



GAVI ALLIANCE

**LESSONS LEARNT FROM THE ACCELERATED VACCINE
INTRODUCTION (AVI) PROJECT**

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FINAL REPORT

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ACRONYMS AND ABBREVIATIONS

Acronym	Full description
A&C	Advocacy and Communication
ADIP	Accelerated Development and Introduction Plans
AEFI	Adverse Effects Following Immunisation
AMC	Advanced Market Commitments
AMT	AVI Management Team
APPG	United Kingdom's All Party Parliamentarians Group
AVI	Accelerated Vaccine Introduction
AVI TAC	AVI Technical Assistance Consortium
BMGF	Bill & Melinda Gates Foundation
C4D	Communication for Development
CCL	Cold Chain and Logistics Systems
CDC	Centres for Disease and Control
CHAI	Clinton Health Access Initiative
CEO	Chief Executive Officer
CEPA	Cambridge Economic Policy Associates
CRO	Country Responsible Officer
CSO	Civil Society Organisation
EoI	Expression of Interest
EPI	Expanded Programme on Immunisation
EVM	Effective Vaccine Management
FAQ	Frequently Asked Questions
FTE	Full Time Equivalent
GACVS	Global Advisory Committee on Vaccine Safety
GAVI	(The) Global Alliance for Vaccines and Immunisation
GSK	Glaxo SmithKline
HepB	Hepatitis B Vaccine
H5N1	Influenza A Virus Subtype H5N1
Hib	Haemophilus Influenzae Type b
HI	Hib Initiative
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HPV	Human Papilloma Virus vaccine
HSFP	Health Systems Funding Platform
HSS	Health Systems Strengthening
IB-VPD	Invasive Bacterial Vaccine Preventable Diseases
IBD	Invasive Bacterial Disease

Acronym	Full description
ICC	Immunisation Coordinating Committee
IFFIm	International Finance Facility for Immunisation
IRC	Independent Review Committee
IVB	Department of Immunisation, Vaccines and Biologicals, WHO
IVFS	Integrated Vaccines Forecasting Suite
JE	Japanese Encephalitis
JHSPH	Johns Hopkins Bloomberg School of Public Health
LMIC	Low and Middle-Income Countries
M&E	Monitoring and Evaluation
MC	Management Committee
MenA	Meningococcal A conjugate vaccine
MI	Measles Initiative
MoU	Memorandum of Understanding
MSD	Measles Second Dose vaccine
MVI	PATH Malaria Vaccine Initiative
NAGI	South African National Advisory Group on Immunisation
NIP	National Immunisation Programme
NITAG	National Immunisation Technical Advisory Groups
NRA	National Regulatory Authorities
NGO	Non-governmental organisation
NVS	New and Underused Vaccine Support
NUVI	New and Underused Vaccine Implementation
ODA	Overseas Development Aid
OECD	Organisation for Economic Co-operation and Development
P&P	Policy and Performance (GAVI Secretariat)
PCV	Pneumococcal Conjugate vaccines
PIE	Post-introduction Evaluations
PPC	Policy and Programme Committee
R&D	Research and Development
RFP	Request for Proposal
RRL	Regional Reference Laboratories
RVP	PATH Rotavirus Vaccine Program
SAGE	Strategic Advisory Group of Experts
SDF	Strategic Demand Forecast
SG	Strategic Goal
SSF	Strategic Supply Forecast
SVS	Strategic Vaccine Supply
TAC	AVI Technical Assistance Consortium

Acronym	Full description
ToR	Terms of Reference
UN	United Nations
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
US	United States
USAID	United States Agency for International Development
VIS	Vaccine Investment Strategy
WHA	World Health Assembly
WHO	World Health Organisation
WPD	World Pneumonia Day
YF	Yellow Fever vaccine

EXECUTIVE SUMMARY

This report presents the findings and lessons learnt from a review of the Accelerated Vaccine Introduction (AVI) Project undertaken by Cambridge Economic Policy Associates (CEPA) for the GAVI Alliance. The review period spans from February to June 2012.

E.1 Context and framework for the review

The AVI initiative was established in 2008 with two core goals to be achieved over the period 2009-15: (i) broaden and speed-up access to rotavirus and pneumococcal vaccines; and (ii) create a platform for introducing other new vaccines. The initiative was established to build on and implement the work started by the Accelerated Development and Introduction Plans (ADIPs) for rotavirus and pneumococcal vaccines and the Hib initiative (HI). The AVI is hosted within the GAVI Secretariat and its activities are delivered through its Partners – WHO, UNICEF and the Bill & Melinda Gates Foundation (BMGF) as an observer – and a competitively selected outsourced entity AVI Technical Assistance Consortium (TAC).

This review has been structured around four questions as presented in Figure E1. Our methodology includes desk based review and analysis; extensive stakeholder consultations (including a short email questionnaire on AVI value add to the AVI Management Team (AMT) members); some quantitative analysis; and a comparison with a matrix management model.

Figure E1: Framework for review of the AVI initiative

Lessons Learnt from the AVI Project				
	I. AVI concept and objectives	II. AVI design, structure and organisational management	III. Results	IV. Future of the model
Review questions	To what extent is the AVI initiative – its concept and objectives relevant and appropriate in the context of GAVI's strategy and business plan?	To what extent is the AVI design, structure and organisational management appropriate to deliver its objectives?	What has been the progress in achieving the overall goals and outcomes of the AVI initiative and what has been AVI's contribution to these?	What improvements may be required for the model to effectively deliver its current and possible future objectives?
Review sub-questions	1. To what extent are the 'theory of change' and objective(s) of the AVI initiative appropriate and is there a shared understanding amongst stakeholders? 2. To what extent has the AVI initiative responded to the findings and recommendations of the ADIP evaluations? 3. How are AVI's concept and objectives positioned to contribute to the GAVI strategy and business plan 2011-15?	1. To what extent is the AVI design and structure appropriate vis-a-vis its objectives and the changes in the overall context of the initiative? 2. What has been the role of the GAVI Secretariat in the AVI initiative, and how has this been performed to date? 3. What lessons can be learnt from the TAC outsourcing exercise?	1. What has been the progress on the five intended AVI outcomes? 2. What has been AVI's contribution to the progress achieved?	1. What are the possible improvements to the AVI operational model to ensure effective and efficient vaccine introduction in countries? 2. How well is AVI positioned to absorb additional new vaccines and under what operating model? 3. To what extent is the model applicable to other areas of GAVI's work, such as HSS?

E.2 AVI concept and objectives

With respect to the first review sub-question, our analysis has identified two overarching issues:

- Notwithstanding the AVI's core goals, there is an absence of a clearly agreed theory of change underpinning the initiative, with differences in stakeholder views about the AVI

concept and how it is to be implemented. Despite this uncertainty, the majority of AVI and wider GAVI stakeholders agree that much has been achieved in terms of vaccine introduction in countries. However, the lack of conceptual clarity has potentially reduced the efficiency and effectiveness of the initiative and it is a widely held view that AVI could have achieved more had its concept been defined/ agreed upfront.

- We view all of the five AVI outcomes as relevant.¹ However, it is less clear whether it is appropriate² for all of these outcomes to be housed within the AVI. Outcome 3 (well-informed country decision on introduction of the vaccine) and Outcome 4 (country introduction of the vaccine) are core value-adding activities of the initiative and we view them as appropriate. The outcomes on ‘sufficient quantity of safe, effective, and appropriate vaccine to meet the demand’ and ‘financing available to pay for the vaccines and systems cost’ are, however, potentially duplicative of work undertaken by other teams in the Secretariat. The final AVI outcome on ‘establishing a platform for the sustained use of the vaccine’ has been interpreted differently by stakeholders. Whether this activity should be retained with AVI in the future very much depends on how the Alliance decides to structure the initiative. Our view is that it is more appropriate for the AVI to support vaccine introductions, rather than spread it too thinly across the entire lifecycle of vaccine uptake and use in countries (which is the focus of the wider Alliance).

In terms of the second review sub-question, the AVI closely follows the recommendations that led to its establishment. However, more could have been done in: making the initiative more target-oriented and milestone-driven; strengthening the management function with better alignment of the type of skills/ experience required and greater resources; and providing for more time for the leadership and strategic oversight functions to be undertaken, although we recognise that this has been strengthened as the initiative evolved.

With respect to the third review sub-question, the AVI is well aligned with the Alliance’s mission and strategic goals. Whilst this alignment is clearly positive, the lines between the AVI and the wider Alliance functions on some of the strategic goals are blurred. This has made it difficult to identify the contribution of the AVI activities to the business plan indicators and targets.

E.3 AVI design, structure and management

The AVI structure comprises the AMT and a number of task and/ or vaccine specific sub-teams which the AMT oversees. Given the absence of an agreed terms of reference (ToR) for the AMT and for most of the sub-teams, it is somewhat ambiguous as to how AVI stakeholders interact with each other and what their roles and responsibilities are. It is also not entirely clear as to who makes decisions and provides strategic direction to the initiative – the collective AMT, GAVI Secretariat lead, or senior members of respective Partner organisations.

Despite this uncertainty, the AMT has pragmatically focused on its tasks and ensured that the AVI has added value – a clear reflection of the considerable efforts made by the stakeholders involved to improve coordination of vaccine introduction work. From a management efficiency

¹ We refer to ‘relevance’ in terms of whether something is supportive of GAVI’s mission and strategic goals.

² We refer to ‘appropriateness’ in terms of whether AVI is the ‘right’ way in which the support to the GAVI mission and strategic goals is provided.

perspective however, more could have been achieved if it had been possible to sustain a stronger matrix management type structure attempted at the start. The AVI improved communication and interaction, and built trust, among the main immunisation Partners. At the same time, external stakeholders have suggested that it has been difficult to understand what the AVI is doing, how to access its outputs, and how to engage with it.

The AVI was set up as a single window for all vaccine introductions within the GAVI Secretariat, which was a reasonable design choice. The Secretariat has, however, faced two structural difficulties in managing the AVI from the beginning: (i) challenges in directing and managing Partners who have stronger reporting lines to their home organisations and who oversee the Secretariat activities through their organisational membership on the GAVI Board; and (ii) pressure to keep the Secretariat headcount low. Given the centrality of the AVI to the Alliance mission, we believe that it would have significantly benefited from: (i) more senior time and oversight (e.g. reporting regularly to the GAVI CEO/ Deputy CEO, with major issues raised at the GAVI Board/ PPC); (ii) more resources to help manage this complex initiative and support the AVI Director; (iii) direction from a lead with extensive project management/ organisational leadership experience, beyond technical vaccine expertise; and (iv) better coordination/ information sharing on AVI matters within the country programme team.

In terms of the TAC outsourcing, it might have been better to have issued separate and shorter term contracts (rather than the current seven years) for the required areas of work,³ enabling more flexibility in AVI accessing external resources. There were benefits of having the same organisations involved in the TAC as in the ADIPs/ HI in terms of continuity and institutional memory. However, there were some difficulties in managing the change of working culture.

E.4 Review of results

Considerable progress has been made in the country introduction rates (both number of countries and speed of introduction) for pneumococcal and rotavirus vaccines. It is expected that the original targets of 44 and 42 introductions for the two vaccines will be surpassed by 2015 (the revised projections are now 58 and 47 respectively). This has been supported by successful efforts to make available the required vaccines, such as the WHO pre-qualification, UNICEF supply contracting, and AMC price negotiation. The unprecedented demand from countries has, however, resulted in short term supply shortages and temporary delays in introductions, which has majorly constrained serving the increased demand.

A comparison of the introduction rates for the AVI-supported vaccines of pneumococcal and rotavirus with other GAVI-supported vaccines (HepB, Hib and YF) points towards the added value of AVI. Notably, there has been a considerably reduced time lag between the first licensed vaccines and the first country introduction for pneumococcal and rotavirus vaccines, as well as faster uptake of both vaccines over the years as compared to the other vaccines.

The above progress notwithstanding, it is difficult to establish AVI's contribution to this acceleration, given the absence of a results framework and consolidated reporting on the same,

³ We recognise that this would have increased the transaction costs of managing more than one contract, but on balance, the advantages are likely to have justified this. Managing a large seven-year contract, with multiple organisations of a Consortium, has not necessarily been a low cost exercise either.

as well as the existence of other influencing factors (e.g. Alliance funding, role of ADIPs, AMC, country efforts). Despite these challenges, our view is that a number of AVI activities/ outputs have: (i) enhanced coordination across Partners; (ii) supported global-level demand and supply management; (iii) helped develop the evidence base for vaccine introductions; and (iv) supported countries as they introduce vaccines. On the whole, there is considerable consensus, with which we agree, that the AVI is likely to have contributed in some measure to the unprecedented increase in country introductions of pneumococcal and rotavirus vaccines.

E.5 Suggestions on the future of the model

There continues to be a need for the main immunisation stakeholders, most of who are Partners of the GAVI Alliance, to coordinate their work and exchange information at global and country levels to facilitate the introduction of new vaccines – a much needed function that the AVI has performed well to date. We therefore support the ongoing organisational changes to the initiative, including its re-branded focus on “vaccine implementation”. In shaping the future model of the initiative, the following lessons from AVI should be noted:

- Build on what has worked well. This includes bringing all of the vaccine introduction activities under one management, clearly specified goals, building trust and open communication across Partners, competitively contracting out specialist work, maintaining the sub-team approach, and focusing on developing tangible tools.
- Address issues such as clarifying/ agreeing the concept and scope of the initiative, institutional structure, decision making processes, and roles and responsibilities in approved ToR; developing and reporting on a results framework that is closely aligned with the GAVI business plan; being proactive in information sharing within and across the AVI and external stakeholders, and ensuring transparency in activities.

It seems sensible to house the vaccine introduction support in a single organisation. This is well aligned with the country-level structures and roles in immunisation and ensures economies of scale in pan-vaccine activities. Although the majority of introduction activities are applicable across vaccines, any specific requirements of a vaccine should be recognised. We would also suggest that any future initiative of this nature is retained within the GAVI Secretariat and working closely with the country programme team. It should be provided the requisite seniority of oversight and direction within the Secretariat and in the respective Partner organisations.

An ‘AVI-like’ structure would help a multi-dimensional area of work where a number of Partners/ countries are actively working and which is core to GAVI’s mission and business. Its application to the Health Systems Strengthening (HSS) and other cash based GAVI programmes is not immediately obvious. The lessons from AVI’s review may however help improve coordination across the organisations involved in the Health Systems Funding Platform (HSFP). Pursuing an AVI type structure is not costless; and if other already existing GAVI partnering approaches are fit for purpose, they should be considered first.⁴

⁴ Clearly, setting up other structures such as new time limited task teams/ working groups is not without cost, but may on a case by case basis, be relatively more light-weight in terms of institutional infrastructure required.

E.6 Conclusions and lessons learnt from the AVI review

Our review has underscored the added value of the AVI in terms of it: (i) providing a needed coordination and communication platform amongst the Partners and the GAVI Secretariat; and (ii) enhancing the focus and priority placed on this important set of activities. Further, the initiative is unique in its attempt to identify, cost and house all of the necessary activities related to vaccine introduction across countries, in a single framework. This ‘single window’ across vaccines conceptually aligns well with supporting the country structures and activities that decide on, prepare for, and ultimately introduce vaccines in routine immunisation programmes.

Whilst the AVI model has demonstrated some strong advantages, its translation into practice has encountered a number of difficulties. These have included: (i) lack of clear documentation and ambiguity amongst the AVI and broader Alliance stakeholders on its theory of change, concept and design; (ii) whilst the five AVI outcomes are relevant, it may not necessarily be appropriate to have them all ‘housed’ within the AVI; (iii) absence of an agreed ToR for the AMT and a number of its sub-teams; and (iv) absence of an AVI results framework.

However, the AVI initiative, despite these difficulties, has succeeded in delivering many important activities necessary for accelerating vaccine introduction in countries. Planned country introductions of pneumococcal and rotavirus vaccines have surpassed the original AVI targets, even if it is difficult to identify and isolate the contribution of AVI specifically. The key lessons learnt from this review are that any future model for supporting new vaccine introduction should have, as a minimum, the following attributes:

- clarity and agreement on the concept and scope, ideally documented in a: (i) concept note and strategy; (ii) costed multi-year work plan and budget; and (iii) results framework;
- better defined terms of reference for the management team and its components, including roles and responsibilities for the Partners and entities to whom aspects of the work is outsourced;
- agreed management and decision-making process, accountability and reporting lines;
- sufficient resources to manage and deliver the work; and
- methods for sharing information and improving transparency of its activities across Partners and the wider Alliance stakeholders.

The wider applicability of an ‘AVI-like’ structure to other GAVI programmes is not very intuitive, and the benefits of a specific-purpose initiative should justify the costs. However, where a particular area of work is core to GAVI’s business and is at the same time: complex, includes a number of Partners/ stakeholders and countries, calls for external specialist skills and resources, and requires regular communication and coordination that may not take place within the existing Alliance framework – an AVI-type focused coordinating mechanism may be deemed appropriate.

1. INTRODUCTION

This report sets out the findings and conclusions from Cambridge Economic Policy Associates' (CEPA's) review of the 'Lessons Learnt from the Accelerated Vaccine Introduction (AVI) Project' for the GAVI Alliance.^{5, 6} The work underpinning this review was undertaken within a short timescale (between February and May 2012) relative to the scope and complexity of the initiative.

1.1. Objectives and scope of the review

The Request for Proposal (RFP) states the purpose of this consultancy as to:⁷

- review the achievements of the AVI initiative to date;
- assess the effectiveness and value-added of the AVI design in the context of the GAVI Alliance Strategy 2011-15 and the current governance structure;
- identify the strengths and weaknesses of the model, document lessons learnt, and provide options for improvement; and
- consider potential applications of the model to other areas of GAVI's work, such as Health Systems Strengthening (HSS).

Based on the consultations as part of this work, we understand that the main priority of this review is to identify what has worked well with the initiative and what has been difficult to implement in practice. This will support GAVI's management decision on whether to introduce any changes to the present AVI model as well as inform any future approaches for new vaccine introductions in countries.⁸

Whilst we have sought to meet the above review objectives, our work has been constrained by the absence of important documentation and shared views among stakeholders on the concept and theory of change of the AVI initiative, the terms of reference for various constituents of the initiative, and a results framework. In addition, we note that this report does not seek to evaluate:

- the performance of specific stakeholders/ Partners⁹ and their individual contributions to the AVI objectives;
- the work and outputs of individual sub-teams, some of which have undertaken quite extensive work in scope and depth (although this is covered at a high-level); and

⁵ In the rest of this report, we refer to the collection of activities within the Accelerated Vaccine Introduction framework as the 'AVI initiative' or 'AVI' or the 'initiative'.

⁶ The report has benefited from review and contributions by CEPA's associates on this assignment, Claire Broome and Rachel Feilden.

⁷ RFP for Lessons learnt from Accelerated Vaccine Introduction (AVI) project, dated November 2011.

⁸ At the time of writing however we note that some changes are already being implemented within the GAVI Secretariat in this regard. To the extent possible, the review seeks to take account of the organisational changes affecting the initiative, which have been taking place in parallel to our work.

⁹ Partners refer to the Alliance Partner organisations represented on the AVI Management Team (AMT) and include: (i) World Health Organisation (WHO); (ii) United Nations Children's Fund (UNICEF); (iii) members of the AVI Technical Assistance Consortium (AVI TAC), and (iv) the Bill & Melinda Gates Foundation (BMGF). In addition, the GAVI Secretariat is also a member of the AMT.

- whether the initiative has met its objectives, given the mid-term nature of this review – although, to the extent possible, we consider the progress made towards the AVI goals and outcomes.

1.2. Structure of the report

This report is structured as follows:

- Section 2 provides our understanding of the context and background to the AVI initiative and this review;
- Section 3 describes our review framework and methodology, including the four high level review questions and their respective sub-questions;
- Sections 4, 5 and 6 present the discussion and our findings on the first three of our review questions, and as related to the AVI: (i) concept and objectives; (ii) design, structure and organisational mandate; and (iii) results to date;
- Section 7 provides our views on the final review question related to the future of the model; and
- Section 8 sets out our conclusions and lessons learned.

The main report is supported by the following annexes (included as a separate document):

- Annex 1 provides a bibliography and data sources;
- Annex 2 lists the consultations undertaken as a part of this review;
- Annex 3 provides an overview of Accelerated Development and Introduction Plans (ADIPs) and Hib initiative (HI), along with key issues and recommendations from the HLSP evaluation;
- Annex 4 sets out a summary on the AVI Management Team (AMT) sub-teams;
- Annex 5 presents the expected costs of the AVI initiative, as outlined in the “Report on the mapping and costing, AVI”, 2008;
- Annex 6 provides a description of the matrix management approach;
- Annex 7 provides a summary of the key issues discussed and the decisions made by the GAVI Board and the Programme and Policy Committee (PPC) with regards to the AVI initiative;
- Annex 8 sets out the main outputs of the AVI initiative as collated by CEPA from various documents; and
- Annex 9 describes the data sources and methodology for comparing introduction rates across GAVI-supported vaccines as part of the ‘results’ review question.

2. BACKGROUND AND CONTEXT

In this section, we set out our understanding of the background to the AVI initiative and its institutional structure. In addition, we present our understanding of the key contextual issues that have influenced the conceptualisation of the initiative and note how these factors have changed over the years; the latter having an influence on the shape and relevance of the initiative going forward. Whilst much of the presented context is known to GAVI and the AVI stakeholders, we consider it important to briefly articulate these as they inform the findings and conclusions of this review.

2.1. Establishment and overview of the AVI initiative

The GAVI mission is to save children's lives and protect people's health by increasing access to immunisation in poor countries.¹⁰ To achieve this, the current Alliance's Strategic Goal (SG) 1 is to accelerate the uptake and use of underused and new vaccines. The experience of introducing vaccines such as hepatitis B (Hep B), yellow fever (YF), and Haemophilus influenza Type b (Hib) has demonstrated that once a vaccine appears on the market, there is a need for significant support to ensure speedy vaccine adoption and uptake by GAVI eligible countries.

In response to this need, GAVI supported the establishment of the rotavirus and pneumococcal ADIPs in 2002, and later the HI in 2005.^{11, 12} These initiatives have been an important step forward in coordinating and implementing activities to support the adoption of these vaccines in GAVI eligible countries, and in providing a clear signal of their demand to the industry.¹³

At the end of the terms of the ADIPs and the HI, GAVI wished to build on the work undertaken by these initiatives and support the next stage of vaccine introductions in countries. As a result, the GAVI Board recommended in May 2007 that the Secretariat work with the Partners to undertake a detailed mapping and costing exercise to identify the activities and resources required to achieve rapid uptake of rotavirus and pneumococcal vaccines in GAVI eligible countries. The output of this work was presented at the June 2008 Board meeting¹⁴, when the creation of AVI initiative was approved with two core goals and five outcomes (as set out in Table 2.1 below):^{15,16}

¹⁰ GAVI Alliance website (<http://www.gavialliance.org/about/mission/>), accessed 11.05.2012.

¹¹ Further details on the ADIPs and the HI initiative are set out in Annex 3.

¹² Pneumo ADIP was located at John Hopkins University (JHU), the Rota ADIP was hosted by PATH as the PATH Rotavirus Vaccine Program, and the HI was composed of four members including JHU, Centers for Disease Control (CDC), WHO, and the London School of Tropical Medicine and Hygiene.

¹³ 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)"

¹⁴ GAVI (2008), "Accelerated vaccine introduction, report on the mapping and costing of activities".

¹⁵ GAVI Alliance website (www.gavialliance.org/about/gavis-business-model/avi/), accessed 23.04.2012.

¹⁶ GAVI (2008), "Accelerated vaccine introduction, report on the mapping and costing of activities".

Table 2.1: AVI goals and outcomes

	Description
Core goals	• Broaden and speed-up access to rotavirus and pneumococcal vaccines • Create a platform for introducing other new vaccines, such as meningococcal type A conjugate (MenA), Human papillomavirus (HPV), typhoid, Japanese encephalitis (JE), and rubella
Outcomes ¹⁷	• Sufficient quantity of safe, effective, and appropriate vaccine to meet the demand • Financing available to pay for the vaccines and systems cost • Well-informed country decision on introduction of the vaccine • Country introduction of the vaccine • Establish platform for the sustained use of the vaccine

In approving the AVI initiative, the GAVI Board was adopting some of the recommendations of the evaluations undertaken in 2007 of the ADIPs and the HI.¹⁸ In particular, the recommendations considered by the Board included:¹⁹

- The post-ADIP implementation period needs an investment to support introduction in countries; existing structures lack capacity to address all the issues.
- ADIPs for different vaccines should be focused in a single organisation, with a strong manager, and be target-oriented, time-limited and milestone-driven.
- GAVI should consider an implementation mechanism either within the Secretariat, housed at a GAVI Partner organisation, or at an outside organisation selected through an RFP process.
- A mechanism for in-country implementation for products that are programme ready could be based on the HI. An integrated and coordinated approach would avoid competition and confusion at the country level for introduction activities, and allow for provision of tailored information to each country for a variety of products.
- For implementation support, oversight needs to involve the Board, through a Management Committee selected with appropriate skills, and with liaison through specifically charged GAVI Secretariat teams.

In addition to the evaluation recommendations, in November 2007, the ADIP Management Committee (MC) made the following recommendations to the GAVI Board:²⁰

- vaccine introductions are to be coordinated by a specifically appointed senior team within the GAVI Secretariat;

¹⁷ Annex 8 provides details on each of these outcomes, including listing relevant AVI objectives and activities.

¹⁸ HLSP (2007), "An evaluation of GAVI Alliance efforts to introduce new vaccines via ADIPs and the HI".

¹⁹ GAVI (2008), "Accelerated vaccine introduction, report on the mapping and costing of activities".

²⁰ Recommendation from the ADIPs and Hib Initiative Management Committee on managing new vaccine introduction activities. Submitted November 8, 2007 by Jan Holmgren, Chair, ADIP Management Committee as Annex 1 of board paper AF-11 Accelerating Vaccine Introduction.

- scaling up support for vaccine introduction to countries and through the Partners should be in line with their mandates; and
- managing additional support could through outsourced activities where needed.

Pursuant to the ADIPs evaluation and the ADIP MC recommendations, the Board chose to host the AVI initiative within the GAVI Secretariat (rather than contract it out to a third party), and for it to be delivered through the Partners in line with their mandates. Activities identified at that time as outside the remit of the Secretariat/ Partners were decided to be outsourced to a third party.

The then estimated cost of all the activities set out under the mapping and costing exercise was approximately US\$ 776m over the period 2009-15²¹, with US\$ 99.6m estimated for activities to be delivered by the outsourced entity, later known as the AVI Technical Assistance Consortium (AVI TAC).²² These cost estimates have however never actually been translated into a ring-fenced AVI budget within the overall GAVI business plan (except for the AVI TAC outsourcing budget, which was approved by the Board in October 2008 but at a lower amount of US\$ 51.3m²³). The GAVI Secretariat related AVI budget is managed by it internally, whilst all AVI related activities undertaken by Partners are covered under Memorandums of Understanding (MoU) and contracts between the GAVI Alliance and the individual Partners. Approval and setting up of new Partner budgets is part of the ongoing 2013-14 business planning processes and is not specifically under the auspices of the AVI.

The AVI target was to launch the rotavirus vaccine in 44 countries, and the pneumococcal vaccine in 42 countries by 2015.^{24, 25} The initiative also had to define the organisational and operational foundations to support the future introduction of other new vaccines.

2.2. Structure of the initiative

The AVI initiative is overseen by the AMT, which is led by the GAVI Secretariat and consists of representatives from World Health Organisation (WHO), United Nation Children's Fund (UNICEF), the Bill and Melinda Gates Foundation (BMGF) as an observer, and the AVI TAC. The latter is a consortium of PATH, Johns Hopkins Bloomberg School of Public Health (JHU),

²¹ See Annex 5 for further details on the cost assumptions at the time.

²² See Table 4.1 – Costs of AVI activities performed by different entities, grouped by phase of introduction (2009-2015) in GAVI (2008), “Accelerated vaccine introduction, report on the mapping and costing of activities”.

²³ 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”.

²⁴ The reference to this target was sourced from GAVI (2008): “RFP for Accelerated Vaccine Introduction Initiative”, July 2008. However, these targets are somewhat different in the “Part I Overview - GAVI Alliance Strategy and Business Plan 2011-2015” on the GAVI website. This latter document, on page 33, defines targets for country introduction of pneumococcal vaccine as 45 and for rotavirus vaccine as 33 by 2015. The targets of 44 country introductions for rotavirus and 42 country introductions for pneumococcal vaccine were also stated by most of the AVI stakeholders we consulted. As such, and for consistency purposes, we will assume as correct the 44 and 42 country introduction targets respectively.

²⁵ Based on the May 2011 New and under-used Vaccine Support (NVS) application round, and as discussed later in this report, there is a strong suggestion that this target will be met and potentially exceeded. Although, it should be noted that this is now potentially constrained by the ability of countries to implement approved vaccines as well as the availability of a sufficient quantity of vaccines.

and the Centers for Disease and Control (CDC)²⁶, that was selected through a competitive process to provide specialist skills required for the successful introduction of new vaccines in GAVI eligible countries.

The draft terms of reference for the AMT²⁷ and a majority of our consultations suggest that the AMT was envisaged as an organisational platform to enable the Partners to coordinate (through improved and regular communication) their vaccine introduction related activities as well as to oversee the implementation of activities undertaken by the cross-organisational AMT sub-teams. The draft strategies for delivering these terms of reference (which were never actually formally agreed and adopted by the AMT) proposed that the AMT will:

- propose, review and inform GAVI policies to promote development of evidence-informed policies and assure as rapid as possible successful vaccine introductions;
- prepare countries and Partners to assure as rapid as possible successful vaccine introductions;
- build, strengthen, sustain (and not bypass) country immunisation systems;
- ensure efficient procurement and supply management;
- promote stringent monitoring processes and accountability; and
- maximise use of complementary mandates and skills of Partner agencies.

It was also proposed that specific sub-teams are to be established by the AMT as and when necessary, depending on work load and complexity. Sub-team leaders would be appointed by the AMT and invited to participate in AMT meetings; composition of these sub-teams is generally meant to be representative of AVI constituents, although this would not be a necessity.

At present, there are 11 AMT sub-teams²⁸, led by the different Partners. More details on each of the sub-teams are set out in Annex 4 of this report. We note that the sub-team structure combines a 'horizontal' and 'vertical' approach to vaccine introduction. The earlier sub-teams (such as advocacy and communication) focus on cross-cutting issues across the vaccines, whilst the more recently introduced sub-teams examine vaccine-specific implementation strategies.

2.3. Contextual issues

Four years have passed since the AVI initiative was approved by the GAVI Board.²⁹ In setting up the initiative, a number of key contextual issues were taken into account, such as:

- End of the ADIPs and the HI, and subsequent recommendations for next steps to support vaccine introductions in GAVI eligible countries.

²⁶ The contributing Partners are the Aga Khan University, International Vaccine Institution, Norwegian Institute of Public Health, and the University of the Witwatersrand, Johannesburg.

²⁷ Draft of updated Terms of Reference dated 05/10/2010, as shared by GAVI Secretariat.

²⁸ We understand that the AVI initially had a large country sub-team chaired by WHO which was later discontinued and moved to a GAVI task team.

²⁹ GAVI (2008), "Board meeting notes", June 2008.

- The need to maintain momentum on introductions for pneumococcal and rotavirus vaccines, given the success of ADIPs and the necessity to now work with countries. In particular, GAVI had set targets for the number of countries to introduce these two vaccines, which in turn needed implementation support.
- The pilot pneumococcal Advance Market Commitment (AMC), announced in February 2007 and which was launched in June 2009³⁰, was to make available pneumococcal conjugate vaccines appropriate for GAVI eligible countries, contingent on countries' accelerated demand for and introduction of the vaccine.³¹
- Recognition, based on experience gained to date (e.g. as noted in the work of the ADIPs and the HI), that coordinated and concerted efforts were required for vaccine adoption and uptake in GAVI eligible countries. In addition, there was an understanding that the decision to introduce a vaccine could be a difficult and slow process at country level.^{32, 33}
- Prior to the global financial crisis of late 2008, there was greater confidence that GAVI would have the required finances to support the introductions of new vaccines.

These issues provided the required backdrop to the establishment of the AVI initiative. Since then, a number of contextual changes have impacted the way in which the implementation of the initiative has progressed, and particularly on its relevance going forward. These can be considered in four categories of: (i) funding; (ii) country applications; (iii) new GAVI strategy and business plan; and (iv) changes in the Alliance and the Secretariat operations. These are briefly discussed in turn below, with some observations on how they may affect the AVI initiative.

Funding

The financial crisis of 2008 had a considerably negative impact on both the availability of resources and the confidence that global health stakeholders more generally had in future funding flows. CEPA's detailed (unpublished) work on overseas development aid (ODA) trends shows that since the financial crisis, there has been a decline in the growth rate of ODA, although in absolute terms, ODA has been increasing (albeit with considerable disparity among donors). The future of ODA however continues to be uncertain, particularly as the most recent Organisation for Economic Co-operation and Development (OECD) estimates suggest an absolute decrease in 2011.³⁴

³⁰ The governments of Italy, the United Kingdom, Canada, the Russian Federation, Norway, and the BMGF launched the pilot AMC against pneumococcal disease with a collective US\$ 1.5bn commitment.

³¹ As noted at the time, the reasons included that: (i) country requests for the pneumococcal vaccine under the AMC are needed to trigger the release of AMC funds; (ii) vaccine supply must be guaranteed by ensuring that production capacity of the multinational vaccine manufacturers matches the expected demand, and by stimulating the capacity of emerging market vaccine manufacturers to bring new products to market; and (iii) the AMC design also assumes that countries would co-finance the vaccines, which in turn is linked to the country capacity for decision-making and national health financing for new vaccine introduction.

³² Sourced from stakeholder consultations.

³³ Although in reality, and as judged by the greater than expected country decisions to introduce vaccines, these decision processes may be less challenging than vaccine implementation itself.

³⁴ CEPA work undertaken under a different assignment.

The GAVI Alliance and its Partners (e.g. WHO) have also been affected by the slowdown in the growth of and consequent future uncertainty around the funding flows for global health and immunisation more specifically. Until the summer of 2011, GAVI faced a US\$ 3.7bn funding shortfall for its plans to accelerate the introduction of new vaccines to 2015, which resulted in a 'pause' in vaccine funding approvals.³⁵ This gap was eventually met at GAVI's resource mobilisation effort in 2001, and in fact exceeded, with US\$ 4.3bn raised.

However, the uncertainty up to that point meant that the AVI's focus (which was established in 2008 and just as the crisis was starting) was shifted, for example, to developing approaches to prioritise the limited resources, as well as to supporting the Alliance's advocacy efforts to raise funding, as opposed to the originally envisaged advocacy efforts aimed at supporting country decisions to adopt the vaccines.

Country applications

Since the AVI initiative was set up, GAVI has witnessed an unprecedented number of countries applying for the introduction of pneumococcal and rotavirus vaccines. The reasons for this have included:³⁶

- the well documented and understood burden of pneumonia and diarrhoea in developing countries;
- release of built up demand following the 'pause' (as noted above) in GAVI's acceptance of proposals on account of lower resource availability;
- rush of countries applying for funding prior to the expected changes on country eligibility for GAVI support;
- publicity associated with GAVI's successful fundraising effort in 2011 and hence knowledge that resources are available; and
- work undertaken by GAVI on the introduction of these vaccines (including that conducted under the auspices of the AVI initiative, and prior to that, the ADIPs).

The unexpected number of country applications shifted some of the envisaged activity focus for AVI. This included a greater focus on managing vaccine supply shortages that resulted from greater than anticipated demand. At present, only seven out of the 13 countries newly recommended for approval will be able to introduce the pneumococcal vaccine in 2012. The current analysis also identifies a gap in the supply of rotavirus vaccines in 2013, which is a serious concern for both the AVI and the GAVI Alliance.³⁷

Introduction of a new GAVI strategy and workplan

In November 2010 – two years after the AVI was established – the GAVI Board approved the 2011-15 strategy to deliver the Alliance's mission. The new strategy sets out the Alliance's operating principles, redefines its strategic goals (including a more comprehensive approach to

³⁵ The period of 'pause' was referred to and confirmed by many stakeholders during consultations.

³⁶ As discussed during a number of stakeholder consultations.

³⁷ As suggested during stakeholder consultations.

its health systems strengthening goal and a new goal on shaping vaccine markets), and provides a detailed results framework with defined objectives and progress indicators, which were not included in its previous strategy. Broadly speaking, these changes have not affected the objectives of the AVI initiative, although they have had an impact in some areas of its focus – for example, a new goal on shaping vaccine markets could lead to some duplication in the GAVI Secretariat and the AVI's activities on ensuring security of supply.

Changes in the GAVI Alliance and Secretariat operations

A number of changes in the way that the Alliance and the Secretariat operate have also had an impact on the AVI initiative.³⁸ These have included:

- The GAVI Alliance has evolved in terms of multiple vaccines being approved for its support. This has meant that the AVI initiative's initial focus on pneumococcal and rotavirus vaccines has been expanded to now include other vaccines, such as Rubella, Typhoid, HPV, JE, YF, and MenA.
- There has been a growth in the size of the Secretariat team. This has resulted, for example, in there being greater availability of in-house skills and resources (resulting in some AVI TAC activities, such as developing strategic demand forecasts (SDF), now being moved to the GAVI Secretariat, for example), and an increase in the number of Country Responsible Officers (CROs) placing greater emphasis on interaction between the AVI initiative and the Country Programmes team at GAVI.

³⁸ This is clearly not an exhaustive list, but aims to illustrate the types of changes that would have affected the way that the AVI initiative is run and managed.

3. REVIEW FRAMEWORK AND METHODS

In this section, we provide an overview of our review framework, followed by a discussion of the review methods and their potential limitations. We then describe the four overarching review questions, as well as their respective sub-questions and how they have shaped our approach. Subsequent sections discuss the questions in turn, setting out our findings and key lessons learnt.

3.1. Overview of the AVI review framework and questions

Figure 3.1 provides our review framework along with the review questions and sub-questions.

Figure 3.1: Framework for review of the AVI initiative

Lessons Learnt from the AVI Project				
I. AVI concept and objectives		II. AVI design, structure and organisational management		III. Results
IV. Future of the model				
Review questions	To what extent is the AVI initiative – its concept and objectives relevant and appropriate in the context of GAVI's strategy and business plan?	To what extent is the AVI design, structure and organisational management appropriate to deliver its objectives?	What has been the progress in achieving the overall goals and outcomes of the AVI initiative and what has been AVI's contribution to these?	What improvements may be required for the model to effectively deliver its current and possible future objectives?
Review sub-questions	1. To what extent are the 'theory of change' and objective(s) of the AVI initiative appropriate and is there a shared understanding amongst stakeholders? 2. To what extent has the AVI initiative responded to the findings and recommendations of the ADIP evaluations? 3. How are AVI's concept and objectives positioned to contribute to the GAVI strategy and business plan 2011-15?	1. To what extent is the AVI design and structure appropriate vis-a-vis its objectives and the changes in the overall context of the initiative? 2. What has been the role of the GAVI Secretariat in the AVI initiative, and how has this been performed to date? 3. What lessons can be learnt from the TAC outsourcing exercise?	1. What has been the progress on the five intended AVI outcomes? 2. What has been AVI's contribution to the progress achieved?	1. What are the possible improvements to the AVI operational model to ensure effective and efficient vaccine introduction in countries? 2. How well is AVI positioned to absorb additional new vaccines and under what operating model? 3. To what extent is the model applicable to other areas of GAVI's work, such as HSS?

We have structured the review framework in a logical and chronologically progressive manner. The framework initially explores the conceptualisation and objectives of the AVI initiative, followed by an examination of whether its design and structure are appropriate to deliver these objectives. We then assess the results/ progress to date in meeting the AVI goals and outcomes, and the extent to which the initiative has contributed to these. Having undertaken the review, we consider the future of the model and the lessons learnt for improving GAVI's support to new vaccine introduction and uptake in countries. These four 'pillars' of the review are inter-related, and therefore our findings on any one of the review questions have a bearing on others (for example, our conclusions on the AVI concept and objectives would influence our judgement on whether its structure is fit-for-purpose to deliver these objectives).

We note that the AMC is relevant to the work of the AVI; but we understand that GAVI is undertaking a separate evaluation of the AMC. As such, we have only looked at the AMC at a high level to the extent that it has a bearing on AVI outcomes in relation to the pneumococcal

vaccine introduction, and have not undertaken a detailed review of the AMC rationale, design, structure, activities, and outcomes.

3.1.1. AVI concept and objectives

The first of the four review questions examines the extent to which the concept and objectives of the AVI initiative are relevant and appropriate in the context of GAVI's 2011-15 strategy and business plan, with our definition of these two terms being:

- '*relevance*', as to whether the AVI concept and its theory of change (as discussed below), are supportive of GAVI's mission and four strategic goals (i.e. do AVI's aims align with those of the Alliance); and
- '*appropriateness*', as to whether the proposed concept is likely to be fit for purpose and the 'right' way in which this support to the GAVI mission and strategic goals is provided.

In this regard, we note that there is a degree of uncertainty as well as a lack of a common understanding amongst the AVI and broader Alliance stakeholders on what the AVI initiative is and what it seeks to achieve. This difference in views of course raises some fundamental questions about the nature of the initiative and its ability to deliver its objectives.

The three sub-questions under this review question examine the conceptual/ strategic issues underpinning the AVI initiative, as follows:

- **To what extent are the 'theory of change' and objective(s) of the AVI initiative appropriate and is there a shared understanding amongst stakeholders?** As part of this question, we have attempted to identify whether there is a clearly articulated theory of change underpinning the AVI initiative (the intention was to assess whether the theory of change is appropriate and if it is commonly understood and owned by the stakeholders). In addition, we set out our findings on the relevance and appropriateness of the objectives/ outcomes for the initiative and how these had been linked to the GAVI's then strategy and business plan (2007-10).
- **To what extent has the AVI initiative responded to the findings and recommendations of the ADIP evaluations?** The AVI initiative was set up as the ADIPs and HI were wound up and in response, amongst other issues as noted earlier, to the findings/ recommendations from the evaluation of these initiatives. As part of this question, we set out the extent to which the initiative responded to these recommendations in terms of its concept, design and activities.
- **How are AVI's concept and objectives positioned to contribute to the GAVI strategy and business plan 2011-15?** As noted earlier, we recognise that there have been a number of changes to the environment/ context within which AVI operates, including the adoption of a new GAVI strategy and business plan. The issues here relate to how the new strategy and some of the contextual changes (e.g. the global financial crisis) have affected AVI and whether the concept and objectives continue to be relevant and appropriate.

3.1.2. AVI design, structure and organisational management

As part of the second review question, our analysis looks at how the AVI concept has been implemented from an institutional perspective. In doing so, we have focused our attention on the following three sub-questions:

- **To what extent is the AVI design and structure appropriate vis-a-vis its objectives and the contextual changes?** We have analysed the linkages between the design and structure of the AVI, coordination among the Partners, and the initiative's proposed outcomes. Related to this, we have explored the continued appropriateness of the AVI design and structure in the context of the ongoing changes in relation to the GAVI Alliance and the external environment more generally.
- **What has been the role of the GAVI Secretariat within the AVI initiative, and how has this been performed to date?** The Secretariat is ascribed an overall management and leadership role for the AVI initiative. In this context, we have explored the extent to which this role embodied leadership and decision making power and responsibilities, whether it has been adequately resourced and supported by the GAVI Alliance and its Partners, and if its work was affected by a substantial proportion of AVI technical staff working for other Partners.
- **What lessons can be learnt from the TAC outsourcing exercise?** We have examined a number of aspects of the TAC outsourcing experience, including whether the tender attributes (e.g. single tender, long contract timeframe with annual checkpoints) were appropriate, the role and activities allocated to TAC, and the extent and manner in which the work of the TAC was integrated into the overall AVI initiative, including if its contract was supportive of such integration.³⁹

3.1.3. Results

As part of this third review question, we examine, to the extent that it is possible, the progress that has been made towards achieving the overall goals and outcomes of the AVI initiative, including AVI's contribution to these. More specifically, our sub-questions consider:

- **What has been the progress on the five intended AVI outcomes?** The focus has been on assessing what was achieved on the five AVI outcomes, rather than the specific contributions of AVI (which is the subject of the following sub-question).
- **What has been AVI's contribution to the progress achieved?** This sub-question deals with the difficult issue of contribution of the results achieved to the AVI initiative. Here, the focus has been on analysing the 'value-addition' of the initiative.

³⁹ It is beyond the scope of our review and we have therefore not considered whether the institutions that were awarded the contract had the right skills and expertise to undertake this work.

3.1.4. Future of the model

This final review question explores any lessons learned that could be applied to a possible model of Partner coordination in terms of effectively delivering the current and possible future objectives of a vaccine introduction initiative. The sub-questions considered here are:

- **What are the possible improvements to the AVI's operational model to ensure effective and efficient vaccine introduction in countries?** The objective has been to identify any possible changes that might improve the performance of the AVI model, including as related to its: (i) design and institutional structure; (ii) management, control and decision-making processes; and (iii) activities, roles and responsibilities.
- **How well is AVI positioned to absorb additional new vaccines and under what operating model?** We have considered whether the current AVI model, and its existing resourcing, is well-positioned to absorb managing the introductions of new vaccines.
- **To what extent is the model applicable to other areas of GAVI's work, such as HSS?** We have assessed the suitability of the current AVI model for activities that might be broader than vaccine introduction. Given that AVI covers a broad range of activities – from vaccine supply management to financing, and communications and advocacy – we have examined areas where the model worked well, and where it did not. We will also assess whether the model has operational attributes, such as Partner coordination, mix of skills/ experience from different responsible entities including those outside the Alliance, and management support from GAVI Secretariat, that could be considered sufficiently valuable and transferable to other programmes of the Alliance.

3.2. Review methods

In undertaking the review, we have employed the following methodological approaches.

- **Desk based review and analysis.** We have undertaken a review of the available documentation about the AVI initiative and GAVI more generally, as shared by the Secretariat and AVI stakeholders, and from our own research. Review of documentation has been an important approach to answering the review questions in terms of gaining a better understanding of the emerging issues. The list of documents we have reviewed include the AVI Progress Reports (presented to the Board and the PPC), AVI TAC annual reports, documents outlining the design of the AVI initiative such as the 'Mapping and Costing report' presented to the Board in 2008, the 'Technical Proposal' submitted by the PATH Consortium in 2008, AVI specific outputs such as SDFs, AVI Country Readiness Dashboard, amongst others. The list of documents referred to in this study are included in Annex 1.
- **Quantitative analysis.** Quantitative techniques have been employed in a limited manner to try and answer the review question on results. This has included the analysis of data on country applications, vaccine introduction and vaccine uptake (for rotavirus, pneumococcal, and any other relevant vaccine).

- **Comparator analysis/ benchmarking.** AVI is an innovative approach that aims to ensure, among other things, increased and faster access to rotavirus and pneumococcal vaccines. It is unlikely therefore that we could have easily compared the AVI operations with ‘comparable’ entities, as possible in say, analysing different private sector companies’ performance in standardised commodity markets. However we have considered an industry product launch team/ matrix management structure to offer lessons in relation to the management aspects of the AVI model.⁴⁰
- **Consultations.** Consulting with AVI stakeholders has been the most important source of information. This was particularly relevant for this review, given, among other issues, different stakeholder views on the exact nature of the AVI initiative and its activities and the apparent absence of some important supporting documentation (such as an agreed terms of reference, and a results framework⁴¹ for the initiative). Although views expressed by interviewees are inevitably subjective, when consolidated and triangulated across a diverse range of consultees (who have been a mix of AVI and other GAVI stakeholders) they have been an important qualitative source of evidence for the review. We had also circulated a short email questionnaire to the AMT members⁴² seeking inputs on how AVI has facilitated activities and added value in relation to the five outcomes.
- **Counterfactual analysis.** In most evaluations, an important but challenging review method is to undertake a counterfactual analysis. What would have been the outcome if AVI had not been established; and/ or managed and implemented differently? Whilst this analysis is hypothetical, we have sought to develop some basic counterfactual analysis under the results question, focusing on the speed at which vaccines other than pneumococcal or rotavirus were introduced in GAVI-eligible countries.

In developing our judgements and conclusions from the evidence collated from these review methods, we have implicitly taken into account the: (i) quality of the underlying evidence source⁴³; and (ii) degree to which different evidence sources point towards a similar conclusion.

3.2.1. Methodological limitations

Some key limitations of our review methods include the following:

- A key limiting factor has been the absence of agreed documentation (e.g. agreed terms of reference for the AMT, an AVI specific results framework) for us to analyse, which is largely on account of a lack of consensus among AVI and wider GAVI stakeholders on what the AVI concept and theory of change are (this is explained further in the subsequent sections).

⁴⁰ We had also planned to study the Measles Initiative (MI). However, despite our follow-up, we have not been able to schedule a consultation with the MI management, without which the case study could not be developed.

⁴¹ In this report, we refer to a results or a monitoring and evaluation (M&E) framework interchangeably.

⁴² These include WHO, UNICEF, AVI TAC, and the GAVI Secretariat. We had received responses from only some of the stakeholders contacted.

⁴³ For example, we have considered whether a particular consultee has been closely aware of the initiative, the extent to which an evidence source draws upon facts versus opinions, and if a specific document has been approved/ adopted by AVI or GAVI or is it a draft version.

- Whilst consultations have been an important source of qualitative information, it is inevitable that the choice of consultees and the inherent biases in their views and interpretations of issues and events introduce an element of subjectivity. We have sought to reduce these effects by reaching out to as many relevant stakeholders as feasible, including all AMT members.⁴⁴ In addition, in developing our judgements, we have endeavoured to triangulate views across consultations as well as used documentary evidence.⁴⁵
- We have not been able to place much emphasis on comparator analysis, given both GAVI stakeholders' feedback to that effect, as well as our appreciation of the relative uniqueness of the AVI initiative and its objectives. Case studies of other initiatives have already been undertaken in many instances, and generic descriptions of what others do was not likely to add value. We have therefore only studied the industry product launch team/ matrix management structure as a theoretical comparator.
- There have been some discrepancies between different data sources in this review (for example, year of introduction of pneumococcal and rotavirus vaccine for certain countries was different across WHO database and the GAVI AVI Progress Reports). Our approach has been to identify and note these discrepancies, and where necessary justify the sources that we have used.
- In the absence of an agreed AVI results framework, we have used our judgement in presenting the progress/ results achieved by the initiative to date. We have however, developed and proposed a results framework that attempts to align in a logical and easily accessible format with GAVI's overall results framework, and which might be used in future evaluations of a new vaccine introduction initiative. Regardless of the framework used, however, there have been inevitable differences of views on the relative contributions of the AVI initiative, versus, for example, those of the GAVI Alliance as a whole (even if one tries to differentiate the two, which in itself may not necessarily be appropriate). For example, it is not fully clear to us (or to the Partners we have discussed this with) what activities they undertake to support vaccine uptake are part of AVI and what activities are part of their wider Alliance role. This has been compounded by the fact that budget allocations to as well as results reporting by Partners are not distinct for AVI related activities.
- Given that countries are at the heart of this initiative, there not being the budget or time to undertake any country visits as part of our evidence gathering has been a constraint. This would have helped us better appreciate the key drivers of country decisions to introduce new vaccines and actual uptake, and the extent to which AVI may have contributed to these through Partners' activities in countries. There are limitations to

⁴⁴ The list of our consultees is provided in Annex 2.

⁴⁵ Our approach to consultations was structured so that we achieve a 'triangulation' of views as much as it was possible. All consultations followed a pre-defined outline of issues, with responses recorded by consultee for each of the questions. The responses by issue (respondent blind) were then analysed to understand the general views expressed by the different stakeholders. The assumption was that all respondents who had a view on an issue are equally weighted, which also helped in balancing the inevitable biases in views. These views were then complemented, for each issue, with any documentary evidence identified through desk research. Finally, the overall analysis was moderated by the CEPA team for coherence and basis of our judgements.

seeking telephonic feedback from country stakeholders, and despite our best efforts in scheduling meetings, we have spoken to only one country-level Partner representative and one regional representative from a Partner organisation as part of our consultations.⁴⁶

⁴⁶ These consultations with country-based/ regional stakeholders, together with the views on this issue from global stakeholders we have spoken to, have underscored that the AVI is not recognised as such at country level. In many ways (and as expressed by some AVI stakeholders), this is not a criticism of the initiative; on the contrary, AVI's value is to coordinate activities of Partners to deliver activities and therefore it is unlikely to have a recognisable 'brand' in countries nor would this necessarily be desirable. However, in the context of consultations with country stakeholders, the lack of knowledge about AVI and its activities made it difficult for these individuals to provide their views on the effectiveness of the initiative.

4. REVIEW OF THE AVI CONCEPT AND OBJECTIVES

The first review question considers the conceptual and strategic underpinnings of the AVI initiative. The question is as follows:

To what extent is the AVI initiative – its concept and objectives relevant and appropriate in the context of GAVI's strategy and business plan?

We examine three interrelated sub-questions as part of this, as follows:

- (i) To what extent are the 'theory of change' and objective(s) of the AVI initiative appropriate and is there a shared understanding amongst stakeholders?
- (ii) To what extent has the AVI initiative responded to the findings and recommendations of the ADIP evaluations?
- (iii) How are AVI's concept and objectives positioned to contribute to the GAVI strategy and business plan 2011-15?

We consider each of these in turn below. At the end of the section, we provide a summary of our findings and conclusions on this question.

4.1. AVI theory of change, concept and outcomes

Our analysis has identified two overarching issues on the AVI theory of change, concept, and outcomes. These are listed below and then discussed in turn:

- Fluidity in the definition of the initiative's theory of change, with related differences in stakeholder views about the AVI concept and how it is to be implemented.
- Not all of the five original AVI outcomes continue to be appropriate and of added value for the initiative presently.

4.1.1. The AVI theory of change and concept

For the purposes of our discussion, we define 'theory of change' as a description of the types of interventions (a single programme or a comprehensive initiative) and the underlying assumptions that help achieve the outcomes depicted in the desired pathway of change, reflecting the often complex web of activity that is required to bring about that change. Stakeholders value theories of change as part of programme planning and evaluation because they create a commonly understood vision of the long-term goals, how they will be reached, and how progress/ success will be measured.⁴⁷

There is agreement amongst a majority of AVI stakeholders that much has been achieved under the initiative. At the same time, some important differences in understanding amongst the constituent stakeholders about what exactly AVI is have potentially resulted in more complicated operational realities (e.g. time taken to agree terms of references, ongoing discussions on roles and responsibilities, coordination with the work of other Partners and the Country Responsible

⁴⁷ www.theoryofchange.org, as accessed on 26 April 2012

Officers at the GAVI Secretariat) which may have frustrated progress and reduced the effectiveness of the initiative.

At the highest level, there is agreement amongst stakeholders on the two core goals of AVI:

- broaden and speed-up access to rotavirus and pneumococcal vaccines; and
- create a platform for introducing other new vaccines, such as MenA, HPV, typhoid, JE, and rubella.

However, the pathway of change to achieve these goals is less commonly understood and agreed. As part of our review, we have not been able to identify an agreed document that clearly articulates how AVI will achieve its core goals. The closest document that goes towards describing this is the AVI report on the mapping and costing of activities⁴⁸, which provides a list of activities/ sub-activities that we understand was the starting point for discussions on what needs to be done more generally to introduce vaccines into countries and hence the main background document for the Board decision to establish the AVI initiative. This document sets out in considerable detail the activities (and estimated costs) required to support country introduction of vaccines, as agreed by the AVI Partners. However, in our view, it does not go far enough in actually providing a clear theory of change that would articulate:

- how the identified activities fit within the broader work that is being undertaken by the Alliance and its Partners and leading towards the same agreed goals (i.e. how do these activities link to and/ or are supported by other ongoing vaccine support work; do they form the totality of required activities to introduce vaccines, if not, what else needs to be done etc.); and
- how the implementation of this initiative will be organised (e.g. in terms of institutional linkages, reporting and results framework), including how the long term goals will be reached, and how will AVI's progress/ success be measured both at the country level and for the initiative as a whole.

We understand from our consultations that the time which was available for the preparation of this 2008 report and other supporting documents was very limited, and discussions with individual Partners were ongoing (without yet a firm agreement) about a common vision on the nature of the AVI initiative. These operational realities are likely to have contributed to the lack of clarity at the start. Whilst it would have been better to have ironed out these differences immediately, we recognise that it was a reasonably pragmatic option to move forward with the initiative expecting to agree on outstanding issues once the work began. In this context, the AVI has continued to evolve since its inception in 2008, with changes introduced along the way (e.g. in May 2009, it was decided that any sub-teams to be formed will need AMT approval, and that the PPC will likely keep the AVI report as a regular agenda item).⁴⁹

This continued evolution has led to an unhelpful fluidity in the definition of the AVI's concept and theory of change. Overall, we have identified two primary views amongst the stakeholders

⁴⁸ GAVI (2008), "Accelerated vaccine introduction, report on the mapping and costing of activities".

⁴⁹ AVI AMT Retreat, 30th April/ 1st May 2009, Note for the File. The second reference suggests that the PPC had not had the AVI report as part of its regular agenda and that its continued inclusion was still not confirmed then.

about what the AVI initiative is. These are set out below, although limitations of such a simplification should also be noted:⁵⁰

- **A coordinating and ‘reactive’ approach.** One understanding is that ‘AVI’ is a name given to a coordination platform for a set of activities necessary for introducing new vaccines in GAVI eligible countries. These activities are assumed to be undertaken by the Partners (primarily UNICEF and WHO) and the GAVI Secretariat in their normal course of GAVI Alliance operations, except that some supplementary activities have been provided by an outsourced entity in cases where it was agreed that the required expertise did not exist at Partner organisations at the time. As such, this coordinating mechanism allows Partners to discuss and have an opportunity to resolve at a common forum their respective operational issues as relevant to country vaccine introduction. However, the initiative does not have decision making powers nor does it itself necessarily set the agenda for work going forward. It therefore has more of what could be described as a **‘reactive’** existence.
- **A product launch and ‘active’ approach.** The other understanding is that the AVI is more than a coordination mechanism. This view sees AVI as having – at least to some degree – an institutional identity of its own that is clearly encompassed within but at the same time not entirely identical to that of the GAVI Alliance as a whole. It is more of an industry type ‘Product Launch Team’ built along the lines of a strong matrix management approach (discussed in more detail, as an institutional construct, in Section 5 of this report). It seeks to actively promote a product through driving forward the relevant set of activities, proactively managing the close collaboration of individuals providing functional expertise (as opposed to representing their ‘home’ organisations or departments⁵¹), and holding those individuals accountable for delivering on their responsibilities. In that sense, AVI’s role is beyond simply coordinating the activities of existing Partners, but has an **‘active’** presence, through the AMT and its sub-teams, in driving the support for country launches of new vaccines.

We understand from our consultations that a number of individuals from the GAVI Secretariat who were tasked by the Board to develop the AVI concept had the ambition to develop the initiative similar to an industry product launch team and through a collaborative process engage its cross-functional Partners in introducing new vaccines. Whilst this concept was described broadly to the Board and set out in related presentations, we understand that the exact nature of the initiative was left to be defined by the AMT and as appropriate to the circumstances in which the initiative was to operate.

This vision notwithstanding, CEPA’s view is that the AVI has functioned in a more reactive approach of a coordination mechanism to date. However, arguably, the industry product launch approach is more fit for purpose for such an initiative in terms of bringing together different and

⁵⁰ There were a wider range of views on what the AVI is, forming a spectrum across the reactive versus proactive and product launch versus coordination dimensions. Some views have suggested that aspects of AVI (e.g. some of its well functioning sub-teams) operated more on the lines of ‘proactive coordination’. Whilst recognising the spectrum nature of the understanding, our judgement is that these two broad categories continue to capture the essence of the two general approaches described of the AVI.

⁵¹ This would be different from what they are meant to do as Board members of the GAVI Alliance.

necessary functional skills and experience to assist in the country introduction of new vaccines. Nonetheless, given that the two sets of stakeholder views are not reconciled, we are unable to define a retrospective theory of change as such for the initiative. We believe that any theory of change can be adopted only when the constituent partners of an initiative reach an agreement on what it is meant to do and how. Whilst the division of activities and tasks as per the 2008 costing and mapping report has enabled AVI to function and achieve results (as discussed in Section 6), the absence of an agreement on the exact way of working has probably deterred it from achieving its full potential.

The potential consequences of this uncertainty include:

- The terms of reference for the AMT were drafted but never agreed by the Partners and approved. Among other issues, we understand that there were disagreements about reporting lines for the participating stakeholders.⁵²
- As a result, the Partners, the GAVI Secretariat, and the AVI TAC have had to work with a degree of uncertainty on their roles and responsibilities.⁵³ This has obscured the conceptualisation of the AVI initiative and made it more difficult to explain what the initiative is to stakeholders within and outside of the GAVI Alliance.
- The absence of an agreed results framework to measure progress made by the initiative (as discussed in detail in Section 6). While notable results have nevertheless been achieved, it is reasonable to think, however, that more could have been achieved if these difference in views were resolved earlier and the focus of the initiative (both in terms of what it does and how) was sharper.

At the same time, the lack of clarity about the AVI theory of change did potentially enable greater flexibility in the way that AVI's resources (and TAC's role in particular) could be adapted to deliver its mandate.

4.1.2. Relevance and appropriateness of the five AVI outcomes

The five outcomes of AVI, when taken together, task it with a very broad mandate, which has led to suggestions by a number of stakeholders that the initiative has been asked to achieve 'everything' that the GAVI Alliance is meant to undertake in relation to vaccine pre-introduction, introduction and post-introduction support. The potential for results may have been higher, had the AVI been developed as a less ambitious, more focused, and better defined initiative.

In the rest of this sub-section, we briefly discuss the relevance and appropriateness of the five AVI outcomes in turn, making references to their linkages to the then GAVI strategy and workplan (2007-10).

Outcome 1: Sufficient quantity of safe, effective, and appropriate vaccine to meet the demand

This outcome is closely aligned with GAVI's mission and particularly the second aspect of the then SG 2, i.e. 'improve vaccine supply security'. The outcome continues to be relevant today

⁵² The issue of reporting lines is further discussed in Section 5 of this report.

⁵³ As confirmed by a number of stakeholders.

and aligns closely with the new SG 4 of the GAVI strategy and business plan 2011-15, i.e. the market shaping goal.

The appropriateness of the outcome – i.e. whether it was right to have this outcome as part of the AVI initiative – is less clear. Our concern is that the greater emphasis on market shaping accorded by the current GAVI business plan that was approved after AVI's establishment⁵⁴ (through having it as a separate strategic goal and a dedicated Director at the Secretariat⁵⁵) creates the potential for duplication of efforts. It is therefore important to clearly define what aspects of ensuring adequate supply of the appropriate vaccine are the responsibility of the AVI initiative, that are over and above the activities of the market shaping and other teams within the Secretariat.

Outcome 2: Financing available to pay for the vaccines and systems cost

The relevance of the financing outcome to the GAVI mission and goals is clear, particularly with SG 3 in both the Phase II and Phase III GAVI strategies, aiming to increase predictability and sustainability of financing for immunisation.

However, in our view, including an outcome on financing for AVI is an unnecessary duplication of fund-raising activities that are already being undertaken by the GAVI Secretariat and the Alliance Partners in this regard. Further, it is difficult and arguably not very productive to split the financing functions of new vaccine introduction (that the AVI is tasked with) and the other immunisation goals of GAVI. We would argue that resource mobilisation activities are not the core strength of the AVI initiative as currently structured, and are better placed with the other teams within the Secretariat.

Since AVI was set up, the Secretariat has increased its resources for the financing function with a number of teams working in this area, including the programme financing team, innovative financing team, and the co-financing team. We also understand that in some cases, the advocacy activities undertaken under the auspices of the AVI initiative were not clearly known to all members of the Secretariat, which could have led to further coordination issues on the Alliance's fund-raising related advocacy efforts more generally. That said, the AVI may be well-positioned to provide the research and evidence base in relation to new vaccine introduction, to support GAVI's wider fund-raising efforts.⁵⁶ There is merit in undertaking a more concerted effort to delineate and define roles and responsibilities with regards to the advocacy work so that the AVI and broader GAVI activities are supportive of each other rather than duplicative or incongruent.

Outcome 3: Well-informed country decision on introduction of the vaccine

Outcome 3 (and outcome 4 below) appear to us to be the core value adding activities of the AVI initiative. We see clear relevance of this outcome to the GAVI mission and its strategic goals (particularly SG 2 in Phase II and SG 1 in Phase III GAVI strategy).

⁵⁴ Noted as one of the key contextual changes, see Section 2.2 of this report.

⁵⁵ Director, Policy and Market Shaping

⁵⁶ For example, we understand that one of the contributions of the ADIPs and HI was the development of investment cases to support greater donor funding in particular vaccine areas.

Assuming, as noted above, that the AVI team will be moved to the Country Programme department, it seems reasonable to keep this outcome within the AVI initiative. There are, however, two issues to be borne in mind, including:

- The experience to date suggests that countries did not need as much support as may have been anticipated in order to make decisions on adopting the pneumococcal and/ or the rotavirus vaccines.⁵⁷ This should be taken into account when considering the level of resources and effort required to provide the support under this outcome. It may be however that decisions to introduce other vaccines, such as HPV, could need greater support at country level, given the difference in target population and less epidemiological experience with cervical cancer than pneumonia and diarrhoea.
- This outcome will remain appropriate only if there are strong communication and follow up processes between the AVI Partners at global level, their country offices, and the GAVI Secretariat CROs.

Outcome 4: Country introduction of the vaccine

Supporting country introductions is core to what we believe should be AVI's focus. There is no question that this outcome is relevant to the GAVI mission and the relevant strategic goals. We would also argue that the AVI initiative should be built around this particular outcome, as being the most appropriate for focusing the Partners' and GAVI Secretariat's concerted efforts to overcome the particular initial challenges that are associated with vaccine introduction in countries.

Outcome 5: Establish platform for the sustained use of the vaccine.

The 2008 report on the mapping and costing of AVI activities interprets this outcome in terms of activities and tasks essential to evaluate and monitor the impact (including safety) of vaccine introduction in countries, and to document and disseminate lessons learnt.

There is, however, a fundamental lack of clarity amongst the AVI stakeholders and more broadly, in the GAVI Alliance, on the definition of this outcome, and particularly as regards where the role of AVI 'ends'. In particular, there is ambiguity as to whether AVI is mandated to only support countries in deciding on and introducing the new vaccines, or does its remit extend to improving vaccine coverage and sustained use after the initial roll-out. Many AVI stakeholders interpret this outcome as related to the current SG1 of the Alliance (accelerate the uptake and use of underused and new vaccines); and others view it as sustaining the use of the pneumococcal and rotavirus vaccines beyond their introduction (and some even look at this as sustaining vaccine use after GAVI support ends). Further, some have also interpreted this outcome to relate to the creation of a platform for country introductions of other new vaccines such as MenA, JE, etc. All of these various interpretations are a reflection of the absence of an agreed theory of change and concept for the AVI.

This uncertainty makes it harder to comment on the relevance and appropriateness of this particular outcome. We recognise the importance of sustainability post introduction as one of

⁵⁷ Prior work of the ADIPs and HI, as well as work by national stakeholders, are also likely to have contributed to the faster than originally anticipated adoption of vaccines.

the key requirements for successful delivery of GAVI's mission and more importantly sustaining in-country health impacts. The question therefore is not whether activities to ensure sustainability are important, but what is the most appropriate institutional mechanism to ensure that both vaccine introduction and longer term sustainability are supported by GAVI and the Partners more generally. The definitive answer to this is subject to the eventual definition of what AVI is, as agreed by its constituent Partners:

- Partners may decide that there is merit in focusing the attention of the AVI initiative only on vaccine introduction. This will have the benefits of a smaller and more focused scope of work for the initiative, requiring potentially fewer resources and resulting in development of specialist skills and material. The risks associated with this approach are possible fragmentation of efforts to supporting immunisation efforts globally, and the continued need for a coordination mechanism for supporting vaccine coverage scale-up.
- Partners may, on the other hand, decide to have an initiative with a much broader remit to support all the vaccine introduction related activities as well as those related to increasing coverage and sustainability. This is a considerably larger undertaking that would support a continuum of work between vaccine introduction and country coverage, encompassing a set of activities that relate to most, if not all, of what the GAVI Alliance does. Such a broad scope for AVI would make it the main implementation vehicle for the delivery of GAVI's overall mission, and would need the resources and recognition commensurate with such an important remit.

Our view is that the role of AVI (or any other future model) would be more fit for purpose to support and provide the much-required focus on vaccine introductions, rather than spread it too thinly across the entire lifecycle of vaccine uptake and coverage in countries – unless as noted, its remit and resources are increased commensurately. Arguably, the unique challenges of new vaccine introduction, particularly country-level differences in their capacity for introduction, require a special initiative to ensure that Partners' activities are focused and well-coordinated.⁵⁸ Further, the role of the wider Alliance and the important work undertaken by its Partners already cover issues of vaccine coverage. Increasing vaccine coverage presents a different set of challenges that are generally country-specific (e.g. last mile coverage) – one might therefore contend that these call for less coordination across countries and at the global level and are well covered within the current roles of the GAVI Alliance and its Partners.

4.2. Progress on recommendations of the ADIPs and HI evaluation

GAVI commissioned an evaluation of the ADIPs and the HI in 2007 to: (i) take stock of the way the environment for new vaccine development and introduction has evolved over the previous four years; (ii) assess the progress made and highlight the lessons learnt through the innovative ADIPs approach, the HI, and other new vaccine introduction related GAVI supported activities; and (iii) make recommendations to the GAVI Board on the structure and financing of its continued support in this priority area in the coming years.⁵⁹

⁵⁸ Coverage of underused and new vaccines is a key indicator of GAVI's Strategic Goal 1.

⁵⁹ 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)"

In summary, the evaluation team recommended that a stronger focus is required to support vaccine introduction in countries along with making structural changes to the initiative. These included recommendations that ADIPs should be focused in a single organisation; the implementation mechanism should be housed either at GAVI Secretariat, GAVI Partner organisations, or at an outside entity selected through RFP process; the Board should be involved to provide oversight through a Management Committee; amongst others.

Specific recommendations on improving the structure of a vaccine introduction initiative are listed in Table 4.1 below, with CEPA's comments and judgements on the extent to which these have been implemented/ achieved to date (being informed by analysis of AVI specific documents, such as AVI Progress Reports, and consultations with various stakeholders). Our view is that some of the key recommendations have been implemented under AVI, however some outstanding issues remain with the lack of an AVI results framework; skills/ experience required for the manager position; and adequate leadership and strategic oversight.

Table 4.1: ADIP evaluation recommendations⁶⁰

S.no	Recommendation	CEPA comments on extent of implementation	Status
1	The post-ADIP implementation period needs an investment to support introduction in countries; existing structures lack capacity to address all the issues.	The AVI was established to attempt to bring together and coordinate Partners to build on and implement the work undertaken by the ADIPs. Where existing capacity among the Partners and Secretariat were deemed limited, the AVI TAC was competitively selected to provide specialist skills.	
2	- ADIPs for different vaccines should be focused in a single organisation, with a strong manager, and be target-oriented, time-limited and milestone-driven. - Vaccine introduction to be coordinated by a specifically appointed senior team within the GAVI Secretariat. (ADIP MC)	- The AVI has brought together Partners responsible for driving forward the introduction in countries of the pneumococcal and rotavirus vaccines under one roof. It has also started putting in place, through its sub-team structure, the institutional processes that would support introductions of other vaccines supported by GAVI. - The AVI is housed in a single organisation (GAVI Secretariat). - The initiative was approved by the Board to be time-limited (i.e. from 2009 to 2015). - Three aspects were not, in our judgement, implemented fully: - the AVI results framework, with targets/ milestones, has not been developed (see Section 6); - type of skills/ experience required for the manager position have not been fully met (see Section 5); and - the AVI has faced challenges in adequately resourcing the leadership and strategic oversight functions to begin with, both in terms of senior resources within the Secretariat and Partner-wide senior sponsorship (see Section 5), although this has been strengthened as the initiative evolved.	

⁶⁰ GAVI (2008), “Accelerated vaccine introduction, report on the mapping and costing of activities”, summarising the recommendations set out in the 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)”. The GAVI (2008) report also included recommendations as set out by the ADIP Management Committee (ADIP MC). We have based the table on the GAVI (2008) summary of recommendations, assuming that these were the ones that were accepted from the HLSP report.

S.no	Recommendation	CEPA comments on extent of implementation	Status
3	- GAVI Alliance should consider an implementation mechanism either within the GAVI Secretariat, housed at a GAVI Partner organisation, or at an outside organisation selected through an RFP process. - Managing additional support through outsourced activities where needed.	- The AVI is housed within the GAVI Secretariat. - The AVI included relevant Partners and a competitively selected entity (AVI TAC), commissioned to deliver activities that were not deemed as then available within the Secretariat or the Partners.⁶¹	
4	- A mechanism for in country implementation for products that are programme ready could be based on the Hib Initiative. An integrated and coordinated approach would avoid competition and confusion at the country level for introduction activities, and allow for provision of tailored information to each country for a variety of products. - Scaling up support for vaccine introduction to countries and through the Partners to be in line with their mandates. (ADIP MC)	- The AVI acted at country level through offices of its respective Partners (primarily WHO and UNICEF). A small sample of country level stakeholders suggested that the AVI as a separate 'brand' has no in country recognition. - Partners continued to fulfil their roles, in line with their mandates.	
5	For implementation support, oversight needs to involve the Board, through a Management Committee selected with appropriate skills, and with liaison through specifically charged GAVI Secretariat teams.	- The AVI AMT was instituted as the recommended 'Management Committee'. - The AMT is led by the GAVI Secretariat and consists of members from WHO, UNICEF, AVI TAC and the BMGF (as an observer). The AMT conducts weekly meetings to discuss progress on AVI and address bottlenecks in implementation. The coordination through the AMT has been cited as very helpful by most stakeholders consulted. - AMT presents Progress Reports to the Board on a six-monthly basis and reports two to three times a year to the PPC.	

Legend:

	Implemented		Partially implemented/ In the process of being implemented		Not implemented
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⁶¹ It should be noted that the AVI TAC mandate was changing annually. This allowed for flexibility from the AVI perspective to direct the AVI TAC activities in line with the changing external circumstances. At the same time, it has also led to greater difficulty from the AVI TAC perspective in planning for required resources.

4.3. AVI and the GAVI strategy and business plan 2011-15

The review sub-question we are examining here relates to how AVI's concept and objectives are positioned to contribute to the GAVI strategy and business plan 2011-15.

The establishment of the AVI initiative in 2009 predates the period of the current GAVI Alliance strategy and business plan (2011-15). However, fundamentally, it is quite clear that the overall goals, outcomes and activities of AVI are in line with the 2011-15 GAVI strategy and business plan and therefore continue to be relevant. In terms of funds allocation, the GAVI business plan sets out budget lines for the TAC. Funding for Partners for their various Alliance activities, as noted earlier, is contractually covered under existing institutional MoUs and contracts in place between the GAVI Alliance and the individual Partners.

GAVI's SG 1 (vaccine support) is to accelerate the uptake of new and underused vaccines, which is GAVI's "core business" and "represents the majority of its business plan budget".⁶² As part of this goal, GAVI aims to:

- maintain the momentum on its previously supported vaccines (i.e. YF, HepB and Hib vaccines);
- accelerate the introduction of routine meningitis, pneumococcal and rotavirus vaccines (and supporting campaigns against YF and meningitis); and
- begin activities to prepare for the HPV, JE, typhoid and rubella vaccines.

In support of these aims, the business plan notes that the Alliance will help countries improve decision-making and strengthen vaccine introduction. Given that this is the core mandate of AVI, it is most closely aligned with SG 1 of GAVI's strategy and business plan. AVI has commenced with supporting the introduction of pneumococcal and rotavirus vaccines, and its mandate includes providing a platform for other new vaccines such as HPV, JE, typhoid and rubella. The vaccine-specific AMT sub-teams in the AVI's structure reflect this.

AVI's work also seeks to contribute to GAVI's other Strategic Goals, although it would be difficult to specifically identify/ link the role of AVI towards achieving these goals (as discussed earlier, there may be reasons to reconsider the appropriateness of maintaining the breadth of outcomes and activities within AVI including in terms of avoiding duplication with other activities already underway in the Secretariat after the 2011-15 strategy and business plan were approved). In particular:

- AVI's work supports GAVI's SG 2 on strengthening the capacity of country health systems to deliver immunisation through a range of activities such as developing relevant data (e.g. on disease burden, health and economic impact), guidelines and decision-making tools (e.g. cold chain assessment tool); improving cold chain and vaccine logistics management; supporting effective vaccine management; and training health care professionals.

⁶² Phrases in quotes taken from the GAVI strategy and business plan, 2011-15.

- One of AVI's five outcomes is on financing for vaccines and systems costs – thereby supporting GAVI's SG 3 on predictable and sustainable financing. However, as noted previously, in practice, this outcome is potentially less appropriate for keeping within the AVI initiative going forward, being one of the key functions of the GAVI Secretariat.
- AVI's work also impacts GAVI's SG 4 – to shape vaccine markets. It does so, for example, through the work of the Strategic Vaccine Supply (SVS) sub-team on demand forecasting, and interacting regularly with vaccine manufacturers in terms of ensuring adequate supply to meet demand. AMC, which is a part of AVI's activities, is also a market-making innovative financing mechanism to support the introduction of pneumococcal vaccines at an affordable prices in countries that demand it.

Given the cited issues with regards to a degree of ambiguity of AVI's concept, one might argue that the initiative per se could have been structured slightly differently to serve as a more effective mechanism in support of GAVI's business plan. Further, given that vaccine introductions are at the heart of GAVI's mission, the AVI initiative would have benefitted from having a 'risk matrix' in terms of key risks and mitigating strategies (e.g. risks at the country level in terms of assessing their readiness for vaccine introduction), to feed into the risk management assessment framework in the business plan.

4.4. Summary findings and conclusions

Table 4.2 provides a summary of the main findings on this review question.

Table 4.2: Summary findings on AVI concept and objectives

Review sub-question	Key findings
Objective of the AVI initiative and 'theory of change'	• There is not a shared understanding among the stakeholders (within AVI and in the broader Alliance) about what 'AVI' should be – is it more of a coordinating and 'reactive' approach to introducing vaccines in GAVI eligible countries or more of an industry product launch and 'active' approach. • The consequences of this lack of clarity include: ○ Terms of reference for the AMT were drafted but never agreed by the Partners and approved (we understand that there were disagreements about reporting lines for the participating stakeholders). ○ Partners, the GAVI Secretariat, and the AVI TAC have had to work with a degree of uncertainty on their roles and responsibilities. ○ Whilst notable results have been achieved, it is reasonable to think, however, that more could have been achieved if these difference in views were resolved earlier and the focus of the initiative (both in terms of what it does and how) was sharper. • CEPA's view is that the AVI has functioned as a more reactive approach of a coordination mechanism to date. Arguably, the industry product launch approach is more fit for purpose for such an initiative in terms of bringing together different and necessary functional skills and experience to assist in the country introduction of new vaccines, although challenging to operationalise in the Alliance context. • Given that stakeholder views are not reconciled, we are unable to define a retrospective theory of change for the initiative.

Review sub-question	Key findings
	• All of the five original AVI outcomes are relevant in terms of their alignment with the GAVI mission and strategic goals. There are questions however as to how appropriate it is to have supporting the vaccine supply, financing, and the platform for sustained use of vaccines and their respective activities set within the AVI initiative (given for example, overlaps with the Secretariat activities), Whether the latter should be included as part of the AVI initiative depends on the role that its constituent Partners want it to play. Our view is that AVI should be focussed on vaccine introduction activities, with the broader Alliance and the Partners focussing on coverage issues.
Recommendations of the ADIP evaluation	• In our judgement, most of the recommendations related to the overall establishment of the AVI initiative have been implemented. • The area where we thought more could have been done include: ○ AVI results framework, with targets/ milestones, has not been developed (see Section 6); ○ type of skills/ experience required for the manager position have not been fully met (see Section 5); and ○ AVI has faced challenges in adequately resourcing the leadership and strategic oversight functions, both in terms of senior resources within the Secretariat and Partner-wide senior sponsorship (see Section 5), although this is being strengthened as the initiative has evolved.
AVI positioning within the GAVI strategy and business plan 2011 - 15	• Although AVI pre-dates the GAVI strategy and business plan 2011-15, its outcomes and activities are well aligned with SG 1 in particular, but also contribute to the other GAVI strategic goals as currently defined.

5. REVIEW OF THE AVI DESIGN, STRUCTURE AND MANAGEMENT

In this section, we consider the design, structure and management of the AVI initiative. Our key review question is as follows:

To what extent is the AVI design, structure and organisational management appropriate to deliver its objectives?

As part of this, we consider the following sub-questions:

- (i) To what extent is the AVI design and structure appropriate vis-a-vis its objectives and the changes in the overall context of the initiative?
- (ii) What has been the role of the GAVI Secretariat in the AVI initiative, and how has this been performed to date?
- (iii) What lessons can be learnt from the TAC outsourcing exercise?

We discuss each of these sub-questions in turn below. A summary of our findings and conclusions are provided at the end of the section.

5.1. AVI design and structure

In our analysis under this time limited review, we have focused our attention on what we have identified as the most important issues and related lessons in terms of the design and structure of the AVI initiative. These are set out below and then discussed in turn:

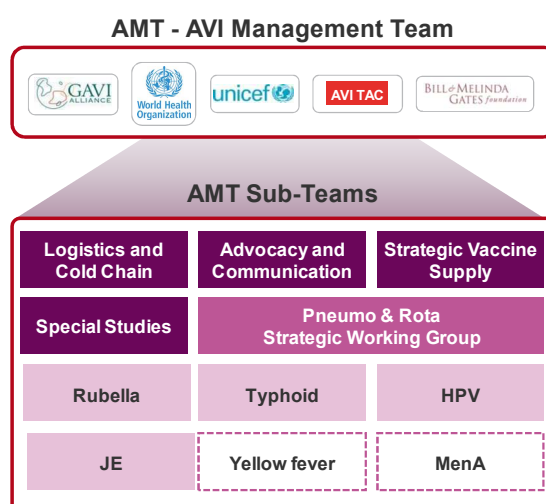
- whether the AVI structure should be that of a coordinating mechanism or more akin to an industry Product Launch Team (based on a strong matrix management model);
- the extent to which the internal coordination is managed well, and if this extends to the AVI's ability to communicate with other stakeholders (including other GAVI Secretariat teams, other Partner teams etc.); and
- clarity on the roles and responsibilities of individual AVI stakeholders.

The coordination achieved between the AVI Partners has been unanimously recognised as helpful and supportive of the efforts to introduce new vaccines in GAVI eligible countries. Whilst there has been some ambiguity in the way that the initiative is understood to be structured, this should not detract from the results that the initiative has achieved.

5.1.1. Coordinating mechanism or a Product Launch Team

As set out in Figure 5.1 below, the AVI structure is based around a management team and a series of sub-teams.

Figure 5.1: Structure of the AVI Initiative⁶³



The management team or the AMT includes representatives from the Partners (WHO, UNICEF and BMGF), the GAVI Secretariat (representatives from the Policy and Performance and Country Programme teams) and AVI TAC. It is also planned to have representatives from the Measles Initiative, Men A Working Group, HPV sub-team and Yellow Fever working group.

Whilst the overall structure is relatively simple, the details of how the involved stakeholders interact with each other have been somewhat ambiguous. We assume that this is mainly driven by the ongoing stakeholder differences in their understanding about the AVI concept; and the absence of an agreed terms of reference for the AMT. We also understand that there is a lack of clarity among the stakeholders about who has the responsibility for providing strategic direction to the initiative – whether this is the collective role of the AMT, the GAVI Secretariat lead (i.e. is this position one of a ‘coordinator’ or ‘decision maker’), or senior members of the respective Partner organisations. In this context, a pragmatic approach has been adopted to work through the issues that arise on vaccine introductions, which is the main focus of the initiative, and to seek consensus in making any decisions so as to avoid impasses as much as possible.⁶⁴

Given this situation, our view is that the AVI design and structure in practice is more reflective of a coordinating mechanism. As set out in Annex 6, the product launch team structure envisages a more balanced matrix based reporting mechanism for individual participants, who would report to both their home organisation/ department and the product team manager. In an industry setting, this type of a team is centred around a particular product (with participants drawn from across functions – Research and Development (R&D), manufacturing, quality control, marketing, commercial, etc.), and is supported by a strong in-company sponsor who would oversee the implementation and has the requisite decision making powers (including on allocation of resources). In the GAVI context, a product launch type team would of course not focus on any particular vaccine (produced by a single supplier), but would be structured around pneumococcal, rotavirus or other new vaccines more generally.

⁶³ GAVI (2011), “Accelerated Vaccine Introduction update” by Jon Pearman, GAVI Alliance Board Meeting, November 2011 and power point presentation as shared by the GAVI Secretariat.

⁶⁴ Latest suggestions, still under discussion, that have emerged from the 2012 AVI retreat state that should there be any impasses, the AMT will present the issues and potential options to the PPC and/ or the GAVI Board.

Which of these two approaches is more appropriate for the AVI is dependent on the view held by the constituent Partners about what the AVI is, which, as discussed earlier, is not fully agreed.

Nevertheless, it is possible to make the following observations:

- **The coordination aspect of the AVI initiative is fairly universally acknowledged by the stakeholders we have spoken to as adding considerable value to the work undertaken by individual Partners and the GAVI Alliance more generally.** It enables Partners to work closely together, build trust and more regularly share information on vaccine introduction related activities. This is likely to have achieved more than a series of bilateral communication channels, and is therefore believed to have been more beneficial to countries and their decision making processes on whether to introduce the new vaccines. A few examples of this include the work across Partners in developing the country readiness dashboard, approach to managing prioritisation of vaccine introductions in the context of constrained supply, and the regular information flow between Partners on implementation issues (as we witnessed during our participation in the AMT conference call). The value achieved by this communication must not be lost and continues to be relevant today, despite the contextual changes since the start of the initiative.
- Reflecting the current nature of the Alliance, **the reporting lines of individual Partners on the AMT are stronger to their respective organisations and take precedence over those to the GAVI Secretariat lead in the AVI.**⁶⁵ Participants on the AMT see themselves as representatives of their organisations first and foremost, rather than individual specialists or subject matter experts (as would have more been the case in a product launch based matrix management setting). Initial expectations of some stakeholders that the AVI would bring together relevant expertise from different Partners to support new vaccine introduction, which can be managed and directed by the GAVI Secretariat, has not materialised in practice.
- In addition, **the AVI does not seem to have benefitted from a strong sponsoring entity/ group of individuals within the GAVI Alliance that would oversee and guide its work.** Such a resource could have provided greater clarity on the direction of work and potentially alleviated the issues of dual reporting lines. In 2009, it was decided that there will be a group of high level officials (“sponsors”) from each AVI Partner organisation to resolve any major issues that the AMT cannot resolve.⁶⁶ Stakeholder consultations and feedback have, however, suggested that this has not worked well and that, as a consequence, a new mechanism for resolving any impasses has been proposed – to bring these issues to the PPC and/ or eventually the GAVI Board.⁶⁷ As also recognised by the Secretariat and the AMT members, this is, to some extent, a structural issue. The institutional positioning of the AVI saw it embedded in one (of a number) of GAVI Secretariat teams (Policy and Performance (P&P)) that has a considerably broader mandate than managing the work of the AVI initiative.

⁶⁵ This was a common theme emerging from most of our consultations with stakeholders.

⁶⁶ AMT Retreat, 30th April/ 1st May 2009, Note for the File.

⁶⁷ Internal AMT e-mail summarising discussions on 15th February 2012, AMT call.

The issues noted above are, to some extent, present in many matrix management teams – whether they be more of a coordinating or decision making nature. As is partly set out in Annex 6, some of the strategies to tackle these issues and the lessons that could be considered for taking forward the AVI initiative include:

- Agreeing and communicating the vision and objectives of the project across members as a useful way to minimise discord and clarify any ambiguity.
- Project teams must have clear guidelines and descriptions on roles/ areas of responsibility, assignment of accountability for objectives, a single point of contact for information or approvals, and a set plan for communication and information sharing.
- The need for a strong ‘sponsor’ who is responsible to identify best practices that can be disseminated throughout the organisation and is in a position of influence within the organisation. The sponsor needs to be able to set the strategic direction for the work and oversee its implementation, providing steers as appropriate.
- Defining expectations on the ‘loyalties’ and ensuring that the team members buy into the concept of the project and the management structure. This may need to be undertaken at a sponsor level, to ensure that individuals representing their teams/ institutions have the clarity and confidence to work under two reporting lines.

The design and structure of the AVI can be improved and the current institutional changes that are taking place provide an excellent opportunity to implement some of the noted strategies.

5.1.2. Helpful internal coordination, with some difficulties in communicating outwards

Our review has suggested that there is good internal communication amongst the participating Partners, who have to date met regularly through a weekly teleconference. These teleconferences have tended to be well organised (clear agenda and supporting materials shared in advance of the call), and participation has generally been high. We participated in one of the AMT weekly calls as part of this review. Whilst participation in one call is clearly not sufficient to make a general statement about their utility and performance, our impression of the discussions is that they are well run, promote open and frank discussions on pertinent global and country-level issues, with the participants being helpful and engaged. This platform of trust and close cooperation must be preserved and built on going forward.

At the same time, some external stakeholders have suggested that it has been more difficult to understand (from the outside) what the AVI is doing and how to access its outputs. We have some sympathy with this view. For example, the web-based information that is available about the work of AVI is relatively limited, does not provide links to outputs from the AVI work⁶⁸ or specify a contact person for information on the work and outputs of individual sub-teams. Stakeholder consultations have also suggested that whilst the AVI staff work in relatively close physical proximity to other GAVI Secretariat colleagues, there have been suggestions that more can be done to improve the flow of communication within the Secretariat on AVI’s work.

⁶⁸ For example, information on the GAVI website suggests that “AVI collects and communicates the evidence-base and GAVI policy information needed to support decisions regarding vaccine introduction” but it is not clear how this evidence-based/ policy information can be accessed from outside the organisation.

Similarly, some stakeholders have suggested that the flow of information from participants of the AMT with their departments and home organisations can be improved.

5.1.3. Ambiguity in roles and responsibilities of Partners and sub-teams

In the absence of an agreed terms of reference, there is limited clarity on the exact roles and responsibilities of the AVI Partners. This is probably less acutely felt by the AMT given the high level of ongoing communication between the Partners and their view that their participation in the AVI initiative does not change their roles as members of the GAVI Alliance anyway. However, this is potentially more of an issue in relation to the sub-teams.

Out of the 11 sub-teams, we have been able to identify *draft* terms of reference for the Special Studies, SVS⁶⁹, and the HPV sub-teams. We would have, for example, expected that such terms of reference would be developed and agreed at the inception of each sub-team, and easily accessible and transparent from outside the AVI. Some stakeholders have also commented that in the absence of more institutionalised systems, it is often left to the management and leadership capabilities of individuals to lead the sub-teams – this can of course work well in the right circumstances (and feedback received on the work produced by some of the sub-teams has testified to this effect), but is less sustainable in the long run and produces differentiation between the sub-teams.

There is not sufficient information for us to undertake a more detailed assessment on the relevance, budgets, possible duplication of work, action plans of sub-teams. We would suggest that this is an important area of work to take forward in the future.

Finally, and as will be discussed in Section 6, the absence of a results framework also adds to the uncertainty as to the roles of individual sub-teams and their responsibilities in terms of the overall AVI outcomes.

5.2. Role of the GAVI Secretariat

Focus on a single organisation

An important recommendation from the ADIPs and HI evaluation was that any new activities related to supporting country vaccine introductions should be focused in a single organisation. This is a useful recommendation, in that:

- Much of the introduction activities are not necessarily vaccine specific, and it seems reasonable to suggest that important synergies could be achieved if these were brought together under one leadership and management structure.
- Apart from the efficiencies/ economies of scale to be gained, more importantly, there is a need to avoid countries being faced with competing organisations promoting ‘their’ vaccines (e.g. pneumococcal versus rotavirus versus HPV etc.). Rather, countries need to be provided with the relevant support and information to make an informed decision about the vaccine introduction that makes most sense from the national perspective.

⁶⁹ While the updated version of SVS terms of reference (entitled “Strategic Vaccine Supply sub-team – Terms of References, Doc. Name: SVS ToR draft 2.0”) has not been approved, the earlier version was finalised and approved by the AMT.

- Further, this unified pan-vaccines model is aligned with the single authority structure in countries that is responsible for introducing new vaccines (i.e. Ministries do not have different Officers for each vaccine).

Selection of the GAVI Secretariat to house AVI

The ADIPs and HI evaluation recommendations encouraged GAVI to consider an implementation mechanism either within the GAVI Secretariat, housed at a GAVI Partner Organisation or at an outside organisation selected through an RFP process. Whilst we have not seen documents that would explain the reasons for the decision to house the AVI initiative within the GAVI Secretariat, it seems to us to be a reasonable choice in the context of (among others):

- GAVI Secretariat already undertaking coordination work between Partners and as part of the day to day operations of the GAVI Alliance;
- individuals within the Secretariat being very familiar with the work of the ADIPs;
- this model providing greater promise in terms of integration with other global and country-level vaccine support activities and the wider work of the Alliance; and
- outsourcing AVI may not have necessarily got the level of engagement/ ownership from the Alliance.

GAVI Secretariat therefore undertook to host the initiative, made available the institutional infrastructure, and provided the necessary management/ coordination.

Issues in practice and suggestions going forward

This proposed way forward, whilst reasonable, has had two inbuilt structural difficulties, which we believe have affected the management of the initiative and include:

- **Roles and responsibilities of the Secretariat vis a vis Partners.** There is an ongoing debate, and not just in the GAVI Alliance but also at many, if not most, of the global health partnerships, about the roles and responsibilities of their respective Secretariats. Reporting lines can be particularly difficult to manage when the Secretariat staff are ultimately responsible to their Boards (made up of Partners), whilst often trying to manage the work and outputs of the representatives of these Partners on individual work streams/ initiatives. In the case of AVI, we have perceived this institutional complexity reflected in the different views about the nature of the initiative.
- **Secretariat capacity.** Secretariats are often viewed (rightly or wrongly) as ‘overheads’ to any global health partnership operations, with consequent and perfectly reasonable ambitions to keep the cost of any such Secretariat functions as low as possible. During uncertain economic times, these pressures are only amplified. Similar pressures are of course present in GAVI, and it is our view that this pressure to maintain the GAVI Secretariat as ‘lean’ as possible has in some measure led to a significant under resourcing of Secretariat interaction with and management of AVI. This was originally reflected in relatively few individuals engaged (original plan had two full time equivalents (FTEs) and

one temporary FTE). This number has increased over time to five FTEs now, in recognition of the workload and importance of the work undertaken.

In addition to these two structural issues, we have identified the following points which should be noted when thinking about any future development of a vaccine introduction initiative:

- **Recognising the importance of AVI within the Secretariat.** The activities grouped under the AVI are clearly very important to the delivery of GAVI's mission. A large part of GAVI's primary role and value-add in the global immunisation space is its support for new vaccine introductions. In this context, it seems rather incongruent that the AVI initiative, as currently structured, appears to be somewhat institutionally de-emphasised within the GAVI Secretariat. It is such a central activity to what the Alliance does, that it might be more conducive to being overseen by or at least reported regularly to the CEO or the Deputy CEO. Further, we agree with the current proposal to raise any major AVI-related issues (e.g. key decisions on new vaccine introduction approach and strategy, selection of new vaccines for introduction, any major vaccine demand-supply issues) to the GAVI PPC and/ or Board which would provide an appropriate governance platform to highlight and discuss any major challenges in new vaccine introduction.⁷⁰
- **Improving coordination with country programmes.** Given its institutional place within the P&P, there were potentially opportunities missed in terms of better coordination of AVI activities with that of the CROs – although we note that the Managing Director of the Country Programmes team is a member of the AMT. We understand that there are organisational reforms under way to address this issue, with AVI activities being moved to the Country Programmes team (once a new Managing Director for this team is recruited). Given the country implementation focus of the initiative, we believe that this shift should enhance the coordination role of the initiative.
- **Matching skills for leadership/ management needs.** Regardless of whether the Partners eventually agree for the AVI to be a more reactive coordinating mechanism or a more active product launch type team, managing the initiative is a very complex task. In our view, to deliver such an undertaking requires many years of project management and organisational leadership experience, and not necessarily as much technical vaccine expertise (even though the latter is important in terms of technical input into the operations, however not that essential for the overall project manager). GAVI's choice of leadership for the initiative should reflect this, as well as the resources that are provided to support that role.

The pressure on maintaining a low headcount at the Secretariat has meant that resources from the AVI TAC were seconded to the Secretariat to support the work of the AVI. This is a reasonable approach to take in the context of limited ability for expanding existing staffing cohort, but it does introduce some issues such as:

- Without making any judgements on the abilities of any one individual, it is inevitably more difficult to have the 'core' management team made up of individuals from different

⁷⁰ It would be overly time consuming and institutionally onerous for all decisions to be taken to the PPC and/ or the Board, so judgements should be made so that these governance bodies are only involved when necessary.

organisations. This may be particularly acute in an area of such central importance to the work of the GAVI Alliance.

- Some suggestions have been made by individuals consulted that it would have been better in terms of developing longer term capacity at the Secretariat to have invested the resources in in-house staff.
- At the same time, the contracting approach provides greater flexibility in managing resource requirements at times of peak activity.

On the whole, however, our view is that the extent of external contractors working on this initiative is not a major issue. The more important need is in achieving greater clarity on what the AVI initiative is and how it is expected to achieve its outcomes; a set terms of reference will make it easier to identify the required resources and to manage them – whether they be internal or external to the initiative.

5.3. What lessons can be learnt from the TAC outsourcing exercise?

5.3.1. Background

Extensive work was undertaken in 2008 on mapping and costing activities that are required for country introduction of vaccines. This work identified a series of activities which required skills that are not present within the Alliance, Partners or the then GAVI Secretariat. These include activities such as developing and updating the strategic supply and demand forecasts; country-level economic evaluations for rotavirus and pneumococcal; and developing an advocacy strategy for country level decision makers.

The GAVI Secretariat ran a procurement exercise to outsource the required skills for these activities, and issued an RFP to procure a TAC to cover three broad areas where the successful applicant would have the lead responsibilities, including:

- Communications and advocacy – to increase the support and financing of new vaccines and to support global, regional and country level decision making.
- Special studies – scientific and economic studies to support decision making and assess impact.
- SVS – managing the strategic supply and demand dynamic.

The ultimate goal set out for this work is to introduce pneumococcal vaccine in 42 countries and rotavirus vaccine in 44 countries by 2015. Following a competitive bidding process, the contract to deliver on the three broad areas of work was issued to a consortium (made up of the same institutions who worked on the ADIPs). The contract was structured as a seven year framework agreement, with individual ‘exhibits’ (or contracts) setting out the exact activity requirements and budget on an annual basis.

Considering this outsourcing exercise in retrospect, a number of important issues emerge. These are related to the following two areas, which are discussed in turn below: (i) nature of the procurement and the contract awarded; and (ii) implementation of the activities by the TAC.⁷¹

5.3.2. Nature of the procurement and the contract awarded

We have identified a number of issues with regards to the nature of the procurement and the contract awarded. These have had both advantages and difficulties/ risks – as discussed below/ These should be noted when considering the lessons learned from the implementation of the AVI initiative.

Issuing a single contract for all three areas of activity⁷²

- The advantages are mainly centred around potentially achieving: (i) more effective delivery based on better coordination and synergies of teams delivering the activities (assuming that the awarded consortium worked well as a team); (ii) a better price for the outsourced activity, assuming that bundling the activities will provide some savings based on economies of scale (at least in terms of management cost); and (iii) a single coordinating interface for GAVI Secretariat with the consortium.
- The risks are that outsourcing to a single consortium in effect places all ‘eggs in one basket’. It also potentially reduces the flexibility that the Secretariat has in managing the contract, as it is dealing with a single organisation for contracting purposes but has to contend with multiple delivery stakeholders forming part of the consortium that it did not individually and directly contract (hence potentially giving up some control). Further, a Consortium approach generally implies significantly greater coordination and management demands, which increases the challenge of managing an already complex initiative.

On balance, we think that it would have been better to use different contracts for the three separate areas of work required under the outsourcing contract.

The contract was issued as a seven year framework, with annual exhibits stating more specifically the work that needed to be done in each year.

The implications of this contract structure include:

- The advantages of the framework nature of the contract is that it provides the Secretariat with a degree of flexibility around the work that TAC is going to implement during the seven year period (a flexibility that was used to support a change in advocacy work for example, as discussed in the next sub-section) whilst maintaining the relationship with the same consortium. It also provides TAC with a longer term engagement, even if the details of the exact work required are not necessarily apparent in advance.

⁷¹ It is outside the scope of this work to re-examine whether the choice of the actual organisations awarded the contract was correct.

⁷² Whilst the bidding consortia had the choice of bidding for one or more of these areas of work, the consortium able to provide all three in one package would have probably had an advantage during the evaluation process.

- The difficulty with this approach is that seven years is a long time in any industry, including in the global health space. The risks are that:
 - The emerging needs for expertise – for example, addition of new vaccines – over the whole period may not be available within the TAC and also that the overall flexibility of the Secretariat is reduced in its ability to restructure the contract (including potentially changing providers of expertise). Whilst the annual contracting does provide some flexibility, this requires strong management and forward planning resources at the Secretariat – as discussed earlier, the Secretariat is potentially under resourced to provide this management and the uncertainties about the nature of the AVI makes planning and direction setting more difficult.
 - Further, given some overall changes in the AVI context, e.g. increase in Secretariat size and staffing since 2008 when the AVI was set up, there is a reduced business case for outsourcing all of the services currently contracted to the TAC (e.g. developing SDFs, leading some special studies, fund-raising, etc.) with some of these activities better fitting within the GAVI Secretariat now. We understand that moving some of the TAC activities to the Secretariat is underway as part of the ongoing institutional reforms.

On balance, we think that it would have been better to use shorter term contracts, potentially as part of a framework arrangement with a number of pre-qualified organisations, which would have been more aligned with an anticipation that GAVI's requirements might change over the period in question.

Following a competitive process, the contract was awarded to a consortium comprised of the same organisations that were involved in managing the ADIPs and HI.

This was not surprising, given the extensive experience that these organisations had in managing pneumococcal and rotavirus vaccine pre-introduction work and the relevant know-how that may not have been available to other organisations internationally. Placing all three areas of work in single terms of reference would have further encouraged consolidation of these organisations into a single consortium. Again, there are advantages and risks of this, to some extent inevitable⁷³, result of the tender:

- Advantages: The work would have certainly benefited from the continuity and experience that was brought to AVI by the organisations who clearly had the relevant context and knowledge for pneumococcal and rotavirus introductions. In addition, established working relationships between relevant individuals would have probably helped.
- Risks: The risks, however, include the potentially more difficult adjustment of the organisations that delivered ADIPs and HI to a new way of working. Under the ADIP and HI model, the organisations had much greater independence to deliver work under

⁷³ In noting the possible 'inevitability' of the tender result, there is no suggestion of any impropriety in the procurement processes from any of its participants; it is simply a reference to the fact that bundling the three areas would have encouraged consortium building of those organisations originally involved in the ADIPs, which in turn captured most if not all of the available experience in this area at the time within one consortium.

their terms of reference, with minimal if any oversight by the GAVI Secretariat. This is quite different from the AVI. The latter requires the AVI TAC to, on the one hand, coordinate more closely with other AVI stakeholders and be managed closely by the Secretariat; whilst on the other hand, it requires the Secretariat (or at least the AMT) to provide more active and coherent direction to the work that the TAC is contracted to undertake. This was a cultural shift for both and is likely to have contributed to some of the challenges that were experienced in managing the AVI work as a whole.

5.3.3. Implementation of the activities by the TAC

Once the contract was in place, a number of implementation related issues have emerged, as follows:

- **Differences in perceptions about the nature of the relationship between the GAVI Secretariat and the AVI TAC.** One understanding is that this is very much a grantor-grantee relationship, given that these activities were outsourced through an RFP process. At the same time, there have been expectations that this relationship should be based on a more equal partnership and not be different to the relationship between the Secretariat and the Alliance Partners. This difference in expectations, and the fact that they have not been resolved early on in the contract, are likely to have led to ongoing management challenges.
- **Secondment of TAC members to the Secretariat.** In the communications and advocacy area of work, many of the TAC members are practically seconded to the Secretariat to work alongside full time staff. This provides the required resources to the Secretariat, although sensible questions have been raised about whether longer term sustainability would be better served if staff were simply recruited into the Secretariat directly (notwithstanding, of course, the pressures noted earlier about keeping the Secretariat staff count 'lean').
- **Moving activities to the Secretariat.** In the context of the previous point, some activities are in fact now being moved into the Secretariat (such as developing SDFs), and the learning that has taken place in collaboration with the TAC is being put into practice. The risk here is that contributions by TAC, particularly in terms of specialist thinking and approaches that some have suggested were brought into GAVI by these external entities, may potentially be diluted in due time.⁷⁴

Our review has not had the scope to evaluate the work undertaken by the AVI TAC against projected costs and reporting requirements. The focus has been more on structural/ procedural aspects of the TAC. We would expect that a detailed review of the TAC will be undertaken in the future as part of their contract management. One of the issues to be examined then is the

⁷⁴ There is no suggestion here that the GAVI Secretariat lacks innovation or specialist skills; it simply recognises that outside expertise will often bring in new perspectives and new ways of working.

reason why the TAC did not develop an AVI results framework, as was stated in its original proposal.⁷⁵

5.4. Summary findings and conclusions

Table 5.1 provides a summary of the main findings on this review question.

Table 5.1: Summary findings on AVI design, structure and organisational management

Review sub-question	Key findings
Design and structure of the AVI initiative	- The overall AVI structure is relatively simple, but the details of how the involved stakeholders interact with each other have been somewhat ambiguous. There is also a greater need for clarity on who is responsible for providing strategic direction to the initiative. - In this context, the following observations can be made: - coordination aspect of the AVI is fairly universally acknowledged as adding value to the work undertaken by individual Partners; - reporting lines of Partners to their respective organisations are stronger and take precedence over those to a GAVI Secretariat led management mechanism such as the AVI; - AVI does not seem to have benefitted from a strong sponsoring entity/group of individuals within the GAVI Alliance that would oversee and guide its work. - The initiative would have benefited from greater transparency about its work by, for example, having greater clarity on the Alliance's website about what it does, how it does it, and where external stakeholders could access information/ outputs produced by the initiative.
Role of the GAVI Secretariat	- Housing the AVI mechanism within the Secretariat seems to be a reasonable choice, although the Secretariat faces two inbuilt structural difficulties: - reporting lines can be difficult to manage when the Secretariat staff, who are ultimately responsible to their Boards made up of Partners, try to manage the work and outputs of the representatives of those same Partners on individual work streams/ initiatives; and - the ongoing pressures to keep the Secretariat 'lean' in staffing terms. - AVI appears to have been de-emphasised within the GAVI Secretariat structure – such a central activity seems to us to have warranted closer oversight by the CEO or the Deputy CEO, with major issues being flagged to the GAVI Board/ PPC (as implemented recently). - The skills and experience needed to lead an organisationally complex initiative such as the AVI seem to us to be more reflective of a senior project management individual with experience of coordinating across different Partner organisations, with less of a requirement for in-depth vaccine knowledge.
Lessons from the TAC outsourcing exercise	There are both advantages and disadvantages of issuing a single, seven year, framework contract to cover all required outsourced activities. On balance, our view is that the magnitude of potential disadvantages is greater and so it would

⁷⁵ Page 51 of the technical submission states: "Working with the GAVI AVI project team and in consultation with the other AVI partner organisations, our OSE consortium will develop a comprehensive results framework to guide M&E at project inception. The PMC will finalise this framework within three months of project inception."

Review sub-question	Key findings
	have been better to issue: ○ different contracts for the three separate areas of work required under the outsourcing contract; and ○ shorter term contracts, potentially as part of a framework arrangement with a number of pre-qualified organisations, which would have been more aligned with an anticipation that requirements might change over the period in question. • There are clear benefits of having the same organisations involved in the AVI TAC as in the ADIPs and HI, in terms of continuity and institutional memory. However, there were some difficulties in managing the change of working culture (e.g. in terms of TAC needing to report to Secretariat on performance on its grant and annual reviews etc.).

6. REVIEW OF RESULTS

In assessing the ‘results’ of the AVI initiative, our overarching review question is as follows:

What has been the progress in achieving the overall goals and outcomes of the AVI initiative and what has been AVI’s contribution to these?

The sub-questions below seek to address the two components of this question:

- (i) What has been the progress on the five intended AVI outcomes?
- (ii) What has been AVI’s contribution to the progress achieved?

Our assessment of both sub-questions has been informed by a review of available documentation and data (e.g. AVI Progress Reports, WHO database on country introductions), stakeholder consultations as well as specific written feedback from some AMT members on the role/ value addition of AVI.⁷⁶

We discuss below the key issues in assessing the results of the AVI initiative to date, followed by our assessment of the two sub-questions in turn.

6.1. Key issues in assessing the results of the AVI initiative

There are some fundamental challenges in assessing the results of the AVI initiative, stemming from:

- lack of clarity on AVI’s ‘theory of change’, as already discussed;
- the consequent absence of a results framework; and
- absence of a single consolidated progress report on AVI outputs (there are currently multiple sources of reporting/ information).

The challenges of assessment do not imply that the AVI activities were not undertaken, but they make it difficult to identify and monitor the progress made by the initiative in supporting countries in their vaccine introductions, and importantly, what gaps or constraints remain.

6.1.1. Lack of clarity on AVI’s theory of change

An important issue with the initiative, as discussed in Section 4.1, is that there are differences in stakeholder views on its theory of change and concept. This ambiguity creates an issue for results measurement, as the initiative’s concept drives the nature of outputs expected under each of its five outcomes. For example:

- As a ‘coordination mechanism’, a suitable results framework would measure outputs related to increased interaction between Partners (in addition to broader outcomes and impacts that the GAVI Alliance/ Partners would measure).
- If the initiative is modelled on an industry product launch team, with a strong matrix management approach focusing on specific deliverables that are within the control of

⁷⁶ CEPA circulated a short questionnaire on this to the AMT members. We have received responses from AVI TAC and WHO, which have been drawn upon for this analysis.

that team, the results indicators would need to be broader than those focusing on coordination and more centred around achievements of various outputs related to vaccine introduction in countries against a given budget and expected timelines.

6.1.2. Absence of a results framework

We have not been able to identify a clearly defined results framework for the initiative. While it may be argued that the AVI may be assessed on the indicators of the GAVI strategy and business plan 2011-15, our view is that it is important to have a distinct AVI initiative performance framework so as to: (i) keep track of whether the initiative is delivering on its activities within expected timeframes and budgets; and (ii) highlight the value addition/contribution of the initiative in the context of the Alliance as a whole.

We note that the AVI TAC was responsible for developing a results framework for the initiative. However, this was not taken forward – although we have not been able to ascertain why this was the case. The consortium developed a list of illustrative results indicators for the AVI initiative as part of its original proposal⁷⁷, but the TAC annual reports provide updates only on some of the TAC specific outputs.

Notwithstanding the challenge that the ambiguity around the AVI concept creates for defining a suitable results framework, we have developed a *proposed approach* which could be used in the future for assessing the results of the AVI initiative (and any subsequent intervention for new vaccine introduction). This is based on considering the broader GAVI framework for vaccine introduction, and defining particular indicators that would capture the AVI's value add.

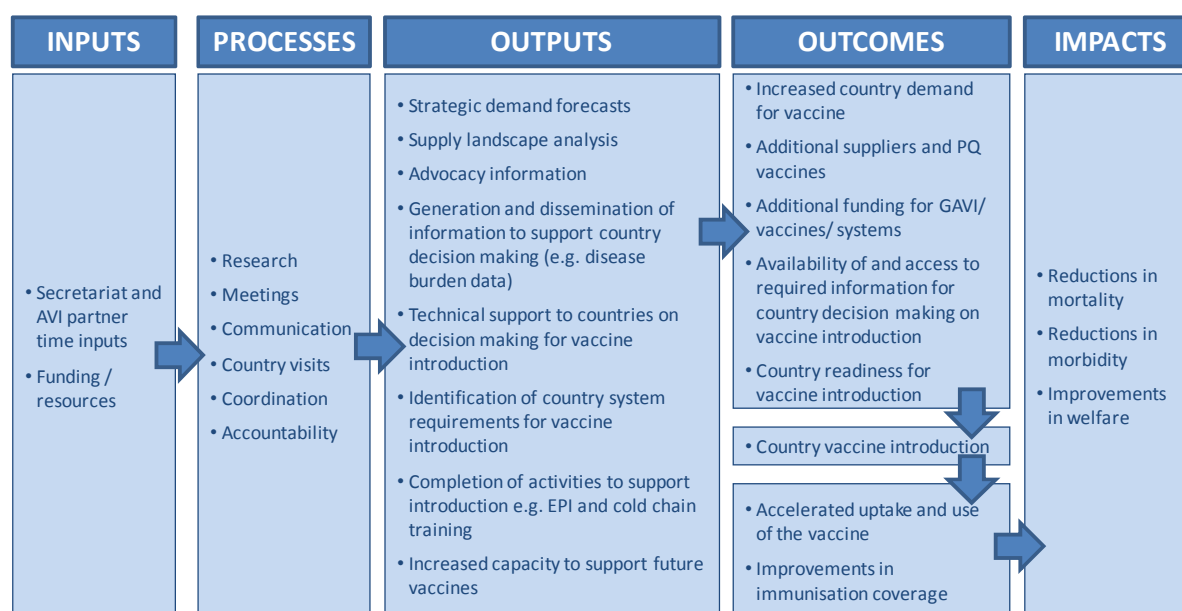
A broader results framework for vaccine introduction

The proposed results framework, as set out in Figure 6.1 below, takes account of the five AVI outcomes for vaccine introduction (although we note that GAVI may wish to re-examine the appropriateness of these outcomes in the future) and maps linkages from inputs and processes to outputs, outcomes and impacts.

The framework seeks to track the broader efforts of the Alliance towards new vaccine introductions, of which AVI is an integral part. In this sense, the proposed approach maps closely to the GAVI results framework. For example, the outcome on country vaccine introduction could be measured by GAVI's business plan indicators for SG 1 on: (i) number of GAVI supported countries introducing new and underused vaccines; and (ii) coverage of new and underused vaccines. (We propose that a count of the number of countries per se is not as relevant as a consideration of the birth cohort covered. Arguably the total impact is higher when large birth cohort countries introduce vaccines).

⁷⁷ Pg 51-54, "Accelerated Vaccine Introduction Initiative – A technical proposal submitted by PATH, Johns Hopkins University Bloomberg School of Public Health, and US Centers for Disease Control and Prevention", August 2008.

Figure 6.1: Possible results framework for vaccine introduction⁷⁸



Defining indicators that capture AVI's value add

While the above framework would help track progress in general, it would be important to also develop suitable metrics that capture AVI's value add, i.e. its particular contribution to the results achieved. Our suggested approach would be to track the following:⁷⁹

- **'New' or 'unique' activities under the initiative.** For example, several activities undertaken by the AVI TAC were not previously undertaken by the GAVI Partners or the Secretariat; the country readiness dashboard is a new intervention developed under the aegis of AVI; etc.
- **Improvements that the AVI has made to the work of the Partners.** It would be useful to consider what AVI is doing 'better'; what 'more' the Partners are doing as a result of their involvement in the initiative; and what activities/ outputs are being delivered more 'efficiently' or 'effectively'. For example, some potential indicators could be:
 - number of additional coordination meetings held between Partners;
 - number of country-level issues dealt with by the Partners and time taken to resolve these (e.g. we understand that the AVI Partners have been trying to resolve vaccine supply issues arising out of the recent *coup d'état* in Mali);
 - whether there has been an increased emphasis on Effective Vaccine Management (EVM) and related improvement plans in support of vaccine introduction;
 - whether there has been faster pre-qualification of vaccines by WHO.

⁷⁸ AVI initiative's mandate focuses on introduction and not scaling-up, and hence coverage improvements may only in part reflect its contribution.

⁷⁹ This suggestion draws on CEPA's approach to measuring value add under the GAVI Second Evaluation.

- whether there have been any improvements to the work done previously under the ADIPs/ HI (e.g. the SDFs under AVI uses an improved methodology and covers all vaccines).

There could be other indicators as well that could be developed to track the added value of the AVI initiative. Care should be taken to select a few pertinent indicators for efficient monitoring.

6.1.3. Multiple sources of reporting on AVI's results

There are a number of reports that provide information on the progress being achieved in relation to the various AVI outcomes. While these multiple mechanisms have been helpful in noting some of the progress achieved on vaccine introductions, there appears to be a lack of systematic reporting on the performance of the initiative as a whole and as against a predetermined set of indicators (which relates to the absence of an AVI results framework). This contributes to the challenge of assessing the specific contribution/ value add of AVI.

Specific issues with each source of reporting are as follows:

- **AVI Progress Reports to the GAVI Board and PPC.** While the Progress Reports provide a useful summary update on work undertaken towards new vaccine introduction in countries, it is not clear: (i) to what extent the activities reported emanate directly from the work undertaken as part of the AVI initiative, given some of the activities are part of the Alliance's and Partners' mandate anyway under the GAVI business plan; and (ii) how much more work is required in order to achieve each outcome (i.e. what else is required in addition to the reported activities, who is working on it, and when will it be completed). There has also been a limited description in these reports of country-level activities.
- **AVI TAC Annual Reports.** The Annual Report provides a summary of results achieved by the AVI TAC on an annual basis. These reports provide detailed outputs and deliverables of the Special Studies, SVS and Advocacy and Communication sub-teams⁸⁰. These are helpful in analysing the progress made on the key activities assigned to the outsourced entity, but given substantial work undertaken by other Partners, these are not sufficient to measure the progress of the initiative as a whole. Again, the absence of a results framework makes it very difficult to fit the work undertaken by AVI TAC within the 'bigger picture'.
- **GAVI workplan update.**⁸¹ Progress updates on the GAVI business plan also serve as a source of information on the five intended outcomes of the AVI initiative. Despite these links however, our view is that the goal-level indicators alone are not sufficient to measure the results of the AVI – as it would be important to measure the value add of the initiative, as discussed above.

⁸⁰ We note that there are certain outcomes reported on AVI TAC's support to the Large Country Introduction task team as part of the Annual Report.

⁸¹ GAVI (2011), "2010 Work Plan Information/ Update", December 2011.

6.2. Progress on the AVI goals and outcomes

The AVI initiative was conceived with the overall goals of broadening and speeding-up access to rotavirus and pneumococcal vaccines, as well as creating a platform for the introduction of other new vaccines such as MenA, HPV, typhoid, JE and rubella. In support of these goals, considerable progress has been achieved across the five outcomes of the initiative. We provide a summary below of the key areas of progress.

This progress reporting does not suggest a contributory role of the AVI initiative for all aspects of these results. This is dealt with in more detail in the next sub-question.

6.2.1. Country demand and introduction of pneumococcal and rotavirus vaccines

Figure 6.2 presents ‘country demand’ for new vaccine introductions, as represented by the number of country applications for pneumococcal and rotavirus vaccines. The figure suggests that:

- by 2011, 68% (48 countries) of all GAVI-eligible countries had applied for pneumococcal vaccines, and 46% (33 countries) for rotavirus vaccines; and
- while the number of applications has been increasing for both vaccines, the applications for pneumococcal vaccine have been significantly higher as compared to rotavirus.

Figure 6.2: *Pneumococcal and rotavirus applications by GAVI-eligible countries*^{82, 83, 84, 85, 86}

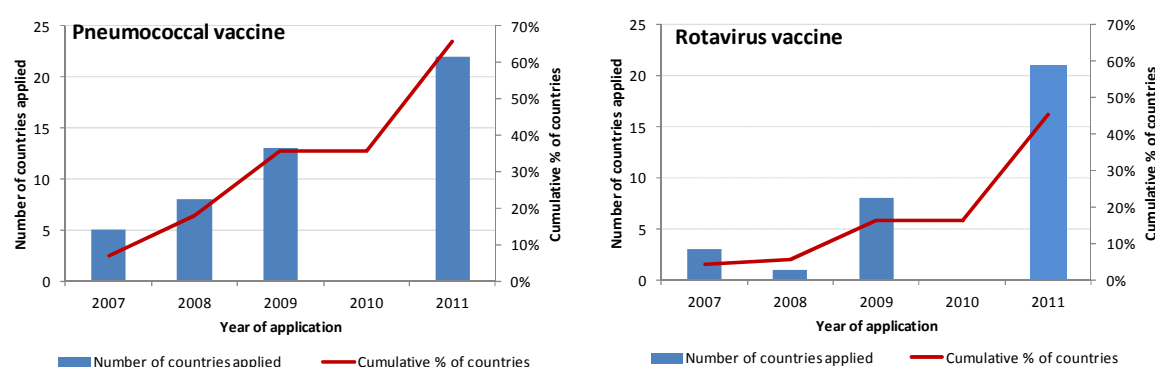


Figure 6.3 below presents trends in country introductions of both vaccines (actual and projected). In considering the information provided, we note that:

⁸² Source: IRC review decisions for 2007-2011. We have cross-checked the information with a spreadsheet titled “Application metrics for CEPA_Final_Updated (version 1)” provided by the GAVI Secretariat. There are some discrepancies between the two sources, and the graphs here are based on the IRC review decisions summary.

⁸³ Applications that were required to respond to certain conditions/ clarifications have been counted in the year in which the application was first submitted. Applications that have been asked to be resubmitted have also been included in the first year of submission.

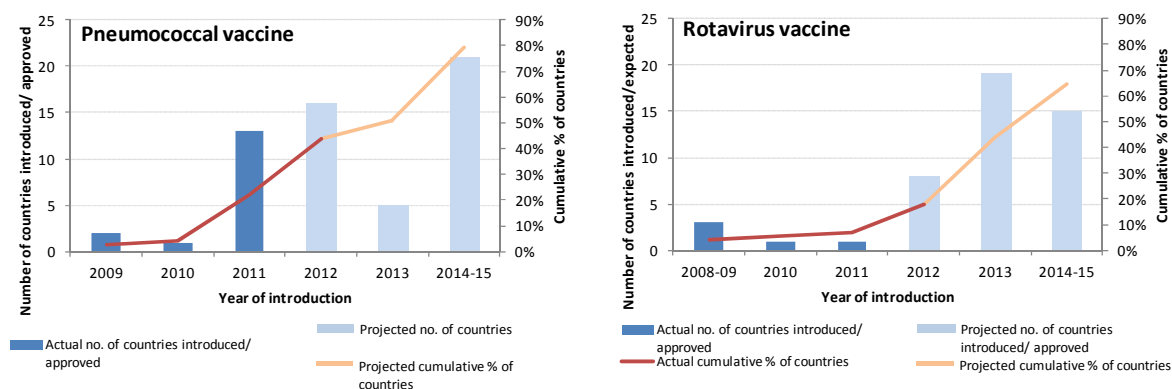
⁸⁴ ‘Cumulative percentage of countries’ refers to the number of countries as a proportion to GAVI-eligible countries. Since in 2011, all previously eligible countries were permitted to apply, the total number of GAVI-eligible countries for all years presented in the graph is 73 (including South Sudan).

⁸⁵ We understand that rotavirus introduction in a number of GAVI-eligible countries was delayed, pending results of efficacy trials by rota ADIP and partners in Asia and Africa.

⁸⁶ There was no GAVI application round in 2010 due to issues with GAVI’s financing. The steep rise in 2011 also reflects this, along with the temporary waiver of 70% DTP coverage requirement and a last opportunity for graduating countries to apply.

- 16 countries have introduced the pneumococcal vaccine by 2011, and an additional 21 countries are projected to introduce it by 2013;
- for the rotavirus vaccine, while there have been only five country introductions by 2011, 27 further country introductions are expected during 2012 and 2013;

Figure 6.3: Country introduction of pneumococcal and rotavirus vaccines^{87, 88, 89}



When the AVI initiative was approved in 2009, targets were set at 44 and 42 country introductions for pneumococcal and rotavirus vaccines respectively by 2015.⁹⁰ Given faster than planned country introductions, and according to the forecast SDF (v4.0) provided to CEPA, GAVI anticipates that the introductions will reach 58 countries for pneumococcal vaccine and 47 countries for rotavirus vaccine.⁹¹

6.2.2. Vaccine pre-qualification and supply

The key areas of progress with regards to the pre-qualification and supply of pneumococcal and rotavirus vaccines are discussed below.

WHO pre-qualification of vaccines

Two pneumococcal and rotavirus vaccines respectively have been prequalified, manufactured by two suppliers each – GlaxoSmithKline (GSK) and Pfizer (Wyeth) for pneumococcal, and GSK and Merck Sharp & Dohme Corp for rotavirus.

Initiation of procurement mechanisms and supply status

Procurement of these vaccines (through UNICEF procurement; and using price and supply guarantees from the AMC for pneumococcal vaccine) has commenced. However, unprecedented demand has resulted in some supply shortages. Details include:

⁸⁷ Source: GAVI (2011), “Report to the GAVI Alliance Board, November 2011”

⁸⁸ Note that the data mentioned in the footnote above considers the projections for pneumococcal vaccine introduction as based on the number of country applications that have been approved, while projections for rotavirus vaccine also include countries that received ‘conditional approval’ and ‘resubmission’.

⁸⁹ GAVI eligible countries for the period 2014-15 have been considered to be 73 to ensure comparability across years.

⁹⁰ GAVI (2008), “Request for Proposals – Accelerated Vaccine Introduction Initiative”

⁹¹ GAVI (2011), “Report to the GAVI Alliance Board, November 2011”

- In 2010, following the first call for supply offers under the AMC, annual supply commitments of 30m doses of pneumococcal vaccine were signed with GSK and Pfizer each, with the vaccines to be supplied in January 2012 and 2013 respectively. The second call for supply was initiated in 2011 and contracts were signed with GSK and Pfizer for an annual supply of 18m doses each, starting from January 2014 for both. The manufacturers will supply the vaccine at US\$ 7 initially, and have committed to a tail price of US\$ 3.50 for the subsequent years, as part of the AMC.⁹²
- For rotavirus vaccine, GSK and Merck have been contracted to supply for the period 2012-16 with a price of US\$ 4.93 per course for the two-dose vaccine (which represents a 67% reduction on the previous price of US\$ 15 per course) and average weighted price of the three-dose course at US\$10.50 (which is 30% reduction from the lowest available price).⁹³
- However, an unprecedented number of country applications in 2011 has resulted in short term supply shortages, resulting in some temporary delays in introducing the vaccines in a sub-set of countries approved for new introduction.
 - In 2012, supply constraints for pneumococcal vaccine have implied a postponement of its introduction in a maximum of six out of the 13 newly approved countries by a year and a similar delay for the five approved countries planning introduction in 2013. The supply situation is expected to improve from 2014, as current manufacturers continue ramping up production levels.⁹⁴
 - A temporary supply gap on account of production issues at GSK is anticipated for 2013 for rotavirus vaccine as well, resulting in a one year introduction delay in a sub-set of countries.⁹⁵

6.2.3. GAVI and country-level financing

GAVI has secured donor commitments of US\$ 4.3bn following its June 2011 pledging conference. This resulted in an increase in GAVI's available resources from US\$ 3.3bn (pledged prior to June 2011) to US\$ 7.6bn between 2011-15 – of which direct resources account for almost US\$ 5bn, AMC funds are US\$ 880m, and International Finance Facility for Immunisation (IFFIm) funds are almost US\$ 1.5bn (with the balance being investment income).

⁹² In addition to the supply agreements, GSK and Pfizer Inc. agreed to provide 7.2m, 24.2m and 20m doses for the years 2010, 2011 and 2012 respectively as part of the AMC capacity development period in the first round of procurement. As part of the second agreement in 2011, GSK and Pfizer Inc. agreed to provide an additional 9m doses for each of the years 2012 and 2013 as part of the AMC capacity development period.

⁹³ New market entrants, including Bharat Biotech, the Serum Institute and Shantha Biotechnics, are developing rotavirus vaccines for GAVI-eligible countries. However, these are not expected to be ready for purchase through UNICEF until approximately 2015. Bharat Biotech has proposed that it would further lower the price of the vaccine to US\$ 1.5 a dose. (Source: <http://www.gavialliance.org/library/news/press-releases/2011/gavi-welcomes-lower-prices-for-life-saving-vaccines/>)

⁹⁴ GAVI (2011), "Report to the GAVI Alliance Board, November 2011"

⁹⁵ It is suggested that if GSK is able to increase production, GAVI will be able to increase rollouts to additional approved countries in 2013 (numbers not yet decided), cover all 28 approved countries and meet 85% of forecasted demand in 2014 and similarly in 2015 cover all 28 approved countries and meet 77% of the forecasted demand. Ref: Update on supply situation as of 23 April, 2012-04-21, prepared by Katie Moore and Johanna Fihman, AVI

With regards to country level financing of vaccines, we have specifically looked at the co-financing amounts for the two vaccines.⁹⁶ For pneumococcal vaccine, total country co-financing has increased from US\$ 0.24m in 2009 to US\$ 4.4m in 2011. This is projected to increase to about US\$ 34.68m by 2015, based on the planned introductions to date. For rotavirus vaccine, country co-financing amounts increased from US\$ 1m in 2008 to US\$ 2m in 2011 and is projected to be US\$ 12.5m by 2015.⁹⁷ Given the limited role of AVI on country co-financing (as discussed below in Section 6.3) we have not explored further as to whether these co-financing amounts are on target or not.

6.2.4. Progress on other vaccines

There has also been some progress in a number of the other new vaccines, including:

- **MenA:** In 2011, GAVI supported the first national immunisation campaign in Burkina Faso for 1 to 29 year olds against meningococcal meningitis A, following the 10 year development of the MenAfriVac vaccine (a meningococcal conjugate vaccine). GAVI Men A support has now been rolled out to Chad, Cameroon, Mali, Niger, and the northern states of Nigeria.
- **Rubella:** Responding to projected demand from 30 countries and WHO recommendations, GAVI is inviting proposals for support from countries in 2012. GAVI-funded rubella vaccines will be combined with measles. GAVI plans to reach 588m children with the rubella vaccine by 2015.⁹⁸
- **YF:** As of November 2011, 12 countries had introduced the vaccine through preventive campaigns with GAVI support. Campaigns have been conducted/ planned for Guinea, Ghana, Cote d'Ivoire, and Sudan, reaching over 22m people.⁹⁹
- **HPV:** In December 2011, the GAVI Board decided to support countries to introduce HPV vaccine. By 2020, more than 28m girls are expected to be immunised through GAVI's support. GAVI has been working with vaccine manufacturers to ensure that HPV vaccines are affordable and has been able to drive down its price to US\$ 5 per dose for GAVI supported countries, a 67% reduction on the lowest public price.¹⁰⁰

6.2.5. Summary

In summary, considerable progress has been made in terms of countries introducing/ planning to introduce pneumococcal and rotavirus vaccines. Arrangements for vaccine supply have been progressing, although the recent supply shortage present a major setback. We discuss in the next

⁹⁶ We have not explored broader progress in country-level financing, especially on account of the limited role of AVI in this area – also discussed in Section 6.3 below.

⁹⁷ Source: Country co-financing data as received by GAVI on 20 April 2012.

⁹⁸ www.gavialliance.org/library/news/press-releases/2011/gavi-takes-first-steps-to-introduce-vaccines-against-cervical-cancer-and-rubella/

⁹⁹ GAVI (2011), "Report to the GAVI Alliance Board, November 2011".

¹⁰⁰ <http://www.gavialliance.org/library/news/press-releases/2011/gavi-welcomes-lower-prices-for-life-saving-vaccines/>

section our views on the role of AVI in relation to the achieved outcomes, including the key AVI activities/ outputs that have contributed to the progress achieved.

6.3. Contributions of the AVI initiative

This sub-section presents our findings on AVI's contribution to the progress noted above on the demand, supply and financing of the pneumococcal and rotavirus vaccines.

Given the absence of a results framework and cohesive reporting on these results, it has been very challenging to identify (and isolate from the broader GAVI Alliance activities) the contribution of AVI. Also, as noted in the introduction to this report, whilst we did not seek to evaluate in detail the work and outputs of individual sub-teams, references have been made to specific work as delivered by some of the sub-teams.

Despite these caveats, we have attempted to present our understanding of the contribution of AVI, drawing on our reading of the various Progress Reports and stakeholder feedback. We present in this section:

- First, a comparison of introduction rates for the two AVI focus vaccines (pneumococcal and rotavirus) versus other vaccines supported by GAVI (specifically HepB, Hib, and YF) – as a measure of ‘value-add’ of the initiative and using the other vaccines as a proxy for the counterfactual analysis.
- Second, a discussion of some of the key activities and outputs of the AVI initiative and whether/ how these might have contributed to the outcomes achieved. In doing so, we have tried to collate activities/ outputs that have: (i) enhanced coordination across Partners; (ii) supported global-level demand and supply management; (iii) helped develop the evidence base for vaccine introductions; (iv) supported countries as they introduce vaccines; and (v) supported the work towards GAVI support of other new vaccines.
- Finally, some overarching thoughts on the role of AVI on each of its five outcomes.

6.3.1. Comparison of vaccine introduction rates

In order to provide a sense of the extent to which AVI has potentially contributed to the acceleration of the introduction of pneumococcal and rotavirus vaccines to date, we compare the historic delay from first licensed vaccine¹⁰¹ to introduction of other vaccines. These include introductions of YF, HepB, and Hib-containing vaccines, as possible counterfactuals to the introduction of the pneumococcal and rotavirus vaccines in GAVI-eligible countries.¹⁰² This is

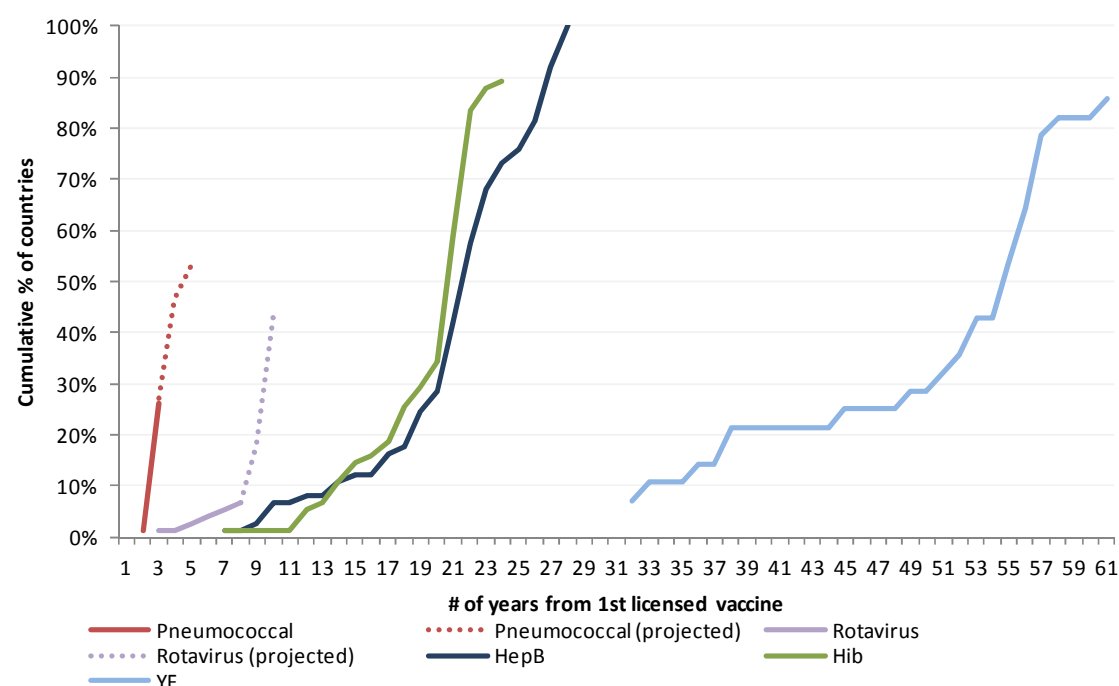
¹⁰¹ Year of licensing of a particular vaccine is the year in which the first vaccine for the disease was licensed, ignoring any subsequent developments in the presentation, dose, etc. However, for pneumococcal we have considered PCV10 (2009) given PCV7 was not appropriate for low income countries; and for rotavirus, we have considered the second rotavirus lyo vaccine that was licensed for EURO and AMRO in 2004, as the first rotavirus vaccine (licensed in 1998) was subsequently withdrawn.

¹⁰² Prior to the establishment of GAVI (i.e. before 2000), we have included GAVI Phase I eligible countries in our analysis.

set out in Figure 6.4 below, and the data sources and methodology used are presented in Annex 9.¹⁰³ As can be seen from the figure:

- The lag between the first licensed pneumococcal and rotavirus vaccines and the first country introduction (one and two years respectively) is much lower than that for HepB-containing vaccines (six years), Hib-containing vaccines (six years) and YF (31 years).
- The uptake of both vaccines over the years has been much more rapid as compared to HepB, Hib and YF vaccines.

Figure 6.4: Cumulative percentage of GAVI-eligible countries introducing vaccines by year from first licensed vaccine^{104,105}



The above graph highlights the ‘acceleration’ in the introduction for both pneumococcal and rotavirus vaccines, as compared to the other GAVI-supported vaccines. Although difficult to establish conclusively, this might suggest some contribution of the AVI initiative. The historic delay and slower introduction of some of the other vaccines has been on account of factors such as vaccine affordability, lack of disease burden and vaccine impact studies, poor country readiness, lack of availability of prequalified vaccines, and clear policy guidance; and the AVI was set up to address these issues. However, we note that other factors would inevitably have also impacted the introduction of pneumococcal and rotavirus vaccines. These other non-AVI factors have included the establishment of the AMC, GAVI Alliance funding for these vaccines, prior work of the ADIPs, country government own initiatives, etc.

¹⁰³ The analysis draws on previous work undertaken as part of the Applied Strategies and CEPA evaluation of GAVI’s performance on SG2 (Phase II) for the GAVI second evaluation.

¹⁰⁴ The dashed lines refer to the gap years based on projections for 2012 and 2013 for pneumococcal and rotavirus vaccines.

¹⁰⁵ 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.

6.3.2. AVI activities and outputs

Another approach to assessing potential contributions of the AVI initiative is to consider the outputs that have been prepared as part of its work, and how they may have contributed to the initiative's outcomes.

As noted, we have not identified a results framework for the initiative, which would provide us with a means to assess whether and how these outputs have actually contributed to the agreed AVI outcomes (i.e. what are the linkages between individual activities, outputs and outcomes; whether the noted activities form the totality of required activities to deliver the outcome or are they a small/ large proportion of the activities that are required, etc.). In addition, the available reporting on activities, whilst relatively comprehensive in parts¹⁰⁶, does not clearly distinguish between Partner delivered AVI activities as compared to the 'normal course of business' for GAVI Secretariat and the Alliance Partners.

Nevertheless, we provide some commentary on the activities and outputs as reported by the AVI TAC annual reports and AVI Progress Reports, that in our view are most likely to have contributed to the overall progress (although these are not, by any measure, exhaustive). While noting these, we highlight some issues identified by stakeholders with regards to these outputs.

The rest of this sub-section is therefore structured along AVI activities/ outputs that have:

- enhanced coordination across Partners;
- supported global-level demand and supply management;
- helped develop the evidence base for vaccine introductions;
- supported countries as they introduce vaccines; and
- supported the work towards GAVI support of other new vaccines.

AVI activities/ outputs that have enhanced coordination across Partners

As discussed in Section 4, working through the AVI initiative, the Partners have been working together and sharing information on their respective vaccine introduction related activities. We highlight two specific activities noted in the Progress Reports that emphasise improved coordination between Partners:

- *Country readiness dashboard.* The dashboard is a web based tool that has been prepared to allow tracking of activities and bottlenecks in the introduction of new vaccines. It is currently being piloted for the pneumococcal introduction group, and is expected to track the availability of financial resources, supply considerations, and country readiness factors such as cold chain capacity. Information for the dashboard is being collated from inputs by all the Partners.¹⁰⁷ Feedback to date suggests that the dashboard is a very positive and useful tool (albeit still under development) for ensuring easy access to information relating to country readiness to introduce a new vaccine. The dashboard has

¹⁰⁶ AVI TAC annual reports are quite comprehensive in nature, setting out the activities against GAVI contracted requirements.

¹⁰⁷ GAVI (2011), "Report to the GAVI Alliance Board, July 2011"

the potential to support more coherent results tracking on the work by the Partners in supporting country preparations for introductions of new vaccines, and to enable more targeted discussions with countries on what additional steps need to be taken in order to complete all the necessary requirements.

- *The pneumo and rota ad-hoc working groups/ AVI Strategic Working Group.* AVI established ad-hoc introduction sub-teams for pneumo and rota in 2010 (later merged as a joint AVI Strategic Working Group for both vaccines) to share information updates related to introductions (pre and post launch). In their work, these groups have covered issues such as: country readiness including expected introduction date; cold chain capacity; regular updates on implementation such as reports of faster (or slower) uptake of vaccines post launch; changes in product preferences; etc. In our view, the formation of this group was an important step towards making available better knowledge/ information for improved coordination in Partners' activities.

AVI activities/ outputs that have supported global-level vaccine demand and supply management

Forecasting the demand and supply of vaccines is a critical input into any planning for vaccine introductions in countries. We discuss AVI's contribution to each of these in turn below.

The Strategic Demand Forecasts (SDF)

AVI TAC provides twice yearly SDFs covering all GAVI's current vaccine portfolio and the Vaccine Investment Strategy (VIS) vaccines¹⁰⁸. The SDF is viewed by many stakeholders as an innovative and comprehensive mechanism for bringing together information from various sources so as to present a coherent picture about the demand for new vaccines in GAVI eligible countries. The added value of the SDFs is brought out by the following:

- The work of the AVI TAC to prepare demand forecasts is a critical input for: (i) manufacturers, to help guide their investment strategies; (ii) the GAVI Secretariat, to consider its financial requirements (including co-financing projections); and (iii) GAVI as a whole, in communicating its resourcing requirements to the donors. It is also used to inform estimates of potential health impact and supply needs.
- Unlike in ADIPs, where the Pneumo and Rota ADIP were responsible to prepare SDFs for the two vaccines separately, preparation of SDFs under the AVI initiative benefits from a greater integration of resources and skills since SDFs for all the new vaccines have been housed within the AVI TAC.¹⁰⁹
- For pneumococcal vaccines, the SDF predicted that 27 countries would apply for GAVI support, of which 23 actually applied (85%), whereas for rotavirus vaccines, the SDF predicted 21 country applications, of which 18 actually applied (86%) – suggesting

¹⁰⁸ Currently, SDFs are prepared for HPV, JE, MenA, pentavalent, pneumococcal, rotavirus, YF, rubella and typhoid vaccines

¹⁰⁹ We understand that going forward, SDFs are going to be developed by the GAVI Secretariat.

reasonable accuracy (although we have not compared the specific countries forecasted and actually applying).¹¹⁰

At the same time, certain issues have been raised in consultations and through our review that may potentially hamper a more optimal utilisation of this work. They include the following:

- **Transparency on SDF assumptions.** There is an ongoing tension about the extent to which assumptions underlying the SDFs can be made public. On one hand, for demand forecasts to influence industry investment decisions, they need to be sufficiently transparent and their assumptions open to scrutiny so as to engender confidence from relevant stakeholders. On the other hand, some stakeholders have suggested that it is important to protect the confidentiality of country level decision making processes about the types of vaccines they are potentially considering for introduction as part of their immunisation plan so that these processes are not open to any potential undue influence. Our view is that further work could be done to explain as much as possible the methods that have been used; and where information is confidential, to explain why that is the case.
- **Differences between SDF and UNICEF forecasts.** UNICEF forecasts are more operational in nature, and with a considerably shorter term focus than the SDF. It is not inconsistent to have a shorter term forecast different to that of a more strategic forecast; however, the variance across the two has added to the uncertainty in the market.
- **Potential for more frequent interaction with suppliers.** Currently, the AVI TAC produces the SDFs bi-annually, covering all GAVI's current vaccine portfolio and the Vaccine Investment Strategy (VIS) vaccines. On an annual basis, the SDF team presents the forecasts to the suppliers, including discussions on the assumptions underlying the SDF. It has been suggested that there would be value from the supplier perspective, if these presentations are more frequent (some suggestions have been made for quarterly reporting) given that the demand situation evolves and suppliers need to be regularly updated to give them sufficient time for investment decisions. In addition, there may be scope to consider taking account of supplier views, in an open and transparent manner, as one of the inputs during the demand forecasting work.

Strategic Supply Forecasts (SSF)

Since 2010, AVI TAC has been preparing the SSF to provide an overview of the available supply. In 2011, AVI TAC provided an updated overview of the development pipeline for pentavalent, pneumococcal, rotavirus, HPV, and typhoid vaccines. This information is viewed as critical to understand the expected market for vaccines, which in turn has implications for financial and procurement planning.

While this is a useful activity, it is unclear how these are being used by the Partners to determine interventions in case of an expected supply constraint, as has been noted recently. Going forward, it will be important to have greater clarity on the processes to be instigated by GAVI and its Partners when significant divergences between the expected demand and forecast supply arise.

¹¹⁰ AVI TAC (2012), "AVI TAC Annual Report 2011".

AVI activities/ outputs that have contributed to the evidence base for vaccine introductions

In considering issues here, we have focused on the work of the AMT sub-team on Special Studies as well as the WHO work on enhancing surveillance. While the former has been created under the aegis of AVI, the latter has been a core function of WHO for many years. We do not have further information here on how this function may or may not have been enhanced under AVI, but view this as an important area to explore going forward.

Special Studies

This AMT sub-team has conducted a number of studies targeted at addressing needs for new vaccine introduction. These have included 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. Studies have been conducted on various formulations of pneumococcal and rotavirus vaccines in African and Asian countries. The AVI TAC Annual Report suggests that the sub-team has made efforts to disseminate the findings of these studies to GAVI and its Partners as they become available as well as use the evidence generated to support country decision making.¹¹¹

The work on these studies is useful in a number of ways:

- In general, data on effectiveness and impact are valuable at the country level, to document expected value for the country in investing funds for the vaccine in the future; and at the global level, to inform donors of the value received for their investments in GAVI. In addition, effectiveness studies specific to the GAVI-eligible setting can reveal issues which require policy changes. An AVI special study illustrates this: “Interim findings from two Special Studies in South Africa on pneumococcal vaccine effectiveness indicated a point estimate of vaccine-type effectiveness among Human Immunodeficiency Virus (HIV)-negative children that was lower than observed in efficacy trials, a finding that may be due to the alternative schedules used in routine immunisation as compared to the clinical trials. Vaccine effectiveness for prevention of invasive pneumococcal disease was lower than expected among HIV-positive children, a finding that has already led to a policy change in South Africa which now recommends a three-dose primary series for HIV-positive children instead of the 2+1 schedule used for all other children.”¹¹²
- Another value adding function of special studies is to provide data to address issues or controversies which arise during the introduction process, and which could undermine the interest of countries in a new vaccine. For example, concerns were raised that vaccinated populations may experience an increase in pneumococcal disease due to serotypes not in the vaccine, eliminating the benefit of pneumococcal vaccine. Although a BMGF funded review of PCV7 studies has allayed some of the concern, well designed

¹¹¹ 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. Source: AVI TAC (2012), “AVI TAC Annual Report 2011”.

¹¹² AVI TAC Annual Report 2011.

effectiveness and impact studies of PCV10 and PCV13 extending five years after introduction in GAVI-eligible countries will be crucial to address this concern. The South African studies funded by AVI should be able to provide key data if supported over sufficient time; additional studies to address this question will be done by extending two legacy Pneumo ADIP studies in Kenya and the Gambia, with funding from the BMGF.¹¹³

- Special studies in GAVI populations have rapidly addressed questions which were pre-conditions for GAVI introduction of a new vaccine – e.g. rotavirus vaccine efficacy in Africa and Asia (Rota ADIP)¹¹⁴ and the safety of a 2 dose preservative free vial presentation for PCV10, assessed as part of the Kenya pneumococcal vaccine introduction (Pakistan and Madagascar introductions are on hold pending results of the latter assessment).

Looking ahead, the impact and utility of a special study could be enhanced by:

- a transparent process for identifying priority studies, which includes input from countries and Partners on what studies are required to support vaccine introduction; and
- considering experience to date to inform optimal process for funding and implementing the studies (GAVI, outsourced entity, WHO, specific focused working groups, etc).

Surveillance

WHO surveillance supports the vaccine introduction process at the national and local levels by providing decision makers with information on the benefits of disease reduction.

WHO coordinated global surveillance networks have been successfully established in 48 countries for rotavirus and 57 countries for invasive bacterial vaccine preventable diseases (IB-VPD) – approximately 70% of these countries are GAVI eligible. WHO has also established a network of global and regional reference laboratories to perform a range of supporting activities, and have also established surveillance indicators to monitor programme performance. The successive AVI Progress Reports note that initial data from the rotavirus network is reported as being ‘relatively robust’, although further data on the quality and consistency of the IB-VPD data is required. In this regard, WHO’s current focus is to improve data quality, as well as improve the diagnostic capacity of laboratories.

AVI activities/ outputs aimed at supporting countries in introducing vaccines

As noted in the AVI Progress Reports, this has primarily been through the work of WHO and UNICEF. It is difficult to comment here on the added value of AVI, but feedback from WHO in particular emphasises more joint work in several areas as well as increased emphasis through the AVI on this activity.¹¹⁵

¹¹³ It is worth noting that data generated from routine country surveillance will generally be insufficient to resolve this controversy - and in fact, the tendency of new surveillance systems to improve over time, thereby detecting more cases after the vaccination is implemented, has contributed to misperceptions about lack of impact from the vaccine.

¹¹⁴ Demonstration of efficacy was a precondition for the WHO policy statement to recommend rotavirus vaccines.

¹¹⁵ This is based on our reading of WHO’s response to the questionnaire circulated by CEPA on AVI’s value add.

In addition, as part of its country-level work, AVI TAC has undertaken various advocacy-related activities to support vaccine introduction in countries. It has also supported the Large Country Task Team and conducted consultations 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; and also provided GAVI with regular updates on the India advocacy programme and its progress in achieving greater interest in the pentavalent vaccine at the state level, amongst other related activities.

AVI activities/ outputs focusing on other new vaccines

The AVI Progress Reports over the years suggest a number of activities being undertaken in support of GAVI's funding for the other new vaccines going forward.

- The 2010 Progress Report to the Board notes that the AVI has been involved in developing guidelines and country application forms for these new vaccines.
- The 2011 Progress Report notes that the AVI coordinated a four-month process to refine the 2008 implementation strategies for each new vaccine. Sub-teams were formed for each vaccine to review WHO guidelines and the Strategic Advisory Group of Experts (SAGE) recommendations, availability of vaccines, and revised SDFs.

These appear to be useful contributions by AVI. No further comment can be provided given lack of information on timelines of these activities (e.g. to assess efficiency, timeliness), role of other players, etc.

6.3.3. Role of the AVI in contributing to the progress achieved

As described above, there has been a considerably higher than expected demand from countries for the pneumococcal and rotavirus vaccines, witnessed by a higher than expected number of countries introducing/ expecting to introduce the two vaccines.

Concrete evidence, in terms of data, that would provide direct linkages between the AVI work and faster introductions of the two vaccines is not available. However, and given the preceding discussion, we believe that the AVI initiative, through the range of its activities, is very likely to have contributed to this unprecedented increase in country introductions. A results framework for the initiative and better clarity on the roles/ responsibilities of AVI stakeholders (as compared to their roles and responsibilities as part of their activities within the broader Alliance) would improve the possibility of contributing results directly to the initiative.

At the same time, while efforts have been made to make available the vaccines (through WHO pre-qualification and initiation of supply contracts), the recent supply shortages present a major issue in terms of serving the increased demand. This represents wasted effort/ distraction for countries as they gear up for introducing a new vaccine (designing new ledgers and reporting forms, altering the Health Management Information System (HMIS), upgrading cold chain, training, etc) without the concomitant supply availability. This ramp up in demand can in part, be viewed as a success of AVI's efforts, as well as the work of the responsible Partners. At the same time, it may also point to lesser than necessary planning/ preparation undertaken to ensure that the supply will be available to meet this increasing demand – given AVI's central role in

managing the demand-supply balance. However, it is noted that other players – including the Alliance and its Partners as well as the ADIPs, along with related external circumstances – also play a major role to this imbalance.

Further, another key risk is with regards to country readiness – as also identified in the latest AVI Progress Report to the Board (November 2011). While country readiness is assessed during GAVI approval of country applications, this remains an important issue – especially as countries begin introducing multiple vaccines in their immunisation schedules. The WHO reports that of the 72 GAVI-eligible countries, 63-67% have sufficient capacity to introduce either pneumococcal or rotavirus vaccines, while 50% would have sufficient storage space to introduce both vaccines over the coming years. Moreover, there remain significant issues in some fragile countries.¹¹⁶ It would be important to ensure that countries are able to implement their improvement plans in advance of the actual introduction of vaccines. In addition, sustainability of funding is a key issue that deters country introduction of these new and relatively more expensive vaccines.

In terms of the financing outcome, our understanding is that the AVI initiative has played a very limited role. Its contributions have been through supporting advocacy efforts, but only partially so, through AVI TAC individuals that are seconded to the GAVI Secretariat to help in fund-raising activities. Country-level financing activities have been outside its remit – these activities are undertaken by the GAVI Immunisation Financing and Sustainability Task Team.¹¹⁷

Finally, the AVI has been working on the other new vaccines (MenA, rubella, etc), and we note that progress is being made in terms of GAVI's support of these vaccines.

6.4. Summary findings and conclusions

Table 6.1 provides a summary of the main findings on this review question.

Table 6.1: Summary findings on results

Review sub-question	Key findings
Key issues in assessing the results of the AVI initiative	• There are some fundamental challenges in assessing the results and value-add of the AVI initiative, stemming from lack of clarity on its 'theory of change', absence of a results framework and of a single consolidated and coherent progress report on AVI outputs by outcome (there are currently multiple sources of reporting on AVI results, with each organised differently). There is also a lack of clarity on whether the progress reported relates specifically to AVI or the broader work of the Alliance/ Partners. • An approach that could be used in the future for assessing the results of the AVI (or a similar) initiative should encompass a broader inputs-processes-outputs-outcomes-impacts framework for vaccine introduction. Such an approach would also have specific indicators to capture the initiative's value add (e.g. 'new'/ 'unique' activities under AVI, and how it has enabled Partner outputs to be delivered more 'efficiently'/ 'effectively').

¹¹⁶ GAVI (2011), "Report to the GAVI Alliance Board, July 2011"

¹¹⁷ This Task Team comprises members of the Secretariat and Alliance Partners, some of which also belong to the organisations that are included under the AVI umbrella. However, the individuals that have been involved in the work of the Task Team have been different from those engaged as part of the AVI initiative.

Review sub-question	Key findings
Progress on the five intended outcomes	- Country introductions of pneumococcal and rotavirus vaccines have been higher and faster than expected, with the expectation that the original targets of 44 and 42 introductions respectively will be surpassed by 2015 (revised projections are 58 and 47 respectively). - The unprecedented number of country applications in 2011, whilst among other factors, is a reflection of a successful drive to introduce vaccines, has resulted in short term supply shortages and temporary delays in introductions. This is despite the efforts to make vaccines available (through WHO pre-qualification and initiation of supply contracts).
Contribution of AVI to results	- A comparison of vaccine introduction rates for the AVI vaccines and other GAVI supported vaccines (YF, HepB and Hib) shows that: (i) the lag between the first licensed pneumococcal and rotavirus vaccines and the first GAVI country introduction is much lower (one and two years respectively) than for the other GAVI supported vaccines; and (ii) the uptake of both pneumococcal and rotavirus vaccines over the years has been much more rapid as compared to the other GAVI vaccines. Amongst other influencing factors (GAVI funding, AMC, ADIPs, etc), this might suggest some contribution of the AVI initiative (although difficult to conclusively establish). - A number of AVI activities/ outputs have: (i) enhanced coordination across Partners (e.g. the country readiness dashboard, pneumo and rota ad-hoc working groups/ AVI Strategic Working Group); (ii) supported global-level demand and supply management (e.g. SDFs, SSFs); (iii) helped develop the evidence base for vaccine introductions (e.g. Special Studies); (iv) supported countries as they introduce vaccines (primarily through the work of WHO and UNICEF, but also the AVI TAC); and (v) supported the work towards GAVI support of other new vaccines. - On the whole, we believe that the AVI initiative, through the range of its activities, is very likely to have contributed to this unprecedented increase in country introductions.

7. SUGGESTIONS ON THE FUTURE OF THE MODEL

Our final review question is as follows:

What improvements may be required for the model to effectively deliver its current and possible future objectives?

In this context, we consider the following sub-questions:

- (i) What are the possible improvements to the AVI operational model to ensure effective and efficient vaccine introduction in countries?
- (ii) How well is AVI positioned to absorb additional new vaccines and under what operating model?
- (iii) To what extent is the model applicable to other areas of GAVI's work, such as HSS?

We then provide our conclusions.

7.1. Possible improvement in the overall operational model

There is considerable consensus, with which we would agree, that a lot of the work that has been undertaken under the AVI initiative has been very useful in supporting country introductions of pneumococcal and rotavirus vaccines. This has included:

- Whilst not easily measurable, we would argue that the AVI platform for ongoing stakeholder discussions was a very important contribution to better coordination, more information exchanges, and trust building between Partners for vaccine introductions.
- In addition to the work undertaken by Partners (which is difficult to 'attribute' to the influence of AVI per se), the AVI TAC has produced a number of important deliverables, such as:¹¹⁸
 - numerous studies on providing evidence-based data related to pneumococcal and rotavirus vaccines;¹¹⁹
 - products such as the strategic demand forecasting suite and country readiness dashboard; and
 - advocacy and communication work and products.

The greater than expected number of introductions are at least to some extent a result of this work.

We think that there continues to be a need for key immunisation stakeholders, most of who are Partners of the GAVI Alliance, to work together at a global and operational/ country level to support the introduction of vaccines in GAVI eligible countries. As such, we think that the role

¹¹⁸ Sourced from the AVI TAC annual reports. It was outside the scope of this review to undertake an 'audit' of the work that is reported by the AVI TAC in its annual reports. As such, we have not independently verified the information presented in these reports.

¹¹⁹ Special studies are an important output of the AVI. Whilst assessing them in detail was outside the scope of this review, we would suggest the relevance and usefulness of each of the special studies would warrant a more focused review by GAVI at an appropriate time in the future.

for an AVI or a similar initiative continues to be relevant, ensuring that approaches that have worked well are built on and that opportunities are taken to improve on those areas which have proven more difficult to implement in practice. These are discussed in turn below.

7.1.1. Lessons on what has worked well

One of the defining features of today's global health aid architecture and national immunisation processes is the growing institutional and procedural complexity, compounded by the large numbers of stakeholders involved in this important work. The key to reducing adverse impacts of this complexity and to ensure that children in GAVI eligible countries receive life saving vaccines is to improve the coordination and alignment of policies, stakeholder engagement, and the application of resources towards this goal. Agreeing and coordinating high level policies is often done at Board level fora, and whilst clearly facing their own considerable challenges, these debates are often more manageable than the challenges faced by the organisations and individuals who are considering these policies at an operational level.

The GAVI Alliance brings together Partners from a wide spectrum of private and public sector stakeholders towards its mission. Implementing this mission and working across countries and vaccines requires considerable operational coordination. Providing a 'single window' and forum for this regular communication and coordination to take place is the most significant value addition in our view that the AVI initiative has introduced.

The other significant area of value add is the focus and enhanced thrust that the initiative has provided to the diverse set of activities required to accelerate new vaccine introduction in GAVI eligible countries, as has been discussed in Section 6 in particular. These have included, for example, developing the country readiness dashboard (enhancing coordination across Partners), publishing strategic demand and supply forecasts; and developing a series of special studies on pertinent issues to develop the evidence base for vaccine introductions.

Historically, there have been substantial time lags in the introduction of vaccines in the developing countries from when they are available in the market for a host of reasons relating to country readiness, availability and affordability of the vaccine, amongst others. Whilst difficult to specifically evidence the linkages to AVI's role, we think that AVI has been a key contributor to the accelerated introduction of new vaccines in developing countries, and thereby helping in some measure to remedy this issue.

The main lessons on what we think has worked well in the AVI initiative, and which might be built into the structure of any new approach to accelerating vaccine introductions, include:

- bringing all of the activities required to support vaccine introduction under one management umbrella (GAVI Secretariat being an obvious choice¹²⁰), instead of replicating multiple structures and initiatives for each new vaccine;
- having clear, high level, and measurable goals to focus the work undertaken by stakeholders (e.g. number of countries introducing particular vaccines and the timelines

¹²⁰ Given that country introductions of new vaccines are at the core of the GAVI mission, it seems appropriate that this function continues to be managed and coordinated by the GAVI Secretariat in close cooperation with the Partners. Outsourcing the management might lead to a lack of control and integration of these vital activities with the roles and governance structures of the Alliance (an issue raised with the ADIPs structure).

for introduction), and which are relevant and in line with the GAVI mission and strategic goals;

- building trust, and ensuring open and transparent information exchange between the main operational-level stakeholders, through structured telephone and/ or in-person engagement;
- recognising that not all of the expertise necessary for vaccine introduction are necessarily available at the Partners organisations, and that therefore valuable inputs can be sourced from leading international service providers competitively selected for the tasks;
- producing specific deliverables (such as SDFs and special studies) through Partner sub-team mechanisms as a delivery model; and
- focusing, as much as possible, on producing tangible tools that can be used by wider groups of stakeholders, including countries, to support vaccine introductions (e.g. web based country readiness dashboard).

7.1.2. Lessons on opportunities for greater clarity and improvement

The main lesson that we have identified as part of this review is that there needs to be greater clarity on the initiative in a number of areas. The need for clarity is particularly acute as the process of introducing new vaccines in GAVI eligible countries is complex, given that:

- institutional, regulatory and economic environments in resource constrained countries are not very well developed;
- the vaccine logistics and supply chain/ delivery systems in countries may need significant improvements (and therefore resources) to ensure that they can handle the 'load' of additional new vaccines;
- standard market functions (that might relate to introducing a commercial/ consumable product) need to be replaced and 'simulated' in these challenging environments through coordinated public sector intervention; and
- there are many stakeholders (at global and country level) whose activities need to be coordinated.

Specifically, greater clarity needs to be focused in terms of: (i) concept and scope for the initiative; (ii) institutional structure and decision making processes; and (iii) roles and responsibilities of those involved. These three areas are discussed in turn below.

Concept and scope

The overriding difficulty that we have identified with the AVI initiative is that its fundamental concept and scope were not agreed fully at the start or soon after the start of the initiative. This meant that stakeholders have different understandings of the initiative and expectations of their roles and those of other stakeholders.

The lesson learnt is that it is important to ensure that such an agreement is reached (through a consultative and joint process) when any initiative or indeed, any new programme is conceived/

established by the Alliance (to help achieve its goals and objectives). This agreement should be laid out very clearly in a set of agreed documents, which are aligned with GAVI's strategy and business plan and likely to include:

- **Concept note and strategy.** Setting out the aims and objectives of the initiative, its operating principles (including approaches to dealing with unexpected changes in the contextual environment), governance structure, and fit within the overall GAVI strategy and business plan.
- **Costed multi-year work plan.** Describing specific activities leading to tangible outputs by the initiative, with anticipated costs and sources of funding, measurable indicators, and stakeholder roles and responsibilities for delivery over a defined time period.
- **Results framework.** To support the delivery of the strategy and workplan, and to help individual stakeholders manage their time and input into activities, a results framework will be essential. The framework should not be about simply ticking boxes for lists of deliverables, but a tool that enables the participating Partners to check on progress as well as continuously map their activities to the ultimate aims and objectives of the initiative (how does what they are doing fit within the overall plan of action, which leads to the ultimate goal). This would include setting out the inputs, processes, outputs, outcomes and impacts of the initiative. (See Section 6 for a possible results framework for vaccine introduction).

Institutional structure and decision making processes

An important issue faced by the AVI initiative is the ambiguity around its institutional identity. Some stakeholders see the initiative as having its own institutional identity, whilst others do not perceive any difference between the AVI and the coordination/ facilitation work that the GAVI Secretariat is responsible for and should provide anyway to the Alliance Partners.

In this context, lessons that we have identified for any future initiative include:

- **Align the importance of vaccine introduction activities with seniority of oversight.** The institutional design of an initiative that coordinates this critical activity needs to reflect its importance and cross cutting nature. Some of the activities associated with vaccine introductions are better suited (from an implementation management perspective) to being situated within individual GAVI Secretariat departments. At the same time, we believe that the centrality of vaccine introductions to the GAVI mission and their cross-departmental nature warrants ultimate oversight by the Secretariat CEO and/ or Deputy CEO (whereby a Director of the initiative reports into them).
- **Nature of the management structure.** From a management efficiency and effectiveness perspective, we think that ideally an effective structure for a complex and multi-functional activity like vaccine introduction would be a strong and well functioning matrix management model; which would be proactive and have the power to make decisions within its terms of reference. We note that this model was attempted at the start but it was not possible to sustain in this complex multi-stakeholder initiative, where the reporting lines of participating Partners to their home institutions are strong and

often understandably take precedence over activities related to the initiative - indeed, this is a challenge faced by the Alliance more generally as well. Therefore, realistically, we believe that a practical structure going forward is one that draws on the specialist skills and experience of the participating organisations, and which plays a vital coordination role across them. However, we would suggest that the reporting lines and accountability structures are clearly specified, and strengthened with senior management oversight and involvement from all the Partner organisations, akin to the sponsoring entity in a matrix model.

- **Integrated institutional identity.** With the purpose of such an initiative being at the heart of GAVI's mission, and ideally hosted by the Secretariat, we do not think that the initiative would benefit from having its own institutional identity that is somehow separated from GAVI.¹²¹ This is based on a number of reasons, including:
 - given the centrality of these activities to the four strategic goals of GAVI and the work of GAVI Partners and the Secretariat, it seems inappropriate to separate out an initiative for vaccine introduction from other vaccine support activities across the Alliance;
 - a separate institutional identity is likely to create unnecessary barriers, and related transaction costs, within the GAVI Secretariat and Partner institutions, and may prevent rather than promote information sharing and cooperation; and
 - 'branding' this type of activity under another institutional umbrella, when there are so many that already exist in the international aid architecture, is only likely to confuse national stakeholders in their attempts to negotiate through the various institutional channels to request and receive the required support in their immunisation plans.
- **Clear management and decision making responsibilities.** For a complex and coordinated workplan to be delivered, there needs to be clarity on management responsibilities, accountability and reporting mechanisms, and finally decision making powers with regard to activities and resource allocations. At the same time, these processes are some of the principal challenges that confront global health partnerships in general, and GAVI is no different (as discussed in Section 5.2 of this report). If Partners engaged in the AVI type activities agree that there is a need to have a more proactive coordination mechanism that will manage and direct relevant implementation issues related to these activities across countries and Partners, then the challenge is that there needs to be an agreement to work to a mutually accepted management and decision making structure, and accountability framework. This does not need to replace the reporting and accountability responsibilities to host organisations, and could in fact be viewed as supportive in the context of the need to deliver on the Partners' respective roles and responsibilities.

¹²¹ There will inevitably be a degree of initiative or team identity within the GAVI Secretariat (as a cross functional area of work), and as defined by the suggested concept note, costed multi-year workplan and results framework. This would be an expected operational outcome and is not incongruent with the suggestion that the initiative should not have a separate identity from that of GAVI more generally.

- **Information sharing.** It is very important that any new initiative places a high priority on ongoing information sharing and transparency – both internally and externally. Possible approaches to improve this may include regular (electronic) information sharing on the work, issues and progress; sharing of summarised minutes of management meetings; better web based presentation and explanations of the workplan, the work processes themselves and any outputs. Given high workloads at the GAVI Secretariat and Partner organisations, care needs to be exercised in structuring information sharing in a targeted and relevant manner.

Roles and responsibilities

Finally, it will be essential to specify very clearly the roles and responsibilities of the stakeholders involved in such a mechanism. This is best achieved through a set of complementary and inter-related Terms of Reference for individual participants, including the management team and any sub-teams, which are aligned with the overall results framework, workplan, and ultimately the aims and objectives of the initiative as set out in its concept note.

7.2. Applicability of the AVI model to new vaccines

An important recommendation from the ADIPs and HI evaluation is that the support to countries in introducing new vaccines should be focused in a single organisation, versus having separate efforts undertaken for different vaccines (e.g. one organisation focusing on pneumococcal, one of rotavirus etc.). This, in our view, is a sensible approach, from both the perspective of the countries and Partners:

- Countries make decisions on introducing individual new vaccines in the context of their overall routine vaccination programme and any new vaccines that might be available, within the constraints of the resources and health systems infrastructure that they have. It is therefore likely to be more helpful to decision makers in countries and their advisers (e.g. National Immunisation Technical Advisory Groups) to have more aligned and coherent (as oppose to competing) information and support to make those decision. Further, given that country structures and roles in immunisation (both at the Ministry of Health and the supporting Partners/ donors) are not bifurcated by vaccine, it makes sense to have these housed in a single entity.
- Many of the activities (e.g. disease burden evidence, country preparedness in terms of cold chain, vaccine logistics management etc., surveillance, etc.) that are aimed at supporting countries to make decisions on which new vaccines, if any, to introduce into their immunisation programmes are similar and combining them into a single initiative (such as the AVI) makes sense from a number of perspectives. It enables Partners to coordinate their activities, avoids duplication of efforts, and reduces country level transaction costs for both Partners and country stakeholders.

The coordination aspect that underpins the AVI model is therefore very applicable to the attempts to provide the required coherence in support to countries. The proposed improvements to the model going forward, as discussed in the previous section, will be required to enable bringing together of all of vaccine introduction activities under a strong senior project

management coordinated effort. The aim would be to continue to provide a platform at which important work undertaken/ overseen by Partners (e.g. valuable work undertaken by WHO on EVM assessments) will be quickly and easily shared with other respective stakeholders to help, for example, in decision making about vaccine orders and/ or vaccine funding. Other work that has been done to date, for example on SDFs for nine relevant vaccines¹²², will provide evidence and information for this collective discussion and advice on decisions.

Caution will of course need to be exercised in distinguishing between support that might be required for different vaccines, based on their specific requirements. This is something that the AVI platform could also provide support on, identifying, for example, the different needs that should be taken into account. Although individual vaccines may be at different stages of their R&D/ clinical trials, for example, the supporting AVI type mechanism should be able to cope with these variations in terms of adapting and/ or emphasising specific activities so that they are fit for purpose for a specific vaccine.

One example of this are any future introductions of the HPV vaccine, which has a very different immunisation demographic (young adolescents as opposed to infants) and would entail targeted country support in that regard. Also, different vaccines may have different demands at a country level in terms of cold chain capacity, training of manpower/ health workers, etc. which need to be taken into account. AVI could address this issue by working through different vaccine sub-teams. Using the sub-team mechanism could account for any implementation differences, whilst maintaining a horizontal overview through the cross-vaccine sub-teams (e.g. logistics and cold chain) and an AMT equivalent oversight team. Given that many of the vaccine sub-teams are new, whether this approach will work is not easily discernable at this stage.

7.3. Applicability of AVI model to other areas of GAVI work

As noted in Section 4, ambiguity related to the AVI concept creates some difficulty in defining what the ‘model’ entails per se. However, at a high-level, one could characterise the model broadly as a coordinated approach that aims to draw on the comparative advantages of the Partners/ stakeholders of the Alliance to deliver a focused objective (i.e. accelerating vaccine introduction), and one that is integral or core to GAVI’s mission. While this characterisation appears attractive, a number of issues have been identified in its operationalisation, as discussed throughout the report. These provide important lessons for any future applicability of the model in other GAVI areas of work.

In the GAVI context, a number of partnership approaches have been employed – such as the GAVI Working Group (that existed in the initial years of GAVI); and Task Teams (which are time-limited groups constituted from amongst GAVI Partners (and other stakeholders) with a particular focus). For example, the current Immunisation Financing and Sustainability Task Team comprises members from the Secretariat, WHO, UNICEF, World Bank, PAHO and the BMGF, and has a mandate to support the predictability and sustainability of long-term financing for national immunisation programmes.¹²³

¹²² We understand that SDFs have been undertaken for pentavalent, pneumococcal, rotavirus, YF, MenA, HPV, JE, rubella, and typhoid vaccines.

¹²³ <http://fr.gavialliance.org/about/governance/boards/taskteams/index.php>

Looking at the current 2011-15 strategy and business plan, theoretically, HSS appears to be an area where an AVI like approach (in terms of allowing for institutionalised communication and better coordination among Partners) could be considered – in that, many of GAVI's Partners are extensively involved in this area and it is also core to GAVI's work.

However, notwithstanding the above noted issues with the current AVI model, our view is that in general, HSS encompasses a very different set of activities that might be quite difficult to integrate into this type of approach, and based on the following:

- GAVI itself is not the main/ lead stakeholder for HSS (and other cash based support more broadly) as an intervention, having embarked on this area of work fairly recently. Other organisations such as the World Bank, WHO and other bilateral donors such as United States Agency for International Development (USAID) have been providing HSS and other types of cash based support to countries over a number of years now. Further, the scope of HSS in general, as supported by these donors, extends beyond immunisation related systems and outcomes that is the focus of GAVI. Therefore, whilst improved coordination and harmonisation is generally useful, any initiative that brings Partners together on HSS or other cash based programmes may not necessarily be led by GAVI (although it would be a key stakeholder).
- An initiative supporting a programme such as HSS would be predominately country-focused, with more limited global aspects. The country-level specificity of HSS, including the diversity in requirements across country health systems, raises the question of whether it would be the most effective or efficient approach to have a global-level initiative lead the activities associated with this programme of work.
- The planned transition to the Health Systems Funding Platform (HSFP) serves as a base for partner coordination of efforts in this area – given the need to optimally design, implement, and monitor results of the Platform in the pilot countries initially, and the feedback loop thereof to inform the scaling up of the concept to other countries. We understand that the involved organisations (The World Bank, WHO, GAVI, and the Global Fund) have been meeting regularly over the last few years to develop and implement the Platform. Perhaps, any further efforts to improve the coordination of the organisations in implementing this Platform, may draw on the lessons identified from the AVI experience.

There may be other areas within the GAVI strategy and business plan that might merit a more concerted effort to manage and direct Partner coordination (or indeed, draw upon specialist external resources as needed). This is not, however, a costless process, both in terms of resources and people's time and should be considered on an individual case by case basis. These considerations should be underpinned by a detailed assessment of the possible benefits of greater levels of focus and Partner/ country coordination on specific issues set against the costs and wider implications of doing so. Also, any such coordination model or special initiative should be aligned and encompassed within the Alliance strategy, structures, and governance processes, i.e. not assuming an institutional identity of its own.

In fact, there may well be circumstances where attempting to structure such an AVI type mechanism for other components of GAVI's work could be institutionally over-engineering the

solution leading to potentially suboptimal results. The suitability of time limited working groups or task teams may be considered for the purpose, before embarking on structuring a new initiative.¹²⁴

7.4. Summary findings and conclusions

Table 7.1 provides a summary of the main findings on this review question.

Table 7.1: Summary findings on the future of the model

Review sub-question	Key findings
Possible improvement in the overall operational model	• There is considerable consensus, with which we would agree, that a lot of the work that has been undertaken under the AVI initiative has been very useful in supporting country introductions of pneumococcal and rotavirus vaccines. • We think that there continues to be a need for key immunisation stakeholders to work together and coordinate their activities to support the introduction of vaccines in GAVI eligible countries. As such, we think that the role for an AVI or a similar initiative continues to be relevant. • In structuring and implementing any new initiative, the following lessons should be noted: ○ continue with what has worked well, including bringing all of the vaccine introduction activities under one management umbrella, having clearly specified goals, building trust and ensuring open communication across Partners, competitively contracting out any specialist work, maintaining the sub-team approach, and focusing on developing tangible tools; and ○ address issues faced to date such as clarifying and agreeing the concept and scope of the initiative, institutional structure, decision making processes, and roles and responsibilities in approved terms of reference; developing and reporting on a commonly agreed results frameworks that are closely aligned with and supportive of the GAVI business plan; being proactive in information sharing both within and across the AVI and external stakeholders and ensuring transparency of operations.
Applicability of AVI model to new vaccines	• The coordination aspect that underpins the AVI model is very applicable to providing the required coherence in support to countries on vaccine introductions. Maintaining these activities within one organisational umbrella continues to be a sensible option. • Although a majority of the introduction activities are applicable across vaccines, any specific requirements of a vaccine should be recognised (e.g. the different immunisation demographic targeted by the HPV vaccine).
Applicability of AVI model to other areas of GAVI work	• In our view, an ‘AVI-like’ structure would help an area of work where a number of Partners are actively working and that is core to GAVI’s mission and business. Its application to the HSS and other cash based GAVI programmes is not immediately obvious however, given, among other things, the diversity of requirements across country health systems that may not benefit from a common list of AVI-type activities and tasks. The lessons from AVI’s review may be instructive though to improve coordination across the organisations involved in the HSFP.

¹²⁴ Clearly, setting up any new time limited task teams/ working groups is not without cost in itself, but may on a case by case basis, be relatively more light-weight in terms of institutional infrastructure required.

Review sub-question	Key findings
	• Pursuing an AVI type structure is not costless; and if other GAVI partnering approaches (e.g. time limited task teams/ working groups) are fit for purpose, they should be considered first.

8. CONCLUSIONS AND LESSONS LEARNT

This section sets out our key conclusions and lessons learnt from the AVI review as well as identifies a few areas for more detailed analysis, should GAVI wish to do so in the future.

Our review has underscored the added value of the AVI initiative in terms of it: (a) providing a much-needed coordination and communication platform amongst the Partners (and the GAVI Secretariat) to help accelerate the complex activity of introduction of vaccines in countries; and (b) enhancing the focus and priority placed on this important set of activities, which are core to GAVI's mission, but have historically confronted major delays in terms of the time taken to introduce a new vaccine (from its licensure) in developing countries. Further, the initiative is unique in its attempt to identify, cost and house all of the necessary activities related to vaccine introduction across countries, in a single framework. This 'single window' across vaccines conceptually aligns well with supporting the existing country structures and activities that decide on, prepare for, and ultimately introduce one or more vaccines in their routine immunisation programme; as well as supports Partner coordination activities.

Whilst in theory, the AVI model has some strong advantages as mentioned above, the translation of the envisioned goals into practice has encountered a number of pitfalls. In discussing these, however, it should be highlighted that the AVI initiative, despite these difficulties, has managed and ensured the delivery of many of its important deliverables on accelerating vaccine introduction in countries.

At the most fundamental level, there is ambiguity amongst the AVI and broader Alliance stakeholders on the AVI theory of change, concept and design. This stems particularly from different understandings on whether it is simply an important coordination mechanism, or a more proactive industry product launch team with a strong and decision making matrix management structure; and how it is different, if at all, from the Alliance's and Partners' core vaccine-related activities. In addition, our view, as also reflected by many of our consultees, is that whilst the five original outcomes of the AVI are relevant in terms of their alignment to the GAVI mission and strategic goals, it is not immediately obvious that there is a consensus that they should all be 'housed' within the AVI initiative.. This is partly reflecting some of the contextual changes within GAVI and its wider operating environment since 2008, when the AVI was approved by the Board. For example, the financing outcome of the AVI is arguably better placed within other teams of the GAVI Secretariat, who are already working on this area, whilst the fifth AVI outcome on sustained vaccine use has been subject to different interpretations. The remit of the initiative itself – i.e. whether it focuses on vaccine introduction only or has a much broader remit including scaling up coverage, with commensurate resources provided – is something for its constituent Partners to decide on taking into account the relative merits of each approach. In our view, any post introduction outcomes related to scaling up vaccine coverage would probably encumber AVI with too wide and with a 'do it all' mission that the Alliance as a whole is responsible for. Further, the current staffing and resources available to AVI may not be appropriate for this wide remit of responsibilities, that are arguably better placed with the Partnership.

The lack of conceptual clarity has had a cascading effect on operationalising AVI. There have been no agreed terms of reference for the initiative as a whole, the AMT, and several of its sub-teams. There is also not an agreed results framework to assess the progress and achievements of the initiative. The consequent lack of a shared understanding on stakeholder roles and responsibilities is complicated by the envisaged ‘matrix’ reporting structure for the initiative, i.e. where Partners with primary responsibility and accountability (understandably) to their host institutions are also anticipated to report on AVI outputs to the GAVI Secretariat. This has not been easy to implement in practice, as also experienced by the GAVI Alliance as a whole and several other global health partnerships. In the AVI context, this issue is compounded as it is not clearly evident ‘where AVI ends and GAVI begins’; do the Partners need to carry out any additional activities or reporting for AVI (and if so, the merit of these) outside of the Alliance business plan requirements?

The effectiveness of the initiative has also been hampered by the absence of a clear strategic direction and oversight, as well as strong senior sponsorship within the Secretariat and the Partners. Also, the benefits of the improved communication *across* Partners filtering through to enhanced information sharing *within* the Partner organisations (including the relevant GAVI Secretariat teams) has been questioned. In addition, we note that the nature of the procurement process for the AVI TAC, including the seven year duration of the framework contract (albeit with the flexibility to annually set priorities), is not optimal.

The above constraints notwithstanding, planned country introductions of pneumococcal and rotavirus vaccines have surpassed the original AVI targets. According to the latest SDF (v4.0), GAVI anticipates that 58 and 47 countries will introduce pneumococcal and rotavirus vaccines respectively by 2015 (vis-a-vis the original AVI target of 44 and 42 countries). A number of Partner activities have supported these introductions, including pre-qualification of vaccines and disease surveillance work by WHO; supply contracting through the AMC for pneumococcal and UNICEF procurement for rotavirus; securing of additional finances by the Secretariat to help fund its business plan; and a range of Partner activities to support country readiness and decision-making. However, one difficulty that has emerged from such a higher than anticipated level of introductions has been a shortage in supply of these vaccines creating a demand-supply mismatch – resulting in delays in the introduction of both vaccines.

It is difficult to identify/ isolate the contribution of AVI specifically to these outcomes (given the absence of a results frameworks and lack of consolidated reporting on its performance by outcome). However, our analysis and consultation feedback suggest that it has played a contributory role to accelerating the introductions of the pneumococcal and rotavirus vaccines. Its added value is its role as a coordinating mechanism across Partners, as well as some specific outputs such as the SDFs, the country readiness dashboard, and Special Studies.

Looking ahead, we support the decisions that have been made by the GAVI Secretariat management to move on from the AVI concept as currently defined and create a ‘vaccine implementation’ team. In doing so, it will be important to ensure that the approaches that have worked well within the AVI are built upon and that areas which have proven more difficult to implement are addressed. Regardless of the final shape that AVI takes, it is very important that it continues to be a forum in which Partners can improve coordination of their activities, information exchange and trust building.

The key lessons learnt from this review are that any future model for supporting new vaccine introduction should have, as a minimum, the following attributes (some of which have worked well to date with others less so):

- all of the activities required to support vaccine introduction under one management umbrella;
- clarity and agreement amongst Partners on the concept and scope of the initiative, and ideally documented in a: (i) concept note and strategy; (ii) costed multi-year work plan and budget; and (iii) results framework;¹²⁵
- better defined terms of reference for the initiative and its main components, including agreed roles and responsibilities for the Partners and any outsourced entities;
- agreement on the management and decision-making processes, including accountability and reporting lines; and
- methods for sharing information and improving transparency across activities across Partners and the wider Alliance stakeholders.

Our suggestion is that housing all of the introduction activities for any new vaccine under one umbrella is efficient given the synergies and reflecting country and Partner structures and processes for vaccine introduction. However, it is important to tailor the relative emphasis of the core activities based on the specific requirements/ stage of development/ target beneficiaries of each new vaccine. We would also suggest that any future initiative of this nature is retained within the GAVI Secretariat, and provided the requisite seniority of oversight and direction both within the Secretariat and in the respective Partner organisations.

The wider applicability of an ‘AVI-like’ structure to other programmes is not very intuitive, and the benefits of a specific-purpose initiative should justify the costs. In our judgement, partnering models such as time limited task teams and working groups may be more fit for purpose for several of GAVI’s cross-Partner initiatives (as have been adopted). However, where a particular area of work is core to GAVI’s business and is at the same time: complex, includes a number of Partners/ stakeholders and countries, calls for external specialist skills and resources, and requires regular communication and coordination that may not take place within the existing Alliance framework – an AVI-type focused coordinating mechanism may be deemed appropriate. The HSFP might be an area where such additional coordination may be beneficial (given multiple organisations and countries involved), but the relative costs and benefits of structuring a special purpose initiative to support it need to be assessed.

Areas for further study

This review has identified a few detailed areas that could potentially benefit from more analytical work being undertaken and which are outside the scope of this review. These include:

- **Evaluation of sub-teams.** This review did not attempt to evaluate the work and outputs of individual sub-teams, some of which have undertaken quite extensive work in

¹²⁵ This approach is something that could be adopted for all GAVI initiatives, as best practice for ensuring a greater level of clarity around the concept and subsequently any related terms of reference for initiatives/ interventions.

scope and depth. Going forward, and given that the AVI sub-teams are an important delivery mechanism for AVI activities, there will be merit in undertakings specific reviews of the way in which individual sub-teams fit within the overall AVI type model, what their roles and expected outputs are, how these teams are organised internally, what they have each delivered/ achieved, etc.

- **Evaluation of Special Studies.** As noted in this report, much has been produced by the Special Studies sub-team. However a detailed examination of their relevance and contribution to AVI outputs and achievements is a considerable undertaking and as such was beyond the remit of this review (which had an institutional focus on the AVI). The importance of these studies, for AVI but also for the immunisation field more generally, would warrant a more focused review at an appropriate time in the future.
- **Applicability of AVI to other programmes within GAVI.** Our review has to some extent considered the applicability of the AVI model (particularly its value added role in providing a coordination and communication platform across Partners) to other programmes within GAVI, particularly the HSS. At the same time, without a clearly agreed concept of what AVI actually is, it is difficult to consider its specific applicability to other programmes. Furthermore, such an undertaking will require a much more detailed analysis of the other programmes within GAVI.