The Vaccine Provision Project (VPP)

Lessons Learned from the Pilot Phase
July 02 – October 03

Draft 29 Nov 03
Under Institutional Review

EXECUTIVE SUMMARY

This paper summarizes the outcomes and the lessons learned in the second round of vaccine forecasting and procurement organized by the Global Alliance for Vaccines and Immunization (GAVI) for countries eligible for support from the Vaccine Fund.

It has been prepared by Paul Richard Fife[1] in consultation with the institutions tasked by the GAVI Board to pilot the coordinated planning and execution of forecasting and procurement of Vaccine Fund supported vaccines for 2004-06 through the Vaccine Provision Project (VPP), i.e. UNICEF, WHO and the Vaccine Fund, with support from the GAVI Secretariat.

Project background and justification

The GAVI Board established the Vaccine Provision Project in June 2002 based on an in-depth analysis of the global vaccine market and a review of the lessons learned in the first round of GAVI procurement in 2000[2]. Key recommendations endorsed by the Board were as follows:

- Given GAVI's strategic objectives of accessing new products early and obtaining affordable pricing, the GAVI alliance should seek to maintain/enhance large multinational supplier engagement and expand the number of economically viable and high quality emerging suppliers by providing for appropriate returns, creating credible and predictable demand (in part through firm contracting) and working in a collaborative and open fashion with suppliers.

- In light of the shortcomings and inefficiencies observed during the first round of procurement, the alliance should adopt a multi-disciplinary project management approach to forecasting and procurement across program, supply and finance and pilot this with the GAVI forecasting and procurement for 2004-06, with WHO responsible for program issues, UNICEF Supply Division for supply issues, the Vaccine Fund for finance issues, and responsibility for overall coordination and accountability vested in a project manager located in UNICEF Programme Division (to retain a strong program focus WHO and UNICEF PD were provided as options).

Main outcomes

Offers

43 products were offered from emerging suppliers and from US and Europe based multinationals. This confirms that GAVI has been successful in stimulating the projected entry of new manufacturers in the production of HepB, Hib and Yellow Fever vaccines for low-income countries, in particular DTP-HepB. Provided efforts are maintained, this will stimulate competition and lead to price pressure as more suppliers enter the market and products mature.

GAVI/Vaccine Fund procurement 2004-06: Summary of Offers

[1] Sr. Health Advisor and VPP Project Manager in UNICEF PD/Health Section until July 2003

[2] Lessons Learned: New Procurement Strategies for Vaccines, Mercer Management Consulting, 28 June 2002

Product	Number of offers	Number of WHO pre-qualified products	Number of non WHO pre-qualified products
HepB	13	6	7
HepB uniject	4	0	4
Hib	4	2	2
DTP-HepB	11	1	10
DTP-HepB+Hib	4	1	3
DTP+Hib	1	1	0
Yellow Fever	4	2	2
Total	41	13	28

Source: UNICEF SD

Awards 2004-06

While awards were originally scheduled to be finalised in June 2003, awards for the full period 2004-06 have as of mid-November 2003 not been issued and made public.

- To date the Vaccine Fund Executive Committee has given its financial approval for the procurement of combination vaccines for the period 2004-06 for already approved countries. These quantities are firmly contracted and represent an estimated total value of US$281.3 million.

- Subject to parameters of the Five Year Supply Approval policies approved by GAVI and the Vaccine Fund in June 2003, financial approval has been given for all monovalent products for 2004-06 representing an estimated total value of US$145.4 million.

- Procurement arrangements for combination vaccine for countries that plan to switch products or that are not yet approved are still outstanding and not secured following the request from the Vaccine Fund Executive Committee to not lock into this option and to explore alternatives.

Procurement arrangements for 2004 have been completed in order to secure timely vaccine delivery. Concerned suppliers have being kept abreast of the situation.

Vaccine prices

The price of monovalent HepB continued to decrease in this procurement cycle, with weighted average price per dose decreasing from $0.32 in 2003 to $0.28 in 2004, and to $0.26 in 2006. This represents a decrease of 22% between 2003 and 2006.

Prices for DTP-based combination vaccines increased in this procurement round, with a price jump between 2003 and 2004 of 10% for DTP-Hep+Hib and of 27% for DTP-HepB. Compared with 2001, dose prices in 2006 will increase from $3.50 to $3.60 (i.e. 3%) for DTP-hepB+Hib, and from $1.10 to 1.29 (i.e. 15%) for DTP-hepB.

Overview of volume quantity and price of vaccines 2004-06

		2004	**2005**	**2006**
DTP-HepB	Quantity	11,834,800	15,615,550	44,500,000
	Price	$1,21	$1,25	$1.29
DTP-HepB+Hib	Quantity	15,942,956	33,384,448	37,950,000
	Price	$3.65	$3.60	$3.60
HepB	Quantity	42,400,000	35,500,000	16,000,000

	Price	$0,28	$0,26	$0,25

Quantity: Quantities delivered in 2001-2003 and forecasted 2004-2006
Price: US$ per dose, weighted average price for HepB
Source: UNICEF Supply Division

The price increase is a significant setback and constitutes at least in the near-term a significant challenge for countries and their global partners.

Apparent causes for this increase are the accelerated recouping of investments costs (principally investment into new production facilities but also of original costs), the significant strengthening of the Euro against the US dollar since 2001 when initial prices were set, and supplier pricing strategy (multinational manufacturers typically offer low volumes at relatively high price and chose to exit the market as emerging suppliers enter with larger volumes and lower priced products).

Regarding Hib-containing products, analysis of all offered products indicates that the price of Hib is high compared with the basic pediatrics, but not unreasonably high at this point in time, considering estimated production and regulatory costs, price differences between multinational and emerging suppliers for other basic vaccines, and historical experience. Hib prices are comparable across products and across manufacturers, and the price obtained is also comparable with the one recently obtained by the Pan-American Health Organization (PAHO).

The prices obtained for combination vaccines in this procurement highlight the dependency of pricing on product lifecycle and maturity. Despite considerable supplier movement, the combination products preferred by countries became commercially available specifically for GAVI and are still early in their lifecycle.

Significant and sustained price reductions are not likely to be seen until competition has been established. This will occur earlier for DTP-HepB than for DTP-HepB+Hib, which is a more complex vaccine to produce. Two additional producers of DTP-HepB could be expected to enter the market with pre-qualified products nearing 2006 and product maturity is expected to be seen in 2007-09.

Application of recommended procurement strategies

The procurement strategies recommended in the Mercer report were to a large extent applied in this round of procurement:

- Awards have been designed to seek to enhance the supply base with multiple manufacturers for each product type, engaging both multinational and emerging suppliers. Nine product presentations (4 HepB in different dose sizes, 1 DTP-HepB, 1 DTP+Hib, 1 DTP-HepB+Hib, 2 Yellow Fever in different dose sizes) will be contracted from 8 manufacturers (3 multi-nationals and 5 emerging), based in Belgium, Brazil, Cuba, France, India, South Korea and the United States of America.

- Though permanent demand is not yet in place, considerable progress has been made towards establishing credible and predictable demand. A product-specific forecast for Vaccine Fund support vaccines was established despite severe time constraints and used in the tender, and systems for maintaining the forecast and communicating changes with suppliers have been established. The accuracy of the forecast will be tracked during implementation in 2004-06.

- Firm contracting, seen as proof of the commitment to share risks, helped in this round to leverage some price concessions for DTP-HepB and DTP-Hep+Hib vaccine. So far,

around 40% of the total vaccine value in the round is scheduled for firm contracting. The prevailing monopoly situation for combination vaccines with several buyers vying for limited supply may have limited in this round the value of firm contract on price and volume concessions, and was seen as most useful in assuring supply availability.

- Manufacturer movement and interest may be seen as indication that appropriate returns have been provided for suppliers.

- Though there is still discussion among the partners on how best to engage manufacturers, collaboration and communication with manufacturers improved compared with the first round with access to the forecast and clearer lines of communication.

Project execution

It is important to recognize that the VPP was a pilot effort and something that had never been done before at least in this fashion, and that it was challenged by real time constraints, a maturing alliance that was learning as it worked and unforeseen external factors such as the pentavalent supply crisis. This was compounded by difficulties caused by staff transition, the US based location of the project manager, and the absence of senior staff from the executing agencies on the Oversight Committee.

The VPP pilot confirmed the usefulness and benefits of working in a coordinated manner across the areas of program, supply and finance. With the addition of the GAVI Secretariat, team composition was found to be appropriate with relevant disciplines and partners represented on the team.

The project management approach allowed for better communication among partners, helped to make headway in defining institutional accountabilities, and was instrumental in improving collaboration across institutions and across disciplines. It was especially beneficial at the start of the project and it is doubtful that a product-specific forecast would have been available for use in the tender without the use of a project management approach.

However, shortcomings and inefficiencies were experienced related to project management and control, in particular in the final stages of the project leading to "slippage" in finalising the procurement. This needs to be considered seriously as the alliance takes stock of the situation and decides on the way forward.

The main causes for these inefficiencies may be attributed to:

- Inherent institutional resistance to a project management model, with institutional lines of authority and communication not supporting or not compatible with project management requirements. This includes accountability of team members to the project manager, project manager authority to direct the work of others, and partner access to information and participation in decision-making processes. Though the team members to the most extent worked well together and the project management model allowed for some flexibility, representation by individuals may not have replaced the strength that can be provided by more formal institutional representation and may also have reduced institutional ownership.

- Failure to appropriately identify in advance potential obstacles, set and sequence milestones in particular for new steps and workprocesses, and allow for enough time to address unanticipated challenges. Again it should here be emphasised that it was the first time many of these processes were undertaken, and that future activities will gain from the experiences gained in the pilot.

- Residual ambiguity around partner roles and responsibilities, and failure to effectively address partner differences. This ambiguity led to inefficiencies that could have been

minimized by addressing partner expectations and concerns at an earliest possible stage of the project.

Looking ahead, issues of strategic importance

Seek to decrease the price of combination vaccines as early as possible through increased competition

Significant price reduction for combination vaccines are not likely to be seen until competition is established. GAVI partners should ensure that conditions remain favourable and stimulate competition in the period leading up to the next round of procurement. Current prices for combination vaccines should serve as solid incentives for suppliers.

The GAVI Board should encourage WHO to establish the necessary capacity to enable timely processing of requests for prequalification of new products, so that suppliers can complete vaccine development and pre-qualification processes and be considered for awards.

Firm up demand for Hib-containing vaccine

While demand for HepB and DTP-HepB vaccines is on track to become as established as for the traditional EPI vaccines, demand for Hib-containing vaccine is at critical risk due its relatively high price and the financing gap in the post-Vaccine Fund period. Successful Hib vaccine introduction is critical not only for the credibility of GAVI but also for the credibility of future vaccine introduction initiatives.

WHO and other GAVI partners should continue their efforts to support countries in assessing the appropriateness and the program readiness for introducing Hib-containing vaccines, taking into account the supply situation, financial sustainability and other program priorities.

It is encouraging to see that several countries are taking steps towards phasing in locally-mobilized resources as Vaccine Fund support nears its end. GAVI partners should continue to support country efforts including the implementation and realization of national financial sustainability plans.

GAVI and the Vaccine Fund should as part of their strategic planning for 2005-2015 explore ways of addressing the financing gap for currently supported vaccines. Extending support to products still early in their lifecycle may be an option to consider in order to firm up demand until competition is established and more affordable pricing has been achieved.

In view of the DTP-HepB+Hib supply constraints, countries wanting to introduce Hib vaccine may wish to consider alternative Hib-containing products (monovalent Hib, DTP+Hib). Though this in itself would not contribute to increase competition for DTP-HepB+Hib vaccine, it would help accelerate the use of Hib vaccine, protect more children from Hib disease and reduce dependency on one single product. It should be emphasised however that such decisions need to be made by countries themselves.

Recommendations

VPP Project Scope 2004-05

1. As already reflected in the draft GAVI workplan for 2004-05, efforts of the Alliance should be structured around two main areas of work:

(a) A primary focus on risk management at global level of HepB, Hib and Yellow Fever vaccine introduction.

With the majority of Vaccine Fund eligible countries well underway with the introduction of newer vaccines, and with a US$570 million procurement plan for 2004-06 soon in place to support this effort, the need to effectively manage vaccine provision at global level is critical. In particular, the alliance needs to have the capacity to detect and act when problems or changes related to program implementation, supply or funding arise, such as new approvals, changes in supply availability, or funding shortfalls.

At global level, a risk management approach grounded on close monitoring of vaccine provision performance across the areas of program, supply and finance would provide significant "added value" to the efforts of any single agency, and would increase the likelihood that changes in any area are known to and appropriately addressed in the other areas.

Such a risk management approach would benefit from building on the experiences and the tools and processes established through the VPP and would be characterized by the establishment of key monitoring parameters, individual partner accountabilities, effective modes of communication and collaboration between partners, and metrics to measure progress and performance.

(b) Medium -term planning, in particular extending the period of the current forecast; and preparing for the next round of GAVI procurement.

In order to track evolution of demand and contribute to the longer-term provision of currently supported Vaccine Fund supported vaccines, the current 2004-06 forecast would benefit from being extended so that it reflects new approvals and changes in country uptake and in supply availability. This forecast will also form the basis for issuing the next tender and maintaining it will increase its quality and prevent the time rush experienced in this round of procurement. It is recommended that WHO, together with UNICEF and the Vaccine Fund, establish specifications for a medium-term forecast including timeframe (possibly a rolling forecast looking 5-7 years ahead), partner accountabilities, periodicity of maintenance and ways of sharing it with suppliers and other interested parties.

By starting to plan early for the next round of procurement, GAVI has an opportunity to avoid the time pressure experienced in the first two rounds of procurement and to address the constraints experienced in this last round. Given the complexity of the exercise and the importance of reaching partner consensus on strategies, workprocesses and respective accountabilities *before* implementation starts, it is recommended that the plan for the next round of procurement be prepared for GAVI Board consideration in early 2005. Building on the experiences from this procurement and considering the market situation, elements to be considered include recommended timespan for the next tender; timelines, milestones and indicators; and detailed partner assignments and accountabilities. Accountable focal persons in each institution should be identified as well as institutional oversight mechanisms.

Organizational set-up and implementation

2. Provided that the above recommended areas of work are endorsed, the alliance should retain a multi-disciplinary approach to planning and implementation across program, supply and finance, and assign global execution responsibilities in 2004-05 to the same team of partners, i.e. UNICEF, WHO, The Vaccine Fund, with support from the GAVI Secretariat, with the following areas of responsibility:

Responsibility areas for workplan implementation 2004-05

Scope areas	WHO	UNICEF SD	The Vaccine Fund	The GAVI Secretariat
Risk management for HepB, Hib and YF vaccine introduction	Country forecast	Supply delivery	VF funding	Country funding
Medium-term planning (extension of the forecast, preparation for next round of procurement)	Country forecast	Vaccine availability, pipeline products	VF funding	Country funding

3. Review the membership, terms of reference and consider changing the set-up of the Oversight Committee

It is critical that senior staff of the implementing agencies be included to assure a high level of institutional accountability and ownership. There may also be scope to include 1-2 subject matter experts relevant to the task at hand in a supportive advisory role to the Board members serving on the committee. In addition to monitor the performance of implementation, the oversight committee should focus on ensuring that agencies work effectively and efficiently together and that partner concerns and differences are addressed in a timely fashion.

Two options for Oversight Committee structure are presented for consideration by the GAVI Board:

Option 1: Transfer Oversight Committee functions to the Executive Committee:

The membership and terms of reference for the newly established GAVI Executive Committee are compatible with membership and functional requirements for the oversight committee. Transferring the Oversight Committee functions to the Executive Committee would allow to engage agency representatives at highest level in these critical issues, simplify the GAVI architecture and minimize transaction costs.

Option 2: Retain the Oversight Committee as a distinct structure:

Keeping a distinct Oversight Committee focusing on forecasting, procurement and vaccine introduction issues would likely allow more time for in-depth discussions and assessment of issues brought to GAVI Board level. Transaction costs however may be higher and institutional representation not as high as at Executive Committee level.

4. At implementation level, further explore optimal option for partner coordination

To address the shortcomings experienced in the pilot phase of the VPP, in particular institutional resistance to a project management model and the residual ambiguity around partner roles and responsibilities, it is recommended that the concerned partners closely work with the Oversight Committee (or the Executive Committee) and reach agreement on optimal management structure for the period 2004-05, and that this is reported back to the GAVI Board as early as possible in 2004.

Two different approaches are presented below as options for further consideration by the partners and the GAVI Board. Regardless of the type of arrangement selected, broad cross-institutional agreement and support at highest-level is a precondition for attaining the level of institutional ownership and commitment required for effective and successful implementation.

Option 1: Institutional model with heightened level of accountability

This approach seeks to address the constraints met by the VPP in implementing a project management model across institutions with different cultures and established rules and regulations. The main principle is to replace accountability at individual level (of the project manager and of individual team members) with accountability at institutional level, and ensure effective implementation by increasing the level of institutional accountability.

To achieve this, the following steps are proposed:

- Based on the responsibility areas outlined above for 2004-05 activities, request WHO, UNICEF, the Vaccine Fund and the GAVI Secretariat to develop detailed institutional accountabilities and areas of collaboration

- Formalise these agreements through a Memorandum of Understanding (or other appropriate mechanism as agreed by the partners) and incorporate activities into regular institutional workplans

- Secure institutional accountability by requesting executing partners to appoint senior staff at oversight committee level and be externally accountable for the performance of their institutions

- Establish a convening function to ensure periodic interaction of all parties, monitoring of workplan implementation, and resolution of problems. UNICEF could be asked to assume the convening function, with the understanding that this will rotate among the parties as agreed with the GAVI Board or its Oversight Committee.

- Following determination of the convening function, formalization of institutional accountabilities and streamlining of VPP activities into partners' on-going operations, phase-out the project manager position.

Option 2: Continue with a project management model

The main benefit of retaining a project management model is to keep a fully dedicated project manager as an accountable point of coordination and management across the partners. Constraints met during the pilot phase would however still need to be addressed.

INTRODUCTION

This paper summarizes the outcomes and the lessons learned in the second round of vaccine forecasting and procurement organized by the Global Alliance for Vaccines and Immunization (GAVI) for countries eligible for support from the Vaccine Fund[3].

It has been prepared by Paul Richard Fife[4] in consultation with the institutions tasked by the GAVI Board to pilot the coordinated planning and execution of forecasting and procurement of Vaccine Fund supported vaccines for 2004-06 through the Vaccine Provision Project (VPP), i.e. UNICEF, WHO and the Vaccine Fund, with support from the GAVI Secretariat.

Its main purposes are to systematize the strategic and implementation lessons learned during the pilot phase (July 2002 – October 2003), and bring issues of strategic and operational importance to the attention of the GAVI Board.

PROJECT JUSTIFICATION: THE 2002 MERCER REPORT

In June 2002, the GAVI Board endorsed the recommendations of the Lessons Learned report commissioned from Mercer Management Consulting[5]. The Mercer report provided an in-depth analysis of the implications of the global vaccine market and vaccine manufacturing economics for GAVI's procurement strategies; reviewed the lessons learned in the first round of GAVI procurement in 2000; and laid out strategic and implementation recommendations.

Procurement strategies

In order to increase competition for basic pediatrics and accelerate access to products as they mature, the Mercer report recommended that GAVI should seek to maintain/enhance large multinational supplier engagement to ensure access to new/newer products, while expanding the number of economically viable and high quality emerging suppliers, which can provide affordable pricing on mature products.

It was further recommended that procurement strategies be designed and managed to increase multinational supplier engagement – thereby also creating incentives for emerging suppliers – by providing for appropriate returns; creating credible and predictable demand in part through firm contracting; and working in a collaborative and open fashion with suppliers

The report also recommended that GAVI on new products focus to maximize leverage and minimize costs and that production and use of multi-dose presentations should continue since presentation is a key factor in affordability and access regardless of the type of supplier.

[3] Information on GAVI and the Vaccine Fund can be found at www.vaccinealliance.org
[4] Sr. Health Advisor and VPP Project Manager in UNICEF PD/Health Section until July 2003.
5 Lessons Learned: New Procurement Strategies for Vaccines (Mercer Management Consulting, 28 June 2002) http://www.vaccinealliance.org/reference/eighth_board/word/FinalMercerRept.doc

Organizational structure and implementation

The Mercer study noted that opportunities were missed in the first round of GAVI procurement to demonstrate credible and predictable demand and to work with suppliers in a collaborative and open fashion. Shortcomings were attributed to extreme pressure of time, an excessive focus on financing as the key constraint (with inadequate attention to program and supply issues); the ineffectiveness of a loose alliance in implementing policy with unclear and overlapping roles and a lack of accountability; and significant discomfort with suppliers as partners in the effort.

To address these shortcomings, the report recommended that GAVI implement a multi-disciplinary approach to plan and manage the introduction of vaccines with contributions from program, supply and financing, and that the alliance ensures that a strong coordinating mechanism between these disciplines is in place.

The GAVI board endorsed the following specific recommendations:

- Increase coordination, decision-making and implementation effectiveness by adopting a project management model.

- Pilot this approach with the upcoming 2004-06 procurement round, with a key objective being to produce an accurate, product-specific forecast that enhances the credibility of demand and commands sufficient confidence amongst partners to allow the majority of GAVI's vaccine to be procured on a firm contract basis.

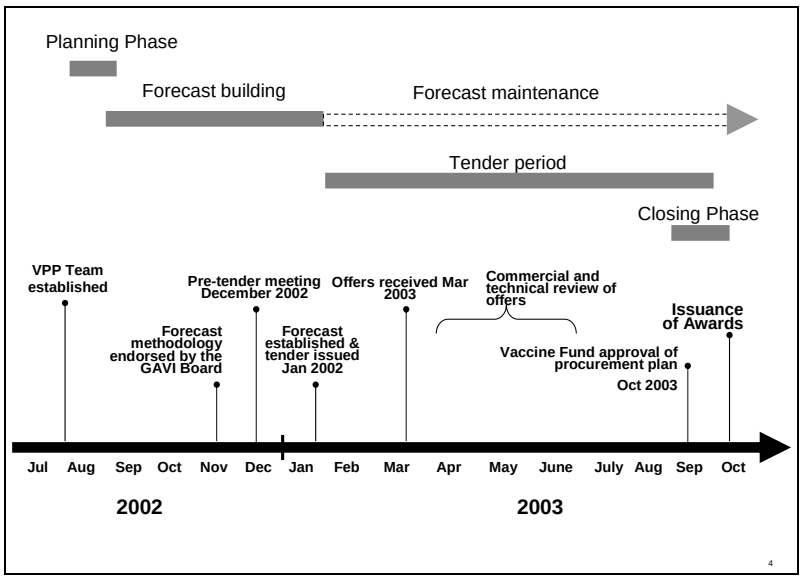
- Assign the Project Manager function to UNICEF Programme Division (WHO or UNICEF PD were in the Mercer report recommended as options in order to retain a strong program focus); lead responsibility for program issues within the project team to WHO; lead responsibility for supply to UNICEF Supply Division; and lead responsibility for finance to The Vaccine Fund.

- Ensure that information on demand, product preference and future needs is shared with industry, unless there is a well-defined reason not to do so; and further ensure that bilateral meetings are held with industry when key decisions need to be made or there is a major development.

VPP ACTIVITIES JULY 2002 – OCTOBER 2003

The chart below shows the different phases and key milestones of the Vaccine Provision Project, from the GAVI Board meeting in June 2002 until October 2003. Activity areas are described more in detail in annex III.

The Vaccine Provision Project: Project Phases and Schedule



PROGRAM OUTCOME

The Mercer report emphasized the establishment of an accurate product-specific forecast as a central strategy to implement for the GAVI alliance, both to accommodate the long lead-times for vaccine production and as a basis for issuing contracts that would assure suppliers that procurement awards would translate into actual purchases.

Forecast methodology

The methodology for establishing the country forecast was presented to the GAVI Board in November 2003[6]. Central elements were the concepts of "pure demand" and "supply-adjusted" forecasts and of country segmentation.

- "Pure demand" represents countries' preferred product choices and is important for longer-term planning. The "supply-adjusted" forecast takes into account the anticipated market situation and matches country demand with what is available on the market. The supply-adjusted forecast is a "living" forecast that is maintained and reflects changes in country uptake and in available supply.

- Countries were grouped according to their application status and to whether they would be receiving their preferred product or not. This segmentation was useful for assessing the level of uncertainty and risk of change (in choice of product, volume needs or timing) and for considering the use of firm contracting arrangements.

[6] http://www.vaccinealliance.org/site_repository/resources/vpp_forcasting_191102.doc

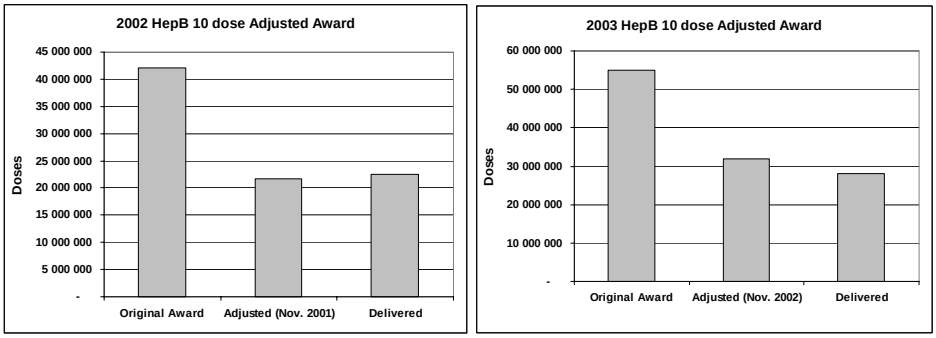
Forecast accuracy and credibility

The accuracy of the forecast will only become apparent as implementation proceeds in 2004-06. There are indications that the strength and credibility of the GAVI forecast is on the increase:

- As implementation proceeds, the number of countries approved for Vaccine Fund support is increasing and this contributes to reduce uncertainty around product choice and time of introduction.

- For approved countries, with the exception of DTP-HepB+Hib vaccine (for which the original formula for calculating vaccine requirements needed to be adjusted with a 10% increase in volume needs), overall variance between forecasted quantities adjusted each November based on country annual reports and actual quantities delivered to countries in 2001-03 was around 5%. This is shown in the charts below and is a major improvement compared with the discrepancy noted in the Mercer report between awarded and actually bought quantities of monovalent Hepatitis B in 2001 and 2002.

Monovalent HepB (10d): original awards (2001), adjusted forecasts and actual deliveries in 2002 and 2003



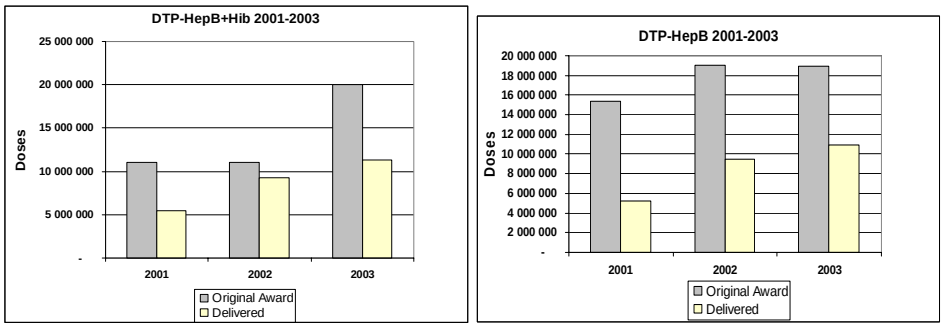
Source: UNICEF SD

- Aggregation and management of country forecasts at global level by UNICEF helps to level off individual country variance and decrease overall risk. Forecast accuracy for traditional EPI vaccines in the market managed through UNICEF procurement is now around 80%.

There was a 25% increase in the DTP-HepB+Hib forecast between December 2002 when the "pure demand" forecast first was established to support the issuance of the tender and May 2003 when WHO updated the forecast to support issuance of awards. This indicates that countries are still making decisions on their final product preferences. Forecast for new demand (i.e. countries not yet approved for Vaccine Fund support) is as such dynamic and needs continuous monitoring and communication. To allow for adjustments as early as possible, UNICEF and awarded suppliers will in the future exchange monthly updates on projected delivery and production plans.

Greater manufacturer accuracy in production planning is required. The charts below show the difference between awarded and delivered quantities of DTP-HepB and DTP-Hep+Hib in 2001-03. While the difference in 2001 is mainly due to delays as countries were preparing for introduction, the variance in 2003 is caused by the reduced availability of these vaccines (overall a 40% loss in 2002 and 2003), forcing several countries to delay introduction of these vaccines. This underscores that in the early stages of implementing the introduction of new vaccines, the availability of products on the market will determine the scope and speed of program implementation.

Quantities delivered vs. original award (2001-03)



Source: UNICEF SD

Program considerations

The supply constraints and the relatively high price of combination vaccines raise questions about the evolution of country demand and the overall pace of introduction of Hib-containing vaccine.

The magnitude of the financing gap for vaccines has been documented by the Financing Task Force[7] for some of the early introducer countries and is of great concern. Some countries have indicated that they may drop Hib and fall back onto DTP-HepB when Vaccine Fund support ends after five years. The price increase seen in this round of procurement is likely to exacerbate in-country discussions, as policy-makers are faced with constrained resources and competing priorities, not least related to the fight against AIDS.

PROCUREMENT OUTCOME

The Mercer report recommended a procurement approach that would engage large multinational suppliers (to ensure access to new/newer products) as well as emerging suppliers (key to affordable pricing as products mature).

Product offers

38 manufacturers from the WHO and UNICEF lists of manufacturers currently or potentially producing vaccines were invited to provide offers. Manufacturers with plans for vaccine products to be WHO pre-qualified were invited to submit as part of their offers timelines for the development of new products, completion of clinical trials, licensing with their National Regulatory Authority (NRA) and submission of prequalification files to WHO. Given that vaccines are complex commodities and various factors need to be considered, including linkages with other products, UNICEF designed the tender as a Request for Proposal (RFP). Offers received are summarized in the table below.

GAVI/Vaccine Fund procurement 2004-06: Summary of offers

Product	Number of offers	Number of WHO pre-qualified products	Number of non WHO pre-qualified products
HepB	13	6	7
HepB uniject	4	0	4
Hib	4	2	2
DTP-HepB	11	1	10
DTP-HepB+Hib	4	1	3

[7] http://www.vaccinealliance.org/home/Board/Board_Reports/11_board_financialsus.php

DTP+Hib	1	1	0
Yellow Fever	4	2	2
Total	41	13	28

Source: UNICEF SD

Two additional products were offered but not considered as programmatically suitable by WHO for this round: (1) Hep+Hib due to operational issues (two doses of Hep+Hib and one additional dose of HepB are required to fully vaccinate a child, complicating the scheduling) and (2) DTP-HepB+Hib-MenA/C due to the need to further assess its epidemiological and programmatic suitability.

Awards 2004-06

Awards are issued by UNICEF on behalf of GAVI and the Vaccine Fund in the form of Long Term Agreements (LTA) for three years (2004-06), with total quantities awarded for each product equal to forecasted quantity needs.

Evaluation of offers included the review of mandatory requirements (e.g. WHO pre-qualification and compliance with UNICEF general terms and conditions); a quantitative review of proposals (products offered, quantities, price, delivery schedule and lead-times, ability to maintain buffer stock, shelf-life, VVM); and a qualitative review of proposals (proven experience and past performance, ability to perform account management / good communication, on-time delivery performance).

Awards have not been given to manufacturers for products that are not WHO pre-qualified. However, proposals of commercial interest will be considered when the products become WHO pre-qualified. Manufacturers have been informed that quantities may be awarded or re-allocated if there is a monopoly or near-monopoly situation, a lack of performance from current manufacturer(s), or insufficient production capacity of current manufacturers (i.e. demand exceeds available supply).

While awards were originally scheduled to be finalised in June 2003, awards for the full period 2004-06 have as of mid-November 2003 not been issued and made public.

- To date the Vaccine Fund Executive Committee has given its financial approval for the procurement of combination vaccines for the period 2004-06 for already approved countries. These quantities are firmly contracted and represent an estimated total value of US$281.3 million.

- Financial approval has also been given for all monovalent products for 2004-06 representing an estimated total value of US$145.4 million, subject to parameters of the Five Year Supply Approval policies approved by GAVI and the Vaccine Fund in June 2003[8].

- Procurement arrangements for combination vaccine for countries that plan to switch products or that are not yet approved are still outstanding and vaccines not secured, following the request from the Vaccine Fund Executive Committee to not lock into this option and to explore alternatives.

At its Dakar meeting in November 2002, the GAVI Board recommended that all vaccines purchased by the Vaccine Fund should include vaccine vial monitors (VVM) after 2003, in line with the WHO/UNICEF global policy on the use of VVM. Except for GSK who will phase in VVMs on GAVI/Vaccine Fund shipments during 2004 and Aventis who is developing its implementation plan,

[8] http://www.vaccinealliance.org/home/Board/Board_Reports/telcon_060603.php

all manufacturers with awards have confirmed that their vaccine will be supplied with VVMs in 2004-06.

No award was given for Hepatitis B in single dose pre-filled device (i.e. Uniject™) since no manufacturer had obtained WHO pre-qualification for this product. In view of the relatively high price on offer and limited confirmed country demand, the cost-effectiveness and viability of this product need to be further considered and criteria for what constitutes an acceptable price established. In view of the limited confirmed demand, country recommendations for the use of these products may also benefit from being more explicitly defined.

Working with manufacturers in an open and collaborative fashion

The purpose of open and collaborative relationships with suppliers is to facilitate production planning, avoid conflicting messages and minimize costs to serve GAVI. It is critical to ensure fair and equal access to information and to maintain confidentiality when appropriate.

As discussed with the VPP Oversight Committee, partners still have different perspectives on how manufacturers should be engaged. Approaches employed by the VPP in this round of forecasting and procurement were presented at a Board teleconference in September 2002 and are reported below.

Pre-tender period

The VPP provided information on the forecast methodology and on the "pure demand" forecast in written communication to all manufacturers in October 2002 and in the tender document in January 2003. The methodology was publicly available through GAVI Board proceedings in December 2002 and on the GAVI website, and was presented together with the "pure demand" forecast at the pre-tender meeting in December 2002. Feedback was overall positive though limited. It was suggested for the future to further quantify and model risk (i.e. issues that could affect forecast accuracy) into "optimistic" and "pessimistic" scenarios.

Tender period

During the tender period, to maintain confidentiality and ensure consistent messages to suppliers, communication with manufacturers was handled bilaterally between UNICEF Supply Division and each individual manufacturer. Meetings were held with all manufacturers that submitted an offer to present and discuss the offer with extensive consultations with suppliers offering the most interesting products.

Post-tender period

Manufacturers have been invited for a debriefing meeting at UNICEF to have a chance to review the outcome of the procurement and discuss issues related to their specific proposal. Manufacturers with awards will during 2004-06 receive monthly updates forecasted needs and monthly meetings will also be organised.

FINANCING OUTCOME

For strategic and financial planning purposes, it is important for the alliance to assess the likely causes of the price increase seen for the combination vaccines in this round, assess whether obtained prices can be considered "fair and reasonable" at this point in time, and get an indication as to how prices are likely to evolve in the future.

Product pricing

The table below provides an overview of the evolution of pricing and volume quantity for HepB, DTP-HepB and DTP-HepB+Hib obtained by UNICEF SD on behalf of GAVI and the Vaccine Fund from 2001-2006.

Quantities and price of vaccines 2001-06

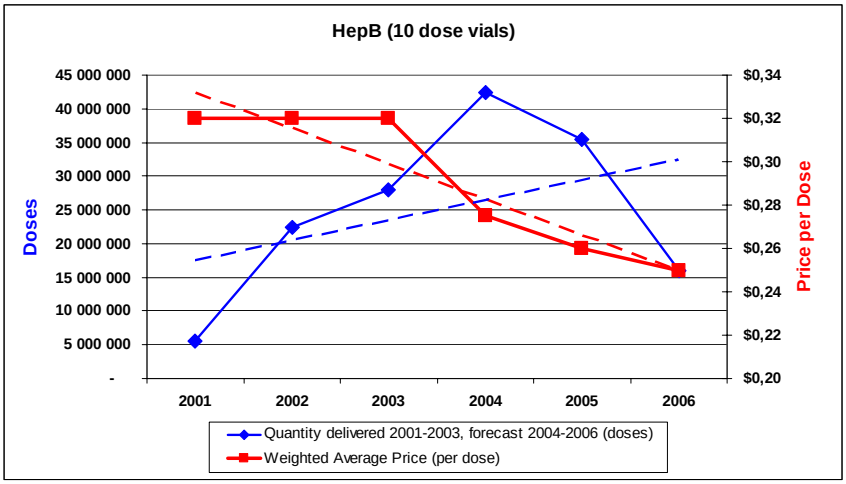
		2001	2002	2003	2004	2005	2006
DTP-HepB	Quantity	5,264,500	9,440,500	10,895,500	11,834,800	15,615,550	44,500,000
	Price	$1,10	$1,05	$0,95	$1,21	$1,25	$1.29
DTP-HepB+Hib	Quantity	2,718,200	11,301,400	11,293,940	15,942,956	33,384,448	37,950,000
	Price	$3.50	$3.50	$3.27	$3.65	$3.60	$3.60
HepB	Quantity	5,613,000	22,472,400	28,009,310	42,400,000	35,500,000	16,000,000
	Price	$0,32	$0,32	$0,32	$0,28	$0,26	$0,25

Quantity: Quantities delivered in 2001-2003 and forecasted 2004-2006
Price: US$ per dose (weighted average price for HepB)
Source: UNICEF Supply Division

As noted in the Mercer Study, product lifecycle and maturity are critical for product pricing. Typically, a mature product for low-income country markets will be characterized by solid demand and multiple suppliers, including emerging suppliers, with competition acting as the key driver for lower prices.

Monovalent Hepatitis B is the "text-book" case of a maturing product and weighted average price continued to decrease in this procurement cycle from $0.32 in 2003 to $0.28 in 2004, and to $0.25 in 2006. This is a reduction of 22% between 2003 and 2006.

Monovalent HepB (10d/v): vial price and quantity 2001-06

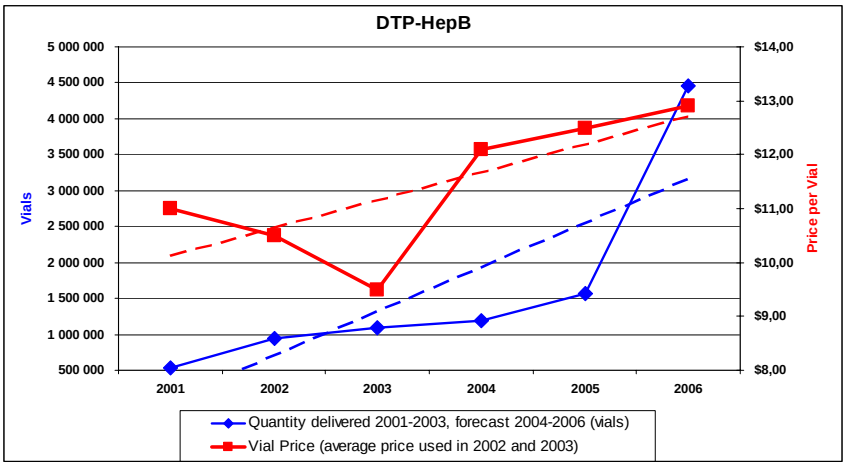


Despite considerable supplier movement, the combination products preferred by countries (DTP-HepB and DTP-HepB+Hib) became commercially available specifically for GAVI and are still early in their product lifecycle.

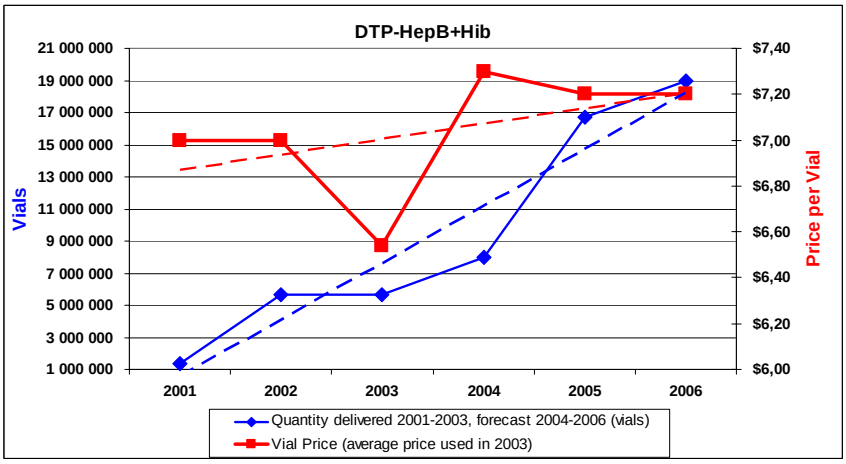
The charts below show price evolution relative to quantities delivered in 2001-03 and forecasted for 2004-06, showing a price jump between 2003 and 2004 of 10% for DTP-Hep+Hib and of 27% for DTP-HepB.

Compared with 2001, dose prices in 2006 will increase from $3.50 to $3.60 (i.e. 3%) for DTP-hepB+Hib (2-dose/vial), and from $1.10 to 1.29 (i.e. 15%) for DTP-hepB (10-dose/vial).

DTP-HepB: vial price and quantity 2001-06



DTP-HepB+Hib: vial price and quantity 2001-06



Discussions with manufacturers and analysis of market conditions indicate that the price increase seen for combination products in 2004-06 compared with 2003 may be attributed to:

- Accelerated supplier recouping of investment costs, principally investments in new DTP production facilities but also of original investments

- pricing strategy: multinational manufacturers typically offer low volumes at relatively high price and chose to exit the market as emerging suppliers enter with larger volumes and lower priced products

- the significant strengthening (of around 20%) of the Euro against the US dollar since 2001, when initial prices were set.

Price analysis of all Hib-containing products offered in the tender (Hib, DTP-HepB+Hib, DTP+Hib, HepB-Hib) indicates that the price of Hib is high compared with the basic pediatrics, but not unreasonably high at this point in time:

- Prices of Hib-containing combination vaccines offered in the tender (including products not yet pre-qualified) are comparable across products offered and across manufacturers.

- The price seems to reflect actual production and regulatory costs and is consistent with price differences between multinational and emerging suppliers for other basic vaccines.

- The price is comparable with the price for DTP-HepB+Hib (in single-dose vial without VVM) obtained by the Pan-American Health Organization (PAHO) through its pooled procurement system ($3.76 for 2004, i.e. 3% higher than UNICEF price and an increase from $3.00 in 2003)

- From historical experience, significant and sustained price reductions are not likely to be seen until competition has been established

Price outlook

Global demand for DTP-HepB is now well-established. Two additional manufacturers could be expected to enter the market with pre-qualified products nearing 2006 and this will lead to competition and decreasing prices. Product maturity is expected to be seen in 2007-2009.

DTP-HepB+Hib is technically more complex to produce than DTP-HepB. Considering development and licensure requirements, it is conservatively estimated that additional quantities are not likely to become available from additional manufacturers until 2006, with maturity and price pressure expected when competition is established.

Country demand for DTP-Hib combinations (in liquid or lyophilized form) has overall been very limited compared with DTP-HepB. This has influenced production planning with only one manufacturer currently offering a pre-qualified product. The future demand for this product is still unknown.

Yellow Fever vaccine

Due to the change of vial size from 20 dose to 10 dose the price per dose of this vaccine has increased from $0.34 in 2002 to $0.80 in 2004, and to $0.97 in 2006 (the price of 10d vials was $0.63 in 2002). It is expected that the increased costs to the program will partly be offset by the reduced vaccine wastage at point of use (less so during campaigns when wastage typically is low).

Firm contracting – a means to an end not an end in itself

The Mercer Study identified the use of contractual commitments (e.g. firm contracting) as a critical tool for GAVI and "proof" of the commitment to share risks associated with the forecast.

In theory, the main benefits for the buyer of entering into a firm contract arrangement are to secure supply quantity and to obtain price concessions. The risk of financial loss (in case countries do not use forecasted volumes) and opportunity costs (i.e. lost investment opportunities) represent significant down-sides. For suppliers, the major benefit lies in the assurance of future purchase and this is expected to influence company decisions on investments and production scale-up.

The use of firm contracting was assessed on a case-to-case basis for all awards considering the level of uncertainty and risk associated with the forecast (using the country segmentation approach) and whether prevailing market conditions for the product in question indicated a strategic need to enter into a firm contracting arrangement.

As of mid November 2003, firm contracting arrangements have been established for products in short supply to secure their availability but only for quantities of already approved countries. The value of firmly contracted supply represents so far around 40% of the total value of this procurement, less than what the Mercer report recommended.

Firm contracting was not entered into for readily available products. While this would have reduced risk for the supplier, it was considered not to be justified in view of its limited utility in securing product availability (since the product is in abundant supply) and in reducing price further than what was achieved. Moving forward it will be important that these non-firm awards translate into actual purchases, and that unforeseen changes be communicated well in advance with suppliers to allow for adjustments.

While firm contracting did allow for some moderate price concessions for DTP-HepB and DTP-HepB+Hib, its overall leverage on price and volumes in this round of procurement proved somewhat limited due to the established monopoly situation and several buyers vying for scarce supply. Under such conditions, firm contracting may first of all be useful in locking supply and securing vaccines rather than leveraging significant price and volume concessions.

Establishment of financial frameworks to support procurement operations

A significant achievement during the period was the design and establishment of the Five Year Supply Approval Framework approved by the GAVI Board and the Vaccine Fund Executive Committee in June 2003[9]. This Framework reconciles the use of multi-year contracting while retaining a performance-based approach to country support.

The delay in closing the procurement and issuing awards is a shortfall and is due to difficulties met in updating the forecast, assessing proposed procurement plans and establishing the legal and fiduciary frameworks necessary to support the implementation of firm contracts.

While this was the subject of discussions between the Vaccine Fund and appropriate units at UNICEF throughout the project cycle with financial estimates shared several times between February and September 2003, fiduciary arrangements between the two institutions were as of mid-November 2003 not yet finalized. Though funding for 2004 procurement has been transferred and vaccines for 2004 have been secured, financial backing needed for the full 2004-06 contracting was not yet available.

Looking back, the project significantly underestimated the time required and potential difficulties related to these processes, many taking place for the first time. While most of these will be resolved in order to complete this procurement, future efforts should realistically set and sequence milestones and allow for unanticipated challenges.

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[9] http://www.vaccinealliance.org/home/Board/Board_Reports/telcon_060603.php

Constraints have also been experienced in relation to release of funds to support on-going operations and vaccine deliveries with delays in funds transfer despite accurate timing and quantity forecasts. This indicates the need to further work on making financing more responsive to program and supply needs, while making sufficient provision for institutional requirements related to fiduciary responsibilities and due diligence processes.

PROJECT EXECUTION

The performance, benefits and shortfalls of the VPP may be assessed at four different levels:

- Did the VPP meet the original targets of schedule and quality (meeting targets)?
- Was it managed in an efficient manner (project efficiency)?
- To what extent did it contribute to fulfill the overall mission of vaccine provision to GAV/Vaccine Fund supported countries (project utility)?
- And what can the organizations and the alliance learn from the pilot project and how can this knowledge be used to improve operations (organizational improvement)?

Did the VPP meet the original targets of schedule and quality (meeting targets)?

With regard to schedule, the project was successful in getting quickly off the ground and meeting deadlines for establishing the forecast and issuing the tender.

The procurement, which was originally scheduled to be completed in June 2003, was as of mid November not fully completed for reasons described in previous sections. Procurement arrangements for 2004 however have been made and delivery of supply to countries assured, and concerned manufacturers have also been kept appraised of the situation.

In terms of quality, several of the project metrics measuring progress and performance across the three disciplines (such as forecast accuracy, delivery reliability, uptake of firm offtake and supplier information-sharing) pertain to the implementation period in 2004-06 and will be tracked and reported as implementation proceeds.

With regard to pricing, while price pressure on monovalent HepB was achieved and weighted average price is expected to decrease by 22% between 2003 and 2006, the price increase of combination vaccines is a significant disappointment and constitutes at least in the medium term a major challenge for countries and their global partners.

Was the VPP managed in an efficient manner (project efficiency)?

While several aspects of project management were taken into consideration in the development and implementation of the project, several important aspects did not receive sufficient attention. While headway has been made and experiences in this round will be very valuable in informing the design and implementation of future activities, one should recognize looking back that unclarities remained in setting the goals and the strategies of the project, terms of reference (for the VPP as a whole, the project manager, staff detailed to the project from implementing institutions, and the Oversight

Committee), formulating and addressing expectations of each of the partners, and identifying project metrics for each of the partners.

While project planning and control was overall adequate in the first half of the project, inefficiencies became apparent and delays occurred in the final phase in relation to updating the forecast, establishing policy and fiduciary frameworks needed for multi-year contracting and reviewing and approving proposed procurement plans.

Staff transition affected the efficiency of operations and this may also have reduced institutional ownership in the project. The WHO team member responsible for developing the forecast and oversee programmatic issues transferred to another location in December 2002 and the programmatic "leg" of the VPP was sub-optimal until the new WHO team got in place in July 2003. In July 2003, the project manager left the project for family reasons and project coordination was taken on by the GAVI Secretariat.

The success of individual team representatives in drawing on the resources in their institution varied considerably and sub-optimal communication within organizations was also experienced, possibly pointing to the downside of a project team approach based on individuals against a more formal institutional representation.

Despite extensive travel, the project manager remained throughout his assignment based at UNICEF NYHQ in New York and several partners raised this as a drawback compared with a Europe-based location in close proximity to key partners. It was considered though that the institutional backing of UNICEF in its New York Headquarters was important for ensuring supervision and support to the project manager. Overall the project manager did act as a focal point for the project, following up on project activities in the various agencies, and reporting to the Board and its Oversight Committee.

Differing perspectives between partners hampered operations and could have been minimized if expectations or concerns had been addressed earlier in the project or if the project support group had been convened. It should be emphasised that the absence on the Oversight Committee of senior staff from the implementing agencies (as decided by the GAVI Board in June 2002 contrary to the original recommendation in the Mercer report) may have been a mistake, since such presence would have been beneficial as a way to reinforce institutional accountability and ownership, bring problematic issues to a higher level within institutions and ensure that project activities internally receive the required attention and support.

Project costs were assumed by executing agencies as part of their operations, with extraordinary costs borne by UNICEF (for the project manager position) and the GAVI Secretariat (for convening the Oversight Committee).

Finally, while partner investments in the VPP may seem commensurate to the task at hand, the intensity and frequency of VPP interactions was considered by some as too high, noting that work could have been more efficient if VPP tasks had been better planned and streamlined into institutional plans of work. In particular, the numerous requests for inputs and action, often with tight deadlines, have been raised as a source of frustration.

To what extent did the VPP contribute to fulfill the overall mission of vaccine provision to GAVI/Vaccine Fund supported countries (project utility)?

In the short-term, the VPP met its primary objective of establishing a product-specific forecast and systems are being put in place to monitor country performance, maintain the forecast, and communicate changes with manufacturers. Vaccines needed in 2004 have been secured and a GAVI procurement plan for the full period 2004-06 is expected to soon be in place.

With regard to product affordability, the report attributes the price increase of combination vaccines in 2004-06 to the strengthening of the Euro against the US dollar, the accelerated recouping of investments and supplier pricing strategy. It also points to the fundamental issue of product lifecycle and the effects of product maturity on pricing.

DTP-based combination vaccines preferred by countries are still early in their lifecycle. The broadening engagement of multinational and emerging suppliers seen in this procurement should be taken as a strong indication that market competition is on its way with current prices serving as solid incentives for suppliers. Provided efforts are maintained, it is expected that a healthier market with multiple suppliers and more affordable prices will be established, for DTP-HepB in 2007-09. This will in due course contribute to reduce the disparity between high and low-income counties in introducing new vaccines, probably from twenty years as the case was with monovalent HepB to ten years or less for DTP-HepB.

The VPP was instrumental in coordination partner response and managing the pentavalent vaccine crisis in the first half of 2003 when Burundi, Yemen, Zambia were forced to delay the introduction of new vaccine for 18 months and Uganda experienced a country-wide stock-out due to inability at global level to accommodate its increased vaccine needs. The VPP was also useful as a repository for addressing supply-related GAVI policy issues in a cross-disciplinary way, such as the Five Year Supply Approval framework, forecast calculation methodologies and modalities of GAVI/VF supply support.

With regard to Yellow Fever vaccine, the VPP mechanism facilitated the design and establishment of the stockpile approved by the GAVI Board in December 2003. While it is too early to see results yet, this is an example of the facilitative and innovative character of the alliance.

What can the organizations and the alliance learn from the pilot project and how can this knowledge be used to improve operations (organizational improvement)?

It is important to recognize that the VPP was a pilot effort and something that had never been done before at least in this fashion, and that it was challenged by real time constraints, a maturing alliance that was learning as it worked and unforeseen external factors such as the pentavalent supply crisis.

First of all, the VPP pilot confirmed the usefulness and benefits of working in a coordinated manner across the areas of program, supply and finance. With the addition of the GAVI Secretariat, team composition was found to be appropriate with relevant disciplines and partners represented on the team.

The project management approach allowed for better communication among partners, helped to make headway in defining institutional accountabilities, and was instrumental in improving collaboration across institutions and across disciplines. This was especially beneficial at the start of project and it is doubtful that a product-specific forecast would have been available for use in the tender without the use of a project management approach.

However, as noted in previous sections, shortcomings and inefficiencies were experienced and need to be considered as the alliance takes stock of the situation and decides on the way forward. The main causes for these inefficiencies may be attributed to:

- Inherent institutional resistance to a project management model, with institutional lines of authority and communication not supporting or not compatible with project management requirements. This includes accountability of team members to the project manager, project manager authority to direct the work of others, and partner access to information and participation in decision-making processes. Though the team members to the most extent worked well together and the project management model gave some needed flexibility,

representation by individuals may not have replaced the strength that can be provided by more formal institutional representation and may also have reduced institutional ownership in the project.

- Failure to appropriately identify in advance potential obstacles, set and sequence milestones in particular for new steps and workprocesses, and allow for enough time to address unanticipated challenges. Again it should here be emphasised that it was the first time many of these processes were undertaken, and that future activities will gain from the experiences gained in the pilot.

- Residual ambiguity around partner roles and responsibilities, and failure to effectively address partner differences. This ambiguity led to inefficiencies that could have been minimized by addressing partner expectations and concerns at an earliest possible stage of the project.

LOOKING AHEAD, ISSUES OF STRATEGIC IMPORTANCE

Seek to decrease the price of combination vaccines as early as possible through increased competition

Significant price reduction for combination vaccines are not likely to be seen until competition is established. GAVI partners should ensure that conditions remain favourable and stimulate competition in the period leading up to the next round of procurement. In particular, the GAVI Board should encourage WHO to establish the necessary capacity to enable timely processing of requests for prequalification of new products, so that suppliers can complete vaccine development and pre-qualification processes and be considered for awards. .

Firm up demand for Hib-containing vaccine

While demand for HepB and DTP-HepB vaccines is on track to become as established as for the traditional EPI vaccines (as demonstrated by the broad country uptake and the healthy market response), demand for Hib-containing vaccine is at critical risk due its relatively high price and the financing gap in the post-Vaccine Fund period. Successful Hib vaccine introduction is critical not only for the credibility of GAVI (with countries as well as with suppliers) but also for the credibility of future vaccine introduction initiatives.

WHO and other GAVI partners should continue their efforts to support countries in assessing the appropriateness and the program readiness for introducing Hib-containing vaccines, taking into account the supply situation, financial sustainability and other program priorities.

It is encouraging to see that several countries are taking steps towards phasing in locally-mobilized resources as Vaccine Fund support nears its end. GAVI partners should continue to support country efforts including the implementation and realization of national financial sustainability plans.

GAVI and the Vaccine Fund should as part of their strategic planning for 2005-2015 explore ways of addressing the financing gap for currently supported vaccines. Extending support to products still early in their lifecycle may be an option to consider in order to firm up demand until competition is established and more affordable pricing has been achieved.

In view of the DTP-HepB+Hib supply constraints, countries wanting to introduce Hib vaccine may wish to consider alternative Hib-containing products (monovalent Hib, DTP+Hib). Though this in itself would not contribute to increase competition for DTP-HepB+Hib vaccine, it would help accelerate the use of Hib vaccine, protect more children from Hib disease and reduce dependency on one single product. It should be emphasised however that such decisions need to be made by countries themselves.

R E C O M M E N D A T I O N S

Given the tasks at hand and the experiences and outcomes of the pilot, the following recommendations are put forward for consideration and discussion in relation to vaccine provision strategies in general; and on the scope of GAVI-related vaccine provision activities in 2004-05 and options for organizational set-up and implementation in particular.

Scope of the VPP 2004-05

1. Focus on risk management at global level - across program, financing and supply - to support new vaccine introduction

With the majority of Vaccine Fund eligible countries well underway with the introduction of newer vaccines, and with a US$570 million procurement plan for 2004-06 soon in place to support this effort, the need to effectively manage vaccine provision at global level is critical. In particular, the alliance needs to have the capacity to detect and act when problems or changes related to program implementation, supply or funding arise, such as new approvals, changes in supply availability, or funding shortfalls.

It should be stressed that national Governments are responsible for implementation of immunization programs, and that partner agencies, in particular established multilateral agencies, play a critical role in monitoring country progress and providing technical assistance.

At global level, a risk management approach grounded on close monitoring of vaccine provision performance across the areas of program, supply and finance would provide significant “added value” to the efforts of any single agency, and would increase the likelihood that changes in any area are known to and appropriately addressed in the other areas.

Such a risk management approach would benefit from building on the experiences and the tools and processes established through the VPP and would be characterized by the establishment of key monitoring parameters, individual partner accountabilities, effective modes of communication and collaboration between partners, and metrics to measure progress and performance.

For 2004-05, it is therefore recommended to primarily focus on the management at global level of risks associated with the introduction of Vaccine Fund supported vaccines (HepB, Hib, YF) across the areas of program, supply and finance.

2. Extend the forecast of HepB, Hib and YF vaccine to support medium-term planning

The forecast prepared for this procurement round covers primarily the period 2004-06. In order to track evolution of demand and contribute to the longer-term provision of currently supported Vaccine Fund supported vaccines, the current forecast would benefit from being extended so that it reflects new approvals and changes in country uptake and in supply availability.

This forecast will also form the basis for issuing the next tender and maintaining it will increase its quality and prevent the time rush experienced in this round of procurement. The forecast needs to be accompanied by a funding forecast to demonstrate the longer-term reliability of vaccine procurement.

It is recommended that WHO, together with UNICEF and the Vaccine Fund, establish specifications for a medium-term forecast including timeframe (possibly a rolling forecast looking 5-7 years ahead), partner accountabilities, periodicity of maintenance and ways of sharing it with suppliers and other interested parties.

3. Prepare early for the next round of procurement

By starting to plan early for the next round of procurement, GAVI has an opportunity to avoid the time pressure experienced in the first two rounds of procurement and to address the constraints experienced in this last round. Given the complexity of the exercise and the importance of reaching partner consensus on strategies, workprocesses and respective accountabilities *before* implementation starts, it is recommended that the plan for the next round of procurement be prepared for GAVI Board consideration in early 2005.

Building on the experiences from this procurement and considering the market situation, elements to be considered include recommended timespan for the next tender; timelines, milestones and indicators; and detailed partner assignments and accountabilities. Accountable focal persons in each institution should be identified as well as institutional oversight mechanisms.

It should be emphasised that the establishment of a long-term forecast and realistic guarantees of future funding are pre-conditions to an effective procurement.

Organizational set-up and implementation

4. Retain a multi-disciplinary approach involving the same partners as in the pilot phase

Provided that the above recommended areas of work are endorsed, it is recommended to retain the multi-disciplinary approach to planning and implementation across program, supply and finance, and assign global execution responsibilities in 2004-05 to the same team of partners, i.e. UNICEF, WHO, The Vaccine Fund, with support from the GAVI Secretariat, with the following areas of responsibility:

Responsibility areas for workplan implementation 2004-05

Scope areas	WHO	UNICEF SD	The Vaccine Fund	The GAVI Secretariat
Risk management for HepB, Hib and YF vaccine introduction	Country forecast	Supply delivery	VF funding	Country funding

Medium-term planning (extension of the forecast, preparation for next round of procurement)	Country forecast	Vaccine availability, pipeline products	VF funding	Country funding

5. Review the membership, terms of reference and consider to change the set-up of the Oversight Committee

In view of the experiences in the pilot phase, and regardless of partner coordination and management structures chosen at implementation level, it is recommended to review the composition and terms of reference of the Oversight Committee. Specifically, it is critical that senior staff of the implementing agencies be included to assure a high level of institutional accountability and ownership. There may also be scope to include 1-2 subject matter experts relevant to the task at hand in a supportive advisory role to the Board members serving on the committee. In addition to monitor the performance of implementation, the oversight committee should focus on ensuring that agencies work effectively and efficiently together and that partner concerns and differences are addressed in a timely fashion.

Two options for Oversight Committee structure are presented for consideration by the GAVI Board:

Option 1: Transfer Oversight Committee functions to the Executive Committee:

The membership and terms of reference for the newly established GAVI Executive Committee are compatible with membership and functional requirements for the oversight committee. Transferring the Oversight Committee functions to the Executive Committee would allow to engage agency representatives at highest level in these critical issues, simplify the GAVI architecture and minimize transaction costs.

Option 2: Retain the Oversight Committee as a distinct structure:

Keeping a distinct Oversight Committee focusing on forecasting, procurement and vaccine introduction issues would likely allow more time for in-depth discussions and assessment of issues brought to GAVI Board level. Transaction costs however may be higher and institutional representation not as high as at Executive Committee level.

6. At implementation level, further explore optimal option for partner coordination

To address the shortcomings experienced in the pilot phase of the VPP, in particular institutional resistance to a project management model and the residual ambiguity around partner roles and responsibilities, it is recommended that the concerned partners closely work with the Oversight Committee (or the Executive Committee) and reach agreement on optimal management structure for the period 2004-05, and that this is reported back to the GAVI Board as early as possible in 2004.

Two different approaches are presented below as options for further consideration by the partners and the GAVI Board. Regardless of the type of arrangement selected, broad cross-institutional agreement and support at highest-level is a precondition for attaining the level of institutional ownership and commitment required for effective and successful implementation.

Option 1: Institutional model with heightened level of accountability

This approach seeks to address the constraints met by the VPP in implementing a project management model across institutions with different cultures and established rules and regulations. The main principle is to replace accountability at individual level (of the project manager and of individual team members) with accountability at institutional level, and ensure effective implementation by increasing the level of institutional accountability.

To achieve this, the following steps are proposed:

- Based on the responsibility areas outlined above for 2004-05 activities, request WHO, UNICEF, the Vaccine Fund and the GAVI Secretariat to develop detailed institutional accountabilities and areas of collaboration

- Formalise these agreements through a Memorandum of Understanding (or other appropriate mechanism as agreed by the partners) and incorporate activities into regular institutional workplans

- Secure institutional accountability by requesting executing partners to appoint senior staff at oversight committee level and be externally accountable for the performance of their institutions

- Establish a convening function to ensure periodic interaction of all parties, monitoring of workplan implementation, and resolution of problems. UNICEF could be asked to assume the convening function, with the understanding that this will rotate among the parties as agreed with the GAVI Board or its Oversight Committee.

- Following determination of the convening function, formalization of institutional accountabilities and streamlining of VPP activities into partners' on-going operations, phase-out the project manager position.

Option 2: Continue with a project management model

The main benefit of retaining a project management model is to keep a fully dedicated project manager as an accountable point of coordination and management across the partners. Constraints met during the pilot phase would however still need to be addressed.

ANNEX 1: AWARDS 2004-06

Number of doses awarded and weighted average (WA) price per dose of GAVI/Vaccine Fund supported vaccine 2004-2006

HepB 1	2004	2005	2006
Total doses awarded	2 650 000	1 050 000	1 182 000
WA price per dose	0,41	0,41	0,41

HepB 2	2004	2005	2006
Total doses awarded	3 400 000	3 110 000	3 160 000
WA price per dose	0,37	0,36	0,35

HepB 6	2004	2005	2006
Total doses awarded	3 889 980	3 979 980	4 060 020
WA price per dose	0,61	0,61	0,61

HepB 10	2004	2005	2006
Total doses awarded	42 400 000	35 500 000	16 000 000
WA price per dose	0,27	0,27	0,26

DTP-Hib 10	2004	2005	2006
Total doses awarded	3 478 730	201 450	209 910
WA price per dose	2,58	2,80	3,12

YF 5	2004	2005	2006
Total doses awarded	5 000 000	4 000 000	4 000 000
WA price per dose	0,58	0,58	0,60

YF 10	2004	2005	2006
Total doses awarded	13 200 000	11 900 000	11 800 000
WA price per dose	0,80	0,88	0,97

As of 01.12.03

unicef

ANNEX 2: VPP ACTIVITIES JULY 02 – OCTOBER 03

Preparatory and planning phase (lead responsibility: project manager)

- Project definition developed by UNICEF, WHO and the Vaccine Fund, based on Mercer Study analysis and GAVI Board directions
- Project outline endorsed by the GAVI Board in August 2002 including project deliverables, project team composition, terms of reference for the project manager; and composition and terms of reference for the Project Oversight Committee and the Project Support Team
- GAVI Board updated in September 2002 on supplier engagement in the forecast process and on timelines for developing the forecast and issue the tender

Establishment of the forecast (lead responsibility: WHO)

- Pre-meeting of WHO, UNICEF, PATH/CVP and the GAVI Secretariat in July 2002 to review available fact base and identify data gaps
- Methodology for establishing an accurate, product specific forecast developed and endorsed by the GAVI Board in November 2002
- "Pure demand" forecast established and major risks assessed. Feedback solicited at an open pre-tender meeting with 26 suppliers in December 2002.
- Tender with "pure demand" forecast issued in January 2003
- Forecast updated into reflect new country approvals, updated country information and changes in actual vaccine uptake (for example the delay in introducing DTP-HepB+Hib in Burundi, Yemen and Zambia). A final update incorporating these significant changes was made in May 2003.
- "Supply-adjusted" forecast established through the matching of "pure demand" forecast with offers received from suppliers.

Procurement activities (lead responsibility: UNICEF SD)

- Manufacturers (38) on WHO and UNICEF lists of manufacturers currently producing and potentially producing invited to participate in the tender.
- Pre-tender meeting with participation of 26 manufacturers, WHO, the Vaccine Fund and the GAVI Secretariat organized 8 December 2002 to present the procurement process, requirements and timelines, and obtain feedback on the forecast
- Tender issued 20 January 2003, 30 proposals received by 14 March 2003.
- Technical review by WHO in March-May of 30 proposals (18 products), including compliance with mandatory requirements, compliance with preferred requirements, and assessment of timelines for pre-qualification for products not WHO-prequalified at time of offer
- Clarification/negotiation meetings with all manufacturers in the period April-June
- Recommendations for awards allocations and contracts forwarded to the Vaccine Fund Executive Committee end June returned with a request to further negotiate combination vaccines
- GAVI Board updated on the procurement process in July 2003
- Review of procurement and negotiations with new recommendations presented to the Vaccine Fund Executive Committee in September 2003
- Awards issued October 2003

Financing issues (lead responsibility: the Vaccine Fund)

- Inputs provided into principles for firm contracting arrangements
- Establishment of financial/fiduciary agreements with UNICEF to support procurement operations and firm contracting arrangements
- Assessment of financial implications of awards and approval of procurement plans

Policy development (responsibility: project manager, WHO, UNICEF SD, Vaccine Fund)

- Establishment of the Five Year Supply Approval Framework, approved by the GAVI Board and the Vaccine Fund in May 2003.
- Identification of outstanding issues and preparation of supply-related policies for consideration by the GAVI Board, including revised policy for allocation of products in limited supply, inputs into country guidelines and annual report forms, and wastage guidelines for Vaccine Fund supported vaccines

Country support and "trouble-shooting" activities (responsibility: project manager, WHO, UNICEF SD)

- (Country support is provided by partner agencies as part of their regular operations, in particular WHO through its Accelerated Vaccine Introduction project and the network of regional advisors)
- Coordination of response to the reduced availability of combination vaccines, including WHO/UNICEF country missions to Zambia, Burundi and Yemen and identification of interim measures.
- Assessment of pentavalent vaccine stock-out in Uganda, including country visit, updates to the GAVI Board and identification and implementation of stop-gap actions

Establishment of a yellow fever vaccine stockpile (responsibility: WHO, project manager)

- Strategies for establishment of a 6m dose YF vaccine stockpile developed and approved by the GAVI Board in November 2002
- Operational guidelines including definition of respective roles and responsibilities developed in January-March 2003 by WHO, UNICEF and the Vaccine Fund
- Contract arrangements established and vaccine stockpile operational in July 2003.

Closing Phase (responsibility: project manager, GAVI Secretariat)

- Preparation of VPP Lessons Learned
- Preparation of draft workplan 2004-05 as part of the overall GAVI workplanning process.

ANNEX 3: PROJECT CONTEXT: TRENDS IN THE TRADITIONAL EPI VACCINE MARKET

The global availability of basic pediatric vaccines used in low-income countries (BCG, DTP, OPV, Measles vaccine, TT) worsened dramatically in the late 1990s. From a situation with ample surplus of vaccine, increased product divergence between low- and high-income country markets and manufacturer exit/consolidation have resulted in a massive reduction of vaccine quantities offered on the market to countries and procurement agencies.

In 2002 and 2003, the shortage of DTP vaccine led to a reduced production of pentavalent vaccine (DTP-HepB+Hib) and considerable delays in vaccine delivery to countries approved for support by GAVI and the Vaccine Fund.

Since many of the basic pediatrics vaccines are linked (DTP and DTP-based combination vaccines, TT and conjugate vaccine production) or compete for lyophilization and filling capacity, UNICEF Supply Division in agreement with suppliers organized the procurement of basic pediatric vaccines for 2004-06 together with the tender for GAVI/Vaccine Fund supported products.

The main outcomes of the procurement of basic pediatrics are as follows:

- Availability of BCG, DTP, TT and Measles vaccine is on the increase. Supply is expected to meet demand, including DTP needed for the production of DTP-based combination vaccines. However, careful planning and monitoring of vaccine requirements for routine and supplemental activities must continue in particular for measles vaccine.

- The limited number of manufacturers for each product remains a concern in particular for measles. Broadening the supplier base is necessary to reduce the risks related to depending on some few manufacturers.

- Significant price increases for all the basic pediatrics have occurred and prices can be expected to remain at this level in the medium-term. Weighted average price for DTP will increase from $0.08 per dose in 2003 to $0.12 in 2004, and to $0.14 in 2006. This reflects the market response to the imbalanced supply/demand situation and may be considered a necessary trade-off to prevent further manufacturer exit and secure longer-term supply of basic vaccines to low-income countries. Governments and international donors will need to increase their vaccine budgets to meet the price increase of these vaccines.