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STRATEGIC PLAN 2010-15

**DEPARTMENT OF IMMUNIZATION, VACCINES
AND BIOLOGICALS**



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

Foreword

The 2010-15 Strategic Plan of the Immunization, Vaccines and Biologicals (IVB) Department of the World Health Organization (WHO) covers one of the most critical periods for global immunization efforts.

By the end of 2015, immunization is expected to contribute to reducing an estimated 25% of child mortality, as per the goals set out in the *Global Immunization Vision and Strategy* (GIVS).

Current efforts are producing good results. The immunization landscape has changed with observed increases in global immunization coverage and the availability of about 10 vaccines that can be added to the traditional six Expanded Programme on Immunization (EPI) antigens in used in developing countries. Routine immunization is now being expanded beyond the traditional target groups of infants and pregnant women to include adolescents and adults.

Today, immunization reaches a record 106 million children and averts 2.5 million deaths per year. To take this success further and to provoke a step change, IVB's 2010-15 strategy aims to deliver the highest possible levels of technical excellence, collaboration and synergies so that coverage rates of 80% by the end of 2010 and 90% by the end of 2015 are attained.

If and when successful, it is estimated that 4.5 million child deaths will be averted, making a significant contribution to achieving Millennium Development Goal 4 (MDG4) to reduce child mortality rates by two thirds by the end of 2015. To help achieve these goals, IVB has developed the following five priority areas of work.

1. Build upon the routine immunization component of the programme to strengthen and expand immunization delivery in order to reach populations currently unreached.
2. Support accelerated measles control efforts so that several countries and regions can reach the status of near zero measles mortality and measles elimination.
3. Enhance national capacity to introduce new vaccines and create synergies with other programmes to ensure access to a set of complementary disease control interventions.
4. Ensure that all populations have access to vaccines of the highest assured quality through strengthened, streamlined regulatory and vaccine management processes.
5. Formulate new evidence-based policies for the use of newer vaccines.

WHO will contribute to strengthen global advocacy with all other key partners and stakeholders so that immunization remains high on the public health agenda and receives appropriate attention from the countries themselves, and existing and new donors.

This Strategic Plan 2010-15 aims to realize the vision articulated in the *Global Immunization Vision and Strategy*: "A world in which all people at risk are protected against vaccine-preventable diseases."

1. Introduction

1.1 Context of IVB Strategic Plan

In recent years as international efforts have focused increasingly on ensuring the equitable spread of the benefits of modern public health products and practice to all populations in all parts of the world, immunization has continued to demonstrate best value for money.

In the past decade, the global immunization landscape has undergone a number of significant changes due to increased population coverage with traditional vaccines and increased use of under-utilized and newly-developed vaccines. There are several new stakeholders and important global and product-development partnerships that have been established to ensure better coordination of efforts in support of national immunization programmes.

With the availability of several new vaccines and safer and more effective vaccine delivery technologies in the past five years, the scope of immunization work has widened enormously. Furthermore, the potential efficiencies offered by providing preventive health interventions simultaneously at the point of service delivery — for example, immunization, nutrition and malaria control — contribute to the renewed enthusiasm for primary health care implementation.

It is currently estimated that the protection afforded by vaccines prevents more than 2 million deaths per year. The Millennium Development Goals (MDGs) endorsed by the UN Assembly in 2001¹, include among others, goal number four (MDG4) which aims to reduce child mortality by two thirds by 2015 as compared with the base year 1990. By 2015, through the achievement of high levels of vaccination coverage and the introduction of new vaccines, immunization should contribute approximately one fourth of the mortality reduction which is to be achieved under MDG4².

Beyond its traditional mandate to protect infants and children against six diseases targeted by the "traditional" EPI vaccines and child-bearing age women against tetanus, immunization now facilitates morbidity and mortality reduction among all age groups and against both acute and chronic diseases. The benefits from hepatitis B and human papillomavirus (HPV) vaccines that protect against liver and cervical cancer, respectively, in adulthood will be felt deep into the future. Similarly, vaccination against Japanese encephalitis, meningococcal meningitis, rubella, seasonal influenza and typhoid through routine vaccination programmes will benefit individuals in a wider age range than the "traditional" vaccines.

¹ United Nations. General Assembly, 56th session. *Road map toward the implementation of the United Nations Millennium Declaration: report of the Secretary-General* (UN document A/56/326). New York; United Nations, 2001.

² Based on estimates from Wolfson L. et al. Estimating the costs of achieving the WHO–UNICEF *Global Immunization Vision and Strategy*, 2006–2015. *Bull WHO*, 2008;86:27–39, and Okwo-Bele J-M. and Salama P. *Global update on GIVS goals*. Presentation made at the Global Immunization Meeting, New York, 17 February 2009.

The joint WHO/UNICEF *Global Immunization Vision and Strategy*³ has provided a robust framework for global immunization targets and activities during the period 2006-15. This document identifies and explains the strategies to be pursued and implemented by WHO in order to achieve the goals it lays out.

Good progress has been achieved in the pursuit of these goals during the execution of the 2006-09 IVB Strategic Plan and it will be further supported during the present Strategic Plan period.

1.2 Analysis of current status

1.2.1. Current status of global immunization

Through the efforts of a multitude of stakeholders including global, regional and national agencies, governments and Expanded Programme on Immunization partner agencies, more than 100 million infants are immunized annually. This has averted over 20 million lives in the last two decades and currently averts more than 2.5 million deaths every year in all age groups from diphtheria, tetanus, pertussis (whooping cough) and measles. It is calculated that 4-5 million deaths could be averted per annum: this would depend on the application of appropriate strategies, adequate financial and human resources, effective partnerships and the commitment of governments to raise routine coverage to more than 90% and to introduce new and under-utilized vaccines.

Global reported DTP3 (three doses of diphtheria-tetanus-pertussis vaccine) vaccination coverage, which is used as an indicator of overall immunization performance, was 82% at the end of 2008, versus 78% in 2005 and 73% in 2000. At the regional level, performance was best in the Americas, Eastern Mediterranean, European and Western Pacific Regions, and lower in the African and South-East Asia Regions. Out of a total of 193 WHO Member States, 120 (62%) reported national DTP3 coverage of 90% or greater, whereas 73 (38%) reported less than 90% vaccination coverage in 2008. However, of the 131 countries that reported district vaccination coverage in 2008, only 54 (41%) reported DTP3 coverage of 80% or greater in all districts, which is considered essential for effective vaccine-preventable disease control.

A major source of concern is that 25 of the 193 WHO Member States have DTP3 coverage of less than 70%. According to WHO-UNICEF estimates, in 2008 the 10 countries with the lowest DTP3 coverage were: Chad (20%), Somalia (31%), Equatorial Guinea (33%), Gabon (38%), Samoa (46%), Bolivarian Republic of Venezuela (47%), Papua New Guinea (52%), Haiti (53%), Nigeria (54%) and Central African Republic (54%). The largest absolute numbers of unvaccinated children lived, in order of magnitude, in India, Nigeria, Pakistan, Indonesia, Democratic Republic of the Congo, Ethiopia, China, Uganda, Chad and Iraq, with little progress

³ *Global Immunization Vision and Strategy 2006–2015*. World Health Organization, Geneva and UNICEF, New York, 2005 (WHO/IVB/05.05).

between 2005 and 2008 except in China and Ethiopia. In three countries, DPT3 coverage declined by more than 10% points between 2007 and 2008.

Between 2000 and 2008, global mortality due to measles was reduced by 78%⁴ from an estimated 733 000 deaths in 2000 to 164 000 in 2008. All WHO regions, with the exception of the South-East Asia Region, have now achieved the 2010 global goal of reducing measles mortality by 90% compared to estimated levels in 2000. Within the South-East Asia Region, all but one country (India) have achieved this global goal. During the 2000-08 period, approximately 13 million measles deaths were averted globally due to measles control activities; of these, an estimated 4.3 million deaths (39%) were averted as a result of accelerated activities (both increases in routine coverage and implementation of measles supplementary immunization activities [SIAs]). By region, the highest number of deaths averted during 2000-08 was in the African Region (7.2 million), followed by the South-East Asia Region (2.9 million) and the Eastern Mediterranean Region (1.5 million). In 2008, global routine coverage with the first dose of measles-containing vaccine (MCV1) reached 83%, increasing from 72% in 2000, and more than 110 million children were provided with measles-containing vaccine through SIAs in the 47 priority countries that were identified as those with high measles mortality burden.

By the end of 2008, routine vaccination coverage with at least two doses of tetanus toxoid vaccine or tetanus-diphtheria toxoid vaccine was estimated at 74% globally. In addition, since 2000, SIAs have targeted women of reproductive age in high-risk areas in more than 40 countries, protecting more than 90 million women. The cumulative effect of these TT doses, as well as priming with DTP in infancy, results in an estimated 81% of newborns being protected at birth from neonatal tetanus. Out of the 58 countries that in 2000 had not eliminated MNT, 14 have been assessed and found to have achieved the global target (as of August 2009). In addition, 15 states in India with roughly 50% of the Indian population have also achieved MNT elimination.

Global polio eradication is behind schedule for a number of reasons including issues ranging from inadequate vaccine efficacy in parts of India to failure to vaccinate children during SIAs in Nigeria, in addition to problems of access to target populations in areas and countries with active conflict or local insecurity. A new strategic plan for 2010-2012 has been launched to address these complex issues.

Major efforts have been implemented in recent years to accelerate the introduction of new and under-utilized vaccines, with substantial financial support available from the GAVI Alliance and through other mechanisms such as the Pan American Health Organization Revolving Fund. Among the new and under-utilized vaccines receiving close attention since the inception of the GAVI Alliance have been those for hepatitis B (HepB) and *Haemophilus influenzae* type B (Hib). Hep B vaccine has been introduced into national immunization programmes in 177 (92%) countries and, as of the end of 2008, global HepB3 coverage was 69%. Hib vaccine has been introduced in 136 (70%) countries and global Hib3 coverage was 28%.

⁴ Draft estimates to be cleared by EIR – may change as a result of country consultation process.

Globally, as of the end of 2008, rotavirus vaccine had been introduced into 19 countries (17 nationwide, two in parts of the country), whereas pneumococcal vaccine had been introduced into 31 countries (26 nationwide, five in parts of the country).

1.2.2. WHO's achievements

The IVB Strategic Plan for 2006-09 included eight broad programme targets, as follows:

1. Support research for the development of vaccines, technologies and immunization strategies against infectious diseases of public health significance.
2. Develop norms and standards for the production, control and regulation of vaccines and other biologicals, and establish reference standards.
3. Strengthen countries' capabilities to use vaccines of assured quality and to implement safe immunization practices.
4. Strengthen countries' capacities to secure vaccine supply and increase the financial sustainability of their immunization programmes.
5. Strengthen countries' capacities to monitor immunization systems and assess vaccine-preventable disease burden.
6. Strengthen countries' capacities to maximize access to current, new and underutilized vaccines and accelerate disease control efforts.
7. 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.
8. Manage and coordinate the IVB Department efficiently and effectively.

These targets were subsequently sub-divided into 13 sets of expected results, and progress towards these results has been closely monitored through the periodic review of established indicators. The status of implementation of the targets and results is summarized in Annex 1. Overall, with a few exceptions, implementation of the 2006-09 work plan achieved nearly all the targets set, as described below for selected targets.

Policy development

The WHO Vaccine Advisory Committees play an increasingly central role in determining global vaccine policies. WHO Vaccine Advisory Committee recommendations have become a necessary step in the pathway to the introduction and use of vaccines, especially in developing countries and, as a consequence, have clear and significant impact.

Partner agencies, especially UNICEF and the GAVI Alliance, predicate their immunization policy-making on WHO Vaccine Advisory Committee recommendations and Vaccine Position

Papers. Evidence of WHO recommendations driving vaccine introduction and immunization practice includes the rapidly expanding use of Hib and pneumococcal vaccines.

Committee meetings are highly visible and well attended, and reviews by these committees are viewed as critical to the policy pathway for the adoption of new vaccines. WHO has worked to increase the qualifications and credibility of members, transparency of process, effective use of evidence, and quality of resulting reports and recommendations.

WHO has also initiated a programme for creating and/or strengthening National Immunization Technical Advisory Groups to assist countries in taking evidence-based national policy decisions on introducing new vaccines that have recently been developed or are currently in the development pipeline.

Expanding coverage, accelerated disease control and introducing new vaccines

WHO continued to provide technical support to countries and to monitor and evaluate programme performance and quality and safety of the immunization system. At global level, WHO provided estimates of the burden of vaccine-preventable diseases, in addition to monitoring each country's immunization policies, particularly the vaccines and vaccination schedules. Great emphasis is placed on monitoring the overall proportion of eligible individuals who are vaccinated and ensuring that all districts and all people in each country receive adequate and equitable service delivery. Strategies to close immunization gaps were supported, including through approaches such as "Reaching Every District" (RED) and other relevant strategies.

WHO facilitated the expansion of epidemiological surveillance activities in countries, by further enhancing global polio surveillance and supporting case-based measles surveillance in 173 countries (90%) by end of 2008. Building from polio surveillance, the virological surveillance for measles has proven beneficial for identifying the source of outbreaks and tracking virus transmission within and among regions. As of the end of 2008, WHO's measles genotype database contained genotype information on 2587 measles viruses from 59 countries.

During 2008, WHO undertook a process to transition existing surveillance system networks for rotavirus and invasive bacterial diseases (used to monitor the impact of Hib, pneumococcal, and meningococcal vaccines) to a network coordinated by WHO, with financial support provided to GAVI-eligible countries. All sites now use standardized definitions, collect a core dataset, and use standardized quality-controlled laboratory methods. These surveillance data are used to monitor the impact of vaccine introduction, detect changes in strain prevalence, and provide other critical information for decision makers.

In 2009, in collaboration with the Pneumococcal Vaccine Accelerated Development and Introduction Plan and Hib Initiative partners based at Johns Hopkins University and the London School of Hygiene and Tropical Medicine, WHO released new disease burden estimates on Hib and pneumococcal diseases in children under the age of five. This data will assist countries in evidence-based decision-making on vaccine introduction and in the evaluation and cost-effective analysis of vaccine impact after introduction.

WHO has issued a position paper on tetanus that outlines possible schedules to protect all individuals against tetanus at all ages. This recommended schedule focuses on continuing tetanus vaccination after the three DTP doses given in infancy with one dose in childhood, one in adolescence, and one in early adulthood. The switch to this schedule can be an important milestone to sustain maternal and neonatal tetanus elimination and to protect all age groups against tetanus. It can also provide an opportunity to introduce or reinforce school-based immunization, and gain experience with targeting older age groups in anticipation of the introduction of other new and under-utilized vaccines such as HPV vaccine.

In 2009, WHO issued a revised global recommendation for the inclusion of rotavirus vaccination of infants into all national immunization programmes, and not only those in the Americas and Europe. Introduction of this vaccine will provide protection against a virus that is responsible for more than 500 000 diarrhoeal deaths and 2 million hospitalizations every year with 85% of these deaths occurring in developing countries in Africa and Asia.

In 2009, WHO published the first position paper on HPV vaccine use, prequalified⁵ two HPV vaccines, and identified approaches to measure HPV vaccine impact. Introduction of this vaccine will provide protection against a virus which causes 500 000 cervical cancer cases and 260 000 deaths worldwide each year.

The Global Plan of Action on Implementing New and Under-used Vaccines was regularly updated by WHO and partners in annual global meetings, with participants concurring that the challenges of new vaccine introduction require products, vaccine management systems and financing mechanisms tailored to individual country situations. The main priorities to be undertaken were to: support fully informed decision-making on the introduction of new vaccines, balancing new vaccines introduction with routine immunization and delivery systems strengthening; surveillance; and accelerating strategies to mobilize resources to cover the costs of introducing these newly available vaccines.

With the phasing out of the initiatives to accelerate the introduction of Hib, pneumococcal and rotavirus vaccines, the work of coordinating support to GAVI-eligible countries to make evidence-based decisions on the introduction of new vaccines has been carried out by the Accelerated Vaccine Introduction Initiative which is a partnership between WHO, UNICEF, the GAVI Alliance and a consortium that includes PATH, the United States Centers for Disease Control and Prevention and Johns Hopkins University Bloomberg School of Public Health. In this new initiative, WHO leads the work on country implementation and new vaccines disease.

Vaccine norms and standards

⁵ WHO prequalification of vaccines is essentially approval of the product for supply to developing countries via United Nations agencies such as UNICEF and the Pan American Health Organization Revolving Fund, after verification of the vaccine's quality. The WHO prequalification system is over 20 years old.

The Expert Committee on Biological Standardization, which has been meeting annually since WHO was founded in 1948, continues to set technical specifications, as well as norms and standards for vaccines and delivery devices that form the basis of guidelines for vaccine production and prequalification.

The Global Advisory Committee on Vaccine Safety, which has been meeting bi-annually for the past 10 years, provides independent, authoritative, scientific advice to WHO on vaccine safety issues of global or regional concern with the potential to affect national immunization programmes. The Committee reviews the latest information on vaccines in close collaboration with experts from national governments, academia and industry. It assesses the evidence for relationships between vaccines and/or their components and adverse events allegedly attributed to them.

Recognizing the need for the highest standards in quantitative methods and tools that inform policy recommendations in immunization or track progress of work, a new committee (QUIVER) has been established in 2007 that provides independent advice to the WHO Secretariat. Methods related to disease-burden estimates, health economical analysis, and modelling on measles and polio eradication have been assessed, among others.

Efforts to strengthen national regulatory authorities (NRAs) continue. The WHO NRA assessment tool was revised in 2004 by a group of international regulatory experts and a set of indicators was identified as critical for the purpose of the WHO vaccine prequalification scheme. In practice, this means that vaccines are now only eligible for a review under the prequalification scheme provided they are produced in a country where the NRA complies with these critical indicators.

Increasingly, vaccine candidates are being developed, tested and produced in developing countries. The regulatory burden for the authorization and monitoring of clinical trials, which previously fell mainly to industrialized countries, is now increasing in countries that, in many cases, lack the expertise and capacity to undertake this work. WHO continues to support countries in building capacity to assess clinical trial applications, to monitor clinical trials, and to evaluate clinical data in registration dossiers.

Prequalification of vaccines and equipment

The prequalification of vaccines provides for a basic assurance of the quality of the vaccine manufacturing process for specific vaccines, enabling United Nations agencies (UNICEF and Pan American Health Organization) to procure them on behalf of countries lacking adequate regulatory authorities. The quality assurance of vaccine-related equipment, including injection and cold chain equipment, was recently initiated with the establishment of standards of quality that manufacturers should meet.

Innovations in logistics and supply systems

As with immunization services that are introducing more costly and bulky new vaccines, public health interventions that support the delivery of anti-retroviral drugs, bed nets, diagnostic kits, ACTs and other health commodities are also facing expansion and pressure to reach, in a timely fashion, an increasing number of people with quality products. As a result, supply systems are being established to deliver these products. WHO is exploring how best to consolidate these different supply systems thereby reducing costs, eliminating redundancies and improving efficiencies.

Support for vaccine and immunization research

Under the Meningitis Vaccine Project (MVP), WHO conceptualized a public-private partnership development effort and, through a partnership with PATH, managed the collaboration among the partners (the vaccine manufacturer, trial sites, labs and ministries of health) to develop a new conjugate meningococcal A vaccine. The vaccine is expected to be licensed and available to countries of the African meningitis belt in 2010, with initial funding approved by the GAVI Alliance for deployment in three countries.

WHO is developing an aerosolized measles vaccine through a broad partnership with a large vaccine manufacturer and several delivery device companies. This project is jointly overseen by WHO, the American Red Cross and the United States Centers for Disease Control and Prevention. WHO manages the project and ensures that the best technical experts contribute to the development team. The aerosolized measles vaccine will allow administration by non-medically trained personnel and avoids injection-related safety problems, especially in resource-poor settings and in the context of vaccination campaigns. Clinical trials are ongoing and the vaccine could be registered as early as 2011.

WHO has served as the focal point in a funders group for malaria vaccine development comprised of the Malaria Vaccine Initiative at PATH,, the European Vaccine Initiative, ,The European and Developing Countries Clinical Trials Partnership, the US-NHI, the European Commission, USAID, the Wellcome Trust and the Bill & Melinda Gates Foundation. The *Malaria Vaccine Technology Roadmap* was designed as a strategy to develop a malaria vaccine by 2025 with a protective efficacy of more than 80% against clinical disease for at least four years.

Global influenza vaccine production capacity is not sufficient to meet potential pandemic influenza vaccine demand, and production sites are concentrated in a few western countries. Increasing production capacity — particularly in developing countries — is crucial to remedy this situation. To address this challenge, WHO brought together technical expertise, capable developing country vaccine manufacturers, and significant funding in accordance with a global plan to increase the supply of H5N1 influenza vaccine⁶ in the event of a pandemic. Current global vaccine production and storage capacity is far short of the 10-15 billion doses of monovalent pandemic influenza vaccine which would be required in order to provide the entire global population with two doses of vaccine in the case of a severe pandemic. The United

⁶ *Global pandemic influenza action plan to increase vaccine supply*. WHO. WHO/IVB/06.13. Geneva; 2006.

States Department of Health and Human Services, Asian Development Bank, and Government of Japan, through UNICEF, have committed funds to support activities relating to the development of pandemic vaccine production capacity, NRA strengthening for pandemic vaccines, and human resources.

2. Overview of the 2010-15 Strategic Plan

2.1 Mission statement

WHO's mission statement for immunization remains: *A world in which all people at risk are protected against vaccine-preventable diseases.*

2.2 Existing frameworks

WHO's immunization work will continue to be guided by the principles set in the *Global Immunization Vision and Strategy 2006-15*, and in particular those linked to equity in immunization coverage and impact; programme ownership and formulation of policies; and strategies based on evidence and best practices.

WHO's immunization work is cross-cutting and contributes to the realization of four strategic objectives (SOs) developed in the *WHO Mid-Term Strategic Plan*: SO1— To reduce the health, social and economic burden of communicable diseases; SO2 — To combat HIV/AIDS, tuberculosis and malaria; SO10 —To improve health services through better governance, financing, staffing and management informed by reliable and accessible evidence and research; and SO11 — To ensure improved access, quality and use of medical products and technologies.

In its 11th *General Programme of Work* and building on its mandate and comparative advantage, WHO defined six core functions: Providing leadership on matters critical to health and engaging in partnerships where joint action is needed; Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge; Setting norms and standards, and promoting and monitoring their implementation; Articulating ethical and evidence-based policy options; Providing technical support, catalyzing change, and building sustainable institutional capacity; and, Monitoring the health situation and assessing health trends.

These functions are highly relevant to WHO's work on immunization, which is largely reliant on the alignment and inter-dependence of the three tiers of the organization (headquarters, regional and country offices).

2.3 Themes

Despite the current economic downturn, this Strategic Plan will build upon the experience gained during the implementation of the 2006-09 Strategic Plan, and will take into account the dynamic economic environment surrounding immunization today. IVB has sought to give continuity to its work and address the remaining challenges in global immunization with emphasis on the following themes:

- **Technical collaboration** — WHO is expected to provide evidence-based policies, norms and standards for vaccines and immunization and to support countries in planning and

implementing immunization strategies. During 2010-15, WHO will continue to fulfill this normative role notably through the enhanced management of technical advisory committees of experts and the facilitation of information exchange among programme managers. Effective collaboration with other stakeholders per their comparative advantage will be enhanced.

- **Integration and synergies** — WHO will strive during 2010-15 to agree on joint strategies for disease prevention and control in order to maximize improvements in health outcomes. For example, leading killer diseases of under age five children such as pneumonia and diarrhoea will be tackled by promoting coordinated action for prevention through vaccination, protection through improving nutrition and environmental conditions, and early diagnosis and effective case management through the Integrated Management of Childhood Illnesses.
- **Closing remaining gaps** — The limiting factor in many poor and middle-income countries to reaching unreached children with adequate quality service delivery is frequently related to health system weaknesses. These may manifest as quantitative deficiencies such as inadequate human resources, transport, equipment, vaccines and drugs, or qualitative deficiencies such as inadequate management, training, supervision, monitoring and evaluation. During 2010-15, the Department will contribute further to efforts towards identifying and sustainably resolving health system barriers that limit the ability to reach population groups who are eligible but unvaccinated, It will also expand the implementation of strategies such as Reaching Every District⁷ and Child Health Days⁸, in order to close remaining gaps in vaccination coverage with existing and new vaccines.

⁷ *Global Immunization Vision and Strategy, 2006–2015*. World Health Organization, Geneva and UNICEF, New York, 2005 (WHO/IVB/05.05).

⁸ Fiedler JF. and Chuko T. The cost of Child Health Days: a case study of Ethiopia's Enhanced Outreach Strategy (EOS). *Health Policy and Planning*, 23:222-233; 2008.

2.4 Assumptions and opportunities

WHO's work in immunization is grounded in a series of assumptions that may be summarized as follows:

- high-quality vaccine and delivery technology products are available;
- high national priority is afforded to immunization,(prevention);
- high community demand for immunization exists;
- discovery and innovation in vaccine development is accelerating, leading to a richer vaccine pipeline and improved vaccine presentations;
- the number of manufacturers producing quality vaccines that prevent diseases of public health importance is expanding, including in developing countries, leading to the availability of cheaper products;
- public-private partnerships and their support for immunization work in countries continues;
- vaccine-related initiatives continue to receive support from the global community; and
- sustainable financing is available from domestic resources and international partners to strengthen immunization in the context of broader public health service delivery.

2.5 Targets and priority actions

Note - the strategies to achieve the important goal of polio eradication are laid out in a specific strategic plan 2010-2012, which has been reviewed and endorsed by WHA at its May 2010 session (XXXX link)

Below is a description of vaccines and immunization priority actions.

2.5.1 Facilitating reaching unimmunized children

Globally, despite vigorous efforts by government and numerous partner agencies, it is estimated that in 2008, 23.5 million eligible infants did not receive the primary series of three doses of DTP vaccine by their first birthday. Ten large countries (India, Nigeria, Pakistan, Indonesia, Democratic Republic of Congo, Ethiopia, China, Uganda, Chad and Iraq) have the largest numbers of unvaccinated children less than five years of age. Furthermore, within countries with national vaccination coverage of greater than 80%, unvaccinated children are often hidden from view in pockets of low coverage — pockets that may be geographic, racial/ethnic or seasonal in nature. Failure to vaccinate these children results in a substantial burden of preventable morbidity and mortality in developing countries that impedes national development and will delay the global achievement of MDG4 and accelerated disease control goals related to polio, measles and neonatal tetanus.

In line with the goals stated in the *Global Immunization Vision and Strategy*, countries are striving towards 90% or greater vaccination coverage and 80% or greater coverage in all districts by the end of 2010, and maintaining this level of coverage through 2015 and beyond. As key barriers to coverage improvement in countries are identified, local adaptations of strategies and methods of implementation will be developed. The coordinated implementation of solutions to barriers to achieving high coverage deploying a full range of WHO and partner expertise in operational research, best practices for vaccine delivery, and human resource capacity building, all within the context of strengthened health systems, will ensure that unimmunized infants and children are identified and vaccinated in low-performing countries.

WHO will continue to review progress and develop technical recommendations on immunization policies and practices for reaching every infant and child in order to strengthen routine immunization systems and close immunity gaps.

WHO will work to more effectively coordinate and support routine performance monitoring at country level, focusing on district-level performance, accurate vaccination coverage assessment, vaccine stock-outs, vaccine wastage, etc. This will be achieved through the increased engagement of active and competent national Expanded Programme on Immunization Inter-Agency Coordination Committees whose members include representatives from partner agencies such as UNICEF, the World Bank, bilateral agencies, non-governmental organizations and others, under the leadership of national Ministries of Health.

2.5.2 Introducing new vaccines

Moving into the next five years, a key priority in the area of new vaccines will be to ensure that all stakeholders, especially those at country level, are kept well informed of developments and innovations in the updated policies on new vaccines and presentations that are becoming available, as well as the costs of introducing these vaccines, in order to decide which interventions are best suited to their individual situations. To this end, WHO will focus its work on providing policy advice, supporting countries to assess the disease burden of vaccine-preventable diseases and strengthening the capacity of National Immunization Technical Advisory Groups to make informed choices on which strategies to support.

In light of recent financial developments, the immunization community can expect an increased number of countries no longer eligible for support from the GAVI Alliance, but which are not in a position to allocate sufficient domestic resources to finance the introduction of new vaccines. The work of WHO and other partners on developing innovative procurement mechanisms and establishing a healthy market for new vaccines will become increasingly important. With the focus on both affordability at national level, as well as cost-effectiveness considerations of the different strategies, WHO will also support advocacy efforts with governments and donors by providing key information and evidence.

Vaccine specific activities will focus on exploring the possibility of introducing Hib in the remaining countries to achieve global introduction, and on increasing coverage in all countries so that more children are reached.

Countries will also be supported with introducing pneumococcal and rotavirus vaccines where funding allows, and with establishing policy, implementation and monitoring activities for the introduction of HPV vaccine. For these three vaccines, there will be a focus on developing integrated approaches for disease control that will involve other groups not traditionally involved with immunization work, such those working on child and adolescent health, diarrhoea control, reproductive health and cancer prevention and control.

2.5.2 Eliminating measles as a public health problem

During the implementation of the 2010-15 Strategic Plan, WHO will continue and build from progress achieved on measles mortality reduction, in view of its significant contribution towards MDG4. Global targets for 2015 will be pursued as follows:

- Reach *Global Immunization Vision and Strategy* goal of 90% or greater routine first dose measles vaccination coverage in all countries and 80% or more in all districts of all countries;
- Reduce measles incidence to less than five cases per million population in each country;
- Achieve regional measles elimination goals (WHO Region of the Americas achieved elimination in 2002; the WHO European, Eastern Mediterranean, and Western Pacific Regions have targeted elimination by 2015 or earlier; and the African and South-East Asia Regions possibly by 2020).

A critical component of this effort will focus on building effective vaccination coverage monitoring and case-based, laboratory-based epidemiological surveillance systems at country level in order to monitor compliance with recommended practices and to assess the achievement of minimum programmatic indicators.

Given that measles eradication is an ambitious goal, a thorough and comprehensive analysis of its feasibility and appropriateness that has been done will be reviewed by the WHO Strategic Advisory Group of Experts and the World Health Assembly in 2010-11.

2.5.3 Building synergies for disease control

Since the newer vaccines such as Hib, pneumococcal, rotavirus and HPV vaccines address diseases (pneumonia, diarrhoea and cervical cancer) that are caused by multiple etiological agents and for which complementary control strategies (either to protect from or treat those with these conditions), WHO has established collaboration with other health programmes and partners to promote a coordinated and synergistic approach to the control of these diseases.

For example, an informal inter-departmental and inter-institutional working group on HPV vaccine introduction has been established to integrate HPV vaccine delivery with adolescent health packages and cervical cancer secondary prevention. The launch of the WHO and UNICEF Global Action Plan for Prevention and Control of Pneumonia and the release of the comprehensive strategies for diarrhoeal disease control late in 2009 represented the outcome of collaborative efforts of several WHO departments and partners towards a common vision and goal. These efforts will be expanded in the 2010-15 Strategic Plan period. Similar efforts were also undertaken to produce cervical prevention and control strategies.

In 2010-15, the IVB Department aims to build on these foundations to assist countries to take evidence-based decisions on the value of introducing these new vaccines into their national immunization programmes and to support the development of national plans of action and resource mobilization strategies.

Where needed, WHO will also continue to provide technical assistance to ministries of health to establish sentinel site surveillance and laboratory diagnosis to generate baseline epidemiological information and to monitor and evaluate the post-introduction impact of rotavirus, pneumococcal and Hib vaccines. To support these surveillance activities and to generate comparable data across countries and regions, WHO established globally standardized surveillance procedures for rotavirus and invasive bacterial disease, which is the basis of pneumonia surveillance.

2.5.4 Accelerating the availability and use of vaccines for diseases of public health concern to developing countries

WHO remains at the forefront of technical guidance for the late stage development and formulation of policies for the introduction of new vaccines of urgent public health concern to developing countries such as those that prevent HPV, dengue, typhoid, Japanese encephalitis and malaria.

WHO serves as the focal point for the Malaria Vaccine Funders' Group (see above). To allow for comparative evaluation of vaccines and development of correlates of protection of the many candidate malaria vaccines undergoing testing, standardized assays are needed. WHO facilitates the prioritization of the essential immunological measures for leading candidates entering efficacy trials and for enabling access to agreed reagents, controls and harmonized standard operating procedures for the generation of clinical data. WHO will aim to strengthen this process towards development of qualified and validated assays that may be of use as surrogate markers of efficacy and formally established as a regulatory standard by the Expert Committee on Biological Standardization.

Target product profiles will be developed, when appropriate, in order to guide vaccine research to the needs of endemic country decision-makers and vaccine financing systems.

Work also on other poverty-related diseases (human immunodeficiency virus, tuberculosis, diarrhoeal diseases), on vaccines for health security (influenza, dengue and beyond).

2.5.5 Accelerating global production and supply of vaccines of assured quality

This section to include a § on technology transfer to increase global supply- Mention flu and expand to potentially other diseases.

One of WHO's core services is to prequalify vaccines supplied by United Nations agencies to developing countries. During the implementation of the 2010-15 Strategic Plan, the Product Quality and Safety activity will be centralized and expanded to include the prequalification of injection devices and equipment. WHO will work with the Expert Committee on Biological Standardization to develop guidance and testing standards for devices and equipment and to introduce regulatory oversight of equipment used in Member States. Regional focal points will be established to monitor this process and contribute towards the development of a global database on compliance with WHO guidance.

WHO will decentralize the administration of the Global Training Network professional courses for strengthening national regulatory authorities' capacity to comply with WHO guidance on new vaccine registration and clinical trial regulatory oversight. Furthermore, the peer review of course content for technical consistency will be decentralized. Plans are being developed to expand the Communities of Practice web site, decentralize management of this web site to training centres, and to expand distance learning opportunities.

The regulatory network will be further developed and integrated:

- The African Vaccine Regulatory Forum, in which 19 countries currently participate, will hold annual meetings designed to permit participants to exchange and compare experience with clinical trials.
- The global Developing Countries Vaccine Regulators' Network that currently depends upon WHO Secretariat will be expanded and become self-sustaining.
- The Association of Southeast Asian Nations (ASEAN) provides harmonized standards and assessments of pharmacological products. ASEAN has agreed to expand this service to include vaccines and, during 2010-15, guidelines and standards will be developed to guide this process. It is hoped that this might be repeated in other regions.
- A Pan-African Clinical Trial Registry will be created, based on the South African model, and a database will be developed containing key information on all clinical trials in progress.
- WHO will develop an entity called the Pan-African Clinical Trial Alliance, to provide a link between national regulatory authorities, ethical committees and the global clinical trial registry.

WHO's work to prequalify vaccines supplied by UN agencies to developing countries will continue. It is envisaged that national regulatory authorities will eventually have sufficient capacity to regulate vaccines for use in national immunization programmes, rather than use WHO prequalification as a proxy. The Americas Region is the first region with sufficient technical capacity to prequalify vaccines of regional importance. WHO's Secretariat will work with the Pan American Health Organization to structure this decentralized activity while maintaining global standards. During 2010-15, standards for the prequalification of vaccines will be unified across all WHO Regions.

2.6 Monitoring and evaluating implementation

The following Mid Term Strategic Plan indicators will be used to monitor progress:

SO1

1.1.1 Number of developing countries with at least 90% national vaccination coverage and at least 80% vaccination coverage in every administrative unit

1.1.2 Number of developing countries supported to make decisions about appropriate changes and additions to the immunization schedule, including the introduction of new vaccines and/or new technologies

1.1.3 Number of essential child-health interventions integrated with immunization for which guidelines on common programme management are available

1.1.4 Number of countries that have established either legislation or a specified national budget line in order to ensure sustainable financing of immunization

1.5.1 Number of new and improved vaccines or immunization technologies developed through significant WHO assistance receiving internationally recognized approval for use

SO11

11.1.1 Number of countries receiving support to formulate and implement official national policies on access, quality and use of essential medical products and technologies

11.1.2 Number of countries receiving support to design or strengthen comprehensive national procurement and supply systems

11.2.3 Number of priority medicines, vaccines, diagnostic tools and items of equipment that are prequalified for United Nations procurement

11.2.4 Number of countries whose national regulatory authorities have been assessed, supported and accredited

11.3.2 Number of countries using national lists, updated within the past five years, of essential medicines, vaccines and technologies for public procurement and/or reimbursement

Annex 1. IVB Strategic Plan, 2006-09
Initial status and achievements as of end 2009

	Indicators	Initial status in 2006	Current status (end-2008, unless specified)	2009 achievement
Target 1: Support research for the development of vaccines, technologies and immunization strategies against infectious diseases of public health significance.				
ER1: Management of knowledge and provision of guidance and advocacy through effective partnerships to accelerate innovation for new and improved vaccines and technologies	Number of disease-specific research agendas established for four target diseases through broad consultation with developing countries and research partners. (Target diseases: malaria, flaviviruses, diarrhoeal diseases and tuberculosis)	0 of 4		4 of 4 Malaria, tuberculosis HPV, cholera
ER2: Support to research and product development (R&PD) and the enhanced capacity for the development and evaluation of WHO priority new vaccines and technologies	Number of new vaccines against Japanese encephalitis, Meningococcal A or measles that have entered phase 2/3 clinical trials in developing countries.	0 of 3		3 of 3 Japanese encephalitis, measles aerosol and Meningococcal A
	Capacity to conduct vaccine clinical trials meeting international standards established in Mexico, India, Tanzania, Mali, Ethiopia and Kenya ⁹ .	1 of 6		6 of 6 India, Thailand, Mali, Ethiopia, Ghana, The Gambia and Kenya
ER3: Conduct appropriate implementation research and development of tools to support evidence-based recommendations, policies and strategies for optimal use of vaccines and technologies	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		5 of 5 Pneumo, typhoid, rotavirus, HPV, cholera
	Number of targeted countries where pilot testing of a tool to estimate cost-effectiveness of HIV vaccines has been completed (Target countries: Thailand, Kenya, China, Brazil, Peru)	2 of 5		5 of 5 Thailand, Kenya, China, Brazil, Peru
Target 2: Develop norms and standards for the production, control and regulation of vaccines and other biologicals, and establish reference standard				
ER 4: Development of international norms, standards and guidelines for production, control and evaluation of biologicals, including vaccines.	Number of new or revised standards and reference materials established by the WHO Expert Committee for Biological Standardization	0	31 established (4 written standards; 27 reference preparations)	30
	Number of new guidelines established, or globally	0	7 of 8	8

⁹ Clinical trial completed or ongoing, with satisfactory report on Good Clinical Practice from a WHO independent monitor

	coordinated research under way, that contribute to improved safety of biological medicines		a) Established: 3 (YFV potency; men C clinical evaluation; pandemic flu regulatory preparedness) b)Ongoing: 4 (cell substrates; pertussis and biosimilars)	
	Number of global strategies developed to promote and monitor implementation of norms and standards and to facilitate access to WHO collaborating centres.	0	3 of 6 1) implementation workshops 2) international regulatory networks 3) regional NRAs/NCLs networks	6
ER 5: Promotion of good regulatory practices for national regulatory authorities	Percentage of countries producing vaccines where NRAs meet the WHO NRA performance indicators	62% (30 of 48)	33 out of 48 (69%)	100%
	Number of new vaccines for which a regulatory mechanism exists for review during clinical development and/or registration	0	3	5
	Establishment a network of sentinel countries with a monitoring system for AEFIs and post-marketing surveillance of new vaccines	0 countries in the network		10 countries in the network
	Development and implementation of a tool to assess NRAs' oversight of immunization equipment	No Tool	To be completed in 2009	15 countries assessed
Target 3: Strengthen countries' capabilities to use vaccines of assured quality and to implement safe immunization practices				
ER6: Respond to vaccine safety and quality issues of global importance in a coordinated and rapid manner.	A Plan of Action (including investigation, position/statement, ongoing research) to be produced within one month after identification of all vaccine safety issues of global importance	Yes		Yes
ER7: Provide the pre-qualification of manufacturers function for vaccines and equipment for use by countries and UN agencies	Number of eligible vaccine applications for prequalification initiated in the two year period	N/A	18	10 new 8 routine
	Proportion of vaccine applications for prequalification for which reviews are completed within 12 months of submission	0%	15/18 Three vaccines exceeded target timeframe, 2 were due to manufacturers' delays	100%

	Proportion of eligible equipment applications for prequalification for which reviews are completed within the time set for the category of equipment concerned	52 of 52 ¹⁰ applications reviewed in time	21/21 applications reviewed on time 100%	80%
Target 4: Strengthen countries' capacities to secure vaccine supply and increase the financial sustainability of their immunization programmes				
ER 8: Provide advice and technical support to ensure vaccine security	Number of priority countries complying with WHO-UNICEF vaccine store management standards.	2	5	20
	Number of GAVI bridge-financing countries ¹¹ that have transitioned to vaccine co-financing mechanisms	4	11 countries of the initial intended 16 were finally eligible and approved for 1 year bridge funding in 2007	16 (the initial target 16 has been revised to 11)
Target 5: Strengthen countries' capacities to monitor immunization systems and assess vaccine-preventable disease burden				
ER9: Evidence gathered and analyzed to guide policies and strategies and to communicate the value of immunization	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	63% 121 of 193 countries	75%
	A global web-based reporting system that allows countries to input and update key data on a continual basis	No system	1 region (EURO)	System functional
	Proportion of countries with access to proficient laboratories for at least measles confirmation.	77% 148 of 192 countries	94% 183 of 193 countries	100%
Target 6: Strengthen countries' capacities to maximize access to current, new and underutilized vaccines and accelerate disease control efforts				
ER 10: Provide advice and adequate technical support to maximize the impact of immunization and other linked interventions	Number of countries that have developed a financial sustainability plan or a fully costed and comprehensive multi-year plan.	5	69 countries have developed comprehensive multi year plans	45
	Number of countries that achieved >90% first dose measles coverage	97 of 192	60% (115 of 193)*	144 of 192
	Number of countries that have implemented a second opportunity for measles immunization within the preceding five years	168 of 192	94% (183/193)*	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 ¹²	153 of 192	89% (171 of 193) (inc.	192 of 192

¹⁰ The prequalification process is already well in place for injection equipment (during 2005, all 52 acceptable dossiers were reviewed within the stipulated timeframe) and the process is in the final stages for the rest of immunization equipment (cold boxes and vaccines carriers, refrigerators, etc...). For each category of equipment the procedure will stipulate a timeframe that WHO commits to comply with for the review of the dossier, once accepted. 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, therefore targets of 60% and 80% have been set

¹¹ Eleven countries included in the GAVI bridge financing mechanism for HepB & Hib combination vaccine by 2007

¹² Five countries have introduced HepB vaccination in adolescence.

			India and Sudan with partial intro)*	
	Number of countries that have introduced Hib vaccine	92 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	4	5
	Proportion of countries using only auto-disable syringes for immunizations	33% (63 of 192)	41% (79 of 193)*	65%
	Proportion of countries using open burning as a method of immunization waste disposal ¹³	43% (83 of 192)	39% (75 of 193)*	10%
Target 7: 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.				
ER 11: Polio activities integrated into each country's routine immunization services, upon reaching zero polio cases	Guidelines available for four common programme management issues ¹⁴ of the final stages of polio eradication with routine immunization programmes	0	Not eradicated	Polio eradicated
Others: The IVB Department managed and coordinated efficiently and effectively				
Effective global advocacy and communication for immunization	Number of media and advocacy events executed and number of information products developed	20	>250 ¹⁵	80
	Frequency of updating and improving IVB web site	As information is submitted	On a daily basis	Once a week minimum
Sound scientific policy and strategy maintained	Number of new vaccine position papers and updates published in the Weekly Epidemiological Record each year	2-3/year	11 in 2006-08 ¹⁶ 4 planned in 2009	4/year

¹³ Work on medical waste management is carried out within the WHO Department for the Protection of the Human Environment but the IVB Department 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.

* data for 2007

¹³ Integrated surveillance, integrated logistics, integrated management information systems and integrated human resources

¹⁴ Integrated surveillance, integrated logistics, integrated management information systems and integrated human resources

¹⁵ As of end-2007. In 2007, the number of WHO member states and territories increased from 192 to 193.

¹⁶ 4 published in 2006, 5 in 2007, and 2 in 2008. Temporary delays in 2008 were caused by enhanced procedures. Further delays are not anticipated in 2009.

