

Immunization highlights: 2008-09

Foreword

Global immunization has progressed measurably in recent years with more children being immunized than ever before. Polio cases have been further reduced in the few remaining endemic districts, measles mortality down by 78% globally and more equitable access to under-utilized and new vaccines such as those for the major killers pneumonia and diarrhoea.

However, the challenges in vaccinating hard-to-reach children, accounting for about one-fifth of children born each year, cannot

be underestimated. With an ever-increasing annual birth cohort, we must run harder to further cut the number of unimmunized. These key messages were well reflected in a couple of hundred media reports stemming from the Washington D.C. launch of the *State of the World's Vaccines and Immunization* in 2009.

WHO's emergency response to the influenza A (H1N1) pandemic in the area of vaccines and immunization included setting global vaccination policies based on best available evidence; work related to development of pandemic vaccines; ensuring access of developing countries to these vaccines; quality, safety and prequalification of vaccines; training and deployment to countries; and communication. This work contributed to overall efforts to mitigate the risks of the pandemic and made it clear that the world needs to step up

production and use of seasonal vaccines to be better prepared for future outbreaks.

The Immunization, Vaccines and Biologicals Department has begun working under a new strategic plan for 2010-2015 which sets out four major priority areas, with particular emphasis on stronger and expanded immunization systems to deliver all vaccines included in national programmes and working in synergy with other interventions to accelerate the achievement of disease control goals.

With all the pieces now in place to make an even bigger difference in immunization globally, it is important that the fragile gains made in recent years are sustained for the benefit of disadvantaged children and other risk groups worldwide. There is no doubt that immunization represents good value for money and the next decade will provide opportunities to maximize the potential of vaccines in saving and improving lives.

Dr Jean-Marie Okwo-Bele
Director

Department of Immunization,
Vaccines and Biologicals
World Health Organization,
Geneva

Table of contents

WHO's achievements in immunization

A. Global immunization policy	p.2
B. Research and development: vaccines and technologies	p.3
C. Quality, safety and standards for vaccines and immunization	p.5
D. Access to immunization services	p.10
E. Communications, advocacy and media	p.16
Immunization, Vaccines and Biologicals Strategic Plan 2010-2015	p.17

WHO's achievements in immunization

A. Global immunization policy

SAGE and global immunization policy

The Strategic Advisory Group of Experts (SAGE) on Immunization provides evidence-based advice to WHO on overall global policies and strategies relating to vaccines, technologies, research, development, delivery of immunization and its linkages with other health interventions.

SAGE is concerned with all vaccine-preventable diseases. In 2008-09, five SAGE meetings took place, including one extraordinary SAGE meeting focusing exclusively on the influenza A (H1N1) pandemic.

The latter was held in order to urgently make recommendations on the use of pandemic vaccines. Other recommendations issued by SAGE during this period covered the use of measles, HPV, hepatitis B, polio, cholera and rotavirus vaccines.

Strategic recommendations were also provided on hepatitis B control and the unvaccinated. All SAGE reports together with translations are available at:

http://www.who.int/immunization/sage_conclusions/en/index.html



WHO position papers published in 2008-09

Hepatitis B vaccines (revision), October 2009

Human papillomavirus (HPV) vaccines, April 2009

Measles vaccines (revision), August 2009

Pneumococcal polysaccharide vaccine (23-valent), October 2008

Rotavirus vaccine (update), December 2009

Typhoid vaccines (revision), February 2008

All the above-mentioned position papers, together with additional related material and translations, are available at:

http://www.who.int/immunization/documents/positionpapers_intro/en/index.html

Strengthening national technical advisory groups

One of WHO's priorities, as part of the process of ensuring evidence-based decision-making at country level, is to support the establishment and/or strengthening of national immunization technical advisory groups (NITAGs), increasingly called for or solicited given the complexity of immunization programmes and the higher cost of new vaccines. In a global survey conducted in 2008, 61% of the 147 countries which responded to the survey reported the existence of a NITAG. However, only 72% of these NITAGs have formal terms of reference and only 39% require declarations of interest from members, although these elements are essential for a well-functioning, credible NITAG. Standard guidance, terms

of reference and training materials have been developed for establishing or strengthening NITAGs to facilitate the evaluation of evidence for policy decision-making. Regional initiatives include briefing and training NITAGs' chairpersons, providing technical support, and fostering exchanges between NITAGs. Regions are assisted in their efforts by the Supporting National Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative funded by the Bill & Melinda Gates Foundation and by technical partners such as the United States Centers for Disease Control and Prevention (CDC). A web page has been created to facilitate exchange of information between NITAGs:

http://www.who.int/immunization/sage/national_advisory_committees/en/index.html

Providing vaccine policy information to countries and partners

A key component of WHO's immunization policy work is the publication of regularly updated position papers on vaccines and vaccine combinations which protect against diseases that have an international public health impact. These peer-reviewed papers are concerned primarily with the use of vaccines in large-scale immunization programmes; they summarize essential background information on diseases and vaccines, and conclude with the current WHO position concerning their use in the global context. SAGE reviews and endorses them; following this they are published in the *WHO Weekly Epidemiological Record*. Designed primarily for use by national public health officials and managers of immunization programmes, the papers may also be of interest to international funding agencies, the vaccine manufacturing industry, the medical community, the scientific media and the public. In accordance with requests from users, new papers are accompanied by a summary, slides, key references, and grading tables showing the scientific evidence on which recommendations are based. Originally published in English and French, the papers are translated into Arabic, Chinese, Russian and Spanish.

Impact of WHO immunization policy recommendations

An independent evaluation was undertaken on the impact of policy recommendations, norms and standards set by WHO and formulated by its key advisory committees on immunization matters. This evaluation was conducted by an independent panel representing key stakeholders of the global immunization community. At the panel's request, a country survey was implemented. The survey sought to understand the impact of WHO's normative and policy guidance related to vaccines and immunization on key decision-makers in countries, and to obtain suggestions for improvement in content, communication and access. The panel concluded its review in March 2009. Its conclusions and recommendations — http://www.who.int/immunization/sage/1_Stakeholders_panel_final_report_March_17.pdf — were presented and discussed at the April 2009 SAGE meeting. The panel concluded that WHO vaccine advisory committees are playing an increasingly central role in determining global vaccine policy. 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 a clear and significant impact. The key conclusions and recommendations contained in the papers are being republished in the peer-reviewed journal *Vaccine*.

Guiding countries in the development of optimal immunization schedules

To assist countries in creating optimal immunization schedules, WHO has produced tables summarizing its current recommendations on routine immunization. This compilation of the recommendations contained in WHO position papers on vaccines provides a list of the vaccines recommended as part of the routine schedule for all age groups: infants, children, adolescents and adults.

Details on the recommended timing of routine immunization of infants and children are also included. Designed primarily for managers of national immunization programmes and health workers, the tables and their accompanying notes are also intended as key reference material for chairs of national advisory committees on immunization and partner organizations.

Regularly updated, they are expected to serve as a driving force for the review and improvement of schedules, in keeping with the WHO-UNICEF *Global Immunization Vision and Strategy 2006-2015* (GIVS) which promotes immunization of all age groups. For more information: http://www.who.int/immunization/policy/immunization_tables/en/index.html

B. Research and development: vaccines and technologies

Ethical conduct of HIV/AIDS vaccine trials

In collaboration with the Joint United Nations Programme on HIV/AIDS (UNAIDS; AIDS: acquired immunodeficiency syndrome), two training modules were developed (in English and French) for the practical application of the 2007 *WHO/UNAIDS Guidance document on ethical considerations in HIV*

preventive research. In 2009, two pilot workshops (for English and French speakers) were organized in Dakar, Senegal and Durban, South Africa. These workshops were designed using experience from HIV vaccine clinical trials and other trials of interventions to prevent HIV (e.g., microbicides, male circumcision), as well as non-HIV vaccine trials. The workshops targeted not only members of ethics committees and institutional review

boards, but were also attended by representatives of national regulatory authorities, national policy-makers, scientists and community representatives. Participants found the training modules useful. It was clearly recognized that such a multi-disciplinary approach made it possible to obtain input from all parties who are interested in maintaining the highest levels of ethical standards in all vaccine and prevention trials.

Evaluation of dengue vaccines

Despite renewed efforts in vector control, dengue disease continues to be on the rise, as exemplified by major outbreaks in Brazil in 2008 and West Africa in 2009. To support the development and evaluation of dengue vaccines, WHO has produced *Guidelines for the evaluation of dengue vaccines in endemic areas*, published in 2008 and widely disseminated:

http://whqlibdoc.who.int/hq/2008/WHO_IVB_08.12_eng.pdf.

The document proved to be timely, and the guidelines were seminal in the design of a large-scale proof-of-concept dengue vaccine trial launched in 2009 in Thailand. The Guidelines inform regulatory authorities in the review of clinical trial applications and serve as reference material for training. WHO has also embarked on preparing up-to-date guidelines for the production, evaluation and quality control of dengue vaccines as the basis for prequalification of future vaccines. Particular attention will be given to vaccine safety, including environmental safety, as most advanced vaccine candidates contain live, recombinant viruses. WHO is collaborating closely with the Pediatric Dengue Vaccine Initiative and other partners on the study of health and economic aspects of dengue disease and the development of scenarios for immunization strategies.

Economic evaluations of vaccination programmes

A number of reviews have indicated that there is scope for improving the transparency, completeness and comparability of economic evaluations of vaccination programmes. In 2008, WHO released a *Guide on standardization of economic evaluations of immunization programmes*. Adherence to such guidelines would increase the quality, interpretability and transferability of future analyses. Several systematic reviews of cost-effectiveness analyses of pneumococcal and rotavirus vaccines have been published. However, structured, systematic comparisons of the decision-making tools themselves underlying these published cost-effectiveness analysis studies are lacking. Given the complexity and importance of mathematical models and cost-effectiveness tools, it is critical to evaluate their robustness and applicability to vaccine policy. In order to guide country decision-makers on the strengths and potential pitfalls of several existing tools available both in the public and private sectors, WHO facilitated workshops for pneumococcal and rotavirus vaccine models. The objective of these exercises was to provide policy-makers with a menu of tools and their characteristics, rather than to recommend a single model.

Towards more effective malaria vaccines

To provide consensus-based recommendations related to whole organism malaria vaccine research for endemic countries, WHO conducted a scientific consultation in Senegal in 2009. Significant progress, challenges and issues requiring further work were identified.

A potentially deployable subunit malaria vaccine, RTS,S/AS01, reached the pivotal Phase 3 stage in clinical trials in May 2009. WHO technical experts provided guidance on Phase 3 data required for an eventual WHO policy recommendation. In 2009, the Organization published a guidance document on clinical evaluation of *P. vivax* vaccines in endemic populations.

Also in 2009, WHO led the development of a technical agenda for a joint WHO, United States Agency for International Development (USAID), PATH Malaria Vaccine Initiative and European Vaccine Initiative meeting on standardization of the clinical challenge model in malaria. With participation of all centres conducting such challenges globally, recommendations were agreed to standardize and strengthen this model, which has a central role in malaria vaccine development.

From development to use of a group A meningococcal conjugate vaccine

Within the Meningitis Vaccine Project, results from completed clinical trials of the meningococcal A conjugate vaccine demonstrated safety and a sustainable, high immune response, when administered to one to 29 year-olds in Africa and India. These findings led to licensure for export in December 2009 by the Drugs Controller General in India, allowing the vaccine to be used in single-dose mass vaccination campaigns in one to 29 year-olds in the countries of the African meningitis belt, a target population of about 250 million people.

Provac - strengthening country capacity to make evidence-based decisions

The Pan American Health Organization's ProVac Initiative aims at strengthening technical capacity at the country level to make evidence-based decisions on the introduction of new vaccines. Funded by the Bill & Melinda Gates Foundation, through ProVac, analyses have been performed in 14 countries of Latin America and the Caribbean over a two-year period. A working group, comprised of WHO, CDC and other partners, is being formed to implement ProVac models and methodology in other Regions.

Assisting developing countries with influenza vaccine production

Since 2006, WHO has been implementing an ambitious programme to enhance the capacity of developing countries to produce pandemic influenza vaccines. The aim is to facilitate integration of locally-produced influenza vaccines into national and regional pandemic control plans and/or responses to influenza pandemics, and ensure sustainable influenza vaccine production. Under the aegis of the WHO *Global pandemic action plan to increase vaccine supply*, the programme supplies funds and facilitates technology transfer.

During the last three years, the initiative has provided more than US\$ 30 million in financial support. In total, eleven grantees have received funds, with continued support to an initial six manufacturers and new grants provided to five additional producers in 2009. In the context of an ongoing H1N1 influenza pandemic, by the end of 2009 six of the companies had produced clinical lots of pandemic

A (H1N1) vaccine, four had completed or were conducting clinical trials, and two had registered a vaccine for use in their countries to combat the ongoing pandemic. Another grant recipient licensed a new seasonal influenza vaccine in 2009 which was then introduced into the domestic market in Indonesia.

To develop surge capacity, a royalty-free license was negotiated by WHO on the live attenuated influenza vaccine technology (LAIV), and three sub-licenses were finalized with developing country vaccine manufacturers. In 2009, two of the WHO grant recipients initiated pandemic A (H1N1) clinical trials with a LAIV product manufactured at their newly established production facilities. To further support the programme, a WHO technology transfer and training center for egg-based, inactivated influenza vaccines was established at the Netherlands Vaccine Institute (NVI) campus in Bilthoven. After more than €4 million investment by WHO, the center became fully operational in 2009. It provides training and transfers technology to interested developing and emerging economy countries.

Ensuring African leadership in HIV vaccine development

Since its inception in 2000, the African AIDS Vaccine Programme (AAVP) has been hosted at WHO. Over the past years, this initiative has developed well, and is starting to play an active role in the global agenda to promote the development of human immunodeficiency virus (HIV) vaccines. All key stakeholders recommend that AAVP serve as the real voice of Africa, based in Africa and led by African scientists. In 2009, the WHO HIV vaccine team, in collaboration with UNAIDS and the Global HIV Vaccine Enterprise,

initiated a process to transition AAVP to Africa. This process was guided by an external panel composed of representatives from a range of stakeholders. The panel selected the Uganda Virus Research Institute based in Entebbe, Uganda to host AAVP, after an open, competitive and transparent selection process. This was announced at the 5th AAVP Forum which was held in December 2009 in Kampala, Uganda. The Forum also generated a series of recommendations for AAVP and its partners regarding future challenges and the ways that these challenges should be addressed in order to accelerate the development and



future availability of safe and effective HIV vaccines for populations who are most in need of such vaccines.

C. Quality, safety and standards for vaccines and immunization

Paving the way for WHO guidelines on biosimilars

Following recommendations made by the Expert Committee on Biological Standardization in October 2008 on further strengthening the draft WHO guidelines on biosimilars (biological products which resemble innovative products and are marketed following the expiry of their patent), a drafting group met in February 2009 in Tokyo, Japan, to work on the document. The discussion covered a range of topics including: the overall scope of the guidelines; principles for the evaluation of such products; comparability

studies and demonstration of similarity; quality assessment; design of clinical studies; and safety evaluation. Agreement on further revisions was reached, and a deadline set for submission of the revised version to national regulatory authorities and manufacturers for review. The proposed guidelines highlight that existing regulatory pathways for biologics and pharmaceuticals are not suitable for generic versions of medicines using biological material. Based on the inputs received through this extensive consultative process, a revised proposal for new guidelines was made to the Committee at its 2009 meeting.

Regulators in developing and industrialized countries intensify collaboration

The 8th Meeting of the Developing Countries Vaccine Regulators Network, held in Pretoria, South Africa, in May 2008, provided another opportunity for information exchange and skills development among regulators in developing and industrialized countries.

Member countries were joined by non-member countries — Belgium, Canada, the Netherlands, the United Kingdom of Great Britain and Northern Ireland, the United States of America and Viet Nam. Highlights of the meeting included the decision by Brazil and Indonesia to implement a new regulatory process on a pilot basis to regulate the clinical development of new vaccines; the agreement of Indonesia and South Africa to become training centres for the WHO Global Training Network for Vaccine Quality, with three courses to be given in 2008; and agreement on new mechanisms for incorporating Network discussions into the consultation process leading to WHO guidance documents.

Growing demand for expert-approved standards

The WHO Expert Committee on Biological Standardization, established in 1947, sets norms and standards for vaccines. Standards developed through the Committee, at its annual meetings, relate to the production and quality control of safe and effective products. The standards also serve as the benchmark for acceptability of vaccines for supply to countries through international agencies (prequalification). Biological standards (reference preparations) are also established by the Committee and provide the basis for the laboratory comparison of vaccines worldwide. International standards are essential components of dealing with global public health issues such as the H1N1 influenza pandemic, in that they provide the base technical specifications for the manufacture of vaccines and other biologicals. The process that is in place for standard-setting also facilitates the rapid establishment of communities of experts required in such situations. With the increasing pace of development and introduction of new and improved vaccines, the demands on the Committee are growing. Written guidelines that were approved by the Committee in 2008-09 are:

- *Guidelines on Production, Control and Regulation of Snake Antivenom Immunoglobulins;*
- *Amendment to the standard for yellow fever vaccine* (to express potency in International Units);
- *Recommendations to assure the quality, safety, and efficacy of live attenuated influenza vaccines* (revision);
- *Recommendations to assure the quality, safety and efficacy of pneumococcal conjugate vaccines* (revision); and
- *Guidelines on evaluation of similar biotherapeutic products.*

Full reports of Committee meetings are published in the WHO Technical Report Series:

<http://www.who.int/biologicals/publications/trs/en/index.html>.

Thai vaccine regulatory body is fully functional

Based on the outcomes of an external audit process, WHO informed the Government of Thailand that, as of 19 December 2008, the national regulatory authority represented by the Thai Food and Drug Administration was certified as functional, fulfilling the six WHO regulatory functions for vaccines. This paved the way for WHO prequalification of vaccines made in Thailand. Thailand was the eighth developing country with a vaccine producer gaining eligibility for WHO-prequalified products (the other seven countries being Brazil, Bulgaria, Cuba, India, Indonesia, the Russian Federation and Senegal). Given that Thailand is producing influenza and Japanese encephalitis vaccines, this milestone represented a step forward in efforts to increase future global production of prequalified influenza vaccines and for a prequalified Japanese encephalitis vaccine, for which there is presently no prequalified product.

Revising guidelines on pneumococcal conjugate vaccines

Input was provided on proposed revisions to the WHO guidelines on pneumococcal conjugate vaccines at a meeting of vaccine manufacturers, national regulatory authorities and academia held in London, United Kingdom, in June 2009. Consensus was reached on a number of critical issues, such as the design of immunogenicity studies that should be performed to support the licensure of new pneumococcal conjugate vaccines. This facilitated the subsequent steps required before submission of the document to the Expert Committee on Biological Standardization at its meeting of October 2009. The need for revisiting the guidelines was due to the significant advances that have been made in the development and availability of new multivalent pneumococcal conjugate vaccines in recent years.

Review of status and future priorities for reference preparations

Continuing its close collaboration with the National Institute for Biological Standards and Control in the United Kingdom of Great Britain and Northern Ireland, which develops the majority of the reference preparations (biological materials which provide the basis for laboratory comparison) for vaccines and other biological medicines, WHO and Institute staff met in March 2009 to review the status of ongoing work and future priorities. Issues of general importance included the preparation of genetic reference materials, communication with other WHO collaborating centres for biological standardization, and joint

studies with other standard-setting bodies. More than 30 reference preparations were reviewed.

Three quarters of vaccine-producing countries meet high standards of regulatory quality

WHO continued, during the biennium, to strengthen national regulatory authorities. Priority was given to those vaccine-producing developing countries whose production levels have a significant impact on global supply. Countries benefiting from visits by WHO teams (for monitoring of national regulatory authority institutional development plans and training) were Bangladesh, Brazil, China, Cuba, Egypt, India,

Indonesia, Iran, Japan, Senegal, Thailand, and Viet Nam. By the end of September 2009, 20 of the 44 vaccine-producing countries had at least one WHO-prequalified vaccine. This includes five of the eight eligible developing countries. Intensive efforts have been made during the biennium to develop and sustain assured quality of vaccine production in two major producing countries (China and India). Thirty-three (75%) of the 44 countries had been assessed or re-assessed, as of the end of September 2009, as having a regulatory system meeting the critical indicators required to enable WHO prequalification of vaccines. Vaccine supply from these 33 countries constitutes about 75% of that used in national immunization programmes.

Learning about vaccine quality

WHO's Global Training Network for Vaccine Quality was first established in 1996 with the mission of improving practices related to vaccine quality. The overall goal of the Network is to strengthen, expand and maintain vaccine quality-related practices of national regulatory authorities in developing and middle-income countries. Over the last three years, the philosophy behind the Network's courses has dramatically changed and new approaches have been developed to enhance the learning environment and outcomes. In November 2009, the Network changed its name to Global Learning Opportunities for Vaccine Quality to reflect the shift from "training" to "learning". Development of skills required to access and use knowledge in a

changing environment is stressed. In 2008-09, a total of 23 courses were held on the following topics:

- Clinical data evaluation for registration of new vaccines;
- Clinical trials authorization;
- Designing courses for learning;
- Good clinical practice inspection;
- Good manufacturing practice inspection;
- Lot release;
- Quality control of *Haemophilus influenzae* type b (Hib) conjugate vaccines;
- Pharmaceutical cold-chain management;
- Training skills; and
- Vaccine quality control technology.

These courses mainly targeted national regulatory authorities in developing countries, with a special focus on Africa. In late 2008, the Network extended its support to course graduates through establishing on-line communities where extensive discussions take place and experiences are shared. In 2009, new Learning Centres were set up in Africa and South-East Asia, and more courses will be offered in French and through e-learning. It is hoped that participation will increase and costs will be reduced.



Indian national regulatory authority again “fully functional” following internationally-backed efforts and inspection

In April 2009, WHO pronounced the Indian national regulatory authority, the Drug Controller General of India, fully functional. This important achievement was the result of a collaborative effort which followed WHO's assessment in January 2008 that India had failed to meet WHO indicators for licensing and market authorization required for prequalification of vaccines produced in the country. WHO then worked with the Indian national regulatory authority on developing a roadmap to help regain functionality within two years. With the technical assistance of Health Canada and financial support from

USAID, a series of activities followed which included the establishment of a group of scientists working exclusively on vaccine regulation, training of senior officials and junior staff, recruitment of 100 staff funded by the Government of India, and regular technical follow up by WHO. The reassessment, conducted in April 2009 by an international team of regulatory and immunization experts from WHO and the regulatory authorities of Belgium, Egypt, France, Senegal, Thailand, Tunisia and the United States of America, clearly showed that all requirements had been met: the Indian authority was in compliance with all critical indicators for WHO prequalification of their vaccines. Given that vaccines produced in India are used in more than 150 national immunization programmes, the impact of this decision on global vaccine supply is significant.

Safety data on HPV vaccines reassuring

The accumulating evidence on the safety of HPV vaccines reviewed by the Global Advisory Committee on Vaccine Safety at its June 2009 meeting proved reassuring.

By March 2009, more than 60 million doses of the quadrivalent or bivalent HPV vaccine had been distributed either as part of national immunization programmes (in 21 countries) or by private physicians. The most common adverse events were reactions at the injection site and muscle pain, with allergic reactions also reported.

While the safety profile of HPV vaccines is encouraging, the collection of high-quality safety data from different geographical locations and epidemiological settings where the vaccine is being introduced remains a high priority.

Lab testing of vaccine consistency — a critical component of vaccine quality work

Testing of three to five final lots of vaccine for consistency of final product characteristics is performed as part of initial prequalification assessments and for continuous monitoring of the quality of vaccines already prequalified. Lots are tested in parallel by at least two independent WHO-contracted laboratories. In order to address the increased demand for evaluation of traditional and novel vaccines (rotavirus, pneumococcal, HPV, and potentially Japanese encephalitis and typhoid), acceleration of the process of standardization and validation of tests and expansion of testing capacity is under way. Currently, WHO works with 15 laboratories: one in the African Region, two in the Region of the Americas, nine in the European Region, one in the South-East Asia Region, and two in the Western Pacific Region.

Polio vaccines — working towards optimal supply to meet programme needs

Manufacturers of polio vaccines and representatives of national regulatory authorities were updated at an annual meeting hosted by WHO and UNICEF in October 2009 on the status of efforts towards polio eradication, and the current strategy of the Global Polio Eradication Initiative. Participants were briefed about projected demand for all types of oral polio vaccine for 2010-2015 and UNICEF's plan for tenders. Information was presented on the use, in selected countries, of bivalent oral polio vaccine (containing types 1 and 3 only). Results of several clinical trials of monovalent and bivalent oral polio vaccines in endemic countries demonstrated clear evidence of the seroprotection acquired with both types of vaccines. A session on routine immunization highlighted the potential role of inactivated polio vaccine (IPV) in the near future. Also discussed were post-eradication policy and product development, with a special focus on the WHO programme of work to make IPV more affordable.

Global blueprint for vaccine safety: work initiated

An ambitious, much-needed project to analyze vaccine safety infrastructure in developing countries and to develop a blueprint for a global vaccine safety consortium, began in the fourth quarter of 2009.

The first activity of this 15-month project is to gather data on vaccine safety infrastructure in low-income countries.

Analysis of this data will be followed by the determination of the minimum capacity required by countries for ensuring vaccine safety and the development of a strategic plan involving key vaccine safety stakeholders across the world to achieve this goal. Wide consultation with key stakeholders and WHO advisory bodies will follow.

A budget, funding options and governance mechanism for implementation of the strategic plan will then be compiled, with the launch of the consortium expected in early 2011.

Safety profile of candidate malaria vaccine reviewed for the first time

The Global Advisory Committee on Vaccine Safety reviewed for the first time the safety profile of a malaria vaccine — using data from phase I and phase II trials of RTS,S/AS01 — and concluded that currently available safety data are encouraging, although data are only available for a relatively small number of children. The safety profile of the adjuvant (substance added to the vaccine to enhance the immune response) used for the vaccine was also reviewed; this adjuvant is delivered with a number of experimental vaccines, mostly at present in adult volunteers during phase I clinical trials. In addition, the Global Advisory Committee on Vaccine Safety considered in 2008-09:

- diphtheria, tetanus and pertussis (DTP) vaccines and asthma;
- measles vaccination of children infected with HIV;
- mitochondrial diseases and vaccination;
- novel influenza vaccines and advice on preparing for influenza vaccine campaigns;

- reactions related to vaccine components other than antigens (adjuvants, preservatives and by-products from the manufacturing process);
- the analysis of adverse events following immunization through global networks.
- the safe use of vaccines among persons with immune deficiencies;
- thiomersal (a vaccine preservative and inactivating agent); and
- yellow fever vaccines.

New database to monitor vaccine doses

A WHO global database to monitor all doses of vaccines produced, distributed and administered in national immunization programmes has been developed and is currently being tested in several countries. The first phase of testing was completed by the end of 2009, with national regulatory authorities and manufacturers to be invited to use the tool in 2011 and by the end of 2012, respectively.

Vaccine prequalification expedited

Set up over 20 years ago, WHO's seal of approval, or prequalification, is a mechanism for ensuring that all countries can be supplied with vaccines of assured quality. In August 2008, a review was undertaken of the time required for vaccine prequalification by WHO. Analysis showed that the vast majority of applications in process in 2008 were on track to meet set targets: a vaccine must be prequalified 18 months from submission of a file by a manufacturer, or within a maximum of one year (not including periods during which responses from manufacturers were pending — estimated to take about six months). It is expected that 100% of submissions will meet the target deadlines by September 2011.

For one meningococcal vaccine accepted for fast track evaluation, the whole process took just 99 days. Vaccine prequalification is a process by which WHO assesses vaccines for their suitability for provision to countries through international agencies. The system is widely credited with contributing to the growing number and proportion of quality vaccines being supplied by companies in developing countries, such as Brazil, Cuba, India, Indonesia and Senegal. Approximately 53% of global childhood immunizations use WHO prequalified vaccines. A database of WHO prequalified vaccines is available at:

http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/index.html

New global network to help ensure vaccine quality in developing countries

Representatives from Albania, India, Senegal, Tunisia, Uganda and Viet Nam gathered with staff from WHO, UNICEF Supply Division, and the Uppsala Monitoring Centre in October 2008 in Uppsala, Sweden for the first meeting of the Global Network for Post-marketing Surveillance of Newly Prequalified Vaccines. The group discussed network operations, roles and responsibilities of partners, and data management and analysis. This network is a core component of efforts to ensure the quality of vaccines used in WHO-supported programmes. As vaccine products become increasingly divergent in their presentations, developing countries use vaccines that are not used, or are in limited use, in parts of the world with stronger post-marketing surveillance systems. In collaboration with key partners working in immunization programmes and vaccine procurement, this initiative provides an opportunity to harmonize methods, exchange information, and build capacity in countries with weak systems. This will help ensure that the use of vaccines in all parts of the world can be supported by adequate monitoring and response. It will also improve the ability to address rumours and vaccine scares with adequate and locally-generated data. Good progress was made during the remainder of the biennium in moving the work of the Network forward. As of the end of 2009, 10 countries were included in the Network, with initial visits to provide technical support made to all of them.

No evidence that pentavalent vaccine caused deaths in Sri Lanka

A WHO-constituted independent panel of experts concluded in December 2008 that there was no evidence of a causal relationship between administration of the liquid pentavalent vaccine Quinvaxem and any of the five deaths reported following use of the vaccine in Sri Lanka.

The panel was also asked to review eight additional deaths reported in Sri Lanka following vaccination (with varying combinations of DTP, hepatitis B and oral polio vaccines) and found no causal relationships between any of those deaths and the

respective vaccines administered. The independent review followed an initial investigation of the reported adverse events by the national authorities with technical assistance from WHO, and a review of vaccine quality by WHO.

At the request of Member State governments, WHO provides assistance to national authorities for the investigation of serious adverse events following immunization.

In particular, WHO works with national authorities to ensure appropriate investigation and response to serious adverse events reported following the administration of WHO-prequalified vaccines.

Global Advisory Committee on Vaccine Safety

The Global Advisory Committee on Vaccine Safety was established in 1999 to respond promptly, efficiently, and with scientific rigour to vaccine safety issues of potential global importance. At its biannual meetings — and between meetings when necessary — it reviews the latest knowledge on vaccines, in close collaboration with experts from national governments, academia, and industry. It assesses the evidence for purported relationships between vaccines and/or their components, and adverse events attributed to them. All reports of the Committee are available at: http://www.who.int/vaccine_safety/en/

D. Access to immunization services

Polio eradication – cause for optimism

In 2008, recognizing delays in achieving global polio eradication, the World Health Assembly called for a new strategy to eradicate polio from the remaining affected areas. Consequently, a special one-year Programme of Work for 2009 was developed and implemented to examine new tactical innovations in each endemic area; conduct clinical trials of new oral polio vaccine formulations (i.e. the new bivalent oral polio vaccine containing both serotypes 1 and 3); and facilitate an independent evaluation of major barriers to interrupting poliovirus transmission.

By the end of 2009, it became clear that important serologic, programmatic and epidemiological progress had been made, particularly in key reservoir areas of northern Nigeria and northern India. The evaluation also confirmed that different thresholds of population immunity are required to achieve success in the remaining affected areas of Africa and Asia.

In Asia, transmission is persistent in an extremely limited number of districts where levels of population immunity of more than 95% are required to interrupt transmission of wild poliovirus. In sub-Saharan Africa, virus transmission persists over a much broader area, but with a significantly lower population immunity threshold for stopping the virus (i.e. greater than 80%).

Validating maternal and neonatal tetanus elimination

Maternal and neonatal tetanus kills tens of thousands of newborns each year, most of them in developing countries. Yet, it is preventable through hygienic birth practices and immunization of women of childbearing age with tetanus toxoid vaccine. Three countries – Bangladesh, the Democratic Republic of the Congo and Turkey – were validated in 2008-09 as having eliminated maternal and neonatal tetanus. With Turkey's validation, all countries in the WHO European Region have met the maternal and neonatal tetanus elimination goal. In addition, two Indian states – Himachal Pradesh and Gujarat – achieved elimination status, making a total of 15 states and union territories that have so far been validated in India. This progress is due to the increase in tetanus toxoid coverage rates in the routine immunization programme; implementation of tetanus immunization campaigns to increase protection levels among women of reproductive age living in high risk areas; and a better use of skilled birth attendants. By the end of 2009, 14 out of the 58 countries where maternal and neonatal tetanus persist as public health problems had achieved elimination. As tetanus cannot be eradicated, countries that have eliminated maternal and neonatal tetanus need to ensure that appropriate strategies remain in place to maintain their elimination status.

Monitoring progress and challenges in reducing measles deaths

During 2000-08, measles deaths worldwide fell by 78% from an estimated 733 000 deaths in 2000 to 164 000 in 2008. Global routine vaccination coverage with the first dose of measles vaccine reached 83%, its highest level ever. About 686 million children aged nine months to 14 years received a second opportunity for measles immunization through supplementary immunization activities (SIAs) in 2008. In addition, an estimated 4.3 million deaths were prevented as a result of increases in routine immunization coverage and implementation of SIAs. Despite impressive progress, the majority of global measles deaths in 2008 occur among children under the age of five years. About three quarters of the estimated measles deaths were concentrated in South-East Asia. Since 2008, there has been a considerable decline in funding and political commitment for measles control that has resulted in the stagnation of progress. Being one of the most contagious diseases, measles is making a rapid comeback. In 2009, there were large measles outbreaks in twenty-two countries: Afghanistan, Angola, Bangladesh, Botswana, Bulgaria, Burkina Faso, Chad, Ethiopia, France, Indonesia, Lesotho, Liberia, Malawi, Mali, Namibia, Nepal, the Philippines, South Africa, Thailand, the United Kingdom of Great Britain and Northern Ireland, Viet Nam and Zimbabwe. More alarmingly, WHO estimates that the combined effect of decreased financial and political commitment could result in a return to over 500 000 measles deaths a year by 2012, wiping out the gains made over the past decade.

Mobilizing debt relief resources for immunization financing

Since 2006, WHO technical experts have conducted an in-depth study of debt relief initiatives for low income countries. The aim is to get a better understanding of the mechanisms through which debt relief funds are managed and possibly channelled to the health sector. Forty-one of the poorest and most heavily indebted countries – of which 33 are located in Africa – are currently eligible to benefit from debt reduction under the enhanced Heavily Indebted Poor Countries Initiative and from cancellation of multilateral debt under the more recent Multilateral Debt Relief Initiative. Taken together, participating creditors have committed over US\$ 110 billion to 34 countries which have already qualified. Routine immunization coverage is used as an indicator of progress for countries to access debt relief. Donors and beneficiary governments have agreed on the principle to use the available resources from debt relief for higher public spending on poverty reduction. The relevance of these debt relief initiatives — in terms of boosting health and immunization expenditure — depends on the compliance of donors to provide debt relief in addition to other forms of foreign aid and the success of health and immunization officials to advocate for an adequate share of additional fiscal resources. In November 2008, analysis from the study showed that in countries such as Burundi, Cameroon, Madagascar and Mauritania, between 20% and 35% of total available debt relief resources have been allocated to the health sector, with a significant part devoted to priority interventions such as immunization. For more information on the findings of the study:

<http://www.who.int/bulletin/volumes/86/11/08-053686/en/index.html>

Examining the feasibility of global measles eradication

A report on the global eradication of measles was discussed by delegates at the 125th session of the WHO Executive Board held in May 2009. The report summarizes the progress and challenges towards achieving the regional measles elimination goals and reducing global measles deaths by 90% over the period 2000-10. The report also highlights the programme of work initiated by WHO to examine the feasibility of global measles eradication including reviewing the biological aspects and cost-

effectiveness of such a goal. Member States were encouraged by the progress in measles mortality reduction in a number of regions and the success in the Americas in interrupting measles transmission (i.e. achieving measles elimination at a regional level). Cognizant of the challenges ahead, Member States raised the following issues: vaccine supply security, public concerns over the perceived safety of vaccination, the importance of maintaining high routine vaccination coverage, funding gaps and the need to do more in the South-East Asia region. WHO reported back to the Executive Board on the feasibility of measles eradication in

January 2010. For more information: http://apps.who.int/gb/ebwha/pdf_files/EB126/B126_17-en.pdf

Preparing for the deployment and use of pandemic vaccines

From September to November 2009, WHO conducted training workshops in all regions to support countries to develop national plans for vaccine deployment. Technical guidelines on pandemic influenza vaccine deployment, developed by WHO, were used during the training.

Expanding the global measles laboratory network

In 2008, 183 countries reported measles surveillance data to WHO and UNICEF through the annual Joint Reporting Form, up from 169 countries in 2000. The number of reported measles cases declined by 67% from an estimated 850 000 in 2000 to nearly 282 000 in 2008. In addition, 173 of WHO's 193 Member States had implemented case-based surveillance, up from 120 countries in 2004 when data collection on global case-based surveillance began. In 1988, there were fewer than 40 laboratories in WHO's measles and rubella laboratory network. By the end of 2009, this network had expanded to 679 national and sub-national laboratories serving 183 countries.

Seventy countries with immunization financing plans

Since the launch of the WHO-UNICEF *Global Immunization Vision and Strategy* in 2005, over 70 low- and lower-middle-income countries have developed comprehensive multi-year plans to finance their immunization programmes. A review of the plans show that countries are planning to introduce new vaccines in the coming years and increasing efforts are being made to integrate immunization with other health programmes and disease surveillance activities. To achieve the immunization goals, expenditures will need to double over the next three years. However, the needed financing is not yet secured.

Updating training materials for immunization managers

In response to the evolving world of immunization, WHO developed eight concise and comprehensive modules on immunization training for mid-level managers. Training on new vaccine introduction is addressed in all of the modules. Each module is organized into a series of steps, in which technical information is followed by learning activities. A compact disc entitled *Resources for immunization managers*, has also been produced which includes an extensive collection of technical documents, reports and training materials that are useful for immunization staff in the field.

Evaluating and improving systems for vaccine delivery

Optimize, a five-year WHO-PATH collaboration, has been given a unique mandate to design innovative vaccine supply chains and technologies that are flexible and robust enough to handle an increasingly large and costly portfolio of vaccines. Putting technological and scientific advances to work, Optimize is helping to define a set of ideal characteristics that will guide the development of new vaccines and products, ensuring that they are designed for maximum efficiency and safety in the field. In 2009, Optimize launched a collaborative study with WHO's Quality, Safety and Standards team to explore the possibility of re-licensing hepatitis B vaccine to take advantage of the vaccine's stability profile. While the vaccine is currently licensed to be stored between 2°C and 8°C, preliminary data indicates it could be stable for a few months at 37°C. A re-license reflecting this would provide countries with the flexibility to deliver a hepatitis B birth dose in remote areas where maintaining 2°C to 8°C storage conditions is not feasible. Optimize is also collaborating with five countries — Albania, Guatemala, Senegal, Tunisia and Viet Nam — to test innovative approaches to strengthening supply systems so that vaccines and other health products reach the right place at the right time and in the right quantities, without compromising quality. In addition, Optimize began a collaborative process to develop a vision for the future of immunization supply chains, from health products to policies and logistic systems. Key to this will be developing consensus and building momentum around this vision among major partners and stakeholders.

Building capacity to reach more Indian children with vaccines

India accounts for the largest number of unimmunized children in the world with nearly ten million children remaining unimmunized each year. To improve India's immunization coverage, a training workshop was jointly organized by the Government of India and WHO in collaboration with CDC, USAID, UNICEF, PATH and other partners.

The purpose of the workshop was to update immunization health officers on current policies and strategies in immunization including new vaccines available for introduction in national programmes. Trainers assisted Expanded Programme on Immunization (EPI) managers to analyse issues and problems in their respective work areas and to develop a plan of action to improve immunization coverage in priority districts. Managers from all 29 states in India, as well as WHO and UNICEF field staff, participated in the training session.

At the end of the session, managers presented their plans of action and highlighted several areas that needed strengthening such as human resources, earmarking of additional funds for immunization activities and improving vaccine management, including logistics and vaccine supply. Increased resources available through the National Rural and Urban Health Missions were identified that could be utilized to strengthen the country's immunization programme.

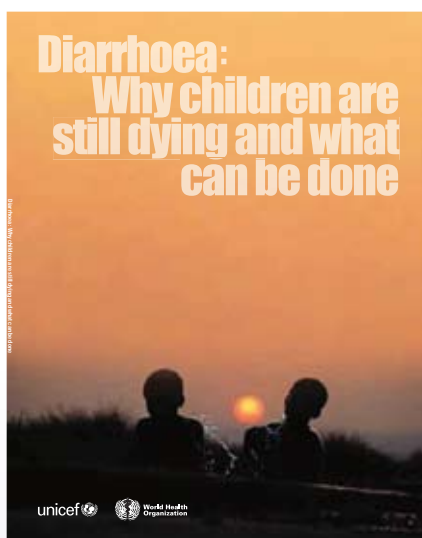
Launching of the Accelerated Vaccine Introduction Initiative

Historically, the time lag between introduction of a vaccine in the developed world and the developing world has been up to 15 to 20 years. The Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative were established to reduce the time between vaccines being proven safe and effective for use and their introduction in developing countries. With the phasing out of the ADIPs and the Hib Initiative, the work of supporting countries to make evidence-based decisions on the introduction of new vaccines will be carried on by the Accelerated Vaccine Introduction (AVI) initiative. The AVI is a partnership between WHO, UNICEF, the GAVI Alliance and a consortium which includes PATH, CDC and Johns Hopkins Bloomberg School of Public Health. WHO leads the country implementation and disease surveillance work of the Initiative.

Supporting the introduction of pneumococcal vaccine in the Gambia and Rwanda

In 2009, the Gambia and Rwanda introduced pneumococcal vaccine into their national immunization programmes. The vaccine protects children against pneumococcal disease, which can cause potentially life-threatening illnesses such as pneumonia, meningitis and sepsis. These accelerated introductions were made possible by the partnership between the governments of the Gambia and Rwanda, the GAVI Alliance, UNICEF, USAID, WHO and Wyeth Pharmaceuticals. Accelerating routine use of this lifesaving vaccine in low-income countries has the potential to save millions of lives and put these countries significantly closer to reaching Millennium Development Goal four, to reduce by two-thirds, between 1990 and 2015, the under-five mortality rate.

Introducing vaccines as part of comprehensive disease control strategies for diarrhoea and pneumonia



In 2009, WHO and UNICEF launched two reports outlining comprehensive strategies to prevent and treat diarrhoea and pneumonia – two leading causes of death among children under five years of age globally. Diarrhoea kills an estimated 1.4 million children each year. Inexpensive and effective treatments for diarrhoea exist but in developing countries, only 39% of children with diarrhoea receive the recommended treatment. Pneumonia kills about 1.8 million children each year, more than

98% of which occur in 68 developing countries.

The report *Diarrhoea: why children are still dying and what can be done* focuses on the prevention and management of diarrhoeal diseases as central to improving child survival. Most importantly, it lays out a seven-point plan to reduce childhood deaths from diarrhoea and a prevention strategy to ensure long-term results. The seven specific points are: (1) fluid replacement to prevent dehydration; (2) zinc treatment; (3) rotavirus and measles vaccinations; (4) promotion of early and exclusive breastfeeding and vitamin A supplementation; (5) promotion of hand washing with soap; (6) improved water supply quantity and quality, including treatment and safe storage of household water; and (7) community-wide sanitation promotion. The report is available at:

http://www.who.int/child_adolescent_health/documents/9789241598415/en/index.html

The *Global action plan for the prevention and control of pneumonia* (GAPP) includes recommendations on what needs to be done, specific goals and targets, estimates of what it will cost and how many lives will be saved. The cost of implementing the GAPP by scaling up the recommended

measures in 68 high burden countries is estimated at US\$ 39 billion for 2010–15. The costs are expected to double over the six-year period, rising from an annual need of US\$ 3.8 billion in 2010 to US\$ 8.0 billion by 2015. The GAPP has a three-pronged vision:

1. Protecting children by providing an environment where they are at low risk of pneumonia. This can be achieved with exclusive breastfeeding for six months, adequate nutrition, preventing low-birth-weight, reducing indoor air pollution, and increasing hand washing;
2. Preventing children from becoming ill with pneumonia. This can be achieved with vaccination against its causes: measles, pertussis, *Streptococcus pneumoniae* and Hib, as well as preventing and treating HIV in children, and providing zinc for children with diarrhoea; and
3. Treating children who become ill with pneumonia. This can be achieved with effective case management (including treatment with) antibiotics in communities, health centres and hospitals.

The action plan is available at:

http://www.who.int/child_adolescent_health/documents/fch_cah_nch_09_04/en/index.html

Publication of new Hib and pneumococcal disease burden estimates

In 2009, WHO released new disease burden estimates on Hib and pneumococcal diseases in children under the age of five. Globally, about 363 000 and 735 000 children died from Hib and pneumococcal diseases, respectively in 2000. The majority of these deaths were in Africa and Asia. The data represent a significant improvement on previous estimates and were developed through a rigorous process that involved a systematic and comprehensive review of related literature. The work was carried out in collaboration with the PneumoADIP and the Hib Initiative partners based at Johns Hopkins University and the London School of Hygiene and Tropical Medicine. The data will assist countries in evidence-based decision-making on vaccine introduction and in the evaluation and cost effectiveness analysis of vaccine impact after introduction. For more information: http://www.who.int/immunization_monitoring/burden/Pneumo_hib_estimates/en/index.html

Global use of rotavirus vaccines recommended

In December 2009, WHO recommended that rotavirus vaccination be included in all national immunization programmes to provide protection against a virus that is responsible for more than 500 000 diarrhoeal deaths and 2 million hospitalizations every year among children. More than 85% of these deaths occur in Africa and Asia. This new policy paves the way for countries in Africa and Asia eligible for GAVI support to apply for funds to introduce the vaccine. In 2009, ten countries in the African and Eastern Mediterranean regions submitted applications for support for rotavirus vaccine introduction.

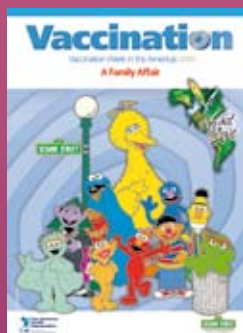
Child Health Days bring a range of health interventions to Somali children

In 2008-09, for the first time, a range of live-saving interventions were delivered to Somalia's children through Child Health Days. During this initiative, which was the result of the joining of forces between WHO, UNICEF and other partners at country level, vaccination against diphtheria, tetanus, pertussis, polio and measles was provided, as were vitamin A supplements, de-worming medicine, oral rehydration salts solution, and water purification tablets. The Days took place in phases, taking into consideration access, security, the operational capacity of partners, and the availability of trained health workers at district level. Interventions were delivered through fixed posts in health facilities, temporary posts such as schools and marketplaces, and mobile teams for hard-to-reach areas. The coverage of these interventions ranged from 71-95%. The experience has proved that scaling up child health interventions is possible even in countries with many hard-to-reach children, such as Somalia.

Activities to reduce yellow fever incidence in the African Region

As of December 2009, 23 out of the 31 countries at risk of yellow fever in the African Region had introduced yellow fever vaccine in their routine immunization schedules. With technical support from WHO and partners such as Médecins Sans Frontières, national Red Cross and Red Crescent Societies, and UNICEF, mass vaccination campaigns have been conducted in eight of the 12 countries at high risk of yellow fever: Benin, Burkina Faso, Cameroon, Liberia, Mali, Senegal, Sierra Leone, and Togo.

Two regions uniting to protect millions of children, adults and seniors



Americas

In April 2009, the Americas Region celebrated the seventh anniversary of Vaccination Week in the Americas (VWA) with participation from 45 countries and territories. Since its inception, VWA has provided more than 288 million individuals with life-saving vaccines. Many of those targeted are vulnerable populations with limited access to vaccination such as those located in remote areas, the outskirts of urban areas, along borders, in low coverage municipalities, and in indigenous communities. The support and participation of presidents, first ladies and health ministers in VWA events, together with the distribution of social communication materials, have been vital elements in communicating on a wide range of vaccine-related issues.



Europe

Thirty-six countries in the European Region participated in the fourth European Immunization Week in April 2009, up from 32 in 2008. From Tajikistan in the east to Ireland in the west, a variety of activities — including debates, workshops, training, exhibitions, and education and media events — were carried out during the week. Social media were used extensively to raise awareness of the benefits of vaccination. A short animated film was posted on YouTube and other web sites; messages relating to the event were also communicated via social communication sites, blogs and discussion forums.

Introducing a new surveillance network for vaccine-preventable diseases

In 2009, a sentinel surveillance network — an active surveillance system that collects data from health care providers in medical clinics and hospitals — was launched. The surveillance network monitors diseases targeted by newer vaccines such as Hib, pneumococcal and rotavirus. The network, coordinated by WHO, provides information for: (a) evidence-based decision-making on vaccine introduction; (b) monitoring disease epidemiology; and (c) evaluation of vaccine impact after introduction. Data generated by the surveillance network include the different types of organisms causing Hib, pneumococcal and rotavirus disease. A standardized process has also been established to detect and investigate cases, collect, analyse and report the data, and to support surveillance activities through a network of high-quality laboratories. In December 2009, the first WHO global rotavirus and invasive bacterial diseases information and surveillance bulletin containing data from the global network were published. For more information:

<http://www.who.int/nuvi/surveillance/resources/en/index.html>.

The Revolving Fund for vaccine procurement — key to the sustainable availability of new vaccines in the Americas

The Pan American Health Organization (PAHO) Revolving Fund continues to play a key role in the sustainable introduction of new vaccines. For 30 years, safe, affordable vaccines have been purchased for countries in the Region through the Fund. The Fund has been pivotal in enabling the Americas to achieve many disease reduction targets and to introduce new life-saving vaccines as soon as they become available. In 2009, during the PAHO Directing Council, Member States expressed their continued support to the Revolving Fund as both a purchase mechanism and a tool for technical cooperation in immunization.

Establishing efficient health-care waste management in Kyrgyzstan

An innovative pilot project to examine approaches for improved management of immunization-related waste in the context of the broader health system

Increasing use of Japanese encephalitis vaccine

Japanese encephalitis vaccine is another important vaccine for the WHO South-East Asia Region. This vaccine is used in India, Nepal, Sri Lanka and Thailand. Since 2006, India has been expanding the introduction of the live attenuated SA14-14-2 Japanese encephalitis vaccine as part of efforts to reach 105 endemic districts across the country. Nepal has introduced the same vaccine in the districts along the southern Terai belt. Sri Lanka introduced the inactivated Japanese encephalitis vaccine in 1988. Thailand introduced the same vaccine in 1991. In order to improve uptake of the vaccine in countries of need, staff at WHO's Regional Office for South-East Asia are consulting with colleagues in the Western Pacific Region and partners to establish an informal bi-regional working group to assist countries in developing their Japanese encephalitis control plans and mobilizing the resources required for implementation. With the ending of PATH's Japanese encephalitis project in October 2009, financing for activities has become scarce, posing risks for the regional Japanese encephalitis/acute encephalitis syndrome laboratory network.

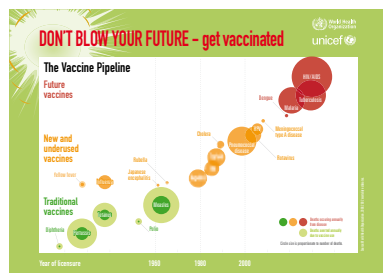
was introduced by WHO in Kyrgyzstan in August 2009. Additionally, a practical guide has been developed to help central and eastern European health-care facilities establish an efficient and cost-effective approach to the management of health-care waste.

Reducing chronic hepatitis B infection rates among children

Twenty-six countries and areas in the Western Pacific Region, comprising 87% of the population of the Region as a whole, are estimated to have reduced the chronic hepatitis B infection rate to less than 2% (the regional goal by 2012) among children at least five years of age, compared to a pre-vaccination rate of 8-10% in most of these countries. This implies prevention of more than 1.5 million new chronic hepatitis B infection carriers in each birth cohort. Malaysia and China, Hong Kong Special Administrative Region (SAR) completed serosurveys and are in the process of certification of achievement of the goal. These are in addition to China, Macao SAR and the Republic of Korea, which have already received certification status.

E. Communication, advocacy and media

“Don’t blow your future — get vaccinated”



With the slogan “Don’t blow your future — get vaccinated,” the information stand of WHO’s Department of Immunization, Vaccines and Biologicals (IVB) at

the 61st World Health Assembly in May 2008 featured a banner and flyer illustrating the vaccine pipeline and past, present and future deaths averted through immunization. Between two and three million deaths are averted through immunization every year. Widespread use of available vaccines will avert, by 2015, an additional 2.5 million deaths every year. Two brightly coloured helium-filled balloons floated above the stand, with the phrases “Reach more - expand vaccination coverage” and “Introduce new vaccines.” To mark WHO’s 60th anniversary, the balloon tails provided key historical and future dates in immunization.

http://www.who.int/immunization/newsroom/advocacy_events_WHA_stand_2008/en/index.html

“Any way you look at it...vaccine quality is critical”



The importance of vaccine quality, safety and standards was featured at the IVB exhibit at the 62nd World Health Assembly in 2009. With the slogan “Any way you look at it... vaccine quality is critical,” the exhibit showcased superimposed, lenticular

images that changed as visitors walked by the exhibit. A 12-page brochure explained the Department’s work in this area: generating the standards to which vaccines of assured quality and safety must comply; ensuring that all people have access to the full range of quality vaccines; and effectively managing the vaccine safety concerns that can now cross the globe in minutes. The brochure is available in English and French.

http://www.who.int/immunization/newsroom/advocacy_events_WHA_stand_2009/en/index.html

An introduction to the Global Immunization Vision and Strategy



An introduction to the Global Immunization Vision and Strategy

This WHO-UNICEF brochure captures the essence of the *Global Immunization Vision and Strategy 2006-2015* (GIVS) which aims to protect more

people against more diseases. Illustrated with photos and the brand new visual identity for GIVS, it describes achievements in immunization and the benefits of this key and cost-effective health intervention. Needs, challenges, the cost of immunization programmes and resource requirements are given. The brochure outlines the four strategic areas of GIVS as well as the immunization goals established therein.

http://whqlibdoc.who.int/hq/2008/WHO_IVB_08.13_eng.pdf

Ten facts on immunization: a multimedia feature



A multimedia feature on immunization – highlighting important facts illustrated with photos – was first published on the WHO web site in

April 2008 and revised in October 2009 with the latest available data. Vaccination against diseases is essential to reaching MDG 4. Many of these deaths occur from diseases that can be prevented with vaccines. Immunization is also a key strategy to ensure global health security and to respond to the threat of emerging infections such as pandemic influenza.

<http://www.who.int/features/factfiles/immunization/en/index.html>

State of the World's Vaccines and Immunization launch

In October 2009, the third edition of the *State of the World's Vaccines and Immunization* was published by WHO, UNICEF and the World Bank. This flagship publication was launched side-by-side with representatives from over 100 organizations involved in immunization, as well as 20 journalists, in a packed room at the National Press Club in Washington,

D.C. The overarching message, conveyed at this media and advocacy event, was that tremendous strides have been made in immunization, while challenges still remain, such as the estimated 24 million children each year who still do not benefit from immunization.

<http://www.who.int/immunization/sowvi/en/>



Immunization, Vaccines and Biologicals Strategic Plan 2010-2015

The Immunization Department's near term work is governed by the Strategic Plan for 2010-2015. In line with the WHO/UNICEF *Global Immunization Vision and Strategy*, this Plan aims to deliver the highest possible levels of technical leadership, collaboration, integration and synergies to empower the immunization community to sustain achievements, and to reach vaccination coverage rates of 80% by end 2010 and 90% by end 2015. The Strategic Plan pursues five priorities:

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.

In addition, a new Strategic Plan for eradicating polio has been developed and is available at:

<http://www.polioeradication.org/content/publications/StratPlan.2010-12.asp>

This publication was produced by the World Health Organization's Department of Immunization, Vaccines and Biologicals.

The Department has a document catalogue listing all documents produced and distributed by the Department since its establishment in 1998. Documents are classified by categories such as immunization policy, innovation, financing, surveillance, safety, research and development. All documents produced since 2000 are available at:

<http://www.who.int/immunization/documents/en/>

For further information on WHO's work on vaccines and immunization, contact vaccines@who.int.

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