

# Immunization Focus

A quarterly publication of the Global Alliance for Vaccines and Immunization

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## GAVI

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## Immunization Focus

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## Tough lessons – and rapid reform – for vaccine procurement system

THE ALLIANCE must adopt a more efficient and transparent process for buying vaccines, its Board has agreed. The decision follows a review<sup>(1)</sup> of the first round of procurement and introduction of new vaccines which identified significant shortfalls in the system and recommended immediate changes.

In large part, the problems with the first round of buying vaccines, which took place during 2000 and 2001, resulted from the ambitious timetable that GAVI set itself. Immediately after its launch, the Alliance set out to enable low-income countries to introduce new vaccines against two important diseases – hepatitis B and *Haemophilus influenzae* type b (Hib). In the process, it sought to demonstrate to a sceptical industry that there is a real market for newer vaccines in developing countries.

But while the review found that the Alliance had made remarkable progress in getting new vaccines to more children at reasonable prices, it found a lack of credible and predictable demand for vaccines, mixed messages to suppliers, and muddled aggregate performance of a group of partners with “unclear overlapping roles”, none of whom was ultimately accountable for the process. In these respects, the review concluded, the first round was “a missed opportunity”.

Most serious was the gap between the awards to manufacturers to supply vaccine and the amounts actually bought. For 2001, UNICEF indicated that it would want 98 million doses of vaccine but bought only 18 million. For hepatitis B monovalent vaccine, only 11% of the volume that was

requested was actually bought.

Mercer Management Consulting, a firm that has previously analysed vaccine supply issues for UNICEF, was commissioned by GAVI's Financing Task Force and the Vaccine Fund to produce the review. The goal was to learn lessons for the immediate future, not to assign blame for the past. Piers Whitehead, a co-author of the report and vice-president in the firm's San Francisco office, told *Immunization Focus* that the first procurement round had been a steep learning curve for all involved.



Piers Whitehead: the world has changed

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“It's important not to ignore the fact that until now, no new antigens have been introduced into the Expanded Programme on Immunization since it was set up in the early 1970s,” said Whitehead. In the past, he added, the public sector had been able to get the vaccines it has needed, and so had not needed to invest as much time and energy in accurate forecasting of demand as it does today. “But the world has changed,” said Whitehead.

To ensure the lessons of the first round of procurement are learnt before the second begins, immediate action is needed. The tendering process for the second round is due to start just weeks from now, in September. At its

### Inside this issue

Fast track to new vaccines

3

Call for intensified research after pneumococcus trial surprises

4

Sustainable financing: the pioneers' tales

5

meeting in Paris on 19 June, the Board approved the review's recommendation that a single project manager will coordinate the procurement of vaccines and the roles of each partner in the process. The project manager will be accountable to a small oversight body to be appointed by the GAVI Board.

As well as assessing the first procurement round, the Mercer review also made an assessment of the global vaccine market and the implications of the market structure for GAVI's procurement strategy. The review confirmed that, although the market has grown sharply, more than doubling since 1992, the growth is primarily in vaccines for the industrialized countries. GAVI is a small player with relatively little leverage in determining the activities of the major pharmaceutical companies, although it is a major player for emerging suppliers in middle-income and low-income countries.

**Mercer review's key recommendations:**

- Institute a project management approach to planning and implementing key Alliance initiatives, such as procurement of vaccines
- Pilot the project management approach with the upcoming procurement round for 2004-6
- Create or instruct an oversight body to monitor progress and hold the project manager and relevant individuals and institutions accountable for performance
- 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

Dr Tore Godal, executive secretary of GAVI, said the review had highlighted the complexity of vaccine procurement and the importance of understanding a market where supplies had once been abundant but are now more closely balanced against demand. "Another lesson is that we need longterm strategic direction," he said. "The industry needs credible multi-year plans from the public sector before it can invest in producing vaccines. Donor commitments need to take account of this."

The review did note some clear positive outcomes of the first round of

procurement. First, the Alliance had achieved a "unique accomplishment" in successfully increasing children's access to under-used vaccines in an unprecedentedly short period of 14 months from start to finish: in total 41 million doses of DTP-HepB and DTP-HepB-Hib are available for delivery during 2002-2003. Second, and equally important, the orders for the vaccines have created a new "pull" on the industry, stimulating manufacturers to increase their capacity to make these vaccines and to compete with each other. In the longer term this will mean more plentiful and affordable vaccines.

Third, the prices negotiated for the vaccines were also reasonable, the review found. For example, the DTP-HepB-Hib combination was bought for almost half the average price at which monovalent Hib vaccine is sold in industrialised countries. These prices benefited the public sector, but also gave manufacturers an appropriate return for their products, breaking the tradition that vaccines for the Expanded Programme on Immunization should be sold at near-cost price. While Mercer acknowledged that this break with tradition is "controversial to some", its review advised that vaccine producers will need appropriate returns if the supply of vaccines for low-income countries is to be sustainable.

The review's analysis of the problems with the first round showed that several factors were responsible for the severe mismatch in forecasted and actual demand. One key reason was that GAVI had promoted the use of combination vaccines before the supply situation was made clear by industry partners. When it emerged that supplies of these products would fall well short of demand, the Alliance was forced to "ration" them and some countries were offered only the option of using the plentiful supplies of monovalent hepatitis B vaccine instead. As a result, two big countries that had initially indicated that they would want hepatitis B vaccine, but in combination, decided to delay its introduction. This was "a significant source of error" in the forecast, said Whitehead. The review says that,

although the gap between the awards and the amount of vaccines bought will narrow as these countries come online, "from the supplier perspective, this delayed volume should probably be considered permanently lost."

Another factor was that awards to manufacturers were based on the most optimistic of three demand scenarios. Further, the award process added an extra 17 million doses to that high figure. Several possible explanations for this decision are suggested by the review. The process of awarding tenders appeared to have been required to serve two contradictory purposes: first, ensuring adequate supplies for countries, which UNICEF has traditionally done effectively, and second, establishing from the industry how much vaccine was available.

**Time pressure**

The extra 17 million doses may have been added because companies had made bids for certain quantities that UNICEF had to accept or reject in their entirety. "Regardless of explanation, the gap between award and offtake does not support the objective of credible and predictable demand," the review concludes.

Because time was so short, vaccine orders had to be placed before demand requirements were clearly known. "Obviously, given the pressure of time and the new ground being broken, some inaccuracy was unavoidable," says the review.

Three "semi-independent" processes had been used by the Alliance to establish countries' vaccine requirements, the review found. These were the countries' own proposals for awards, a forecast developed for the Financing Task Force, and UNICEF's own consultations with countries. "In aggregate, from a procurement and forecasting perspective, these yielded the disappointing outcome for 2001," the review concludes. According to Steve Jarrett, Deputy Director of the UNICEF Supply Division, "The start-up was slower than expected due to delays in the availability of vaccines as well as countries' decisions to change the timing, quantity, and in some cases, types of vaccine demanded."

From the standpoint of the vaccine industry, the problems were centred around a lack of openness and collaboration. Although the forecasting of immunization demand was shared with the industry for the first time by GAVI, the information was in the form of the number of children to be immunized with given antigens, rather than guidance about the actual products – such as combination or monovalent vaccines – that countries wanted. “Further, country level demand data was not shared with suppliers as it became available,” says the review.

One reason for this, says Whitehead, is because the public sector is traditionally wary of providing the private sector with data that might, in theory, be misused by companies to exert inappropriate influence on countries to buy their own particular

products. However, says Whitehead, a well functioning Interagency Coordinating Committee in countries should be able to detect any such inappropriate behaviour.

Of course, the Alliance must ward against conflict of interest – such as giving “insider” information to one company in favour of another. But, says Whitehead, the old tradition in which the public sector saw industry almost as an adversary has to end.

The Mercer review also examined the way the various Alliance partners worked together. It praised the fact that “an incredible amount of work” has been done in a short time. But it highlighted the difficulties faced by a loose alliance in implementing policy – as distinct from developing it. The roles and responsibilities of GAVI’s

different players were not clear. “On a self-reported basis, no partner claims lead responsibility for forecast development, or advising countries on vaccine choices,” says the review, while two partners claim lead responsibility for procurement strategy and development.

GAVI can add value to the multidisciplinary process of forecasting and procurement by bringing different partners with the relevant disciplines and skills together, says the review. But to deliver efficiently, there must be a clear chain of command and a single coordinator to carry responsibility – the model followed by project managers in the private sector. ■

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## Partners back new approach to fast-track vaccine development

WITH a concerted effort, vaccines against two major killers, pneumococcus and rotavirus, could be developed and introduced into the countries that need them most within around five years – a fraction of the time it took for hepatitis B vaccine to reach low-income countries after its licensure. The GAVI Board has approved an entirely new approach to coordinate the remaining R&D on these vaccines and to ensure that manufacturers will invest in producing them.

To support the new approach, the Board authorised use of the Vaccine Fund’s third “window”, or sub-account, up to a maximum of \$90 million over the next three years, subject to regular review. Until now, only the first two sub-accounts, for new vaccines and the strengthening of immunization services, have been opened.

A key aim is to overcome what appears to be the biggest barrier to the development of new vaccines for use in developing countries: a lack of clear, credible evidence that the vaccines will be bought. This lack of evidence has in the past left industry reluctant to invest in building up the capacity to produce these vaccines. Prices have stayed high, and in turn, the public sector has been unable to afford the vaccines, keeping demand low. And so the vicious cycle has continued.

The new approach, developed with the help of the consultancy firm McKinsey & Company, uses “accelerated development and introduction plans” (ADIPs) for each vaccine. With support from the Gates Foundation and the World Bank, draft ADIPs for the two vaccines have been created. One important finding is that ensuring the uptake of new vaccines is not just a matter of access to immediate financing. So the plans set out clear goals for establishing the value of the vaccines, communicating their value and delivering them. If successful, the plans could bring

forward the introduction of the vaccines in developing countries by as much as six years, preventing many deaths.

“This is an incredibly important moment in time for us,” said James Christopher Lovelace, director of health, nutrition and population at the World Bank, and a member of the Board, when the decision was taken on 20 June.

The ADIPs set out the key steps, timelines, players and budgets needed to deliver a specific number of doses of vaccine by a specific date. For example, the preliminary targets are to immunize some 10 million children per year against pneumococcus and some 30 million children per year against rotavirus between 2006 and 2012. Plans will be open to revision as development proceeds.

Each ADIP will be implemented by small teams of four or five people. The teams will be overseen by a steering group appointed by the Board, and will also seek regular advice from a scientific and technical review panel. Details of how and where the teams will work have yet to be decided.

Among the key tasks facing the teams is to get better estimates of the burdens of these diseases in different regions and countries, as well as wider evidence of the efficacy of the vaccines in clinical trials (see Update, next page). Decision makers who will ultimately pay for the vaccines – governments in countries and their international partners – are usually unwilling to invest in vaccines without solid evidence about how many lives they can save.

To avoid the possibility of conflicts of interest over individual vaccine products, industry representatives will be prevented from serving on review panels where specific products are being discussed. Board members also warned of the need to make sure that, while industry has a right to protect its intellectual property, GAVI would need to be explicit about what it expected in return for Vaccine Fund money invested towards product development. ■

# Call for intensified research after pneumococcus trial surprises

AS a key component of the plan to accelerate vaccines against pneumococcus, partners and scientists are calling for research to be urgently stepped up to provide better data on the burden of the disease and the efficacy of current candidate vaccines. Their calls come after trials of the most advanced candidate vaccine against pneumococcus produced unexpected results, answering some important questions but raising as many new ones.

Around 2 million children under five years old die from pneumonia each year in developing countries, according to the latest estimates(1). The bacterium *Streptococcus pneumoniae*, known commonly as pneumococcus, is thought to cause 50% or more of these deaths and a similar proportion of severe cases. A pneumococcal conjugate vaccine is licensed in the US and Europe and has proven efficacy against invasive pneumococcal disease (infections of the bloodstream). But trials are still ongoing to find out whether the vaccine can prevent pneumonia in children in developing countries: if the answer is yes, it could sharply reduce child deaths, alongside vaccines against the other major microbe responsible for pneumonia, *Haemophilus influenzae* type b (Hib).

Assuming that around half of all cases of severe pneumonia are caused by pneumococcus, and assuming that the vaccine has less than 100% efficacy, researchers had hoped that the vaccine could reduce the total number of pneumonia cases by around 30%. Some even hoped that the figure could be as high as 40%. But at the Third International Symposium on Pneumococci and Pneumococcal Diseases in Alaska in May, Professor Keith Klugman of Emory University, Atlanta, presented the results of a trial(2) from Soweto, South Africa, involving 40,000 children in which the vaccine reduced total pneumonia cases by around 22%. This figure is lower than expected and only marginally statistically significant.

However, the trial did confirm that the vaccine, made by Wyeth, reduced the incidence of invasive pneumococcal disease by more than 80%. Even in children infected with HIV, for whom invasive pneumococcal disease is a serious threat, the vaccine halved the incidence. In addition, separate data from studies in the US, also presented in Alaska, showed that the vaccine may help to reduce the spread of pneumococcal infections, as well as protecting those who are vaccinated. When infants in the US are vaccinated, the number of infections in people aged 20-39 and over 60 also drops – suggesting that parents and grandparents benefit.

Klugman is upbeat. If the Soweto findings are borne out elsewhere, then combined use of pneumococcal vaccine and Hib vaccine could cut the overall burden of pneumonia in children by some 40%, as well as offering specific benefits to children with HIV, he says. However, like other researchers, he believes that the pneumococcal vaccine's lower-than-expected efficacy against pneumonia

needs to be better understood.

“These results are forcing researchers to rethink their expectations about the vaccine, and strongly reinforce the need for continuing with other efficacy trials,” says Dr Orin Levine, of the US National Institutes of Health, one of a team charged by GAVI with the task of developing an agenda to rapidly evaluate and introduce pneumococcal vaccines into developing countries.

At present, researchers are missing key pieces of information. First, it is still not clear exactly how big the burden of pneumococcal pneumonia is. Doctors rely on chest x-rays rather than laboratory cultures to diagnose pneumonia, and chest x-rays cannot distinguish between pneumonia caused by Hib, pneumonia caused by pneumococcus or other microbes. The estimate that pneumococcus causes half of all severe cases of pneumonia is based on a handful of studies from developing countries where bacteria have been cultured from patients' lung fluid or blood, but those studies may not be representative. One purpose of vaccine trials is to get a better estimate of the burden.

Another problem is that, to measure a vaccine's efficacy, there must be clearly defined “endpoints” to the trial, such as comparing the number of cases of pneumonia in those children who have been immunized with the number of cases in those who have not. However, with x-ray as the main tool for diagnosing pneumonia, doctors in different settings may disagree over whether some individual cases should be defined as pneumonia or not. This may affect the numbers, and so the estimated efficacy of the vaccine.

The Soweto trial was the first to use standardised criteria for x-ray confirmed pneumonia, developed by WHO, says Klugman. “It may be that the criteria need to be reworked,” he says.

Given these problems, says Levine, it is difficult to know what the impact of the vaccine is. The results from

**“These results reinforce the need to continue with other efficacy trials”**



**Waiting in line: pneumococcal vaccines could save many lives but better data are urgently needed on just how many**

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Soweto could be interpreted in a range of different ways, he says. At one extreme, we might hypothesise that pneumococcus is as big a problem as we expected but we need better vaccines. At the other extreme, the hypothesis would be that the vaccines are highly effective, but pneumococcus is not as big a problem as we thought. It's essential to find out where between these two extremes the truth lies, says Levine. "As long as vaccines remain expensive, we are going to have to have very convincing data of their impact."

"This opens up a whole bunch of questions," agrees Professor Kim Mulholland, a paediatrician specialising in international health at the University of Melbourne, Australia. First, what will other trials show? All eyes are now a major trial of the same vaccine in The Gambia, which is due to end in late 2004. Conditions there may be more representative of Sub-Saharan Africa as a whole than Soweto. Although children in Soweto are disadvantaged in many respects, they have better access to hospital care than in most of rural Africa.

#### Key research questions

The Soweto trial was not designed to measure the impact of the vaccine on mortality, so no one knows how many deaths it could prevent. "It is entirely possible that the vaccine may have a higher impact on the more severe forms of pneumonia," says Dr Thomas Cherian, of the Christian Medical College, Vellore, India, who has been at WHO coordinating pneumococcal vaccine research.

Attention is also turning to other candidates. GlaxoSmithKline has developed a conjugate vaccine that is intended to protect against 11 different strains, or serotypes, of pneumococcus, compared with the 9 serotypes in the Wyeth product. Walter Vandersmissen of GSK told *Immunization Focus* that, following some technical delays, the vaccine is now due to start Phase II clinical trials in Europe and Latin America before the end of the year.

Another candidate pneumococcal conjugate vaccine was developed by Aventis Pasteur. The company recently decided to abandon the vaccine in order to develop a protein pneumococcal vaccine instead (see "This time, a

vaccine for everyone?", *Immunization Focus*, March 2002), but trials of the conjugate vaccine are still continuing in the Philippines. Even if the vaccine produces promising results, there are no known plans to develop it commercially. But scientists say the results of the trial will still be very important in providing information about the efficacy of this type of vaccine.

Another important question is to find out whether vaccines against pneumococcus simply move the goalposts for the microbe. Scientists have been concerned that, in theory, even if a vaccine protects children against the serotypes of pneumococcus included in it, other serotypes may simply take their place and cause disease. The actual findings on this phenomenon, known as serotype replacement, have been mixed. In most studies, there is no evidence that it has happened. In Finland, however, researchers have found that vaccinated children do develop ear infections with different serotypes – but the most severe infections are still prevented and the number of children needing to have ear tubes inserted has been reduced.

Levine says it will be important to find out whether the more severe infections are prevented in pneumonia too, and to monitor carefully for serotype replacement, in the remaining clinical trials.

Dr Tore Godal, executive secretary of GAVI, says the surprise results from Soweto are good for the field. "They force us to answer the important questions about disease burden and vaccine efficacy," he says. Researchers are hopeful that the GAVI decision to back an accelerated development and introduction plan for pneumococcal vaccines (see preceding page) will now help to kick-start precisely the kind of studies needed to answer these questions. ■

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## Sustainable financing: the pioneers' tales

SPECIAL FEATURE

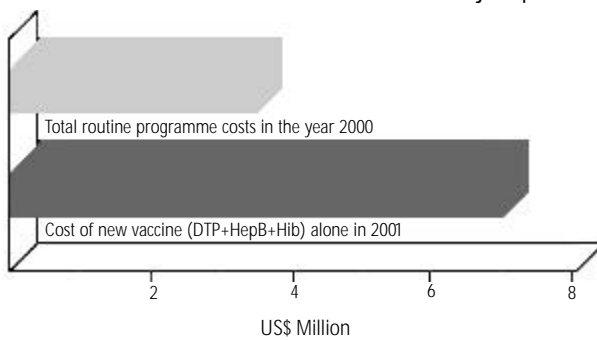
By late November this year, the first 13 countries to receive support from GAVI and the Vaccine Fund must have initiated their plans for sustained financing beyond the initial five-year support period. Cambodia and Ghana have made an early start. Phyllida Brown talks to the teams involved

HOW big will your country's immunization financing gap be in 2007 or 2008? This is a question that many might prefer to ignore, but Dr Mercy Essel Ahun, manager of Ghana's Expanded Programme on Immunization, is not one of them. Together with her colleagues, the health and finance ministries and Ghana's partners, she has looked her programme's future funding gap squarely in the eye – and has begun to work out how to deal with it.

No one pretends it's an easy task. But the truth is, health ministries have never really been challenged to think in this

way before. Data from countries indicate that from one year to the next, funding for direct immunization costs has varied considerably, suggesting that the development of long-term financing strategies has not been given high priority. "For us, as doctors, it was an eye-opener," says Ahun. "Until now we have just delivered the service. But now we have to get firm commitments from government and partners for a fairly long-term period." Particularly because, as the service expands to protect children against a wider range of diseases and to serve those who are

Money worth spending:  
Ghana's direct immunization costs jump



hardest to reach, its costs are rising. When Ghana's routine immunization programme offered just the traditional vaccines – such as diphtheria, tetanus and pertussis (DTP), polio and measles – direct spending was about US\$3.7 million a year (see Figure). With the introduction of new antigens against hepatitis B and *Haemophilus influenzae* type b (Hib) in a new combination vaccine (DTP+HepB+Hib), the cost of the new vaccine alone will be more than \$7 million a year<sup>(1,1a)</sup>.

Support from GAVI and the Fund, which has paid for the new vaccines, is initially intended to last for five years and to act as a catalyst for other sources of finance. What will those sources be? "We have come up with a plan where increasingly, we are going to bear more and more of the costs," says Ahun. The government intends to take increasing responsibility for personnel and other recurrent costs and, depending on the amount of debt relief it secures, will pay an increasing share of the costs of the new vaccines. Several new ways to mobilize resources within the country have been suggested, including money from the decentralized health districts. But, as Ghana and its partners in the Alliance are agreed, external support will still be needed to help buy the vaccines themselves. That means donors, or international partners, must continue to play a key role.

Financial sustainability plans are required from all countries receiving support from the Alliance and the Vaccine Fund in the second year of their funding. The plan is intended to show how the country proposes to support its immunization programme after the end of the initial five-year award (see Box 1). But it's much more than a document, says Ahun. Its creation requires a process that brings people together, sometimes for the first time, to agree on common objectives. By setting out clearly the immunization programme's current costs and its expected future costs, it forces all stakeholders to think about the options and choose how to move ahead.

**Using the plan as a tool to advocate for immunization**

Equally important, the plan provides vital ammunition for the immunization programme to argue its case – both with its own government and with international partners, such as governments in industrialized countries.

"It is good to put something down on paper," says Ahun. "It's about getting a consensus and saying, this is what the

programme has come up with." At the national level, the plan must be signed by the health and finance ministries, so that it commits both to a shared agreement and raises the profile of immunization across the government. "We have had these discussions with people right from the top, and everybody now knows about the financial sustainability plan," she says.

For Ghana, the timing of the plan has been perfect, as it has coincided with the formulation of the wider health system's current 5-year plan. So its goals and targets are being integrated into the wider plan. Indeed, says Ahun, the idea of financial sustainability plans could catch on in other areas of the health system: two other programmes have expressed interest in doing their own.

Abroad, meanwhile, the plan provides the country with a stronger basis for attracting new funds from partners. Local staff of the major partners will have a case to put to their headquarters, Ahun hopes, while at international level, the Alliance can keep up the political pressure.

"Beyond what we can do in our country, the partners need to keep flying the immunization flag very high," says Ahun.

**1: What's the financial sustainability plan for – and when should it be ready?**

All countries receiving support from GAVI and the Vaccine Fund have been asked to prepare a financial sustainability plan (FSP) in their second year of funding to indicate how they propose to support their immunization programme after the initial support ends. For the first 13 countries to receive awards, plans should be initiated by November 2002. The next round of countries will prepare plans in 2003. The first 13 countries will pilot the process; it may evolve as lessons are learnt.

To achieve financial sustainability, a country is not expected to become self-sufficient – at least, not in the near- to medium term. While self-sufficiency is the ultimate goal, it is wholly unrealistic for most eligible countries for the foreseeable future. Instead, achieving sustainability is seen by GAVI as a responsibility that must be shared between countries and their development partners. Last year, the Alliance agreed a definition of financial sustainability as "the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunization performance in terms of access, utilization, quality, safety and equity".

The GAVI Financing Task Force (FTF) has produced guidelines<sup>(2)</sup> for how to draw up the plans. These were developed in close consultation with stakeholders and revised multiple times, including a revision after Ghana and Cambodia had tested them. The FTF is helping to arrange technical support to individual countries in producing the plans, and is also holding two intensive training workshops in July, one in English, one in French, in Kenya and Senegal respectively, to help managers prepare.

More information, including reports from Cambodia and Ghana on the pre-tests of the guidelines, details of the July workshops, and other explanatory documents, are at [www.vaccinealliance.org](http://www.vaccinealliance.org)

## 2: Putting the plan together

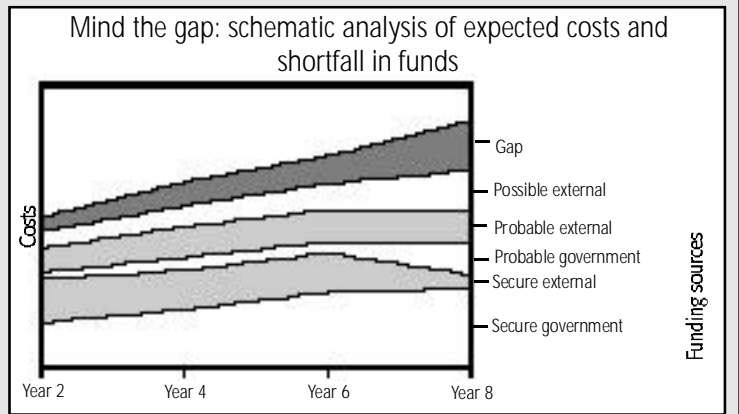
Each country's plan must include:

- Information about the current immunization programme, its costs and the sources of its funds.
- A statement about the programme's key objectives for expanding and improving its services.
- Figures and a graph (see Figure) showing the increase in estimated projected costs from the first year of funding for eight years, expected income, and the gap between what is expected and what is needed. As all players recognise that it will be difficult to get long-term commitments from either a national government or its partners, the Alliance has agreed that the plan should show what proportion of the expected funds is secure, what proportion is probable, and what proportion is possible. Tables allow for itemising of all components of the programme – such as vaccines, personnel, supplies, transport, training, vehicles and cold chain equipment.
- An outline of the strategic priorities for financial sustainability: for example, an indication of the main constraints and the approaches being taken to close the financing gap.
- A description of actions that can be taken to address the problems, who will take these actions and when.
- A set of indicators to monitor progress: for

example, whether a plan of action is in place to generate demand among families for children's immunization, or whether there is a budget line item for immunization.

- The signature of the Minister of Health.
- The signature of the Minister of Finance.
- The signatures of key members of the immunization coordinating committee, including leading financing partners, indicating that they have reviewed the document; and
- Comments on the plan by leading financing partners.

Source: Reference 2



### Political support and public demand

She recognises the scale of the challenge, but is optimistic that resources for Ghana's immunization programme will continue to flow. Her reasoning is twofold: first, because the government is committed to immunization. The evidence in its favour is direct and strong. Ahun points to the success of the measles immunization campaign organized in the Central region of Ghana last year. The peak month for transmission of the measles virus in Ghana has just passed and cases in the Central region are down by 90%. "So the programme has visible effects," she says.

Second, and just as important, people in Ghana want and demand immunization for their children. "the way the mothers descended on the stadium at the launch of the new vaccine showed the faith that people have in immunization."

### Lessons for the Alliance

Ghana's test of the process also gave GAVI some important information. First, that the guidelines needed to be simplified<sup>4</sup>. Second, significant time and resources are needed for preparing the plans, and these may have to be boosted with outside help for specific technical tasks. Ghana had support from external consultants who helped to cost the existing services, for example. Despite having an exceptionally high level of training and specialist knowledge, and an efficient and strong immunization service, Ahun believes that her country would have "struggled" to produce the plan if it had not had help with the cost assessments.

Does she have any worries? Ahun is

aware that in some countries, health ministries could see the demand for a financial sustainability plan for the immunization service alone as a threat to the health sector as a whole. However, if the plan is integrated into the overall health plan, as in Ghana, this need not be a problem, she believes. Ahun and her colleague Dr George Amofah have also warned of the challenges for their government in addressing competing health priorities and new single-issue initiatives, as well as the need to beat down the cost of new vaccines.

### Tough questions for donors

The planning process raises a challenge for development partners. This goes beyond Ghana, and affects all countries. In essence, countries are being asked to change their behaviour and make long-term commitments to immunization, but development partners are not yet ready to do the same. Despite proposals last year that the financial sustainability plans should include firm commitments of 5 or 7 years' money from partners<sup>3</sup>, in reality those partners have been unwilling or unable in law to commit themselves more than a year or two ahead.

It can also be difficult for local staff of a development partner, far from their HQ, to take such responsibility, and awkward for countries to have to ask them in the first place. The current guidelines do require signed comments from partners, but this stops short of a hard financial commitment. Can partners really expect countries to make long-term plans and commitments if they themselves are unwilling to do so? "The new definition of financial sustainability (see Box 1) puts the onus on the international partners as well as the countries," says Vio Mitchell, the coordinator of the GAVI Financing Task

Mercy Essel Ahun: "Ghana's partners must keep the immunization flag flying"



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Force. In that case, doesn't the development partners' unwillingness to commit themselves so far amount to a cop-out? Like Ahun and her colleagues in Ghana, Mitchell believes that the only way to resolve this issue will be through high-level advocacy, with Alliance partners continuing to argue the case for stable financing for immunization with ministers of health and international development.

### Long-range commitment

"The commitment of the GAVI partners to improve immunization has always been a long-range proposal," says Dr Tore Godal, GAVI's executive Secretary. "We know that all issues will not be solved overnight, in five years, or even ten. But we are an initiative that is learning and evolving as we go. We must use the lessons we learn through experience today before we consider what we do in year six and beyond." Godal explains that the Fund may be directed in future to different purposes, such as health system infrastructure, other under-used vaccines, or new approaches to reaching children with essential health care.

### Cambodia: different needs

Ghana may be exceptional in that it has relatively strong expertise in planning its health service finances. Cambodia, which has also tested the FSP process, may be more typical of low-income countries; it has severely limited resources and few people with the relevant technical skills on whom to draw. Its immunization programme staff have not been specifically trained in financial management.

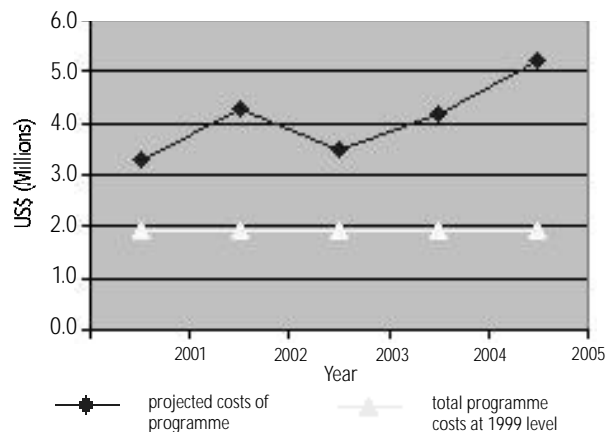
When a cost assessment was done in 2000, Cambodia's projected health budget for 2001 was 1.1% of the country's gross national product, although it is expected to double over the next 4 years. The immunization programme costs were about \$2 million in 2001, with much of the funding coming from outside partners. Costs are expected to more than double by 2005 if all recommended programme improvements, including new vaccines are adopted (see Figure).

Cambodia is now putting together a plan to finance its immunization service into the medium term future. To start the process off, external helpers worked with the government to evaluate the guidelines in the test process, and to develop a timeline for completing the plan on target. Dr Sann Chan Soeung, the director of the national immunization programme, and his colleagues worked with Bryn Sakagawa, a health financing specialist with the consultancy firm Abt Associates in Bethesda, Maryland, and Mike Curtis of the Institute for Health Sector Development in London. A technical consultant, Susan Shin, from WHO's Western Pacific regional office, is now working with the immunization team to provide training in financial management skills.

### Mobilizing skills

In Cambodia, the test of the guidelines was the first opportunity that the hard-pressed health staff had had to discuss the broad concept of financial sustainability, says

Going up: projected costs for Cambodia's immunization programme 2001-2005



Sakagawa. Staff have many other preoccupations delivering the service, such as the replacement of the cold chain to combat vaccine wastage. With these problems, it is not surprising that financial management skills have been on the back burner – till now.

Soeung reports that the initial support has been helpful. However, his team have encountered some of the most basic difficulties in developing financial sustainability plans. First, it has proved very difficult to schedule time to meet with staff from the ministry of finance. Second, much of the immunization team's time has been preoccupied with other meetings with donors on other topics. International partners, as well as national governments, need to set specific time aside for this process. The types of support that will be offered to Cambodia in the production of the plan range from clearing up confusion about the way the health system is financed currently, to training in accounting skills. The support team will also offer practical help, for example in the use of spreadsheet software. "We plan to work on the key analytical skills, too," says Sakagawa, "such as assessing how much the programme is going to cost, and identifying how big the gap will be between what the national programme and the donors are providing and what is needed."

**"The onus is on international partners as well as countries"**

As in Ghana, a key purpose of measuring the size of the gap is to enable the immunization programme to advocate for more support at home and with its development partners, and the team agreed that more training in advocacy would help the immunization staff to do this effectively.

What did Cambodia teach GAVI about the process? Importantly, it reinforced many of the findings from Ghana. It also highlighted that plenty of targeted technical support will be needed, especially where interpreters are required to translate complex sustainability ideas. "All of these concepts are so new that if you work in another language, it will take a lot longer to develop the plan," says Sakagawa.



### Power shift to countries

But often, people with the right skills will be at hand within the national government, says Ruth Levine, a health economist at the World Bank whose analysis led first to GAVI's new definition of sustainability and more recently to the development of the guidelines. "The guidelines are not complex for people who have any facility in dealing with financial concepts, and those people do exist in governments in every country in the world, although they are rarely in immunization teams," she says. A challenge for the team responsible for the plan is to find, wherever possible, those people within the country who can offer those skills.

Ultimately, both countries, Ghana and Cambodia, have gained from the testing of the planning guidelines and GAVI has also learnt lessons to help the remaining countries. Above all, the Financing Task Force hopes, key players have understood the need for mobilizing resources and forging new relationships between finance ministers, health ministers and international partners. "At first," says Ruth Levine, "there was a perception that these plans would just be documents to feed some imagined bureaucratic beast in the GAVI secretariat." Now, she hopes, everyone understands that their real purpose is to make sure that the decision-makers are informed with the facts – decision-makers who decide how the programme operates, those who hold the national purse strings, and, importantly, the development partners – and that they are talking to each other about the major financial challenges and opportunities. The ultimate objective is to strengthen immunization services longterm. As Vio Mitchell puts it: "This is about a powershift to countries." ■

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## Advocacy for financial sustainability

**Heidi Larson, Senior Communications Adviser at UNICEF and Chair of the GAVI Advocacy Task Force, sets out some key principles**

*Advocacy is winning the support of key constituencies in order to influence policies and spending, and bring about social change. Successful advocates usually start by identifying the people they need to influence and planning the best ways to communicate with them. They do their homework on an issue and build a persuasive case. They organize networks and coalitions to create a groundswell of support that can influence decision makers<sup>(1)</sup>*

While accurate financial sustainability plans with a clear understanding of financial gaps are crucial to mobilizing adequate and sustainable resources for immunization, they are not enough. Decision makers who determine budgets for vaccines and immunization services need to be aware of the importance and value of vaccines as a crucial, cost-effective investment so that they commit needed budgets, with adequate long-term planning to ensure uninterrupted supplies of vaccines. They also need to know the public health risks of a vaccine programme running out of resources.

In order to advocate and plan for financial sustainability, clear and concise information is needed on why a country should invest in immunization. Information on how that investment can help to strengthen an overall health system is valuable fuel for advocacy, as is evidence on the impact of immunization in reducing disease burden.

Good advocates also need to know who they have to influence, and understand the environment and language to build an argument that will appeal to that particular person or constituency. While there will be some key messages that will be relevant to everyone, the way in which messages are delivered will likely need to vary – depending on the audience – in order to be effective. What matters to a minister of finance will be different from what matters to a minister of health. Decision makers need to be persuaded that immunization, in the context of other competing demands, is critical and supportive of other health and development concerns.

In order to ensure that financial commitments will prove sustainable, the plans need to be widely owned. Broad participation in the planning process is essential to ownership of the plans – and provides a wider base of support to ensure that the plans are realized. Remember that advocacy for financial sustainability is an ongoing process which will need continual effort. The more people who own and believe in the need for adequate resources for immunization, the more likely the needs will be met. ■

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**Editor:** Phyllida Brown

**GAVI Editorial Adviser:** Lisa Jacobs

**Publisher:** Dr Tore Godal, GAVI Secretariat, C/O UNICEF, Palais des Nations, 1211 Geneva 10, Switzerland. Email: [Gavi@unicef.org](mailto:Gavi@unicef.org)

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