Accelerated vaccine introduction (AVI)

Report on the mapping and costing of activities

GAVI Alliance Secretariat

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1. Introduction

Accelerating new vaccine introduction

The mission of the GAVI Alliance is to save children's lives and protect people's health by increasing access to immunization in poor countries. Since its inception in 2000, a key strategy has been to accelerate the evidence-based introduction of new vaccines and reduce the delay between availability of vaccines in the industrialized world and their introduction in the poorest countries. Of four strategic goals, the second is "to accelerate uptake and use of underused and new vaccines and associated technologies and improve vaccine supply and security".

The experience with hepatitis B, yellow fever and Hib vaccines has demonstrated that, when a new vaccine becomes available on the market, significant support is needed for vaccine adoption and uptake by GAVI eligible countries. The Hib Initiative was created in response to slow Hib vaccine uptake and has been instrumental in implementing activities to address this delay.

The success of the Accelerated Development and Introduction Plans (ADIPs) has presented the GAVI Alliance with a unique opportunity to offer rotavirus and pneumococcal vaccines to developing countries just months or years after licensing in the industrialized world. Successful and rapid uptake can make a substantial contribution to achievement of the Millennium Development Goals in 2015. At the same time, the valuable lessons learned from supporting Hib vaccine introduction will enable GAVI to put in place mechanisms to achieve rapid uptake of these two new vaccines.

The wide range of activities required to support the next stage of vaccine introduction and programme implementation in countries go beyond those covered by the earlier ADIP projects. For this reason, the GAVI Boards recommended in May 2007 that the GAVI Secretariat work with partners to specify the activities and identify a mechanism – based on the ADIPs evaluation and through consultations with partners – to support introduction of pneumococcal and rotavirus vaccines. Success in early adopting countries will establish the evidence base needed to expand vaccination post 2010 in all GAVI eligible countries. In the current transition phase, from the end of the ADIP programs to a new support mechanism, it is crucial to invest in creating the evidence-based demand and ensure the supply to meet and sustain that demand in early adopter countries.

This paper reports on the results of the mapping and costing exercise taken to identify resources required globally to achieve rapid global uptake of rotavirus and pneumococcal vaccines. The resulting activities have been regrouped in GAVI's Accelerated Vaccine Introduction (AVI) Framework. In addition, this report summarises key lessons learned from the GAVI experience with Hib vaccine introduction and the ADIPs.

2. The Road to AVI

The creation of the ADIPs and the Hib Initiative

The GAVI Alliance Board, at its 8th meeting held in Paris in June 2002, endorsed a proposal[1] to finance the Accelerated Development and Introduction Plans (ADIPs) for pneumococcal and rotavirus vaccines each for a 5-year period of 2003 - 2007. The Johns Hopkins University Bloomberg School of Public Health was selected to host the PneumoADIP and PATH was selected to host the Rotavirus Vaccine Program. In addition to this, based on the report of the Hib Task Force, the Hib Initiative was created in 2005 to support partners and countries to collect and analyse data to inform decision-making around Hib vaccine introduction. The Hib Initiative functions as a consortium of four agencies (Johns Hopkins University, the World Health Organization, CDC and the London School of Tropical Medicine and Hygiene). Through the ADIPs and Hib Initiative, GAVI has invested a total of US$143M[2] over a 6 year period.

According to a recent evaluation, the ADIPs have successfully focused on establishing, communicating, and delivering the value of vaccines through strengthening the evidence base for decision-making in the pre-introduction phase and preparing the market. Lessons learned by the GAVI Alliance in accelerating introduction of new and under-utilised vaccines, and from the ADIPs and the Hib Initiative mechanisms, are summarized in Annex 1.

Pilot pneumococcal vaccine advanced market commitment

The pilot pneumococcal AMC, announced in February 2007 and to be launched in 2008, also depends on the success of accelerated pneumococcal vaccine introduction in several ways. Firstly, country requests for any given pneumococcal vaccine under the AMC are needed to trigger the release of AMC funds. Secondly, 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 country vaccine manufacturers to bring new products to market. The AMC design also assumes country to co-finance the vaccines, which in turn is linked to the country capacity for decision-making and national health financing for new vaccine introduction.

[1] Based on a commissioned report by McKinsey Co.
[2] All dollar figures in this document are in US$.

GAVI Board decisions

In November 2006, the GAVI Alliance and Fund Boards considered two separate investment cases for accelerating pneumococcal and rotavirus vaccine introduction. Proposals presented for each investment case were in two phases: Phase 1 for 2007-2010, and Phase II for 2011-2015, with strategic forecasts for 20 years. Milestones and risks were identified for each investment case. The Independent Review Committee highlighted that the systems costs of vaccine introduction were not fully identified and that risky assumptions were made about the use of HSS funding for vaccine introduction.

Therefore, the Boards:

- Approved an envelope of $200M for vaccine procurement ($122M for both vaccines) and strategic and technical activities ($38M for rotavirus and $40M for pneumococcal vaccine) for the period 2007-2010;
- Authorised management to extend the ADIPs for rotavirus and pneumococcal vaccines by one year (through end of 2008), in order to ensure continuity;
- Requested the Secretariat to map non-vaccine costs for introduction of these vaccines.

The Boards also highlighted several issues regarding the investment case roll-out, including:

- Broad partner support will be critical, both to promote country ownership and evidence-based decision making. WHO especially will have an integral role to play.
- Introducing these vaccines will generate additional infrastructure costs, not all of which can be covered within current GAVI funding windows.
- GAVI should consider supporting phase 3 trials for rotavirus and pneumococcal vaccines produced by emerging manufacturers. This could help to ensure future availability of vaccines at more affordable prices.

In May 2007, the GAVI Alliance and Fund Boards received the report of the ADIPs and Hib Initiative evaluation[3]. Key recommendations from this report include:

1. The post-ADIP implementation period needs an investment to support introduction in countries; existing structures lack capacity to address all the issues.
2. ADIPs should be focused in a single organization, with a strong manager, and be target-oriented, time-limited and milestone-driven.

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

3. GAVI should consider an implementation mechanism either within the GAVI Secretariat, housed at a GAVI Partner organization or at an outside organization selected through an RFP process
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.
5. For implementation support, oversight needs to involve the Boards, through a Management Committee selected with appropriate skills, and with liaison through specifically charged GAVI Secretariat teams.

In addition, in November 2007 the ADIP Management Committee made the following recommendations to the GAVI boards[4]:

- That vaccine introduction be coordinated by a specifically appointed senior team within the GAVI Secretariat;
- Scaling up support for vaccine introduction to countries and to partners in line with their mandates; and
- Managing additional support through outsourced activities where needed.

Based on these recommendations, the board requested the Secretariat to work with partners to identify the activities and develop a costed proposal and associated activities for the introduction of pneumococcal and rotavirus vaccines.

Purpose of the mapping and costing exercise

The purpose of the exercise was to:

1. Estimate in broad terms the expected costs to countries and partners of accelerating pneumococcal and rotavirus vaccine introduction,
2. Map the respective contributions of Alliance partners in the effort, and
3. Identify the additional support and approximate funding envelope required for a competitively tendered and outsourced[5] new initiative to help support accelerating vaccine introduction, to be funded with GAVI funds.

The results inform the terms of reference and associated budget envelope for those activities to be outsourced by GAVI as part of accelerating the introduction of new vaccines.

[4] 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.

[5] Commissioned by and contracted out from the GAVI Alliance secretariat.

3. Approach and methods

Approach

The costing exercise was led by the GAVI Secretariat Technical and Policy team under the guidance of a time limited advisory group. The GAVI Alliance Working Group was consulted at regular intervals. Guidelines and a detailed template were provided to WHO, UNICEF and the World Bank (Annex 3). These partners were asked to estimate no-vaccine cost expenditures for each year from 2009 to 2015 in US Dollars to support introduction in GAVI-eligible countries. WHO was also asked to estimate country expenditures for this period.

Table 3.1. Approach to costing accelerated introduction of pneumococcal and rotavirus vaccines

1. Non-vaccine costs only.
2. Additional costs for two new vaccines only.
3. Annually for 2009-2015; summarized for 2009-2010 and 2011-2015.
4. Country and Alliance partner activities, additional support and coordination.
5. Global, regional and country levels.
6. Pre-introduction, introduction and post-introduction phases, and continuous functions.
7. Expected dates of introduction by country: procurement reference group estimates for 2008-2010, and PneumoADIP and Rotavirus Vaccine Program strategic demand forecasts for 2011-2015 and beyond.
8. The expected dates of introduction were used to estimate funds required at country level, for support to prepare for GAVI applications, and for introduction. These are not targets for which partners are held accountable. Goals and objectives can only be finalized when the level of funding available is known.
9. These are non-binding illustrative and provisional cost estimates. Detailed funding requests by agency will be provided through separate mechanisms appropriate to each.
10. Current and future products prequalified
11. SAGE recommends rotavirus vaccine use in Asia and Africa.
12. GAVI-eligible countries.

For years 2009-2010, partners were asked to provide detailed costing where possible, while only ballpark figures were requested for years 2011-2015. Table 3.1 (previous page) summarises the general approach and assumptions for costing.

Vaccine introduction phases

Vaccine introduction activities generally occur in three phases: pre-introduction, introduction and post-introduction[6], at global, regional and country levels. For the purpose of this costing exercise, phases were defined as follows:

> *The **pre-introduction phase** encompasses all activities up to the time when a decision to introduce a new vaccine is made and endorsed at all levels. For GAVI countries, this can be defined as receipt of final approval of an application for GAVI support.*
>
> *The **introduction phase** encompasses activities from the time a decision is made (and GAVI application approved) until vaccination coverage nationwide is consistent with DTP3 (or other vaccine with similar administration schedule) and the vaccine co-financed for at least two years.*
>
> *The **post-introduction phase** includes activities to ensure, monitor, sustain and evaluate new vaccine immunization coverage, vaccine effectiveness, programme performance, public health impact, vaccine supply and demand, and long-term sustainable financing, once the vaccine introduction has been consolidated.*
>
> ***Continuous or cross-cutting functions and activities** are those that support vaccine introduction and cannot be attributed to a particular phase or activity group. These include programme or project management, performance monitoring, coordination and governance.*

For each phase, examples of activities at global, regional and country level were provided for illustrative purposes. Specifically for pneumococcal vaccine, the post-introduction phase includes support for early adopter countries to transition from GAVI funded 7-valent pneumococcal vaccine to AMC-funded products with higher valences.

[6] Lewis R, Zaffran M, Melgaard B. Immunization. In: *International Encyclopedia of Public Health*. Elsevier. In press.

Vaccine introduction dates by country

The anticipated dates of vaccine introduction by country for 2008-2010 were those agreed by consensus of UNICEF, WHO, GAVI Secretariat, PneumoADIP and RVP, through the UNICEF Procurement Reference Group for GAVI.[7] This information is supplemented through consultation with PAHO on expected country applications for the six GAVI-eligible countries in the PAHO region. For 2011-2015 and beyond, the ADIPs provided revised strategic demand forecasts based on letters of expressions of interest sent to the GAVI Secretariat and best available knowledge of country plans. These anticipated dates of introduction were used to estimate costs required to prepare and provide adequate support for the GAVI application process and vaccine introduction. The dates by country as used in this exercise are not in any way binding on countries or partners.

Costing template principles and structure

The costing template was developed from a list of introduction activities and activity groups developed from numerous existing documents and an iterative consultation process. The final list of activity groups by phase is presented below (Table 3.2, next page). The activities for which costs were estimated are those relevant for vaccines provided through routine infant immunization. As the AVI initiative will also serve as a platform for possible inclusion of vaccines approved through the GAVI vaccine investment strategy[8], it should be possible in future to add modules for different types of activities .

For the final results of estimated costs, partner submissions were summed up into a master template of the same design, with all activities added by partners included.

[7] The birth cohorts of these countries are used to estimate the number of vaccine doses required for mid-2008 to 2009, for which UNICEF will prepare a tender document.

[8] The GAVI vaccine investment strategy, presently under development, will be the result of a systematic appraisal of vaccines available and in development, in which the GAVI Alliance could consider investing for country procurement subsidies and/or other activities, in line with the GAVI mission and strategic goals.

Table 3.2 Vaccine introduction costing template phases and activity groups

1. PRE-INTRODUCTION	
	A. PUBLIC HEALTH BENEFIT
	B. VACCINE DEVELOPMENT, REGULATION & LICENSURE
	C. COUNTRY READINESS
	D. VACCINE SUPPLY CHAIN PLANNING
	E. LONG TERM FINANCE PLANNING
2. INTRODUCTION	
	F. MONITORING & EVALUATION
	G. LONG TERM FINANCE IMPLEMENTATION
	H. PROGRAMME ROLL OUT
	I. COLD CHAIN & LOGISTICS
	J. TRAINING
	K. COMMUNICATIONS
	L. VACCINE SUPPLY
3. POST-INTRODUCTION	
	M. MONITORING & EVALUATION
	N. VACCINE SUPPLY
	O. LONG TERM FINANCING SUSTAINABILITY
	P. SUSTAINABILITY SUPPORT
4. CONTINUOUS FUNCTIONS	
	Q. OPERATIONAL & PROJECT MANAGEMENT

4. Overall Mapping and Costing Results

Partner mapping and the AVI Framework

Based on collation of information on the activities named by different partners, the GAVI secretariat mapped all the activities contributing to the goal of introducing pneumococcal and rotavirus in GAVI-eligible countries by the year 2015. The activities were then re-assigned to an AVI framework which was decided during a consultation meeting in Washington DC on May 13-14, 2008.

The AVI framework resulting from the meeting consists of the following five outcomes:

- Sufficient quantity of safe, effective appropriate vaccine to meet the demand
- Financing available to pay for the vaccines and for systems cost
- A well-informed country decision on introduction of the vaccine
- Country introduction of the vaccine
- Establish platform for the sustained use of the vaccine

The partner mapping process brought a consensus regarding the roles of different partners in leading, performing or providing input to activities that help reach these AVI outcomes. In addition, an AVI outsourced entity would be charged with conducting activities under the areas of communications and advocacy, special scientific and economic studies, and strategic vaccine supply.

Detailed outcomes of this mapping exercise are shown in Annex 5. The following chapters outline the key activities to be carried by multilateral partners, industry as well as the proposed AVI outsourced entity.

Table 4.1 – Costs of AVI activities performed by different entities, grouped by phase of introduction (2009-2015)

	Key partner costs				Minor costs					
(in US$1000s)	Out-source	WHO	UNICEF	Country Costs	GAVI Coordinat-ion	World Bank	Rotavirus ADIP	Pneumo ADIP	Hib Initiative	Phase Total
Pre-Introduction	13,900	59,200	12,600	-	-	5,000	8,100	170	1,292	100,262
Introduction	24,400	81,528	16,800	358,709	300	7,500	1,600	560	64	491,460
Post-Introduction	10,200	61,905	5,600	-	600	5,000	1,100	834	2,773	88,011
Continuous Activities	51,087	27,288	-	10,063	6,299	-	-	690	780	96,207
Total	**99,587**	**229,921**	**35,000**	**368,772**	**7,199**	**17,500**	**10,800**	**2,254**	**4,909**	**775,941**

Overall costing results

The costing exercise has consolidated cost estimates for years 2009-2015 submitted from a number of partners. After summation of these cost estimates (see Table 4.1), the global costs related to the accelerated introduction of vaccines would add up to a total of $775.9. The distribution of these costs among the various partners or entities is given in Figure 4.1, and is further broken down by implementation phases in Figure 4.2.

Figure 4.1 – Distribution of all costs related to accelerated vaccine introduction by partner / entity

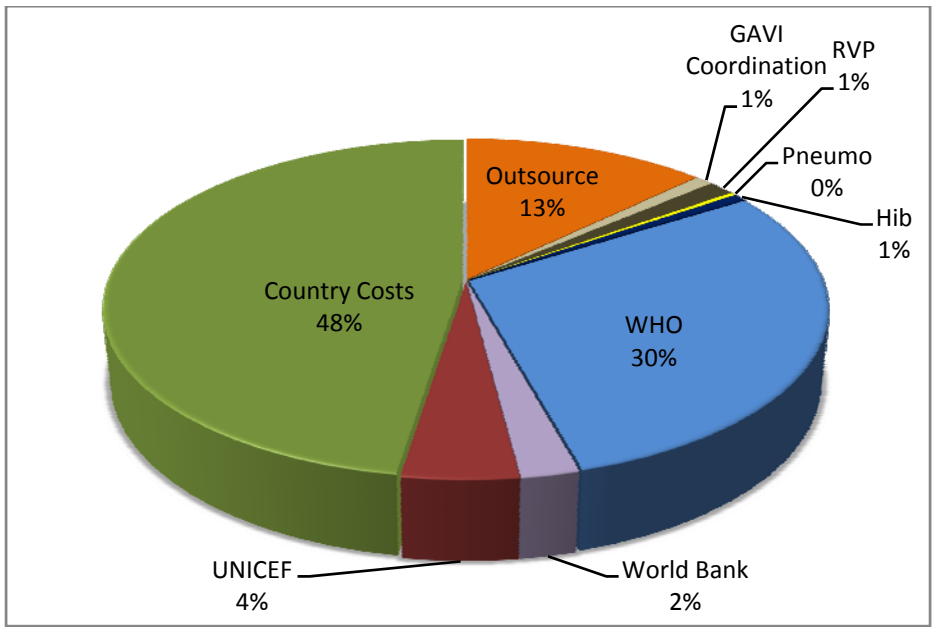


Figure 4.2 – Distribution of all costs related to accelerated vaccine introduction by partner / entity in different implementation phases

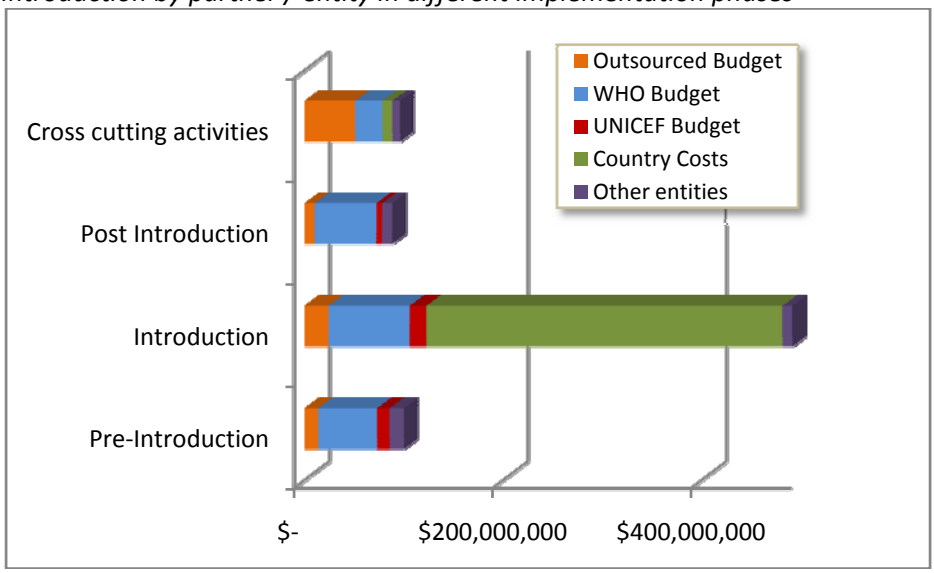
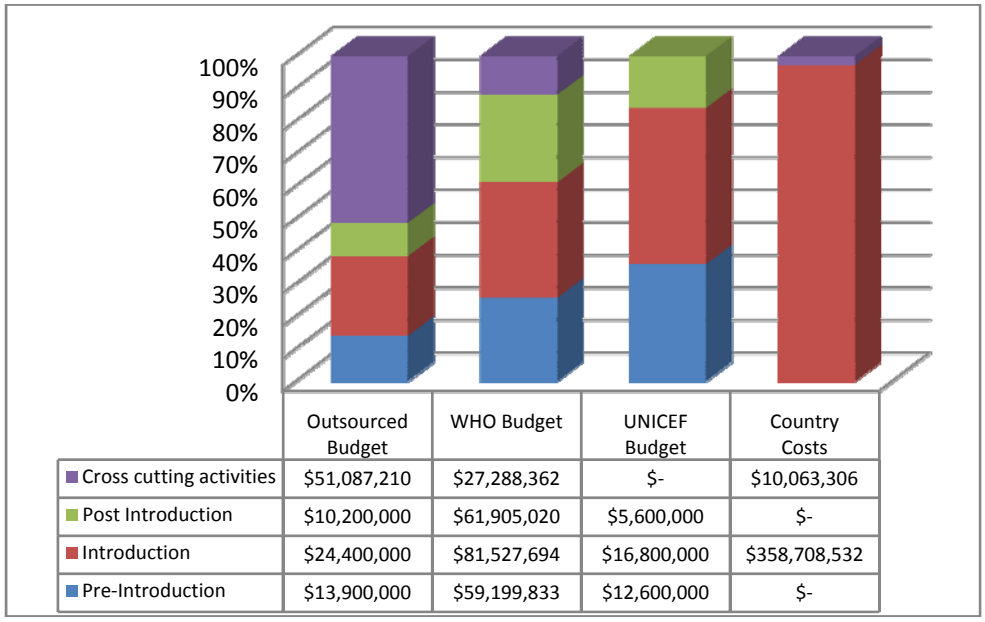


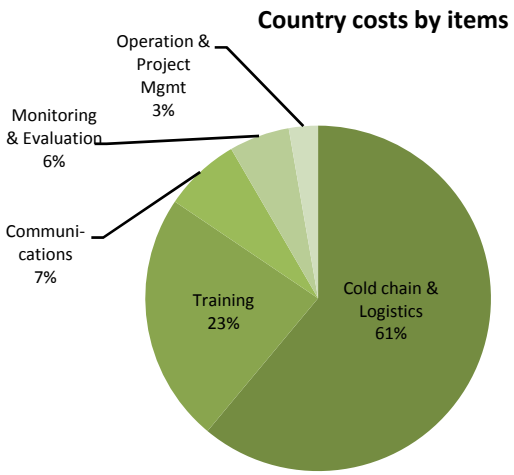
Figure 4.3 – AVI expenditures of key entities grouped by phase of introduction



	Outsourced Budget	WHO Budget	UNICEF Budget	Country Costs
Cross cutting activities	$51,087,210	$27,288,362	$-	$10,063,306
Post Introduction	$10,200,000	$61,905,020	$5,600,000	$-
Introduction	$24,400,000	$81,527,694	$16,800,000	$358,708,532
Pre-Introduction	$13,900,000	$59,199,833	$12,600,000	$-

The key entities that have contributed to the bulk of the expenditure include countries (based on GIVS model), WHO, UNICEF, and the AVI outsourced entity. The AVI outsource entity are largely continuous, where as partners and country expenditures are more associated with time-specific activities during a certain phase of introduction (see Figure 4.3).

5. Country costs and activities



(in US$1000s)	*Country Costs by phase*	*AVI Total by phase*
Pre-Introduction	-	100,262
Introduction	**358,709**	491,460
Post-Introduction	-	88,011
Continuous Activities	**10,063**	96,207
Total	**368,772**	**775,941**

Costing approach

To calculate the non-vaccine systems costs of pneumococcal and rotavirus vaccine introduction, health economists working with the ADIPs used a modeling approach called the Global Immunization Vision and Strategy (GIVS), developed by WHO and adapted specifically for AVI.[9] The national comprehensive costed multi-year plans for immunization serve as the basis of the GIVS analysis, and scale-up costs were estimated using a country-by-country, year-by-year, ingredients-based approach for reaching 90% coverage with new vaccines.

For the purpose of this costing exercise, several assumptions of the GIVS models were modified.

- The expected country introduction dates were modified according to the most recently available information, described above.
- Only the additional costs for introduction of pneumococcal and rotavirus vaccines were calculated. These costs were calculated

[9] Wolfson L, Gasse F, Lee-Martin S-P, Lydon P, Magan A, Tibouti A, Johns B, Hutubessy R, Salama P, Okwo-Bele J-M. Estimating the costs of achieving the WHO-UNICEF Global Immunization Vision and Strategy, 2006-2015.*WHO Bulletin*. 2008;86:27-39.

separately, in line with the assumption that countries would allow a minimum of 3 years between new vaccine introductions.[10]

- To assess the requirements for cold chain expansion, estimates of volume per dose were 12.9 cm^3 for pneumococcal vaccine and 11.8 cm^3 for rotavirus vaccine. These represent the lowest expected volume per dose for these products[11] and therefore conservative estimates of cold-chain expansion costs.
- To help validate the assumptions, the first 12 country applications submitted to the GAVI Secretariat in June 2007 under the new GAVI vaccine introduction grant policy were reviewed for insight into country-perceived needs and spending plans.

Country costs details

Based on the above assumptions, WHO personnel produced budget line estimates for:

- cold chain expansion;
- training and supervision;
- vehicles and transport;
- social mobilization;
- surveillance, monitoring and evaluation;
- waste management; and
- "overheads".

The system costs for the Pneumococcal vaccine include the estimated non-vaccine systems costs of introducing pneumococcal vaccine in 13 countries from 2008-2010, and 29 countries from 2011-2015. The same costs for rotavirus vaccines takes into account introduction in 14 countries from 2008-2010 and 30 countries from 2011-2015.

Estimates of system costs may be higher for each vaccine, as efficiencies gained by introducing two vaccines within 1-2 years of each other in the same country are not fully accounted for in this analysis. Further evaluation using the GIVS model can address these efficiencies, but was not possible at this time. Also, some introduction costs are allocated before the actual year of country adoption. For example, some surveillance costs are included for 2 years prior to introduction.

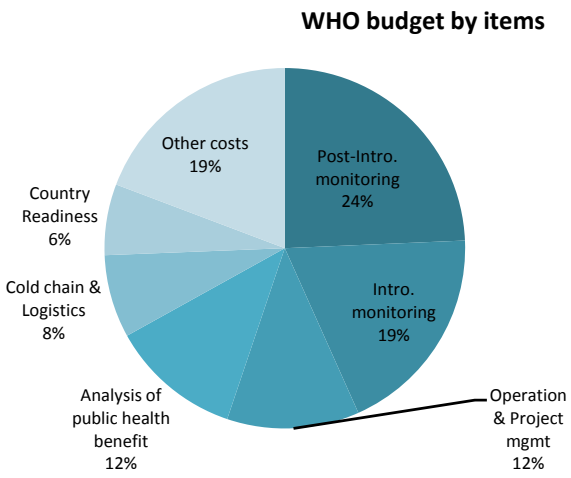
[10] Of 72 GAVI-eligible countries, only Guyana has expressed intention to introduce both products within three years.

[11] For pneumococcal vaccine, this is the approximate volume for liquid injectable vaccines in single-dose vials, which is one presentation expected to be available for AMC funded vaccines. Low multi-dose vials may have a lower volume per dose. Seven-valent Prevenar, for introduction in 2008 and early 2009, requires 59.7 cm^3 per dose. Countries introducing Prevnar will engage additional costs. The rotavirus volume per dose assumes diluent is packed outside the cold chain, and/or future substantial reductions in product volume.

6. Costs and activities of partners – WHO, UNICEF and others

The GAVI Secretariat invited a number of partners to participate in the costing exercise. These included the multilaterals - World Health Organization (WHO), UNICEF, the World Bank; as well as the developing country and industrialized country vaccine industry and project implementing partners funded by the Bill and Melinda Gates Foundation. In this chapter, the details of the costs and activities submitted by multilateral partners will be presented.

World Health Organization



(in US$1000s)	*WHO Costs by phase*	*AVI Total by phase*
Pre-Introduction	59,200	100,262
Introduction	81,528	491,460
Post-Introduction	61,905	88,011
Continuous Activities	27,288	96,207
Total	**229,921**	**775,941**

WHO first engaged in the AVI costing exercise in December 2007. Throughout the duration of the exercise, they were involved in the design of the structure and content of the global costing template as well as the supplementary detail sheets which were intended to capture information pertaining to funding gaps, costing methods, risks and assumptions.

After preliminary meetings and incorporation of WHO suggestions to the costing template, WHO undertook a unit-based costing of activities in line with the general methods outlined above for two main areas:

- Programmatic, technical and managerial support; and
- Disease surveillance.

In addition to the major assumptions that apply to all costing, WHO costing was based on the following assumptions:

- Co-financing price is affordable to countries
- Country cold chain and transport capacities are adequate or can be upgraded
- A safe delivery and disposal mechanism is funded for new vaccines
- Procurement mechanism is streamlined
- WHO offers broad support to prepare and advise countries for introduction
- Salaries for personnel costed in activity groups where possible, in continuous management functions otherwise.
- Coordination meetings and annual NUVI partners' meeting costed as continuous management functions.
- Consulted with WHO/HQ departments; regional office consultation still pending.

WHO proposes to support all GAVI eligible countries in setting up appropriate surveillance by 2014. To do this, a structure of core and enhanced sites with laboratory capacity, population-based surveillance sites, and centres of excellence to conduct specialized epidemiologic studies will be put in place. Laboratory networks will be established or strengthened with the capacity to support and monitor programmes. Data management capacity will be essential at all levels. Surveillance costs in the vaccine introduction phases were estimated with the following assumptions:

- Pre-introduction = capital costs + one year of surveillance
- Introduction = gearing up and impact monitoring for two years
- Post-introduction = impact monitoring for the remaining time period while vaccination programs are in place

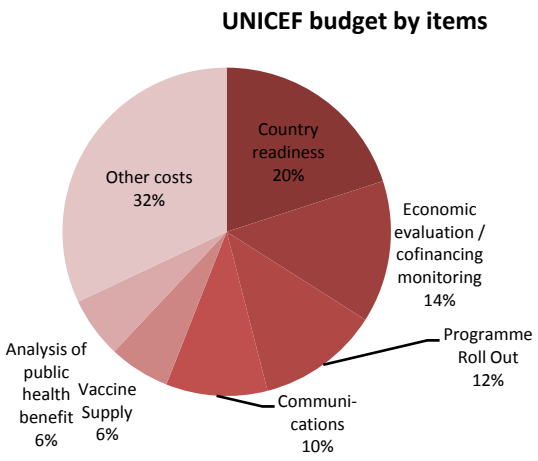
Country surveillance personnel salaries have been costed for the start up period (3 years), after which countries will be expected to take over. Special epidemiologic studies required as a complement to surveillance were not costed by WHO, but would be costed in the estimates for additional outsourced capacity instead.

All costs by activity were estimated in detail for 2009-2010, with more indicative costing for 2011-2015. WHO presented their full methods and results at the costing review meeting. Estimates presented are provisional pending more detailed mapping of existing activities and consultation with WHO regional and country offices.

The final submission from WHO included estimates in two formats for the overall period of 2009-2015. Taken together, the total WHO budget envelope put forth approximated an average of $32.7M per year, over seven years. Approximately 54% of the $229M in costs requested by the WHO for the time period 2009-2015 is dedicated to four priority areas:

1. surveillance activities at country and global level,
2. laboratory networks,
3. monitoring and evaluation and,
4. training, meetings and personnel to support the above activities.

UNICEF



(in US$1000s)	*UNICEF Costs by phase*	*AVI Total by phase*
Pre-Introduction	12,600	100,262
Introduction	16,800	491,460
Post-Introduction	5,600	88,011
Continuous Activities	-	96,207
Total	**35,000**	**775,941**

UNICEF provided a narrative outlining the priority areas for their support to new vaccine introduction in the coming years, and indicated in the costing template the activities in which they have a role to play. Subsequently, UNICEF also submitted a high level estimate of costs using the AVI template for 2009-2015.

UNICEF identified four priority areas in which to provide support for accelerating pneumococcal and rotavirus vaccine introduction. These included:

1. Planning, implementing, monitoring cycle to strengthen overall programme, including capacity for decision-making and budgeting
2. Cold chain and logistics management, planning and maintenance
3. Communication, advocacy and social mobilization
4. Vaccine procurement, supply and industry relations

UNICEF estimated needs based on the assumption that most countries will require at least one to two years of preparatory support, and an additional one to two for implementation.

UNICEF reported that the costs of equipment and materials needed for Cold Chain and Logistics and for Communication were difficult to estimate. In UNICEF's experience with strengthening CCL, even small countries will require millions of dollars in equipment, as well as ongoing support for developing human capacity. UNICEF was not yet certain regarding their ability to invest on these needs.

The fees for vaccine procurement and supply for pneumococcal and rotavirus vaccines is also among UNICEF's costs. In part governed by a Memorandum of Understanding (MOU) between UNICEF and the GAVI Secretariat, UNICEF offers its services as procurement agent available to all governments that wish to seek GAVI support for the procurement of pneumococcal and rotavirus vaccines and associated supplies. The agreed fee is $1.9M for 2008, $2.3M for 2009, and $2.7M for 2010.

In addition to the above priority areas, UNICEF expects to be involved in a range of activities. These are indicated in the activity mapping by partner (Annex 4).

Other partners

World Bank

The World Bank indicated early in the process a preference for providing a narrative on their role, due to the broad nature of the WB mandate and method of working at country level primarily through Ministries of Finance. Subsequently, the World Bank and GAVI have signed a memorandum of understanding for $10M ($2.5M per year for 2007-2010) to support GAVI objectives including new vaccine introduction.

The area of World Bank support to countries which has direct relation to AVI would be the strengthening of health systems. This support focuses on health results, and improving financial sustainability.

The cost estimates for the World Bank's activities associated with AVI were based on the above-mentioned MOU, where the Bank would support country teams and governments in:

- undertaking relevant analysis, engaging in policy dialogue, and sharing findings through papers and participating in relevant regional or global meetings;

- supporting work with partner efforts to create a healthy vaccine market that assures adequate and reliable supplies of quality vaccines at affordable prices and ensures investment in future vaccines;
- supporting global, regional and country staff and governments on analysis, dialogue with ministries of finance, papers, and participation in meetings to assure adequate and sustainable financing of health including immunization;
- performance-based financing, demand side financing, financial flows to district level, fiscal space and other priority topics;
- country operations for the development of efficient and effective financing for health in general and immunization

Bill & Melinda Gates Foundation

After initial analysis, it was determined by members of the steering committee that the contributions of the BMGF were supportive of vaccine introduction overall but not directly appropriate for inclusion in this costing exercise.

7. Initiatives of the vaccine industry

Multinational and Emerging manufacturers are committed to actively support efforts for development, accelerated introduction and distribution of new and under-utilized vaccines for developing country markets.

Following an initial discussion with the vaccine industry representatives on the GAVI Board[12], invitations were extended to the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA) and to the Developing Country Vaccine Manufacturers Network (DCVMN) to participate in mapping and costing for AVI. These activities will be financed by industry and will not incur costs on GAVI.

International Federation of Pharmaceutical Manufacturers' Associations (IFPMA)

The IFPMA represents multinational pharmaceutical companies and includes a sub-group of six major vaccine manufacturers that currently or intend to supply vaccines for developing country markets[13].

A teleconference was held with IFPMA to present an overview of the approach, costing template and guidelines. The group agreed to develop guiding principles for industry engagement and provide information on areas of current or future involvement, but declined to estimate costs for their contributions.

Individual meetings were also held at the Merck and Wyeth vaccine facilities and by teleconference with GSK, as these manufacturers are expected to be major suppliers of pneumococcal and rotavirus vaccines for GAVI-eligible countries in the near term. Each manufacturer outlined their areas of involvement and potential contribution to public sector introduction. These responses were merged into a single narrative.

In relation to AVI, the vaccine industry would carry out a series of activities in preparation for registration of a vaccine intended predominantly for the developing world. These include: research and development, formulation, manufacture scale up, validation of processes and facilities, quality control, pre-clinical safety and clinical safety and efficacy.

[12] The industrialized country vaccine manufacturers' seat on the board is currently held by Merck.
[13] These are Crucell, GlaxoSmithKline, Merck, Novartis, Sanofi and Wyeth

IFPMA commitments are:

1. Supply large quantities of high quality vaccines to the neediest populations in developing countries
2. Invest in the development and supply of new and breakthrough vaccines on a worldwide basis
3. Contribute to the education of immunization providers in GAVI-eligible countries
4. Develop technologies to facilitate the distribution and administration of vaccines
5. Work to engage other private sector organizations in the mission of the GAVI Alliance

Developing Country Vaccine Manufacturers Network (DCVMN)

The DCVMN represents emerging manufacturers from developing countries and are major vaccine suppliers to UNICEF. An interview was conducted with the President of the DCVMN, Dr. Suresh Jadhav, to present the AVI costing exercise and request DCVMN participation. DCVMN companies are expected to start supplying rotavirus vaccines within 3-5 years, pneumococcal vaccines towards the end of the AMC period, and will meet most of the demand for combination Hib vaccines for developing countries.

Using the phases and activities outlined in the costing template, Dr. Jadhav polled the group of manufacturers with pre-qualified vaccines that supply products to developing countries. A narrative outlining areas of involvement of the DCVMN companies was provided, with a listing of activities that could be considered for future support. These activities include:

1. Policy dialogue with different expert groups, recommendation & decision making bodies at global and country levels (WHO, SAGE, GAVI, NGOs, PACE, ministries, etc.) to ensure that vaccines comply with needs and requirements.
2. Special studies may be needed in HIV positive groups, demonstration projects for introduction in GAVI countries, economic evaluation (e.g. cost-effectiveness studies).
3. Epidemiology and surveillance: industry participates technically and by providing some funding directly to support the networks. The industry technical support requires, for example, travel to regional surveillance meetings, presentation of data. Industry frequently funds separate studies to inform their product sero/viral types.
4. Additional clinical trials for GAVI regions: In collaboration with partners, industry provides the following resources (human, scientific and funding): protocol development/data collection forms, consent form development/approval; site visits to the clinical research sites for selection and monitoring for compliance; investigator meetings and training on GCPs, laboratory testing of most or all samples collected (blood, feces, swabs, etc); vaccine donations, country

clearances for vaccine and sample movement, review of the data, and development/support of manuscripts.

5. National Regulatory Authority requirements for registration in countries: In addition WHO prequalification of a product, many countries expect a company to file and be registered. This requires meeting the individual country application and registration requirements, which vary from country to country. In some countries, this may include a "registration trial" with all the additional resource requirements of studies in humans. As part of registration, some developing world NRAs are now conducting inspections of the manufacturing facilities - many of which are expected to be reimbursed by the companies. These inspections must necessarily be treated as a full inspection with all the time, resources and attention required.
6. Prequalification filing with WHO for vaccine procurement by UN agencies: The system for prequalification requires a filing (abbreviated but similar to filing with an NRA) along with submission of data relevant to the climate in countries under consideration.
7. Prequalification also requires sending samples from three lots/batches for testing by laboratories selected by WHO; a site visit (inspection) by a team of inspectors; additional clinical data; data to support the selection and use of a VVM, and any additional work or resources needed to inform the Prequalification process.
8. WHO Prequalification also requires the routine submission of safety reporting similar to that required by other NRAs. The prequalification requirements can be different from national requirements- and therefore there are additional costs for doing the additional work to be prequalified.
9. Additional infrastructure and investment in developing and manufacturing vaccine presentations and packaging to ensure safety and minimize volume and waste.
10. Training and communication for health workers and the medical community; providing resources for implementation of adapted standards and guidelines.
11. Vaccine supply: ensure appropriate and timely supplies and work closely with procurement agencies for the vaccine supply and demand forecasts.
12. Monitoring & evaluation: pharmacovigilance and vaccine safety surveillance; if needed, phase IV studies to investigate vaccine effectiveness and to constitute large safety databases to allow rare safety signals detection.
13. Long term finance implementation: Industry is involved in economic evaluation via its cost/effectiveness studies and the development of cost/effectiveness models.
14. Outbreak response and control: in times of emergency, Industry has made vaccine donations.

In addition to current activities Industry considered other areas for investment: Cold chain and logistics: maintenance and upgrading of cold chain infrastructure; Demand forecasting; EPI Planning and coordinating; Financing mechanisms; Country fiscal space and financing commitment; Advocacy; and Co-finance monitoring.

8. Activities to be outsourced to an outside entity

To achieve desired outcomes of the AVI Framework, GAVI will need to commission an outsourced entity from the social, academic and/or private sectors to perform a range additional technical, advisory, research and managerial support. This chapter outlines how the role of this outsourced entity is defined, and how the costs its activities are derived.

Mapping and Costing Approach

The AVI team attempted to derive an indicative high-level cost estimate for this outsourced support through a three-steps approach: first, by identifying activities selected to remain with the ADIP host institutions; second, by identifying areas of work for additional outsourced support; and third, identifying activities and estimate costs in line with expected future needs for accelerating pneumococcal and rotavirus vaccine introduction.

Step 1. Identifying selected activities to remain with ADIP host institutions

At the ADIP Management Committee in October 2007, at the invitation of the GAVI Secretariat the ADIPs and the Hib Initiative recommended selected activities for continued support through the ADIP host institutions to 2010. These were to include activities that require continuity because of complex transitional issues and would be completed by 2010 and selected activities that could benefit from a more gradual transition to partners or the new integrated entity. PneumoADIP, Rotavirus Vaccine Program and Hib Initiative presented costed proposals and grant extension requests for selected activities through 2009-2010. These were approved by the Joint Fund and Alliance Executive Committee in May 2008.

Step 2. Identifying areas of work for outsourced support

The ADIP Evaluation Report recommended that a future outsourced entity be based on the Hib Initiative and the lessons learned. Using this as a guideline, the Secretariat used this as a starting point for developing a list of activities to be conducted by an outsourced entity. The technical, managerial and

financial experience of the Hib Initiative was summarized by the Hib Initiative using the AVI costing template. The Hib Initiative was consulted on the draft costing template and guidelines and their suggestions incorporated. (See Annex 2 for detailed consultation information)

The Hib Initiative costing was in line with the general methods outlined. However, to record the Hib experience, the costing period was mid 2005 to mid 2009. Costing was completed for mid 2005 to 2007 according to actual activities and expenditures, and for 2008 to mid 2009 according to approved work plans. Expenditures were mapped by the Hib Initiative to the 'Pre-Introduction', 'Introduction' and 'Post Introduction' phases in the costing template, and allocated to global, regional and country levels according to their experience.

Step 3. Identifying activities and estimate costs for accelerating pneumococcal and rotavirus vaccine introduction for an outsourced entity

The next step was to identify the specific activities for which an outsourced entity would play a lead role. The main assumption was that a competitively tendered outsourced entity would have a lead role in agreed-upon key areas for new vaccine introduction: advocacy, strategic vaccine supply, and special scientific and economic studies. Based on the recommendations of the ADIP evaluation and lessons learned, the costing assumed commissioning of support through a single request for proposals.[14] In developing an initial list of activities for outsourced support, considered were areas of work for which countries and partners may benefit from additional capacity to support their leadership and leverage their comparative advantages. Using these assumptions and lessons learned, the Hib Initiative activities and costing were then adapted to a proposed group of tasks and activities. These were additionally informed by the consultations held with the ADIP Management Committee and GAVI Working Group in 2007, data on lessons learned collected from the Hib Initiative, PneumoADIP and RVP during the costing exercise (Annex 1)[15]and discussion of relevance of activities for pneumococcal and rotavirus vaccines. Industry also provided benchmarks and insights that were helpful for the analysis.

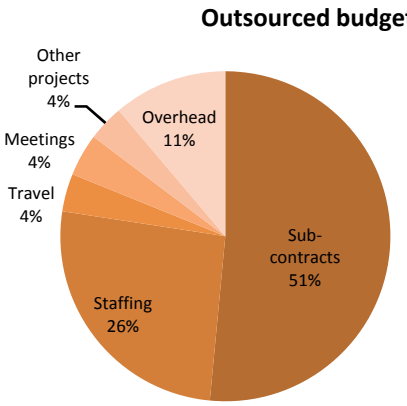
Once these information inputs were gathered, the AVI project team consolidated the activities. These activities were presented at a consensus meeting held in Washington, DC on May 13-14, 2008. At this meeting, consensus was reached on which activities the outsourced entity should have the lead. The group identified three critical areas where the outsourced identity will take charge:

[14] This could be a single institution or a group of institutions with clear lines of authority.

[15] Staff from the Hib Initiative, pneumoADIP and RVP, participated in discussions on lessons learned from the ADIPs but were not invited to discuss any design options for any future outsourced initiative.

1. Communications and Advocacy
2. Special studies
3. Strategic Vaccine Supply

Once consensus was reached on this set of activities, a budget was developed using such inputs as information gathered during the Hib Initiative costing exercise, past budgets from the PneumoADIP and Rotavirus Vaccine Program and guidance from the ADIP Management Committee.



(in US$1000s)	*Outsourced Costs by phase*	*AVI Total by phase*
Pre-Introduction	13,900	100,262
Introduction	24,400	491,460
Post-Introduction	10,200	88,011
Continuous Activities	51,087	96,207
Total	**99,587**	**775,941**

Communications and Advocacy

Considerable progress has been made at the global, regional and country level to introduce rotavirus and pneumococcal vaccines. Over the period 2009-2015, the work will shift increasingly from the pre-introduction phase to the introduction phase focusing on country level decision-making and the actual introduction of vaccines into country programs. A continued focus at the global level is also necessary, however, to sustain and enhance the financial and political support for introduction of these and other new GAVI support vaccines.

The OSE will lead on four Tasks related to Communications and Advocacy. "Leading" involves having the accountability and responsibility for developing strategies and activities to accomplish the Task and for coordinating the players for implementation. The Tasks are:

- Advocate for increased support for new vaccines
- Package vaccine data for decision makers and present to decision makers and the influencers of decision makers
- Document and disseminate lessons learned on the introduction of new and underutilized vaccines

- Develop communications preparedness and response strategies and materials (includes crisis communications)

Special Studies

High quality data are necessary for evidence-based decision-making. The immunization community has vastly improved the information on disease burden, the economic costs of the disease, the safety, efficacy and effectiveness of new vaccines, the cost-effectiveness of introducing new vaccines into country programs, and the health impact on disease post-introduction.

A substantial number of scientific and economic studies have been, or are being, conducted by the pharmaceutical companies, the rotavirus and pneumococcal ADIPs, and others. Many more have been suggested.

There is broad agreement among the GAVI partners that the following types of studies should be conducted:

- Optimization of dosing schedules/delivery schedule
- Herd immunity studies
- Effectiveness studies
- Demonstration projects to measure costs and benefits
- Cost benefit analysis and acceptability

Some of these studies may be conducted by partners, such as WHO or industry.

Strategic Vaccine Supply

Both longer-term, strategic demand forecasts and shorter-term procurement forecasts are important in helping suppliers to plan their capacity. This is due to the capital intensive nature of new manufacturing capacity, which would take at least five years to build. Decisions at the global, regional and country level on which vaccines to procure and in what amounts are heavily influenced by supply. Managing the supply-demand dynamic is never easy, and the complexity for rotavirus and pneumococcal vaccines is substantial as the individual products differ considerably in vaccine composition and in their packaging.

Market research is a critical function underlying much of the proposed work. Understanding the market drivers from the global, regional, and country level decisions-makers and the Key Opinion Leaders that influence those decisions is key to preparing and presenting data and information that is well targeted to its audience. UNICEF will support country introduction at the

consumer level through social mobilization activities. The Agency will have a role here as well in market research, in understanding the demand drivers at the consumer level.

UNICEF is the lead organization for procuring vaccines from pharmaceutical companies on behalf of GAVI. In this role, they oversee the shorter-term, supply chain forecasts that lead to these procurements. The Agency will lead on the longer-term, strategic forecasts and will specifically lead on the following tasks:

- Strategic supply strategy developed
- Suppliers build sufficient capacity to supply vaccine to GAVI

The total budgeted costs for the outsourced entity are $99M. Further details on activities to be carried out by the entity are given in Annex 5.

9. Coordination and oversight – AVI Coordination

Based on the ADIP MC recommendation and the lessons learned from the ADIPs and the Hib Initiative, strong GAVI Secretariat coordination and oversight are required for a complicated set of activities being implemented by many different players. GAVI Secretariat coordination cost estimates provided by senior management include:

1. Personnel – a senior product launch manager based on a UN P5 officer equivalent (100% FTE) to lead and manage the project, a full time project manager at P3 level to track project progress and to identify and overcome barriers to progress, and administrative support at G6 level. An adjustment for 3% annual inflation is included.
2. Overhead costs –expenses for management committee meetings starting at $100,000 per year, and staff travel starting at a total of $75,000 per year. An adjustment for 3% inflation per year is included.
3. Monitoring and Evaluation – costed at $900,000, assuming the project will be evaluated twice - on a small scale in 2010, and more extensively in 2015.
4. Consulting – an additional $150,000 per year is added for consulting services in specific areas of expertise.

The costs associated with this coordinating function would add up to a total of $7.2M.

10. Conclusion and Next Steps

This paper outlined the process of mapping and costing the activities carried out by various entities that would contribute to the accelerated introduction of pneumococcal, rotavirus, and potentially other vaccines. It also describes those activities which partners have agreed should be outsourced through a competitive bidding process.

There are a few assumptions in deriving the costs in this exercise, and this would render the estimated costs higher than the actual amount to be invested. In the country costs, for example, the analysis has not yet fully accounted for the efficiencies gained by introducing two vaccines within 1-2 years of each other in the same country. Also, the team has identified slight overlaps between the activities of partners such as UNICEF and WHO. While the partners have estimated that the overlaps do not account for more than 10% of the total costs of activities between these two entities, they will be harmonized in the course of coordinated planning. The analysis also used the smallest possible cold chain volume estimates, which are likely to be underestimates for the early years.

GAVI will play both a funding and coordinating role in the AVI initiative. It is proposed that GAVI will fund activities to be outsourced, and some portion of activities to be carried out by multilateral partners including WHO, UNICEF and the World Bank. In terms of next steps, the partners will prepare detailed activity plans and associated budgets for independent review. These will need to be harmonized with other submissions to GAVI, including the GAVI work plan and investment cases (approved and pending approval). On

Further, GAVI will take up the role of coordinating an AVI management team consisting of technical experts from multilateral and other partners and independent experts. They will also plan for monitoring and evaluation of all AVI related activities.

Annexes

Annex 1. Lessons Learned from consultations with the Hib Initiative, PneumoADIP and the Rotavirus Vaccine Program

Over the past five years the Hib Initiative, PneumoADIP and RVP have demonstrated their value through the substantial contributions towards accelerating new and under-utilized vaccines. These dedicated groups have had a sweeping impact in areas of disease burden knowledge and awareness at global, regional and country level, disease surveillance through multi-country surveillance networks, credible demand forecasting, advocacy and key message development and positive interaction with manufacturers. These efforts have yielded the acceleration of rotavirus vaccine to 1 year from licensure in industrialized countries to developing countries, pneumococcal vaccine to 7 years from licensure in high income markets and planned Hib vaccine introduction in 50 countries from 2007-2012.

The continued involvement of all partners is critical to maintaining the momentum started by these initiatives. It is important to identify not only the key activities that were successful in accelerating new vaccines but to understand the valuable lessons learned. Highlighted below are the lessons learned from the Hib Initiative, PneumoADIP and RVP.

Summary of Lessons Learned

Technical Support

1. Dedicated teams are needed to collect and synthesize data to support decisions for different stakeholders;
2. Gathering and disseminating disease burden country level data and education on 'best practices' in surveillance data interpretations for local investigators is critical;
3. Creation of a solid foundation to generate the data and evidence needed for global and country-level decision-makers;
4. Building of the case at country level for to assure vaccine investment;
5. Dedicated teams are needed for capacity-building for in-country surveillance systems;
6. Post-introduction special studies for new vaccines to demonstrate impact;

7. Development of a sub-strategy dedicated specifically to countries with large birth cohorts.

Advocacy and Communication

1. Perceptions research and stakeholder mapping should be done early in the process;
2. Additional resources dedicated to communicate activities, e.g. translation of publications, financing solutions, translating data in key messages is necessary for buy-in of all partners at global , regional and country-level;
3. Increased country-level advocacy with key stakeholders;
4. Engagement of the technical community early in the process is needed to create technical consensus and global messaging;
5. Advocacy at both the global and regional level; both are needed for new vaccine introduction;
6. Need for an integrated approach to country consultations and messaging to support evidence-based decision-making;
7. Continuation of communication efforts to sustain momentum.

Industry Relations and Market Dynamics

1. Building of a business case for vaccine manufacturers early in the process is needed to ensure vaccine security;
2. Engage emerging manufacturers early in the process to sensitize them to market trends;
3. Monitoring of supply and demand conditions to coordinate uninterrupted supply of vaccines for accelerated introduction;
4. Inclusion and engagement of UNICEF early in the process;
5. The need for a 'neutral group' or 'honest broker' to engage industry.

Project Management and Governance

1. Development of a reporting and management structure with a clearly defined role that is meaningful and knowledgeable in areas of technical support, Industry, country support and market dynamics;
2. Clearly defined roles and responsibilities for the outsourced entity and each of the partners, specifically GAVI; high level support is needed at the Secretariat to advise and direct for a successful partnership;
3. Transparent communication and advocacy at global, regional and country level regarding the outsourced entity and the defined role it will play in accelerated vaccine introduction;
4. Relationship management for partners, countries and Industry – what role will the outsourced entity have and how will this be managed;
5. Inclusion of Industry as a partner and managing new and current suppliers.

Annex 2. GAVI Secretariat and Alliance Consultations on Accelerated Vaccine Introduction

Date	Topic	Objectives	Attendees
Dec 19, 2008	**AVI Development Phase Consultation with WHO**	• To provide update from GAVI Board meeting in November 2007 • To discuss proposed role of partners 2008-2010 • To request work plans and budgets from 2008-2010 (2 scenarios) • To solicit feedback on recommended core activities for outsourced entity • To discuss shared objectives beyond 2010	GAVI: Rosamund Lewis, Dana Dunne, Jan Grevendonk WHO: Rudi Eggers, Lidija Kamara
Jan 21, 2008	**AVI Development Phase Consultation**	• To provide an overview of AVI background, context, objectives, process, timeline and costing template • To request feedback on the structure of the costing template and criteria application	GAVI: Rosamund Lewis and 25 staff in GAVI WHO: Craig Shapiro
Jan 25, 2008	**AVI Costing Exercise Consultation with WHO**	To discuss the following: • WHO role in support of new vaccine introduction, • Role of outsourced entity • Overall approach to costing • WHO activities for AVI, 2008-2010 and 2011-2015	GAVI: Nina Schwalbe, Rosamund Lewis, Dana Dunne WHO: Rudi Eggers, Lidija Kamara, Thomas Cherian, Gill Mayers
Feb, 4 2008	**AVI Development Phase Consultation with Industry GAVI Board Representative**	• To update industry on the progress of the Accelerated Vaccine Project (AVI) • To discuss proposed industry involvement in the project to accelerate new vaccine introduction in developing country markets.	GAVI Board Rep: Margaret McGlynn and Elaine Esber, GAVI: Rosamund Lewis, Dana Dunne, Angeline Nanni
Feb 8, 2008	**AVI Progress Report to VII Advisory Group**	To discuss the following: • AVI Technical Proposal • Implementation Plan for Costing Exercise • Performance Measurement • Way Forward	VII Advisory Group Members: Craig Shapiro, Anthony Measham, Jan Holmgren, Vance Dietz, Claudia Castillo GAVI: Rosamund Lewis, Andrew Jones, Dana Dunne
Feb 12, 2008	**AVI Development**	To discuss the following: • Program Highlights	GAVI: Rosamund Lewis, Susie Lee, Dana Dunne,

	Phase Consultation with Hib Initiative	• Lessons Learned and Critical Activities • Strategic Plans • Progress Reports Linkage to Activity Costs	Angeline Nanni Hib: Rana Hajjeh, Lois Privor-Dumm, Allyson Bear, Sharmila Shetty
Feb 13, 2008	**AVI Costing Exercise Consultation with PneumoADIP and RVP**	To discuss the following: • PneumoADIP vs RVP country costing methodology for AVI • Desired additional inputs and rationalization of approaches • Timeline to completion To solicit feedback on lessons learned from PneumoADIP experience to inform design of AVI platform	Hib: Allyson Bear, Sharmila Shetty PneumoADIP: Lois Privor-Dumm, Elaine Barumwa, Kate O'Brien, Maria Deloria-Knoll RVP: Debbie Atherly GAVI: Rosamund Lewis, Dana Dunne
Feb 13, 2008	**AVI Development Phase Consultation with Sabin Institute**	• To provide an overview of AVI background, context, objectives, process, timeline and costing template • To request feedback on the structure of the costing template • To gain a better understanding of the nature of the Gates funding award to Sabin Institute for advocacy work related to creating fiscal space for vaccine funding at developing country level and potential overlap with the AVI costing exercise	Sabin Institute: Mike McQuestion GAVI: Rosamund Lewis, Dana Dunne, Angeline Nanni
Feb 14, 2008	**AVI Development Phase Consultation with GAVI Staff in DC Office**	• To provide an overview of AVI background, context, objectives, process, timeline and costing template • To request feedback on the structure of the costing template and criteria application	GAVI DC Staff (approximately 20 members)
Feb 14, 2008	**AVI Development Phase Consultation with PAHO**	• To provide an overview of AVI background, context, objectives, process, timeline and costing template • To request feedback on the structure of the costing template	PAHO: Claudia Castillo GAVI: Rosamund Lewis, Dana Dunne
Feb 14, 2009	**AVI Costing Exercise Consultation with World Bank**	To provide an overview of AVI background, context, objectives, process, timeline and costing template • To request feedback on the structure of the costing template • To request participation in the costing exercise	World Bank: Amie Batson GAVI: Rosamund Lewis, Dana Dunne,

Feb 15, 2008	**AVI Costing Exercise Consultation with UNICEF**	• To provide an overview of AVI background, context, objectives, process, timeline and costing template • To request feedback on the structure of the costing template • To request participation in the costing exercise	UNICEF: Osman Mansoor Patience Kuruneri GAVI: Rosamund Lewis, Dana Dunne
Feb 18, 2008	**AVI Development Phase Consultation with RVP**	• To solicit feedback on lessons learned from RVP experience to inform design of AVI platform	RVP: J. Wecker and staff GAVI: Rosamund Lewis, Dana Dunne
Feb 18, 2008	**AVI Progress Report to VII Advisory Group**	To discuss the following: • Background information on AVI • Inputs considered for exercise • Development phase timeline • Abbreviated costing exercise instructions • Costing template overview • Feedback	VII Advisory Group Members: Max Tello, Deogratias Darakamfitiye, Anthony Measham, Jan Holmgren, Vance Dietz, Kathleen Ruddy, Kevin Reilly, Steve Landry GAVI: Rosamund Lewis, Dana Dunne
Feb 21, 2008	**AVI Development Phase Consultation with EPI Managers at GIM Meeting**	• To review the costing template for edits, feedback or suggestions for refinement and to offer guidance on the use of the template.	GAVI: Raj Kumar, Rosamund Lewis WHO: Rudi Eggers, Gill Mayers, Craig Shapiro and regional NUVI officers VIIAG members
Feb 25, 2008	**AVI Development Phase Consultation with DCVMN**	• To present the AVI project to the DCVMN representative and initiate discussion about the role of industry in supporting accelerated introduction of pneumococcal and rotavirus vaccine.	DCVMN: Suresh Jadhav GAVI: Angeline Nanni, Dana Dunne
Feb 27, 2008	**AVI Development Phase Consultation with IFPMA**	• To present the AVI project to industry representatives through the IFPMA GAVI group, and initiate discussion about the role of industry in supporting accelerated introduction of pneumococcal and rotavirus vaccine.	GAVI: Rosamund Lewis, Dana Dunne,Angeline Nanni IFPMA: Jackie Keith, Shawn Gilchrist, Elaine Esber, Kate Taylor & Kathleen Vandendael-Baudrihaye, Niels Ersboll, Ryoko Krause & Janis Bernat
Feb 27, 2008	**AVI Costing Exercise Consultation with WHO**	• To agree on structure of AVI costing template, level of detail reported, costing assumptions and instruction documentation needed	WHO: Gill Mayers and Cristiana Toscano GAVI: Dana Dunne
March 6, 2008	**AVI Costing Exercise Consultation with Wyeth**	• To engage Wyeth in the Accelerated Vaccine Project (AVI) and initiate discussions on the company's potential activities in the project to accelerate new vaccine introduction in developing country markets • To review the costing template for	Wyeth:Jackie Keith, Lynn Bodarky, John Furey GAVI: Rosamund Lewis, Dana Dunne, Angeline Nanni

		edits, feedback or suggestions for refinement and to offer guidance on the use of the template.	
March 7, 2008	**AVI Costing Exercise Consultation with Merck**	• To engage Merck in the Accelerated Vaccine Project (AVI) and initiate discussions on the company's potential activities in the project to accelerate new vaccine introduction in developing country markets • To review the costing template for edits, feedback or suggestions for refinement and to offer guidance on the use of the template.	Merck: Elaine Esber, Max Ciarlet, Chris Nelson, Kris Natarajan, James Wassel, Adenan Hatim GAVI: Rosamund Lewis, Dana Dunne, Angeline Nanni
March 17, 2008	**AVI Costing Exercise Consultation with GSK**	• To engage GSKin the Accelerated Vaccine Project (AVI) and initiate discussions on the company's potential activities in the project to accelerate new vaccine introduction in developing country markets • To review the costing template for edits, feedback or suggestions for refinement and to offer guidance on the use of the template	GSK: Kate Taylor, Kathleen Vanderalh GAVI: Rosamund Lewis, Dana Dunne, Angeline Nanni
March 21, 2008	**AVI Costing Exercise Consultation with AVI Stakeholders**	• To agree on demand forecasts and level of detail to be used in AVI exercise	GAVI: Rosamund Lewis, Andrew Jones, Dana Dunne, WHO:Gill Mayers, Cristiana Toscano, Rudi Eggers UNICEF: Patience Kuruneri PneumoADIP: Orin Levine RVP: D. Atherly
March 26- 27, 2008	**AVI Harmonization Meeting with AVI Stakeholders**	• To report on partner reports costing methods and results • To present global costing and mapping results • To have a discussion on outsourced entity costing results	VII Advisory Group: Steve Landry, Jan Holmgren, Deo Barakamfitiye, Thomas Cherian, Rudi Eggers, Patience Kuruneri Claudia Castillo, Lucia Oliveira , Vance Dietz GAVI: Nina Schwalbe, Rosamund Lewis, Dana Dunne, Susie Lee, Raj Kumar, Andrew Jones, Arnold Fang, Angeline Nanni, Melinda Moree Additional costing participants: Joachim Hombach, Gill Mayers, Lara Wolfson, Suresh Jadhav, Chris Natarajan, Lynn Bodarky

April 18, 2008	**AVI Meeting to identify duplication in the costing exercise**	• To determine where there are areas of overlap in the list of activities and the costs for the proposed rota and pneumo introduction activities	WHO: Patrick Zuber, Gill Mayer, Cristiana Toscano UNICEF: Osman Mansoor GAVI Secretariat: Susie Lee, Arnold Fang, Angeline Nanni (consultant), Melinda Moree (consultant)
May 13-14, 2008	**AVI Meeting to consolidate the roles of partners**	• To discuss the framework of goals and outcomes • To determine the appropriate entity to lead, perform or influence the various activities	**Both Days* WHO: Thomas Cherian UNICEF: Patience Kuruneri GAVI Secretariat: Nina Schwalbe, Susie Lee, Melinda Moree (consultant), Mary Kate (consultant) Other entities: Nitin Patel (IM), Michael Conway (McKinsey), Susan McKinney (Working Group – USAID) ***May 13 only* Orin Levine (PneumoADIP), John Wecker (RVP), Mathuram Santosham & Rana Hajjeh (Hib), Kevin Riley (ADIP-MC), Tony Meashan (Working Group – WB) ****May 14 only* Ahmed Magan (UNICEF)

Annex 3. Guidelines for completing the AVI costing template

I. BACKGROUND

In November 2006, the GAVI Alliance Board approved the funding of investment cases for accelerating pneumococcal and rotavirus vaccine introduction. Proposals presented for each investment case were in two phases: Phase 1 for 2007-2010, and Phase II for 2011-2015, with strategic forecasts for 20 years.

The board agreed in principle to fund the Phase I investment cases for a total of $200M for 2007-2010 (including vaccines and 'strategic and technical support' costs). Milestones and risks were identified for each investment case. The IRC that reviewed the cases highlighted that the systems costs of vaccine introduction were not fully identified.

In May 2007, the GAVI Alliance board received the ADIP /HI evaluation report and requested the Secretariat to work with partners to identify the additional support required for the introduction of pneumococcal and rotavirus vaccines, who should implement them, and what level of funding would be required to ensure the accelerated uptake of pneumococcal and rotavirus vaccines beyond 2008.

In November 2007, the board agreed to an approach for accelerating vaccine introduction with the following elements. 1. Continue and review support to countries; 2. Mainstream activities and scale up support to partners; 3. Outsource time-limited integrated support for key activities and special studies. This initiative would include a role for regional and country peer support and developing country institutions and would be supported by strengthened coordination capacity.

The next step is to present a costed technical proposal to the GAVI Alliance Executive Committee in May and Board in June 2008. The AVI costing exercise has been undertaken to inform the proposal.

II. GUIDELINES

Section II of this document offers guidance for partners engaging in the costing exercise, with emphasis on completion of the costing template provided by the GAVI Secretariat AVI team.

A. Application of pneumococcal and rotavirus vaccine demand forecasts to costing exercise

The anticipated dates of vaccine introduction by country listed in Annex I are based on the most recent information available to UNICEF, WHO, GAVI and the ADIPs. These should be used in estimating costs in preparation for GAVI applications and vaccine introduction.

B. Cost inputs

Cost inputs should primarily reflect the marginal cost estimates for vaccine introduction activities pertaining to pneumococcal and rotavirus vaccines in GAVI eligible countries. Where impossible to prorate or cost-share activity cost projections, however, an explanation should be provided within the accompanying narrative detailing the nature of the activity.

Special consideration should be given to the activities required for introduction in populous countries. Proposals for specific support to the large countries and countries with many unimmunized children should also be costed.

One-time costs related to supporting introduction of product presentations available on a temporary basis should also be included (e.g. pre-filled syringe for pneumococcal vaccine), as well as the costs required to change presentations (e.g. to AMC-funded products).

C. Denomination and currency

Cost estimates should be made in USD to the nearest 10,000**.**

D. Costing template worksheets

There are four types of Excel worksheets provided:

1. Template summary worksheet: this worksheet provides a roll-up of costs by phase and activity group on a yearly basis. The sheet is automatically populated when filling in the detail worksheet.

2. Comprehensive template worksheet: the comprehensive worksheet includes activities which roll up into their respective activity groups. Each group contains activities labelled “other” for use for activities not represented in the template.

3. Activity group detail worksheet(s): a supplemental worksheet for each activity group is provided to capture the following information: costing methods, planned activities, funding information, assumptions and risks.

4. Activity summary worksheet: this sheet provides an alphabetical overview of all of the activities utilized in the template. If additional activities are needed in Activity Groups, this list should be referenced before creating a new activity in the “other” section of each group (to ensure that it does not already exist).

E. Structure of comprehensive template worksheet

The structure of the template is divided into hierarchical categories:

1. Vaccine introduction phases: there are three consecutive phases listed (pre-introduction, introduction and post-introduction) and one category for cross-cutting activities and continuous functions. Phases are defined and example activities provided in Annex II.

2. Activity groups: these groups appear in each phase and represent significant activity themes that take place during vaccine introduction.

3. Activities: these line items are included in the detail worksheet and are grouped according to relevant phases and activity groups.

F. Template Structure Considerations

- To ensure that the links between formulas on Tab (2) and back up activity group detail tabs remain valid, only add new or additional activities at the end of the activity list in each group.
- Once all new activities are added, it will be necessary to add them in their respective activity group detail pages as well. The formulas will also need to be linked for these activities between Tab (2.) and the respective activity group detail sheet.

G. Questions

Any questions about utilization of the costing template can be directed to Dana Dunne at: ddunne@gavialliance.org or rlewis@gavialliance.orgtelephone: +41 22 909 7166.

II. Country introduction assumptions

PNEUMOCOCCAL VACCINE		ROTAVIRUS VACCINE	
Country Name	**Projected Year of Introduction**	**Country Name**	**Projected Year of Introduction**
AVI inputs for 2009-2010		**AVI inputs for 2009-2010**	
Guyana	2008	Bolivia	2008
Nicaragua	2008	Guyana	2008
Gambia	2009	Honduras	2008
Kenya	2009	Armenia	2009
Rwanda	2009	Ukraine	2009
Yemen	2009	Azerbaijan	2010
Mali	2009	Georgia	2010
Burkina Faso	2009	Kyrgyzstan	2010
Benin	2009	Moldova	2010
Senegal	2009	Nicaragua	2010
Burundi	2009	Uzbekistan	2010
Djibouti	2010	Bangladesh	2010
Ghana	2010	Ghana	2010
AVI inputs for 2011-2015		Yemen	2010
Congo	2011	**AVI inputs for 2011-2015**	
Côte d'Ivoire	2011	Gambia, The	2011
Moldova	2011	Kenya	2011
Cameroon	2011	Malawi	2011
Cuba	2011	Tajikistan	2011
Honduras	2011	Vietnam	2011
Sri Lanka	2011	Benin	2012
Mongolia	2011	Bhutan	2012
Sudan	2011	Cambodia	2012

Ethiopia	2011	Eritrea	2012
Tanzania	2011	Guinea-Bissau	2012
Afghanistan	2012	India	2012
Bangladesh	2012	Mali	2012
Bhutan	2012	Rwanda	2012
Congo, Democratic Republic of the	2012	Senegal	2012
Lesotho	2012	Sudan	2012
Madagascar	2012	Cameroon	2013
Nepal	2012	Indonesia	2013
Pakistan	2012	Mongolia	2013
Sao Tome and Principe	2012	Myanmar	2013
Solomon Islands	2012	Tanzania	2013
Togo	2013	Zambia	2013
Malawi	2013	Zimbabwe	2013
Mozambique	2013	Cuba	2014
Timor-Leste, Democratic Republic of	2013	Lesotho	2014
PNEUMOCOCCAL VACCINE		**ROTAVIRUS VACCINE**	
Country Name	**Projected Year of Introduction**	**Country Name**	**Projected Year of Introduction**
AVI inputs for 2011-2015		**AVI inputs for 2011-2015**	
Uganda	2013	Mozambique	2014
Zambia	2013	Nepal	2014
Indonesia	2014	Pakistan	2014
Viet Nam	2014	Lao People's Dem. Rep.	2015
Bolivia	2015	Madagascar	2015
Georgia	2016	Papua New Guinea	2015
Papua New Guinea	2016	Solomon Islands	2015
India	2017		
Ukraine	2017		
Uzbekistan	2017		
Armenia	2018	**Estimate based on GAVI Procurement Reference Group (PRG) supply chain forecast**	
Azerbaijan	2018		
Kyrgyzstan	2018		
Tajikistan	2018	**Estimates based on ADIP strategic demand forecasts that have been revised for overlap with PRG estimates**	
Kiribati	2019		
Myanmar	2019		
Nigeria	2019		
Zimbabwe	2019		

Cambodia	2020	
Guinea	2020	

III. Phase definitions and sample activities

These definitions are for the purpose of the costing exercise only; activities that could be included in each phase are illustrative and not meant to be comprehensive.

The pre-introduction phase encompasses all activities up to the time when a decision to introduce a new vaccine is made and endorsed at all levels. For GAVI countries, this can be defined as receipt of final approval of an application for GAVI support.

Country level: activities to determine burden of disease and public health benefit, establish surveillance, assist with vaccine introduction decision-making, regulatory approval and country preparedness, identify funding sources, establish long-term financing, and draft proposals for support including GAVI applications, until a decision is made and endorsed at all levels.

Regional level: activities that aim to support work at the country and/or global level to establish burden of disease and public health benefit, coordinate special studies of regional relevance, support countries in decision-making, and assist countries to prepare for introduction, including provision of technical assistance to prepare a GAVI application.

Global level: activities that are upstream of country introduction but must be sustained for successful country introduction. This includes activities that monitor the vaccine pipeline and sustain vaccine supply, demand and quality (e.g. industry relations, pre-qualification); innovative financing and product pricing at global level, work that is specifically undertaken to facilitate introduction in GAVI eligible countries, such as market research for product design, clinical and epidemiological studies in specific regions for available products, and product adaptation for the GAVI market; activities to support country decision-making (e.g. technical assistance, dialogue and decision-making workshops, establishment of monitoring and evaluation), and those that result in demand creation before vaccine introduction (e.g. development of advocacy materials).

The introduction phase encompasses activities from the time a decision is made (and GAVI application approved) until vaccination coverage nationwide is consistent with DTP3 (or other vaccine with similar administration schedule) and the vaccine co-financed for at least two years.

Country level: activities to implement what is required for country preparedness and successful introduction, including continuing advocacy and demand creation; vaccine supply, logistics and delivery systems; training of health workers; surveillance strengthening to monitor introduction, safety and impact; post-introduction evaluation; and stabilizing financing. It is expected that efforts to ensure full integration of the new vaccine into child health programming and the wider health system will be emphasized.

Global and regional levels: Activities that aim to ensure country preparedness and support new programme launch, sustain advocacy and communication, establish monitoring and performance management systems, monitor vaccine impact including serotype replacement and indirect effects, monitor and ensure vaccine safety, manage vaccine supply and procurement, set up operations research and special studies, revise policies and standards, coordinate implementation and ensure financing.

The post-introduction phase includes activities to ensure, monitor, sustain and evaluate new vaccine immunization coverage, vaccine effectiveness, programme performance, public health impact, vaccine supply and demand, and long-term sustainable financing, once the vaccine introduction has been consolidated.

All levels and partners: Activities that contribute to the above objectives. This phase will also include all activities required to support pneumococcal vaccine early adopter countries to transition from 7-valent to higher valency AMC-funding products.

Continuous functions and activities are those that support vaccine introduction and cannot be attributed to a particular phase or activity group.

All levels and partners: Activities and costs for programme or project management, performance monitoring, coordination and governance.

Annex 4. Costing of WHO and UNICEF activities

Vaccine Introduction Phases & Activity Groups (UNICEF)								
	2009	2010	2011	2012	2013	2014	2015	Total
1. PRE-INTRODUCTION	**1,800,000**	**1,800,000**	**1,800,000**	**1,800,000**	**1,800,000**	**1,800,000**	**1,800,000**	**12,600,000**
A. Public Health Benefit	300,000	300,000	300,000	300,000	300,000	300,000	300,000	**2,100,000**
B. Vaccine Development, Regulation & Licensure	100,000	100,000	100,000	100,000	100,000	100,000	100,000	**700,000**
C. Country Readiness	1,000,000	1,000,000	1,000,000	1,000,000	1,000,000	1,000,000	1,000,000	**7,000,000**
D. Vaccine Supply Chain Planning	200,000	200,000	200,000	200,000	200,000	200,000	200,000	**1,400,000**
E. Long Term Finance Planning	200,000	200,000	200,000	200,000	200,000	200,000	200,000	**1,400,000**
2. INTRODUCTION	**2,400,000**	**2,400,000**	**2,400,000**	**2,400,000**	**2,400,000**	**2,400,000**	**2,400,000**	**16,800,000**
F. Monitoring & Evaluation	100,000	100,000	100,000	100,000	100,000	100,000	100,000	**700,000**
G. Long Term Finance Implementation	200,000	200,000	200,000	200,000	200,000	200,000	200,000	**1,400,000**
H. Programme Roll Out	700,000	700,000	700,000	700,000	700,000	700,000	700,000	**4,900,000**
I. Cold Chain & Logistics	600,000	600,000	600,000	600,000	600,000	600,000	600,000	**4,200,000**
J. Training	100,000	100,000	100,000	100,000	100,000	100,000	100,000	**700,000**
K. Communications	500,000	500,000	500,000	500,000	500,000	500,000	500,000	**3,500,000**
L. Vaccine Supply	200,000	200,000	200,000	200,000	200,000	200,000	200,000	**1,400,000**
3. POST-INTRODUCTION	**800,000**	**800,000**	**800,000**	**800,000**	**800,000**	**800,000**	**800,000**	**5,600,000**
M. Monitoring & Evaluation	200,000	200,000	200,000	200,000	200,000	200,000	200,000	**1,400,000**
N. Vaccine Supply	300,000	300,000	300,000	300,000	300,000	300,000	300,000	**2,100,000**
O. Long Term Financing Sustainability	100,000	100,000	100,000	100,000	100,000	100,000	100,000	**700,000**
P. Sustainability Support	200,000	200,000	200,000	200,000	200,000	200,000	200,000	**1,400,000**
4. CROSS-CUTTING ACTIVITIES	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Q. Operational & Project Management	0	0	0	0	0	0	0	**0**
Grand Total	5,000,000	5,000,000	5,000,000	5,000,000	5,000,000	5,000,000	5,000,000	**35,000,000**

Vaccine Introduction Phases & Activity Groups (WHO)								
	2009	2010	2011	2012	2013	2014	2015	Total
1. PRE-INTRODUCTION	**13,528,685**	**10,362,908**	**11,471,948**	**8,117,647**	**5,646,936**	**4,962,677**	**5,109,032**	**59,199,833**
A. Public Health Benefit	9,112,435	5,795,758	6,974,948	3,416,577	1,005,496	385,990	385,990	**27,077,194**
B. Vaccine Development, Regulation & Licensure	1,699,250	1,577,250	1,435,750	1,340,750	1,489,100	1,452,785	1,547,785	**10,542,670**
C. Country Readiness	1,819,000	1,977,900	2,002,900	2,152,190	2,149,190	2,242,054	2,323,409	**14,666,643**
D. Vaccine Supply Chain Planning	453,000	497,000	498,300	548,130	548,130	421,848	421,848	**3,388,256**
E. Long Term Finance Planning	445,000	515,000	560,050	660,000	455,020	460,000	430,000	**3,525,070**
2. INTRODUCTION	**5,461,189**	**13,136,490**	**16,403,071**	**16,437,370**	**14,190,942**	**9,226,424**	**6,672,208**	**81,527,694**
F. Monitoring & Evaluation	537,750	7,785,557	11,222,538	10,856,884	8,732,456	3,617,770	891,468	**43,644,423**
G. Long Term Finance Implementation	821,000	901,000	905,600	991,160	871,160	802,190	978,276	**6,270,386**
H. Programme Roll Out	50,000	50,000	50,000	50,000	50,000	55,000	60,000	**365,000**
I. Cold Chain & Logistics	2,060,000	2,294,000	2,294,000	2,485,400	2,485,400	2,743,540	2,728,540	**17,090,880**
J. Training	850,000	890,000	820,000	886,000	876,000	948,600	948,600	**6,219,200**
K. Communications	577,439	602,933	491,433	519,476	519,476	550,324	550,324	**3,811,405**
L. Vaccine Supply	565,000	613,000	619,500	648,450	656,450	509,000	515,000	**4,126,400**
3. POST-INTRODUCTION	**1,549,000**	**1,654,400**	**1,600,900**	**8,561,922**	**12,318,403**	**17,036,672**	**19,183,723**	**61,905,020**
M. Monitoring & Evaluation	900,000	975,000	825,000	7,521,532	11,278,013	16,133,938	18,280,989	**55,914,472**
N. Vaccine Supply	245,000	269,000	69,500	296,450	296,450	145,000	145,000	**1,466,400**
O. Long Term Financing Sustainability	130,000	125,000	125,000	150,000	150,000	150,000	150,000	**980,000**
P. Sustainability Support	274,000	285,400	581,400	593,940	593,940	607,734	607,734	**3,544,148**
4. CROSS-CUTTING ACTIVITIES	**3,294,900**	**3,624,390**	**3,624,390**	**3,986,829**	**3,986,829**	**4,385,512**	**4,385,512**	**27,288,362**
Q. Operational & Project Management	3,294,900	3,624,390	3,624,390	3,986,829	3,986,829	4,385,512	4,385,512	**27,288,362**
Grand Total	23,833,774	28,778,188	33,100,309	37,103,768	36,143,110	35,611,285	35,350,475	**229,920,909**

The AVI Framework - Partner mapping results

Outcome	Task	Major Activity	Task Lead	Outsourced Entity Role
Sufficient quantity of safe, effective, appropriate vaccine to meet the demand	Prequalify relevant pneumo and rotavirus vaccines	Submit vaccine for prequalification	WHO	
		Identify and resolve potential barriers to WHO prequalification		
		WHO prequalification of submitted vaccines		
		Monitoring of country vaccine regulatory systems through assessment and the creation of institutional development plans in 8-12 countries		
		5-8 WHO NRA assessments and follow-up visits to sustain vaccine prequalification of priority vaccines		
		Database development and maintenance of PQ/NRA/GTN activities		
	Suppliers build sufficient capacity to supply vaccine to GAVI	Update strategic supply and demand forecasts	Outsourced Entity	Lead
		Communicate forecast results to industry, UNICEF, and other major stakeholders to ensure a coordinated relationship between supply and demand		Lead
		Suppliers build capacity		
	Price and supply agreements with suppliers	Negotiations with companies on price and supply agreements with suppliers	UNICEF	
		Develop supply chain demand forecast methodology and forecast demand on an 18 month rolling basis		Input

		Monitor and analyze GAVI financing requests to support timely supply chain forecast updates and supplier capacity planning decision-making		Perform
	Strategic supply strategy developed	Monitor potential suppliers and assess vaccine development pipeline	UNICEF	Lead
		Identify and resolve potential barriers to suppliers building capacity to supply GAVI		Lead
		Conduct market research to reconfirm the drivers of demand		Lead
		Update strategic demand forecast to inform suppliers		Lead
		Outreach to additional manufacturers of rota and pneumo vaccines		Lead
	Ensure vaccines are appropriate for use in GAVI countries	Make information on product presentation and packaging available	WHO	
		Develop target product profiles and communicate to stakeholders		Input
		Hold bilateral meetings with suppliers to promote suitable vaccine packaging and presentation		
Financing available to pay for the vaccines and for system costs	Advocate for increased support for new vaccines	Develop key messages	Outsourced Entity	Lead
		Create a communications and advocacy plan		Lead
		Align partners and stakeholders around the key messages		Perform
		Identify and involve CSOs in advocacy efforts		Lead
	Donor Financing available	Package information on disease burden, cost effectiveness, and vaccine impact, and financing	GAVI Secretariat	Lead
		Create political will for immunization financing through advocacy		Perform
		Support innovative financing mechanisms relative to new vaccines		Input

		Support global policy dialogue on health priorities and immunization financing with data and information on new vaccines		Input
	Country Financing available	Create information on new vaccines to be utilized in country level fiscal space planning	Undecided.(This work will have different leads in different countries. Need to decide a task lead for the purposes of new vaccines. Some suggested a possible role for the OSE but likely not a lead role. WB not able to play the role at this level.)	Perform
		Provide TA to countries on financial planning for introduction of rota and pneumo vaccines		
		Update the immunization financing database		
		Link with broader country planning and budgeting processes for new vaccine fiscal space planning		
A well-informed country decision on introduction of the vaccine.	Create the burden of disease data to support the introduction decision (both at the vaccine and specific vaccine product level)	Maintain and update global disease burden model and estimates as new data become available	WHO	
		Develop an age-structured dynamic model		
		Pneumo and rota: Estimate global, regional, and sub-regional serotype prevalence to inform appropriate vaccine adoption and product development decision making		
		Pneumo and rota: Maintain and update serotype prevalence model and estimates as new data become available		
	Create the health and economic impact data to support the introduction decision	Conduct country-level economic evaluations for rota and pneumo	Outsourced Entity	Lead
		Create user-friendly models that link the disease burden and economic impact		Lead

	Create the vaccine safety, immunogenicity and efficacy data to support the decision	Conduct efficacy trials of rotavirus vaccines in Asia and Africa (Rotarix in Africa, RotaTeq in Africa and Asia)	Outsourced Entity	
		Systematically review and analyze safety, immunogenicity and efficacy data for policy decisions		Perform
		Conduct rotavirus effectiveness study in Asia		
		Obtain consensus among key stakeholders on the data that are necessary for introduction vs. "nice-to-have data"		Lead
		Intussusception case control study in Latin America		
		Support immunogenicity studies of appropriate regimens and formulations		Lead
	Package vaccine data for decision makers and present to decision makers and the influencers of decision makers	Develop an advocacy strategy for country level decision makers	Outsourced Entity	Lead
		Develop an advocacy strategy for KOL at the global, regional and country level including an assessment of KOL needs		Lead
		Create evidence based materials that include:data on disease burden, vaccine safety and efficacy, and health and economic impact		Lead
		Understand the questions and information needs of countries and provide targeted data to assist in decision making		Lead
		Conduct market research on the awareness and attitudes toward pneumonia and pneumococcal disease, rotavirus and diarrheal disease, and vaccines especially in relationship to child survival and development		Lead

	Support the decision making process at the country level	Create tools to assist country level decision makers	WHO	Input
		Work with country decision makers on their introduction decisions		Input
		Support the development of national advisory bodies for immunization		Input
	Assess country readiness to introduce e.g. human resources, cold chain, logistics	Develop and provide data on the cold chain requirements for new vaccines	WHO	
		Develop and update a tool for comprehensive cold chain assessment and provide support to regions/countries to conduct assessments		
		Evaluate GAVI-eligible cold chain capacity status given new vaccine landscape and identify additional capacity needs		
	Ensure global and regional policies are in place and sustained to guide countries in making vaccine introduction decisions	Support SAGE and/or regional recommendation process by providing background papers and evidence	WHO	Input
Country introduction of the vaccine	Countries have sufficient cold chain capacity in place	Establish a global database for cold chain forecasting and monitoring of progress	UNICEF/WHO TBD	
		Implement recommendations of the assessments		
		Align GAVI policies with country needs for cold chain capacity and vaccine management costs		
	Country immunization and health systems prepared for vaccine introduction and uptake	Create tools or link to existing activities to estimate the health systems components in the new vaccine introduction plans	WHO	
		Evaluate and update guidelines and tools for safe vaccine administration and waste disposal		

		Provide TA to countries to create a quality GAVI application		
		Provide TA to countries in the development of cMYP		
	Train health care professionals	Develop rota and pneumo vaccine specific training materials	WHO	Perform
		Conduct bi-regional vaccine safety sensitization meetings		
		Conduct training of trainers courses		
	Vaccine management plans in place	Develop/update comprehensive vaccine stock inventory management software and provide TA for implementation at country level	WHO	
		Conduct vaccine procurement assessments in self procuring countries and develop action plans		
		Provide TA to self-procuring countries		
		Rationalize how supply is allocated to demand to guide country introduction plans		Input
	Large country introduction strategies	Create country specific AVI plans	WHO	Lead
		Focused advocacy efforts		Lead
		Customized stakeholders analyses		Lead
		Identify country specific research studies		Lead
		Customized market research		Lead
	Social mobilization (community level)	Create social mobilization strategies	UNICEF	Perform
		Create core materials to be adapted at country level		Perform
		Identify and train governments/organizations to conduct social mobilization for rota and pneumo vaccines		

Establish platform for the sustained use of the vaccine	Enhance regionally appropriate surveillance systems which produce high quality data for decision making and monitoring and evaluation	Enhance and maintain bacterial meningitis and pneumonia surveillance networks in key countries and regions	WHO	
		Enhance and maintain rotavirus and intussusception surveillance networks in key countries and regions		
		Establish and train laboratory networks and workers		
		Develop toolkits for data collection, data management, information exchange and Standard Operating Procedures (SOPs)		
		Standardize processes and case report forms to enable cross-network analyses		
		Establish baseline surveillance to measure impact of vaccination		
	Monitor safety of the vaccines post-introduction	GACVS review of rotavirus post marketing surveillance data	WHO	Input
		GACVS review of pneumococcal post marketing surveillance data		Input
		Pharmacovigilance		Input
	Evaluate the impact of routine immunization of infants and catch-up immunization of older children	Conduct post-introduction vaccine impact evaluations in Kenya and The Gambia	Outsourced Entity	
		Conduct two rotavirus effectiveness trials in Nicaragua and El Salvador		
		Condcut additional rotavirus and pneumo vaccine effectiveness/demonstration studies if/as needed		Lead
		Support early adopter countries to assess vaccine impact		Lead
	Monitor the impact on disease and adjust implementation policies as needed	Pneumo and rota herd immunity study	Outsourced Entity	Lead
		Pneumo and rota serotype change study		Lead

	Document and disseminate lessons learned on the introduction of new and underutilized vaccines	Package impact evaluation results and communicate to donors and GAVI countries	Outsourced Entity	Lead
	Develop communications preparedness and response (includes crisis communications)	WHO monitoring and response to AEFIs	Outsourced Entity	Input
		Coordinate response in the media and with KOL		Lead