



PROGRESS AND CHALLENGES 2004

GAVI

THE GLOBAL ALLIANCE FOR
VACCINES & IMMUNIZATION

www.vaccinealliance.org

TheVaccineFund
Every child. Everywhere.

www.vaccinefund.org

FOUR YEARS OF PROGRESS

Vaccines are among the greatest public health tools ever invented. The discovery that a simple series of injections or drops could provide nearly failsafe lifelong protection against deadly or disabling diseases transformed the field of preventive health. Millions of lives are saved every year because of vaccines.

Any way you look at it the results are fantastic. Best investment I ever made.

Bill Gates, Co-founder, the Bill & Melinda Gates Foundation

Yet decades after the widespread adoption of vaccines, much of the affluent world has become complacent. The virtual disappearance of diseases that once terrorized populations and communities leads some to forget that this fragile peace depends upon continued universal vaccination.

In many poor countries the terror remains. An estimated 30 million children each year still miss out on vaccination. As a result, two to three million will die annually from easily preventable disease and many more will fall sick, missing school and feeding the vicious circle that links poor health to continued poverty in adulthood.

The Global Alliance for Vaccines and Immunization, GAVI, was launched by its partners in 2000 to revitalize the field of immunization. A new type of public-private

partnership, GAVI brings together governments in developing and industrialized countries, established and emerging vaccine manufacturers, nongovernmental organizations (NGOs), research institutes, UNICEF, the World Health Organization, the Bill & Melinda Gates Foundation and the World Bank.

Making this alliance much more powerful is The Vaccine Fund, established by GAVI partners to raise new resources and provide multi-year grants to the world's poorest countries to strengthen their health systems by improving immunization services and introducing new and under-used vaccines.

Four years later there is much to report. It is estimated that more than 500,000 lives will be saved because of GAVI support provided so far. In one of the most rapid international health scale-ups ever, more than 35 million children have been immunized against hepatitis B, making it the largest cancer prevention effort ever undertaken. The hepatitis B virus strikes most often during childhood, but its ill-effects strike young adults in their most productive years, causing liver cancer and cirrhosis - diseases which kill quickly in developing countries where treatment is prohibitively expensive.

In the countries which have introduced the vaccine against *Haemophilus influenzae* type b (Hib), there has been a dramatic reduction in Hib-related meningitis - a nasty disease that kills 400,000 children annually and disables

thousands more. Finally, many countries have increased immunization coverage - more than eight million additional children have received basic vaccination.

GAVI is also changing the vaccine manufacturing field. Today there is only one manufacturer who produces a vaccine that combines vaccines against diphtheria, tetanus, pertussis and hepatitis B into one shot - highly desirable product in many developing countries. Eleven suppliers have submitted bids to UNICEF to supply this vaccine by 2006.

Meanwhile, the GAVI-supported Accelerated Development and Introduction Plans are working to ensure that the public health community participates early in the development of vaccines against rotavirus and pneumococcal disease. The goal is to ensure that if the vaccines developed are appropriate,

children in the poorest countries will receive these vaccines as soon as possible.

One of the greatest challenges is finding ways to help countries strengthen their health systems over the long-term, so more children can be reached year in and year out. System-wide barriers must be tackled to ensure long-lasting improvements.

And many countries have shown dramatic advances. Uganda has seen a rapid expansion of coverage through political commitment and innovative community mobilization efforts. Madagascar has emerged from deep political crisis and is turning its health situation around, and Afghanistan is overcoming acute political problems and war to immunize its children. These countries are showing us that positive change is possible, even under the most trying circumstances.

GAVI Goals

The GAVI mission is to save children's lives and improve people's health through the widespread use of vaccines. The main focus of work is to:

Increase access to all necessary vaccines.

Focus on strengthening local health facilities to deliver essential health services including immunization.

Shorten the time span between first introduction of a vaccine and its full-scale use in the developing world.

Focus initially on hepatitis B and *Haemophilus influenzae* type b (Hib), and yellow fever, an older but under-used vaccine.

Accelerate the development and introduction of new vaccines

Focus on near-term vaccines against rotavirus, pneumococcal and meningococcal type A.

PROGRESS

Rapid scale-up to help the poorest children

Through GAVI the partners have agreed on priorities, and, equipped with The Vaccine Fund's substantial financial clout, have built a new development grants program that has improved health conditions in many countries ... in just four years. The first step was to design the right kind of support - support that is most effective and has the greatest chances of long-term impact.

There is a general recognition in the international development community that to be effective in reducing poverty, aid should:

- focus on the poorest countries and the poorest groups within countries;
- scale up with the most cost-effective interventions and easy-to-use technologies;
- tie funding to performance;
- increase predictability and reduce transaction costs;
- promote sustainability;
- build on country priorities and harmonize with other types of health funding and programs; and
- include a strong monitoring and evaluation component.

Taking lessons from the research community, GAVI invited all eligible countries to apply for support from The Vaccine Fund instead of hand-picking a few 'demonstration countries'. This new approach led to a rapid, bottom-up response, creating excitement and demand at the highest political levels.

By 2001, 53 countries were already approved for support, and by the end of 2003, 69 out of 75 eligible countries have been approved for support. In total, US\$ 236 million worth of vaccines, safety supplies, and other financing is being used in countries to improve their immunization programs.

According to current estimates of cumulative impact, 35.5 million children have been vaccinated against hepatitis B; 6 million children have been vaccinated against Hib; 2.7 million children have been vaccinated against yellow fever; and 8 million more children have access to basic vaccines.

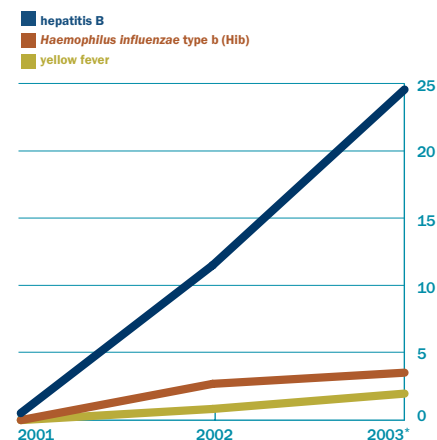
Reduction of child and maternal mortality rates is not only a moral and practical necessity, but a commitment made by all countries in the Millennium Development Goals.

Lee Jong-Wook, Director-General, World Health Organization and GAVI Board Chair

Easy-to-use technologies may not always be the cheapest, but they will accelerate scale-up. Vaccines that combine multiple vaccines into one injection, such as the DTP-hepB vaccine, enable countries to immediately incorporate the new vaccines into their existing systems. Because supply of these vaccines did not meet demand, it is estimated that more than 12 million children have missed out on hepatitis B vaccination already.

Increasing access to vaccines

Annual number of children reached with new vaccines

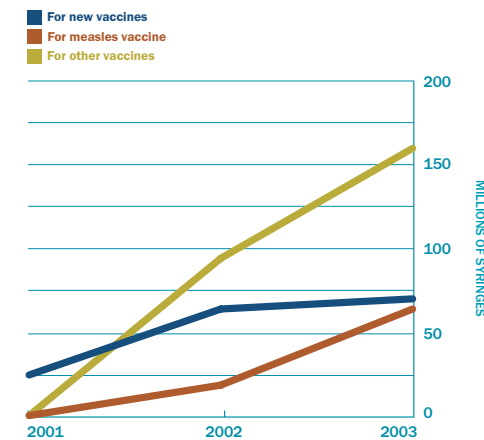


Vaccination programs can scale up quickly because the technology is relatively easy to administer, highly effective, and greatly valued.

* based on estimated 2003 coverage

Improving immunization safety

Annual number of auto-disable syringes delivered



Non-sterilized syringes can spread viruses such as HIV and hepatitis B and C. Auto-disable (safety) syringes can only be used once, reducing this risk at a low cost of \$0.063 per syringe. GAVI has so far provided 486 million syringes to 37 countries, for all of their childhood immunizations.

Criteria for funding

To be eligible for any kind of country support from The Vaccine Fund, countries must have:

1. Annual gross national income (GNI) of less than US \$1000 per capita
2. National coordination of funding and technical input through an inter-agency coordinating committee for immunization (ICC), or equivalent collaboration mechanism
3. A recent assessment of the system to deliver immunization services
4. A multi-year plan for immunization that incorporates recommendations from the assessment
5. A strategy to improve safety of injections

Countries that meet the above criteria may apply for the following support:

- Countries where more than 80% of children receive full immunization against diphtheria, tetanus and

pertussis (DTP3) can apply for support to provide hepatitis B, and *Haemophilus influenzae* type b (Hib), or yellow fever vaccines, as long as they are appropriate considering the country's disease burden (hepatitis B is recommended for use globally).

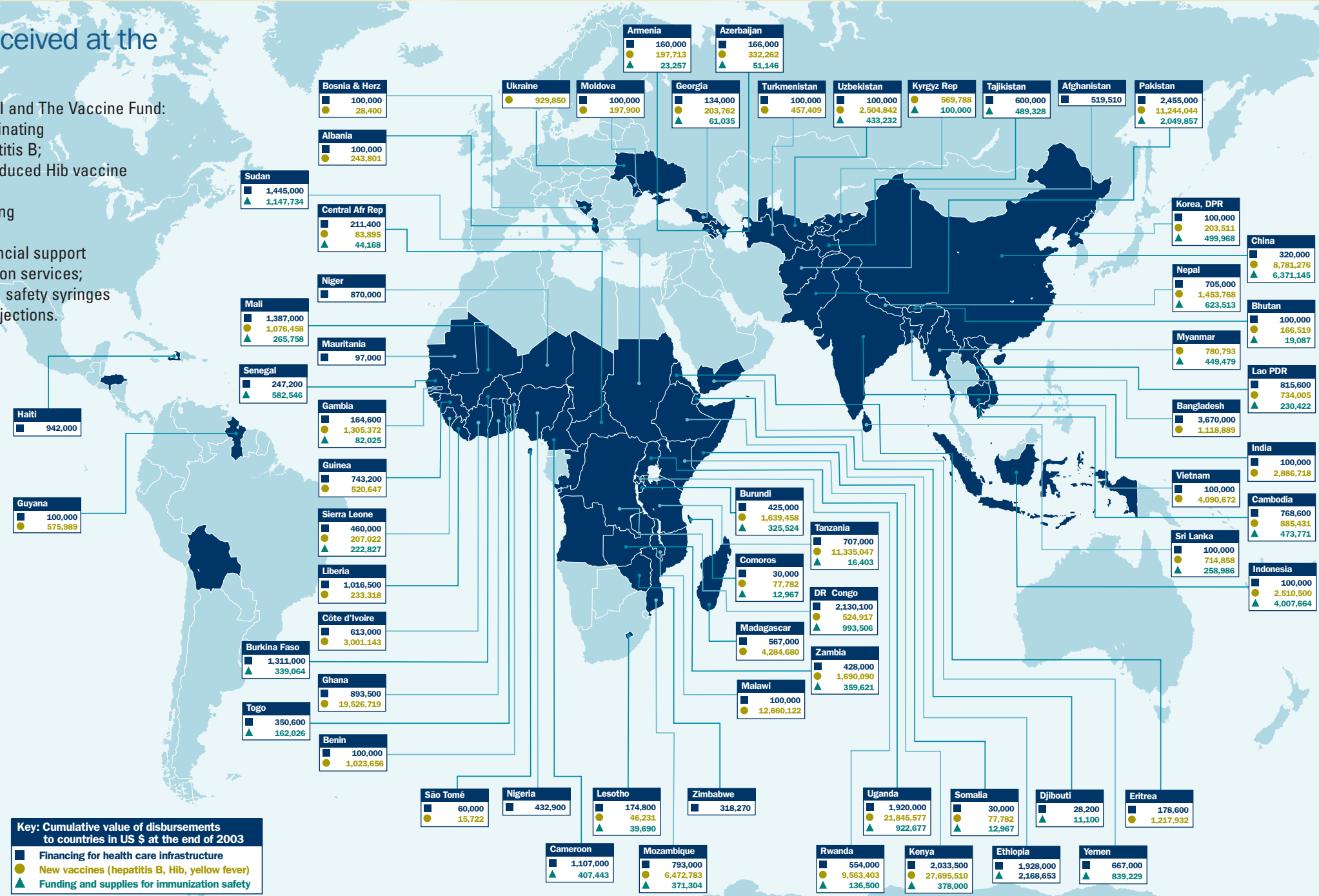
- Countries with DTP3 coverage between 50% and 80% can apply for the above vaccine support and financial support to increase access to immunization under the performance grants program.
- Countries with less than 50% DTP3 coverage can apply for financial support to increase access to immunization and yellow fever vaccine. Once countries have achieved at least 50% DTP3 coverage they qualify for the hepatitis B and Hib vaccines as well.
- All eligible countries can apply for supplies and funding to improve safety of all immunization injections.

INVESTMENT: US \$236 MILLION OUTCOME: SAVING MORE THAN 500,000 LIVES

Resources received at the end of 2003

With support from GAVI and The Vaccine Fund:

- 40 countries are vaccinating children against hepatitis B;
- 9 countries have introduced Hib vaccine into their programs;
- 10 more are vaccinating against yellow fever;
- 48 have received financial support to improve immunization services;
- 37 countries are using safety syringes for all immunization injections.



PROGRESS

Creating incentives to reach the poorest children

GAVI partners have designed a performance-based funding system that provides financial incentives for countries to improve health outcomes - in this case, increased vaccination coverage. It is a truly novel approach to international development aid.

Immunization is central to the Ghana health services because immunization does not discriminate against children from the poor in society.

Prof. Agyeman Badu Akosah, Director General of the Ghana Health Service

Countries receive three years of investment payments, based on the number of additional children targeted to receive three doses of the diphtheria, tetanus, pertussis vaccine (DTP3) - used as a proxy indicator of basic vaccine coverage. There are no global rules about how the money should be used; the government and its technical and development partners make local disbursement decisions. The only global rule is that after the investment phase, a country needs to reliably report increased coverage to receive additional funding, or performance payments. Immunization coverage data are independently audited to ensure system integrity.

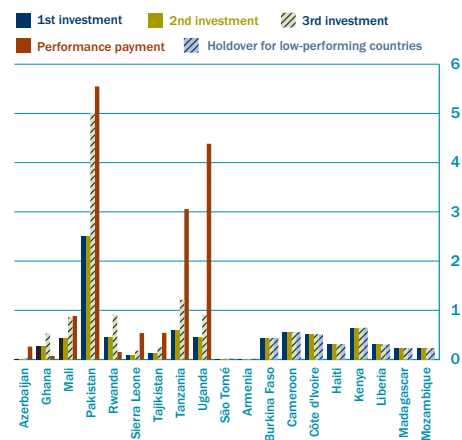
This system builds incentives to put the resources directly where services are the weakest; it is easier to make substantial increases in routine coverage in areas with low vaccination rates. In fact, there is a strong trend that countries are sending a substantial portion of funding to district-level services.

Nineteen countries to date have received three years of investments. Countries that reached many more children, such as Tanzania and Uganda, have received substantial performance payments. Countries that were on a low coverage track were able to cut their 2003 payment in half, so they will receive the remainder in 2004; they will receive performance payments once their coverage and quality of reporting improve.

In 2004 a study to examine more closely how countries are using these funds will be conducted. It is hoped that the results will provide important lessons from both high-performing and low-performing countries.

The performance-based grant system

Countries that began receiving investment payments in 2001



Countries receive three years of investments. In the fourth year, only countries that have actually reached more children receive performance payments.

Countries not able to reach more children in 2002 - or provide reliable data - receive one half of the third investment in 2004 and qualify for performance payments once they reliably demonstrate increased coverage.

CHALLENGES

Ensuring that positive change is lasting

GAVI partners view financial sustainability as a shared responsibility between developing countries and their donor partners. The poorest countries will not become financially self-sufficient until their economies dramatically improve. Development efforts must work toward that ultimate goal, but external aid is needed in the meantime.

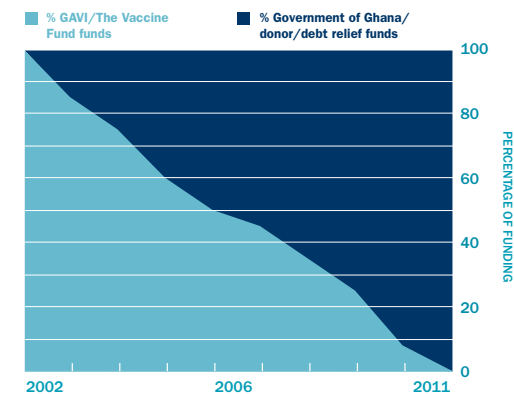
The Vaccine Fund is designed to catalyze new efforts, or revitalize existing ones, but not to fund them into perpetuity. Multiyear commitments are provided with the understanding that after five years of support, countries must replace The Vaccine Fund's contribution with new sources of funding - such as the government's own budget, debt-relief, development loans, or other donor contributions.

GAVI financial sustainability planning tools help high-level decision makers understand current costs, project future costs, and define strategies to reduce unnecessary costs, mobilize new resources, and increase funding reliability. Already in several countries, GAVI financial sustainability plans have provided well-grounded projections that are being used as inputs to long-term budgeting.

Ghana is only one of a number of countries that are identifying new sources of funding so that Vaccine Fund support can be phased out slowly instead of stopping suddenly after five years.

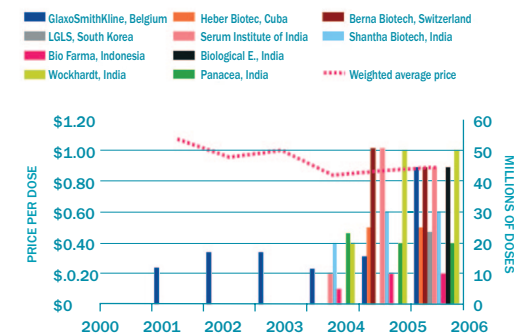
Reducing the cost of vaccines will greatly help ensure sustainability. Because of the predictability of The Vaccine Fund resources, a number of new manufacturers of the DTP-hepB vaccine will soon enter the market (see figure), increasing supply and eventually reducing costs.

Sources of funding for new vaccines in Ghana



Ghana is one example of a country working toward long-term financial sustainability by finding new resources early to cover the cost of new vaccines.

Offers of DTP-hepB vaccine to UNICEF from 2000-2006



In response to the substantial funding available for vaccine purchases for developing countries, a number of new vaccine makers are now investing in manufacturing capacity to produce the most in-demand vaccine products.

CHALLENGES

Raising resources for the longer term

Since its inception The Vaccine Fund has raised \$1.3 billion in new resources for the poorest countries. The \$750 million contribution from the Bill & Melinda Gates Foundation, designed to spur the program and matching funds, broke new ground for sizable multi-year commitments to global health. Most encouraging are contributions from donor countries with growing aid budget in recent years.

To meet the needs of the new millennium we need to dramatically change the way we finance development. Innovative financing mechanisms, such as 'frontloading', may enable significant investment today to develop new or implement existing technology, and so reduce mortality, morbidity and costs in the future.

Julian Lob-Levyt, Chief Human Development Adviser, DFID

GAVI partners launched The Vaccine Fund in 2000 with a five-year vision. The partners decided to defer longer-term planning until some initial results of the new initiative could be assessed. Four years into the alliance, donors and developing countries have requested GAVI to extend its work, at least through 2015.

In planning for the next ten years, the alliance will support the drive for increased

development aid, especially health-related. It will seek to increase overall spending on immunization efforts among partners, donors and developing countries. And it will focus its own resource development goals on raising additional resources that supports the distinct role of GAVI in international development. GAVI added value investment areas can be defined as:

- Time-limited: GAVI provides 'catalyzing' funds and creates innovative approaches to ensure long-term sustainability.
- Front-loaded: Substantial initial investments in the short term can lead to lower costs over time, thereby increasing the chances for long-term sustainability.
- Performance-based: GAVI will continue to place high emphasis on performance. Performance-based indicators will also include those related to effectiveness of partnerships, harmonization, global advocacy and political mobilization achieved as added value of the investment.

Cumulative commitments since 2000 (in US\$)

Bill & Melinda Gates Foundation	\$754m
Canada	\$30m
Denmark	\$1m
European Union	\$1m
France	\$19m
Ireland	\$1m
Miscellaneous private	\$5m
Netherlands	\$86m
Norway	\$121m
Sweden	\$5m
United Kingdom	\$62m
United States	\$219m
Total	\$1.3 billion

CHALLENGES

The Campaign for Child Immunization

A new campaign is being launched to support GAVI's efforts to close the gap between those children who have access to all available vaccines and those in the poorest countries who do not.

Thanks to its rapid start-up and early achievements, The Vaccine Fund has committed about 95% of its available resources to improve immunization services in almost 70 countries by the end of 2003. The challenge now is to replenish The Vaccine Fund so that these achievements can be taken to their full scale.

Despite significant gains, millions of children remain without access to the most basic primary health care, including immunization. The Vaccine Fund's goal over the coming years is to work with all partners to build upon the initial success and expand the availability of child immunization to children not yet reached. To achieve this, additional resources are needed for strengthening of health systems, purchase of vaccines and injection equipment, training and specific immunization services support. GAVI and The Vaccine Fund will aim to save one million lives by 2006.

With The Vaccine Fund, GAVI partners have begun to address a core underlying issue in global public health whose implications have meant disease and death for millions of children - the enormous life and death gap

between children in industrialized countries who have access to and are provided vaccines and those in the poorest countries who either have not had access to all available vaccines or are not being reached at all. The notion that all children should have such access to basic health care has already been enshrined in international human rights law, the Convention on the Rights of the Child.

Life or death for a young child too often depends on whether he is born in a country where vaccines are available or not... the issue is of fundamental fairness.

Nelson Mandela, former President of South Africa

However, it will take continued concerted focus, partnership and resources to ensure that GAVI's promise of access to all available vaccines for the world's poorest children. It will take global commitment and additional resources to achieve this. The Campaign for Child Immunization seeks to do two things: To increase awareness in industrialized countries of the gross inequity between North and South with regard to access to available vaccines, and to urge donor governments, foundations and private sector leaders to support the efforts of the GAVI partners to address this inequity and increase the available resources for health and immunization.

GAVI PARTNERS

Governments in developing countries deliver immunization services to children through their national health systems. Government health ministries manage national coordination - usually through inter-agency coordinating committees - which have become essential to the work of GAVI.

Vaccine manufacturers in developing countries produce vaccines at affordable prices for sale in the developing world. A new GAVI-inspired network was formed to strengthen collaboration among vaccine manufacturers in developing countries.

Governments in industrialized countries help to build political commitment and establish health as a priority for development assistance. Donor governments support countries in their efforts to improve health and immunization programs by participating in national coordinating groups and providing financial and/or technical support to health sectors and immunization programs.

Vaccine manufacturers in industrialized countries, represented by IFPMA - the International Federation of Pharmaceutical Manufacturer's Associations - have been GAVI partners since its inception, and currently the membership includes Aventis-Pasteur, Berna Biotech, Chiron, GlaxoSmithKline, Merck and Wyeth. The development, manufacturing and marketing of vaccines to all countries of the world are core responsibilities of these member companies.

Bill & Melinda Gates Foundation invests in global health efforts, especially in support of immunization, and helps raise awareness of the value of immunization. The Foundation has committed more than \$US 1 billion to projects focused on the prevention and control of infectious disease. These grants help to build coalitions among scientists, universities, nongovernmental organizations and private industry to ensure that all children have access to vaccines and that new drugs, vaccines and diagnostics are developed and delivered.

Nongovernmental organizations - NGOs - have a long history of involvement in the field of child health and immunization. Some NGOs provide technical advice and staff to government programs while others provide additional financial support.

Public health and research institutions provide policy recommendations on global immunization practices, act as reference laboratories for surveillance and quality control and provide technical staff for operations to help build capacity for research and development.

The World Bank Group works to reduce poverty through increased financing to combat communicable diseases and increase immunization through more flexible use of International Development Assistance funds. Immunization is now a key health service indicator in the assessment of a country's eligibility for debt-relief under the Highly Indebted Poor Countries (HIPC) initiative.

UNICEF has been a significant actor in the global effort to protect the health of the world's children through routine immunization. Immunization 'Plus' is one of its organizational priorities. UNICEF hosts the GAVI Secretariat in Geneva, Switzerland; provides administrative support to The Vaccine Fund - disbursing The Vaccine Fund grants to countries - and procures vaccines and safe injection supplies on behalf of GAVI partners.

World Health Organization, the world's leader in global public health, provides technical expertise and strategic support to the alliance. Furthermore, WHO staff in the field play a critical role in support of GAVI objectives.