



World Health Organization

Vaccines and Biologicals

Highlights from 2002-2005 Strategy



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Vaccines and Biologicals (V&B)



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Introduction

THE work of the Department of Vaccines and Biologicals (V&B) of the World Health Organization (WHO) is best illustrated through its mission statement:

“A world in which all people at risk are protected against vaccine-preventable disease.”

Routine immunization is arguably among the most efficient ways to reduce the incidence of child mortality and communicable diseases, saving more lives relative to the money spent than almost any other health intervention.

However, over 25% of the world’s children are not immunized despite the evident benefits of immunization. These children – for geographical, economic and/or social reasons – do not have access to routine services. They are typically the poorest and often the most difficult to reach, many of whom have never received any form of health care.

Immunization is a health intervention whose importance is widely recognized. The following outcomes show the current global concern for providing comprehensive immunization:

- ▶ The Millennium Development Goals (MDGs), adopted at the Millennium Summit of the United Nations in September 2000, call for a dramatic reduction in poverty and marked improvements in the health of the poor. Of the eight goals which address the shared values of the global commons, three are dedicated to issues of health. These latter goals call for the reduction of child mortality, improvement of maternal health, and to combat HIV/AIDS, malaria and other diseases.

- ▶ The Special Session of the UN General Assembly on Children, held in May 2002, reaffirmed these goals among others, as it reviewed the progress made for children in the decade since the 1990 World Summit for Children and the resulting Plan of Action for Implementing the World Declaration on the Survival, Protection and Development of Children in the 1990s. The 1990 World Summit for Children adopted a precise set of goals to be achieved by a specific time. These included reducing the spread of preventable diseases and increasing access to health services for women and children so as to improve the living conditions and survival rates of children.

- ▶ The Commission on Macroeconomics and Health (CMH), established by Dr Gro Harlem Brundtland, Director-General of WHO, assessed the place of health in global economic development. The key recommendation of the Commission was that the world’s low- and middle-income countries, in partnership with high-income countries, should scale up access to essential health services for the world’s poor, including a focus on specific interventions.

Children who lack the protection afforded by vaccines will face a more uphill battle in later years. The burden of disease may rob them of their most productive years, and the loss of income can lead a whole family into a spiral of poverty and desperation.

It is the task for V&B to ensure that every child, regardless of the place or circumstances of its birth, has the same access to safe and high quality life-saving vaccines. This brochure outlines the activities undertaken by V&B to improve the situation.

Framework for action — the Strategic Plan 2002-2005

A strategic plan has been developed to help V&B achieve its goals. The plan charts the way in which appropriate interventions should progress, while allowing flexibility in order to respond to new challenges and a changing environment. The strategy directly addresses the three overarching objectives of V&B: **innovation in vaccine and delivery systems, strengthening of immunization systems and accelerated disease control**. These three objectives are further divided into nine targets, each of which have specific indicators to measure progress. Although each of the nine targets plays a critical role in the overall strategy, specific emphasis has been placed on the three selected as V&B's priorities:

- ▶ accelerated vaccine introduction
- ▶ safety of immunization
- ▶ polio eradication

Innovation

- ▶ **Target 1** – pre-clinically evaluate new vaccines and delivery systems and prepare their clinical evaluation.
- ▶ **Target 2** – clinically evaluate vaccines for use in developing countries.
- ▶ **Target 3** – accelerate the introduction of licensed new and underutilized vaccines.
- ▶ **Target 4** – assess, apply and promote relevant new technologies and methods for the standardization and control of biologicals.

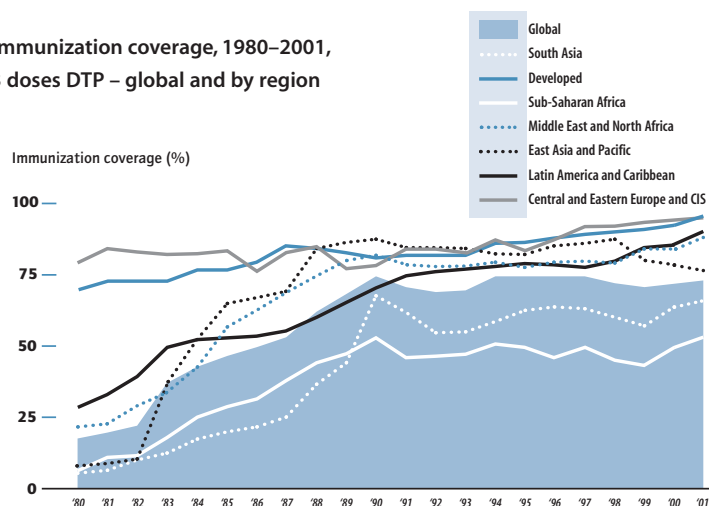
For each target, a range of indicators has been selected to enable us to measure the impact of our work and the progress accomplished. A subset of these, identified as critical indicators, provides a rough and rapid indication of the progress from year to year. An example of a critical indicator would be: the proportion of countries that have introduced hepatitis B and *Haemophilus influenzae* type b (Hib) vaccine.

There is a need to ensure continued research and development of new vaccines against diseases of public health importance, as well as to incorporate these vaccines into national immunization services in a timely manner. Therefore, the work under the Innovation objective on research, development, introduction of new vaccines and biological products, as well as

Immunization facts

- ▶ In 1974 only about 5% of the world's children had access to vaccines.
- ▶ A global effort was launched in the early 1980s to provide basic immunization coverage for specific diseases (i.e. polio, tuberculosis, tetanus, diphtheria, pertussis and measles) to 80% of children worldwide. By 2000, approximately 74% of children had received basic immunization.
- ▶ Each year almost 37 million children still do not have access to basic immunization services.
- ▶ Measles takes the lives of almost 800 000 children under the age of five each year.
- ▶ Routine use of newer vaccines in developing countries could prevent up to 1.5 million deaths per year.
- ▶ Immunization today saves more than three million lives each year.
- ▶ The Global Polio Eradication Initiative has set a goal that by 2005 the world should be polio free.
- ▶ In 2001, 575 million children were immunized with the oral polio vaccine.

Immunization coverage, 1980–2001,
3 doses DTP – global and by region



Initiative for Vaccine Research (IVR)

IVR consolidates WHO's various vaccine research and development programmes into an integrated effort. As a component of V&B, IVR is linking its activities with those of the Special Programme for Research and Training in Tropical Diseases (TDR) for parasitic diseases, and of the UNAIDS/WHO HIV Vaccine Initiative for HIV/AIDS vaccines, the latter being a full component of the Initiative for Vaccine Research. IVR's mandate is to provide a centralized source of leadership, vision, priority-setting and coordination of global vaccine research and development (R&D) programmes. IVR is WHO's key body responsible for drawing together the necessary expertise and efforts to address both worldwide priorities and gaps. IVR's integration within V&B allows integration of R&D activities into the vaccine continuum and facilitate the establishment of selected public/private partnerships. IVR benefits from the wide expertise of V&B in the domain of vaccine development, as well as from knowledge acquired by the parasitic and HIV vaccines in aspects related to ethical issues, clinical testing and capacity-building.

Vaccines soon to be available

- ▶ Cholera
- ▶ Typhoid
- ▶ Measles (new formulation)
- ▶ Meningitis
- ▶ Rotavirus
- ▶ Pneumococcal
- ▶ Human papillomavirus (HPV)



Photo: WHO/J.M. Gibou

Facts on hepatitis B and Hib

Five facts about hepatitis B disease

- ▶ Hepatitis B is a viral infection of the liver.
- ▶ There are three ways in which the virus can be transmitted: through puncture of skin or mucous membrane or the transfusion of infected blood or blood products, from an infected mother-to-child, and through sexual intercourse with an infected person.
- ▶ There are no known effective antiviral agents against it.
- ▶ Globally about 1.8 billion individuals alive today have been infected at some time of their lives; approximately 350 million are chronically infected with this virus.
- ▶ More than 500 000 of these chronically infected persons die each year from cirrhosis or cancer of the liver.

Five facts about Hib

- ▶ Hib is one of six serotypes (a, b, c, d, e and f); Hib bacteria are normally found living in the nose and throat of people.
- ▶ More than 90% of diseases due to *Haemophilus influenzae* in children is caused by type b (Hib).
- ▶ Hib is transmitted from child-to-child in droplets of saliva expelled when an infected child coughs or sneezes; it can also spread when children share toys and other things that they have put in their mouths.
- ▶ Hib causes more than three million serious cases of bacterial infections annually.
- ▶ Hib kills between 300 000 to 500 000 children from severe pneumonia and bacterial meningitis each year.

immunization-related technologies that will help reduce the burden of diseases, is critical.

Innovative developments in delivery technologies and approaches are also crucial to enhancing the performance of current immunization services. The replacement of conventional injectable vaccines with improved delivery methods that permit vaccines to be administered more simply and safely would decrease the logistical, social and financial barriers often associated with low levels of vaccination coverage.

New vaccines are not being used in the developing world even though they are being or have been adopted rapidly in the developed world. Potentially, these new vaccines could prevent millions of deaths per year. Therefore, the **accelerated introduction of vaccines**, with particular emphasis on hepatitis B and Hib vaccines, has been selected as a priority under the Innovation umbrella. The objective of this project is to implement a mechanism for accelerating the introduction of new and underused vaccines of public health importance in the developing world. Barriers to new vaccine introduction in the developing countries which are being targeted by this project include: lack of efficacy; burden and cost effectiveness information for developing country settings; the need for technical assistance with introduction; logistics; supply and quality control issues; and lack of financial resources for new vaccines.

Safe and appropriate use of injections

A safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in any waste that is dangerous for other people. Each year, the overuse of injections and unsafe injection practices combine to cause an estimated 8 to 16 million hepatitis B virus infections, 2.3 to 4.7 million hepatitis C virus infections and 80 000 to 160 000 HIV infections. Of particular concern among unsafe practices is the re-use of syringes and/or needles without sterilization.

Injection-associated transmission of bloodborne pathogens can be prevented through the development of a strategy to reduce injection overuse and achieve injection safety. Its implementation should be monitored by a national coalition, with the assistance of a coordinator.

The three major elements of a strategy for the safe and appropriate use of injections are:

- ▶ Behaviour change among patients and health care workers to decrease injection overuse and achieve injection safety
- ▶ The availability of necessary equipment and supplies
- ▶ The safe disposal of injection equipment

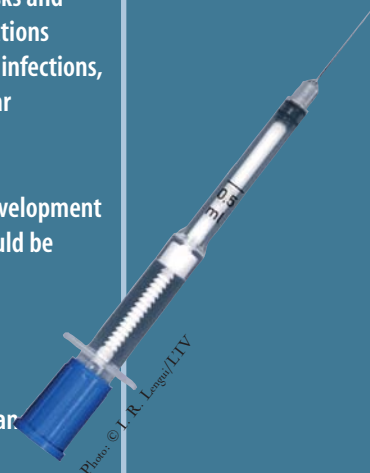


Photo: © I. R. Lopez/LTY

Vaccine vial monitors (VVMs)

VVMs were first included on vials of oral polio vaccine (OPV) in 1996 and are being widely and effectively used both in routine programmes and supplementary immunization activities such as national immunization days (NIDs). VVMs indicate whether the vaccine has been exposed to a combination of excessive temperature over time and whether it is likely to have been damaged. They are the only tool among all time temperature indicators that are available at any time in the process of distribution and at the time a vaccine is administered. They are an invaluable tool in increasing coverage in hard-to-reach communities as well as in areas with a very weak cold chain infrastructure.

Due to their proven utility in vaccine management, WHO and UNICEF issued a policy statement in 1999 which describes the value of VVMs, in addition to recommending that agencies purchasing vaccines request manufacturers to supply all vaccines with VVMs that meet WHO specifications. VVMs on vaccines other than OPV started to become available in 2000. During 2001, many countries began to receive BCG, yellow fever, measles and/or measles–mumps–rubella (MMR) vaccines with VVMs.



Photo: WHO/P. Blanc

Immunization systems

- ▶ **Target 5** – assure adequate supply and quality of all vaccines delivered by national immunization services up to and including the time of administration.
- ▶ **Target 6** – establish a comprehensive system to ensure the safety of all vaccines given by national immunization services.
- ▶ **Target 7** – strengthening key immunization functions and public health managerial capacity at national and district levels.

One critical indicator would be: proportion of countries using vaccines with vaccine vial monitors (VVMs) where relevant.

In 1974, when the Expanded Programme on Immunization (EPI) was launched by WHO, only 5% of the world's children were immunized against the initial six target diseases. Large-scale investment in vaccination saved millions of lives in the 1980s. In 2000, coverage rates reached 76%. However, much remains to be done, as immunization rates have plateaued in the last decade. In many places, they have stagnated or fallen to below 30%. Although immunization systems have vastly improved, millions of children, particularly in the world's most remote areas, still do not have access to the basic vaccines.

The model created by EPI provides an infrastructure that can also be used for other forms of preventive health care. Examples of these benefits



Photo: WHO/C. McNabb

Polio Facts

- ▶ In 1988 over 1000 children were paralysed by polio every day
- ▶ In 2001 – 575 million children were immunized with the oral polio vaccine
- ▶ Since 1988 the number of polio-endemic countries has been reduced from 125 to fewer than 10
- ▶ Polio cases are at the lowest in history, with just 483 reported in 2001
- ▶ Since 1998 over one million childhood deaths have been prevented by the administration of vitamin A during polio national immunization days (NIDs) in over 50 countries.

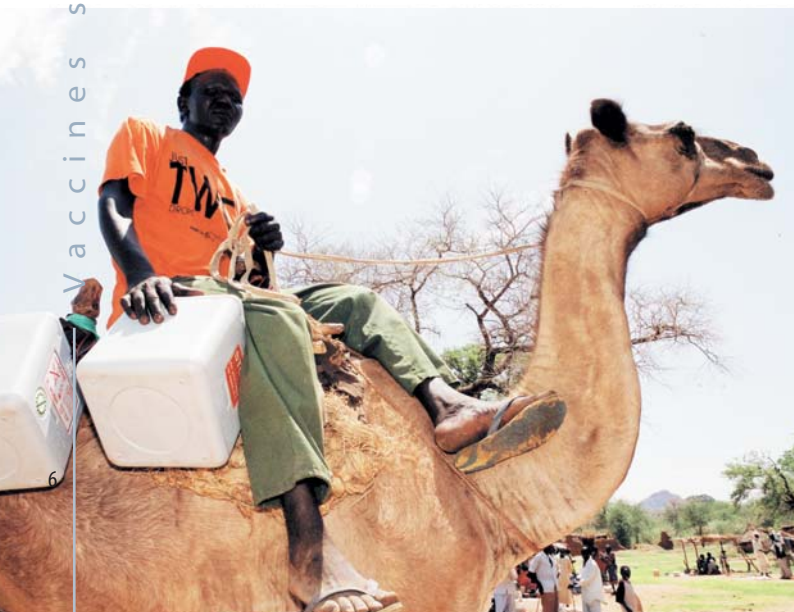


Photo: WHO/P. Blanc

include: training for millions of health workers and volunteers; safe storage and transport of vaccine; efficient surveillance systems and laboratory networks to search for major killers and prevent potentially devastating outbreaks; and global vaccine supply quality control mechanisms.

V&B is currently focusing on strengthening health systems and the sustainability of immunization services. The next step is to broaden the development of immunization systems to include the remote areas that still represent the greatest need, in addition to strengthening health managerial capacity at national and district levels.

To further enhance this objective, **immunization safety** has also been selected as a priority project. Vaccines remain undoubtedly one of the most effective and safest of health interventions. Nevertheless, immunization services face many challenges. “Immunization safety” – ensuring and monitoring the safety of all aspects of immunization, including vaccine quality, storage and handling, vaccine administration and the disposal of sharps – is one such challenge. Activities currently being undertaken include: injection safety assessments using a standard assessment tool; the introduction of auto-disable syringes, which dramatically reduces the risk of unsafe injections and transmission of bloodborne pathogen diseases; and the establishment of a proper adverse events following immunization (AEFI) system in all countries.

Accelerated Disease Control

- ▶ **Target 8** – certify all WHO regions as polio-free in 2005.
- ▶ **Target 9** – define and implement control and elimination strategies for priority diseases that are vaccine-preventable.

One critical indicator would be: number of WHO regions certified as polio-free.

The ultimate aim of immunization is to bring diseases under control, and, in certain cases, to eliminate or even eradicate them. Within this objective, there is a concentration of efforts on specific diseases and routine immunization services are supplemented with particular campaigns and special activities in order to achieve the goals of control, elimination or eradication.

The priority project of **polio eradication** is an example of a concerted effort to rid the world of the scourge of a single disease. In 1988, the Forty-first World Health Assembly launched a global initiative to eradicate polio. In the 14 years since the Global Polio Eradication Initiative was launched, the number of cases has fallen by 99.8%, from an estimated 350 000 cases to just 483 cases in 2001. At the outset of 2002, the number of polio endemic countries was 10, having been reduced from 125 in 1988. Widely endemic on five continents in 1988, polio is now concentrated only in parts of Africa and in south Asia. The intensified efforts to achieve eradication continue and the programme is on track for all WHO regions to be certified or in the process of certification by the end of 2005.

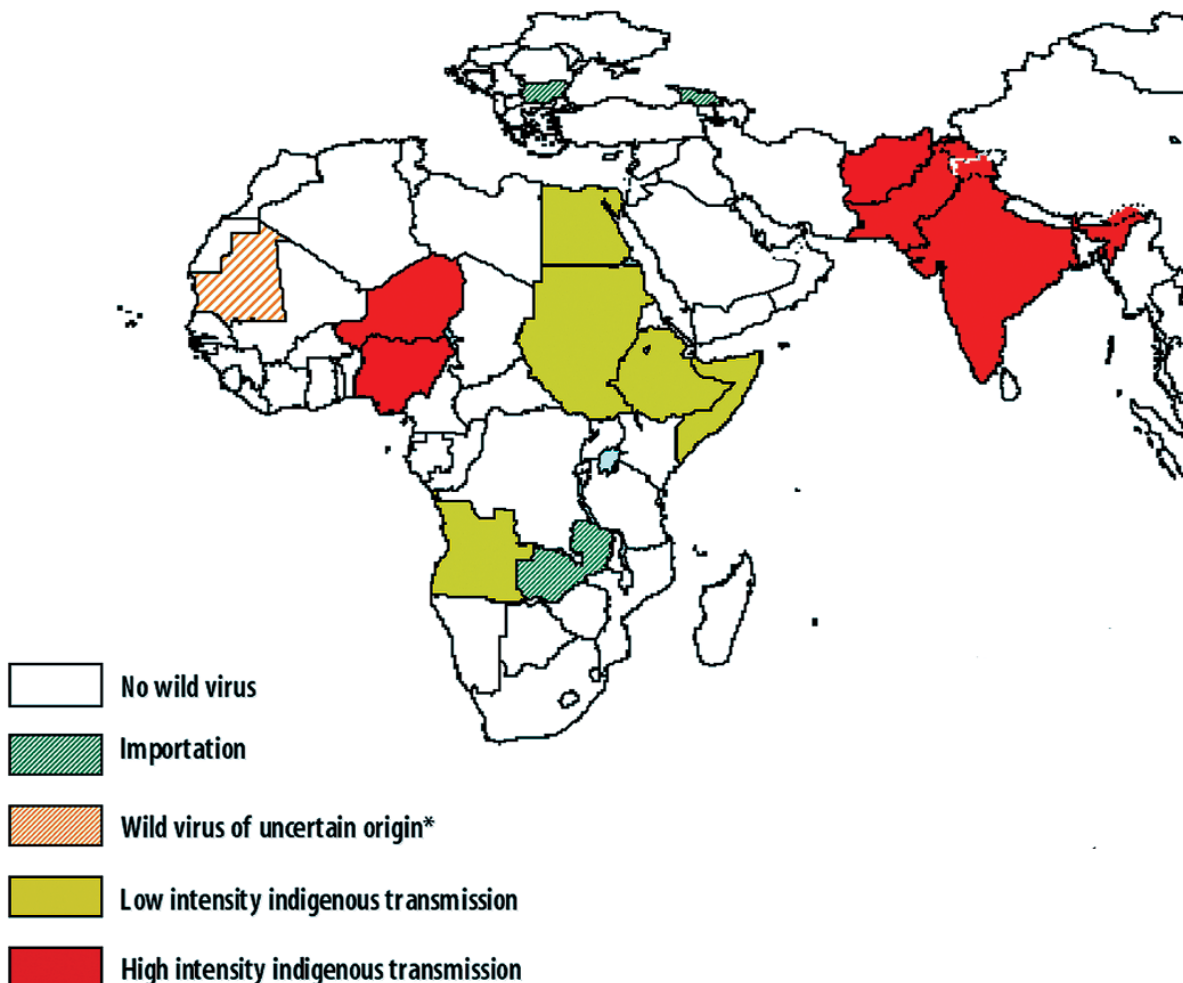
In the process of these activities, the polio eradication initiative has built up an infrastructure of national surveillance systems, trained

epidemiologists and a global laboratory network. Polio has revitalized areas that had been languishing, including cold chain structures. The infrastructure that has been developed to serve the polio objective is serving to strengthen existing health systems through routine immunization and disease surveillance. It has also provided additional mobility for V&B's goals on global immunization.

Polio eradication – Delivering more than vaccine

Since 1998, more than 50 countries have optimized use of the logistics, expertise and trained volunteers of the Global Polio Eradication Initiative to administer vitamin A to children – thereby doubling the health impact of polio immunization campaigns. As one of the most cost-effective child health interventions, vitamin A supplementation not only protects against blindness, but reduces child mortality and morbidity particularly from measles and diarrhoea. Over the past four years alone, more than one million young lives have been saved through the delivery of vitamin A during polio immunization campaigns.

Wild poliovirus in 2001, 10 polio-endemic countries



* the response to wild viruses of uncertain origin is as per indigenous wild virus.

Partnerships

It would be impossible to undertake the vast scale of the immunization services without the many partners throughout the world who are part of this programme. Partnerships are integral to every step of the process, providing a platform from which global immunization goals and objectives can be achieved.

▶ **Polio** – One of the most successful partnerships in the quest to eradicate a disease is the Global Polio Eradication Initiative. The Initiative is spearheaded by WHO, Rotary International, the US Centers for Disease Control and Prevention (CDC) and the United Nations Children’s Fund (UNICEF). It also includes national governments, donors, development banks, foundations, private corporations and civil society. Volunteers in developing countries also play a key role, over 10 million have participated in mass immunization campaigns. From its inception in 1988, the demonstrated success of the polio partnership has led the way to many other partnerships, as well as to similar preventive health campaigns.

▶ **Global Alliance for Vaccines and Immunization (GAVI)** – GAVI, launched in 2000, is an international coalition that forms one of the key partnerships in WHO’s immunization efforts. The Alliance was created to reenergize interest in and support for immunization, and is an innovative partnership of governments, international organizations, major philanthropists, research institutions and the private sector. At the World Health Assembly in Geneva in May 2000, the world’s 74 poorest countries were invited to submit proposals to The Vaccine Fund. Since that time, 66 of the eligible countries have submitted proposals, 54 of which have been awarded support. Over the past two years, the partners in the Alliance have delivered new and underused vaccines to 27 countries and transferred funds to support national immunization services in 24 countries. They have also created a viable market in poor countries for simple-to-use vaccines that combine new and old antigens, such as hepatitis B combined with diphtheria–tetanus–pertussis (DTP), a demand that vaccine manufacturers are

now striving to satisfy. Furthermore, they have agreed to prioritize three new vaccines in late stages of development; these vaccines are intended to combat viral diarrhoea, pneumonia and meningitis, diseases that together cause approximately two million child deaths each year.

The Vaccine Fund was created as a financing mechanism designed to raise new resources and swiftly channel them to developing countries’ health systems, so as to help meet the GAVI immunization goals. The Vaccine Fund has several specific purposes, including: the provision of financial support to strengthen health infrastructures; the introduction of new and underused vaccines, as well as associated safe injection equipment; and the provision of safe injection equipment for all vaccines given according to the standard EPI schedule. As of May 2002, The Vaccine Fund has provided support to 54 out of the 74 eligible countries with 5-year commitments totalling US\$ 833 million. The Vaccine Fund has been supported by bilateral donors (Canada, Denmark, the Netherlands, Norway, Sweden, UK and the USA), the Bill & Melinda Gates Foundation, and other contributors.

▶ **Meningitis Vaccine Project** – In 2001, a partnership, spearheaded by WHO and the Program for Appropriate Technology in Health (PATH), launched an ambitious new 10-year programme to eradicate the meningitis epidemics that have plagued sub-Saharan Africa for more than 100 years. The Bill & Melinda Gates Foundation awarded the partnership US\$ 70 million over a 10-year period to develop and produce meningitis vaccines tailored for children and adults living in Africa.

▶ **Measles Initiative** – Launched in February 2002, this initiative is a long-term commitment to control deaths as a result of measles in Africa. In vaccinating 200 million children, it is estimated that this will prevent 1.2 million deaths over five years. Leading this effort are the American Red Cross, United Nations Foundation, CDC, WHO and UNICEF.

► **Safe Injections Global Network (SIGN)**

– In many developing and transitional countries, injection overuse and unsafe injection practices combine to transmit bloodborne pathogens on a large scale. In response, in 1999, WHO scaled up its injection safety activities and decided to host the secretariat of SIGN. SIGN is an international coalition of stakeholders – including national governments, international agencies, professional associations and nongovernmental organizations (NGOs) – who consider that poor injection

practices can easily be avoided through collaborative efforts. A simple threefold strategy calls for a behaviour change of health workers and patients, ensuring the availability of equipment and supplies, and safe and appropriate management of health care waste. The SIGN alliance now provides a powerful mechanism for information sharing between all partners through a weekly electronic newsletter, an Internet site and an annual coordination meeting.



Photo: WHO

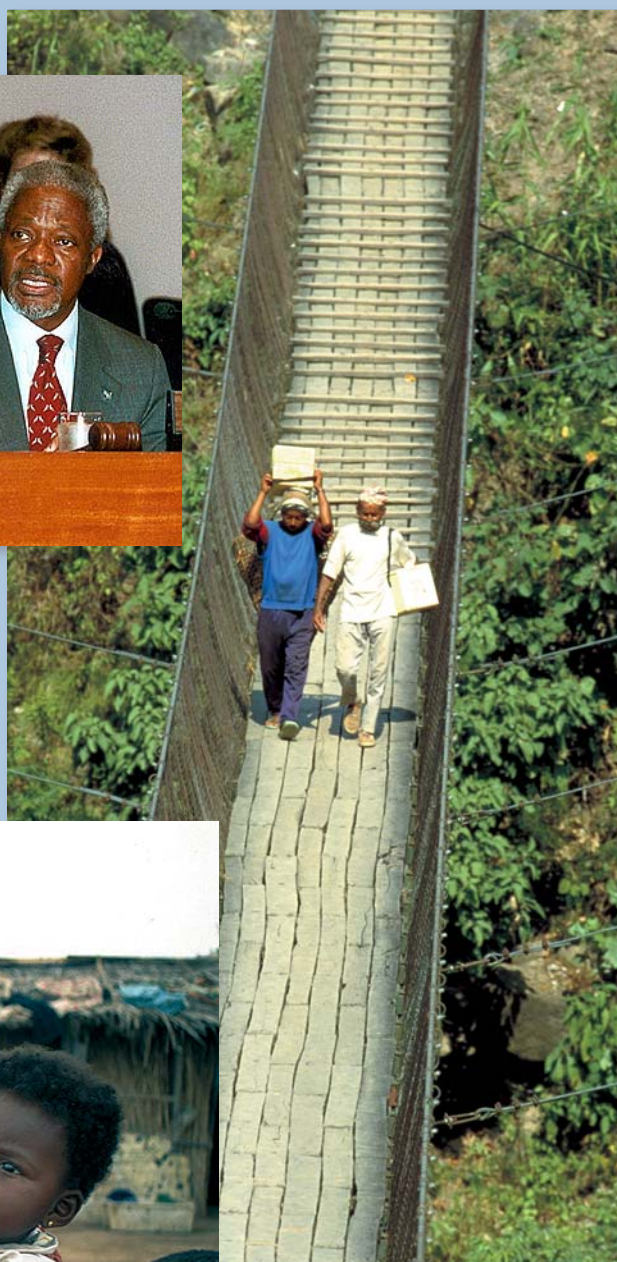


Photo: WHO/J.M. Chaux

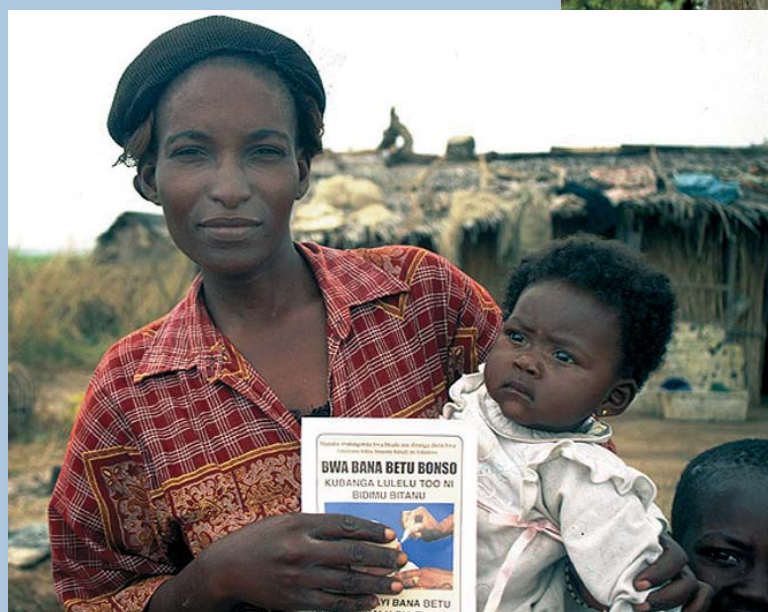


Photo: WHO/C. McNabb

V&B – *who we are*

V&B's major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases. The work of the groups is outlined below:

- ▶ The *Quality Assurance and Safety of Biologicals* (QSB) team ensures the quality and safety of vaccines and other biological medicines through the development and establishment of global norms and standards.
- ▶ The *Initiative for Vaccine Research* (IVR) and its three teams involved in viral, bacterial and parasitic diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.
- ▶ The *Vaccine Assessment and Monitoring* (VAM) team assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.
- ▶ The *Access to Technologies* (ATT) team endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.
- ▶ The *Expanded Programme on Immunization* (EPI) develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.

Departmental publications

Key documents

- V&B biennial report 2000–2001 (WHO/V&B/02.01)
- V&B catalogue 2002 (WHO/V&B/02.06)
- Vaccines, Immunization and Biologicals: 2002–2005 Strategy (WHO/V&B/02.02)
www.who.int/vaccines-documents/DocsPDF02/www728.pdf
- Health Technology and Pharmaceuticals (HTP) Strategic Plan 2000–2003 (WHO/HTP/02.01)

Selected documents

- Immunization policy (WHO/EPI/GEN/95.03 REV.1)
www.who.int/vaccines-documents/DocsPDF/www9401.pdf
- Immunization in practice (WHO/EPI/TRAM/98.01-11 REV.1)
www.who.int/vaccines-documents/DocTrng/h4iip.htm
- WHO vaccine-preventable diseases: monitoring system 2001 global summary (WHO/V&B/01.34)
www.who.int/vaccines-documents/GlobalSummary/GlobalSummary.pdf
- WHO-recommended standards for surveillance of selected vaccine-preventable diseases (WHO/EPI/GEN/98.01 REV.2)
www.who.int/vaccines-documents/DocsPDF/www9742.pdf
- Regulation of vaccines: building on existing drug regulatory authorities (WHO/V&B/99.10)
www.who.int/vaccines-documents/DocsPDF99/www9918.pdf
- Manual of laboratory methods – For testing of vaccines used in the WHO Expanded Programme on Immunization (WHO/VSQ/97.04)
www.who.int/vaccines-documents/DocsWord/www9716.zip
- Global Polio Eradication Initiative Strategic Plan 2001–2005 (WHO/Polio/00.05)
www.who.int/vaccines-documents/DocsPDF00/PolioStratPlan.pdf

All document listed above are available from Vaccines and Biologicals, World Health Organization, 1211 Geneva 27, Switzerland.



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