As GAVI moves into Phase 2, there is an increasing need to set clear objectives and improve coordination across the Alliance on supply issues. In addition, the International Finance Facility for Immunization (IFFIm) and closer scrutiny of Global Health Partnerships more generally have created a need for greater transparency and a demonstrated value for money on supply chain activities such as procurement. In its enhanced role as financial agent and fiduciary for the GAVI Alliance, the GAVI Fund will need to take a more active role in ensuing optimal use of donor funds for procurement activities. The tender for the next procurement round must be in place by June of 2006 (for implementation in 2007).

In April 2005, the GAVI Alliance Board approved updated supply and procurement principles, one of which is that procurement strategies should be tailored to the needs of each individual vaccine. In July of 2005, the GAVI Alliance Board recommended that a small task team of GAVI partners be created to provide immediate recommendations on a supply strategy for *Haemophilus influenzae* b (Hib) and Hepatitis B (HepB) containing vaccines. This paper provides recommendations as a result of the analysis carried out by this team.

FOR DECISION: The Alliance and Fund Boards are requested to consider and decide upon the following recommendations:

4.1 To adopt new procurement objectives found on page 5 and 24.

4.2 To decide on the composition of a reference group to report to the GAVI Secretariat, to oversee supply and procurement issues and work closely with the procurement agent (page 6 and 24). The two options to be considered are:

- A fully independent expert reference group without partner membership; or
- The task team with enhanced membership of independent external experts.

4.3 To endorse the choice of UNICEF, with modifications to the current arrangements, as procurement agent on the condition that the GAVI Fund and UNICEF develop and sign an MOU by February 10th, 2006 in line with the proposed procurement agent criteria. If no agreement is reached in this timeframe, other options would be explored (page 6 and 27).

FOR GUIDANCE: Given the importance of the broader supply issues highlighted in this paper, the task team is seeking Alliance and Fund Board guidance on the following proposed next steps:

- The task team, modified in membership as necessary, will develop an overarching supply strategy for the GAVI Alliance to be provided to the Alliance Board in 2007.
- The task team will develop a strategy (including a code of conduct) for GAVI partners to engage with manufacturers to provide to the Alliance Board in 2006 for approval.
- The Secretariat will also work with relevant partners to develop budgets and plans for additional supply chain related work and integrate this in the strategic plan.
- The Secretariat, consulting with UNICEF as necessary, will improve its financial management systems to allow efficient and timely transfers of funds for procurement by 2007.
- The Secretariat will develop a plan to strengthen country capacity in vaccine management and commission work to explore further the possibility of long-term capacity for in-country procurement.

Recommended Supply Strategy for Hib and HepB Containing Vaccines

Table of Contents

1. Executive Summary

1.1. This paper provides the recommendations and analysis of the GAVI supply strategy task team[1] for a supply and procurement strategy for Hib and HepB containing vaccines.

1.2. This team was created following the approval of the GAVI procurement principles in April 2005 and an initial meeting of procurement experts in June 2005. The team was asked to develop supply strategies for HepB and Hib containing vaccines, based on approved GAVI procurement principles.

1.3. A supply strategy will assure a reliable supply of high-quality vaccines in the presentations and volumes needed to meet developing country demand, at affordable, sustainable prices. The scope of a complete strategy would ideally start seven years or more before introduction of the vaccine; for Hib and HepB containing vaccines, much of the early work has been completed.

1.4. It is generally felt by GAVI partners that the Alliance lacked a comprehensive supply strategy in Phase 1. Although a procurement strategy was in place, the strategy had two competing objectives: rapid scale-up of combination vaccines and an emphasis on a short-term low price without adequate analysis of the supplier landscape.

1.5. Procurement processes during Phase 1 highlighted a lack of consensus among GAVI partners regarding institutional responsibilities and lines of accountability on supply and procurement functions. UNICEF, the procurement agent designated by the Alliance Board during this time, allowed only restricted involvement and oversight by GAVI partners in the solicitation process. This did not meet the expectations of some GAVI partners who were keen to be more involved in the solicitation, evaluation and structuring of awards. Expectations were further compounded by a failure to obtain more affordable vaccine prices over this short time frame.

The Market Context

1.6. Market overview:

- Global market for vaccines generates revenues of about US $10 billion per year;
- High income markets drive 82% of this revenue;
- GAVI alone generates only 2% of the total revenues, but represents approximately 85 % of the market in terms of volume.

1.7. Characteristics of the vaccine market in developing countries:

- *Supply characteristics:* Significant economies of scale must exist in vaccine production to meet developing country demand. Fixed costs representing a large proportion of these costs for vaccine production. The market becomes more attractive to emerging manufacturers as vaccine prices increase.

- *Demand Characteristics:* Credible demand forecasts are a key motivator for industry involvement in developing country markets. Both credible strategic demand forecasts for products in long-term development and supply chain forecasts for licensed and near-term products are necessary for a comprehensive supply picture.

[1] Team membership: Shanelle Hall, Francisco Blanco, Peter Salama (UNICEF), Michel Zaffran, Diana Chang-Blanc (WHO), Mercy Ahun, Andrew Jones (GAVI Secretariat), Angeline Nanni (Ex-Industry), Amie Batson (World Bank), Gargee Ghosh, Steve Landry (Gates Foundation) Don Strombom (Consultant to team)

- *Technology Issues:* Significant barriers to entry exist in the developing country vaccine market. Vaccines are generally harder markets for generic manufacturers to enter than non-biological pharmaceuticals. As a result, producers of new vaccines frequently have a period of market exclusivity of ten or more years. Also, product lead times are significant, as optimal product development timelines range from 7-10 years and can take as long as 15-20 years.
- *Purchasing Characteristics:* The GAVI Alliance is a significant influencer in the developing country vaccine market. To date, GAVI has faced a monopoly supplier situation for a large portion of the vaccine procured. The potential impact of monopolies in the market can keep prices high, which in turn constrains demand for the vaccine.

Analysis of the elements of a supply strategy

1.8. The task team reviewed each of the elements of a supply strategy, looked at current practices, problems or barriers to action and opportunities for improvement.

1.9. Long-term signalling to suppliers to produce HepB and Hib containing vaccines has resulted in the emergence of several new manufacturers. Analysis indicates that up to five suppliers of combination vaccines will be in production by the end of 2007, with total capacity of over 250 million doses at the end of that year for each DTP-HepB and DTP-HepB-Hib. Strong, although uncoordinated signals from the GAVI Alliance that combination vaccines would continue to be supported has helped drive manufacturers to invest in production capacity. It was this lack of coordination among Alliance members and the absence of a clear strategy for long-term signalling from the Alliance Board that were identified as areas for improvement by the team.

1.10. The accuracy of demand forecasts, which are a key driver of the supply strategy (and a necessary element of procurement), has improved through GAVI's first phase but further improvements, such as improving capacity at country level, are needed. Consideration of demand beyond GAVI-eligible countries (such as middle income markets) is essential. A better understanding of the global market will allow for analysis of the function of price, supply, and financing for vaccine uptake and where trigger points exist. Importantly, the impact of proposed Phase 2 vaccine subsidy policies on country demand has not been analyzed and is likely to have significant influence on projected demand.

1.11. Identifying financing as part of a supply strategy is a critical step. Previous differences in GAVI Alliance and GAVI Fund governance and approval processes caused bottlenecks in the financing of procurement. With convergence new processes will need to be designed to improve efficiency. Bridge financing and the proposed Phase 2 vaccine subsidy policies will present additional complexities in identifying financing for procurement. Additional clarity is also needed regarding the specifics of financial management and reporting by the GAVI Fund and UNICEF on procurement, particularly in light of the IFFIm.

1.12. All vaccines purchased by GAVI via UNICEF are subject to pre-qualification and ongoing assurance of quality activities. The bottlenecks at the assurance of quality stage are primarily due to difficulties in securing qualified technical experts, due to lack of funding, weak National Regulatory Authorities and under-supported post-marketing surveillance systems.

1.13. The solicitation, evaluation and award of bids together form the scope of work for the procurement agent. To date, the lack of broader Alliance involvement in providing input to and advice on the procurement process (including length of tender, type of tender, proportion of firm contracts, exploration of alternative risk sharing with manufacturers and decisions on awards) has been an issue. The more secure and predictable financing available to GAVI over the coming ten years provides opportunities to explore innovative procurement mechanisms. This needs to be recognized in any agreement with a procurement agent.

1.14. Following the tender and award process, vaccines are shipped and delivered in country, where systems vary significantly. The delivery of vaccines in countries and the corresponding need for greater capacity in vaccine management and logistics was highlighted. UNICEF and WHO, as key partners on the ground to support these activities, are working with countries and other partners to improve overall management.

1.15. Furthermore, recent work by the OECD DAC Roundtable[2] has highlighted the need to build national capacity in supply chain management. This has been echoed by discussions at the High Level Forum on the Health MDGs and donor discussions on the Global Architecture for Health Aid. To date, vaccine procurement by national governments has largely been absent in GAVI-eligible countries, particularly sub-Saharan Africa. Efforts are needed to assess and support country capacity development in procurement, with an eye to the market complexities associated with an increase in buyers.

1.16. Ensuring that supply activities are adequately monitored is critical to ensure proper implementation of the strategy. The different GAVI partners involved in the various supply elements monitor different parts of the supply chain. However, integration and coordination of these activities is needed. Furthermore, a regular review of high level key indicators will be helpful to assess progress and improve performance in each of the areas to ensure that the implementation of the supply and procurement strategy is done as efficiently as possible.

Recommendation #1: To adopt the following procurement objectives

The proposed procurement objectives provide a framework under which the procurement of Hib and HepB would take place:

- A healthy market: ensuring the sustainable quantity of supply through a diverse supplier base.
- Select products and presentations that best meet the need of client countries.
- Achieving a long-term affordable price that can eventually be sustainably financed by developing countries.

[2] Organization for Economic Cooperation and Development's (OECD) Development Assistance Committee (DAC) Roundtable on Strengthening Procurement Capacities, February 2005

Recommendation #2: To decide on the composition of a reference group to report to the GAVI Secretariat, to oversee supply and procurement issues and work closely with the procurement agent. The two options to be considered are:

- A fully independent expert reference group without partner membership; or
- The task team with enhanced membership of independent external experts.

The task team proposes that a "reference group" be put in place to monitor and advise on supply issues and work in close collaboration with the procurement agent. They would be responsible for monitoring the implementation of the supply strategy as well as the procurement process through key indicators. This group would be appointed by the Alliance and Fund Boards to carry these issues forward and would report to the GAVI Secretariat on a regular basis. It is recommended that this group be formed immediately but that its timeframe is indefinite.

The fully independent committee option ensures that conflict of interest will not be an issue; however, the lack of partner participation in this group will reduce Alliance ownership of the process. In light of previous concerns over broader Alliance ownership of the process, the team feels the second option should be considered.

Recommendation #3: Endorse the choice of UNICEF, with modifications to the current arrangements, as procurement agent on the condition that the GAVI Fund and UNICEF develop and sign an MOU by February 10th, 2006 in line with the proposed procurement agent criteria. If no agreement is reached in this timeframe, other options would be explored.

The GAVI Alliance's purpose of increased access to immunization necessitates strong linkages with countries and an ability to understand and work within the development context. UNICEF's presence in each of the GAVI countries and its role as a core GAVI partner place it well as a procurement agent for the Alliance. Nonetheless, given the problems to date, the team has recommended significant changes to the agreement with UNICEF including development of a detailed MOU to set out responsibilities and a reference group to provide Alliance involvement and oversight.

Criteria for the selection of the procurement agent were developed to address concerns raised during the work of this task team. It is felt that with the recommended modifications and appropriate involvement of the Alliance, UNICEF is best placed to provide these services.

In making this recommendation, the team considered two other options: building procurement capacities within the GAVI Secretariat, and tendering for an outsourced agent, both of which have limitations. Building capacity within the GAVI Secretariat will consume significant resources and staff and duplicate capacities available elsewhere in the Alliance. Outsourcing procurement was considered but it can easily take 9-12 months to prepare competition documents, to specify the evaluation criteria and to select the service provider. This could present difficulties in avoiding unacceptable interruptions in the flow

of vaccines to recipient countries. In addition, commercial providers are generally lacking the needed relationships with developing countries.

Therefore, in line with the above framework, the task team has proposed criteria for the development of an MOU between the GAVI Fund and UNICEF. Given the need for the tendering process to start rapidly, it is proposed that an agreement be signed by February 10th, 2006. This proposed MOU will be provided to the GAVI Fund for approval with detailed definitions of roles and responsibilities, information regarding services provided and their costs (including comparison of other options), and appropriate modification of documents and procedures to correspond with GAVI Alliance objectives. In the event an agreement cannot be reached with UNICEF, outsourcing could be further explored.

Proposed recommendations for Alliance and Fund Board guidance

- The task team, modified in membership as necessary, will develop an overarching supply strategy for the GAVI Alliance to be provided to the Alliance Board in 2007.
- The task team will develop a strategy (including a code of conduct) for GAVI partners to engage with manufacturers to provide to the Alliance Board in 2006 for approval.
- The Secretariat will work to ensure the five year strategic plan includes a mechanism for making early decisions about new vaccine support and financing in order to send appropriate signals to industry. It will also work with relevant partners to develop budgets and plans for additional supply chain related work and integrate this in the strategic plan.
- The Secretariat, consulting with UNICEF as necessary, will improve its financial management systems to allow efficient and timely transfers of funds for procurement by 2007.
- The Secretariat will develop a plan to strengthen country capacity in vaccine management and commission work to explore further the possibility of long-term capacity for in-country procurement.

2. Background

2.1 The need for a supply strategy

As GAVI enters its second phase, the environment in which the Alliance works is changing, with many risks but also many new opportunities; work towards a five year strategic plan is underway in an effort to address this. As GAVI moves into Phase 2, the vaccine environment is becoming more complex, making the need to set clear objectives and coordinate across the Alliance even more important. In this context, a supply strategy is needed to support GAVI objectives for increasing the introduction of future vaccines and to provide clear signaling to manufacturers and countries.

GAVI needs to maximise value for money: In 2005, GAVI will fund over US $200 million worth of vaccines. GAVI has significant new funding essentially guaranteed, allowing for unprecedented long term planning. Several new manufacturers are planning to enter the market in the coming years, adding both opportunity and complexity to supplier relations. GAVI needs to maximize its leverage and become a better and smarter client to achieve its supply and procurement objectives. This also means that GAVI's successes, as well as mistakes, may be magnified.

GAVI needs to prepare for new vaccine prices higher than historical levels: Newer vaccines will mean innovative technologies, greater regulatory oversight, limited supplier development, and other factors, resulting in prices that will be higher than the historical "pennies per dose". Creative strategies for engaging vaccine manufacturers as early as possible are needed to assure affordable and sustainable supplies of vaccines for developing countries.

Current procurement agreements are coming to an end with Phase 1: The previous procurement round covered 2004-06. The process for 2007 onwards needs to start now, within the framework of the newly approved procurement principles.

The Alliance partners need to engage better on supply issues: All partners within the Alliance should have a clear understanding of supply processes, as well as the tradeoffs involved in the management of supply issues.

Financial tools are changing: The recent announcement of the International Finance Facility for Immunization (IFFIm) secures predictable, long-term financing; the IFFIm provides a unique opportunity to use a broader range of procurement mechanisms.

Donors are taking a closer look: The growth of GAVI and other global health partnerships is leading to increased scrutiny of management, including requests for enhanced transparency and accountability.

A comprehensive GAVI supply strategy for Phase 2 is necessary, as production capacities, supply of product and affordability of future vaccines remains uncertain. . Lack of clear signalling to industry and an integrated supply strategy on the priorities of the Alliance will negatively impact their investment decisions. It will also undoubtedly affect countries' decisions with regards to new vaccine introduction, likely resulting in higher prices, limited supply and delayed vaccine introduction and wide scale use.

This task team was specifically assigned the work of a supply and procurement strategy for Hib and HepB vaccines, which is the focus of this paper. However, this work has demonstrated the need for a broader long-term GAVI supply strategy.

2.2 The purpose of a supply strategy

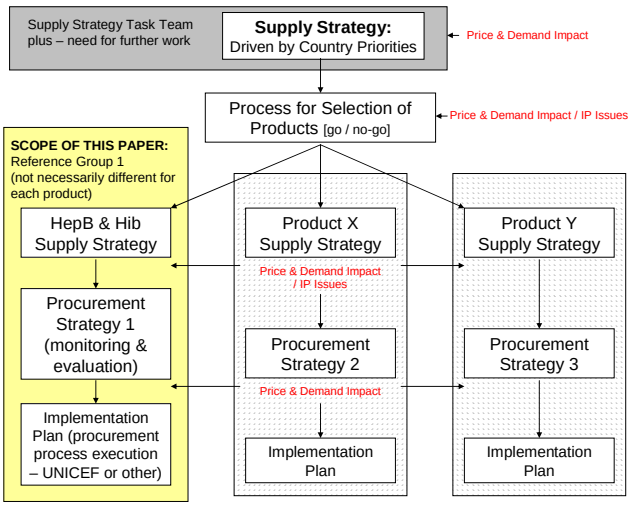
A supply strategy aims to assure a reliable supply of high-quality vaccines in the presentations and volumes needed to meet developing country demand, at affordable, sustainable prices. A successful strategy will:

- Incorporate an effective time scale, allowing for both a focus on long-term strategic planning, as well as details regarding implementation around very specific timelines.
- Utilize and manage data and analyses related to strategic and supply-chain demand forecasting, product profiles, market analyses, and financing and contracting options.
- Closely link supply strategy and evidence-based demand creation.
- Be unique for each vaccine.

GAVI partners bring expertise covering the full range of functions involved in supply and demand, making the Alliance an ideal vehicle for an integrated plan. An effective strategy will build on these inputs to maximise each of them, and proactively address existing gaps or weaknesses. It should therefore include the necessary policy decisions to clarify specific roles and responsibilities of partners, on the basis of their comparative advantages, as well as a mechanism for coordinating activities to ensure accountability and monitor outcomes. Strategies will differ with markets, and vaccine by vaccine.

Following an initial meeting of procurement experts in June 2005, a recommendation was made for a supply task team to be created and report to the Board in December 2005. The mandate for the team was to develop supply strategies for HepB and Hib containing vaccines[3], based on approved GAVI procurement principles[4]. With Hib and HepB, much of the early work on long-term planning has passed and the work in this paper is focused on supply chain forecasting and procurement strategy.

Figure 1: Scope of this paper in relation to broader supply strategy



The work included in this paper, which should be seen within the broader context (see figure 1), has been subject to discussion by the Expert Group included in the TORs and accordingly revised.

[3] This includes: DTP – hepB + Hib (pentavalent), DTP-Hib, Hib monovalent, DTP-HepB, and HepB monovalent.
[4] The TORs, provided in Annex 2, were approved by the Board on a no objection basis in August 2005.

2.3 The organization of this paper

This paper is comprised of the Executive Summary followed by 3 sections. Section 2 provides an introduction to the strategy and places it within the broader context. Section 3 contains the team's analysis of the current supply situation and processes, and identifies opportunities for improvement. Section 4 provides specific recommendations for the supply and procurement of Hib and HepB containing vaccines, with additional longer term recommendations for dealing with the broader framework.

2.4 The vaccine market

The global market for vaccines currently generates revenues of about US $10 billion per year; high income markets drive 82% of this revenue. GAVI, UNICEF and PAHO purchases represent approximately 8% of the remaining 18% of sales. GAVI alone generates only 2% of the total revenues, a small fraction of the total market[5]. However, in volume of doses, GAVI sales represent approximately 85 % of the market. Vaccine markets have a number of characteristics that are important determinants for developing an effective supply strategy:

Supply Dynamics:

Significant economies of scale: Vaccine production is typically characterized by a number of factors that impact economies of scale. In one study[6], Mercer Consulting estimates that for a given production plant, variable costs make up 15% or less of the total cost of vaccine production, significantly less if R&D and marketing costs are included, while fixed costs remain high. Newer vaccines may have more significant variable and semi-variable costs[7] than traditional products, thus analysis of the key drivers of manufacturing each product is critical.

Number of suppliers in the market: As vaccine prices increase, the market becomes more attractive to a broader range of suppliers. Careful analysis of the global market and supply pipeline (as detailed in section 3) can help assure adequate supply capacity from a number of manufacturers.

Demand Characteristics:

Expected demand levels: Analyses from McKinsey[8] and Mercer[4] have identified credible demand forecasts as the key motivator for industry involvement in developing countries. Both strategic demand forecasts for products in near-term development and supply chain forecasts for licensed and long-term products are necessary for a comprehensive supply picture.

Technology Issues:

Barriers to entry: Intellectual property rights and trade secrets, manufacturing complexity (know-how), and regulatory requirements make it difficult for new producers to enter the market. Vaccines are generally harder markets for generic manufacturers to enter than non-biological pharmaceuticals because the process of manufacture is more complex, harder to copy, and subject to different regulatory approval. As a result, new vaccine producers frequently have a period of market exclusivity of ten or more years. However, as Hib and HepB are already existing vaccines, the period of market exclusivity has already passed.

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[5] The Boston Consulting Group on behalf of the World Bank, WHO and Bill and Melinda Gates foundation (http://www.vaccinealliance.org/resources/16brd_supplyStudyUpdate_woods.pdf)

[6] *Lessons Learned: New Procurement Strategies for Vaccines*
http://www.gaviftf.info/docs_activities/pdf/lessons_learned_draft_final.pdf

[7] Manufacturing processes are more sophisticated with additional steps and respective minimum batch sizes at each step. However, as technologies improve, their relative complexity can decrease. For example, the technology for manufacturing HepB vaccine in 1990 was significantly more expensive than it is today.

[8] Weblink to be added

Product Lead Time: Lead time is a key driver in the vaccine market. Optimal product development timelines range from 7-10 years and can take as long as 15-20 years. Investment in production facilities can be made as early as 5 years before product licensure.

Purchasing Characteristics:

Large buyer: GAVI is a significant influencer in the developing country vaccine market. GAVI pools procurement for 75 countries in the developing world, and therefore accounts for a significant portion of global volume in many products. Most vaccines for developing countries are purchased by international procurement agencies such as UNICEF and PAHO, which creates significant market power for purchasers, as well as providing an efficient 'consolidated customer' on behalf of the world's poorest countries to the manufacturers.

Monopoly Supplier: To date, GAVI has faced a monopoly supplier situation for a large portion of the vaccine procured. The impact of monopolies in the market has the potential to keep prices high, which in turn constrains demand for the vaccine.

Procurement: Although a major driver, simply increasing demand for a product does *not* necessarily lead to a decrease in vaccine prices. Multiple drivers, such as increased capacity with additional manufacturers, changes in product presentation or technology, and new or additional financing arrangements for procurement can also influence price declines.

These dynamics were analyzed as part of the task team's work and as part of the recommendations presented in this paper.

2.5 The experience of Phase 1 procurement

A core GAVI activity is support for the introduction of HepB and Hib containing combination vaccines. The recommendation to provide support for combination, rather than monovalent, products was originally made by the GAVI Working Group. The choice of combination vaccines was driven by a concern for safety and programmatic ease, as DTP-based combination vaccines were considered easier to introduce than a stand alone new antigen, which would require an additional injection. The tradeoffs involved in this choice, namely a relatively higher price than for monovalent products and a limited supply base, were not fully analysed, especially in regard to expectations for price decreases and increases in the number of manufacturers able to meet WHO pre-qualification requirements.

GAVI's first phase included two procurement rounds. In the 2004-06 procurement round a total of $406 M was offered for DTP-Hib and DTP-HepB-Hib vaccines, of which firm contracts represented 66.2% (details of procurement round are provided in annex). In both rounds, the absence of an explicit and comprehensive supply strategy was problematic. Although a procurement strategy was in place, it had two competing objectives: quick scale-up of combination vaccines and emphasis on an affordable price. Furthermore, these rounds highlighted a lack of consensus among the partners regarding institutional responsibilities and lines of accountability on the supply and procurement functions within the Alliance. Once the procurement principles were agreed upon by the GAVI Board, UNICEF, as the procurement agent designated by the GAVI Board at that time, allowed only restricted involvement and oversight by GAVI partners in the solicitation process[9]. This did not meet the expectations of some GAVI partners who wanted to be more involved in review of manufacturer bids, contract negotiations and awards. The role of Alliance members as a partner versus service provider has not been clearly defined and concerns over conflict of interest exist. This issue is now being

[9] UNICEF, due to industry membership on the Alliance Board and various working groups/task forces, compliance to UNICEF Financial Rules and Regulations and consistency with good procurement practices and many national laws, considered the procurement process to be confidential and the sole responsibility of the buyer.

addressed as part of GAVI's strategic planning for Phase 2. A task team has been formed to examine this issue in further detail and a strategic issues paper will be presented to the Board at this meeting.

For the first procurement round (2000 – 2001), two supply subgroups were created by the GAVI Financing Task Force (FTF): the first attempted to develop vaccine forecasts based upon clearly defined assumptions that could be shared among all partners. The second focused on vaccine procurement. The procurement group's lack of involvement in the actual solicitation process resulted in the FTF commissioning a study on the vaccine industry by Mercer Management Consulting.

In 2002, the Mercer study[10] found that GAVI's first procurement round suffered from a number of shortcomings, including substantial inaccuracies around demand forecasts and extremely rapid timelines to scale-up vaccine support to countries with an explicit emphasis and preference for combination products.

The Mercer study recommended a coordinated vaccine supply implementation mechanism which led to the establishment of the Vaccine Provision Project (VPP) in 2002. This included a mechanism for better coordinating the efforts of partners to integrate demand, financing and supply functions within the Alliance. Emphasis was also made on making awards to diversify the supply base for each product type, and on increasing use of firm contracting. However, given the difficulty of staff with specific financial, procurement and programmatic accountabilities within their own institutions, reporting to a project manager from an external institution proved to be unworkable and undermined the VPP, rendering it ultimately unsustainable. At the December 2003 Board in Geneva, a lessons learned paper recommended:

1. Continuation of a project management role but with significant changes, or
2. Shift to an institutional model that better defined roles, responsibilities and accountabilities, including:
    - Detailing institutional accountabilities and areas of collaboration among key partners and the Secretariat that would be formalized in work plans and MoUs.
    - Ensuring buy-in and accountability of senior staff at oversight level.
    - Establishing a convening function to ensure regular interaction of all parties.

Before proceeding with the above recommendations, it was suggested that GAVI's procurement principles be updated[11]. In 2004, updated principles were approved by the GAVI Board and included:

- Focus on GAVI's principle of vaccine security (ensuring sustainable supply of quality, affordable vaccines) by supporting a diversified supplier base.
- Efficiency of supply with the greatest affordability.
- Need for transparency with industry and across Alliance partners.
- Effective product-specific procurement strategies and tools to account for market conditions.

[10] *Lessons Learned: New Procurement Strategies for Vaccines*
http://www.gaviftf.info/docs_activities/pdf/lessons_learned_draft_final.pdf

[11] In July of 2004 the Board requested that UNICEF and the Gates Foundation convene a small steering group to elicit suggestions from the Executive Committee and design a process to review and address procurement concerns. In April 2005, the Gates Foundation and UNICEF presented revised procurement principles for GAVI contained in Annex 1.

- Exploration of longer term arrangements and guaranteed minimum volumes in making awards.
- Encouraging entry of new suppliers.

Given the market and management lessons from Phase 1, it is important that the Alliance reach agreement on a supply strategy before detailing the terms of procurement and the roles and responsibilities for specific partners.

3. Analysis of the current situation

In order to provide a clear supply strategy for Hib and HepB containing vaccines, this paper assesses the various elements relating to supply: the supply landscape examines the products available to GAVI over the coming years; assessing demand looks at forecasting anticipated vaccine needs; identifying financing for funding purchase; quality assurance of vaccines; the solicitation process for producing bids; evaluating these bids; country receipt and vaccine management; and monitoring and benchmarking to ensure accountability and measure outcomes. The current processes for these activities are reviewed briefly, past barriers to success and problems are highlighted, and opportunities for improvement are provided building on best practices and past experience.

3.1 The supply landscape and industry signalling

Recent analysis of the supply landscape for a range of vaccines, including HepB and Hib containing combination products, has provided the context for this work[12].
A technical evaluation of development plans and production capabilities of manufacturers was carried out as part of this analysis. Outcomes suggest that the pipeline for DTP based combination vaccines with HepB and Hib looks positive, with a number of new suppliers likely to achieve prequalification for these vaccines in the near future.

3.1.1 Projected supply for DTP combination products

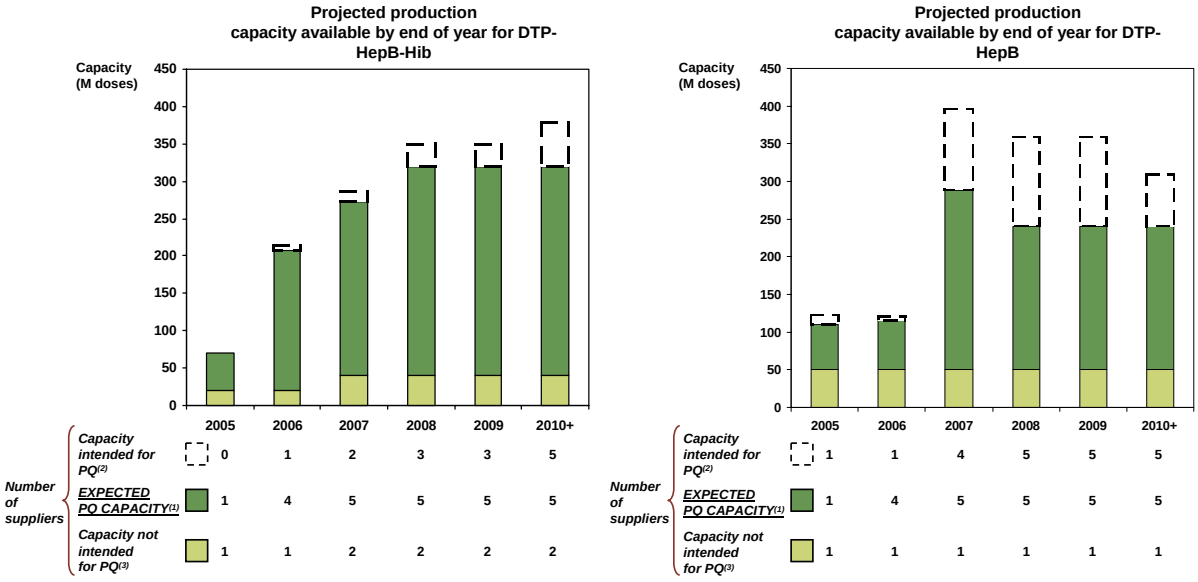
To date, one manufacturer has been the sole supplier for GAVI-funded combination vaccines. However, a number of suppliers have begun investing in DTP combination products (DTP-HepB and DTP-HepB+Hib) over the past few years, and there are now a significant number of projects in various stages of development.

[12] The Boston Consulting Group on behalf of the World Bank, WHO and Bill and Melinda Gates foundation (http://www.vaccinealliance.org/resources/16brd_supplyStudyUpdate_woods.pdf)

DTP combinations

CAPACITY FOR PRODUCTION OF DTP-CONTAINING COMBINATION VACCINES PROJECTED TO BE SIGNIFICANT

Actual Production Will Depend on Multiple Factors



(1) Includes capacity the study team projects to be prequalified based on assessments by a technically experienced team of the capabilities of suppliers interviewed
(2) Includes capacity that suppliers have stated will be used for domestic sales and will not be prequalified; (3) Capacity for which suppliers intend to seek PQ, but for which study team believes there is significant uncertainty about whether or not capacity will prequalified and/or available for production
Note: DTP-combination capacities are additive and non-overlapping; capacity for pentavalent includes different presentations
Source: Company visits; Project Team assessment

Figure 3: Projected Capacity for DTP-based combination vaccines

The emerging picture suggests substantial manufacturing capacity and the likelihood that there should be competition to supply the GAVI market, lifting current constraints on supply. Following a technical review by WHO consultants, it was estimated that by the end of 2007 there could be five suppliers (2 multinational corporations and 3 emerging manufacturers) with a WHO prequalified product (DTP-HepB or DTP-HepB+Hib). Based on manufacturer estimates, this would equate to a potential capacity of over 250 million doses for each product per year.

As noted in the background section, significant lead times exist for manufacturer planning. For the current combination vaccines, signals were sent via GAVI's initial investment in 2000. In this environment, it will have taken seven years for significant capacity to have been built. This is despite the fact that significant capacity for HepB production existed and that two manufacturers had already contracted for Hib antigen technology. For newer vaccines with more sophisticated technologies, the lead time could be even longer, necessitating early signalling to meet anticipated demand.

This investment in DTP combination products by manufacturers was motivated by several signals:

DTP-HepB and DTP-HepB+Hib combination vaccines were identified by WHO as a priority for programmatic reasons: A WHO recommendation for specific products sent a strong signal and encouraged manufacturers to invest in these products.

GAVI was willing to pay higher prices for combination vaccines compared to traditional EPI vaccines: These prices were attractive to suppliers, and as a result over 10 suppliers entered the market since 2000 and made substantial investments to produce a combination vaccine. The BCG study did not evaluate how potential capacity would be affected by a decline in prices paid by GAVI.

Industry received positive financing signals from GAVI: Bridge financing and Phase 2 commitments are providing a consistent message from GAVI on the priority given to combination vaccines.

These strong signals from GAVI attracted a highly heterogeneous group of manufacturers with some significant differences to be aware of, including:

1. Various companies have a range of experience in supplying GAVI and the global public markets.
2. Breadth of product portfolio varies from a few products to numerous products.
3. Financial security, ownership/governance structure, domestic market obligations, management ambition and other organization level factors vary significantly.
4. Technical capabilities in terms of product development vary dramatically, as does the potential and desire to bring future products of interest to GAVI to the market.
5. A new DTP combination vaccine offers some suppliers the opportunity to employ unused existing capacity. Left with excess capacity after the supply of HepB vaccines exceeded demand, these suppliers saw a combination vaccine as an excellent opportunity to maximize existing capacity.

3.1.2 Current practices for industry signalling

Industry and the GAVI Alliance send signals to one another on an ongoing basis, both formally and informally. Industry contributes to GAVI policies and practices as members of the Alliance Board and various task teams. This exchange of information allows for almost immediate signalling. GAVI's core policy discussions (e.g., to fund new and under-utilized vaccines for a large number of eligible countries over a period of time) is another example of GAVI signalling to manufacturers.

Even more formally, the first Request for Proposals (RFP) defined the criteria for which future vaccines would be valued. Outside of the tender process, formal signalling from the Alliance occurs:

1. *At the strategic level* via annual UNICEF / WHO consultations with producers, high-level exchanges of information with UNICEF in its role as procurement agent, and bilateral and Alliance Board-level interaction with all partners including the GAVI Secretariat.
2. *At the commercial level* via pre-tender meetings with UNICEF and regular WHO / UNICEF forecast updates.
3. *At the technical level* via procurement agent directives, guidelines, open meetings, and individual manufacturer consultations to ensure that specific production and product requirements are met and understood
4. *At the country level* via partner's interaction with countries in promoting new vaccines.

Furthermore, the process of bid awards (number of suppliers, number of years for the tender awards, percent of firm contracts) can send signals that will impact the market and future supply.

3.1.3 Past problems and barriers to success

To date, the Alliance has not had a strategy for communication of strategic messages to industry. While the procurement agent has been responsible for negotiations and discussions on the more technical aspects of procurement (i.e. bid procedures, evaluation criteria, shipment plans), strategic signalling (when and to what extent will GAVI invest in a new product, what presentation would be preferred) has occurred through various communication channels without a planned process by the Alliance Board. This lack of clarity from the Alliance has resulted in mixed signals. The recent study by Boston Consulting Group highlighted this, with some

manufacturers (particularly emerging suppliers) indicating that their perception of where the GAVI Alliance would invest was sometimes based on one-on-one discussions with various members of the Alliance who were likely unaware that such conversations were resulting in investment decisions. This has the unwanted result of inconsistent information with some manufacturers being provided with additional information not available to others, compromising the principle of equal information.

Moreover, past decisions regarding Hib and HepB priorities have not take into account the lengthy technical timeframe of manufactures; decisions must be made sooner and communicated more clearly for adequate supplier response.

3.1.4 Opportunities for improvement

Better strategic signalling to industry is indispensable and needs to be handled in a coherent manner by partners, with:

- Coordination among alliance members to avoid confusion and ensure all manufacturers receive the same information at the same time
- Provision of clear objectives and guidelines for communication (standards of conduct in manufacturer discussions could be an option)
- Improved timing of signalling; inconsistent or late signalling may undermine the ability of GAVI to achieve its objectives with suppliers and may harm the negotiating position of the buyer.

Optimal industry signalling, within the framework of a broader supply strategy, is as follows:

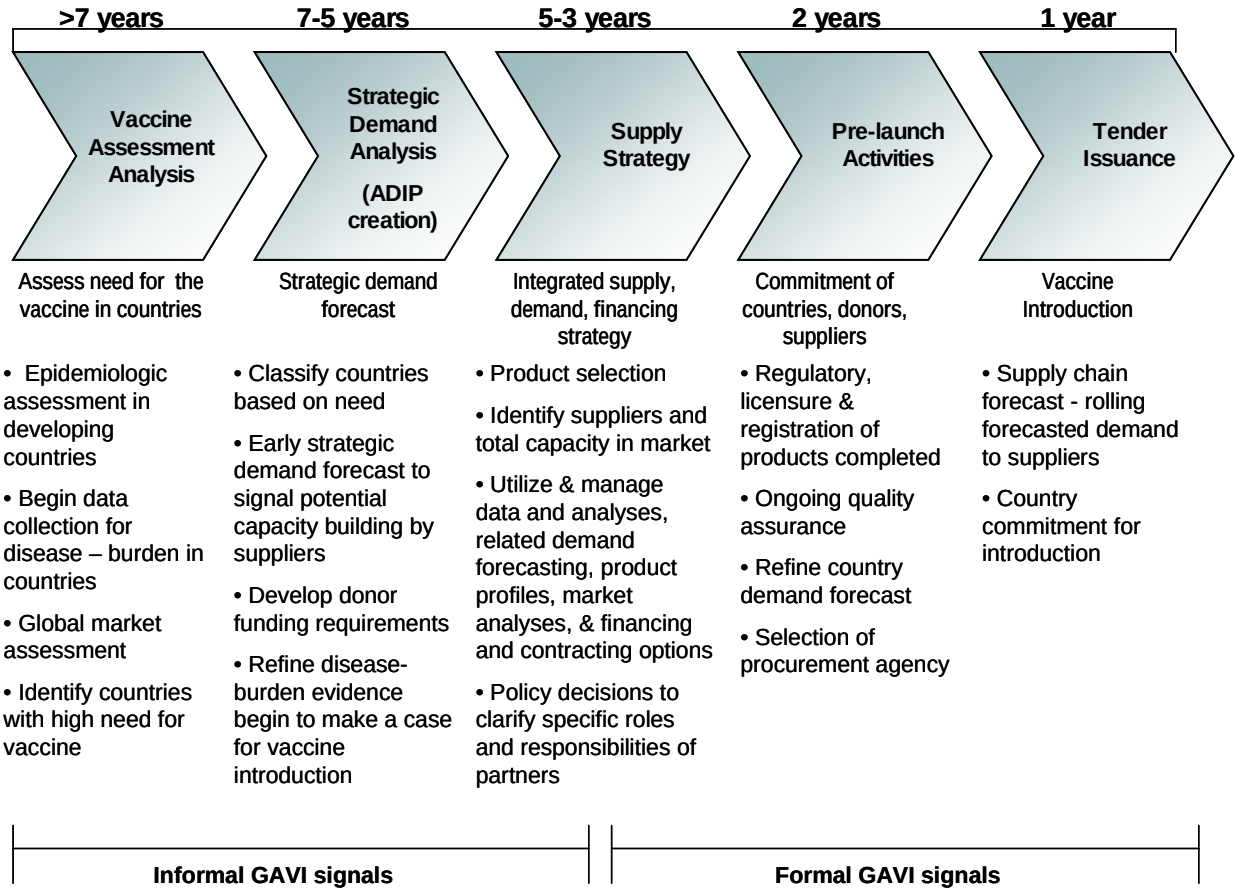


Figure 2: Supply strategy overview

3.2 Assessing demand

3.2.1 Current processes

Demand forecasts are a country driven, bottom-up process. On a country-by-country basis, WHO works to determine anticipated dates of introduction of Hib and HepB vaccines. Then, based on anticipated coverage increases and data on birth cohorts and wastage rates, projections are made for annual totals of required vaccine doses. Critical to the work on assessing demand is the concept of demand creation: ensuring countries are aware of the evidence base surrounding disease burden of the respective disease so that they can make informed decisions about whether it should be introduced into their vaccine schedule.

A gap highlighted in the Mercer study of 2002 was the lack of credible, predictable demand. As a consequence, efforts were made to develop a more accurate mechanism for determining projected country level demand for GAVI-provided vaccines. WHO leads this effort, and along with UNICEF and the GAVI Secretariat, has developed a model[13] which has significantly improved demand forecasts. In addition, an approach similar to GAVI's Accelerated Development and Introduction Plans (ADIPs)[14] was approved for Hib by the Alliance Board, the "Hib Initiative". This effort is meant to generate a better assessment of country demand and uptake, and enhance the evidence base for Hib-containing vaccine introduction[15].

3.2.2 Past problems and barriers to success

Problems around the accuracy of demand forecasting have been an issue since GAVI's inception. Recent work, particularly following the VPP, has significantly improved accuracy. Demand forecasting still has a wide range of uncertainty. However, with regard to Hib vaccine, uncertainty exists regarding the burden of disease and epidemiology at a country level. The Hib Initiative has recently been launched to address this and ensure that countries have the information they need to make evidence-based decisions whether or not to introduce (and sustain) Hib vaccine in their immunization program. GAVI's proposed financing policies for Phase 2, which will be presented to the Alliance Board at the December 2005 meeting, are likely to have significant implications on demand and timing of introduction of the vaccine. Lastly, vaccines GAVI is currently procuring are purchased by other segments of the market. This includes the public sector as well as private sector market in middle income countries. The level and extent of their demand will affect supply and pricing for GAVI vaccines.

3.2.3 Opportunities for improvement

Three broad areas are not adequately being addressed in the assessment of demand:

- *Understanding the differences between strategic and supply chain demand forecast:* Strategic demand forecasts are necessary for planning purposes. Suppliers need to have data on the potential demand for a vaccine so that adequate capacity decisions can be made in advance of new vaccine introduction to meet the needs of the GAVI Alliance. Donors

[13] In the first quarter of 2004, a Delphi panel was constructed to estimate expected dates of uptake into countries (for those that had not yet applied through GAVI). Countries were grouped into five categories based upon local situation and likelihood of uptake. The model for coverage assumed a progression to 95%.

[14] In June 2002, the Alliance Board approved the formation of Accelerated Development and Introduction Plans (ADIPs) for both rotavirus and pneumococcal conjugate vaccines. These ADIPs are designed to coordinate and advance the work of the public and private sectors towards the goal of accelerating the introduction of the vaccines into developing countries.

[15] Following a competitive selection process, a group based at Johns Hopkins University was awarded the $37 M Hib initiative.

need to understand what the potential financing envelope could be in the future. These forecasts are generally developed from the top-down, integrating disease-burden evidence and historical data from countries on prior vaccine introduction and presented in ranges rather than a point estimate. The ADIPs are responsible for and working towards producing credible strategic forecasts. Credible supply chain forecasts, on the other hand, are immediate forecasts that are driven from the bottom up on country-based decisions; these are the basis for procurement decisions. Greater precision and accuracy is needed for forecasting supply chain demand since these impact procurement and GAVI financing requirements.

- *Significant variation in forecast:* Variation in supply chain demand forecasts of GAVI-supplied products is significant. This is primarily due to inaccuracies regarding dates of country introduction. This can be better represented to manufacturers through a rolling forecast in which frequent updates provide greater accuracy than a point estimate.
- *Lack of broader demand picture beyond GAVI countries*: Current demand forecasts are focused on GAVI countries which do not comprise the full market[16]. A better understanding of the full market will allow for analysis of the function of price in vaccine uptake and where trigger points exist.
- *Consideration of new financing policies:* Phase 2 policies for GAVI support are shifting from donation to subsidies. Additional analysis is needed to determine what impact this will have on demand forecasts.

3.3 Identification of financing

3.3.1 Current processes

GAVI's procurement, managed by UNICEF Supply Division, is made in multi-year tenders financed by donors and national governments. There are three distinct parts to the identification of financing. The first is donor financing, the second identification of country financing (a more significant issue in Phase 2 with the new policies) and lastly how those funds flow from donors and the GAVI Fund to the UNICEF Trust Account and subsequently to the procurement agent.

For the first phase, five years of vaccine were provided by GAVI financing, fully guaranteed by pledges from donors. These pledges were channelled either:

1. To the UNICEF Trust Account, or
2. To the GAVI Fund.

Country-level financing is identified by recipient countries with the support of WHO and UNICEF. UNICEF Supply Division works with countries to establish a shipment plan that will determine funding needs and supply plans.

As monies are needed for vaccine purchase, funds are requested by UNICEF Supply Division from the UNICEF Trust Account. If the Trust Account does not have sufficient balance to cover the request, then the Trust Account requested funds from the GAVI Fund. The level of funds in the Trust Account varies depending on the timing of disbursements from donors and from the GAVI Fund; ensuring that sufficient funds are available is necessary to ensure the normal operation of the procurement process. As a part of the MOU between the GAVI Fund and UNICEF, a two-year rolling funding forecast is provided to the GAVI Fund on a quarterly basis.

[16] For whole-cell pertussis based vaccines.

3.3.2 Past problems and barriers to success

The current funding approval process is complicated and has led to bottlenecks, which occur as a result of delays in the approval of funding requests and/or lack of liquid funds in the UNICEF Trust Account when needed.

Delays in the approval of funding requests occur as a result of the nature and duration of the various GAVI Alliance programmatic approvals. While commitments made by the Alliance Board are for five years, the GAVI Fund approves funding on an annual basis; therefore, the approval letters issued from GAVI Secretariat to the country cover one year of supply. Past delays in issuance of approval letters (which define the quantity, type and value of the award and are utilized by the UNICEF Trust Account and GAVI Fund to authorize release of funds) have led to delays in country purchase orders and subsequent deliveries.

3.3.3 Opportunities for improvement

Three issues have been highlighted as needing further work:

- *Approval of disbursements:* The current approval process through the GAVI Alliance and the GAVI Fund for disbursement of funds to the UNICEF Trust Account for procurement is somewhat inefficient. This is due to multi-year approvals by the Alliance Board, but single year approvals by the GAVI Fund[17]. Routine fluctuations[18] in annual country allocations, as well as timing of subsequent-year approval letters, causes delays in verification and fund transfer.
- *Improved certainty over country financing:* Phase 2 policies support a vaccine subsidy with a portion financed by countries from the beginning. Identifying countries' ability to pay this portion is often difficult and not known adequately in advance.
- *Limited flexibility of financing terms for procurement:* The IFFIm necessitates the exploration of letters of credit or similar mechanisms to avoid pre-funding procurement contracts, as this would result in large sums of funds being held out of use[19]. The specifics of financing parameters for procurement (including treatment of interest earned on procurement funds) need to be enumerated in any agreement with the procurement agent.

3.4 Assurance of Quality

3.4.1 Current processes

UNICEF only procures vaccines that have been prequalified by WHO, a process which assesses the acceptability of vaccines for purchase. As vaccines are biological products, ongoing verification of the consistency of production on a batch-to-batch basis is also essential to ensure quality, safety and immunogenicity requirements are met. This ongoing monitoring is performed by the National Regulatory Authority (NRA) of the country of manufacture, which is responsible for consistent and continuing regulatory oversight for the product.

WHO works to strengthen NRAs to ensure they can adequately meet their quality assurance responsibilities. One of these strengthening tools is the Global Training Network on Vaccine

[17] . The approval letters issued to countries by the GAVI Secretariat reflect the single-yearGAVI Fund approval and are the document recognized byGAVI Fund and Trust Account which provides the ceiling disbursements authority for each country.

[18] Changes in coverage rates, birth cohorts and wastage rates can all shift the number of doses required on an annual basis

[19] This is particularly important with IFFIm funds which are borrowed against and therefore accrue a "cost". Should these funds sit in an account without earning interest, the Alliance would effectively be losing money.

Quality (GTN/VQ),[20] which provides educational resources to vaccine regulatory and production staff throughout the world. The emergence of a large number of developing country vaccine manufacturers as potential suppliers of vaccines of relevance to the GAVI Alliance is already a reality.

3.4.2 Past problems and barriers to success

The GAVI Alliance does not work directly in assuring quality, but lack of familiarity and expertise with the prequalification process poses a significant barrier to emerging companies intending to supply vaccines to the GAVI market. This problem is likely to increase as products become more complex and additional manufactures become interested in entering the market. There is not enough money to cover the increasing costs, especially for the validation of tests done in independent laboratories to test these products, and the increasingly complex demands on specialists for the site visits. While current processes are funded by a combination of UNICEF funds and manufacturer fees, additional funding needs exist.

Over the past 2-3 years, the WHO prequalification team has received a large number of applications for prequalification from an increasing number of emerging suppliers. However, the quality of the dossiers submitted varies tremendously, resulting in a relatively high "failure[21] rate." The main reasons for this high rate of "failure" include:

- The NRA of the country of manufacture not complying with functionality requirements.
- Inadequate or incomplete information due to the lack of experience of the companies.
- Insufficient clinical data accepted by the NRA of the country of manufacturer as a basis for granting the marketing authorization.

During prequalification, additional bottlenecks arise. Competent, independent laboratories, usually national control laboratories, are under increasing pressure to become self-sustainable and must therefore increasingly charge real costs. Therefore, in spite of a willingness to collaborate with the international public sector, they are therefore less able to do so unless more resources are made available. After prequalification has been granted, WHO relies on the regulatory oversight exercised by the NRA of the country of production to ensure the on-going quality, safety and immunogenicity of the prequalified products.

The NRAs must continuously strive to keep up to date with fast evolving regulatory requirements and enforce them onto the producer in order to exercise a competent regulatory oversight and adequately assure and control the quality of the prequalified vaccines. NRAs must therefore have ongoing access to the most recent training in quality control, quality systems, evaluation of clinical data of novel vaccines, and other tools.

3.4.3 Opportunities for improvement

- *Significant variation in NRA quality in countries:* In some emerging countries the lack of functionality of the NRA could prevent good quality producers access the prequalification scheme to have their vaccines assessed and considered for purchase by UN agencies and the GAVI Alliance.
- *Better access to qualified experts:* While the WHO prequalification team is adequately staffed to drive and coordinate the process, the availability of external experts with adequate skills and independent laboratories to provide ongoing monitoring of quality through

[20] The Network consists of a number of training centers around the world which offer instruction in priority areas using approved curricula and standardized documentation materials in all areas relevant to vaccine quality.
[21] Roughly 50%

regular testing is often a problem, putting a strain on maintaining the quality assurance system.

- *Post-marketing surveillance systems:* These are particularly critical in the countries where vaccines are being produced and used to ensure proper monitoring and reporting/investigation of Adverse Events Following Immunization (AEFI).

3.5 Solicitation process (to be executed by the procurement agent)

3.5.1 Current processes

UNICEF has procured vaccines on behalf of the GAVI Alliance since GAVI's inception in 2000. The UN (and its agencies and funds such as UNICEF and WHO) has established Financial Rules and Regulations, UNFRR, that set out principles governing how procurement is to be conducted. A basic premise is that all potential suppliers will have equal opportunity to compete for the expenditure of public funds. These principles derive from best practices and audit requirements by the member states' public procurement bodies, which include GAVI partners, and are reflected in GAVI's Procurement Principles.

Requests for Proposals (RFPs) have been used for the past two solicitations undertaken by UNICEF for the procurement of vaccines funded by GAVI in 2000 and 2003. Other potential procurement methods include Invitations to Bid (ITB) and, in some circumstances, direct contracting. Signalling to manufacturers is implicit in the use of each of these methods; the advantages and drawbacks of their use for vaccines funded by GAVI depend on the specific procedures, terms and conditions of each case.

In response to increased volatility in the vaccine market, in 2000, UNICEF moved from annual to three year contracts for the majority of vaccines[22]. The second RFP included provisions for firm quantities of purchases in contracts; the GAVI Fund provided the financial backing for the portion of the award that was firm. For the 2004-2006 procurement round, HepB and Hib containing vaccines were included in one solicitation document, along with other non-GAVI sponsored vaccines, allowing production linkages for manufacturers that offer both traditional and newer vaccines.

3.5.2 Past problems and barriers to success

Other members of the Alliance have requested to be more involved in the contract award process. In addition, there has been some disagreement with the method of solicitation used and the level of transparency of the process. More detailed consideration is needed of the impact that the choice of solicitation method will have on achieving the procurement objectives. Furthermore, the roles and responsibilities of Alliance partners in the various aspects of the procurement process have not been clearly defined.

3.5.3 Opportunities for improvement

Upon approval of this supply strategy for Hib and HepB containing vaccines, a detailed procurement strategy and implementation plan should be prepared that gives explicit recognition to agreed objectives and proposes suitable methodologies for achieving them.

Competitive tendering is the preferred practice in accordance with GAVI-approved principles. Either an Invitation to Bid (ITB) or Request for Proposal (RFP) can be an acceptable method, if documents and procedures are suitably tailored to meet GAVI requirements and to reflect the

[22] Manufacturers requested that the multi-year contracts need to be in place at least six months prior to the first delivery and contract commencement date.

status of the market. Direct contracting should only be considered in cases where it is certain there will be only a single source of supply for the duration of the contract period.

The new procurement plan should consider the optimum duration of contracts, and the portion of tender to be firm contracted, based on analysis of the advantages and drawbacks of all possible scenarios (this could include consideration of ceiling prices, for example).

3.6 Evaluation of bids and agreements with suppliers (to be executed by the procurement agent)

3.6.1 Current processes

The procurement process, as managed by UNICEF, commences with issuance of the solicitation document and receipt of proposals prepared by manufacturers and submitted to UNICEF. An independent 'bid receipt section' confirms timeliness of submission and deems proposals valid or invalid from this perspective. When an ITB procedure is used and bids are publicly opened, this section manages the public opening process. WHO then performs a separate technical evaluation of the received offers. The commercial evaluation and recommendations for awards are made by the UNICEF Contracting Unit and submitted to a UNICEF Contracts Review Committee. The GAVI Fund reviews the financial backing requirements for the firm contracts. The UNICEF Contracts Review Committee makes a recommendation to the Director of UNICEF Supply Division, who has final authority on the process.

Subsequently, UNICEF issues multi-year awards for vaccines. A portion of these awards are termed "good-faith" Long Term Arrangements (LTA), which do not legally bind either signatory, while the remainder are guaranteed firm contracts[23]. Over time, Purchase Orders are issued by UNICEF against the good-faith LTAs and create a legally binding commitment to both parties (essentially the forecasts become purchase orders over time).

If a supplier offers a product that is not WHO prequalified, the proposal must include a detailed plan on the timeline to obtain WHO prequalification. If the vaccine from a new manufacturer achieves WHO prequalification during the tender period, UNICEF would consider reallocating part of the good-faith LTA in circumstances where there is:

- A current monopoly or near-monopoly supply situation;
- Lack of performance of current manufacturer(s); or
- Insufficient production capacity of current manufacturer(s).

3.6.2 Past problems and barriers to success

As with the solicitation process, UNICEF has managed the evaluation of bids and agreements with suppliers in its role as procurement agent. Other partners in the Alliance do not have a clear understanding of this process and consider that there is a need for additional transparency in evaluation methodology. Further, the situation whereby negotiations with manufacturers are, at times, carried out following receipt of offers as part of the Request for Proposals (RFP) process is viewed as a potential problem with regards to equal treatment of manufacturers.

3.6.3 Opportunities for improvement

- *Broader alliance oversight of process,* guaranteeing that the role of the procurement agent is aligned with established procurement principles and objectives. This would have the additional benefit of building further confidence among the donor community in GAVI's practices.

[23] Firm contracts can only be made with WHO pre-qualified products.

- *Broader involvement of GAVI partners* that have expertise in specific supply strategy implementation areas.
- *Review reciprocal risk sharing:* Exploring contracting options, to better share risks between manufacturers and the GAVI Alliance.

3.7 Country delivery, country receipt, storage and logistics

3.7.1 Current practices

The Purchase Order and Long Term Agreement prepared by UNICEF define the conditions under which delivery takes place. Standard shipping procedures are defined in the Guidelines on the International Packaging and Shipping of Vaccines, jointly endorsed by UNICEF and WHO. These guidelines relate specifically to the international shipment of vaccine to countries implementing the Expanded Programme on Immunization.

Countries have the responsibility for ensuring that vaccines are cleared and safely transferred to cold storage. This includes the establishment of guidelines and legal procedures for clearance of vaccines, adequate arrangements for transport to cold storage and most importantly, provision of funds to cover the costs. Partners have a key role in the establishment of such mechanisms within the overall development of procurement structures of Governments.

The timely issuance of shipping notification to the receiving Government is facilitated by UNICEF Country Offices, who also provide support for the receipt of the shipment. Receipt of details by the field office is monitored from UNICEF Supply Division, while the timeliness in the receipt of the shipping notification by the Ministry is monitored after the shipment takes place through the Vaccine Arrival Report (VAR)[24]. The responsibility for providing safe delivery to the intermediate and final destination is shared by the seller, the buyer and the countries. The roles and risks are defined under the terms of the contract, and managed by the parties involved.

3.7.2 Past problems and barriers to success

Country capacity to ensure that adequate financial resources are available to clear and safely transfer vaccines to cold storage is not always sufficient. Furthermore, capacity by countries to monitor needs and update shipment plans accordingly can be limited, requiring extensive support and follow up from UNICEF in order to minimize impact of changes in shipment plans on the availability of vaccines. The significant economies of scale that exist with vaccine procurement make the economics of individual vaccine procurement by countries not particularly efficient. While building country capacity in this area could be a long term GAVI goal, the need to do bulk procurement to obtain the most affordable price makes procurement of GAVI eligible countries in bulk the best option.

3.7.2 Opportunities for improvement

- *Capacity needs to be built in countries to enable better vaccine management.* This includes shipment receipt and rapid transfer into cold chain, central vaccine store and stock management as well as in-country distribution.

3.8 Monitoring; benchmarks for performance

3.8.1 Current practices

[24] The VAR is a tool used to monitor the condition and quality of vaccines on arrival in country. It provides a means for reporting any inadequacies in the shipping process or any problems with the condition of vaccines upon delivery.

Currently, UNICEF conducts contract monitoring on the basis of supply and account management performance of the manufacturer. Contract monitoring assesses delivery (delivery on time, availability), vaccine quality and account performance.

Procurement performance monitoring, conducted internally within UNICEF, covers aspects related to cost (price competitiveness), administration (time to place orders, time to pay invoices), compliance (documentation), skills of personnel, on-time delivery and client satisfaction. Delivery and utilization are monitored through communication with countries.

Additional GAVI partners currently play a role in monitoring supply functions. Countries provide feedback to the GAVI Secretariat on the receipt of vaccines and devices and issues related to supply performance through Annual Progress Reports. WHO is responsible for monitoring AEFI, quality assurance of vaccine manufacturers and NRAs, as well as monitoring the accuracy of the demand forecast. Finally, the GAVI Fund monitors the accuracy of the funding forecast, while the Alliance Board provides oversight to ensure procurement objectives are met.

3.8.2 Past problems and barriers to success

A cohesive set of benchmarks to measure performance, as would be associated with a broad GAVI Supply Strategy or with vaccine-specific supply strategies, does not exist. In additional, while individual partner monitoring processes exist, they are not linked to measure GAVI's broader supply and procurement objectives. There is a need for greater integration of the various monitoring activities associated with supply to enable better feedback and adjustment of practices. A more comprehensive analysis of existing international standards is needed to see what common benchmarking procedures might be used.

3.8.3 Opportunities for improvement

- *Better coordination of information management* is needed to enable integrated analysis of procurement performance.
- *A more formal system for monitoring* implementation of the supply strategy will better ensure objectives are met.

4. Recommendations

Following the analysis above, the Board is requested to make three decisions and provide guidance on five other issues.

4.1 Procurement Objectives

Recommendation #1: To adopt the following procurement objectives

- A healthy market: ensuring the sustainable quantity of supply through a diverse supplier base
- Select products and presentations that best meet the need of client countries
- Achieving a long-term affordable price that countries can eventually finance in a sustainable manner.

While these procurement objectives are largely similar to those in the first phase of GAVI, there is now a significantly better understanding of the supply landscape. Moreover, the proposed reference group (4.2) will examine the implications of these objectives and provide for an ongoing process to re-examine their respective weight as the plan is implemented.

4.2 Creation of a Reference Group

Recommendation #2: To decide on the composition of a reference group to report to the GAVI Secretariat, to oversee supply and procurement issues and work closely with the procurement agent. The two options to be considered are:

- A fully independent expert reference group without partner membership; or
- The task team with enhanced membership of independent external experts.

The task team proposes that a "reference group" be put in place to coordinate, monitor and advise on supply issues and work in close collaboration with the procurement agent. This would ensure that the various elements critical to a successful supply strategy are effectively coordinated with the support of the GAVI Secretariat to ensure congruence with strategic planning. This group would be appointed by the Alliance and Fund Boards and would report to the GAVI Secretariat on a regular basis. It is recommended that this group be formed immediately but that its timeframe is indefinite.

A fully independent expert reference group would not involve GAVI partners but rather act as an impartial body to evaluate the various inputs to the supply strategy and monitor the procurement process. Membership of this group would only be permitted to non-affiliated individuals (or those retired from partner organizations). The composition would be much like GAVI's Independent Review Committee (IRC), which reviews and monitors country applications. This would minimize conflict of interest and allow impartial advice to the GAVI

Secretariat regarding supply activities, and particularly with respect to the solicitation and tender process.

Nonetheless, a group that has adequate familiarity and experience with GAVI issues related to supply, while not being affiliated with partners, is likely to be difficult to find. Moreover, the task team has identified the lack of partner involvement in strategic decisions as one of the critical difficulties with supply (and particularly procurement) to date. An independent group would not rectify this problem.

The team proposes a second option, which builds on core partner expertise by including them in the reference group, thus allowing for overlap with the development of a broader GAVI Alliance supply strategy. Critically, the reference group would also include:

- Range of expertise (partners such as WHO, Hib Initiative, developing countries),
- Specific procurement or supply expertise (not necessarily vaccine-specific), and
- An independent chair.

UNICEF, as the procurement agent (see 4.3), would need to work closely with the reference group, but would not be a member. The proposed roles and responsibilities of the reference group in relation to the procurement agent and partners are outlined below and in figure 3:

Assessment of demand: WHO, as lead partner, would be responsible for working with countries, the Hib Initiative and other relevant experts to produce a rolling demand forecast for Hib and HepB vaccines. The emphasis is to build capacity in countries so that they can increasingly produce reliable accurate demand forecasts. The reference group would review the forecasts and approve the recommended demand ranges, which would be used in the procurement process. The current demand forecasts for the next 5 years are provided in annex 1 with the inclusion of middle income country demand.

Identification of financing. The reference group would define the financing needs (in line with approved demand forecasts) and coordinate amongst the various partners to ensure adequate funds were identified and provided to the agent in a timely and efficient manner.

Quality assurance: WHO, as lead partner, would work with National Regulatory Authorities and manufacturers to assure quality of vaccines and to pre-qualify vaccines.

Solicitation of tenders: The procurement agent would design the tender in line with the approved procurement strategy including length, type of tender and proportion of firm contracting. The reference group would provide confidential advice to the procurement agent on the solicitation proposed.

The mechanisms that are used for procurement – request for proposals (RFPs), Invitations to Bid, (ITBs) or other variations – are simply means for achieving GAVI's objectives. Any of these procedures can and must be adapted in ways that ensure:

- Full transparency, including disclosure of the factors, weightings and methodologies for evaluating offers from suppliers, the procedures for decision-making, and the final results of contract awards.
- Equal opportunity for suppliers to compete, including emerging suppliers with qualified products.
- Due consideration is given for firm contracting as a means of ensuring supply, mitigating risk, risk-sharing while ensuring reciprocal terms.

Evaluation of bids and structuring of awards: The procurement agent would receive and evaluate bids; the recommendations of awards and their structuring (i.e. split awards) would be shared with the reference group for confidential advice and recommendations.

Awarding of firm contracts: The reference group would provide confidential advice to the GAVI Fund Board regarding the financial backing options to support any recommended long-term firm contracts.

Monitoring: The reference group would be responsible for monitoring the implementation of the supply and procurement strategies and track the proposed key indicators. The group would coordinate inputs from various partners to ensure integrated management of information. Supply Strategy Fact Sheets should be created and maintained to provide historical records for vaccines procured on behalf of the GAVI Alliance since the start of its operations[25].

A supply monitoring system would provide a mechanism for examining overall performance and determining how effectively GAVI's objectives are being met. This system would provide a snapshot of current performance based on the key indicators. The responsibility for maintaining the key information would be the responsibility of the specific partners. Several key indicators have been recommended and it is proposed that these indicators be monitored by the reference group with support from the GAVI Secretariat.

1. **Demand forecasting:** Comparison of forecasted quantities, by type of vaccine and by year, with actual purchases and actual shipments.
2. **Financing:** Comparison of forecasted expenditure versus actual funding needs; whether timely release of funds occurs.
3. **Timely delivery of vaccine:** Ensuring that the vaccine is delivered in country as scheduled.
4. **Healthy market** : For each type of vaccine:
    - Number of prequalified products,
    - Total capacity offered to UNICEF over demand,
    - Price per dose versus Bridge Financing targeted price.

[25] These Fact Sheets would be updated as new procurements are carried out and contracts are awarded, and would provide a useful reference for Alliance and Fund Boards and management to see trends in procurement activities.

Procurement: Role of Partners & Reference Group

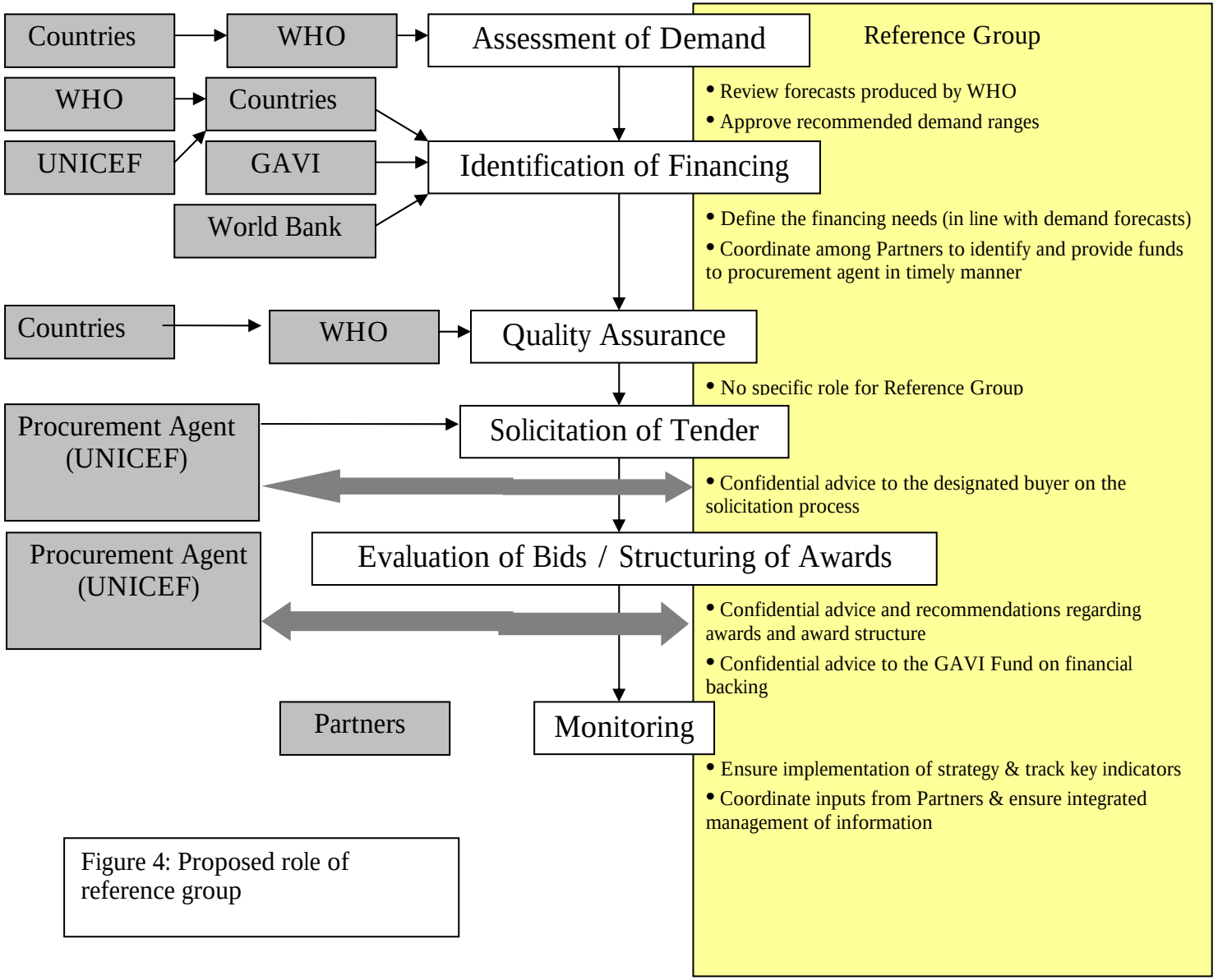


Figure 4: Proposed role of reference group

4.3 Selection of a Procurement Agent

Recommendation #3: Endorse the choice of UNICEF, with modifications to the current arrangements, as procurement agent on the condition that the GAVI Fund and UNICEF develop and sign an MOU by February 10th, 2006 in line with the proposed procurement agent criteria. If no agreement is reached in this timeframe, other options would be explored.

In the particular case of procurement for GAVI, several observations are relevant:

1. Not all aspects can or should be delegated to a procurement agent. The GAVI Alliance needs to be directly involved in some activities, especially the setting of policies and objectives and the communication of its strategic decisions to vaccine manufacturers.
2. Other elements of the procurement process require the participation of more than the procurement agent; e.g., the recipient/user countries and WHO in establishing demand forecasts, the supplier community in providing information about production capacity, etc.
3. UNICEF, the procuring entity since GAVI's establishment, is both an Alliance partner and the provider of procurement services. These somewhat overlapping roles need not create a conflict of interest provided that their responsibilities in both cases are clearly delineated and carried out consistently within the framework of GAVI's policies and objectives.

Therefore, as a starting point, the group has proposed that the Alliance and Fund Boards should:

- Retain the sole right to set procurement policy objectives.
- Provide advice on procurement methods and evaluation criteria for suppliers' offers.
- Maintain direct communications with the supplier community regarding vaccine financing strategies and policies.
- Seek to maintain common procurement practices and processes across all types of funds (e.g. GAVI Fund and IFFIm) for efficiency and ease at the country level.

Additionally, the Fund Board should:

- Utilizing the GAVI application and approval process, have the final decision on the products and quantities that it will finance for recipient countries.

Selecting the procurement agent is a cornerstone of the procurement strategy. The task team recommends the following criteria as requirements for the procurement agent:

1. Willingness to enter into a mutually agreeable Memorandum of Understanding (or other like document) with the GAVI Fund.
2. Adherence to internationally recognized public procurement practices.
3. Demonstrated international experience in large scale procurement and delivery of vaccines.
4. Experience linking to efficient delivery systems in recipient countries.
5. Capacity to execute the applicable antigen-specific procurement strategy.

6. Commitment to share, under appropriate confidentiality agreements, information regarding the procurement process and implementation of the procurement strategy with a designated reference group.
7. Willingness to accept Letters of Credit (LC) or other similar financing mechanisms that will help limit the need for pre-funding for any resultant firm contracting.
8. Ability to manage funds and transactions pursuant to GAVI asset management requirements[26].
9. Manage reporting on procurement activities in formats acceptable to GAVI and consistent with key indicators recommended in this paper.

Given its core competencies as an Alliance partner and it's experience in vaccine procurement and delivery for developing countries, it is proposed that UNICEF be selected as the procurement agent but with enhanced transparency, better definition of roles and responsibilities of all partners involved in supply chain, clearer information regarding services provided and their costs, and appropriate modification of documents and procedures to correspond with GAVI objectives. The analysis in this paper has distinguished between the procurement function that Supply Division performs and some of the other related supply activities that UNICEF performs (such as country support of vaccine management). The procurement functions outlined in section 3 (solicitation of tender and evaluation of bids and awards) would be contained in the proposed MOU between UNICEF and the GAVI Fund.

UNICEF will prepare a proposal for funding through the GAVI workplan for that sets out necessary budget needed to perform the supply functions agreed. Transparent cost estimates are essential to demonstrate that the Alliance is obtaining good value for its funds for procurement services. The creation of a reference group (discussed in further detail in section 4.2) to lead development of supply and procurement strategy and a clear definition of roles and responsibilities are designed to resolve past procurement difficulties. The involvement of the Alliance in the reference group, the proposed process for a collaborative strategy and the increased transparency address the past problems outlined in section 3. As new product-specific supply and procurement strategies are developed for GAVI in the future, this could necessitate revisions and changes to the MOU on procurement services. This proposed MOU will be provided to the GAVI Fund Executive Committee for approval. Should UNICEF be unable to comply with proposed revisions, alternative procurement options would need to be explored.

While other options exist, they are not without limitation. The first alternative would require creating a number of permanent staff positions in GAVI and would include attendant budget implications, time lags in developing the requisite capabilities, etc. It would be a difficult undertaking and is not a practical solution for the GAVI Alliance in the short or long term. The other option would be to specify exactly the activities to be outsourced and conduct a competition among the potential providers of procurement agent services (a number of private sector firms specialize in this business) and select the most attractive offer. This was judged by the task team to be sub-optimal because of the time-lag involved (which could cause interruption in vaccine delivery to countries) and the difficulty in finding a commercial provider that would have the required infrastructure to link with developing countries. Further, UNICEF's basic role and

[26] To be specified in detail (includes treatment of interest gained on procurement funds)

experience as a development agency, vaccine procurement and delivery experience and in-country networks give them a comparative advantage over other commercial service providers.

Given the need for the tendering process to start rapidly, an MOU will need to be signed by February 10th, 2006. If no agreement is reached by that time, alternative options would need to be explored. In the interim, further exploration of the procurement landscape should go ahead with an analysis of whether outsourcing would be an alternative option for GAVI, should this be needed.

4.4 Proposed actions for Board guidance

The task team, modified in membership as necessary, will develop an overarching supply strategy for the GAVI Alliance to be provided to the Alliance Board in 2007.

Engaging in strategic thinking on these vaccines and signalling early and consistently to suppliers can influence product profile, price, capacity and would allow countries to plan appropriately in preparation for vaccine introduction. GAVI would have the ability to establish more realistic plans to better inform countries as to the future vaccine market. Linking existing processes through a common framework for supply is essential to provide an integrated strategy for GAVI in Phase 2. Outlining a timeline for decision making that meets the needs of countries, manufacturers and the Alliance will allow GAVI proactively to take the steps necessary to shape the vaccine market for priority vaccines and ensure timely and adequate supply of affordable and sustainable vaccines.

The creation of a supply strategy for GAVI is critical given the complex environment GAVI enters in Phase 2, the more diverse supplier base, new financing tools such as the IFFIm and the interest of partners to be more involved and informed of supply and procurement issues. The possibility of additional vaccines being supported by GAVI in Phase 2 underlines the importance of GAVI approaching supply in a more strategic manner.

GAVI's experience with Hib and HepB vaccines has taught us that reacting to a market in the absence of a thorough strategic planning process, (which needs to include, among others, gathering disease-burden data, creating evidence-based demand) and linking the plan to a comprehensive supply strategy, has serious consequences; the most critical is a reduced health impact.

The task team will develop a strategy (including a code of conduct) for GAVI partners to engage and signal manufacturers to provide to the Alliance Board in 2006 for approval.

Messaging and communication with vaccine manufacturers is important when market conditions are stable, but becomes even more critical during periods of changing supply and/or demand. Below are recommended guiding principles for this communication:

1. *Focus on objectives:* Partners adhere to a clear set of objectives going into Phase 2. These would be part of a code of conduct for GAVI partners in communicating with manufacturers that will be developed by the team and endorsed by the Board.

2. *Transparency and fair competition:* All relevant information is shared including demand and program uncertainties. All procurement is conducted through public tendering equally open to all WHO pre-qualified manufacturers.
3. *Integrity:* Supply activities are open, fair and honest, and that confidentiality – e.g. in connection with production and bid details – is maintained.

It is critical to understand both the short-term and long-term signals that are needed to effectively engage suppliers over the product life cycle. It is also important to recognize that suppliers are reading signals both by GAVI's actions and its inaction.

Earlier and more extensive involvement of suppliers is one of the most efficient ways to enhance product development performance, productivity, speed, product quality, and demand creation by the Alliance. Consistent, accurate and timely signals early in the product cycle are key to engage suppliers to meet developing country needs. These early signals can be as simple as inclusion in GAVI agendas, discussions on project progress or other informal discussion points with or without financial obligations tied to the commitment. In many instances, manufacturers would be willing to move forward with their products with well-planned and timed strategic messages from GAVI, even before formal financial commitments are made. Long term relationships in which experience is built up can result in a more efficient and effective partnership for future projects. For many products GAVI has already missed the opportunity for signalling industry at the crucial time when they are sizing their production facility. An example of this is the life-saving pneumococcal conjugate vaccine where current capacity exists only for high priced markets. Earlier signalling would have enabled manufacturers to plan additional capacity however now it will take at least five years or more to increase capacity to supply a vaccine in developing countries at an affordable and sustainable price[27]. As a result GAVI has lost the opportunity to have the greatest impact on vaccine price and supply and save lives sooner. In the future, the GAVI partners must be more proactive, anticipating information needs, making the necessary investments that will provide the analyses for evidenced based decision making in a timely fashion to coincide with the timing of production decisions.

In addition to signalling through a policy process, one of the strongest signals GAVI can make for later stage products is to commit financing to procuring a product or category of products. By including products in future financial planning GAVI has the opportunity to drive pipeline prioritization, increase capacity, create product demand, and accelerate vaccine introduction in countries – all of which help GAVI to achieve its objectives for health and immunization.

Following the outcome of the December, 2005 GAVI Board meeting, manufacturers should be updated on the GAVI Supply Strategy Task Team process and outcomes as well as advised of next steps regarding solicitation process.

Complimentary to recognizing the importance of strategic industry signalling, and equally important, is the need for GAVI to make early, transparent and consistent decisions with regards to how new vaccines will be supported through policy and financing mechanisms. These signals will be critical in allowing countries to appropriately plan and enhance the ability for GAVI to have clear, predictable demand.

[27] Information from Pneumo ADIP

The Secretariat, consulting with UNICEF as necessary, will improve its financial management systems to allow efficient and timely transfers of funds for procurement by 2007.

As a consequence of the analysis in section 3 regarding identification of financing and flow of funds for procurement, the following are recommended:

1. *Improving integrated financial systems:* More efficient governance/approval processes at GAVI are needed to ensure smooth flow of funds into the procurement agent; integration of current GAVI financial systems is essential to track shifts in allocation of awards to countries from year to year. It is anticipated that the proposed financial system for GAVI, to be discussed at this Board meeting, will tackle this issue.
2. *Flexibility in financing:* Exploration of more flexible financing arrangements is needed to speed up awards and to ensure that no unnecessary costs are incurred by the Alliance. The GAVI Fund and UNICEF should coordinate efforts in this area.

The Secretariat will also work with relevant partners to develop budgets and plans for additional supply chain related work and integrate this in the strategic plan.

The issues below provide an overview of the areas identified that require further support to partners to improve capacity and reduce bottlenecks. These activities would need to be detailed in the GAVI workplan and funded appropriately.

Quality assurance (WHO)

Weak NRAs in countries with emerging suppliers represents a barrier to prequalification and purchase by UN agencies and GAVI. Therefore, there is a need to:

1. *Strengthen NRAs* through a range of local and regional mechanisms including high level advocacy, technical support through the NRA assessment, and access to training and networking.
2. *Improve the understanding* of the prequalification process and requirements by emerging suppliers and NRAs with materials and training.
3. *Provide an increase in funding* for securing the availability of high level independent expertise and laboratories for the prequalification work.
4. *Strengthen AEFI surveillance systems* through training of NRA and Expanded Program on Immunization (EPI) staff, national workshops, and establishment of a network of sentinel countries for the post marketing surveillance of novel vaccines.

Country vaccine management and receipt of supplies (UNICEF)

1. Advocate with governments on the importance of proper vaccine management and improve understanding of financial implications.
2. Strengthen country capacity to assess vaccine management systems from central to periphery levels through use of existing tools (Effective Vaccine Store Management and Vaccine Management Assessment).
3. Provide support for the development of institutional strengthening plans and access to appropriate capacity building opportunities (such as GTN on Vaccine Management)

The Secretariat will develop a plan to strengthen country capacity in vaccine management and commission work to explore further the possibility of long-term capacity for in-country procurement.

The significant economies of scale that exist with vaccine procurement make the economics of individual vaccine procurement by countries not particularly efficient. However, efforts as part of the High Level Forum on MDGs and the Global Health Architecture, explicit objectives are being set for countries to do their own procurement. While this is a reality for pharmaceutical procurement, to date, country procurement of vaccines, particularly in sub-Saharan Africa remains minimal. The lack of domestic vaccine production in many of these countries is a contributing factor, however, further analysis on the current situation is needed to look at the long-term prospects for building country procurement capacity.

4.5 Conclusions

The task team was created to provide a Hib and HepB supply strategy to the GAVI Boards. Each of the supply elements was analysed by a team composed of both partners and external members. By identifying the problems in the Alliance to date and opportunities for improvement, the team identified three major recommendations for the Boards. These recommendations provide a process for broader involvement in supply issues through the reference group. Furthermore, clearer roles and responsibilities of the procurement agent vis a vis the Alliance through the MOUs is critical. While focused on Hib and HepB, a number of broader issues regarding supply have been raised and the group has proposed a number of actions on which the Board is asked to provide guidance.

Annex 1: GAVI Supply Task Team

Summary on Global Demand Forecasting

Introduction

Industry has emphasized the need for accurate and predictable demand to plan for provision of vaccines to GAVI. Given the analysis in section 3, it was suggested that GAVI assess middle-income country demand to determine the size of the global DTP-combination vaccine market. In addition, given the number of variables influencing demand, projections should best be represented as a range.

The two factors that most influence the forecast are the year of vaccine introduction by a new country and the coverage increase trajectories. In the low uptake scenario, these two factors have been set as follows:

1. Projected dates of new vaccine introduction are very conservative and only include countries already approved or known to have already introduced the vaccine.
2. The immunization coverage trajectories assume continuation of current trends, starting from current estimated levels (WHO/UNICEF best estimates), assuming that no additional resources are provided to countries to scale up.

While there remains some level of uncertainty with this low uptake scenario (e.g. the influence of co-financing requirements on bridge financing countries use of the vaccine or choice of presentations is unknown), GAVI would be able commit itself to purchase these quantities with a limited level of financial risk. It will be important, however, to signal to industry that demand may increase substantially; indication of the higher figures will need to be provided as well.

Purpose

As part of the activity plan of the GAVI Supply Task Team, global demand projections for Hib- containing and Hep B-containing vaccines have been estimated for the years 2006-2010. The modelling includes projections for countries eligible for GAVI Phase II as well as GAVI non-eligible countries. The vaccine demand projections have been calculated for the following formulations: DTP-Hep B+Hib, DTP+ Hib, Hib monovalent, DTP-Hep B, Hep B monovalent.

Projections are based upon countries which had either introduced the relevant vaccine by 2005, or by countries which WHO *anticipates* will introduce the relevant vaccine prior to 2011.

Methodology

From the starting point of 192 Member States of the United Nations, the study focused on **144 Member States**. The total birth cohort all countries studied is 79,643,000 (as at 2004).

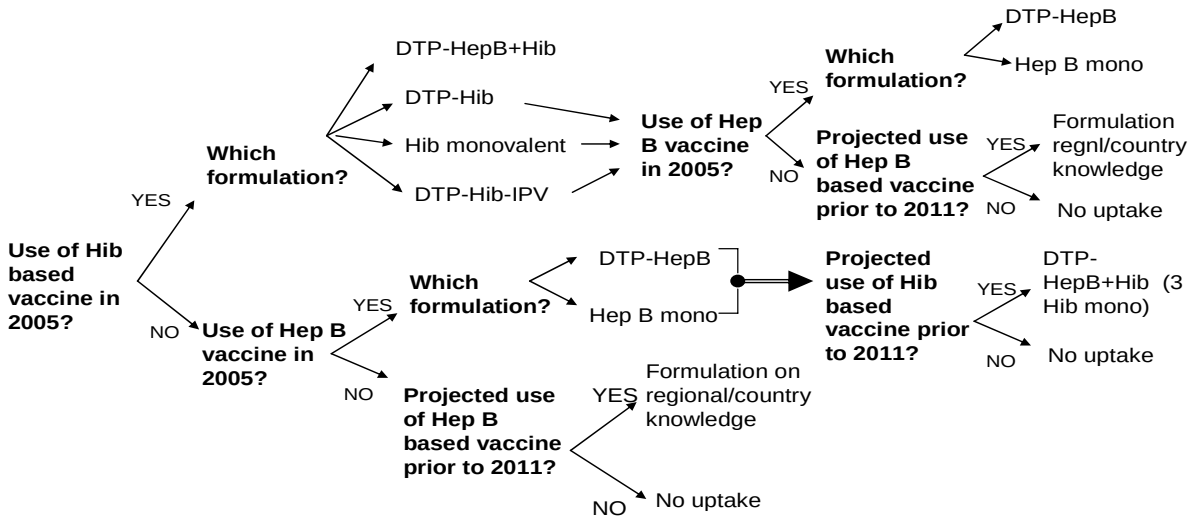
The 48 Member States that were removed from the study were excluded under the following conditions:

a) They currently report using acellular pertussis -- or based upon regional knowledge and trends, it is *anticipated* that this would be the country's formulation choice at adoption.
b) They depend heavily upon local vaccine production so it is presumed that national decisions about vaccine uptake will not significantly influence the evolution of the global market. In this instance, these 'special cases' include only China and India.
c) The population of the country is so small that the size of birth cohort is not available from UNDP sources (i.e., generally less than 5,000 births per year). This includes many of the small Western Pacific Island countries.

Of the 144 Member States included in the study, 68 are considered eligible for GAVI Phase II and 76 non-GAVI eligible. Among these 144 Member States:

- 57 countries reported using a Hib-based vaccine formulation as at 2004
- 114 countries reported using a Hep B-based vaccine formulation as at 2004, with 27 projected to adopt before 2011

The triage of the 144 Member States according to vaccine demand projections was conducted using the following decision tree:



For the 68 GAVI eligible countries, the data generated is extracted directly from the vaccine demand forecasting tool currently used by GAVI to furnish information to UNICEF Supply Division.[28]

Two potential scenarios were projected for all five vaccine types studied and were applied consistently to all country settings, whether GAVI eligible or non-GAVI

[28] The exceptions to this are Bolivia, Cuba, Honduras and Nicaragua, which are GAVI eligible countries, but already procure their new vaccines through the PAHO Revolving Fund.

eligible. The parameters used in the ***high-uptake*** and a ***low-uptake*** model can be described as follows:

	High-Uptake Model	Low-Uptake Model
Immunization Coverage Trajectory	Annual increases in coverage based on standardized step-wise increases in coverage, starting from reference year, 2004. Assumption that countries will attain 90% coverage by 2010. If reference year is =>85%, 2010 coverage estimated at 95%.[29]	Annual increases based on fitted model from WHO ICE-T database. Coverage is predicted to evolve given no additional resources (based on trends between 1996-2002, launching off from reported 2003 coverage)
Projected Date of Vaccine Introduction (prior to 2011)	Based on data extrapolated from GAVI application process, reported in JRF, or knowledge about epidemiogical patterns, national income levels, and neighboring country or regional trends in vaccine adoption. See Table **One** for dates of introduction for these 65 countries.	No assumptions about projected date of introduction or uptake, unless already GAVI approved, or known to have already introduced vaccine by year 2005.[30] Other countries where introduction is not definitive are not included in the vaccine demand model. See Table **One** for dates of introduction for these 14 countries.

Assumptions Used

To estimate global vaccine demand, key data assumptions were used when forecasting needs in both the ***high-uptake*** and a ***low-uptake*** models. These are summarised below.

	GAVI eligible countries:	Non-GAVI eligible countries:
Birth Cohort:	As used to calculate vaccine needs. Typically consistent with JRF, unless the country reports other target population figures in the proposals or Annual Progress Reports (APRs).	Based upon UNDP figures from 2002. (most recent available at time of modelling)
Immunization Coverage:	Based on DTP 1 projected coverage goals 2006-2010, as reported by the country in APRs. If country projections are not given, estimations are based on the Delphi technique.	Reference year is 2004 from JRF (or WHO/UNICEF best estimates if unavailable). Coverage averages used (DTP1+DTP3)/2 to reduce risk of over or under-estimation.[31]
	Based on GAVI application approval or upon Delphi	Based on dates given in JRF or as reported by WHO regional offices.

[29] If reference year coverage =>95%, the projected coverage remained fixed over the five years
[30] The exceptions to this are Iran and Botswana which are both non-GAVI eligible and are certain to introduce DTP-HepB+Hib in 2006.
[31] If available in the JRF, Hib3 or Hep3 coverage figures were used instead of DTP3

Projected Date of Vaccine Introduction (prior to 2011):	technique.	In other cases, based upon country or regional understanding of burden of disease (known/unknown) and economic status (ability to pay).
Wastage Factors:	Based on figures given by country in APRs, or using standard GAVI formulas based on vaccine type, formulation (liquid or lypholised) and presentation (doses/vial)	Using standard GAVI formulas based on vaccine type, formulation (liquid or lypholised) and presentation (doses/vial). If presentation unknown, assumed to be 10 dose.
Buffer Stock:	25% of doses required in 1st year of introduction. In future years, 25% of the annual differential in number of children to be vaccinated.	25% of doses required in 1st year of introduction. In future years, 25% of the annual differential in number of children to be vaccinated.

Limitations

For GAVI eligible countries, accuracy of forecasts are limited by the level of accuracy associated with country self-reported data on population and birth cohort, coverage projections and wastage rates. Under the new GAVI policy framework of bridge financing, where countries increasingly take on the responsibility to finance these vaccines, there is the risk that vaccine demand projections may be erroneous over the long-term.

For non-GAVI eligible countries, calculations had to be based on multiple assumptions, including:

1. Population extrapolations based on UNDP 2002 global data rather than official country data;
2. In the case of the high-uptake model, annual coverage increases were based on a step-wise formula rather than country projections and trends;
3. For countries which had not yet introduced Hep B or Hib containing vaccines as at 2005, projected date of year of adoption based on knowledge about epidemiogical patterns, neighboring country or regional trends in vaccine adoption and national income levels;
4. For countries which had not yet introduced Hep B or Hib containing vaccines as at 2005, projected vaccine presentation of choice (ie, monovalent or combination), based on existing vaccines in EPI schedule and country/regional knowledge;
5. Application of vaccine wastage calculations based on standard GAVI formula rather than on reported country data;
6. For countries using multiple presentations (ie, Hep B monovalent and combination), assumptions made about Hep B birth cohort policy if data unavailable in JRF.

An additional limitation is that countries which report using or are anticipated to use acellular pertussis may also use Hepatitis B monovalent or Hib monovalent products, but this is not reflected in the projected estimates.

Findings

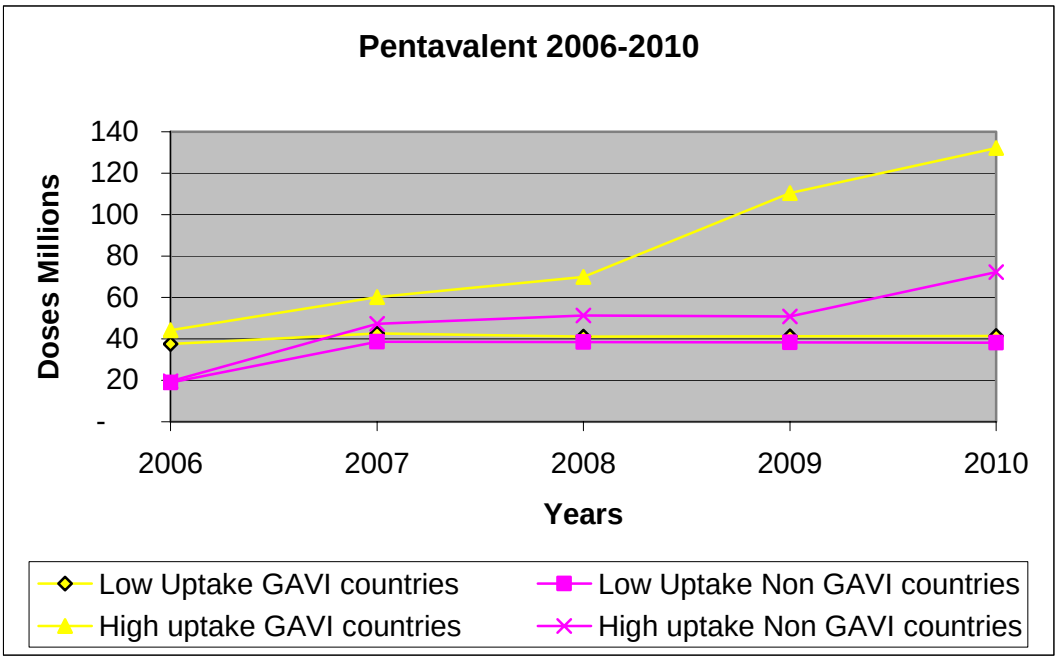
Summary findings regarding vaccine demand for 2006 to 2010 are represented below. Specific data points are included in the tables in **Annex Two**.

Graphic A. DTP-HepB+Hib vaccine demand

For pentavalent vaccine, the vaccine uptake trends for GAVI and non-GAVI eligible countries in the low-uptake model remain relatively stable.

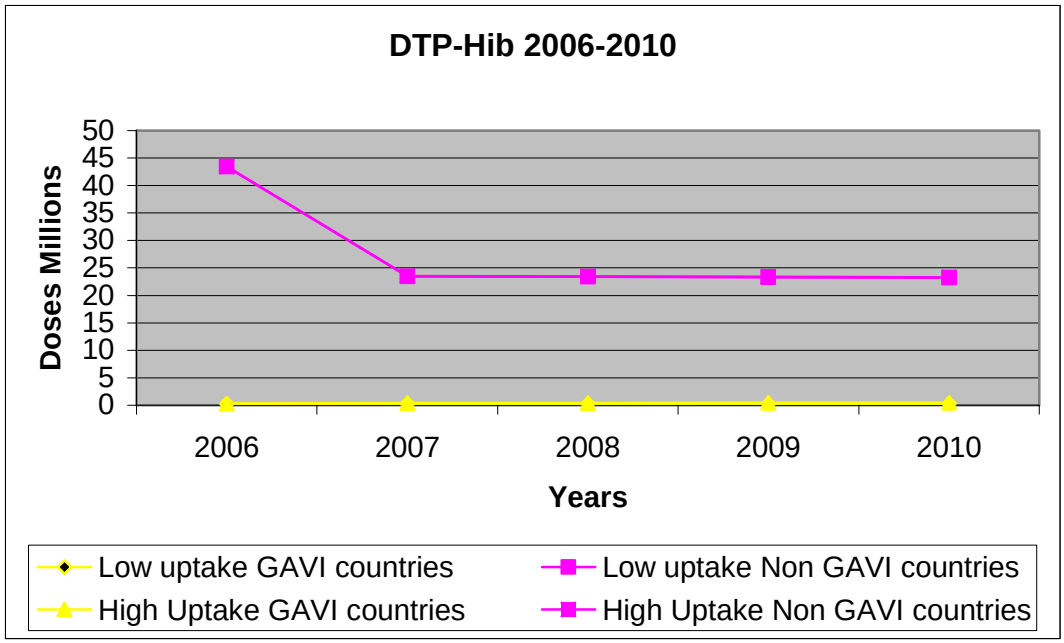
In the high-uptake model, the sudden peak among GAVI countries in the years between 2008 to 2010 are due to the additional vaccine demand of eight large or relatively populous countries. This includes in 2009, Central African Republic, Nepal, Nigeria and Pakistan and in 2010, Bangladesh, Chad, Georgia and Myanmar.

In the high-uptake model among non-GAVI eligible countries, the growth trend between 2009 and 2010 is due to the projected DTP-HepB+Hib introduction of 15 countries, ten of which fall in the European region.



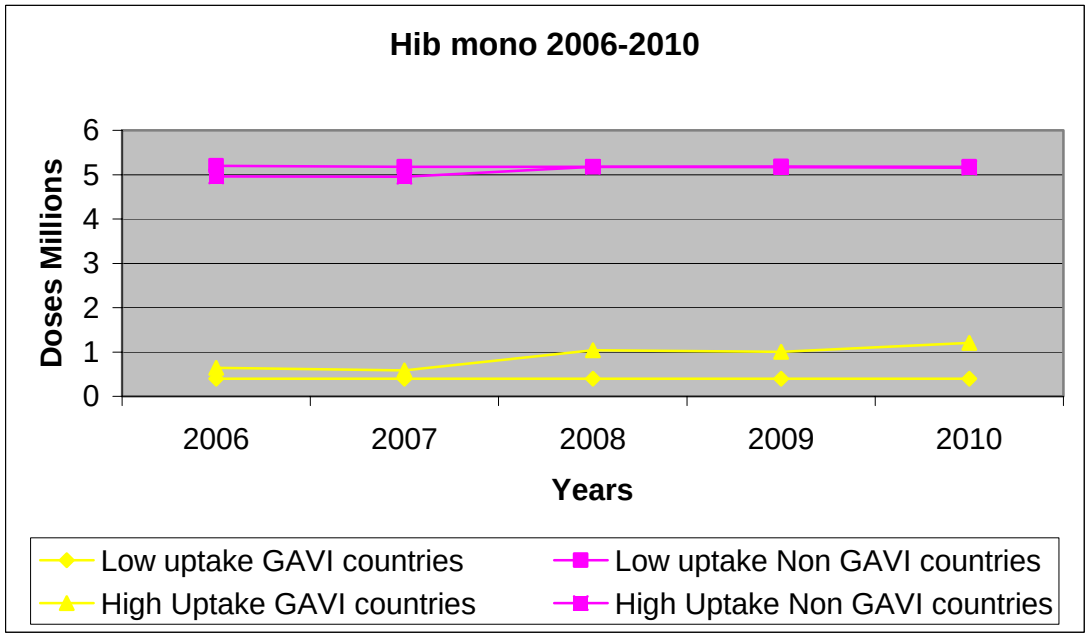
Graphic B. DTP-Hib vaccine demand

For DTP-Hib vaccine, the differential between the respective high-uptake and low-uptake scenarios is not dramatic, as most countries are not projected to adopt this formulation. Additionally, it can be seen that most countries currently using this vaccine type are not GAVI eligible. The sudden decrease in demand of approximately 20 million doses in 2006-2007 (high-uptake non-GAVI eligible) is due to the expected switch of Brazil from use of DTP-Hib to DTP-HepB+Hib.



Graphic C. Hib monovalent vaccine demand

As with DTP-Hib vaccine, most countries currently using Hib monovalent are not GAVI eligible. Similarly, the negligible differential between the respective high-uptake and low-uptake scenarios is because few countries are projected to adopt this formulation prior to 2011. Those GAVI countries which are using Hib monovalent fall primarily in regions of the Americas and Europe.



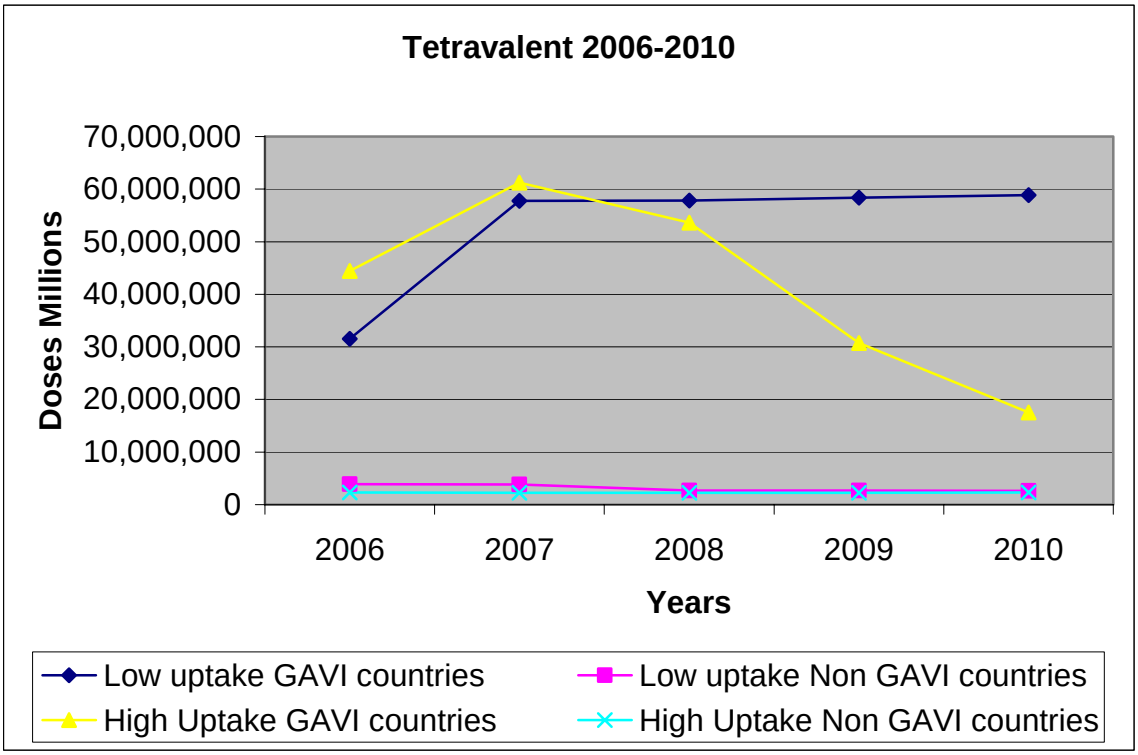
Graphic D. DTP-Hep B vaccine demand

For the non-GAVI eligible countries, vaccine demand for DTP-Hep B remains stable in both the low-uptake and high-uptake models.

In the high-uptake model for GAVI countries, the sudden drop off in demand of approximately 44 million doses from 2007 to 2010 a is largely due to the switch from

DTP-HepB to DTP-HepB+Hib of numerous countries. These include in 2007 Cameroon, Tanzania and Mozambique, in 2008 Bhutan, Cote d'Ivoire, Madagascar and Congo, in 2009 of Nepal, Pakistan and Central African Republic and in 2010 of Bangladesh.

In the low-uptake model for GAVI countries, the increase of 26 million doses is due to the switch of both Pakistan and Bangladesh from Hepatitis B monovalent to DTP-Hep B.



Graphic E. Hep B monovalent vaccine demand

For Hepatitis B monovalent, the low-uptake and high-uptake models for both GAVI and non-GAVI eligible countries almost seem counter-intuitive, as the low-uptake demand consistently exceeds that of high-uptake. But this is because in the low-uptake model, it is presumed that countries will adhere to their current vaccine type with no switch-over; in contrast, in the high-uptake model, the projection is made that countries will shift from use of Hep B monovalent to a DTP-based combination vaccine prior to 2011.

Hence the drop-off of almost 50 million doses in 2006-2007 among high-uptake GAVI countries, which, as stated above includes the switch of both Pakistan and Bangladesh from Hepatitis B monovalent to DTP-Hep B, plus the switch of Tanzania, Sudan, Mozambique and Cameroon to DTP-HepB+Hib. Among the high-uptake non-GAVI eligible countries, the drop-off of 14 million doses in 2009 is primarily explained by the anticipated switch of Iran, the Russian Federation and Turkey to DTP-HepB+Hib. Among the nine non-GAVI eligible countries expected to move away from Hepatitis B monovalent prior to 2011, two-thirds are from the European region.

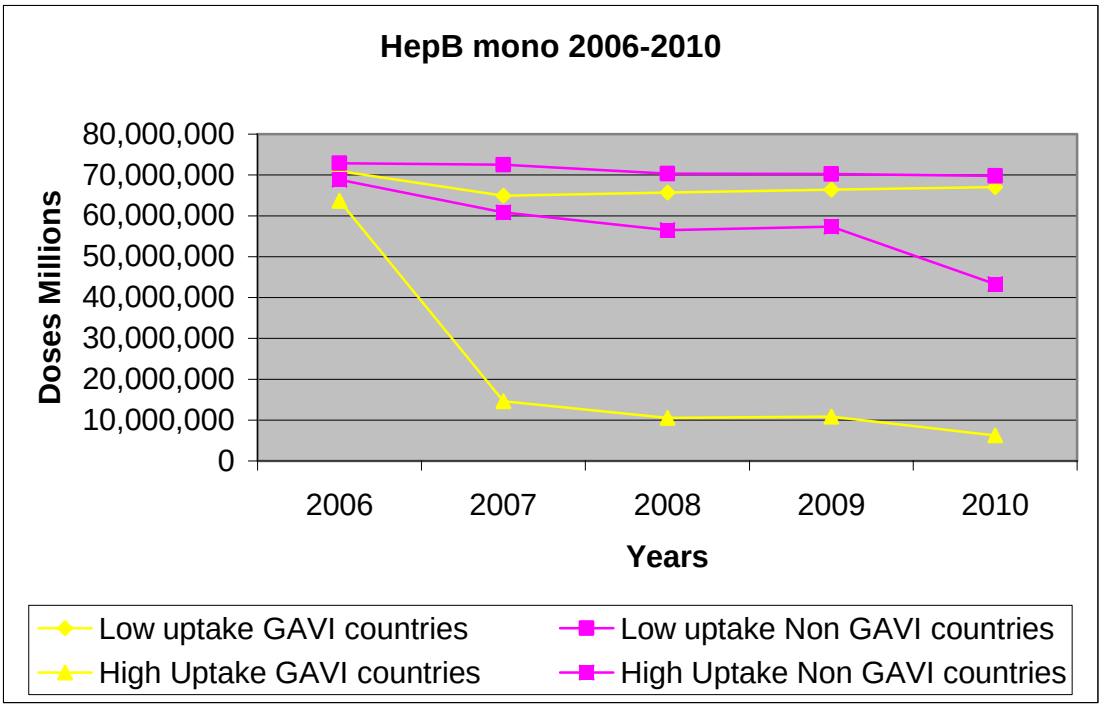

HepB mono 2006-2010
Doses Millions
80,000,000
70,000,000
60,000,000
50,000,000
40,000,000
30,000,000
20,000,000
10,000,000
0
2006
2007
2008
2009
2010
Years
Low uptake GAVI countries
Low uptake Non GAVI countries
High Uptake GAVI countries
High Uptake Non GAVI countries

Table 1

Projected dates of DTP-HepB+Hib introduction in **high-uptake** and **low-uptake** models, organised by region. Lines shaded represent those countries which are GAVI eligible countries as at 2005.

Country name	Region	Vaccine Fund eligible	Date of introduction (High-uptake model)	Date of introduction (Low-uptake model)
Angola	AFRO E/S	Yes	2006	2006
Benin	AFRO W/C	Yes	2006	2006
Burkina Faso	AFRO W/C	Yes	2006	2006
Cameroon	AFRO W/C	Yes	2007	Not introduced
Central African Republic	AFRO W/C	Yes	2009	Not introduced
Chad	AFRO W/C	Yes	2010	Not introduced
Côte d'Ivoire	AFRO W/C	Yes	2008	Not introduced
Eritrea	AFRO E/S	Yes	2007	2007
Ethiopia	AFRO E/S	Yes	2006	2006
Guinea	AFRO W/C	Yes	2007	Not introduced
Guinea-Bissau	AFRO W/C	Yes	2007	Not introduced
Liberia	AFRO W/C	Yes	2007	Not introduced
Madagascar	AFRO E/S	Yes	2008	Not introduced
Mali	AFRO W/C	Yes	2007	2007
Mozambique	AFRO E/S	Yes	2007	Not introduced
Niger	AFRO W/C	Yes	2006	2006
Nigeria	AFRO W/C	Yes	2009	Not introduced
Sao Tome and Principe	AFRO W/C	Yes	2007	Not introduced
Sierra Leone	AFRO W/C	Yes	2007	Not introduced
The Republic of the Congo	AFRO W/C	Yes	2008	Not introduced
Togo	AFRO W/C	Yes	2006	2006
United Republic of Tanzania	AFRO E/S	Yes	2007	Not introduced
Zimbabwe	AFRO E/S	Yes	2007	2007
Algeria	AFRO W/C	No	2008	Not introduced
Botswana	AFRO E/S	No	2006	2006
Mauritius	AFRO E/S	No	2010	Not introduced
Namibia	AFRO E/S	No	2010	Not introduced
Swaziland	AFRO E/S	No	2010	Not introduced
Haiti	AMRO	Yes	2007	Not introduced
Afghanistan	EMRO	Yes	2012	Not introduced
Djibouti	EMRO	Yes	2006	2006
Pakistan	EMRO	Yes	2009	Not introduced
Sudan	EMRO	Yes	2007	2007
Egypt	EMRO	No	2007	Not introduced
Iran (Islamic Republic of)	EMRO	No	2010	Not introduced
Iraq	EMRO	No	2006	2006
Libyan Arab Jamahiriya	EMRO	No	2006	Not introduced
Morocco	EMRO	No	2008	Not introduced
Armenia	EURO	Yes	2006	Not introduced
Azerbaijan	EURO	Yes	2008	Not introduced
Georgia	EURO	Yes	2010	Not introduced
Albania	EURO	No	2010	Not introduced
Belarus	EURO	No	2010	Not introduced
Bulgaria	EURO	No	2010	Not introduced
Kazakhstan	EURO	No	2010	Not introduced
Romania	EURO	No	2010	Not introduced
Russian Federation	EURO	No	2010	Not introduced
Serbia Montenegro (Yugoslavia)	EURO	No	2010	Not introduced
The former Yugoslav Republic of Macedonia	EURO	No	2010	Not introduced
Turkey	EURO	No	2010	Not introduced
Turkmenistan	EURO	No	2010	Not introduced
Bangladesh	SEARO	Yes	2010	Not introduced
Bhutan	SEARO	Yes	2008	Not introduced
Myanmar	SEARO	Yes	2010	Not introduced
Nepal	SEARO	Yes	2009	Not introduced
Sri Lanka	SEARO	Yes	2007	2007

Viet Nam	**WPRO**	**Yes**	2008	Not introduced
Singapore	**WPRO**	**No**	2010	Not introduced
Vanuatu	**WPRO**	**No**	2008	Not introduced

Table 2

Table A. DTP-HepB+Hib vaccine demand

	Low-uptake			High-uptake		
	GAVI countries	**Non GAVI countries**	**Total**	**GAVI countries**	**Non GAVI countries**	**Total**
2006	37,550,835	18,956,874	**56,507,709**	44,232,336	19,565,659	**63,797,995**
	66%	*34%*	*100%*	*69%*	*31%*	*100%*
2007	42,731,851	38,675,352	**81,407,203**	60,295,344	47,352,102	**107,647,446**
	52%	*48%*	*100%*	*56%*	*44%*	*100%*
2008	41,175,216	38,528,015	**79,703,231**	69,897,212	51,340,021	**121,237,233**
	52%	*48%*	*100%*	*58%*	*42%*	*100%*
2009	41,280,880	38,360,461	**79,641,341**	110,437,916	50,749,781	**161,187,697**
	52%	*48%*	*100%*	*69%*	*31%*	*100%*
2010	41,370,378	38,226,355	**79,596,733**	132,090,218	72,183,221	**204,273,439**
	52%	*48%*	*100%*	*65%*	*35%*	*100%*

Table B. DTP-Hib vaccine demand

	Low-uptake			High-uptake		
	GAVI countries	**Non GAVI countries**	**Total**	**GAVI countries**	**Non GAVI countries**	**Total**
2006	273,906	43,417,781	**43,691,687**	290,683	43,437,973	**43,728,656**
	1%	*99%*	*100%*	*1%*	*99%*	*100%*
2007	270,810	23,452,243	**23,723,053**	411,396	23,491,628	**23,903,024**
	1%	*99%*	*100%*	*2%*	*98%*	*100%*

2008	267,750	23,388,074	**23,655,824**	428,681	23,447,193	**23,875,874**
	1%	*99%*	*100%*	*2%*	*98%*	*100%*
2009	264,690	23,306,463	**23,571,153**	446,692	23,378,600	**23,825,292**
	1%	*99%*	*100%*	*2%*	*98%*	*100%*
2010	261,630	23,222,245	**23,483,875**	465,459	23,309,743	**23,775,202**
	1%	*99%*	*100%*	*2%*	*98%*	*100%*

Table C. Hib monovalent vaccine demand

	Low-uptake			High-uptake		
	GAVI countries	**Non GAVI countries**	**Total**	**GAVI countries**	**Non GAVI countries**	**Total**
2006	400,666	5,195,168	**5,595,834**	644,746	4,961,419	**5,606,165**
	7%	*93%*	*100%*	*12%*	*88%*	*100%*
2007	397,535	5,179,152	**5,576,687**	587,236	4,952,431	**5,539,667**
	7%	*93%*	*100%*	*11%*	*89%*	*100%*
2008	397,535	5,179,008	**5,576,543**	1,038,083	5,178,268	**6,216,351**
	7%	*93%*	*100%*	*17%*	*83%*	*100%*
2009	397,535	5,185,442	**5,582,977**	1,001,650	5,168,619	**6,170,269**
	7%	*93%*	*100%*	*16%*	*84%*	*100%*
2010	397,535	5,175,549	**5,573,084**	1,203,080	5,158,596	**6,361,676**
	7%	*93%*	*100%*	*19%*	*81%*	*100%*

Table D. DTP-Hep B vaccine demand

	Low-uptake			High-uptake		
	GAVI countries	**Non GAVI countries**	**Total**	**GAVI countries**	**Non GAVI countries**	**Total**
2006	31,530,856	3,893,181	**35,424,037**	44,453,836	2,303,028	**46,756,864**
	89%	*11%*	*100%*	*95%*	*5%*	*100%*
2007	57,788,202	3,839,936	**61,628,138**	61,234,184	2,277,300	**63,511,484**
	94%	*6%*	*100%*	*96%*	*4%*	*100%*
2008	57,799,799	2,695,513	**60,495,312**	53,642,368	2,255,409	**55,897,777**
	96%	*4%*	*100%*	*96%*	*4%*	*100%*
2009	58,363,230	2,662,979	**61,026,209**	30,738,306	2,235,929	**32,974,235**

	96%	*4%*	*100%*	*93%*	*7%*	*100%*
2010	58,846,049	2,632,609	**61,478,658**	17,529,664	2,312,375	**19,842,039**
	96%	*4%*	*100%*	*88%*	*12%*	*100%*

Table E. Hep B monovalent vaccine demand

	Low-uptake			High-uptake		
	GAVI countries	**Non GAVI countries**	**Total**	**GAVI countries**	**Non GAVI countries**	**Total**
2006	70,971,611	72,862,050	**143,833,661**	63,708,249	68,790,952	**132,499,201**
	49%	*51%*	*100%*	*48%*	*52%*	*100%*
2007	64,902,497	72,487,353	**137,389,850**	14,574,934	60,861,185	**75,436,119**
	47%	*53%*	*100%*	*19%*	*81%*	*100%*
2008	65,735,990	70,280,347	**136,016,337**	10,534,260	56,507,007	**67,041,267**
	48%	*52%*	*100%*	*16%*	*84%*	*100%*
2009	66,373,208	70,214,849	**136,588,057**	10,835,842	57,355,683	**68,191,525**
	49%	*51%*	*100%*	*16%*	*84%*	*100%*
2010	66,998,814	69,756,471	**136,755,285**	6,278,120	43,266,513	**49,544,633**
	49%	*51%*	*100%*	*13%*	*87%*	*100%*

Annex 2: Terms of Reference:

Supply Strategy Task Team

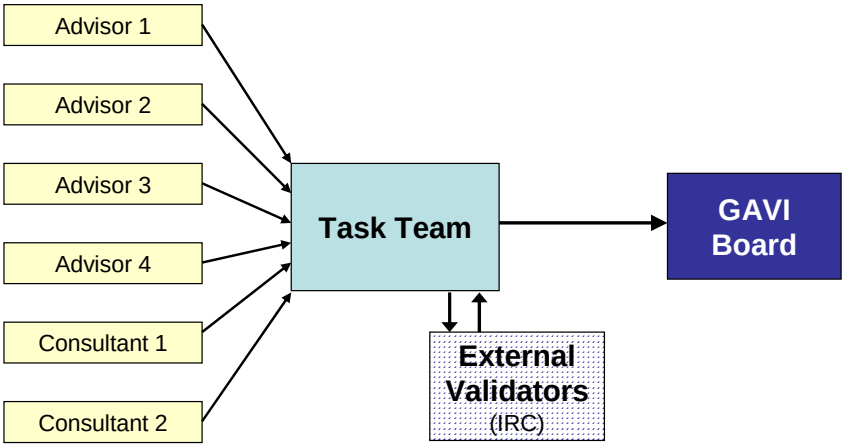
BACKGROUND
Following discussion at the GAVI Board and work to date by Alliance members towards building a supply strategy, it has been proposed that a small task team of GAVI Partners be established to complete the development of supply strategies for GAVI/VF for HepB and Hib containing vaccines, with priority given to combination vaccines.

OBJECTIVE
The objective of this task team is to develop supply strategies for HepB and Hib containing vaccines, based on approved GAVI procurement principles that maximize GAVI/VF's leverage and flexibility. It is anticipated that this will result in an overarching framework that can be used to develop future product supply strategies. Subsequently, these will need to be reviewed and integrated into a comprehensive GAVI/VF supply strategy that addresses inter-linkages.

TASK TEAM
The proposed task team includes members from the following GAVI partners along with a coordinator from the GAVI/VF Secretariat (Andrew Jones). The task team is made up of GAVI partners that have knowledge of the various inputs to a supply strategy. Expertise that does not exist among the members will be brought in throughout the process as needed:

Gates Foundation:	Gargee Ghosh
UNICEF Programme:	Peter Salama
UNICEF SD:	Shanelle Hall
World Bank:	Amie Batson
WHO:	Diana Chang-Blanc / Michel Zaffran / Patrick Zuber
Canada[32]:	Montasser Kamal
Industry Perspective:	Angeline Nanni
Developing countryPerspective:	Mercy Ahun (GAVI Secretariat)

[32] Between the Canada and UK membership, one of the members will have experience in vaccine supply chain and the other will have a good knowledge of the GAVI alliance, it's principles, processes and the programmes. The latter will serve as the Chair.



PROCESS

This is a mix of process (ie, have 3 meetings) and Expected Outcomes (develop and present a final report) -- suggest separate for clarity In developing Hib and HepB containing vaccine supply strategies for GAVI/VF, the task team, in consultation with external advisors and consultants, will be expected to:

- Identify where we are now with regard to the vaccine market and work to date by Alliance members
- Define the necessary inputs for assembling product-specific supply strategy options and set out a clear work-plan for the development of supply strategy options for Hib and hepB containing combination vaccines
  - At a minimum, meet on three occasions to report on progress toward developing options and achieve consensus on recommendations (with interim teleconferences as needed)
  - Provide an interim report to the joint ECs in September
- Engage an independent group of experts proposed by the Board to validate and provide feedback regarding the proposed final deliverables/recommendations
- Develop and present a final task team report on deliverables/recommendations to the GAVI Board

DELIVERABLES

Completed supply strategies for HepB and Hib containing vaccines based on approved GAVI procurement principles that maximize GAVI/VF's leverage and transparency. This is anticipated to inform a broader supply framework for future GAVI/VF procurement.

The supply strategy will include:

1. Description of Current Environment including:

- Market situation analysis including supply and demand landscape
- A situation analysis of supply chain activities including analysis of current practices, constraints, best practices, accountabilities and costs for each activity (e.g. forecasting, procurement, interaction with countries)
- Provision of scenarios which forecast future GAVI demand (with clearly outlined assumptions) including:
  - Future or expected GAVI programme decisions
  - Future expected country programme decisions (based on national priorities and disease burden, etc.)

- Funding availability
- Co-financing policies

2. Supply Strategy Options and Implications

- Supply and procurement options to meet product specific objectives and an analysis of their costs, timing, risks, benefits and potential impact on countries, industry and GAVI partners including meeting country demand

3. Recommended Supply Strategy (including implementation plan)

- Product-specific plans for the initiation in early 2006 of procurement activities for Hib and hepB containing vaccines that would cover vaccines to be supplied from 2007. A completed plan is comprised of, but not limited to, the following:
  - Description of products to be procured: quantities, programmatic and technical specifications, timeframe
  - Demand forecast utilized and identification of limitations of forecast
  - Evaluation of procurement options related to type of solicitation and contracts to be developed
  - Contracting terms for suppliers: duration, risk sharing, incentive systems, evaluation criteria, award procedures, warranties and liabilities, payments
  - Contract execution: contract management, availability management
  - (coordinating supply and demand between suppliers and countries), shipment, in-country clearance and receipt, inspection, AEFI follow-up

- Definition of optimum processes and organizational responsibilities as they pertain to the recommended supply strategy including:
  - GAVI application and reporting processes
  - Financing, including link between national and global support mechanisms
  - Forecasting – improvements to maximize accuracy and timeliness
  - Methodology for selection of procurement agent: scope of services, selection criteria and procedures, contract terms
  - Benchmarks/performance indicators for measuring progress

4. Overall Framework: Product specific strategies for Hib and HepB containing vaccines are anticipated to provide a general template for future GAVI products and inform a broader supply strategy.