

Accelerated Vaccine Introduction (AVI)

Background

GAVI created two Accelerated Development and Introduction Plans (ADIPs) in 2002 to expedite the development of rotavirus and pneumococcal vaccines and accelerate their introduction in developing countries.

As these ADIPs phase out and rotavirus and pneumococcal introduction support activities transition from ADIPs to other entities, in November 2007 the Secretariat was charged by the GAVI Alliance and Fund boards to prepare a budget for a costed proposal for activities to accelerate the introduction of pneumococcal and rotavirus vaccines over the period of 2009-2015. The Boards also noted that the Secretariat would need to build additional capacity in order to serve as an effective coordinating mechanism in this effort.

The GAVI Secretariat conducted a mapping and costing exercise to gather information about activities and costs needed to provide assistance to countries in making decisions about introduction of pneumococcal and rotavirus vaccines. The exercise consisted of developing a list of introduction activities and costing these activities based on historical documents as well as numerous consultations with partners. This exercise is referred to as the Accelerated Vaccine Introduction (AVI) initiative.

In informing the development of activities, terms of reference and budget envelopes for partners, outsourced activities and the management structure, the Secretariat has consulted closely with GAVI Alliance Board members, multilateral partners, WHO, UNICEF, World Bank, donors, ADIP Management Committee, GAVI Working Group, industry, and ADIPs and Hib Initiative. A detailed explanation of the process and methodology, including details on consultations, are available upon request.

A final two day consultation meeting was held in Washington DC on May 13-14, 2008 to review overlaps and gain consensus on which organization would be most appropriate to lead a particular activity. The meeting included representatives from WHO, UNICEF, World Bank, GAVI Secretariat, ADIP Management Committee, PneumoADIP, Rotavirus Vaccine Program, Hib Initiative, vaccine industry and product launch specialists. The meeting resulted in an AVI framework of tasks and activities and a proposed program management structure.

AVI Framework and activities

The AVI framework defines 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

Tasks and major activities are assigned to each of these outcomes, and general consensus has been reached on the appropriate lead entity (see background paper, available upon request). The mapping exercise identified different responsibilities for AVI framework

The results of the costing and mapping exercise are summarized below:

Outsourced Entity: The proposed budget for the outsourced entity is \$99.6 million between 2009 and 2015. The outsourced entity will be responsible for those activities which clearly needed to be funded by GAVI in that they add value, are catalytic, and are not part of the mandate of any of the partner agencies. The outsourced entity will be charged with conducting activities under the following areas:

- **Communications and Advocacy:** increasing the support and financing of new vaccines and to support global, regional and country level decision making
- **Special Studies:** scientific and economic studies to support decision making and assess impact
- **Strategic Vaccine Supply:** understanding the drivers of demand through market research and managing the strategic supply and demand dynamic and
- **Other:** supporting efforts around large county introduction and acting as a platform for other new vaccines in the future

The outsourced entity should maintain a number of leadership, technical and managerial capabilities. In addition, the entity must be able to work globally in a cost-effective and efficient manner. A structure that includes global partnership and engagement of developing country institutions would be strongly encouraged.

The ADIP Management Committee reviewed and endorsed the scope, capabilities and budget (See Annex 1 for the proposed RFP and Annex 2 for the ADIP Management Committee's endorsement).

With regard to the budget, it should be noted that \$40 million of this budget is allocated for subcontracts for special studies. It is expected that approximately \$10 million of this \$40 million would be awarded up front and the remaining \$30 million would be held in reserve for future special studies and dispensed as approved by an AVI management structure. Upon completion of the RFP process, the selected proposal would be presented to the Boards at the October 2008 meeting for approval.

Countries: WHO estimated the country costs using the GIVS model for the countries expected to introduce the two vaccines by 2015 at \$369M. These costs include those around activities for cold chain, training and supervision, vehicles and transport, social mobilization, surveillance, monitoring and evaluation and waste management. Although some of these expenditures may be part of GAVI's HSS support (depending on countries' own plans) with the exception of the waste management support for the pneumococcal vaccine noted below, these costs will not be requested from GAVI.

Partners: WHO, UNICEF and World Bank have estimated expenditures of approximately \$282.5 million from 2009-2015, although some of these are covered by other funding sources and will not all be requested for funding from GAVI. WHO AVI-related activities are dedicated in four priority areas: surveillance activities at country and global level, laboratory networks, monitoring and evaluation and training, meetings and personnel to support the activities. UNICEF priority activity areas include communication, advocacy and social mobilization as well as vaccine procurement, supply and industry relations. World Bank supports countries in strengthening health systems, focusing on health results and improving financial sustainability. Two of the sets of activities included in the above are time sensitive and thus have been put forward to the board for consideration of funding. The ADIP Management Committee reviewed and endorsed these proposals and budgets.

- 1. WHO surveillance activities (transitional):** In order to ensure minimum disruption of surveillance activities, the ADIP Management Committee recommended that WHO prepare a minimal budget proposal to sustain ADIP surveillance sites to be approved ahead of other WHO AVI activities. This proposal was part of a larger plan for sentinel site surveillance developed through a global partners meeting in November 2007, but was limited to only GAVI eligible countries and pneumococcal and rotavirus diseases. It addresses a functional sentinel surveillance network for vaccine preventable diseases and aimed to achieve high quality as well as promote country ownership and sustainability. This project aims to start at the beginning of 2009 and the budget for these activities is \$14.9 million from 2009-2010. GAVI will need to decide whether to fund these activities post-2010, depending on the exercise that will be undertaken in the coming months. Note that the budget for these activities is higher under WHO management than under the ADIPS because of budgeting of laboratory activities in Regional Reference laboratories to support the existing surveillance activities, and WHO personnel required for project management and technical oversight. Further, figures presented account for US Dollar depreciation since the time when the budgets were developed and expected inflation rates. (See Annex 3 for detailed transition work plan and budget and Annex 4 for the ADIP Management Committee's endorsement).
- 2. Country and WHO/UNICEF activities in introducing pneumococcal vaccine in pre-filled syringes:** There are six GAVI eligible countries¹ that are approved or shortly expected to be approved for introduction of pneumococcal vaccine. Prequalification of the Prevnar pre-filled presentation will likely be a restricted prequalification for limited introduction in selected countries that indicate they are able to manage the safe use and disposal of the pre-filled presentation. This requires countries to meet additional challenges of introduction due to the unusual, non-standard presentation in the area of injection safety, waste management, training, cold chain capacity and vaccine management and distribution. WHO worked with countries to formulate an initial costing of country costs that would be required, over and above the normal 30 cents per child provided for new vaccines introduction, to accommodate these additional costs. These costs amount to \$2.8 million for the six countries. There is also a component of support for WHO and/or UNICEF in the amount of \$256,800 (includes estimated WHO PSC costs of 7%) to conduct pre- and post-introduction assessments. This proposal was shared with the GAVI New Proposals Independent Review Committee (IRC) at their 6 June 2008 meeting for their information. The IRC supported the programmatic components and intention of the proposal. (See Annex 5 for detailed work plan and budget for introducing pneumococcal vaccine in pre-filled syringes and Annex 4 for the ADIP Management Committee's endorsement)

ADIPs: The ADIPs and Hib Initiative will continue with certain activities through 2010. Including clinical trials, special studies and some limited communications activities. The total costs necessary for ADIPs to maintain these certain activities have already been approved in previous Board decisions and total approximately \$18.0M through 2010.

AVI management: As encouraged by the Boards during their November 2007 Board meeting, it is proposed that an AVI management team coordinate the various activities and funding streams in the AVI framework. This management team would be led by the GAVI Secretariat and include representatives and/or technical experts from WHO, UNICEF, World Bank, the outsourced entity as well as independent experts, as needed. The total estimated budget for this including costs staff, travel, meetings, consultants and monitoring and evaluation for the period of 2009-2015 is approximately \$7.2 million. A detailed budget for this activity will be presented at the October 2008 Board meeting through the regular administrative budget process.

¹ Guyana, Honduras, Nicaragua, Rwanda, Yemen, Kenya

Financial implications

Of the total costs presented through the costing exercise, the GAVI Boards will be asked at their October 2008 meeting to consider funding for multilaterals, funding for the outsourced entity, and funding for the Secretariat. Note that future requests for additional funding in support of introduction of pneumococcal vaccines in pre-filled syringe presentation will be considered as part of the country application process.

Monitoring and evaluation

AVI will be monitored and evaluated based on its success toward meeting the goals of introducing pneumococcal conjugate and rotavirus vaccine into GAVI-eligible countries. Furthermore, the AVI management structure will monitor and evaluate success of AVI based on progress toward the five outcomes defined in the AVI Framework structure that is outlined above. The detailed implementation for monitoring and evaluation will be finalized by the end of the year.

Board decisions

The Boards are requested to:

- Approve the scope, capabilities and budget envelope of \$99.6 million (2009-2015) for a request for proposals to allow for follow on activities to the ADIPs through an outsourced entity (\$30 million of which would be set aside for future special studies). (Annex 1: proposed RFP; Annex 2: ADIP Management Committee endorsement)
- Approve a budget of \$14.9 million for WHO for surveillance activities in 2009-2010 (GAVI will need to decide whether to fund these activities post-2010). Currently funded under the ADIPs, these activities are scheduled to come to an end as of December 2008 (Annex 3: Proposed budget; Annex 4: ADIP Management Committee endorsement).
- Approve a budget of \$256,800 for WHO/UNICEF, and \$2.8 million for six countries to support the introduction of pneumococcal 7-valent vaccine in pre-filled syringes (Annex 5: proposed budget; Annex 6: ADIP Management Committee endorsement).

UNICEF, WHO and the World Bank will be submitting budgets in support of their AVI activities as part of the work plan budget process, to be presented to the Boards in October. The Secretariat will work with them to ensure that funding requests are appropriate for GAVI support, that there is no overlap with other GAVI funding (meningitis investment case, etc), and that activities and budgets can be challenged, tested and independently peer reviewed.

Next steps

If the Boards approve the above, they would be requested to make the subsequent financial decisions at the October 2008 Board meeting.

- To review the AVI-specific work plans and budgets for partners
- To review the AVI management structure and budget
- To approve the outsourced entity selected during the competitive RFP process

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**Excerpt from the GAVI Accelerated Vaccine Introduction RFP
For ADIP Management Committee Review
May 28, 2008**

Scope of Work

The work to introduce new vaccines into GAVI countries happens in the context of an alliance. The introduction activities are highly interdependent and different organizations will take the lead role at both the Task and Activity level. The Scope detailed below are the main Tasks where the Agency will take a leading role.

There are three broad areas where the Agency will have lead responsibilities:

- **Communications and Advocacy**—to increase the support and financing of new vaccines and to support global, regional and country level decision making
- **Special Studies**—scientific and economic studies to support decision making and assess impact
- **Strategic Vaccine Supply**--understanding the drivers of demand through market research and managing the strategic supply and demand dynamic and

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 Agency 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)

The Applicant should describe in detail the strategies and activities that will be needed for the Communications and Advocacy scope of work in the contract period. It is especially important that the Applicant describe which activities have the highest priority, how the activities will be sequenced, and the dependency of these activities on others.

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. The Applicant should outline the special studies it believes are critical to introduce or sustain the use of rotavirus and pneumococcal vaccines and the rationale for why these should be carried out by the outsourced entity. Substantial rationale should be provided for how these specific studies will support the AVI Goals and Outcomes.

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It is likely that funds for special studies will not be wholly awarded in the initial contract with the Agency. Funding for studies to commence in 2009/2010 will be awarded in the initial contract. Funding for studies to be commenced in 2011 or later will be held at the GAVI Secretariat, and will be released upon approval by the Management Committee. All the proposed studies, and the Agency staffing to conduct the studies, should be budgeted for in the proposal.

Strategic Vaccine Supply

At least five years are required to build new manufacturing capacity, and the capital investments are considerable. Suppliers rely on both longer-term, strategic demand forecasts and shorter-term procurement forecasts to plan their capacity. 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 Applicant should detail the strategies and activities necessary to accomplish the overall Goals and Outcomes. It will be important to describe how the Agency would work with UNICEF to ensure coordination of the overall supply-demand dynamic.

Other Key Activities

There are Tasks where the Agency will not lead, but where it will perform substantive work under the leadership of a partner organization. A large effort is expected from the Agency in the area of vaccine introduction into large countries. Experience has shown that countries with large numbers of unimmunized children, such as Nigeria, India, Pakistan need introduction strategies that are geared to their political and geographic realities. WHO will lead the overall work with large countries and the Agency is expected to perform much of the strategic and on the ground effort.

The Applicant should detail how it will work with large countries and how it will coordinate the array of partners involved in these efforts. It will be important to cover the barriers and lessons learned in providing the rationale for the chosen strategies.

Platform for New Vaccine Introduction

Many vaccines with the potential to save millions of lives in poor countries are nearing licensure. GAVI will likely add several of these vaccines to its portfolio over the next 5-10 years. It is envisioned that the recipient Agency will conduct these activities through add-on contracts from GAVI.

The original ADIP structures were vaccine specific with one program for pneumococcal vaccines (PneumoADIP hosted by The Johns Hopkins University), one for rotavirus vaccines (Rotavirus Vaccine Program hosted by PATH) and one for HIB vaccines (HIB Initiative hosted by The Johns Hopkins University). This RFP integrates the activities related to the introduction of rotavirus and pneumococcal vaccines and may be expanded to include activities related to the introduction of Hib and any other vaccines GAVI decides to support in future.

The Applicant should describe how it would serve as a platform for adding new vaccines to its scope.

Capabilities

The agency will need to demonstrate either directly or through alliances access to the following capabilities.

Leadership

- The overall leadership of the Agency is a critical component of the proposal. This Project Leader should have experience in international product launch, alliance management, and multi-disciplinary team leadership. He/she should possess the important quality of being able to push activities forward in

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a consensus driven environment. He/she should also have demonstrated openness and success in applying best practices and innovative ideas from multiple sectors on his/her work.

- It is expected that there will be full-time leadership in the three key areas of work; Communications and Advocacy, Strategic Vaccine Supply and Market Research, and Special Studies. These individuals should have considerable technical expertise in their areas, and have demonstrated experience in strategic planning and leadership. Demonstrated experience in international product launch is expected. All should have the ability to drive action while working in a multi-party, consensus driven environment.

Technical

The Agency will need to demonstrate senior level, full-time expertise in:

- Communications—the ability to communicate complex scientific and economic information to many stakeholders through multiple channels.
- Advocacy—the ability to create evidence-based information and to package this information for decision makers at the global, regional and country level to enable action. Experience with identifying and working with Key Opinion Leaders is critical.
- Epidemiology, clinical trials and vaccinology—understanding of the disease dynamics and the methods to test effectiveness, post-launch safety, health impact and impact on microbial changes post-introduction.
- Health economics—the ability to determine which health economics data are important for policy and introduction decisions and the expertise in designing and creating studies to create the data. Experience in industrial pharmaco-economics is a plus.
- Strategic vaccine supply—the ability to work with suppliers to create products that are appropriate for the needs of GAVI countries and to build sufficient supply to satisfy demand. Experience in market research and the diffusion of innovation is also important.

Managerial

- Ability to attract and retain key talent.
- Ability to create and manage alliances. It will be important to present concrete plans on how the alliance partners will have a voice at the leadership and strategic level of the project.
- Ability to build strong relationships with the scientific community, civil society, policy makers and GAVI partners.
- Able to balance the voices of the functional expertise.
- Project management—mapping out timelines, identifying precedents activities, tracking project progress and raising issues for decision making. This activity is for the work of the Agency and the project manager will work closely and collaboratively with the GAVI project manager based in Geneva.

Other

- The Agency must establish a presence in or near Geneva Switzerland.
- The Agency must be able to work globally in a cost-effective and efficient manner. Setting up new offices with this funding would not be supported. Use of existing organizational offices or alliances to enable global reach is encouraged.
- A structure that includes global partnerships and engagement of developing country institutions (either private or public) is encouraged.

Evaluation criteria

The following criteria will be used to compare and evaluate the proposals.

- **Vision and Knowledge:** Does the Applicant demonstrate a deep understanding of the challenges faced in introducing new vaccines into GAVI eligible countries? Does the Applicant propose, prioritize and justify the highest impact strategies and activities?
- **Innovation:** Does the Applicant propose, novel ways of introducing new vaccines into GAVI eligible countries? Does the Applicant describe ways in which best practices, especially from the private sector, will be incorporated into their strategies and activities?
- **Technical expertise:** Does the Applicant have high-quality expertise in the technical areas outlined for the proposal?
- **Proposed management and coordination structure and processes:** Does the Applicant demonstrate an understanding of the operating environment and propose structures and processes to facilitate project implementation? Does the Applicant propose specific mechanisms for ensuring country feedback into its programs?
- **Engagement of GAVI partners.** Does the applicant demonstrate appropriate engagement of GAVI technical partners, in particular the WHO, UNICEF and WHO?
- **Outcomes and Accountability:** Does the Applicant propose a monitoring and evaluation framework that will allow a clear assessment of project performance?

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- **Cost-efficiency:** Does the Applicant provide value for money? Does the Applicant budget sufficient resources to accomplish the objectives? Are the costs in line with the average costs of similar activities? Does the Applicant propose novel solutions to decrease the overall costs of new vaccine introduction? Are the activities of others, especially industry, leveraged?
- **Organizational capacities:**
- *Partnership:* Does the application present sufficient evidence of global partnership and engagement with developing country institutions?
- *Human resources:* Does the Applicant clearly outline and justify the positions needed and the qualifications and experience required? Does the Applicant present high quality staff with appropriate technical and managerial expertise for the proposed work? If staff are to be hired, does the Applicant have a track record in hiring similar professional level staff in a reasonable time period? Is there an appropriate gender balance of staff, by staffing level proposed?
- *Contracting:* Does the Applicant have a track record in negotiating contracts with private and public sector organizations? Does the Applicant demonstrate evidence sufficient flexibility to quickly negotiate and sign contracts?
- *Logistics:* Does the Applicant provide sufficient assurance that they have travel planning capabilities, meeting planning capabilities, and sufficient office space and related equipment available to meet the needs of the project in a timely fashion?

BUDGET

Line Item by Activity					
	Comm & Advocacy	Vaccine Supply	Special Studies*	Project Management	Total
Amount	22,759,046	6,096,499	58,343,894	12,387,771	99,587,210

*Approximately \$10 million in Special Studies will be awarded upfront. The remaining \$30 million will be held in reserve and dispensed as the Management Committee approved subsequent studies.

ANNEX 2

**ADIP Management Committee Endorsement
Outsourced Entity component submitted to the GAVI Alliance and Fund Boards as part
of Accelerated Vaccine Introduction Initiative (AVI)
June 2008**

ADIP Management Committee Members: Professor Jan Holmgren, University of Göteborg (chair); Dr. Regina Rabinovich, BMGF; Dr. Harry Greenberg, Stanford University School of Medicine; Ms. Nina Schwalbe, GAVI Secretariat

Permanent Observers: Dr. Thomas Cherian, WHO; Dr. Deogratias Barakamfitiye, former WHO and former MoH Burundi; Mr. Max Tello, Communications Professional

Recused from review: Mr. Kevin Reilly, formerly Wyeth Vaccines; Dr. Brian Greenwood, London School of Hygiene and Tropical Medicine; Dr. John Clemens, International Vaccine Institute (GAVI Alliance Board member); Dr. Mathuram Santosham, Johns Hopkins University Bloomberg School of Public Health; Dr. Christopher Elias, PATH

Outsourced Entity (OSE) scope, capabilities and budget: The AVI Framework as well as the scope, capabilities and budget for the OSE component of the AVI was submitted for review to the ADIP Management Committee. These were reviewed via teleconference and via e mail. Those members recusing themselves from these reviews because of possible conflicts of interest are listed above. The scope, capabilities and accompanying budget are included as an annex submitted to the June 2008 Boards.

ENDORSEMENT: The ADIP Management Committee endorsed the scope, capabilities and budget of \$99.6 million from 2009-2015.

ANNEX 3

Proposal for GAVI Support - Transition of the Ongoing Surveillance Sites Coordinated by the ADIPs to WHO								
Network								
Region	Country	Sites	Current funding mechanism	Project end date	2008 budget	Projected 2009 budget	Projected 2010 budget	Total Budget for Transition
AFRO								
Surveillance networks								
Rotavirus network	Support for the network + the following GAVI eligible countries: Ethiopia, Kenya, Tanzania, Uganda, Zambia, Zimbabwe, Malawi, Cameroon, Senegal, Ghana, Cote d'Ivoire, Guinea Bissau, Togo		Rota RVP through WHO HQ	12/31/2008	150,000	172,500	177,675	350,175
PBM network	21 countries in the AFRO Region		Hib initiative through WHO HQ	Jul-09	310,000	356,500	367,195	542,771
NetSPEAR	Ethiopia, Kenya, Tanzania, Uganda		Direct from PneumoADIP	12/31/2008	300,000	345,000	355,350	700,350
Bacterial Reference laboratory		MRC Gambia	Direct from PneumoADIP			347,540	260,337	607,877
Rotavirus Reference laboratories					125,000	143,750	150,938	294,688
Personell for project management and technical oversight						242,439	242,439	484,878
AMRO								
Surveillance networks								
Rotavirus network	Support for the network + the following GAVI eligible countries: Bolivia, Honduras, Guyana, Nicaragua		Direct from Rota RVP to AMRO	12/31/2008	150,000	172,500	177,675	350,175
SIREVA 2+: Invasive bacterial diseases and pneumonia	Support for the network + the following GAVI eligible countries: Honduras, Nicaragua, Cuba		Direct from PneumoADIP to AMRO	12/31/2008	300,000	345,000	362,250	707,250
Bacterial Reference laboratory						200,000	200,000	400,000
Rotavirus Reference laboratories					125,000	143,750	150,938	294,688
Personell for project management and technical oversight						184,250	184,250	368,500
EMRO								
Surveillance networks								
Rotavirus network	Support for the network + the following GAVI eligible countries: Pakistan, Sudan, Yemen		Rota RVP through WHO HQ	12/31/2008	150,000	172,500	177,675	350,175
Hib and Pneumo	countries: Pakistan, Sudan, Syria, Yemen (level of support had been reduced, as compared to ADIP-HI contributions, to limit the		Hib initiative and PneumoADIP through WHO HQ	09/30/2008	700,000	805,000	845,250	1,650,250
Bacterial Reference laboratory			already considered in the network budget estimate					
Rotavirus Reference laboratories					125,000	143,750	150,938	294,688
Personell for project management and technical oversight						175,000	175,000	350,000
EURO								
Surveillance networks								
Rotavirus network	Support for the network + the following GAVI eligible countries: Azerbaijan, Georgia, Tajikistan, Ukraine, Kyrgyzstan, Uzbekistan		Rota RVP through WHO HQ	12/31/2008	150,000	172,500	177,675	350,175
Bacterial meningitis	Support for the network + the following GAVI eligible countries: Ukraine, Moldova, Uzbekistan, Georgia, Azerbaijan		Hib initiative through WHO HQ	Jul-09	230,000	264,500	277,725	208,294
Rotavirus Reference laboratories					125,000	143,750	150,938	294,688
Personell for project management and technical oversight						186,500	186,500	373,000
SEARO								
Surveillance networks								
Rotavirus network	various		Direct from Rota RVP to sites	Throughout 2007-08	150,000	172,500	177,675	350,175
ICDDRDB			Direct from PneumoADIP	12/31/2008				
	Bangladesh	hospital based	Direct from PneumoADIP	12/31/2008	120,000	138,000	144,900	282,900
		Kamalapur	Direct from PneumoADIP	12/31/2008	374,000	430,100	451,605	881,705
SAPNA								
	Sri Lanka		Direct from PneumoADIP	12/31/2008	104,000	119,600	125,580	245,180
	Nepal/Patan		Direct from PneumoADIP	12/31/2008	258,000	296,700	311,535	608,235
Rotavirus Reference laboratories					125,000	143,750	150,938	294,688
Personell for project management and technical oversight						198,000	198,000	396,000
WPRO								
Surveillance networks								
Rotavirus network	various		Direct from Rota RVP to sites	Throughout 2007-08	150,000	172,500	177,675	350,175
Mongolia	Mongolia	hospital based	Hib initiative and PneumoADIP through WHO HQ	12/31/2008	150,000	172,500	181,125	363,625
Rotavirus Reference laboratories					125,000	143,750	150,938	294,688
Personell for project management and technical oversight						5182,000	160,000	342,000
Personell at WHO HQ for project management and technical oversight						294,000	294,000	588,000
TOTAL ESTIMATED BUDGET (NET)								13,959,990
Indirect costs (7% PSC or overhead)								977,199
TOTAL ESTIMATED BUDGET (with 7% PSC)						4,496,000		14,937,189

ANNEX 4

**ADIP Management Committee Endorsement
WHO 2009-2010 Surveillance Activities Budget submitted to the GAVI Alliance and Fund
Boards as part of Accelerated Vaccine Introduction Initiative (AVI)²
June 2008**

ADIP Management Committee Members: Professor Jan Holmgren, University of Göteborg (chair); Mr. Kevin Reilly, formerly Wyeth Vaccines; Dr. Regina Rabinovich, Bill and Melinda Gates Foundation; Dr. Harry Greenberg, Stanford University School of Medicine; Dr. Brian Greenwood, London School of Hygiene and Tropical Medicine; Ms. Nina Schwalbe, GAVI Secretariat

Permanent Observers: Dr. John Clemens, International Vaccine Institute (GAVI Alliance Board member); Dr. Mathuram Santosham, Johns Hopkins University Bloomberg School of Public Health; Dr. Christopher Elias, PATH; Dr. Deogratias Barakamfitiye, former WHO and former MoH Burundi; Mr. Max Tello, Communications Professional
Recused from review: Dr. Thomas Cherian, WHO

WHO Surveillance Transition Work Plan and Budget: At the 21-22 April 2008 ADIP Management Committee meeting, the ADIP Management Committee made the recommendation for WHO to prepare a minimal budget proposal for the June Board to sustain ADIP surveillance sites. A transition work plan and budget was submitted and reviewed by ADIP Management Committee members via teleconference and e mail. WHO was recused from this review. Based on points of discussion, the ADIP Management Committee requested a resubmission of the work plan and budget. Upon resubmission, the Committee endorsed the revised work plan and budget.

ENDORSEMENT: The ADIP Management Committee endorsed the WHO work plan and budget for \$14.9 million for 2009 – 2010.

² Proposals, work plans and accompanying budgets described in this endorsement are included as annexes submitted to the June 2008 Boards as part of the AVI Board paper or AVI background paper.

ANNEX 5**CHALLENGES IN INTRODUCING PNEUMOCOCCAL VACCINE IN PRE-FILLED SYRINGES****DISCUSSION PAPER ON THE ADDITIONAL RESOURCES AND SUPPORT REQUIRED BY APPROVED GAVI-ELIGIBLE COUNTRIES TO MEET THE INTRODUCTION CHALLENGES****Current Status and problem statement:**

- Four GAVI eligible countries currently have an **approved** application for introduction of pneumococcal vaccine: **Guyana, Honduras and Nicaragua** in the PAHO Region, and **Rwanda** in the AFRO region. A further two countries - **Yemen** (EMRO) and **Kenya** (AFRO) received conditional approval to their applications submitted in October 2007 and are expected to submit revised applications in the May 2008 round of applications.
- **Prequalification** of the Prevnar pre-filled presentation is expected by the end of April 2008. The prequalification will likely be a restricted prequalification for limited introduction in selected countries that indicate they are able to manage the safe use and disposal of the pre-filled presentation, until a vial presentation becomes available - currently expected in 2010.
- The pre-filled syringe presentation of this vaccine requires countries to meet additional challenges of introduction due to the unusual, non-standard presentation. These challenges are mainly in the area of injection safety, waste management, training, cold chain capacity and vaccine management and distribution. Failure to meet these challenges pro-actively may expose the GAVI Alliance to criticism of inadequate country preparation and support, especially as it relates to poor injection safety, the potential re-use of syringes and the disposal of hazardous waste.

Key Management, Delivery, Safety and Waste Management Issues:

- Hib introduction with pentavalent was a relatively simple procedure of replacing one vaccine (DTP) with another (DTP-HepB-Hib). Introduction of pneumococcal vaccine involves adding another vaccine to the schedule and an additional injection for infants at the DTP-HepB-Hib contact. Additional social mobilization and advocacy message will need to be incorporated into the health worker training to ensure a seamless uptake of this new vaccine.
- The pre-filled presentation is provided in a glass syringe without an auto-disabling (AD) mechanism normally required by WHO/UNICEF. In addition, a needle needs to be fixed to the pre-filled syringe. After vaccination both the syringe and the needle can potentially be re-used, thus raising serious concerns about injection safety. Additionally, if incinerated in a standard incinerator, e.g. the DeMontfort model currently in use in many countries, and not in a high temperature incinerator, the glass barrel of the syringe will melt and clog the incinerator, not be reduced to ash, thus raising concerns about waste disposal.
 - **Immunization safety and waste management assessments** will need to be carried out in all countries prior to introduction to ascertain the existing facilities that can accommodate the safe disposal of this presentation and to document the precise requirements of each country.
 - Immunization staff will have to be specifically **trained in safe administration and disposal** issues related to the pre-filled presentation to provide countries with the capacity to introduce this new vaccine safely.
- The pre-filled presentation requires 2.5 times the **cold chain capacity** required for current EPI vaccines. Most countries, except for the Americas, will need to significantly upgrade their cold chain to accommodate the pre-filled presentation

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either through purchase of additional equipment, or, more realistically, through **enhanced management and planning** of existing capacity. *The actual increase in cold chain space that may be required is not addressed in this document, and is already planned and outlined in the application for this vaccine.* However, in addition to the expansion of the cold space, the following have to be considered:

- This will require careful **assessment of the current cold chain capacities** at national and sub-national levels and development of plans to enhance capacity to meet the storage and transport needs. For example, in some countries, the number of shipments to provincial level will need to be increased from 4-6 per year, and the number of cold boxes to be transported till be 2.5 - 5 times more, thus generating **additional costs for transportation**.
- Specific guidance will need to be provided to vaccine management and logistics staff to **plan for and manage the additional storage and transport** requirements of introducing this particular presentation.
- Before introducing this presentation into other countries beyond the six countries mentioned above, it is strongly advised that **post-introduction evaluations** be conducted in all countries approximately six months after introduction. This would give the GAVI Alliance partners (WHO & UNICEF) the opportunity to evaluate the programmatic impact of the introduction, to rectify any problems in the countries, and to form the basis for guidance for the subsequent countries who may be introducing this presentation given the uncertainty on the availability of the vial presentation.

Costing Methodology:

Waste management

Each country has considered the various options open to them for disposing of the pre-filled syringes without damaging existing facilities, among them: burning in small scale incinerators; incinerating in the high temperature ovens of existing cement factories; burying in pits in remote areas - with or without cement lining and capping; treating in large centralized facilities incinerating/autoclaving. The costs indicated are based on the options so far chosen by the countries.

Transport and vaccine management

Given the increased size of the packaging of the pre-filled presentation, countries will need to increase the number and frequency of their vaccine deliveries. Increased costs will be incurred for the additional fuel and per diem of the drivers. The additional training required to prepare countries for this enhanced vaccine management and supervision costs are included in the training budget.

Training

Using WHO materials, each country will use the 'cascade approach' to train health staff working at the various administrative levels. The process will start at national level with a Trainer of Trainers (TOT) course to be provided to the national staff and continue on down to province, district and health facility levels. During the proposed one day training course, half of the day would focus on injection safety and the remaining half day would cover all other aspects of vaccine introduction including storage and stock management, data management, supervision, social mobilization, AEFI reporting etc.

In-country pre and post assessments

Based on previous experience, \$50,000 per large country, and lesser amounts for smaller countries, would be an accurate estimate of the resources required to conduct 1-2 week pre-introduction assessments that would evaluate the immunization safety issues,

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waste management options, vaccine management and cold chain planning requirements of each country. This sum would also cover the 1-2 week post-introduction evaluation that would evaluate the programmatic impact of the introduction of this presentation.

Proposal:

- As discussed with GAVI, WHO has taken the initiative to work with countries to start reviewing some of these issues, and has formulated an initial costing of country costs that would be required, *over and above the normal 30 cents per child* provided for new vaccines introduction to accommodate these additional costs.
- The table below provides a breakdown of the **\$2,833,125** requested for the **six countries** for the first year of introduction. It is would be anticipated that these funds would be made directly available to the countries as an "enhanced" and additional NVI introduction grant.
- This costing has been prepared based on the assumption that countries will only be using the pre-filled presentation for the first year of introduction and that a vial presentation with AD syringe will be available thereafter.
- It should be noted that all other countries beyond the six mentioned here also planning to introduce the pre-filled presentation should receive similar support.
- There is also a component of support for WHO and/or UNICEF in the amount of **\$240,000** (excluding PSC) to conduct the pre- and post-introduction assessments detailed above. With PSC costs of 7%, the total for this component is \$256,800.

ESTIMATED COSTS FOR ONE YEAR FOR ADDITIONAL COUNTRY NEEDS TO INTRODUCE PNEUMOCOCCAL VACCINE IN PRE-FILLED SYRINGES

	Country Costs - through new vaccine introduction grant						
	Kenya	Yemen	Rwanda	Honduras	Nicaragua	Guyana	Total
Birth cohort	1,032,000	900,000	370,000	205,000	170,000	16,000	
Activity							
Waste Management	\$810,000	\$580,000	\$315,000	\$220,000	\$170,000	\$50,000	\$2,145,000
Final disposal				\$150,000	\$120,000	\$28,000	\$298,000
Burial	\$440,000	\$300,000	\$95,000	\$25,000			\$860,000
Rehabilitation of large incinerators	\$70,000						\$70,000
High temperature incineration			\$5,000				\$5,000
Transport of waste	\$230,000	\$200,000	\$135,000	\$5,000	\$10,000	\$4,000	\$584,000
Training in waste management	\$50,000	\$50,000	\$60,000	\$20,000	\$20,000	\$8,000	\$208,000
Additional supervision	\$20,000	\$30,000	\$20,000	\$20,000	\$20,000	\$10,000	\$120,000
Transport & Vaccine Management	\$108,360	\$135,000	\$83,250	\$46,125	\$38,250	\$4,800	\$415,785
Training in all topics, including injection safety	\$72,900	\$96,720	\$24,400	\$29,160	\$29,160	\$20,000	\$272,340
Total country costs	\$991,260	\$811,720	\$422,650	\$295,285	\$237,410	\$74,800	\$2,833,125
	WHO and/or UNICEF costs						
	Kenya	Yemen	Rwanda	Honduras	Nicaragua	Guyana	Total
In-country pre- and post-introduction assessments	\$50,000	\$50,000	\$40,000	\$40,000	\$40,000	\$20,000	\$240,000
Total partner costs - excluding PSC	\$50,000	\$50,000	\$40,000	\$40,000	\$40,000	\$20,000	\$240,000

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**ADIP Management Committee Endorsement
WHO/UNICEF/Country components to address challenges in introducing pneumococcal
vaccine in pre-filled syringes submitted to the GAVI Alliance and Fund Boards as part of
Accelerated Vaccine Introduction Initiative (AVI)³
June 2008**

Country and WHO/UNICEF activities in introducing pneumococcal vaccine in prefilled syringes: There are six GAVI eligible countries that are approved or shortly expected to be approved for introduction of pneumococcal vaccine. Prequalification of the Prevnar pre-filled presentation will likely be a restricted prequalification for limited introduction in selected countries that indicate they are able to manage the safe use and disposal of the pre-filled presentation. This requires countries to meet additional challenges of introduction due to the unusual, non-standard presentation. A work plan and budget from WHO/UNICEF/Countries addressing these challenges was submitted to the GAVI Secretariat and to the ADIP Management Committee for review via e mail. These were subsequently endorsed by the ADIP Management Committee.

ENDORSEMENT: The ADIP Management Committee endorsed the country work plan and budget of \$2.8 million and WHO/UNICEF work plan and budget for \$256,800 (includes estimated WHO PSC costs of 7%).

³ Proposals, work plans and accompanying budgets described in this endorsement are included as annexes submitted to the June 2008 Boards as part of the AVI Board paper or AVI background paper.