WHO/IVB/05.22 ORIGINAL: ENGLISH

Immunization, Vaccines and Biologicals: Strategic Plan 2006–2009

Immunization, Vaccines and Biologicals



World Health Organization

WHO/IVB/05.22 Original: English

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The Department of Immunization, Vaccines and Biologicals thanks the donors whose unspecified financial support has made the production of this document possible.

> This document was produced by the Department of Immunization, Vaccines and Biologicals World Health Organization

> > Ordering code: WHO/IVB/05.22 Printed: December 2005

This publication is available on the Internet at: www.who.int/vaccines-documents/

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Printed by the WHO Document Production Services, Geneva, Switzerland

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Executive summary

Significant strides have been made towards implementing essential immunization practices in developing countries. However, the complexities of developing new vaccines and the obstacles faced in bringing them to vulnerable populations demand continued action. WHO's Department of Immunization, Vaccines and Biologicals (IVB), in close collaboration with WHO regional and country offices, has played a vital role in the enhancement of such programmes worldwide and looks towards continued progress through a focus on innovation, quality and safety, and increased access. Activities in the Department's strategic plan for 2006–2009 reflect its commitment to these three core areas. The plan outlines achievements of IVB with regard to the improvement and increase of immunization practices and presents objectives and future activities aimed at building upon those achievements.

The recently developed Global Immunization Vision and Strategy (GIVS)* outlines in broad strategic terms the direction that WHO and UNICEF believe immunization programmes of the world and their partners should take in the period from 2006 to 2015; IVB will clearly draw its strategic direction from this document over the next four years. The new direction proposed by GIVS provides a vision of an expanded role for immunization in improving public health, commits all stakeholders to unprecedented efforts to reach the "hard-to-reach", and extends the scope of immunization beyond infancy to other age groups and beyond the existing confines of immunization programmes into other settings, while maintaining the priority of vaccination in early childhood. It encourages the implementation of a package of health interventions to reduce child mortality and contributes to global preparedness against the threat of emerging pandemics, promoting data-driven ways to solve problems for improving programme effectiveness. It prepares the way for the introduction and widespread use of new and underused vaccines and technologies all of which will require long-term financial planning – and promotes the development of case-based surveillance for all vaccine-preventable diseases, with expansion of laboratory networks for viral and bacterial diseases.

Research and vaccine development offer fertile ground for the development of new solutions to overcome the burden of infectious diseases in developing countries. In addition, progress can be achieved through novel approaches to increasing awareness of vaccines and promoting collaboration for vaccine development and deployment. By focusing on innovation, IVB will concentrate on activities that include expansion of research networks, preparation for the introduction of new and underused vaccines, continued provision of evidence-based information to country-level decision-makers and sharing of experiences from lessons learned.

^{*} Global Immunization Vision and Strategy (GIVS), World Health Organization, Geneva (WHO/IVB/05.05), 2005.

With further expansion of coverage – and as technology and innovation continue to be used in global immunization practices – it becomes increasingly important to ensure the safety and regulation of biological products. A primary focus of IVB activities in the next four years centres on the development and implementation of guidelines and standards for production, evaluation, and control of vaccines and other biological products, particularly vaccines that have been newly developed and released. IVB provides leadership in such oversight and guidance, as evidenced by the successful development and global dissemination of regulatory guidelines, five-step capacity-building efforts to strengthen national regulatory authorities (including training through the WHO Global Training Network, the establishment of independent safety review committees, and other capacity-strengthening activities. Along with providing standards of regulatory practice, IVB plans to promote their use among national regulatory authorities and work with countries to expand networks for information exchange and long-term evaluation.

To ensure that traditional and new vaccines reach the populations that need them, IVB's activities will emphasize increased access among the "hard-to-reach" populations – both urban and rural. WHO's "Reach Every District" strategy and the launch of surveillance networks for targeted diseases have laid the foundation for efforts to help countries identify and reach vulnerable populations. To support advocacy for new vaccine introduction, IVB will provide evidence of the value of immunization by maintaining global intelligence on key indicators and disseminating information to guide strategies. In countries that plan to adopt a new vaccine agenda, IVB will collaborate with their governments and other partners to develop mechanisms for monitoring immunization financing and programme sustainability. Increased access will also involve expansion of immunization services to other groups besides infants, including adolescents and adults, and will reach out beyond health facilities to schools and places of employment.

The new departmental structure for IVB will streamline activities and support future plans towards new vaccine development and introduction, as well as the activities that support expansion of immunization practices, such as surveillance, capacity-building, and laboratory enhancement. IVB is now organized into units that are directly responsible for addressing innovation, quality and safety, and improved access. IVB's focus on these core functions will help collaboration among units in the Department, as well as with partners, and will inform and enhance activities on a global level.

In line with organizational policy, several areas of work and components specifically related to country activities and to implementation are to be decentralized. Additional support and responsibilities for these activities will be located in WHO regional and country offices.

Introduction

Mission statement of the Department of Immunization, Vaccines and Biologicals:

A world in which all people at risk are protected against vaccine-preventable diseases.

Context of the Strategic Plan 2006–2009

The Global Immunization Vision and Strategy (GIVS) document¹ outlines in broad strategic terms the direction that WHO and UNICEF believe immunization programmes of the world and their partners should take in the period from 2006 to 2015, and how immunization will contribute to reaching specific Millennium Development Goals. The World Health Assembly in May 2005 and UNICEF Executive Board in June 2005 welcomed this document as a framework for planning and implementing national immunization programmes.

WHO's Department of Immunization, Vaccines and Biologicals (IVB) will draw its strategic direction from this document over the next four years. The broadening of the strategies described in GIVS has encouraged IVB to expand its scope of activities. IVB's strategy now includes supporting countries in their efforts to move beyond delivering immunization against the traditional six Expanded Programme on Immunization (EPI) diseases, and adopts a wider focus than just immunization of infants and women of childbearing age. The new direction proposed by GIVS for the coming decade can be summarized as:

- providing a vision of an expanded role for immunization in improving public health, with broad strategic directions for national policy and programme development, in the context of support to immunization programmes by all partners;
- committing all stakeholders to unprecedented efforts to reach the "hard-to-reach";
- extending the reach of immunization beyond infancy to other age groups and beyond the existing confines of immunization programmes into other settings, while maintaining the priority of vaccination in early childhood;

¹ *GIVS – Global Immunization Vision and Strategy 2006–2015*. World Health Organization, Geneva and UNICEF, New York, 2005 (WHO/IVB/05.05).

- encouraging a package of health interventions to reduce child mortality;
- contributing to global preparedness against the threat of emerging pandemics;
- promoting data-driven ways to solve problems for improving programme effectiveness;
- preparing the way for the introduction and widespread use of new and underused vaccines and technologies, all of which will require long-term financial planning; and
- promoting the development of case-based surveillance for all vaccine-preventable diseases, with expansion of laboratory networks for viral and bacterial diseases.



Figure 1: Defining IVB strategic direction

The overarching results that all levels of WHO (global, regional and country) are committed to achieve over the coming two years are described in the WHO Organization-Wide Expected Results (OWERs)². These are broad statements of outcomes for the entire Organization; they provide the mandate under which IVB and the whole Organization work, and ensure unity of direction throughout the Organization within a results-based budgeting framework.

² *Programme Budget 2006–2007.* World Health Organization, Geneva (WHO/PRP/05.3), 2005.

The Strategic Plan was further informed by the following agreed core competencies of WHO IVB headquarters:

- policy and strategy development;
- knowledge management capturing the knowledge and experience from regions and countries and from basic research to inform further strategy development and refinement;
- standards development and evaluation, especially in the field of vaccine formulation; Good Manufacturing Practices for vaccines and development of global programmatic policies and guidelines;
- collaboration with partners in support of immunization, such as the Global Alliance for Vaccines and Immunizations (GAVI), private foundations, bilateral donors and other agencies;
- technical advice and support for immunization systems, surveillance, programme sustainability and overall disease control; and
- advocacy for the implementation of technically sound interventions.

Finally, the achievements and weaknesses of the previous IVB Strategic Plans (2002–2005 and 1998–2001) provided further input to this document.

Document outline

This document outlines seven IVB Targets which are further developed into 11 outcomes (or Departmental Expected Results) that will be achieved by the work of the WHO Department of Immunization, Vaccines and Biologicals in Geneva between 2006 and 2009.

Three functions are outlined in this Plan.

- The innovation function focusing on research and development of new or improved vaccines and technologies and the investigation of strategies for optimal use of vaccines and technologies.
- The quality and safety function focusing on the development of vaccine norms and standards, national regulatory strengthening, pre-qualification of vaccines and global vaccine-safety issues.
- The **improved access function** focusing on strategies to reach more people with more vaccines by ensuring that immunization systems are strengthened, that surveillance data and information are used to direct the programme and that links are established between immunization and other potentially life-saving interventions to reduce child mortality.

For each of these functions, the Strategic Plan describes IVB's plans by providing the following:

- the IVB Target based on the Organization-Wide Expected Results;
- the Departmental Expected Results for each IVB Target, to be achieved through the activities of the teams within IVB;
- the indicators that will be used to measure the achievement of results, including the current status, targets for the end of 2007, and targets for the end of 2009.

The new departmental structure that will come into effect on 1 January 2006 was created to support the functions described above and is described in the penultimate section of this document. The document concludes with a description of past and future funding, giving details of where the funds have come from, and how they were – and will be – used.

Departmental functions

1. Innovation

1.1 Status

The Department's work in the area of innovation spans from knowledge management, antigen discovery and product development to support the introduction of new vaccines and technologies through implementation research and strengthening vaccine-research capacity in developing countries. Likewise, IVB's vaccine portfolio is broad, covering – among others – the three main poverty-related diseases (HIV/AIDS, tuberculosis and malaria), respiratory and diarrhoeal illnesses, tropical parasitic diseases and meningitis. Within IVB, the Initiative for Vaccine Research (IVR) is responsible for undertaking these activities; further details are provided in a separate IVR Strategic Plan³. The following paragraphs present highlights of recent achievements in the area of innovation.

- In 2002, WHO established the African AIDS Vaccine Programme (AAVP) to promote HIV vaccine research and evaluation through capacity building and regional and international collaboration. The AAVP is currently recognized as the "voice of Africa" on HIV vaccine matters and has gained broad international support. In this context, WHO provided support to countries for the development of their national AIDS vaccine plans or strategies. These define overall national policies and frameworks, as well as plans to develop national infrastructures and capacity, ensuring the appropriate scientific and ethical standards of HIV vaccine-related research and clinical trials.
- The Meningitis Vaccine Project (MVP) is a ten-year partnership between WHO and the Program for Appropriate Technology in Health (PATH), created in June 2001 through core funding from the Bill & Melinda Gates Foundation. The goal of MVP is to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, introduction, and widespread use of conjugate meningococcal vaccines. Three clinical batches of meningococcal A conjugate vaccine were prepared and a Phase I clinical trial was conducted in India. Further, a unique approach has been taken for the development this vaccine: WHO and PATH have secured agreements with a technology provider and a developing country manufacturer in order to ensure the future availability of a conjugate meningococcal A vaccine with a guaranteed price of US\$ 0.40 per dose. If successful, the strategy may be replicated in the future to accelerate the development and introduction of other vaccines that would not otherwise have been produced at an affordable price.

³ *Initiative for Vaccine Research, 2004–2005, Strategic Plan.* Geneva, World Health Organization, 2004 (WHO/IVB/04.13).

- Vaccines have been licensed for two of the major child-killer diseases rotavirus and pneumococcus and vaccine introduction projects, called accelerated development and introduction plans (ADIPs), have been established in many developing countries under GAVI sponsorship. ADIPs focus on assuring that developing countries have access to new vaccines licensed by industrialized country manufacturers. The ADIPs for pneumococcus and rotavirus vaccine are hosted by the Johns Hopkins University and PATH respectively; WHO remains a strategic partner to both institutions. Further, WHO complements the work of the ADIPs by taking a broad perspective on the rotavirus and pneumococcal research agenda, supporting early-stage products, and investigating neonatal and alternative vaccination schedules, among others.
- In the area of product research and development, the Measles Aerosol Project, led by WHO, is engaged in the development of a new aerosol formulation and device for the delivery of measles vaccine; this could increase immunization coverage in developing countries.
- In collaboration with UNICEF/United Nations Development Programme/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, WHO's work on other new vaccines has included sponsorship of a malaria vaccine trial in China in 2004, establishment of a network of laboratories for testing tuberculosis vaccine candidates, and support to the elucidation of immune responses elicited by flavivirus vaccines. Specifications were established for the use of cell cultures for the production of influenza vaccines. This new technological development has the potential to facilitate accelerated scale-up of vaccine production in case of an influenza pandemic. WHO also provided guidance on the use of reverse genetics to derive suitable prototype influenza strains for vaccine production, as well as on potency assays for quality control of diphtheria and tetanus vaccines.
- Advocacy by WHO and partners resulted in accelerated introduction of auto-disable syringes; between the end of 2001 and 2004 the proportion of non-industrialized countries using them increased from 42% to 62%. Work was also done on addressing the issues of needle-stick injuries and safer waste disposal by testing needle-remover devices during mass immunization campaigns in Madagascar and Myanmar. Currently, WHO is working on the development of disposable-cartridge jet injectors for safe needle-free immunization; this holds the potential to eliminate the use of "sharps" in immunization programmes and to facilitate safe waste disposal.
- Finally, and most importantly, WHO has supported developing country capacitystrengthening in the areas of ethics, regulation and Good Clinical Practices.

1.2 First IVB Target: Research for vaccines, technologies and immunization strategies

Support research for the development of vaccines, technologies and immunization strategies against infectious diseases of public health significance.

IVB will focus in 2006–2009 on promoting research and product development, as well as on supporting the transition of successful vaccine candidates through development stages to licensing and introduction. In addition, research will be conducted to provide evidence to support policy decisions for introduction of new and underutilized vaccines into national immunization programmes and to optimize delivery strategies, especially in developing countries.



Research and development of new vaccine antigens requires work under carefully controlled laboratory conditions.

1.2.1 First Departmental Expected Result: Knowledge management of new vaccines and technologies

Management of knowledge and provision of guidance and advocacy through effective partnerships to accelerate innovation for new and improved vaccines and technologies.

With the advent of new and improved vaccines and immunization-supportive technologies, IVB has the mandate to maintain an overview of available information on these interventions. From this collective information reservoir, guidance and advocacy will be provided and decisions informed. Where possible, partnerships will be established to accelerate development and introduction of new vaccines and technologies.

This Expected Result includes, among other activities, facilitating the development of global vaccine research and development (R&D) agendas for priority infectious diseases; collecting and disseminating critical information on vaccine R&D; developing training courses on selected biomedical sciences applied to vaccinology, Good Manufacturing Practices and bioethics; providing advice and guidance to partners and analysing intellectual property rights issues and their impact on the global vaccine pipeline.

This Expected Result will be reached by focusing on two areas:

- management of vaccine and immunization technology knowledge, research and portfolio; and
- analysis of intellectual property rights issues.

Table 1: Indicators of achievements - First Departmental Expected Result

Indicator	Status	Target for	Target for
	2005	end 2007	end 2009
Number of disease-specific research agendas established for four target diseases through broad consultation with developing countries and research partners and endorsed by the IVR Advisory Committee (Target diseases: malaria, flaviviruses, diarrhoeal diseases and tuberculosis)	0 of 4	2 of 4	4 of 4

1.2.2 Second Departmental Expected Result: Support for capacity strengthening

Support to research and product development (R&PD) and the enhanced capacity for the development and evaluation of WHO priority new vaccines and technologies.

The ability to produce vaccines that impact diseases of public health concern relies on discovering antigens and further developing them into effective products that can be introduced broadly into immunization programmes. Priority will be given to developing vaccines that have the greatest impact on public health and to broadening vaccine production to a wide range of vaccine manufacturers.

Activities under this Expected Result include, among others, leading or co-managing vaccine development projects; facilitating global vaccine R&D; supporting the discovery of new antigens; conducting clinical trials; developing clinical, laboratory and ethical standards and procedures; as well as sponsoring specific research capacity-strengthening projects in developing countries.

WHO has been facilitating coordination of international efforts to develop crossprotective influenza vaccines. Indeed, currently available vaccines do not induce good protection when vaccine strains are not well matched with circulating wild viruses, and availability of vaccines that protect against a broad spectrum of influenza viruses and that induce a long-lasting immunity would permit the current yearly vaccination strategy to be revised to a schedule that is more feasible to implement in developing countries. These vaccines should contribute to reducing the burden of epidemic situations and should be important assets in the control of potential influenza pandemics. WHO has further engaged in the promotion of research to investigate strategies (new delivery systems, use of adjuvants) to reduce the quantity of antigen in influenza vaccines in order to increase the global supply of vaccines in case of a pandemic.

This Expected Result will be reached by concentrating on five areas:

- strengthening capacity in developing countries for vaccine production and evaluation;
- support to and optimization of clinical trials;
- development and evaluation of new technologies;
- antigen discovery; and
- product development.

Table 2: Indicators of achievements - Second Departmental Expected Result

Indicator Status Target for Target for 2005 end 2007 end 200				
Number of new vaccines against Japanese encephalitis, meningococcal A or measles that have entered phase II/III clinical trials in developing countries	0 of 3	2 of 3	3 of 3	
Capacity to conduct vaccine clinical trials meeting inter- national standards established in Ethiopia, India, Kenya, Mali, Mexico and the United Republic of Tanzania ^a .				
^a Clinical trial completed or ongoing, with a satisfactory report on Good Clinical Practice from a WHO independent monitor.				

1.2.3 Third Departmental Expected Result: Implementation research

Conduct appropriate implementation research and development of tools to support evidence-based recommendations, policies and strategies for optimal use of vaccines and technologies.

Revisions to a country's national immunization policy have to be driven by evidence that the changes will lead to improved results. Thus, appropriate operational and costeffectiveness research and modelling of data needs to be conducted to inform these policy decisions.

Activities in this Expected Result will include, among others, researching appropriate strategies for vaccine introduction and evaluating improved immunization schedules, regimen and delivery methods. This research will focus on the means of increasing coverage of newly introduced vaccines among the poorest segments of the population. Other activities within this Expected Result include modelling of disease burden and vaccine impact, as well as researching the cost-effectiveness of preventive interventions to allow prioritization of new vaccines in national immunization strategies.

This Expected Result will be reached by focusing on four areas:

- development tools and models to assess disease burden, cost effectiveness and impact of vaccines and delivery strategies;
- design and conduct of vaccine and new technology acceptability studies;
- design and conduct of vaccine and new technology effectiveness trials; and
- development of models to estimate the impact of multiple interventions, including immunization, against infectious diseases.

Table 3: Indicators of achievements - Third Departmental Expected Result

Indicator	Status 2005	Target for end 2007	Target for end 2009
Number of new vaccines (particularly, pneumococcal, meningococcal A, Japanese encephalitis, rotavirus, human papilloma virus [HPV]) for which evidence has been generated on the appropriateness for introduction into immunization programmes	0 of 5	2 of 5	5 of 5
Number of targeted countries where pilot testing of a tool to estimate cost-effectiveness of HIV vaccines has been completed (Target countries: China, Brazil, Kenya, Peru, Thailand)	2 of 5	5 of 5	N/A

2. Quality and safety

2.1 Status

Biological medicines such as blood products, vaccines, cell regulators and related in vitro diagnostic tests are life-saving components of every-day medical practice worldwide. The quality assurance of such essential biopharmaceutical products and devices, however, raises particular safety considerations due to the biological nature of the starting materials used, the manufacturing process involved and the test methods needed to characterize production consistency. The increasing complexity and sophistication of biological products and technologies and the rapid growth in this field present a considerable additional challenge for regulatory authorities as well as manufacturers. The following are highlights of activities that aim to ensure quality and safety.

- WHO has played a key role for over 50 years in establishing the WHO International Biological Reference Preparations and WHO Guidelines and Recommendations on the production and control of biological products and technologies. These norms and standards, based on wide scientific consultation and international consensus, are intended to assist WHO Member States in ensuring the consistent quality and safety of biological medicines and related in vitro biological diagnostic tests.
- WHO's Expert Committee on Biological Standardization (ECBS) adopted new guidelines on regulatory expectations for the elimination, reduction or replacement of thiomersal from licensed vaccines and also revised or adjusted recommendations related to smallpox vaccines, inactivated poliovirus vaccine, and meningo-coccal C conjugate vaccines. Guidelines on dengue vaccines were also developed.
- Efforts to strengthen national regulatory authorities (NRAs) have continued, with a total of 55 assessments completed at the end of 2004. The WHO NRA assessment tool was revised in June 2004 by a group of international regulatory experts from Belgium, Canada, China, France, India, Indonesia, Russia, United Kingdom and the United States of America. During this process, a set of indicators was identified as critical for the purpose of the WHO vaccine prequalification scheme. In practice, this means that vaccines will only be eligible for a review under the prequalification scheme provided they are produced in a country where the NRA complies with these critical indicators.
- Substantial capacity-building efforts have been made through the Global Training Network on Vaccine Quality, whereby staff of NRAs, national control laboratories, public-sector manufacturers and national immunization programmes are given access to training opportunities in the field of vaccine regulation, surveillance of adverse events and vaccine quality. This effort has been critical in enhancing regulatory capacity for the oversight of production and control of vaccines and in the monitoring of adverse events following immunization (AEFIs).
- New regulatory pathways are being explored for clinical evaluation of new vaccines and delivery technologies in developing countries. To this end, the Developing Country Vaccine Regulators Network was established in September 2004. In addition, in collaboration with the European Medicines Agency, a regulatory mechanism to facilitate the licensing of vaccines that are

produced for markets outside the country of manufacture was elaborated (Article 58)⁴.

- In 2004 and 2005, following guidance provided by the Ad Hoc Advisory Committee on Poliomyelitis Eradication, WHO coordinated support to accelerate the process of regulatory approval of monovalent types 1 and 3 oral polio vaccine (mOPV). In early 2005 mOPV1 was made available for use in critical polioendemic countries to stop transmission of the type 1 wild polio strain and to prevent outbreaks in non-endemic areas. In September 2005 mOPV3 was licensed and will be introduced by end 2005 in areas where type 3 wild polio virus is of concern.
- Global dissemination of information on vaccine safety has been improved, in part through the Vaccine Safety Net sharing its information via the Internet and other channels. IVB's work on AEFIs continues to be emphasized, and training on adverse events monitoring and response was offered for the first time in Russia in 2004.
- The WHO vaccine prequalification procedure has been streamlined to address the challenges of exploding demand for new vaccines such as the new DTP– HepB–Hib combination vaccines and the advent of novel vaccines. According to the new procedure, WHO commits to a 12-month timeframe for the review of applications, a decrease of six months on average; this period could be further shortened in case of emergency.
- Significant gains have been made in global immunization safety during the last years. Factors contributing to improved immunization safety have included the realization by countries of the importance of injection safety, the increase in the number of manufacturers producing devices meeting WHO specifications and the support provided by the GAVI Vaccine Fund. In 2004, 68% of countries reported the existence of a national system for AEFI surveillance, compared with 53% in 2001. While these data are encouraging, it is evident from direct interactions between WHO, national regulatory authorities and national immunization programmes that there are still many challenges to meet in ensuring that all countries have a functional adverse events surveillance system.
- The Steering Committee on Immunization Safety has continued to review progress in ensuring global immunization safety. At its sixth meeting, held in September 2005, the Committee commended the progress made in recent years, and emphasized that, to maintain and increase the gains achieved, WHO must continue to pay attention to related activities. It recognized the importance of political commitment by national governments to ensure safety but encouraged WHO and partners to maximize funding and advocacy opportunities afforded by the World Alliance for Patient Safety, the G8 communiqué on HIV prevention, care and treatment services, and the implementation of the GIVS.
- The Global Advisory Committee on Vaccine Safety (GACVS) has continued to meet twice a year. Issues considered by the Committee during its existence have been the purported relationship between hepatitis B vaccine and multiple sclerosis, and the measles-mumps-rubella (MMR) vaccine and autism,

⁴ The European Medicines Agency, 23 May 2005. Committee for Medicinal Products for Medicinal Human Use (CHMP). Guideline on procedural aspects regarding a CHMP scientific opinion in the context of cooperation with the World Health Organization (WHO) for the evaluation of medicinal products intended exclusively for markets outside the Community. EMEA/CHMP/ 5579/04, www.emea.eu.int.

and the safety of thiomersal-containing vaccines. During the last few years, it has become clear that in the future it will be important for the Committee to systematically review safety issues potentially associated with vaccines recently introduced or under development. The Committee's conclusions and recommendations are published in the WHO *Weekly Epidemiological Record⁵* and posted on the GACVS web site⁶. The web site is published in the six official United Nations languages (Arabic, Chinese, English, French, Russian, and Spanish).

• GACVS-related material is a cornerstone of the Vaccine Safety Net project, which aims to improve global dissemination – via the Internet – of information on vaccine safety that adheres to good information practices. Since the August 2004 launch of the Vaccine Safety Net, over 20 organizations providing information on vaccine safety have joined the network. Member sites cater for audiences speaking Dutch, English, French, German, Italian and Spanish. Organizations represented include international medical organizations, national and regional governments, professional medical associations and WHO-associated bodies⁷.

2.2 Second IVB Target: Standards for vaccine production and regulation

Develop norms and standards for the production, control and regulation of vaccines and other biologicals, and establish a reference standard.

2.2.1 Fourth Departmental Expected Result: International norms and standards for biologicals

Development of international norms, standards and guidelines for production, control and evaluation of biologicals, including vaccines.

WHO International Standards (Biological Reference Preparations with defined biological activity) serve as the basis for comparison of biological measurements worldwide. WHO biological reference materials are evaluated through international collaborative studies, the outcomes of which are considered by the ECBS and, if acceptable, established. They are held and distributed by the WHO Laboratories for Biological Standards. Their timely availability is essential to ensuring the quality of biological products, as well as the consistency of production.

During 2006–2009, WHO norms and standards for production, control and regulation of vaccines will continually be developed and established.

Priority will be given to development of standards to facilitate evaluation of new vaccines and novel combinations, as well as the revision and replacement of standards already in place for licensed vaccines.

In addition, the development of appropriate strategies to promote the use of WHO standards, monitor their implementation and facilitate access to WHO

⁵ Recommendations from the most recent meeting were published in the WHO Weekly Epidemiological *Record*, 28, 15 July 2005, 242–247.

⁶ See http://www.who.int/vaccine_safety/en

⁷ For more information see http://www.who.int/immunization_safety/safety_quality/ vaccine_safety_websites/en/



collaborating centres with expertise in biological standardization has been recognized as a priority in the coming biennium.

This Expected Result will be reached by focusing on four areas:

- development or revision of norms, standards, reference preparations and guidelines for quality and safety of vaccines, biologicals, devices and immunizations;
- coordination of global normative activities;
- validation of WHO international norms and standards through the ECBS; and
- monitoring of implementation of international norms, standards and safety-related guidelines.

Indicator	Status 2005	Target for end 2007	Target for end 2009
Number of new or revised standards and reference materials established by the WHO Expert Committee for Biological Standardization	0	15	30
Number of new guidelines established, or globally coordinated research under way, that contribute to improved safety of biological medicines	0	5	8
Number of global strategies developed to promote and monitor implementation of norms and standards and facilitate access to WHO collaborating centres	0	3	6

Table 4: Indicators of achievements - Fourth Departmental Expected Result

2.2.2 Fifth Departmental Expected Result: Good regulatory practices

Promotion of good regulatory practices for national regulatory authorities.

The World Health Assembly has repeatedly called upon countries to ensure that the vaccines used in immunization programmes are of assured quality; it has also requested the WHO Secretariat to assist Member States in their efforts.

It is therefore critical that countries' capacities be strengthened to exercise an independent and competent oversight of the quality of vaccines used nationally, irrespective of their source or whether they are traditional, new or pandemic control (such as influenza) vaccines.

In addition, countries would also strengthen their abilities to assess the performance, quality and safety of the equipment used in national programmes – from injection devices to cold-chain equipment. Increasingly, a country's NRA should be capable of providing an oversight of medical equipment similar to their oversight of pharmaceuticals and biological products.

Support is urgently needed for some risk-prone countries which are developing influenza vaccines or establishing influenza vaccine-manufacturing capacities. WHO will therefore coordinate the provision of international expert advice to support regulatory activities in developing countries that plan to increase influenza vaccine production capacity. To facilitate the release of vaccine lots worldwide, international reference reagents, supplied through WHO, are needed to calibrate regional, national and manufacturing standards. An international consensus in terms of standards for product characterization, preclinical safety and clinical evaluation is essential and will be obtained in the forum of regulators, vaccine developers and manufacturers. Development of harmonized procedures for vaccine registration and batch release is of critical importance for international access and will be facilitated by WHO. A need for monitoring safety aspects of vaccine use has been identified as an area which requires WHO coordinated activities across countries.

IVB's efforts to strengthen NRAs will continue to focus on the three following groups of countries:

- countries that produce vaccine;
- countries that procure their vaccines directly; and
- countries from the above groups and/or from countries with UN agencysourced vaccines that are likely to host clinical trials for new vaccines

In the area of new vaccines, efforts will aim to establish regional networks to facilitate the exchange of information and expertise and to gradually explore the possibilities of joint reviews of dossiers and mutual recognition of regulatory decisions.

An increasing number of new vaccines will be licensed through novel regulatory pathways and will be marketed in developing countries without being first introduced in industrialized countries. It is therefore critical that systems be in place to monitor the long-term performance and safety of these vaccines. A network of developing countries with strong surveillance systems to record AEFIs will be established for the purpose of systematically collecting post-marketing surveillance data. This Expected Result will be reached by achieving four outcomes:

- promotion of effective regulation systems for vaccines;
- development and promotion of new regulatory pathways for priority vaccines;
- strengthened global capacity for the monitoring and management of AEFIs; and
- establishment of systems for the regulatory oversight of immunization-related equipment.

Table 5: Indicators of achievements - Fifth Departmental Expected Result

Indicator	Status 2005	Target for end 2007	Target for end 2009
Percentage of countries producing vaccines where NRAs meet the WHO NRA performance indicators	62% (30 of 48)	80%	100%
Number of new vaccines for which a regulatory mechanism exists for review during clinical development and/or registration	0	2	5
Establishment of a network of sentinel countries with a monitoring system for AEFIs and post-marketing surveillance of new vaccines	0 countries in the network	5 countries in the network	10 countries in the network
Development and implementation of a tool to assess NRAs' oversight of immunization equipment	No tool	Tool developed and 5 countries assessed	15 countries assessed

2.3 Third IVB Target: Vaccines of assured quality and safe immunization practices

Strengthen countries' capacities to use vaccines of assured quality and to implement safe immunization practices.

2.3.1 Sixth Departmental Expected Result: Coordinated response to safety and quality issues

Respond to vaccine safety and quality issues of global importance in a coordinated and rapid manner.

Global awareness of vaccine benefits and safety issues has never been higher, and vaccine-related safety issues – or perceived safety issues – are reported even in the lay press. This increased awareness of vaccines is of great benefit to immunization programmes, enabling health workers and parents to make informed d ecisions about preventive measures available to them. Activities aimed at vaccine safety are therefore of the greatest importance in ensuring that the trust placed in the vaccine is not jeopardized by adverse events.

Potential safety issues must be identified and corrected early. Yet, the global capacity to identify and properly manage such safety issues is still limited and needs further strengthening. There is a definite need for global coordination of investigations into vaccine safety issues of potential global importance, particularly – but not only – when involving prequalified vaccines.

The Global Advisory Committee on Vaccine Safety (GACVS) was established in 1999 to respond promptly, independently, efficiently and with scientific rigour to vaccine safety issues of major global importance. Over the last few years, it has become clear that it will be important for the Committee to also systematically and proactively review safety issues that could emerge or potentially be associated with vaccines recently introduced or under development.

IVB will provide support to – or be directly involved in – the epidemiological and laboratory investigation of potential vaccine-safety issues. The GACVS will continue to call for the establishment of ad hoc task forces and the implementation of necessary research where needed. The Committee's conclusions will continue to influence immunization policy setting.

Due, in part, to the limited regulatory capacities in many of the countries where new vaccines will be introduced, it is critical that WHO takes responsibility for ensuring thorough and independent analysis of the real and theoretical safety risks involved. As such, the GACVS will advocate for studies to address such issues.

The Committee will also support improved global monitoring and analysis of vaccine-related adverse events through the work of the international drug monitoring programme. A sub-group of GACVS will be established to help improve detection and response to AEFIs.

IVB will carry out activities and participate in global initiatives that will strengthen capacity to identify and address vaccine safety issues of global importance. These activities include the development of reference and guidance documents, the development of standard case definitions⁸ and the establishment of the vaccine working group of the Council for International Organizations of Medical Sciences.

This result will be reached by achieving two outcomes:

- assessment of vaccine safety issues of potential global importance; and
- advocacy and communication on safety issues.

Table 6: Indicators of achievements - Sixth Departmental Expected Result

Indicator	Status	Target for	Target for
	2005	end 2007	end 2009
A plan of action (including investigation, position/ statement, ongoing research) to be produced within one month of identification of all vaccine safety issues of global importance	Yes	Yes	Yes

⁸ Assisted by the work of the Brighton Collaboration.

2.3.2 Seventh Departmental Expected Result: Prequalification of vaccines and equipment

Provide the function of pre-qualification of vaccines and equipment for use by countries and UN agencies.

Countries that do not have a functional NRA rely, to a great extent, on the supply of vaccines and immunization equipment by United Nations procurement agencies such as UNICEF and the Pan-American Health Organization (PAHO) Revolving Fund. These agencies only procure vaccines and equipment that has been thoroughly assessed by the WHO prequalification scheme and, in principle, deemed acceptable. The scheme is well recognized for vaccines. In the case of equipment, the performance, quality and safety prequalification scheme is being established.

Activities in this area will focus on the timely review of prequalification dossiers submitted by vaccine manufacturers. A priority list will be prepared each year in collaboration with the main vaccine procurement agencies (UNICEF and the PAHO Revolving Fund), as well as with WHO regional offices, to ensure that priority is given to the most needed vaccines.

The revised procedure for the prequalification of vaccines states that WHO shall complete the review process within 12 months. This time measurement does not include delays due to missing data⁹ (an average of 18 new dossiers are reviewed each biennium).

In the case of immunization equipment, the prequalification process is already in place for injection devices (during 2005, all 52 acceptable dossiers were reviewed), and the process is in the final stages for review of other immunization equipment (cold boxes and vaccines carriers, refrigerators). For each category of equipment, the procedure will stipulate a timeframe for the review of the dossier – once it is accepted¹⁰ – that WHO will commit to comply with.

Indicator Status Target for Target for end 2007 end 2009					
Number of eligible vaccine applications for prequalification initiated in the two-year period	N/A	10 new 8 routine	10 new 8 routine		
Proportion of vaccine applications for prequalification for which reviews are completed within 12 months of submission 0% 100%					
Proportion of eligible equipment applications for prequalification for which reviews are completed within the time set for the category of equipment concerned52 of 52° applications reviewed in time60%80%					
^a Since the workload will substantially increase with the expansion of the prequalification scheme to other categories of immunization equipment, it will not be possible to achieve 100% compliance immediately. Targets of 60% and					

	Table 7: Indic	ators of achievement	ts – Seventh Depa	rtmental Expected Result
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⁹ The acceptability of vaccine dossiers is defined in the published vaccine prequalification procedure.
¹⁰ The acceptability of equipment dossiers is defined in the published prequalification procedure related to each category of device or equipment.

80% have therefore been set.

3. Improved access

3.1 Status

Globally, in 2004, 78% of children under one year of age were immunized by their first birthday (measured by coverage with three doses of diphtheria-tetanus-pertussis vaccine). More than 2 million deaths from vaccine-preventable diseases and 600 000 hepatitis B-related deaths from liver cirrhosis and hepatoma that may otherwise have occurred in adulthood were prevented. With support from governments and their partners, including GAVI, several countries have improved access to immunization services by implementing strategies such as WHO's "Reach Every District" (RED) strategy in Africa. Similarly, successful Immunization Weeks have been held in the Region of the Americas, a strategy recently replicated in European Region. Highlights of efforts to improve access are described below.



• By the end of 2003, polio elimination had been achieved globally, with the exception of six countries – Nigeria, India, Pakistan, Niger, Afghanistan and Egypt – of which the first three accounted for more than 90% of all polio cases. The Global Polio Eradication Initiative worked hard to contain a major polio outbreak in northern Nigeria; it continues to focus its efforts in polio-endemic countries and to address new cases of polio that emerge (in 2005 in Indonesia and elsewhere). Certification of the European Region as polio-free in 2002 was an important achievement, as it was the third region to be certified polio-free after the Region of the Americas and the Western Pacific Region. In order to prepare for the ultimate cessation of oral polio immunization, WHO developed strategies and guidelines for poliovirus containment, sustainability of acute flaccid paralysis surveillance and vaccine stockpiling.

- The number of measles deaths fell an average of 10% globally per year during the past four years, and between 2000 and 2003 the following regional reductions in measles deaths were recorded:
 - African Region: 33%;
 - Region of the Americas: endemic transmission of measles eliminated;
 - South-East Asia Region: 18%;
 - European Region: 0% (measles mortality already at a very low level);
 - Eastern Mediterranean Region: 34%;
 - Western Pacific Region: 31%.
- Countries in the Region of the Americas, the the European, Eastern Mediterranean and Western Pacific Regions established regional measles elimination goals. In the African Region, WHO has worked with UNICEF and the Measles Initiative to synchronize measles-mortality reduction activities and has encouraged activities to reach measles-mortality reduction targets in Africa and South-East Asia. A special intervention was implemented for measles control in Aceh, Indonesia, following the tsunami in 2004.
- The Ministers of Health in the Region of the Americas and the European Region voted to eliminate rubella and congenital rubella syndrome by 2010. The English-speaking Caribbean countries have not reported a case since 2000.
- Progress continued to be made toward elimination of maternal and neonatal tetanus achieved to date by 140 out of 192 (73%) countries.
- In terms of new vaccine introductions, the Western Pacific Region became the first WHO region to introduce hepatitis B vaccine into all its countries. *Haemophilus influenzae* type b (Hib) disease was given special prominence, and new global recommendations were developed for its control.
- GAVI promoted a new immunization financing database, established in 2004 for 22 countries, to show estimates of immunization programme costs and current and future financing gaps. Another 20 countries will be added to the database by the end of 2005. This is a major step forward for countries and partners as it provides comparative data to enable more informed decisions to be taken on the cost of immunization for managing long-term financial sustainability.
- New surveillance networks for bacterial meningitis and diarrhoeal diseases have been launched in the African and South-East Asia Regions to gather information for future introduction of new vaccines. Through various partnerships, rotavirus surveillance networks are now firmly established in Asia and in the Americas; surveillance of yellow fever in African countries was improved in 2002–2003.
- Through the WHO/UNICEF Joint Reporting Form (JRF), countries report annually on a series of selected indicators in their vaccination programmes. Over the past 4 years, the number of countries reporting has increased, with 191 of 192 WHO Member States reporting data for 2004. Data gained from the JRF have become the standard by which programme performance is measured, not only by WHO and UNICEF, but also by other immunization partners.

• WHO continued to produce quality policies, guidelines and other documentation for policy-makers, health-care workers and the media. Recent publications include WHO policy on health-care waste management¹¹ and global criteria for vaccine store management¹². Training materials were developed and revised, including simple, practical materials for health workers (*Immunization in Practice series*) and mid-level managers (global MLM modules). Other new documents are regularly posted on the WHO web site, and in 2004 seven new documents were developed for the media. In addition, WHO regional offices also published materials to respond to the specific needs of their respective regions.

3.2 Fourth IVB Target: Secure vaccine supply and financial sustainability

Strengthen countries' capacities to secure vaccine supplies and increase the financial sustainability of their immunization programmes.

3.2.1 Eighth Departmental Expected Result: Vaccine security

Provide advice and technical support to ensure vaccine security.

Sustainability – both in terms of vaccine supply and vaccine financing – is pivotal to successful country immunization programmes. IVB endeavours to support countries by allowing informed decision-making in terms of supply and financing. This is particularly important for countries embarking on co-financing vaccines through GAVI.

To assure countries a secure supply of quality vaccines at affordable prices, IVB will engage in an ongoing dialogue with vaccine manufacturers as well as with procurement agencies, such as the UNICEF Supply Division and the PAHO Revolving Fund. Activities to achieve this result will include regular updates of the global vaccine production and supply capacities and a thorough forecast of vaccine demand to ensure that high quality vaccines are available at the right time and place. IVB will work with countries and partners to develop innovative immunization financing mechanisms, support countries to cost and finance their immunization multi-year plans, better align immunization cost and financing information with national planning and budgeting processes, and support advocacy efforts for governments and partners to progressively increase vaccine budgets.

On a global level, IVB will be a core partner in the immunization world and combine forces with other immunization partners to reach the common goals, as described in GIVS - Global Immunization Vision and Strategy¹³. Through the WHO regional and country offices, technical and policy support will be offered with full engagement of the relevant partners at international and national levels.

¹¹ Safe health-care waste management, policy paper. Geneva, World Health Organization, 2004. Available on the Internet at: http://www.healthcarewaste.org/en/160_policy.html

¹² Ten global criteria for vaccine store management. Geneva, World Health Organization, 2004 (WHO/IVB/04.17).

¹³ GIVS – Global Immunization Vision and Strategy 2006–2015. World Health Organization, Geneva and UNICEF, New York, 2005 (WHO/IVB/05.05).

This result will be reached by achieving the following four outcomes:

- consistent affordable supply of all EPI vaccines with assured quality, in line with global demand;
- effective vaccine procurement, logistics and management systems;
- decreased barriers to sustainable financing of national immunization programmes; and
- effective partnerships for coordination of technical advice and advocacy for vaccine supply and immunization programme financing.

Table 8: Indicators of achievements - Eighth Departmental Expected Result

Indicator Status Target for Target for end 2005 end 2007 end 2009					
Number of priority countries complying with WHO/UNICEF vaccine store management standards.	2	10	20		
Number of GAVI bridge-financing countries ^a that have transitioned to vaccine co-financing mechanisms 4 11 16					
^a Eleven countries included in the GAVI bridge-financing mechanism for HepB and Hib combination vaccine by 2007.					

3.3 Fifth IVB Target: Capacity to monitor immunization systems and assess disease burden

Strengthen countries' capacities to monitor immunization systems and assess vaccine-preventable disease burden.

3.3.1 Ninth Departmental Expected Result: Evidence and data to guide policy

Evidence gathered and analysed to guide policies and strategies and to communicate the value of immunization.

Effective monitoring of the number of immunizations administered and occurrence of diseases (surveillance) is a cornerstone of national immunization programmes and provides substance to global policy-making. In the key disease initiatives – polio eradication and measles-mortality reduction – as well as in the constant monitoring of the routine immunization programmes, disease surveillance and monitoring data are instrumental in guiding programmatic work, both for immunization campaigns and for accelerating routine immunization services and outreach. These data also target priority environments that remain underserved.

Through WHO regional and country offices, IVB develops standards and guidelines to assist programmes measure their performance and impact. This information is used to identify programme failings and take action toward improving operations.

Programme monitoring and disease surveillance data are gathered at the service-delivery level and are used for action at all levels. Data submitted for global analysis and redissemination will enable effective management of common issues such as vaccine supply, prequalification of quality vaccine manufacturers and disease tracking.

Data gathered to demonstrate reductions in death and disease due to immunizations will form the basis of public advocacy on the value of immunization.

This result will be reached by focusing on the following four activity areas:

- analysis and dissemination of evidence and information to guide global policies and strategies;
- regional strengthening of surveillance, monitoring systems and laboratory capacity;
- establishment of global databases with up-to-date information on vaccine supply, production capacity and immunization costing and financing; and
- communication and global advocacy.

Table 9: Indicators of achievements - Ninth Departmental Expected Result

Indicator	Status 2005	Target for end 2007	Target for end 2009
Proportion of countries providing timely (by 15 May of the following year) and complete information to WHO HQ through the WHO/UNICEF Joint Reporting Format	43% (83 of 192 countries)	50%	75%
A global web-based reporting system that allows countries to input and update key data on a continual basis	No system	System piloted	System functional
Proportion of countries with access to proficient laboratories for, at least, measles confirmation	77% (148 of 192 countries)	85%	100%

3.4 Sixth IVB Target: Access to vaccines and increased disease control efforts

Strengthen countries' capacities to maximize access to current, new and underutilized vaccines and accelerate disease control efforts.

3.4.1 Tenth Departmental Expected Result: Maximize immunization impact

Provide advice and adequate technical support to maximize the impact of immunization and other linked interventions.

Reaching each child with vaccines is at the centre of all vaccination activities. Policies, strategies and guidelines that increase this reach and go beyond traditional age and target groups are therefore crucial in the overall mission of IVB.

Figure 2 (below) illustrates the challenges facing the immunization community. At present there are five diseases that have high levels of mortality and vaccines exist for them but are underutilized – namely influenza, typhoid, and infections caused by Hib, pneumococcal bacteria and rotavirus. Figure 2 also shows that, within two to three years, during the timeframe described in this Strategic Plan, two more vaccines against diseases causing high mortality will become available – HPV vaccine and pneumococccal vaccine. Finally, after 2009, the end date for this Plan, it is probable that at least one malaria vaccine will also become available; preparations for its introduction should begin soon.¹⁴

¹⁴ Adapted from *The evolving vaccine pipeline; possible implications for GAVI investments*-a presentation made at the 15th GAVI Board Meeting, 28–29 April 2005.

Figure 2: Vaccine horizon



The focus on district-level support to immunization programmes has been the central thrust of recent immunization strengthening policies. In collaboration with countries, IVB will develop these strategies, identify and remedy the weaknesses and formulate global policies based on these experiences. A pivotal component will be to devise strategies and activities for reaching hard-to-reach children.

The work in strengthening immunization systems will enable countries to achieve a minimum of four immunization contacts with all infants, especially among hard-toreach populations (geographically, socially or culturally). Infants will be reached using a district-based approach that provides immunization through fixed sites, outreach services, mobile teams, supplementary immunization and the private sector. Appropriate strategies will be devised and introduced to rapidly reduce disease burden and to prevent and respond to epidemics and outbreaks in at-risk populations.

Links to other programmes and interventions will seek to gain efficiency in joint programme planning and execution, and will harmonize preventive child survival interventions. IVB will explore, plan and implement appropriate links between immunization and other interventions, tailored to the local context. It will aim to reach high coverage for immunization and other child survival activities, as well as establish joint programme management systems to ensure sustainable links.

Support will be provided to expand immunization services beyond infancy to other age groups to maximize the impact of existing vaccines. IVB will develop guidelines and provide support to countries that are ready to expand their immunization programmes beyond the infant target-age group to older children, adolescents and adults. This will include new approaches to go beyond health facilities to reach populations, such as at schools or the workplace. With several new vaccines¹⁵ close to full production, programmatic and safety considerations will be developed and distributed to countries ready to introduce them. Vaccine management practices, including logistics, will be strengthened to ensure the availability of safe and effective vaccines at all times.

IVB will provide support to countries through the WHO regional and country offices to make evidence-based decisions on the introduction of new vaccines – programmatically, financially and in terms of disease burden.

Similarly, IVB will develop the norms and standards for an effective surveillance system, including laboratory support to surveillance to monitor the effectiveness of a new vaccine and to diagnose possible programmatic failures. These surveillance components are an opportunity to integrate into, and strengthen, existing surveillance systems.

National immunization programmes will have an extensive infrastructure that is capable of delivering new vaccines, including those that will be used to respond to a global influenza pandemic. Technical support will be given to develop tools (checklists, decision guides, operational guides) for national immunization programmes to prepare for vaccination response to pandemic influenza. IVB will also provide support to regions and countries in developing activities to strengthen their ability to deliver vaccines and antivirals to combat the threat of pandemic influenza. Global disease surveillance networks for vaccine-preventable diseases will be strengthened to address new and emerging threats such as pandemic influenza. In addition the laboratory networks used to support surveillance of vaccine-preventable diseases will be used to support to the global influenza laboratory network as needed.

This result will be reached by achieving the following outcomes:

- strategies developed and technical assistance provided to regions and countries to increase immunization coverage at district level;
- support provided to extend immunization programmes to other age groups; and
- epidemiological and programme information available for informed decision-making on introduction of new vaccines.

¹⁵ In this document the term "new vaccines" refers to vaccines against rotavirus, Japanese encephalitis virus, meningococcal A virus, human papilloma virus and pneumococcal bacteria.

Table 10: Indicators of achievements - Tenth Departmental Expected Result

Indicator	Status 2005	Target for end 2007	Target for end 2009
Number of countries that have developed a financial sustainability plan or a fully costed and comprehensive multi-year plan	5	25	45
Number of countries that achieved >90% first dose measles coverage	97 of 192	125 of 192	144 of 192
Number of countries that have implemented a second opportunity for measles immunization within the preceding five years	168 of 192	182 of 192	192 of 192
Number of vaccines for which a global recommendation has been developed for immunization beyond infancy	0	2	4
Number of countries that have introduced HepB vaccine in infant immunization schedules ^a	153 of 192	185 of 192	192 of 192
Number of countries that have introduced Hib vaccine	92 of 192	105 of 192	125 of 192
Number of interventions integrated with EPI for which guidelines are available for common programme management (e.g., malaria, Integrated Management of Childhood Illness, nutrition, and intestinal helminth programmes)	1	3	5
Proportion of countries using only auto-disable syringes for immunizations	33% (63 of 192)	40%	65%
Proportion of countries using open burning as a method of immunization waste disposal ^b	43% (83 of 192)	25%	10%

^a Five countries have introduced HepB vaccination in adolescence.

^b Work on medical waste management is carried out within the WHO Department for the Protection of the Human Environment but IVB will continue to collaborate to ensure that waste from immunization programmes is disposed of safely and in a way that is consistent with policies for all medical waste disposal.

3.5 Seventh IVB Target: Polio activities within mainstream health delivery systems

Integrate efforts to interrupt circulation of poliovirus, certify eradication, develop products for the cessation of oral polio vaccine and integrate these activities into mainstream health delivery systems.

Note: The Polio Eradication Initiative¹⁶ is managed from the Director-General's Office of WHO; however, some aspects of the final phase of global eradication will continue to be achieved in collaboration with EPI+.

3.5.1 Eleventh Departmental Expected Result: Integrated polio activities

Polio activities integrated into each country's routine immunization services, upon reaching zero polio cases.

Given that it is expected that polio transmission will be interrupted globally by 2006, the strategic approach to be taken by IVB between 2006 and 2009 will be to ensure that countries continue to take advantage of the components of the immunization system that polio eradication has strengthened. The greatest contributions have been made to supplementary immunization campaigns, active surveillance with laboratory investigation of cases, and heightened partnership coordination at global and national levels. In order to build upon these contributions, IVB will document best practices and develop guidelines for activities to integrate the systems of surveillance, logistics, management information and human resources into national immunization programmes.

The final phase of this Expected Result will be accomplished in collaboration with the WHO Director-General's office by achieving the following outcomes:

- integrated surveillance;
- integrated logistics;
- integrated management information systems; and
- integrated human resources

Table 11: Indicators of achievements - Eleventh Departmental Expected Result

Indicator	Status 2005	Target for end 2007	Target for end 2009	
Guidelines available for four common programme management issues ^a of the final stages of polio eradication with routine immunization programmes	0	4	(Polio eradicated)	
^a Integrated surveillance, integrated logistics, integrated management information systems and integrated human resources.				

[&]quot;Enhanced routine immunization coverage against polio. The fourth priority will be to support the work of WHO and UNICEF, especially within GAVI, to improve routine immunization coverage. In polio-free areas enhanced routine immunization coverage will be central to limiting the spread of importations ... Polio funded staff will continue to work on routine immunization strengthening, giving particular emphasis to transferring polio lessons and experiences to the efforts to 'Reach Every District' (RED) in the areas of highest risk of importations. Special attention will be given to microplanning, logistics, social mobilization, and monitoring and evaluation in areas with low OPV3 coverage." – *The Global Polio Eradication Initiative Strategic Plan 2004–2008*, Geneva, World Health Organization, page 13.

4. Enabling functions

Office-specific Expected Result: The IVB Department managed and coordinated efficiently and effectively

This final section, on Departmental functions, describes three further activities that will be carried out that support the work of the whole Department of Immunization, Vaccines and Biologicals.

4.1 Communications for immunization

Global immunization coverage reached a plateau starting in the early 1990s. In 2004, 27 million children were not immunized with DTP3. Approximately 2 million annual deaths occur in all age groups as a result of diseases *preventable* by vaccines currently recommended by the World Health Organization. Global advocacy and communication will focus on conveying the message that immunization is a safe, highly beneficial and cost-effective preventive health measure. Communications objectives will be achieved through the following activities:

- enhanced advocacy to ensure continued progress and investments toward expanded use of life-saving vaccines, both currently used and underutilized; and
- dissemination of information about vaccine research and development, access to immunization, and quality and safety of vaccines and immunization.

Three audiences will be targeted:

- high-level political forums such as the G-8, European Union, Organization of African Unity and others;
- multilateral and bilateral international aid donors; and
- national political leaders and their governments, as well as civil society and, as needed, the general public.

The IVB Communications, Advocacy and Media team will work in conjunction with WHO regional offices and appropriate partners to publicize the GIVS, to provide information on progress achieved towards GIVS immunization goals and to draw attention to shortcomings. IVB will continue to disseminate media materials using departmental and WHO web sites, publications such as the *Weekly Epidemiological Record* (WER) and *WHO Bulletin*, and other channels.

Indicator	Status 2005	Target for end 2007	Target for end 2009
Number of media and advocacy events executed and number of information products developed	20	40	80
Frequency of updating and improving IVB web site	As information is submitted	Once a week minimum	Once a week minimum

4.2 Resource mobilization

The Department has received and continues to receive important contributions from 41 donors. These include the Global Alliance for Vaccines and Immunization, the Canadian International Development Agency, the United States of America through USAID and the Centers for Disease Control and Prevention, the Bill & Melinda Gates Foundation, the United Kingdom's Department for International Development, Australian Overseas Aid Program and the Governments of the Netherlands, Norway and Sweden. However, there is still a need to accelerate resource mobilization efforts to ensure achievement of Departmental and global immunization goals. Such grants require ongoing tracking and management, including the donor-required reporting on status and progress.

Improved coordination, joint planning and alignment of resource mobilization activities between the various Departmental technical units at HQ, in collaboration with our Regional Offices and immunization partners, should result in the department mobilizing required resources to meet its programme goals and objectives.

Indicator	Current	Target for	Target for
	status	end 2007	end 2009
Joint fundraising plan across IVD offices developed, IVB budgets met and regional offices supported to meet their budgets	None	Available	Updated

Table 13: Indicators of resources mobilized and grants managed

4.3 Policy setting and strategy maintained

IVB is further responsible for managing the Strategic Advisory Group of Experts (SAGE) that serves as the principal advisory group to the World Health Organization for vaccines and immunization. The SAGE is charged with advising the WHO Director-General on global policies and strategies, ranging from vaccine and technology research and development to delivery of immunization and its links with other health interventions. The SAGE will not be restricted to childhood vaccines and immunization, but it will incorporate expanded terms of reference to cover all vaccine-preventable diseases.

Technical output from various ad hoc WHO technical advisory groups and the standing WHO advisory groups such as the Expert Committee on Biological Standardization (ECBS) and the Global Advisory Committee on Vaccine Safety (GACVS) will inform SAGE's overall policy development. The SAGE will closely liaise with immunization-related regional technical advisory groups and other relevant advisory groups.

The oversight and strengthening of the process by which vaccine-specific position papers and the general WHO position on vaccines are elaborated will continue and the dissemination and easy access to the WHO policies through the work of its Documentation Centre will be ensured.

Indicator	Status	Target for	Target for
	2005	end 2007	end 2009
Number of new vaccine position papers and updates published in the Weekly Epidemiological Record each year	2–3	4	4

Table 14: Indicators of sound scientific policy and maintenance of strategy

Departmental structure

Form follows function. – Louis Henri Sullivan

The Department of Immunization, Vaccines and Biologicals was restructured in line with the decentralization policy of the WHO during 2005 in a process of consultation with the WHO Director-General's Office, regional offices, and the Departmental staff. This re-structuring reflects IVB's three fundamental functions: innovation, quality and safety, and access.





Each of the three new components (one unit, two teams) has clear functions, with a clearly defined working relationship between them. For example, the Initiative for Vaccine Research Unit (IVR) will work closely with the Expanded Programme on Immunization Plus Team (EPI+) on the logistical impact of any proposed changes to immunization schedules. Similarly, the Quality and Safety Team (QSS) will work with both IVR and EPI+ on new vaccine production and control requirements and regulatory review, as well as the establishment of standards for new immunization equipment that needs to be developed.

To improve the streamlining of overlapping and joint areas of work, some activities have been transferred to other WHO departments.

- After two years of close collaboration, safe medical-waste disposal has now become the responsibility of the Department for Protection of the Human Environment.
- The assessment of vaccine management systems, vaccine store operations and injection practices has become the responsibility of the regional offices.
- Some activities have been given higher priority and visibility than previously, such as the normative functions coordinated by QSS.

The new structure is designed to encourage better and more productive links with other departments within WHO Geneva, such as in the areas of influenza pandemic preparedness, malaria, de-worming and vitamin A supplementation. The new structure also enhances partnerships with other organizations, such as GAVI, UNICEF and the World Bank.

Departmental budget and resources

During the past biennium, WHO invested significant efforts in decentralizing a significant part of its headquarters resources to the regional and country offices. Accordingly, IVB has re-centred its work around its *core functions* (i.e. those of a global and policy-setting nature). This has significantly reduced its budget requirement and the number of staff based in Geneva. The World Health Assembly endorsed a budget ceiling of US\$ 500 million for the area of work on immunization and vaccine development at global, regional and country levels in the 2006–2007 biennium. Within this budget, US\$ 299 million is allocated to polio eradication. Of the remaining US\$ 201 million, the distribution of budget ceiling between WHO headquarters and its regional offices is shown in Figure 4*(below)*. In addition, US\$ 8 million of additional budget ceiling has been granted to cover GAVI-related activities. This new budget ceiling represents a reduction of approximately 45% of IVB's 2004–2005 approved budget.



Figure 4: Programme budget 2006–2007 breakdown between regional offices and headquarters (US\$ millions)

While operations at headquarters are being realigned, activities will continue to be carried out at regional and country levels. This shift in focus means that joint planning and resource mobilization by IVB and its regional and country counterparts will be crucial to ensure that all financial gaps are identified and filled.



Figure 5: Distribution of funds within IVB in WHO/HQ

The World Health Organization has managed cooperation with its Member States and provided technical support in the field of vaccine-preventable diseases since 1975. In 2003, the office carrying out this function was renamed the WHO Department of Immunization, Vaccines and Biologicals.

The Department's goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases. Work towards this goal can be visualized as occurring along a continuum. The range of activities spans from research, development and evaluation of vaccines to implementation and evaluation of immunization programmes in countries.

WHO facilitates and coordinates research and development on new vaccines and immunization-related technologies for viral, bacterial and parasitic diseases. Existing life-saving vaccines are further improved and new vaccines targeted at public health crises, such as HIV/AIDS and SARS, are discovered and tested (Initiative for Vaccine Research).

The quality and safety of vaccines and other biological medicines is ensured through the development and establishment of global norms and standards (Quality Assurance and Safety of Biologicals). The evaluation of the impact of vaccinepreventable diseases informs decisions to introduce new vaccines. Optimal strategies and activities for reducing morbidity and mortality through the use of vaccines are implemented (Vaccine Assessment and Monitoring).

Efforts are directed towards reducing financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies (Access to Technologies).

Under the guidance of its Member States, WHO, in conjunction with outside world experts, develops and promotes policies and strategies to maximize the use and delivery of vaccines of public health importance. Countries are supported so that they acquire the technical and managerial skills, competence and infrastructure needed to achieve disease control and/or elimination and eradication objectives (Expanded Programme on Immunization).

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