliography section, under Annex 1).

Table A7.1: Summary of GAVI Board minutes as related to the AVI initiative

Meeting date	Issues discussed	Key Board decisions
June 2008	*Meningitis investment case, Claire Broome, Chair of the IRC investment case team* • While discussing the Meningitis investment case, it was suggested that the budget for Meningitis would be restructured to reflect areas that will be funded outside of the investment case, for instance those included in GAVI's AVI support. *AVI support strategy, Nina Schwalbe, Director of Policy, GAVI* Subsequent to the presentation of AVI support strategy, the discussion focussed on the following points: • Although the strategy focussed on pneumococcal and rotavirus vaccines, it was suggested that AVI serve as a platform to support the introduction of future vaccines, reducing the costs and time for their introduction. • In order to support country capacity building, the outsourced entity that was to support country decision making on vaccine introduction was required to actively partner with in-country institutions. • The additional budget set aside for future special studies was to allow GAVI to support countries in their decision making on vaccine introduction. The studies were said to be needed on a case-by-case basis and would help countries address such issues as disease burden and optimisation of a new vaccine introduction within existing schedules. These individual studies were likely be conducted with the help of in-country research partners.	• Delegated authority to the Secretariat to work with the investment case developers to conduct an in-depth review of the budget, up to an envelope of US$ 370m (2009-15), and define the specific amounts in funding agreements with WHO and UNICEF to implement their components of the strategy. The Boards were to be presented with the final budget for approval at their October 2008 meeting. • Endorsed the scope, capabilities and budget envelope of US$ 99.6m (2009-15) for a request for proposals to allow for follow on activities to the ADIPs through an outsourced entity (US$48m of which would be set aside for future special studies). • Endorsed a budget of US$ 14.9m for WHO for surveillance activities in 2009-2010 (GAVI will need to decide whether to fund these activities post-2010). Currently

Meeting date	Issues discussed	Key Board decisions
		funded under the ADIPs, these activities are scheduled to come to an end as of December 2008. • Endorsed a budget of US$ 256,800 for WHO/UNICEF and US$ 2.8m for six countries to support the introduction of pneumococcal 7-valent vaccine in pre-filled syringes.
October 2008	*AVI outsourced entity, Nina Schwalbe, Director of Policy, GAVI* Overview of the RFP selected for the AVI outsourced entity was provided. The Secretariat recommended a consortium lead by PATH. The following points were subsequently discussed: • Board members requested further clarification on the management structure for the AVI at the meeting scheduled for June of 2009.[30] • The Secretariat was said to be negotiating the final terms of the agreement with the consortium selected to serve as the outsourced entity. The draft proposal was proposed to be available to board members upon request.	• Approved US$ 51.3m for 2009-2015 for PATH/JHU/CDC to conduct work as the AVI outsourced entity.
June 2010	*Report to the PPC, AVI, Jon Pearman, Head, AVI* The management structure and activities were reviewed as well as the current priorities were set out. The following points were then discussed: • AVI is a core alliance activity. As such, AVI should remain a standing item on the Board's agenda. • Tracking and raising vaccine demand was said to be a comparative strength of GAVI as demonstrated by the introduction of Hib vaccine. AVI was suggested to be the proper place to house and monitor this function. The Secretariat should be properly resourced to support the initiative.	No decision was taken in this regard.
November-December	*AVI Progress Report, 2010, update provided by Jon Pearman, Director AVI* It was highlighted that the pneumococcal vaccine supply is tight for 2011-12 but it is being	No decision was taken in this regard.

[30] We did not see any references to AVI in the relevant minutes for meetings that took place in 2009.

Meeting date	Issues discussed	Key Board decisions
2010	managed and supply beyond 2013 was said to be solid based on indications from suppliers. The following points were then discussed: • The Chair noted the importance of linking AVI activities with broader advocacy messages and the GAVI replenishment. • It was noted that AVI has created an effective platform for, and provided important lessons on, the roll out of future vaccines.	
July 2011	*AVI update, Jon Pearman, Director, AVI and Carsten Mantel, Medical Officer, WHO* • AVI's managements structure, planned introduction of pneumococcal, rotavirus, MenA and YF vaccines were explained. • The potential implementation of HPV, Typhoid, JE, and Rubella vaccines was discussed, highlighting the unprecedented number of country introductions forecast for new vaccines. • Further, they reported on building a platform for new vaccine introduction, the role of GAVI and partners in evidence based decision making assisted by monitoring and surveillance, and strengthening introduction. • The pneumococcal supply situation was summarised as 'sufficient' in 2011, 'tight' in 2012-13 with close management needed, and 'solid' from 2014. They noted that the initiative is in good shape and there is strong demand for new vaccines and that there is special focus on 2012 business planning to ensure appropriate emphasis on AVI's activities. Following points were then discussed. • The Chair confirmed that AVI updates will remain as a standing item on the Board's agenda. • WHO's participation in the update was welcomed. • A workplan that lays out the roles and responsibilities of the Secretariat and each partner (at global and local levels) was suggested to be helpful. There were various opinions with regard to how quickly GAVI should open new vaccine windows, particularly since its credibility will depend on the successful introduction of pneumococcal and rotavirus vaccine. • There could be examples of best practice to be drawn upon, as demonstrated by the positive experience of HPV introduction in Rwanda and the activities of civil society	No decision was taken in this regard.

Meeting date	Issues discussed	Key Board decisions
	organisations in many GAVI countries. • Much of GAVI's advocacy was said to be focused on lives of children saved. However, GAVI's work also reduces childhood morbidity and adult illness. GAVI and implementing partners may consider determining appropriate metrics for measuring impact in these areas and further strengthen and improve administrative data collection and surveillance systems. They should then include them in advocacy activities. • Countries were said to be largely responsible for success on the ground. GAVI and implementing partners were suggested to have a role in facilitating and expanding country capacity and should have an aligned plan in supporting countries. Continued concern was expressed over the potential bottleneck to rapid introduction from lack of country cold chain and logistics systems especially at peripheral levels where there is limited electricity and the cold chain can be fragile. • The number of vaccine introductions per year averaged four over the first seven years of GAVI's existence. Notably, over the last few years the number had risen to 20, and in 2013 is anticipated to reach 50 per the current strategic demand forecast.	
November 2011	*Programme update, AVI, country programmes and large countries, Jon Pearman, Director AVI and John Wecker, PATH, AVI TAC* • Progress on vaccine introduction was summarised and the ongoing challenges on building a successful platform for future introduction of new vaccines were reviewed. • Potential new windows for HPV and Rubella were discussed along with the status of introduction of pneumococcal, rotavirus, MenA and YF vaccines. • In addition, status update on specific work streams which support vaccine roll-out; the role of GAVI and partners in tracking country readiness, cold chain surveillance, special studies, demand forecasting and advocacy and communications. • Unprecedented demand for vaccines by countries and supply constraints were also discussed. It was hoped that GAVI will perform over and above business plan requirements in terms of pneumococcal and rotavirus introductions, reaching 58 and 46 introductions respectively by 2015. The following points were then discussed: • The Board acknowledged that the coordination of implementing partners through the AVI platform is an important function of the GAVI Alliance structure.	No decision was taken in this regard.

Meeting date	Issues discussed	Key Board decisions
	• In addition to reporting on the number of introductions there was a request to report on coverage and numbers of children vaccinated. • There was a discussion on the reasons for supply shortage, a request for clarity on the countries impacted, and an explanation of how mitigation strategies were being actively pursued. • Participants also requested that the strategy for special studies come back to the Board after review by the PPC. • Several Board members queried whether some countries have the capacity to maintain routine immunisation and introduce and sustain new vaccines. It was noted that country priorities should drive new vaccine introduction. • Board members noted that an evaluation of the AMC is scheduled for 2012 and that the results may be interesting for many as a model. • The Board also discussed the importance of accurate demand forecasting as this is critical for determining supply.	

Table A7.2: Summary of GAVI PPC minutes on the AVI initiative

Meeting date	Issues discussed	Actions
April 2009	*AVI initiative Update (Jon Pearman, joined by Rudi Eggers)* Jon Pearman, AVI manager, gave an update on AVI. Jean-Marie Okwo-Bele, Director of Immunisation, Vaccines and Biologicals (IVB) at WHO, added relevant highlights from the recent SAGE meeting regarding H5N1 stockpiles, measles 2nd dose, hepatitis birth dose, and rotavirus. The following points were then discussed: • The PPC discussed the meaning of the word "accelerated" in AVI and recognised the significant potential contribution to lowering childhood mortality of widespread adoption of rotavirus and pneumococcal vaccines. The PPC felt that it was appropriate to raise the visibility for pneumonia and diarrhoea and position the vaccines as the centrepiece in a coordinated and comprehensive response. • There was consensus that it is important to learn from the introduction of Hib and consider the potential risks of "pushing out" routine vaccines in favour of new vaccines. GAVI needs to help ensure appropriate resources are in place at country level for introduction of these new vaccines. • The PPC requested regular updates on whether or not milestones were being met with a particular focus on what was happening at country level. • There was broad support for the use of advocacy at country level and a comparison was made with the introduction of anti-retrovirals where change was brought about through innovation and activism. GAVI needs to understand the current and anticipated barriers and work as quickly and efficiently as possible to address them. GAVI should also consider ways to involve Civil Society Organisations (CSOs)/Non-governmental Organisations (NGOs) in mitigating anticipated barriers to the introduction of new vaccines.	• The AVI team will provide regular updates to the PPC, including an analysis of current and potential bottle necks (October). • The Secretariat will distribute the integrated work plan when it is completed. This will include a description of all special studies (June).
October 2009	• PPC members requested regular updates on the AVI. It was noted that information had been included in the materials sent out in advance of the meeting. Members were thus asked to advise the Secretariat about the kind of information required.	The PPC asked that any updates that are provided regularly to Board members be provided to the PPC members as well.
February 2010	Jon Pearman, Head, AVI reviewed the AVI programme structure, updated the Committee on AVI activities and described the programme's current priorities. The following points were then discussed:	No action was taken in this regard

Meeting date	Issues discussed	Actions
	• The Committee recommended that the AVI be made a standing agenda item at Board meetings. • It was suggested that Secretariat with support from WHO, UNICEF and other AVI members as required brief those PPC members interested in more technical aspects of the AVI prior to each PPC meeting, possibly the afternoon before the regular PPC meeting. • It was suggested that AVI develop and monitor indicators of the "quality" of vaccine introductions in addition to the number of countries that introduce Pneumococcal and rotavirus vaccines.	
May 2010	Jon Pearman, Head, AVI, PPC updated the committee summarised key AVI activities completed since the prior PPC meeting and ongoing activities for the remainder of 2010. He also described the cross functional production launch approach that had been applied to project management. The following points were then discussed: • The PPC welcomed the update on AVI and thanked the Secretariat and partners for the technical briefing conducted on the day prior to the PPC meeting. The quality of that briefing and information provided was commended by those PPC members who had been in attendance. • The consensus of the committee was that it was important to be briefed on the full breadth of the work being done in the AVI, particularly from a risk management perspective. • Committee members acknowledged that the AVI is at the centre of the Alliance and demonstrates the innovation and added value that can be achieved through partnership. They also acknowledged that partnerships are not "cost free" and that was important to keep learning from innovation. • The committee suggested that June Board presentation emphasise the overall framework and breadth of the AVI, as opposed to operational details. • For the next PPC meeting, they requested additional information on management structure including links with resource mobilisation activities and country level work by WHO and UNICEF. Further, as per the briefing, the presentation would focus on cold chain assessment and special studies.	No action was taken in this regard
October 2010	Jon Pearman, Head, AVI, PPC provided a summary of key AVI activities completed since the prior PPC meeting and ongoing activities for the remainder of 2010 and beyond.	No action was taken in this regard

Meeting date	Issues discussed	Actions
	• Given the large populations of unimmunised children in large countries like Nigeria, India and Indonesia, the Committee agreed that it needed to formulate viable options to support immunisation in these countries. • The Committee noted the Secretariat's plan to conduct a management review of AVI and asked that options be explored on the most appropriate means of engagement with PPC.	
March 2011	*AVI general update* Jon Pearman, Director of AVI for the Secretariat reviewed the AMT structure and how it supports Strategic Goals 1 (regarding underused and new vaccines) and 4 (regarding shaping vaccine markets). • He presented version three of the SDF, noting that the applications for support were expected to increase from previous years. However, associated expenditure projections would hold steady based on expected vaccine price declines and increased co - financing support. • On the rollout of pneumococcal and rotavirus vaccines, it was expected that 19 countries would introduce pneumococcal vaccine to 14m children by 2012; five countries would introduce rotavirus vaccine to three children in the same period. A dashboard tracking vaccine introduction was presented and key challenges were highlighted, including introduction in India and Nigeria and human resource constraints given the expected number of applications. The following points were then discussed: • Though sufficient supply to support all of the introductions was anticipated, several Committee members were concerned with the human resource impact on partners, in particular in view of the increase of country introductions of pneumococcal and rotavirus vaccines. • The dashboard was praised as a tool to monitor progress and it was hoped to improve. • The Secretariat was asked to present an options paper to the PPC on future GAVI investments in evidence for decision making and assessing impacts of vaccines. This was to be presented to the PPC in September 2011 and would address whether the funds endorsed prior to the governance transition to support special studies were available. • An evaluation of AVI was discussed by the Evaluation Advisory Committee. The Secretariat will circulate the minutes of the Evaluation Advisory Committee, which	No action was taken in this regard

Meeting date	Issues discussed	Actions
	include recommendations on the scope and nature of such a review. In short, they recommended it be included as part of a wider effort to evaluate the partnership aspects of the Alliance, rather than a specific effort focused on AVI management arrangements. • The Committee queried the timeline for funding decisions on the May 2011 round. The Secretariat clarified that the Executive Committee requested a paper on this issue and it will be presented to that committee in April. *AVI Special Studies* Orin Levine, Director of Special Studies for the AVI TAC outlined GAVI's history of strategic investments in research and surveillance, noted that past and current studies provide key evidence for decisions GAVI and its partners take in funding immunisation. As examples, he reviewed how 2003-06 studies on rotavirus herd immunity "bounced-back" and pneumococcal serotype analysis had informed decisions to pursue interventions against these diseases. The current studies were said to be winding down and new investments were suggested be considered to inform future decisions. The following point were then discussed: • Anne Schuchat, Mickey Chopra, and Jean-Marie Okwo-Bele noted their organisations' (U.S. CDC, UNICEF, and WHO, respectively) interests in all matters pertaining to AVI given they receive funding from the initiative. • The Committee agreed that although GAVI does not fund the research and development of vaccines, the Alliance has brought a lot of value funding vaccine impact studies. To prevent ambiguity between GAVI, its partners, and stakeholders, GAVI should define what research or evaluation activities it is willing to fund and what is out of scope. This could help facilitate decision making by other funding agencies. • Impact research on health systems should be considered as part of the review of research funding. In addition, some clarification on the research aims of the Decade of Vaccines would be helpful to prevent overlap.	
May 2011	Application guidelines and implementation strategies for HPV, JE, Typhoid and Rubella vaccines were discussed.	No action was taken in this regard
September 2011	Jon Pearman, Director, AVI, Carsten Mantel, WHO and John Wecker, PATH updated the Committee on AVI activities, including recent pneumococcal and rotavirus vaccine introductions. Following points were then discussed: • Committee members appreciated the update. They also expressed appreciation for the	No action was taken in this regard

Meeting date	Issues discussed	Actions
	inclusion of MenA and YF in the presentation and requested to receive more information on these activities in future reports. • Some members commented that surveillance data and special studies were necessary as new vaccines are introduced to allow countries to make more informed decisions on impact and value for money, which could lead to faster uptake and post-graduation commitment to the new vaccine. Further, the Committee requested the Alliance to explore opportunities to streamline surveillance activities and work with other partners so that countries do not end up with parallel surveillance teams for each new vaccine introduced. Members requested that the next AVI report should present a long term look at surveillance and asked to receive the results of the ongoing special studies prior to the spring of 2012 to inform decision-making. • Committee members requested more information on AVI-TAC, how it was working, how much it feeds into in-country coordination and more on regional and sub-regional activities. • With respect to supply shortage, the PPC asked about lack of product availability for the GAVI market. • Given that some countries during their introduction of the pneumococcal vaccine provided vaccinations to children outside of the EPI schedule, in a supply constrained environment, GAVI must develop clear guidelines on GAVI-supported vaccines and communicate those guidelines clearly to countries. • In response to questions, the Secretariat explained that the vaccine allocation process is being used, along with other considerations, in cases where demand is greater than supply to determine the order and time frame for countries to receive the product	
November 2011	The PPC expressed the need to get more details on the implementation of the vaccine introductions and health system strengthening activities. The CEO would regularly report back to the PPC and the Board on this matter. He also pointed out that there are a number of mechanisms in place to manage these activities where most partners are represented (e.g. AVI management team weekly meeting).	No action was taken in this regard

ANNEX 8: OUTPUTS OF AVI ACTIVITIES

In this Annex, we set out some of the main outputs (as collated and summarised by CEPA) that have been delivered to date for AVI initiative related activities. These are not exhaustive and are grouped under each of the five identified outcomes of AVI, including[31]:

(i) sufficient quantity of safe, effective appropriate vaccine to meet the demand;

(ii) financing available to pay for the vaccines and systems cost;

(iii) a well-informed country decision on introduction of the vaccine;

(iv) country introduction of the vaccine; and

(v) establish platform for the sustained use of the vaccine.

The outputs listed in Table A8.1 below have been sourced from the GAVI workplan report (2010), various progress reports presented to the Board and the PPC and the Annual TAC Reports.[32] These have helped inform the AVI results analysis.

Table A8.1: List of AVI outcomes to date

Year	Outputs
Outcome 1: Sufficient quantity of safe, effective, appropriate vaccine to meet the demand	
2011	*Suppliers build capacity to supply vaccine to GAVI* • Supply constraints in the period 2012-13 are being managed through active monitoring of demand, utilisation and supply, particularly in countries with large birth cohorts. Several risk mitigation procedures are being implemented including discussions with manufacturers to understand the potential availability of additional supply. It is anticipated that the supply situation will improve from 2014 as current manufacturers continue ramping up production levels. • Second Call for Supply Offers to contract additional doses of pneumococcal vaccine was issued in 2011 by UNICEF. Four offers were received which were to be finalised by November 2011. • An Expression of Interest (EoI) was issued to industry to inform future procurement strategies for rotavirus vaccine. Subsequently a Request for Proposal was issued to five vaccine manufacturers, having either a prequalified vaccine or vaccines in the pipeline expected to

[31] The activities/ outputs have been categorised by CEPA based on the tasks defined in 'The AVI Framework – Partner mapping results", Report on the Mapping and Costing of Activities.

[32] AVI TAC Annual Reports 2009, 2010 and 2011 include further details on deliverables by the AVI TAC for the three years. These are not covered comprehensively in these tables.

Year	Outputs
	reach the market by 2016. Prior to the pledging conference, several suppliers made their prices publicly available and committed to provide rotavirus vaccines at a significantly lower price. • AVI TAC through its SVS team defined a standardised transparent methodology and reporting process and facilitated communication across stakeholders within the Alliance through ongoing consultations. SDF 4.0 was subsequently delivered in August 2011.
2010	*Prequalify relevant pneumococcal and rotavirus vaccines* • Regulatory mechanisms: Pre-qualification of the two pneumococcal conjugate vaccines was completed through a fast-track mechanism in 2010 making it possible for Nicaragua to introduce the vaccine the same year. Two rotavirus vaccine candidates had previously been prequalified by WHO and in 2010 one GAVI - eligible country (Guyana) introduced a rotavirus vaccine. • A WHO prequalification database to monitor applications submitted to WHO was finalised in 2010 and data is now being systematically uploaded. • WHO conducted assessments of four countries' National Regulatory Authorities (NRAs) in 2010 and worked with a further six countries to develop their institutional development plans that will allow them to ensure quality of vaccines being used in-country and also, where relevant, to be eligible to export domestically produced vaccine to other GAVI-eligible countries. *Suppliers build capacity to supply vaccine to GAVI* • As part of AVI, the SVS team provided GAVI with strategic demand and adjusted forecasts for all nine vaccines in the GAVI portfolio. Two versions were delivered (in January and August) in advance of key GAVI Alliance meetings and a third version was begun in late 2010. • The SVS team also delivered a draft version of supply forecasts for pneumococcal, rotavirus and pentavalent vaccines to provide an initial overview of the global supply available. During 2010, the development of the new integrated vaccines forecasting suite (IVFS) platform progressed with delivery in November 2010. • Through inter-country workshops and individual country visits WHO supported all regions to strengthen countries' capacity for assessing vaccine demand and supply thus enhancing their ability to manage their vaccine stocks optimally. Examples in 2010 include: the launching of a feasibility study to establish pooled vaccine procurement in the Eastern Mediterranean region, and joint work with UNICEF Bangkok Regional Office and Supply Division on the demand forecast and planning in Pacific island Countries.
Outcome 2: Financing available to pay for the vaccines and for system costs	
2011	*Advocate for increased support for new vaccines* • AVI TAC supports the GAVI Programme Delivery Team in the provision of targeted messaging on GAVI policies, procedures and Board decisions for decision makers and other key stakeholders in GAVI countries. Examples include the development of a communication strategy identifying audiences; messaging, timelines and evaluation methods; Frequently Asked Questions (FAQs) on co-financing and graduating countries; standardised presentations for GAVI country visits and sub-regional meetings; a survey on country communications; a "How to Apply" guide on the Health Systems Funding Platform; and, content for the GAVI website.

Year	Outputs
	• The United Kingdom's All Party Parliamentarians Group (APPG) undertook several activities in support of GAVI, including a May event hosted by the UK government in the House of Parliament in support of GAVI's June pledging conference. The Secretariat of the APPG, housed by AVI TAC, also provided an analysis of public and parliamentary reaction to the June pledging conference and suggested ways to maintain solid support for GAVI funding by the UK government after the conference.[33] • AVI TAC-supported media tour in Sierra Leone generated a lot of media attention along with reaching millions in key donor countries including Australia, France, Germany, Ireland, Norway, UK, and US. A three -minute video was also prepared on pneumonia and diarrhoea in Sierra Leone that showcased how vaccines can protect children from the leading causes of these two killer diseases, together with positive coverage in specialist health and scientific media and websites which further amplified reach.[34]
2010	*Advocate for increased support for new vaccines* • A&C supported advocacy workshops for the International Paediatrics Association and the Pan African Parliament, country-level activities for World Pneumonia Day (WPD), and provided potential spokespeople for special meetings and events at GAVI's request. The team also continued collaborations with the APPG, the Pneumococcal Awareness Council of Experts, and the Global Coalition against Childhood Pneumonia.[35] • A&C led a media tour to Rwanda one year after pneumococcal vaccine roll-out, attended by six major international news organisations and resulting in over 150 news items, many in donor countries. The Lancet featured a story in the success of the Rwandan health model, the role of GAVI, and the importance of the pneumococcal vaccine.[36]
Outcome 3: A well-informed country decision on the introduction of the vaccine	
2011	*Create the vaccine safety, immunogenicity and efficacy data* • Strategies were being refined to assess the risk of the disease in new areas and ascertain the immediate needs for ongoing country support for YF prevention • GAVI funded a number of activities in 2011-2012 for WHO to prepare for the November 2011 GAVI Board discussions on the possibility of opening an application window for HPV vaccines in 2012. The activities included developing and communicating updated technical guidance on HPV vaccine introduction and comprehensive cervical cancer prevention; developing and disseminating tools for countries to collect data needed for decision making on introduction; additional operational research to identify how to ensure affordable and sustainable delivery and monitoring introductions in early adopter countries.

[33] AVI TAC (2012), "AVI TAC Annual Report 2011"
[34] Ibid
[35] AVI TAC (2011), "AVI TAC Annual Report 2010"
[36] Ibid

Year	Outputs
	• Since no JE vaccines had been prequalified by the WHO, timelines for introduction and plans to date were considered to be preliminary. • Rubella vaccine was decided to be implemented only in countries that have reached measles coverage of at least 80 percent. • Though typhoid vaccines have a WHO recommendation for use, the use of polysaccharide and oral vaccines was suggested to be re-assessed in view of the delays in the development of the conjugate vaccine. *Package vaccine data for decision makers and present to decision makers and the influencers of decision makers* • In Burkina Faso, AVI TAC supported GAVI to build an African Francophone CSO network of advocates for child health and immunisation and helped organised a mini symposium in Burkina Faso on advocacy and vaccinology for 100 African paediatricians. [37] • AVI TAC implemented an advocacy strategy in Georgia to support in-country decision making. [38] • AVI TAC supported pneumococcal roll-out in Kenya, along with assisting the Government of Kenya in Diarrheal Disease Control Policy launch and supporting communications input and background briefings to support a parliamentary visit to Kenya that resulted in members of parliament from Cameroon, Germany, Kenya, and the UK becoming GAVI champions. [39] • Similar advocacy efforts were also extended in Malawi, Sudan and Yemen as part of its country communication strategy. • Ensure global and regional policies are in place to guide countries in making vaccine introduction decisions • Results from the landscape analysis of pneumococcal vaccine dosing schedules were presented to SAGE in November 2011. These findings contributed to a new SAGE statement supporting either 3+0 or 2+1 schedules.[40] • Findings from the Gates Foundation's pneumococcal Serotype Replacement Review were presented to SAGE in November 2011 and were incorporated into a new SAGE statement.[41] *Support for country level decision-making* • With coordination provided by WHO, the Men A working group supported the introduction of the new vaccine in two additional countries, Mali and Niger – reaching nearly 19m people to date. • Through GAVI's investments in AVI TAC Special Studies and WHO Surveillance, new studies regarding vaccine introduction and sustainability are being conducted to help countries and advisory bodies to make evidence-based decisions by providing data that directly answer key policy questions. Most of the current studies are due for completion in late 2011 and 2012 and several of the reports will help

[37] AVI TAC (2012), "AVI TAC Annual Report 2011"
[38] Ibid
[39] Ibid
[40] Ibid
[41] Ibid

Year	Outputs
	inform rotavirus introduction in the coming years. A paper on the results of a meta-analysis of trial data on strain specific protection for rotavirus vaccine was submitted for publication, the pneumococcal conjugate vaccine impact assessment manual and generic case-control study protocol was submitted to WHO for internal review and clearance, and a paper on the mathematical modelling of rotavirus transmission patterns to inform optimal vaccine schedules was said to be undergoing peer review. • AVI is currently working on (i) pneumococcal vaccine schedules; (ii) serotype replacement following introduction of pneumococcal vaccine in national immunisation programmes; and (iii) surveillance for invasive bacterial diseases through collaboration between WHO and AVI TAC to help inform global use of pneumococcal vaccine. • Preliminary results on the effectiveness of pneumococcal vaccine among HIV-positive populations from were presented to the South African National Advisory Group on Immunisation (NAGI). Results informed NAGI's decision to recommend a three -dose primary schedule for HIV-positive children instead of a 2+1 schedule used for all other children.[42] • Results from the RotaTeq® vaccine effectiveness study in Nicaragua were shared internally with a PAHO Technical Advisory Group and the Ministry of Health of Nicaragua.[43]
2010	*Create health and economic impact data* • Global estimates of the number of cases of severe illness cases and deaths due to Hib and Streptococcus pneumonia for the year 2000 were published by WHO in September 2009. These estimates are being updated for the year 2008 (after widespread introduction of Hib and partial introduction of pneumococcal vaccines) and will be available for public use in 2011. *Support for country level decision-making* • No application round was held in 2010 by GAVI, therefore no formal applications were prepared. However, WHO continued to provide support and advice to countries considering introducing new vaccines. Examples of activities in 2010 include: providing consultancy and advocacy support to accelerate decision-making on introduction of new vaccines in seven countries in the European region. • Work on the Vaccine Product Selection Menu was completed by WHO, in collaboration with UNICEF and other global and regional partners, and all decision- making tools and materials are grouped in one area of the New and underused Vaccine Implementation (NUVI) website. • In 2010 UNICEF provided technical support to 13 countries (against a target of 10) to make evidence based decision on new vaccine introduction and to design and prepare new and underused vaccine support applications. In addition, UNICEF is working to maximise the benefits of pneumococcal conjugate vaccines and rotavirus, by using their introduction to enhance other aspects of pneumonia and diarrhoea control. The approach was further endorsed by the 2010 World Health Assembly (WHA) resolution on pneumonia. *Vaccine data packaged and presented to decision makers*

[42] Ibid
[43] Ibid

Year	Outputs
	• Some of the activities in 2010 included development of regional and country targeted materials (Kenya, Nicaragua, Tanzania country briefing packets), building advocacy coalitions (advocacy training at the Pan African Parliament), delivery of key advocacy and communications messages (media tour of Rwanda one year after pneumococcal vaccine roll- out), supporting the execution of regional and country- specific events (materials development for World Pneumonia Day). *Assess country readiness to introduce* • WHO has been supporting countries to assess their cold chain status and vaccine management capacity in preparation of introducing new vaccines in 2011 through the global development of standardised tools, inter-country workshops to train countries in the implementation of these tools, and through technical support provided in countries in the use of the new tools. In 2010 WHO supported Effective Vaccine Management Assessments (EVM) in 14 countries (plus two states in India) and cold chain assessments in 10 countries, meeting the 2010 targets in both instances. *Global policy guidance* • A global guidance document was updated and published in April 2010 in a Vaccine supplement, which also contains articles from 15 countries about specific National Immunisation Technical Advisory Groups (NITAGs) as a means of sharing information between countries. WHO regional offices continue to support and conduct country workshops and meetings on NITAG establishment and strengthening.
Outcome 4: Country introduction of the vaccine	
2011	• Since November 2010, GAVI, WHO, UNICEF and AVI TAC have been working closely through the Pneumo Ad-hoc Introduction group to ensure day-to-day operational coordination, information sharing and trigger country support activities. • AVI has been collecting data from GAVI countries which are implementing pneumococcal programmes and have offered vaccines to all children under one year of age, irrespective of their pentavalent status, to see its impact on demand levels within the country. • In order to successfully accelerate vaccine introductions and monitor AVI's progress towards achieving its mission, GAVI and AVI TAC developed a country readiness dashboard currently being piloted for both the pneumococcal introduction group and the rotavirus introduction group. • Rota Ad-hoc group was said to be reviewing in-country data that could influence demand in the following years. • Men A vaccine working group was set up to facilitate the introduction of the Men A vaccine across affected countries in Africa. *Countries have sufficient cold chain capacity in place* • WHO assessments of cold chain capacity at the national level reveal that of the 72 GAVI-eligible countries, 63% – 67% already have sufficient capacity to introduce either pneumococcal or rotavirus vaccines, while 50% of GAVI eligible countries would have sufficient central storage space to introduce both vaccines. This readiness has been attributed to the efforts by countries over the last 10 years to increase capacity in order to receive the single or two dose vial presentations of pentavalent vaccine which are far more voluminous than the

Year	Outputs
	traditional EPI vaccines in multi-dose vials. *Large country introduction* • A Large Country Task Team was established to evaluate GAVI policy options for India and Nigeria, with consultations being carried out with India (May 2011) and Nigeria (July 2011). • In Nigeria, AVI TAC supported the government in their application for pentavalent and pneumococcal vaccine and by advising on a number of issues. Consultations were also conducted by the TAC as part of an analysis of the strengths and weaknesses of the Nigerian immunisation programme which helped form the basis of an AVI TAC's large country advocacy and communication strategy in Nigeria. AVI TAC has undertaken an analyses of the situation of the routine immunisation program down to the state level to facilitate discussions at the state level where the barriers to immunisation need to be addressed.[44] • AVI TAC regularly briefs GAVI on the environment in India and discusses crisis communications plans, linking GAVI with local agencies within India. The TAC monitors and investigates negative media and provides background information to the Media and Communications team. AVI TAC developed an FAQ document identifying criticisms, truths, and technical facts in the media and has worked with experts in India to gather input on use of and responses to the document.[45] • AVI TAC provided GAVI with regular updates on the India advocacy program sponsored by the and its progress in achieving greater interest in the pentavalent vaccine at the state level. Through that project, AVI TAC leverages the work of partner JHU to provide technical input to answer some of the more difficult questions and maintain regular contact with the technical community in India that responds to the anti -vaccine lobby. [46] • In January 2011, AVI TAC and GAVI's External Relations Office jointly issued a crisis communication plan for handling partner responses to global media from the anti -vaccine lobby; AVI TAC has been engaging partners in discussions about significant issues during the year.[47] *Social mobilisation* • UNICEF developed a Communications Framework to support the introduction of new vaccines. The Framework provides guidance for countries to develop and implement communications plans to inform and motivate families to adopt healthy actions – such as breast feeding, hand-washing and care-seeking to prevent, protect and treat pneumonia and diarrhoea.
2010	Given that there were no application round in 2010, no new countries have been in a position to apply or receive GAVI support for new or underused vaccines. The WHO focus was redirected to providing support to countries with pending application decisions including responding to conditions proposed by the GAVI Independent Review Committee (IRC) for country applications.

[44] AVI TAC (2012), "AVI TAC Annual Report 2011"
[45] Ibid
[46] Ibid
[47] Ibid

Year	Outputs
	Train health care professional • Due to the lack of country introductions in 2010, limited health care worker training was conducted in countries. However, WHO continued to prepare training materials for pneumococcal and rotavirus vaccines. *Countries have sufficient cold chain capacity in place* • UNICEF continues its interagency work to support developing country capacity in building Cold Chain and Logistics systems (CCL) systems. UNICEF hosted a CCL Guidance Workshop in October 2010 to review and synthesise CCL guidance available, identify gaps and resolve discrepancies, and provide a dissemination platform for users on the ground. UNICEF supported WHO in the development of the new Effective Vaccine Management Assessment tool. This also includes support for the first Global Effective Vaccine Management Training in Cairo in July 2010. Twelve Logistics and Supply Managers from 12 GAVI-eligible countries participated in the training. At country level, a range of CCL-system strengthening activities was supported by UNICEF in 2010, including: Support to develop a National Maintenance Plan for the CCL in DRC, A Vaccine Management Training for 33 provincial cold chain managers in Indonesia, Technical cold chain support and funds provided to Yemen, North and South Sudan and Djibouti. *Large country introduction strategy* • In 2010, WHO supported Democratic Republic of Congo (DRC) to prepare for introduction of 13-valent pneumococcal conjugate vaccine (PCV13) in 2011 by developing a detailed calendar of pre-introduction activities and specifically assessing the readiness of the cold chain for the vaccine. Extensive discussions have been ongoing with the Governments of Pakistan and India to assist these countries in their decision - making processes. Extensive support was provided by WHO in Kenya to enable the country to introduce 10-valent pneumococcal conjugate vaccine (PCV10) vaccine which had certain conditionalities around its prequalification. Such support was provided in the area of safety and programmatic monitoring and in intensified training for health - care workers. *Social mobilisation- Communication strategies at community level* • Example of Communication for Development (C4D) work conducted by UNICEF in 2010 includes: scale up of overall C4D capacity, strategic planning and coordination, while providing specific focus on immunisation, new vaccines and meningitis in the Western and Central African Region; a Central and Eastern Europe/Commonwealth of the Independent States regional initiative to strengthen national heath communication and promotion capacities from a health systems strengthening perspective.
Outcome 5: Establish platform for the sustained use of the vaccine	
2011	*Enhance regionally appropriate surveillance systems* • WHO's focus during 2011 and 2012 is to further improve data quality. Global laboratory external quality assurance programmes have been established this year to improve laboratory diagnostic capacity. Training of laboratory staff is being undertaken using a tiered approach, with the global reference laboratory supporting the regional reference laboratories who in turn train national and sentinel site staff. Invasive Bacterial Vaccine Preventable Diseases (IB-VPD) guidelines are being revised and posters are being developed to provide support to clinical, laboratory and data managers.

Year	Outputs
	Country communication strategies • AVI TAC shall be focusing on advocacy and communications activities at the country level to strengthen political ownership for rotavirus and pneumococcal vaccines programmes and to continue to focus on the importance of delivering on country commitments. Evidence-based materials were proposed to be developed to raise disease and vaccine awareness in priority countries, as well as showcase progress being made in early adopter countries. • Links were to be established with a variety of coalitions operating in GAVI-eligible countries, as well as national and regional media outlets to heighten the quality of media coverage of diseases, vaccines and public health benefits
2010	*Enhance regionally appropriate surveillance systems* • In 2010, the visibility of the Invasive Bacterial Disease (IBD) and rotavirus surveillance networks has been increased through the WHO supported workshops and meetings. During 2010, WHO received rotavirus surveillance data from 55 countries (both GAVI-eligible and non-eligible) that had been provided with technical support by WHO Regional Offices. In addition, WHO received IBD surveillance data from 47 countries. Global Surveillance Bulletins that describe and synthesise the 2009 data were drafted, distributed to partners, and posted on the WHO website. • WHO has entered into contracts with Regional Reference Laboratories (RRLs) in all regions and with two Global Reference Laboratories (GRLs) so that these bodies can assist countries in the quality assurance of their laboratory processes to ensure quality data is available to all at the global, regional and country levels. *Monitor safety of the vaccines post-introduction* • Training materials for causality assessment of Adverse Effects Following Immunisation (AEFI) monitoring have now been fully revised and are available together with a pool of trainers covering all WHO regions. Training in AEFI monitoring has been conducted in four WHO regions in 2010. The safety profiles of three GAVI-supported vaccines (rotavirus, YF and MenA) were reviewed at the Global Advisory Committee on Vaccine Safety (GACVS) in 2010. • Impact of adding new vaccines on routine immunisation: In 2010, post-introduction evaluations (PIE) were conducted in 12 countries in three WHO regions (against a target of at least five countries). The PIE tool was published in 2010 and provides a systematic method for evaluating the impact of the introduction of a vaccine on the existing immunisation system in a country. • WHO coordinated global surveillance networks for rotavirus and. IB-VPD were successfully established with 55 and 47 countries reporting rotavirus and IB-VPD data to WHO, respectively, (January to June 2010). Approximately 70% of these countries were GAVI-eligible. *Crisis communication* • AVI TAC provided GAVI with updated crisis communications planning in 2010. Media monitoring allowed AVI TAC to proactively identify and prepare responses to crisis communications -related issues that emerged in 2010.

ANNEX 9: METHODOLOGY FOR COMPARING VACCINE INTRODUCTIONS RATES

This annexes provides a description of the data sources and methodology for comparing vaccine introduction rates for the vaccines of focus for AVI (pneumococcal and rotavirus) and other GAVI-eligible vaccines (specifically HepB, Hib and YF). It provides a background to the analysis presented in Section 6 of the main report.

Data sources

Data on the year of country introduction of various vaccines has been procured from the WHO (database of 20 September 2011).

Data on projections on year of country introduction for pneumococcal and rotavirus vaccines (2012 and 2013) has been sourced from GAVI – specifically "Report to the GAVI Alliance Board" GAVI, November 2011.

There are some discrepancies between the two data sources[48], and we have used the WHO data in these cases.

Methodology[49]

The following points are relevant with regards to our methodology:

- We have calculated the 'number of years from first licensed vaccine' for a country as the difference between the year in which vaccine was introduced by the country and the year of licensing of the particular vaccine.
    - Year of country introduction refers to introduction of vaccine in the entire country (and not introduction in part of the country, which is also reported in the WHO database).
    - Year of licensing of particular vaccine is the year in which the first vaccine for the disease was licensed, ignoring any subsequent developments in the presentation, dose, etc. For pneumococcal vaccine, we have considered vaccine licensure for PCV10 as against PCV7 since the latter is not considered to be appropriate for Lower and Middle Income Countries (LMIC).[50] For rotavirus vaccine, the year of licensing has been considered as 2004 since (when the vaccine was licensed for EURO and AMRO only) as the first rotavirus vaccine was withdrawn in 1998.

[48] Discrepancies for pneumococcal are for the following countries: Guinea-Bissau, Madagascar, Pakistan, Benin and Nicaragua. Discrepancies for rotavirus are for the following countries: Guyana and Sudan

[49] A similar methodology was employed in the GAVI second evaluation (CEPA and Applied Strategies).

[50] We note that Gambia and Rwanda had introduced PCV7 in 2009 and they switched to PCV13 in subsequent years. For the purpose of our data analysis, we have considered vaccine introduction year for both the countries as 2011, based on our desk based research.

- Prior to 2000, we have only considered countries that were eligible in GAVI Phase I. For these countries, we have considered the total number of GAVI-eligible countries as equal to the those in Phase 1 (i.e. 74).
- In Phase 1 (2000-06), GAVI-eligible countries were 74. In 2002, Timor-Leste was added to the list of eligible countries as it became an independent state and hence GAVI eligible countries from 2002-06 were 75. In GAVI Phase 2 (2007-10), the number of countries eligible for GAVI support was reduced to 73 and includes South Sudan. For 2010-12, we have considered GAVI-eligible countries to be 73 since in 2011, all previously eligible countries were permitted to apply.
- For YF vaccine, 28 countries have been considered to be GAVI-eligible countries, as considered in the SG2 report of GAVI Second Evaluation. We have considered this number for all the three phases of GAVI.
- While the projections for pneumococcal vaccine introduction are based on the number of country applications that have been approved, projections for rotavirus vaccine also includes countries that received 'conditional approval' and 'resubmission' in July 2011 application round.