A proposal for an

International Finance Facility for Immunization (IFFIm)

Prepared by the Global Alliance for Vaccines and Immunization (GAVI)
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GAVI Partners:

World Health Organization
UNICEF
The World Bank Group
The Bill & Melinda Gates Foundation
Developing Country Governments
Industrialized Country Governments
Vaccine Industry-Industrialized Countries
Vaccine Industry-Developing Countries
Nongovernmental Organizations
Research Institutes
Technical Health Institutes

The International Finance Facility for Immunization
Executive Summary

The need
It is widely recognized that efforts to improve a nation's health will also help fuel economic development[1], especially in the poorest countries. Investment in health could save millions of lives every year – increasing life expectancy, boosting productivity and reducing poverty. The needs are immense. Currently, more than 10 million infants and children under five[2] die each year from illnesses such as pneumonia, diarrhoea, malaria, measles, meningitis – diseases that can be prevented or treated effectively, through basic health services. It is estimated that 2-3 million of those child deaths are from diseases that could be prevented by vaccines that are available now or that are likely to be available in the near future[3].

The Millennium Development Goals (MDGs) have been widely embraced as ambitious but achievable targets aimed at halving poverty by 2015. With adequate resources and the necessary political will, the goals could be achieved on – or close to – schedule. Today, developing country efforts to reallocate resources to benefit the neediest are intensifying, and donors have reconfirmed their pledges to increase international development aid over the next few years. However, these gradual increases are not enough to bridge the resource gap of at least US$50 billion per year, if the goals are to be met[4].

A novel financing mechanism could bridge the funding gap
Under a proposed new mechanism called the International Finance Facility, the additional financing urgently required to meet the goals would be raised by selling bonds in the international capital markets, based on legally-binding long-term donor commitments. The result: a substantial increase in development funds available immediately – in predictable and stable aid flows – for the poorest countries. This mechanism will incur some borrowing and transaction costs, making it somewhat more expensive than traditional aid. It would therefore be optimal for activities that can accomplish benefits rapidly and reduce costs over time.

Immunization: a test case
The partners in the Global Alliance for Vaccines and Immunization (GAVI) have been in discussions with the United Kingdom, France and other donors to explore using the IFF principles to fund immunization. Substantial 'front-loaded' funding for immunization could be used to accelerate increased availability of new vaccines and to secure better pricing. It could also be used to support the substantial system improvements required to ensure that immunization systems are able to absorb the new vaccines and scale up coverage to 90% nationwide in every country, in accordance with the goals set in 2002 in the World Fit for Children Declaration.

Immunization is well suited to demonstrate the viability of the IFF mechanism because it:
- is an essential and highly cost-effective intervention that is integral to the public health system;
- can be scaled up quickly, even in resource-poor settings;
- can have an immediate impact on child mortality;
- can use frontloaded funds to accelerate vaccine market forces; and
- is a key first, and sometimes only, contact for mothers and children with the health systems, and can be used to ensure other health needs are addressed.

Building on a proven governance and allocation structure
GAVI was launched in January 2000 as a collaborative, consensus-driven alliance to promote common goals. Its efforts largely focus on disbursing resources available through its financing arm, The Vaccine Fund – created to help the poorest countries achieve internationally-agreed immunization goals. With an

[1] See the report of the Commission on Macroeconomics and Health
[2] State of the World's Children, UNICEF New York, 2004
[3] World Health Report, WHO, 2004
[4] Report of the High-Level Panel on Financing for Development, Chaired by Ernesto Zedillo, 2001.

innovative approach that allows countries to make local allocation decisions and rewards good performance, the funding has catalyzed increased national and external investments in health systems. Moreover, the GAVI alliance has re-energized international commitments to immunization, and stimulated increased technical support to and partnership with countries.

To date, The Vaccine Fund has raised US$1.3 billion, of which 90% has already been committed to countries. Though existing structures may need certain modifications, it would be relatively straightforward to disburse the significant additional funds through the current GAVI system.

How the funds would be used

The poorest countries also have the highest incidence of vaccine-preventable diseases. They would be the focus of funding, as these investments would be most likely to have a rapid and profound impact on reducing under-five morbidity and mortality. Furthermore, investments would be specifically targeted to areas in which the use of significant front-loaded investments would reduce costs over time and continue to pay dividends long after the initial investment period. For example:

- Increasing vaccine supply and promoting affordability by offering manufacturers secured financing ('advance contracting') for priority vaccines for the developing country public sector market would help stimulate new private sector investment and greater competition, leading to a more rapid reduction in vaccine prices.
- Rapid gains in increasing access to an expanded offering of vaccines would save children's lives in the short term. In the longer term it would reduce the overall risk of disease in the wider population, and would help spur economic benefits which accrue from reduced child mortality and general improvements in health.

The GAVI Alliance would define the allocation policies for these funds through an evidence-based process. The principles underlying the new Global Immunization Vision and Strategy now being developed would help guide these decisions. Vaccines against *Haemophilus influenzae* type b (Hib), hepatitis B, rotavirus, pneumococcus, meningococcus A, and Japanese encephalitis could have considerable impact on reducing disease burden. However, their widespread use will only be possible if funding to strengthen health systems is also provided. Many of the poorest countries are barely managing to deliver the most basic immunization services; significant investments are needed to expand access to the traditional vaccines, and to manage and deliver the new vaccines. The scaled-up immunization efforts would require increased levels of technical support from partners such as WHO and UNICEF.

Countries would access the funds through a country-driven application process, based on comprehensive multi-year plans that integrate all immunization activities and financial planning to ensure that funds fill clearly identified gaps and do not replace existing funding for immunization. To avoid budget distortions, tight integration with national planning processes, early involvement of the finance ministry, and strict monitoring of potential substitution will be integral to the process.

Projecting the impact

Though the actual funding programme would depend upon countries' own analysis of needs as identified through the application process, a set of illustrative scenarios have been used to estimate potential impact. Calculations are based on projections of annual estimates of vaccine-preventable disease mortality[5], the likely availability of new vaccines to combat these diseases, current estimates of immunization coverage, projected future trends in coverage and the estimated investments in delivery systems needed to expand coverage.

Even at the lowest level of investment (US$4 billion) it is estimated[6] that the lives of more than 5 million children could be saved over the 10-year period, and more than 5 million future deaths due to hepatitis B related liver disease in adulthood could also be prevented. This is in addition to the estimated 1.5 million children's lives that will be saved over the same period if GAVI resources continue at their current level. At higher levels of investment (US$8 billion), it is estimated that more than 8 million deaths in children

[5] As calculated each year in the WHO World Health Report
[6] Source: provisional WHO-IVB estimates

under 5 could be prevented.

Monitoring the risks

The International Finance Facility for Immunization (IFFIm) would test a brand new financial tool for development aid; it will involve risks. In view of this, due care will be taken to ensure that the risks are calculated and assessed so that appropriate risk management strategies can be put in place. The most significant risks include budget and programme distortion and lack of sustainability. These would be addressed largely through provision of direct financing to countries, based on countries' own multi-year plans and existing national budget frameworks.

Conclusion

The IFFIm would not only deliver a critical mass of aid but would also achieve a major breakthrough in aid effectiveness – allowing countries to maximize the benefits of long-term investment and ensuring that the aid is used to finance key investments that will help put countries on a sustainable path to poverty reduction and prosperity.

The International Finance Facility for Immunization

The proposed International Finance Facility for Immunization (IFFIm) could save millions of children's lives and contribute to meeting the Millennium Development Goals (MDGs), while testing the viability of a new mechanism for financing development. This proposal describes the principles and concept of this new mechanism and the estimated impact it would have on the MDGs. The stable, predictable – and significant – flows of resources that the IFFIm could generate offer a solution to many of the financing constraints that have affected immunization and other public health interventions in the past. Since an innovative new programme such as this would involve breaking new ground, a risk-management approach would be employed in both the design and implementation of the programme. The IFFIm would build on proven governance and allocation mechanisms and would channel the new funds directly to countries through a 'bottom-up' approach, whereby countries request funds based on country analysis of local needs. An illustrative programme for the use of the funds is provided in this proposal, together with a range of different funding scenarios, each with detailed estimates of the expected impact on mortality.

I. A new way to fund development

The second half of the 20th century was a period of unrivaled economic growth, in rich and poor countries alike. One of the benefits – and indeed one of the causes – of this economic growth is that more people have access to basic health services and education than ever before. Despite this, a stark divide exists between the rich and poor, especially in terms of their access to basic services.

The scale of death and ill health in the world today remains staggering. Despite progress in reducing child mortality rates, in 2000 over 10 million children died from illnesses such as pneumonia, diarrhoea, malaria, measles, HIV/AIDS, meningitis and neonatal causes– diseases that can be prevented or treated effectively, where the health system is capable of delivering basic services. In addition, over half a million women in developing countries die every year during pregnancy or childbirth.

World leaders are rising to the challenge. With an overarching goal of poverty reduction, the Millennium Development Goals (MDGs) have become a rallying call for developing countries and the international community. These eight goals have been widely embraced as ambitious but achievable targets aimed at halving poverty by 2015. Progress in meeting these goals will be assessed in 2005.

The Millennium Development Goals

Goal 1 Eradicate extreme poverty and hunger
Goal 2 Achieve universal primary education
Goal 3 Promote gender equality and empower women
Goal 4 Reduce child mortality
Goal 5 Improve maternal health
Goal 6 Combat HIV/AIDS, malaria and other diseases
Goal 7 Ensure environmental sustainability
Goal 8 A global partnership for development

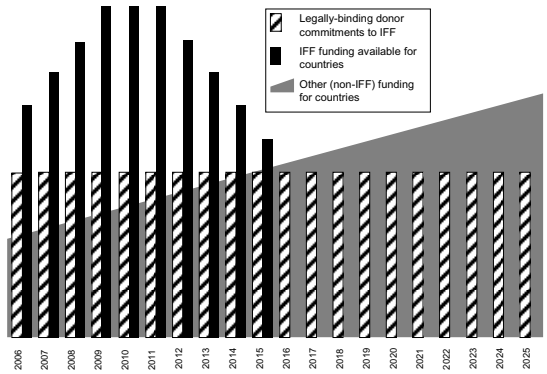
With adequate resources the goals could be achieved on – or close to – schedule. Donors have reconfirmed their pledges to increase international development aid to 0.7% of their gross domestic products (GDP) – a target set in the 1970s but met by only four countries so far[7]. And in 2002, at the Financing for Development Conference in Monterrey, Mexico, donors pledged to increase international aid by US$16 billion a year from 2006.

[7] Denmark, Netherlands, Norway and Sweden.

It is estimated that international aid needs to double – from today's US$50 billion to about US$100 billion per year – to achieve the MDGs by 2015[8]. Despite this, many countries today are fiscally constrained from substantially increasing aid levels in the short- to medium-term, and gradual increases in funding will not bring about the dramatic improvements required.

To bridge this financing gap, the UK Treasury has proposed a novel mechanism, the International Finance Facility (IFF). New long-term donor commitments (which would be legally binding) would be leveraged in the capital markets by issuing bonds. The result: 'frontloaded' financing, with a substantial increase in development funds available immediately – in predictable and stable aid flows – for the poorest countries. The risk that future resources will be insufficient to meet needs is expected to be mitigated by a decline in development costs and an increase in overall donor funding. This concept of frontloading donor commitments is shown in Figure 1.

Figure 1: ILLUSTRATIVE EXAMPLE OF FRONTLOADING



The IFF would provide greater stability and predictability of donor commitments – allowing recipients to plan and implement long-term strategies. It could be used to obtain market guarantees for needed products, or to quickly make available financing – for instance when a new vaccine is licensed. Transaction costs could be kept manageable, as donor disbursements and recipient reporting would each go through a single mechanism. Moreover, it could improve aid effectiveness through donor agreement to high-level aid principles such as untying aid and a focus on the poorest countries with the greatest burden of disease. However, in order to have a significant impact on the MDGs the funds raised through the IFF must not replace current annual aid flows.

The partners in the Global Alliance for Vaccines and Immunization (GAVI), have been in discussions with the UK, France and other donors to explore using the IFF principles to fund immunization. The use of front-loaded funding for immunization could help to accelerate increased availability of new vaccines and to secure better pricing. It could also be used to support the substantial system improvements required to ensure that immunization systems are able to absorb the new vaccines and scale up coverage to 90% nationwide in every country, in accordance with the goals set in 2002 in the World Fit for Children Declaration.

II. Why immunization is ideal for an IFF structure

The IFF characteristics of predictable, stable and significant resources offer an excellent way to overcome the problems of unpredictable, uncommitted and short-term flows that have constrained immunization financing in the past. In addition, immunization is particularly well-suited for the use of IFF-generated funds because it:

- is an essential and highly cost-effective intervention that is integral to the public health system;

[8] Report of the High-Level Panel on Financing for Development, Chaired by Ernesto Zedillo, 2001.

- can be scaled up quickly, even in resource-poor settings;
- can have an immediate impact on child mortality;
- can make use of front-loaded funds to accelerate vaccine market forces;
- is a key first, and sometimes only, contact for mothers and children with the health system, and can be used to ensure other health needs are addressed; and
- can channel funds through a proven governance and allocation structure.

Achieving the MDGs is the central aim of the IFF concept. Immunization will contribute to the achievement of the goals by:

Reducing child mortality: Childhood immunization, one of the most cost-effective public health interventions available, is pivotal to the goal of reducing under-five mortality rates by two-thirds between 1990 and 2015. An estimated 2-3 million children under five die every year[9] from diseases that could be prevented by vaccines available now or likely to be available in the near future. In addition, providing tetanus vaccination to women of childbearing age would contribute to reducing maternal mortality.

Reducing poverty and improving access to education: Efforts to reduce the incidence of vaccine-preventable diseases would help increase school attendance and prevent the loss of productive work by adults when children are sick. Education is widely recognized as a key to economic development, but poor health directly reduces cognitive potential and indirectly undermines schooling through contributing to absenteeism, poor attention span, and early drop-outs.[10] In addition, hepatitis B vaccination in childhood pays long-term dividends by preventing the development in later life of liver cancer — the most common form of cancer worldwide, which kills people in their most productive years.

The cost of vaccinating a child is relatively modest compared to other health interventions. In addition, immunization is often the first, and sometimes only contact a child has with primary health care services. Building upon that critical contact with key essential health interventions could improve a child's health prospects for life. [11]

Strengthening immunization services is part of improving access to basic health care for women and children. In the World Fit For Children Declaration of 2002, a goal of reaching 90% national coverage, with 80% coverage reached in every district, was set as the target needed to help reach the MDGs. However, based on current WHO and UNICEF projections, given existing financial commitments to immunization, this level of coverage may not be achieved until 2037 at the earliest.

Scaling up can happen quickly

A major international effort in the 1980s to bring basic vaccines to all children – no matter how

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[9] Source: provisional WHO-IVB estimates

[10] Commission on Macroeconomics and Health, WHO, 2001.

[11] In 2003, through the African Measles Partnership, a measles campaign in Zambia was extended to include the administration of mebendazole (for the treatment of intestinal worms) and vitamin A supplementation, as well as the distribution of insecticide-impregnated bednets to prevent malaria. Six months after the campaign, not only were immunization rates equally high among all income groups, but there was a three and a half-fold increase in bednet usage in the poorest fifth of the population. A recent study in Tanzania has used routine immunization services to deliver preventive treatment for malaria and anaemia, major causes of hospital admission and mortality among children in developing countries; the incidence of clinical malaria was reduced by almost 60% and the incidence of severe anaemia by 30%.

poor – brought global immunization rates from 20% in 1980 to over 70%[12] by 1990. As a result, child mortality rates declined. However, between 1990 and 2000, immunization coverage stagnated or deteriorated in many developing countries. Despite this, the basic infrastructure of immunization still exists in every country as an integral component of health services. This infrastructure can be further improved to expand access to immunization and other health services and enhance the prospects for introduction of new vaccines.

The Global Alliance for Vaccines and Immunization (GAVI), has demonstrated how quickly a scale-up can occur. Although vaccines provided by the Vaccine Fund only started flowing in 2001, nearly 42 million children in the world's poorest countries have already been reached with the required three doses of the hepatitis B vaccine, and general immunization coverage rates have begun to rise.

Building on a proven governance and allocation structure

GAVI was launched in January 2000 as a collaborative, consensus-driven alliance that works toward common goals. Its efforts largely focus on disbursing resources available through its financing arm, The Vaccine Fund – created to help the poorest countries achieve internationally-agreed immunization goals. To date, The Vaccine Fund has raised US$ 1.3 billion, of which 90% has already been committed to countries. With an innovative approach that allocates resources based on country analysis of needs and rewards good performance, the funding has catalyzed increased national and external investments in health systems. Moreover, the GAVI Alliance has re-energized international commitments to immunization and helped ensure a substantial increase in both the amount and quality of technical support provided to countries through cooperative partnership.

Based on independent review of country-generated proposals, GAVI is already supporting 71 countries with Vaccine Fund resources. Though existing structures may need certain modifications to disburse the significantly increased funds that would be available, integration of IFFIm funds through the current system would be relatively straightforward.

The performance of each country is well documented through the existing GAVI country application and monitoring processes. This will form a strong evidence base for informing future allocation decisions. Furthermore, current work on overcoming health systems barriers and addressing problems in countries with chronically low coverage rates can be used to guide IFFIm investments.

Frontloading: A solution to immunization funding gaps

Funds raised through this mechanism would be somewhat more expensive than traditional aid, due to transaction and borrowing costs. Investments would therefore be particularly suited to areas in which significant outlays upfront would reduce costs over time and continue to pay dividends long after the initial investment period. For example:

- **Increasing vaccine supply and promoting affordability** by offering manufacturers secured financing ('advance contracting') for priority vaccines for the developing country public sector market would help stimulate new private sector investment and greater competition, leading to a more rapid reduction in vaccine prices.

[12] *State of the Worlds Vaccines and Immunization, 2002*. The basic package of vaccines includes diphtheria, tetanus, pertussis (whooping cough), polio, measles and BCG (which protects against childhood forms of tuberculosis). The percentage of children who receive the full three dose regimen of the combined diphtheria, tetanus, pertussis (DTP) vaccine is used as a proxy indicator for basic immunization coverage.

- Rapid gains in increasing access to an expanded offering of vaccines will **save children's lives** in the immediate term. In the longer term it will reduce the overall risk of disease in the larger population, and is likely to **spur economic benefits** which accrue from reduced child mortality and general improvements in health.

Front-loaded investments would need to be catalytic and time-limited, stimulating and complementing other resource flows and creating an environment where benefits can be sustained. GAVI was created with precisely these criteria in mind and as such is well suited to utilize the unique funds the IFFIm would generate.

Increasing vaccine supply and promoting affordability

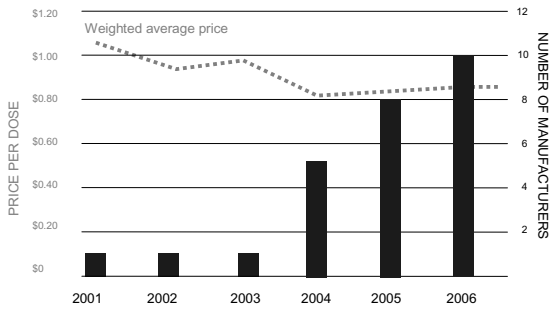
In recent years vaccine producers in both the North and South have shown increased interest in and commitment to developing and manufacturing new vaccines for low-income countries. Since the beginning of GAVI there has been a mutual agreement on a tiered-pricing system, i.e., that the lowest prices would be available to the poorest countries.

Vaccines are expensive to develop. As biological products they are extremely sensitive to minute changes in the environment and manufacturing processes. Hundreds of quality control tests are needed to manufacture even one batch of a complex vaccine. Highly skilled workers are required to manage the difficulties, risks and complexity of manufacturing and testing vaccines. In a natural market, once research and development investments for a particular vaccine have been recouped and production reaches scale, market risks are reduced and the price of the vaccine can fall. Increasing competition and patent expiration will further reduce prices. However, this process takes many years.

Advance contracting – agreeing on predictable price and/or volume flows for medium-term purchase – is a potentially high-impact mechanism for encouraging industry investment in the research, development, and supply of a wide range of health products including vaccines. The IFFIm will provide committed financial resources that will support long-term procurement contracts within the existing regulatory and procurement frameworks of WHO and UNICEF. This approach could have a powerful impact on late-stage (near licensure) products that are much needed by the developing world.

Advance contracting for a new vaccine is already being implemented. A new polysaccharide conjugate meningococcal A vaccine is being developed by an Indian manufacturer who has signed an advance contract with an NGO partner, PATH.. The manufacturer has committed to provide tens of millions of doses to the public sector at a very low maximum price of US$ 0.40 per dose up to end-2023.

Figure 2: OFFERS OF DTP-hepB VACCINE TO UNICEF
For both WHO pre-qualified and non pre-qualified vaccines



The experience of GAVI has highlighted that predictable and sustainable funding for the purchase of vaccines for use in the poorest countries stimulates demand for the vaccine, which can encourage vaccine producers to serve this market. As seen in Figure 2, more producers will soon be making DTP-hepB vaccine. Although this competition has not yet led to a significant reduction in the market price, producers are committed to ensuring a substantial price reduction over the next 10 years. It is hoped

that the use of advance contracts will further accelerate the availability of and price reductions for this vaccine and for the pentavalent DTP-hepB-Hib vaccine, which is even more expensive.

The experience to date with the Hib-containing pentavalent vaccine (DTP-hepB-Hib) has underlined the importance of appropriate research and strategic planning. Countries have so far been unwilling to take up Hib vaccine in significant numbers, due to uncertainty about disease burden and a higher price. To learn from these lessons and attempt to avoid these problems in the future, the Accelerated Diseases and Introduction Plans (ADIPs) were created. By generating information relevant to national and global decision-makers, as well as to vaccine manufacturers, the ADIPs will improve the quality of vaccine-related decisions and seek to avoid the difficulties with Hib vaccine where adequate planning had not been done. In addition, the pentavalent Hib vaccine has seen supply constraints and a lack of adequate planning keep prices high.

The GAVI ADIPs seek to achieve two primary goals: (1) To generate evidence that enables developing country governments and the global donor community to make data-based decisions regarding the introduction of new vaccines against pneumococcus or rotavirus; and (2) to accelerate the availability of an affordable, sustainable supply of vaccines to meet the demand in developing countries.

Saving lives today; reaping long-term economic benefits

The IFFIm, through significant investment upfront would have a rapid impact on reducing under-five mortality. This benefit would be two-fold:

- Direct benefit through increasing immunization coverage rates and reducing the number of child deaths from vaccine-preventable diseases.
- Indirect benefit through improvements to the public health infrastructure which would enable the scaling up of other essential health interventions (e.g., distribution of insecticide-treated bednets and vitamin A, etc).

Moreover, studies have shown that the cost of vaccination is relatively cheap, costing from US$ 13 to US$ 115 per year of life gained, even for new and more expensive vaccines such as rotavirus[13].

In environments with high rates of infant and child mortality, higher rates of fertility exist, in part to compensate for the frequent deaths of children. However, large family size reduces the ability of poor families to invest in the health and education of each child. Furthermore, disease depresses the returns to business and infrastructure investment in society as a whole, in addition to the effects on individual worker productivity. Meanwhile, epidemic and endemic diseases can also undermine social cooperation and even political and macroeconomic stability[14].

III. The proposed programme

The poorest countries in the world have the most unimmunized children and the highest incidence rates of vaccine preventable diseases. These countries would be the focus of funding, as these investments would be most likely to have a rapid and profound impact on reducing under-five morbidity and mortality. For this proposal, the GAVI threshold of a GNI below US$1000 per capita will continue to be used, with the list updated based upon the most recently available data.[15]. It is estimated that 84% of the world's unimmunized children are born in the 74

[13] Miller MA, McCann L; *Health Economics;200;9;19-35, 2000* and Jha P, Bangoura O et al. *Health Policy And Planning, 1998*
[14] Commission on Macroeconomics and Health, World Health Organization, 2001.
[15] While there are countries above this threshold with high child mortality rates, they also have higher vaccination rates, so adding support to immunization would likely not contribute significantly to reducing mortality. WHO data.

countries that would be eligible for support.

Allocation of funds from the IFFIm would be approved by the GAVI Board, including the provision of funds for technical assistance to be allocated to technical partners, including WHO and UNICEF. The principles underlying the new Global Immunization Vision and Strategy now being developed would help guide these decisions.

The best measure of needs is determined at a national level – by countries themselves. Once the allocation policies have been defined, each eligible country would have the opportunity to request funding based on their own analysis of needs, with support as needed from technical partners. This support would build upon countries' multi-year plans and complement existing resources. Factors such as immunization coverage levels, vaccine availability and pricing, fiscal constraints and the state of the health system will determine where resources can best be used. In certain clearly defined cases – such as countries which lack the basic immunization capability to achieve increased immunization coverage, GAVI may decide to allocate funds to implementing partners in countries such as WHO and UNICEF.

Current knowledge points to two key areas where the IFFIm resources could make a substantial and immediate impact: **supporting new and underused vaccines** and **strengthening immunization services**.

The two funding streams are inextricably linked. There is a clear justification for frontloading resources to accelerate vaccine development and availability. However, their widespread use will only be possible if funding to strengthen health systems is also provided. Many of the poorest countries are barely managing to deliver the most basic immunization services; significant investments are needed to expand access to the traditional vaccines, and manage and deliver the new vaccines. Furthermore, the scaled-up immunization efforts will require increased levels of technical support from partners such as WHO and UNICEF.

The balance between the different streams of funding will be determined both by country planning processes and articulated needs, as well as by strategic analyses at the global level. For the purpose of illustration, it has been assumed that programme funds at the global level would be allocated roughly equally between the two windows.

As the programme proposed below would use a country-based application process, in order to prepare the system appropriately, the 10 year investment has been calculated to flow from mid-2005 to mid-2015 (see Annex 1).

Supporting new vaccines

The vaccine window will focus on new, under-used and newly licensed vaccines that combat diseases which cause a significant proportion of child mortality. In the near term, IFFIm funds would be used to stimulate increased manufacturing capacity for the combination DTP-hepB and DTP-hepB-Hib vaccines – vaccines which are currently supported by GAVI and The Vaccine Fund but are not produced at the level of capacity or at the prices needed to satisfy current demand. New vaccines against rotavirus and meningococcus A could have a significant impact on reducing disease burden. In the longer term, vaccines against pneumococcus and Japanese encephalitis could prove quite valuable and attractive.

Countries will need data and quantitative evidence to make informed decisions about whether to introduce a given vaccine. Since reliable information about disease burden and cost effectiveness relative to other interventions is scarce, a limited amount of funds could be used to finance practical, operational research. This type of research activity, designed to improve risk

assessment and ensure rational decision-making, would in the long run ensure a more efficient use of resources – clearly a case for front-loaded investment.

The experience of GAVI has demonstrated that co-financing arrangements with countries could greatly improve the prospects for long-term sustainability as well as stretch IFFIm funding to more countries over a longer period of time. Several possible options are currently being considered by the GAVI Board.

An additional component is for the creation of an emergency stockpile of oral polio vaccine (OPV) for use in the event of an outbreak of polio after wild poliovirus transmission has been halted. Once the world is declared to be polio-free, a stockpile of type-specific monovalent OPV will be required to protect against any future recurrence; but this vaccine will have to be produced very rapidly in the narrow window of opportunity that exists between the interruption of transmission of the virus and the halting of production of the existing trivalent OPV. Polio outbreaks after eradication has been achieved would seriously threaten the gains achieved and lead to greater costs.

Strengthening immunization services

Scaling up immunization coverage in the poorest countries will require substantial investments in the health systems that deliver vaccines. Many of the constraints that affect immunization delivery also affect the delivery of other essential health interventions. By keeping IFFIm resources flexible, countries would be able to use them to alleviate these system-wide barriers — potentially leading to major improvements in the overall provision of health services. The GAVI partners have experience in the use of flexible funding. Meanwhile, GAVI support for immunization services under current policies has just been reviewed[16] and the lessons learned from this evaluation will inform future GAVI Board decisions.

It is likely that IFFIm funds will be allocated on the basis of need and absorptive capacity; countries with lower DTP3 coverage, high numbers of unvaccinated children and large internal disparities (e.g., between different provinces or states) would get more resources. Investments would also be made in better performing countries, recognizing that lower-income countries still need additional resources to maintain achievements and further improve the quality of their immunization services.

In an effort to rapidly reduce the number of under-five deaths from highly infectious vaccine-preventable diseases such as measles, mass campaigns would be funded in the countries where the need is greatest. This would be particularly valuable in low-income countries which are not yet able to reach sufficient numbers of children through their routine immunization services. Such mass campaigns would need to be carefully planned and executed with a particular focus on efforts to strengthen – not undermine – routine services. The achievements of these campaigns in reducing under-five deaths would need to be sustained through a concomitant increase in routine immunization coverage also supported through the same funding window.

As expenditures for campaigns are once-only or uneven in nature, and the need for campaigns is reduced over time, campaigns are ideally suited to be financed through a front-loaded financing mechanism. In addition, the health benefits derived from campaigns occur within a very short time period and can cover a larger population than routine, 'on-demand' services.

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[16] Abt Associates, Evaluation of GAVI Immunization Services Support, 2004..

Projecting the potential impact of the programme

Illustrative scenarios have been constructed for three potential levels of funding: US$4 billion, US$6 billion and US$8 billion over 10 years. This funding would be additional to the US$2 billion which is the current projection of funding for The Vaccine Fund – in the absence of the IFFIm – over the same time period.

The proposed scenarios described below include significant support for the use of pentavalent DTP-hepB-Hib vaccine — an investment which would free up some Vaccine Fund resources already committed for vaccine purchase, enabling them to be used for other investments in immunization. However, GAVI funds already committed for systems support would be expected to continue, resulting in a modest increase in coverage, establishing the baseline for calculating the incremental impact of reaching the 90% coverage target with the IFFIm. It is envisaged that the level of IFFIm funding needed for strengthening immunization systems would be based on the incremental difference needed to increase coverage from the current rate of increase to one that reaches 90%. In some cases, countries are already raising coverage to the rates needed to reach 90% by 2015, and these countries would not receive IFFIm funding for systems support. Further information on the methods used to estimate the costs of the illustrative programme, and to project immunization coverage levels with and without the additional IFFIm resources, are described in Annex 3.

Even at the lowest level of investment (US$4 billion) it is estimated[17] that the lives of more than 5 million children could be saved over the 10-year period, and more than 5 million future deaths due to hepatitis B related liver disease in adulthood could also be prevented. This is in addition to the estimated 1.5 million children's lives that will be saved over the same period if GAVI resources continue at their current level. At higher levels of investment (US$8 billion), it is estimated that more than 8 million deaths in children under five could be prevented.

With a US$ 4 billion IFFIm investment, the estimated incremental cost per life saved would be US$ 755[18]. While the higher proposed scenario at US$ 8 billion would entail a higher incremental cost per life saved (at just under US$ 1000), this is due to the inclusion of a new rotavirus vaccine, which is expected to be more expensive than existing vaccines.

The projected costs for the different scenarios are based on the latest available information on projections for vaccine prices (including availability) and on country-specific estimates of unit costs, which are derived from WHO-CHOICE cost-effectiveness analysis and based on estimates of the support required in each country to scale up immunization coverage and introduce new vaccines. Countries were grouped into six categories based on a combination of coverage levels, income and burden of disease. Detailed profiles of each of the country groups are available in Annex 2.

For each funding scenario, the illustrative interventions are described by country groupings. Where systems costs are included, the estimates shown are for the *incremental* amount needed in each eligible country in order to raise coverage from projected trends to the 90% goal by 2015.

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[17] Source: provisional WHO-IVB estimates

[18] As the *total* costs of the existing immunization systems have not been costed, these represent only *incremental* costs per life saved - additional to current resources.

Scenario 1: US$4 billion – preventing 5.3 million deaths among children under five and 5 million future deaths among adults (from hepatitis B related liver disease)

An illustrative programme has been generated using the following assumptions[19]:

- *New and underused vaccines includes:* Pentavalent DTP-HepB-Hib vaccine for all countries except India and DTP-HepB vaccine in India. Yellow fever vaccine in the 11 countries at risk where the vaccine has not yet been introduced into routine immunization services, and Meningococcal A/C conjugate vaccine in the 21 countries at risk. The polio stockpile.
- *Immunization services support includes*: The amount required for the 26 countries with low overall DTP3 coverage (< 50%) in 2003 to scale up coverage beyond the current trends (68% by 2015) to reach 90% by 2015, including cost of traditional EPI vaccines and mortality reduction campaigns against measles and tetanus. Systems infrastructure costs associated with introducing new vaccines. Systems infrastructure and vaccine costs of introducing a 2nd dose of measles vaccine into routine services for all countries, when 1st dose of measles coverage reaches 80%.

Figure 3: ILLUSTRATIVE PROGRAMME EXPENDITURES

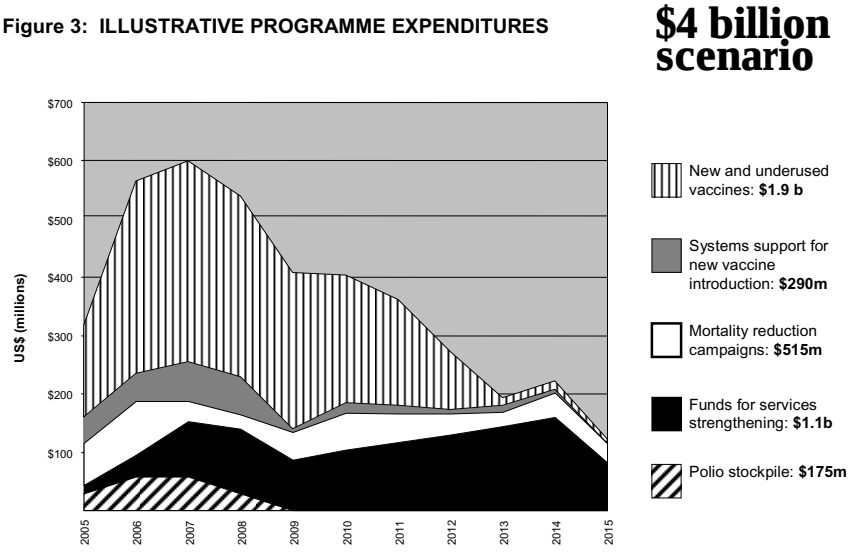


Figure 4: Distribution of the 5.3 million prevented deaths among infants and children

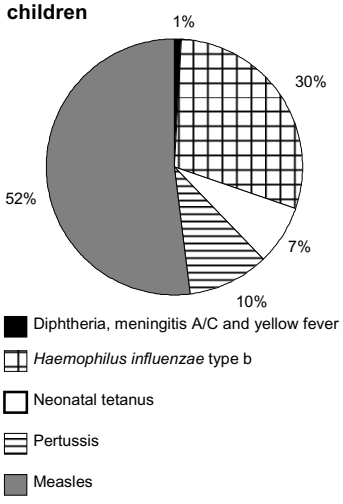
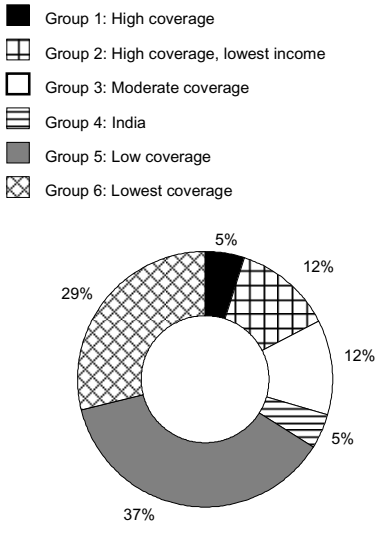


Figure 5: Distribution of funds



[19] Please see Annex 3 for a full explanation of assumptions used to estimate costs and impact.

Scenario 2: US$6 billion – preventing 6.4 million deaths among children under five and 5 million future deaths among adults (from hepatitis B related liver disease)

An illustrative programme has been generated using the following assumptions:

- *New and underused vaccines includes:* All components in Scenario 1, plus rotavirus vaccine for 30 countries with 2003 DTP3 coverage higher than 80%.
- *Immunization services support includes:* All components in Scenario 1, plus systems support for an additional 17 countries with overall 2003 DTP3 coverage of 72%.

Figure 6: ILLUSTRATIVE PROGRAMME EXPENDITURES

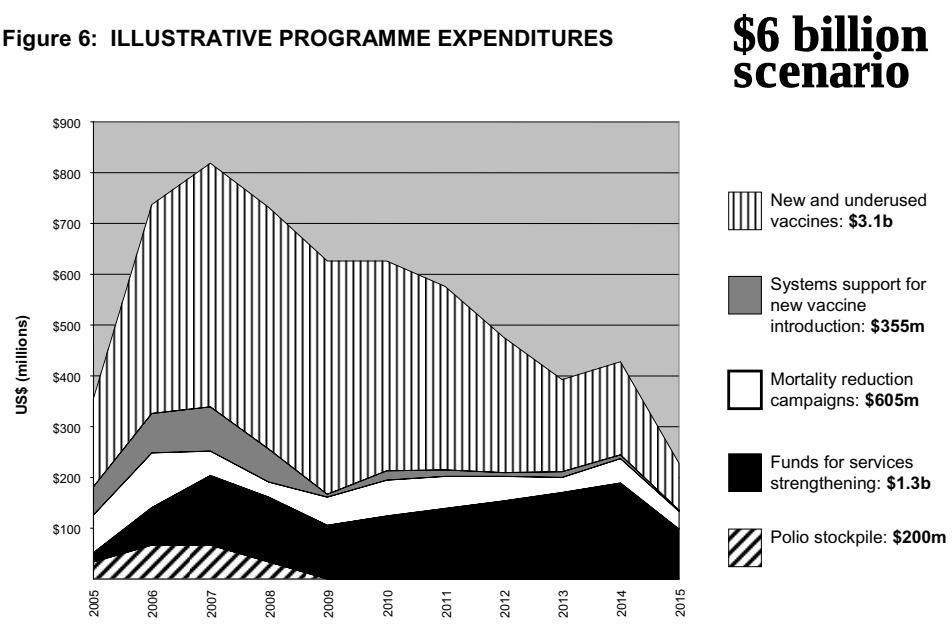


Figure 7: Distribution of the 6.4 million prevented deaths among infants and children

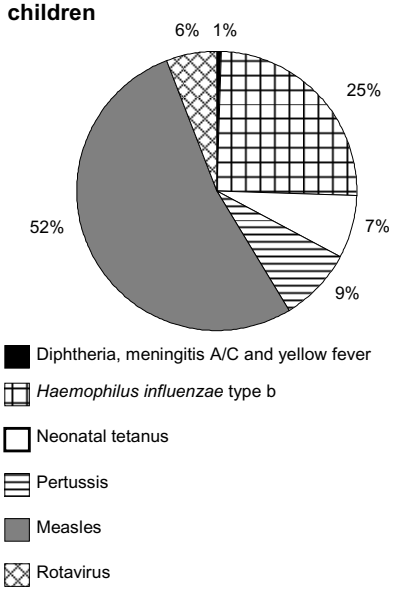
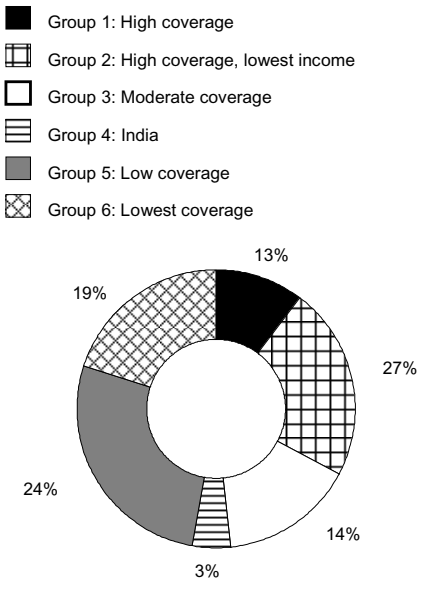


Figure 8: Distribution of funds



Scenario 3: US$8 billion – preventing 8 million deaths among children under five and 5 million future deaths among adults (from hepatitis B related liver disease)

An illustrative programme has been generated using the following assumptions:

- *New and underused vaccines includes:* All components in Scenarios 1 and 2, plus rotavirus vaccine extended to all countries.

- *Immunization services support includes:* All components in Scenarios 1 and 2, plus systems support (not including campaigns for tetanus) for an additional 15 countries with overall 2003 DTP3 coverage of 86%, but 2003 GNI less than US$440 per capita. Measles mortality reduction campaigns in India.

Figure 9: ILLUSTRATIVE PROGRAMME EXPENDITURES

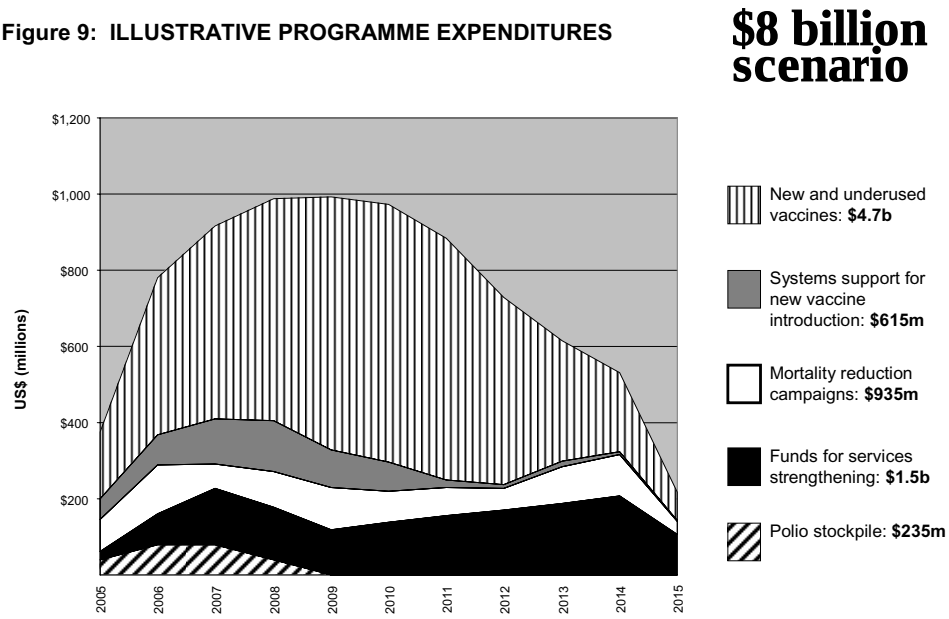


Figure 10: Distribution of the 8 million prevented deaths among infants and children

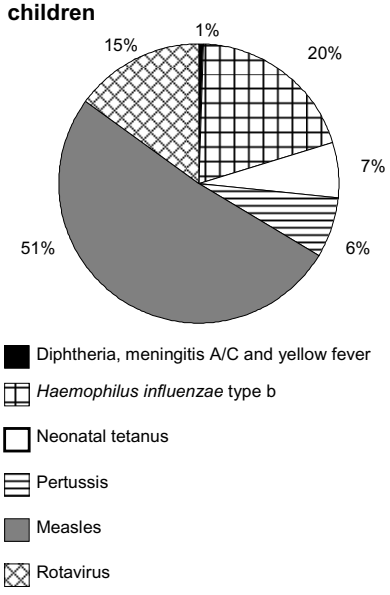
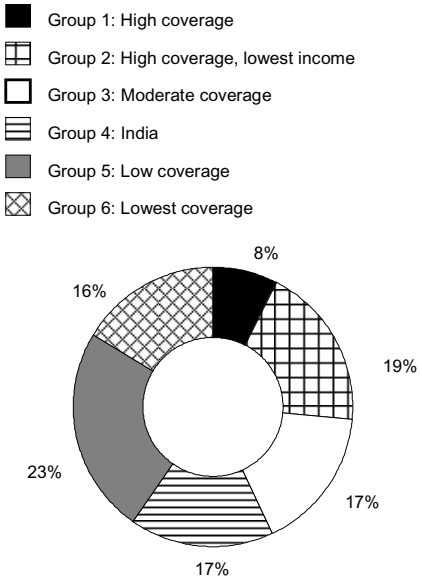


Figure 11: Distribution of funds



IV. Implementing through GAVI

The current governance structure that manages GAVI and The Vaccine Fund would be used – modified as needed – to make allocation policies and country disbursement decisions for funds leveraged through the IFFIm financing mechanism. The alliance uses the following principles in allocating resources:

- Funds are catalytic and promote improvements to the immunization system
- Funds are additional and should not replace existing national or external resources
- Funds are allocated through an innovative approach which rewards good performance

In its five years in operation, the flexible, action-oriented nature of the GAVI alliance has allowed it to adapt to new challenges – critical for a start-up venture. Its membership includes a wide range of development partners: developing country and donor governments, WHO, UNICEF, the World Bank, the vaccine industry (from North and South), research and technical agencies, NGOs, and the Bill & Melinda Gates Foundation. The Vaccine Fund has its own board of prominent individuals largely devoted to advocacy and resource mobilization. The Vaccine Fund serves primarily as the fund-raising arm of GAVI.

The GAVI partners have developed a process in which countries apply for the resources they need, based on allocation policies decided by the GAVI Board. An Independent Review Committee (IRC) of national experts in immunization programmes, health economics, and health systems, reviews proposals and progress reports submitted by countries, offering a peer review. The IRC then makes its recommendations to the GAVI Board, which in turn requests the release of funds from The Vaccine Fund.

The overall governance and allocation platform for the IFFIm would be the GAVI Board – with a subsequent financing decision to be taken by the Vaccine Fund Board – in a way that is similar to the current process.[20] This approach reflects the view that the GAVI Board/Vaccine Fund Board construct brings together all of the key immunization stakeholders – and has the added merit of being in place already. Under this structure, funds raised through the IFFIm would be distributed through the Vaccine Fund Trust Account at UNICEF. [21] One remaining issue concerns the management arrangements for the issuing vehicle. The two options under consideration are the World Bank and the Vaccine Fund. The final choice will reflect i) donor and investor preference, ii) lowest estimated costs (set up, running, and borrowing), and iii) timing – i.e. which structure can be set up in time for an end-January 2005 close. A recommendation on the management arrangements for the issuing vehicle will be provided by the end of October.

In July 2004 the GAVI Board decided to review the efficiency and effectiveness of its current decision-making structures; the group assigned to this task would include issues relating to the IFFIm in its review and recommendations. The country application and monitoring process may need to be revised to ensure principles of frontloading. More responsibility and support to national decision-making mechanisms – currently the Interagency Coordinating Committees – will be required. The necessary governance adaptations will be finalized by the time the IFFIm goes to market, now planned for early 2005. This ambitious timeline will be a challenge that all partners will strive to meet.

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[20] The Vaccine Fund Board may delegate the financing decisions to its Executive Committee – as it does now.

[21] It is anticipated that IFF donors will ask for separate reporting on the utilization of IFF proceeds. GAVI will need to determine whether this can be accommodated through the existing Trust Account – or whether a 'twin' trust account needs to be established for this purpose.

GAVI may also consider the need to adjust its allocation mechanism to allow for the distinction between IFFIm funds and traditional donor funding. While developing countries will not see a difference in the resources they receive, the Board will want to ensure that the appropriate source of funding is being used.

Governance and allocation decisions will be based upon agreed principles

The following key founding principles will guide the GAVI Alliance as it makes decisions about governance and allocation policies for the IFFIm:

1. Investments should be made in response to country-driven strategies based on countries' own multi-year plans for immunization within the wider context of the overall health system, and they should aim to strengthen and complement ongoing initiatives for immunization. The Global Immunization Vision and Strategy currently under development will help to guide decisions.
2. Efforts should be specifically designed to contribute to, and not detract from, the strengthening of countries' overall health systems and to be compatible with national planning cycles and budgeting for the health sector and immunization (including Sector-Wide Approaches (SWAp), Medium Term Expenditure Frameworks (MTEF), Poverty Reduction Strategic Plans (PRSPs) etc.).
3. Funds must be additional to and not replace existing immunization resources, and should be disbursed in ways that strengthen the ability of countries to take over the financial responsibility of their immunization programme.
4. Funding should be prioritized to areas which are appropriately frontloaded.
5. Funding should be made available for international partners (including WHO and UNICEF) to provide technical assistance, for planning and proposal development, as well as support for implementation, including systems strengthening and monitoring.
6. Reporting requirements for monitoring and evaluation should continue to be kept light and coordinated, and should fit as much as possible with existing country monitoring processes and cycles.

Allocation of resources to countries will follow country-identified needs

The GAVI Board is currently developing a systematic process to prioritize resource allocation. One approach being considered is the request and review of investment cases developed for the various options within a specific area, for example, introduction of a rotavirus vaccine, introduction of a pneumococcal vaccine, or investment in new technology to improve quality and efficiency of immunization services. The investment cases will draw upon the most comprehensive data available to enable evidence based decisions. This is the type of process that could help decide how to use IFFIm resources.

As described in the programme section, countries would access the programme funds through a country driven proposal process, based on comprehensive multi-year plans that integrate all immunization activities and financial planning to ensure that funds fill clearly identified gaps and do not replace existing funding for immunization. The application and reporting process, building on the experience of the current GAVI procedure, would be designed to minimize additional burdens on applicant countries. To avoid budget distortions, country applications would need to describe how the proposed programme has been integrated with national planning processes (PRSPs and SWAPs) and budgeting processes (MTEFs), and how the finance ministry had been engaged.

For low income countries under stress (where there is war or civil unrest, or where national governments are not functional) there would be different mechanisms for support (i.e. channeled through partners), particularly in view of the drop in absorptive capacity usually associated with crisis situations.

The following illustrative criteria would be considered in making allocation decisions:

Immunization services

- Support would be targeted to the countries in greatest need and with a demonstrated ability to use the additional funds efficiently. It would not be allocated on the basis of an equal portion for each country.
- Special consideration would be given to large population countries (e.g., sub-national support).
- Funding would be flexible and 'systems-neutral' as much as possible, taking advantage of SWAps and 'basket-funding' channels wherever possible. Mechanisms for providing resources that are tied to outcomes as opposed to inputs are now being explored.
- Campaigns would be fully integrated into the multi-year plans for immunization and designed as one of the many strategies available to countries for reaching out to the target population. They would not be funded as ad-hoc isolated activities.

New vaccines

- To be eligible for new vaccines, in addition to relevant disease burden data, countries must already have a relatively strong and stable immunization system (DTP3 national coverage of at least 50%) and demonstrate that they are working toward financial sustainability.
- Co-financing of vaccines will be considered in order to secure country ownership at a very early stage in the process. From the outset, most countries will need to contribute some portion of the cost of the vaccines.
- Vaccines will not be provided to countries with GNI above US$ 1000 per capita; however, to facilitate the lowering of vaccine prices through bulk purchasing, the establishment of a revolving fund for use by these countries will be explored.

Monitoring and evaluation

The GAVI partners have developed and used a set of monitoring and evaluation processes at the country, regional and global level in order to track implementation and impact. To avoid an escalation of reporting requirements, GAVI monitoring and evaluation of the use of IFFIm funds would be aligned with broader health sector or district monitoring arrangements. Partners such as WHO and UNICEF will be critical in helping track the impact of these investments.

Efforts to improve information systems will require the use of front-loaded investment but will have long-term benefits. Better information and data are needed to monitor programme effectiveness. In the past, impact has often been measured in terms of immunization coverage rates, and GAVI has invested in efforts to strengthen the quality of such routine monitoring data. However, the IFFIm focus on the MDGs will require annual monitoring of changes in both overall under-five mortality and disease-specific mortality. And this will require a much stronger evidence base than currently exists. In order to properly evaluate the mortality impact on a country-by-country basis, there is a need to strengthen both surveillance and systems for recording births and deaths in the recipient countries. GAVI partners are working to identify critical impact metrics for this programme, including whether the poorest have been helped. Epidemiological studies to better understand the levels and proportional distribution of mortality

will also be a key component in building the necessary evidence base.

In addition to programme effectiveness, the feasibility and impact of the financing tool itself will need to be evaluated. The case for IFFIm funding rests on highly cost-effective investments both in influencing the vaccine market and improving country capacity and performance. In order to assess the impact and financial accountability arrangements at country level and the market effects in vaccine supply at the global level, an in-depth review would be implemented within the first three to five years.

V. Potential risks

The IFFIm will test a brand new financial tool for development aid; it will involve risks. While it is recognized that companies in the private sector would not prosper without a willingness to accept certain levels of risk, in the case of public monies, all care must be taken to ensure that the risks are calculated and assessed so that appropriate risk management strategies can be put in place. Understanding and assuming an acceptable level of risk would be a key component of the IFFIm. The most significant risks, and how they would be addressed, are outlined below.

National priorities and budgets could be distorted. In developing countries where resources are extremely limited, we have seen that when a large influx of new funding is offered for a specific programme, such as immunization, national authorities may alter their budgets and personnel to accommodate the new funding. This could involve transferring national budget lines away from the area receiving the external funding, or diverting scarce personnel from their regular duties to meet the needs of the enlarged programme.

In addition, a greater emphasis on specific areas within immunization might negatively impact on routine health services. While there may be some beneficial impact from reliable and coordinated funding, the IFFIm will not by itself turn around a national programme with weak institutions.

To be addressed through: Direct financing to countries, based on the countries' own multi-year plans. Direct funding supports government planning and administration, and reduces problems of coordination, programme distortion and sustainability. Many countries have coordinated sector programmes of donor support (known as SWAps) in which immunization is one activity, to which various donors contribute funds. In addition, there are agreements on the broader allocation of resources between sectors that reflect country PRSPs, often known as MTEFs, and budget support is provided in line with these. Additional immunization funding may require trade-offs for countries which operate under SWAps and MTEFs. It will be critical to ensure that adequate support and operational research is provided to determine how IFFIm funds can be reconciled with national processes, and how immunization programme budgets can be rolled into government budgeting processes that are not based on programme-level budgeting. IFFIm funds channeled via GAVI would be integrated in a transparent way into these national planning and budget structures, building upon GAVI's documented success in work on sustainability to understand current and future costs, financing and financing flows.

It should be noted that natural distortions do occur – even in resource rich environments. For example, since most major health budget decisions are made by officials based in urban centres, teaching hospitals in the capital may be equipped with the latest medical technology while outlying health posts can run out of aspirin. Ensuring that basic services such as immunization receive adequate resources can help correct these types of distortions.

The programme could replace other funding today; frontloading donor commitments would reduce available funding in the future. A founding principle of the IFFIm is that it

will provide additional funding and not replace current funding streams to health systems. Existing investments by governments and their partners for immunization activities will need to be maintained to accrue the added benefits of the IFFIm. Unless complementary funding is committed, positive effects of the IFFIm could be undermined.

To be addressed through: It is expected that, in addition to their financing of the IFFIm, donor governments will increase bilateral and multilateral contributions as their economies grow. This is consistent with the target of contributing 0.7% of their GDP to international development aid – promises reiterated at the Monterrey Conference on Financing for Development. Donor contributions to the IFFIm would be a part of their overall effort to reach the 0.7% target.

Countries may have difficulty absorbing the resources into their weakened systems. The benefits of front-loading will be lost if countries prove unable to use the funds promptly. Years of enduring extreme resource constraints can lead to a perverse situation in which managers given new resources do not know where to begin in deciding on their use.

While analysis suggests that even the poorest countries can absorb considerable amounts of additional support effectively,[22] this is not always borne out by experience on the ground. Important lessons from funding initiatives such as the Global Fund to fight AIDS, TB and Malaria, and the US President's Emergency Plan For HIV/AIDS Relief (PEPFAR), will be heeded in an effort to avoid the same pitfalls.

Even GAVI has run into difficulty. While the health systems in most countries are able to deliver vaccines – from central vaccine stores to stock management and refrigerators, from trained health workers and safe injection materials to community awareness and data gathering techniques – financial infrastructures are uneven in many of the poorest countries, leading to inefficient use of new resources. Vaccines and funds from The Vaccine Fund were not used as quickly as anticipated at the onset, though current data show usage trends are increasing now that countries have become familiar with the GAVI system.

To be addressed through: Resources would be allocated through existing vehicles, based in part on the absorptive capacity of a given country. Experience gained through GAVI and other global funds (such as the recently completed evaluation of GAVI's funding for immunization services[23]), would be tapped in developing and monitoring absorption and use. The review process would be on guard for requests that exceed local capacity; these would be returned to national teams with requests for modification. Annual progress reports would be closely followed to ensure that countries whose programme objectives were overtaxing local capabilities would be appropriately supported, and schedules for programme improvements modulated accordingly.

In circumstances where the national government absorptive capacity is inadequate (for example, in low-income countries in difficult circumstances), the partners would be relied upon to provide the necessary structure, capacity, and oversight to efficiently use the resources available (see section in governance).

Gains will not be sustainable. The overall aim of IFFIm is to scale up country immunization

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[22] Andrew Keith and Mick Foster, *The Case for Increased Aid,* Final Report to the UK Department for International Development (DFID), December 2003.

[23] Abt Associates, Evaluation of GAVI Immunization Services Support, 2004.

efforts in order to reach the MDGs. Yet these activities must be sustained in the long run, through increased national support and participation from the international community. Sustainability must be addressed at two levels: both existing levels of bilateral and multilateral support and the improvements in national immunization programmes.

To be addressed through: To receive IFFIm funding, a country's immunization plan would need to be thoroughly costed, with projections on how costs would be covered beyond the time-frame of the IFFIm. The commitments of governments and their local and international partners would need to be carefully described, as well as how immunization planning and budgeting had been incorporated in national planning and budgetary processes and cycles (i.e. Medium Term Expenditure Frameworks, Poverty Reduction Strategy Credits). Strengthened coordination will help ensure that partners shoulder their increased responsibilities and work efficiently together. Long-term projections suggest that once increased coverage levels are reached, the amount of resources needed to sustain the system will be less than the funds needed during the scaling-up phase.

Co-financing strategies would be employed so that countries gradually assume responsibility for financing new vaccines, thereby avoiding abrupt increases in the financial requirements from governments and national partners.

GAVI has accumulated a great deal of experience in this area. When it became clear that countries were facing grave challenges in sustaining financing for immunization, the GAVI Board approved a new initiative that would both train programme managers in financial planning skills and build stronger ties between health and finance ministries. The result: a growing number of countries have developed Financial Sustainability Plans and are increasing focused efforts to secure new or increased budget lines in order to ensure their programmes have the resources they need.

VI. Conclusion

There are significant opportunities for global health gains, both now and in the future. But these will not be realized without substantial new financing. The IFFIm has the potential to demonstrate the capacity of health programmes to rapidly absorb and utilize new resources. At the same time, it will be actively demonstrating the ability of the IFF mechanism to garner long-term donor commitments, execute market transactions, and disburse funds through existing mechanisms. In addition, massive scale-up of immunization will have a measurable impact on accelerating progress towards the MDGs.

The GAVI Alliance anticipates that initial proceeds from the IFFIm could be put into service by 2005, with major investments increasing in 2006. The analysis and planning work will continue to be refined and expanded upon over the coming months in the lead-up to the proposed launch of the IFFIm.

List of Annexes (attached separately)

Annex 1: Annual cash flows
Annex 2: Country group profiles
Annex 3: Costing methods and estimation of mortality impact
Annex 4: Financial and legal issues