

Vaccines and Biologicals



2000-2001 HIGHLIGHTS



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THE culture of disease prevention gained momentum in the biennium, particularly through the impressive debut of the Global Alliance for Vaccines and Immunization (GAVI) and the intensive efforts to eradicate polio. Reported polio cases were drastically reduced from 7141 to 480 globally between 1999 and 2001, as accelerated immunization activities successfully cornered the virus. The remaining polio-endemic countries in Asia and Africa increased the number of rounds on national immunization days (NIDs) and began house-to-house vaccine delivery to reach every child.

As polio eradication reaches a crescendo and GAVI's support to poorer countries gains momentum, there is a sharper focus on how to strengthen routine immunization and surveillance and to build on lessons learned. Though much has been achieved, much still needs to be done. Immunization coverage rates have stagnated and in many countries the infrastructure is in decay. There is still a huge mortality from measles in developing countries despite a cheap and effective vaccine. *Haemophilus influenzae* type b (Hib) and hepatitis B (HepB) also have high mortality and morbidity, while effective vaccines against these remain underused. Vaccines still do not exist against various other killer diseases, and research and development (R&D) efforts must be renewed.

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GLOBAL ALLIANCE FOR VACCINES AND IMMUNIZATION (GAVI)

AT the forefront of the movement to make safe quality vaccines and immunization accessible and available to all is the newly launched GAVI initiative.

GAVI was launched in January 2000, dedicated to ensuring the right of every child to have a healthy start in life by promoting one of the most-cost effective health interventions available – immunization. Two years after launch, Partners in GAVI have made great strides toward improving access to sustainable immunization services and expanding the use of new and underused vaccines in some of the world's poorest countries.

The Alliance forges together the efforts of national governments, WHO, the United Nations Children's Fund (UNICEF), the World Bank, Bill and Melinda Gates Foundation, the vaccine industry, technical agencies, public health and research institutions, and nongovernmental organizations. Through the Vaccine Fund, it provides 75 of the poorest nations (GNP/capita less than US\$ 1000) the opportunity to build up their immunization services and introduce vaccines against hepatitis B, *Haemophilus influenzae* type b and yellow fever. In addition, the Alliance provides safe injection equipment in the form of auto-disable (AD) syringes and safe disposal boxes for all routine immunization injections, or the equivalent funding to support the implementation of the national plan for injection safety. Since its inception, GAVI has received and processed 126 proposals from 64 of the 75 countries that are eligible for Vaccine Fund support. As of 31 December 2001, 88 applications have been approved from 52 countries for new vaccines, strengthening immunization systems and/or immunization safety. The total five-year financial commitment to developing country health programmes exceeds US\$ 800 million. ■



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STRATEGIC PLANNING

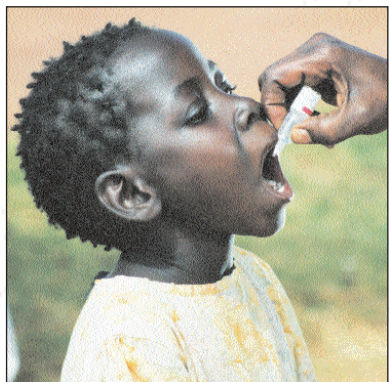


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THE *Vaccines, Immunization and Biologicals Strategy*, published in 2000, for the period 2000–2003 and updated at the end of 2001 for the period 2002–2005, maps out what Vaccines and Biologicals (V&B) aims to achieve in the areas of innovation in vaccines and vaccine delivery, strengthening of immunization systems and accelerated disease control. The work on these main objectives is presented in terms of targets to be achieved and a detailed discussion of the expected results. Each target and product has well-defined indicators which ensure that progress is closely monitored. Among the nine targets in the plan, three have been given extra prominence and selected as priority projects: **polio eradication, accelerated vaccine introduction and the safety of immunization**. These priority projects draw on the expertise of all the groups within V&B. ■

1 PRIORITY PROJECTS

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POLIO ERADICATION ON TRACK

THE Global Polio Eradication Initiative had two remarkable years during 2000–2001. After intensive efforts to immunize every child, the incidence of polio fell from over 7000 cases in 1999 to only 480 in 2001, bringing the disease to the brink of eradication.

With extensive routine immunization and gigantic immunization campaigns involving millions of volunteers, the world of the wild poliovirus shrank fast during the biennium. Circulation is now limited to parts of 10 countries, down from 30 countries in 1999.



Photo: © WHO

Three WHO regions are free of indigenous poliovirus (the Region of the Americas, the Western Pacific Region and the European Region). The Western Pacific was certified polio-free in October 2000, and in November 2001 the European Region completed three polio-free years, on track to be certified polio-free in 2002. In polio-free areas, laboratory containment of wild polioviruses and the eventual cessation of polio immunization have come under increasing focus, as has high-level surveillance worldwide.

PROGRESS IN NEW VACCINES INTRODUCTION

THE V&B Priority Project on Accelerated Vaccine Introduction seeks to implement a mechanism for accelerating introduction of new and underused vaccines. In 2000–2001, the focus was to accelerate the introduction of hepatitis B and Hib vaccines. By December 2001, hepatitis B vaccine was used in routine infant immunization services in 142 countries, up from 114 countries in 1999 and only 20 countries in 1990. By the end of the biennium, Hib vaccine had been introduced in 90 countries, up from only 44 countries two years previously. A boost for the introduction of new vaccines came with the launching of the Vaccine Fund, and so far 40 countries have received approval for support from the Fund.



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ENSURING IMMUNIZATION SAFETY

THE Priority Project on the Safety of Immunization, established in 1999, has now completed its third year of activity. The main target of this priority project is to establish a system to ensure the safety of all vaccination given through national immunization systems, and to encourage an overall culture of safety. As the threat from polio, measles, diphtheria, etc. recedes due to the success of immunization parents become more insistent that immunization should be totally free of risk from complications.

Major achievements have been accomplished with the AD syringes. The use of AD syringes has tremendously increased over the last couple years in parallel with a move toward an exclusive use of AD syringes for mass campaigns and a gradual shift to AD syringes for routine vaccination. ■



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2 OTHER HIGHLIGHTS IN THE FIELD OF INNOVATION

A BOOST IN NEW VACCINE DEVELOPMENT

AN over-arching programme, the Initiative for Vaccine Research coordinates the different R&D efforts into a single WHO-wide activity. The focus is broad including improved delivery systems for developing country use and vaccines against diseases of both global and purely local significance. Viral diseases under focus for new vaccine development include human immunodeficiency virus (HIV) infection, Japanese encephalitis (JE), polio, measles, rotaviral diarrhoea and dengue. A second team is devoted to tackling vaccine for parasitic diseases like malaria and leishmaniasis, while a third team focuses on bacterial diseases like TB, pneumococcal pneumonia and meningococcal meningitis. Examples of such projects concern pneumococcal, rotavirus, Japanese encephalitis, and meningococcal vaccine development. In May 2001, the meningitis vaccine project (MVP) was launched with core funding of US\$ 70 million for 10 years from the Bill and Melinda Gates Foundation.

QUALITY AND SAFETY STANDARDS FOR BIOLOGICALS

VACCINES and other biologicals are derived from living materials and present particular problems with respect to assuring their efficacy and safety. The WHO Expert Committee on Biological Standardization (ECBS) plays a key role in reviewing scientific progress and establishing international reference preparations and recommendations on production and control of such products. At the 51st ECBS meeting in 2000, new quality control procedures for oral polio vaccine were adopted and recommendations for inactivated polio vaccine updated.

Guidelines for the production and control of live attenuated Japanese encephalitis vaccines were also adopted.

The 52nd ECBS meeting in 2001 adopted recommendations /guidelines for the production and control of group C conjugate meningococcal vaccine, inactivated oral cholera vaccine and regulatory expectations in the clinical evaluation of vaccines. Several candidate HIV-vaccines are now available for clinical evaluation and a consultation in 2001 addressed standardization and regulatory needs in this vital area. In 2000–2001, following extensive laboratory studies, the Expert Committee established 19 new or replacement International Biological Standards or Reference Reagents covering a wide range of products. ■



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3 OTHER HIGHLIGHTS IN THE FIELD OF IMMUNIZATION SYSTEMS

STRENGTHENING IMMUNIZATION SERVICE DELIVERY

IMMUNIZATION systems are stagnating. Many countries that were dramatically successful in raising their immunization coverage in the 1980s are now finding it difficult to lift coverage rates from 50% up to a target of at least 80%. In sub-Saharan Africa, only around half the children are vaccinated. It is estimated that every year as many as 37 million children, mostly in Africa and Asia, do not receive essential doses of vaccine.

Thus the challenge now is to build upon the successes of polio eradication, the boost of GAVI support and the revitalized culture of prevention, to lay the foundation for sustainable immunization services that will deliver vaccine – safely – to all children. An important part of V&B’s mission is to examine the immunization infrastructure, pinpoint problems and seek solutions, together with partners and the WHO regional offices.

Lessons from polio: microplanning

The Expanded Programme on Immunization (EPI) has developed simple guidelines for increasing coverage at the health facility level through a process of microplanning, including the preparation of an outreach workplan and regular communication between the health services and the local community. As polio is eliminated, WHO regional offices are helping countries to put microplanning in action for control of other diseases.

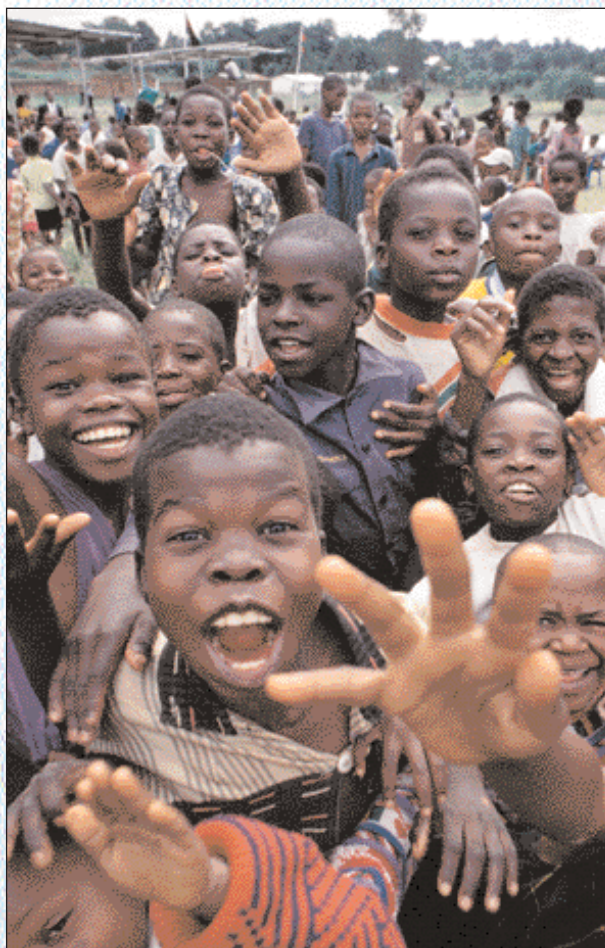


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Sustainable outreach services

Most countries with low routine coverage have managed to reach over 80% of their children under five years of age with supplementary immunization campaigns, helped greatly by community involvement. The sustainable outreach services (SOS) focus on reaching the unreached children, informed by lessons from the Polio Eradication Initiative. SOS is currently being piloted in four countries (Chad, Mali, Mozambique, and Uganda) and will become a key element in strengthening immunization services. After a slow start in 2000, progress was considerable in 2001.

MONITORING (INCLUDING SURVEILLANCE) AND ASSESSMENT

V&B take active part in global monitoring and assessment of vaccine-preventable diseases. The following were among some of the activities in 2000–2001:

- A paediatric bacterial meningitis (PBM) surveillance network was launched in 27 countries of WHO’s African Region. The goal of this activity is to establish surveillance systems that can

document the burden of bacterial meningitis disease and the success of vaccination programmes. A similar bacterial meningitis surveillance network is being developed in WHO's Eastern Mediterranean Region.

- For maternal and neonatal tetanus elimination, a global tracking system is under development in collaboration with UNICEF. Action plans were developed in four WHO regions.
- WHO and UNICEF completed a review of national immunization coverage for the years 1980–1999. The estimates were based on officially reported data by Member States, the UNICEF database, the published literature and surveys from ministries of health. Local experts were consulted to help explain the observed trends. Based on all available information, the most likely true level of immunization coverage for each year was determined.

ASSURING VACCINE QUALITY

NOT only must vaccines be safe; they must also be potent. Ensuring all countries have access to vaccines of assured quality, and that the quality is maintained up to the time the vaccine is administered, are critical goals of V&B. Quality of vaccines is assured when they are produced in countries where a national regulatory authority (NRA) exercises six critical functions identified by WHO, with no unresolved problems. There has been an important increase in activities to strengthen national regulatory authorities. In 2000–2001 all regional offices were provided with technical support in planning activities to strengthen NRAs and conduct country assessments against indicators. Assessments or reassessments were organized and conducted in 33 countries. The WHO Global Training Network – which includes 13 collaborating centres – offers a set of courses aimed at strengthening the national regulatory authorities. In 2000–2001, training was provided to 217 NRAs and production staff from 56 countries.



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LOGISTICS AND VACCINE MANAGEMENT UNDER FOCUS

VACCINES are delicate products. When there is an equipment or management failure, large quantities of vaccine can be destroyed in a few hours, placing the immunization services of an entire country at risk. This is not just theoretical – it has happened. Criteria for effective vaccine store management were agreed at a meeting of experts at WHO in December 2001. These 10 criteria form the policy foundation for a cold store certification initiative by WHO and UNICEF to assist countries to fully protect vaccines in the stores. ■



➤ **A GLOBAL PLAN TO REDUCE MEASLES MORTALITY**

In spite of the availability of an inexpensive and highly effective vaccine, measles still causes almost 800 000 deaths each year. In May 2000, global experts reviewed the strategies for measles mortality reduction and elimination. Among the goals of the global plan are: (i) to halve annual global measles-related mortality by the year 2005 (compared with 1999); and (ii) to interrupt transmission of indigenous measles virus in large geographical areas including the Region of the Americas, the Eastern Mediterranean and European regions.

➤ **RUBELLA: INTEGRATION WITH MEASLES CONTROL AND SURVEILLANCE**

In a pregnant woman, rubella infection can lead to spontaneous abortion, stillbirth, or delivery of an infant with congenital malformations due to congenital rubella syndrome (CRS). As of December 2001, 118 of 214 countries reporting to WHO have included rubella-containing vaccines in their routine immunization system.

➤ **ELIMINATION OF MATERNAL AND NEONATAL TETANUS**

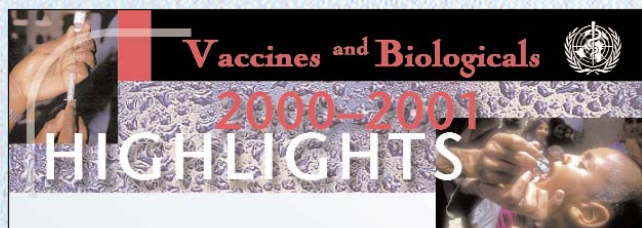
Every year some 200 000 babies and 30 000 mothers die from maternal and neonatal tetanus (MNT). All WHO regions have prepared a plan of action for MNT elimination by 2005. WHO has published a template for streamlining planning at country level.

➤ **YELLOW FEVER OUTBREAKS AND VACCINE SHORTAGES**

The biennium witnessed an upsurge of yellow fever infection, with epidemics in West Africa and South America. Meanwhile, a shortage of yellow fever vaccine hampered yellow fever control. A response to the two-edged problem has been establishment of a yellow fever vaccine stockpile, and mechanisms for distribution and support.

➤ **VITAMIN A "BONUS"**

Globally, 140–250 million children under five are deficient in vitamin A, thus facing an increased risk of death from measles and diarrhoea. However, current strategies for delivering vitamin A miss children under six months of age, who suffer the greatest morbidity and mortality. A proposed new schedule recommends vitamin A supplementation to mothers just after delivery, and vitamin A supplementation to infants under six months of age, preferably at the first three DTP routine immunization contacts. Field trials have been initiated in Ghana and Tanzania, and results are expected by the end of 2002. ■



Further information may be obtained from World Health Organization, Department of Vaccines and Biologicals, CH-1211 Geneva 27, Switzerland.
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Documents may be ordered through the same address, or may be downloaded from the Internet at <http://www.who.int/vaccines-documents>
Ordering code for this document: **WHO/V&B/02.22**

